ORAL ARGUMENT NOT YET SCHEDULED

Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CENTER FOR BIOLOGICAL DIVERSITY, CENTER FOR FOOD SAFETY, and DEFENDERS OF WILDLIFE,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

and

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION LLC, and DOW AGROSCIENCES LLC,
Intervenor-Respondents.

Petition for Review of Order of U.S. Environmental Protection Agency (Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351)

PETITIONERS' OPENING BRIEF

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES AND CORPORATE DISCLOSURE STATEMENT

A. Parties and Amici.

No parties have appeared before the district court because these consolidated cases involve direct review of orders of an administrative agency.

The following parties appear before this Court in these consolidated cases:

1. Center for Biological Diversity, as Petitioner (all cases);
2. Center for Food Safety, as Petitioner (15-1054, 15-1176);
3. Defenders of Wildlife, as Petitioner (15-1054);
4. U.S. Environmental Protection Agency, as Respondent (all cases);
5. Bayer CropScience LP, as Intervenor-Respondent (15-1054);
6. Syngenta Crop Protection LLC, as Intervenor-Respondent (15-1176, 15-1389); and
7. Dow AgroSciences LLC, as Intervenor-Respondent (16-1351).

At the time of this filing, no amici have appeared.

B. Rulings Under Review.

The following rulings are at issue in these consolidated cases:

1. January 14, 2015 Order issued by the U.S. Environmental Protection Agency, Registration decision for the new active ingredient flupyradifurone and pesticide products containing flupyradifurone. JA ___, [FL Doc. 103, Registration

Decision], Administrative Proceeding Docket No. EPA-HQ-OPP-2013-0226-0044 on regulations.gov. EPA did not publish this Order in the Federal Register.

2. April 24, 2015 Order issued by the U.S. Environmental Protection Agency, Registration decision of the new active ingredient bicyclopyrone and pesticide products containing bicyclopyrone. JA ___, [BCP Doc. 77, Registration Decision], Administrative Proceeding Docket No. EPA-HQ-OPP-2014-0355-0077 on regulations.gov. EPA did not publish this Order in the Federal Register.

3. August 28, 2015 Order issued by the U.S. Environmental Protection Agency, Conditional Registration decision for the new active ingredient benzovindiflupyr and pesticide products containing benzovindiflupyr. JA ___, [BE Doc. 66, Registration Decision], Administrative Proceeding Docket No. EPA-HQ-OPP-2013-0141-0066 on regulations.gov. EPA did not publish this Order in the Federal Register.

4. October 6, 2015 Order issued by the U.S. Environmental Protection Agency, Registration decision for the new active ingredient cuprous iodide and pesticide product containing cuprous iodide. JA ___, [CI Doc. 126, Registration Decision], Administrative Proceeding Docket No. EPA-HQ-OPP-2013-0433-0008 on regulations.gov. EPA did not publish this Order in the Federal Register.

5. July 28, 2016 Order issued by the U.S. Environmental Protection Agency, Final registration decision of the new active ingredient halauxifen-methyl

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and pesticide products containing halauxifen-methyl. JA ___, [HM Doc. 322, Registration Decision], Administrative Proceeding Docket No. EPA-HQ-OPP-2012-0919-0024 on regulations.gov. EPA did not publish this Order in the Federal Register.

C. Related Cases.

None of these consolidated cases has been before any other court. To the best of Counsels' knowledge, there are no other related cases.

D. Corporate Disclosure Statement.

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, Petitioners make the following disclosures:

Center for Biological Diversity: Center for Biological Diversity has no parent companies, and no publicly held company has a ten percent or greater ownership interest in Center for Biological Diversity.

Center for Biological Diversity, a corporation organized and existing under the laws of the State of California, is a national non-profit organization dedicated to the protection and enjoyment of the environment and our nation's endangered and threatened species and their habitats.

Center for Food Safety: Center for Food Safety has no parent companies, and no publicly held company has a ten percent or greater ownership interest in Center for Food Safety.

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Center for Food Safety, a corporation organized and existing under the laws of the District of Columbia, is a national non-profit organization dedicated to improving the quality of the human environment and protecting the nation's endangered natural resources.

Defenders of Wildlife: Defenders of Wildlife has no parent companies, and no publicly held company has a ten percent or greater ownership interest in Defenders of Wildlife.

Defenders of Wildlife, a corporation organized and existing under the laws of the District of Columbia, is a national non-profit organization dedicated to the protection and enjoyment of the environment and our nation's endangered and threatened species and their habitats.

Respectfully submitted this 4th day of March, 2019

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GLOSSARY OF ABBREVIATIONS

Conservation Groups	Petitioners Center for Biological Diversity, Center for Food Safety, and Defenders of Wildlife
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act, 16 U.S.C. §§ 1531 *et seq.*
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*
Academy	National Academy of Sciences
Wildlife Agencies	National Marine Fisheries Service and U.S. Fish and Wildlife Service

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INTRODUCTION

The United States Environmental Protection Agency ("EPA") has conceded that it violated the Endangered Species Act ("ESA") when it registered the pesticides at issue in these consolidated cases. Congress mandated that each federal agency ensure that its actions do not jeopardize species already on the edge of extinction or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2). The ESA requires EPA to consult with certain the National Marine Fisheries Service and U.S. Fish and Wildlife Service ("Wildlife Agencies") before taking any action that "may affect" protected species or their habitats. *Id.*; 50 C.F.R. § 402.14(a). EPA admitted to this Court that the ESA "requires it to make a determination regarding the effects of each of the challenged registration actions on ESA-listed species and critical habitat" and that it has not done so, "nor has it initiated any consultation that might be triggered by such effects determinations." EPA Motion to Consolidate at 1, Case No. 15-1054, Doc. #1722049 (Mar. 13, 2018). EPA cannot now contest the merits of these consolidated cases.

All that is at issue is the remedy for EPA's violations of law. The appropriate remedy is to vacate EPA's registration decisions that authorize the use of pesticides containing the insecticide flupyradifurone, the herbicide bicyclopyrone, the fungicide benzovindiflupyr, the antimicrobial cuprous iodide, and the herbicide halauxifen-methyl. Congress prescribed vacatur as the

presumptive remedy, mandating courts to set aside EPA's invalid orders. 7 U.S.C. § 136n.

EPA cannot carry its burden to demonstrate that this Court should deviate from the presumptive and usual remedy of vacatur. EPA's unlawful actions are serious violations of statutory mandates enacted to ensure, in no uncertain terms, that the registrations do not jeopardize the continued existence of any endangered species or threatened species. EPA's own findings in the record show that endangered and threatened species and their habitats are at increased risk, while EPA, at the same time, intentionally stopped short of engaging in consultation.

EPA also cannot show that vacating the registrations of these pesticides would be highly disruptive. Leaving the registrations in place puts at risk our most vulnerable wildlife, endangered and threatened species, by allowing continued use of these pesticides before EPA has ensured that their use is not likely to jeopardize these species. In contrast, vacating the registrations is not highly disruptive of a complex regulatory scheme designed to protect people and the environment.

On balance, the equities do not weigh in favor of remand without vacatur. This Court should vacate EPA's authorizations to use pesticides that are likely to harm endangered and threatened species. EPA intentionally disregarded its duties to consult and ensure these pesticides would not push these species closer to extinction before it registered them for use across the nation.

STATEMENT OF JURISDICTION

Jurisdiction is proper in this Court under section 16(b) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136n(b). EPA provided a "public hearing" by providing the public notice and opportunity to comment prior to each registration decision in these consolidated cases. *See Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 187-88 (D.C. Cir. 2017); JA ___, [FL Doc. 60]; JA ___, [BCP Doc. 14]; JA ___, [BE Doc. 7]; JA ___, [CI Doc. 290]; JA ___, [HM Doc. 310]. Each petition for review was filed within 60 days of the entry of the order registering the pesticide. *Ctr. for Biological Diversity v. EPA*, No. 15-1054, Doc. 1542423 (Mar. 13, 2015); No. 15-1176, Doc. 1558360 (June 18, 2015); No. 15-1389, Doc. 1580497 (Oct. 27, 2015); No. 15-1462, Doc. 1590365 (Dec. 18, 2015); No. 16-1351, Doc. 1640538 (Oct. 7, 2016); *see* 40 C.F.R. § 23.6 (date of entry of order for purposes of section 16(b) is two weeks after it is signed).

STATEMENT OF THE ISSUES

1. Whether EPA violated its mandatory duty under the Endangered Species Act to insure against jeopardy of protected species by completing consultation on its registrations of new pesticides when EPA conceded that it has not done so and EPA's own analyses show the pesticides may affect protected species and critical habitat?

2. Whether the appropriate remedy is to vacate EPA's unlawful orders when vacatur is the presumptive remedy under FIFRA, EPA's intentional failure to consult is serious where Congress gave endangered and threatened species the highest priority, and vacating the orders is more environmentally protective and is not highly disruptive of a regulatory scheme?

STATEMENT OF THE CASE

I. LEGAL BACKGROUND.[1]

A. The Endangered Species Act.

The Endangered Species Act is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). In passing the ESA, Congress made a conscious choice to "give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185. "The plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, whatever the cost." *Id.* at 184.

Section 7(a)(2) of the ESA creates both substantive and procedural obligations that apply to every federal agency. *See Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 667 (2007); *Defenders of Wildlife v. Jackson,* 791 F. Supp. 2d 96, 112–13 (D.D.C. 2011). Under section 7(a)(2), every federal agency "shall, in consultation with and with the assistance of the Secretary, insure

[1] Pertinent statutes and regulations are included in an addendum bound with this brief.

that any action authorized, funded, or carried out by such agency … is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat.[2] 16 U.S.C. § 1536(a)(2). The substantive duty of every agency to "insure" that its actions will not jeopardize the survival and recovery of any protected species is constant, relieved only by an exemption from the Endangered Species Committee. 16 U.S.C. § 1536(h).

Section 7 establishes a procedural interagency consultation process to assist federal agencies in complying with their substantive duty to ensure that their actions do not jeopardize listed species. "Consultation is designed as an integral check on federal agency action, ensuring that such action does not go forward without full consideration of its effects on listed species." *Defenders of Wildlife*, 791 F. Supp. 2d at 100 (internal quotation marks and citation omitted). If a project is allowed to proceed without consultation, there can be no assurance that a violation of the ESA's substantive provisions will not result. *See Nat'l Parks Conservation Ass'n v. Jewell*, 62 F. Supp. 3d. 7, 20-21 (D.D.C. 2014). Completion

[2] The Secretaries of the Interior and Commerce have delegated the administration of the ESA, including the interagency consultation process, to the National Marine Fisheries Service (for marine and anadromous species) and the Fish and Wildlife Service (for land-based and freshwater species), together referred to here as the "Wildlife Agencies."

of the consultation process is central to compliance with the ESA's protective, substantive mandates.

Federal actions that "may affect" a listed species or critical habitat may not proceed unless and until the agency ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14, 402.13. The threshold for a "may affect" determination and ESA section 7 consultation is low. *See* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement."). As a result of consultation, the federal agency will obtain either a written concurrence letter from the Wildlife Agencies that the proposed action is "not likely to adversely affect" listed species or their habitat, 50 C.F.R. §§ 402.13, 402.14(b)(1), or a biological opinion evaluating the effects of the federal action on listed species and their critical habitat. 50 C.F.R. § 402.14(a).

B. The Federal Insecticide, Fungicide, and Rodenticide Act.

Under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), EPA is charged with regulating the nationwide sale and use of pesticides. A pesticide may not be sold or used in the United States unless it has an EPA registration and approved label authorizing that use. 7 U.S.C. § 136a(a). EPA may only register a pesticide if it determines, among other factors, that the pesticide

"will not cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5).

For purposes of the FIFRA registration process, EPA prepares an ecological risk assessment that assesses the risks and concerns for certain categories of fish and wildlife, e.g. mammals, birds, and fish, including, in some instances, concerns for categories of species that are "listed" (protected) under the ESA. These risk assessments are based on studies submitted by the registrant (usually the pesticide manufacturer or other entity asking EPA to register the new pesticide) as part of the application process under FIFRA. *See* 40 C.F.R. § 158.630 (data requirements for wildlife and fish studies on toxicity of a new pesticide active ingredient).

C. EPA's Longstanding Failure to Comply with The Endangered Species Act Prior to Authorizing Pesticides.

Pesticides are toxic by design. Pesticides regularly kill, injure, or impair not only the targeted pests, but also endangered plants and animals in harm's way. Where a pesticide may affect a threatened or endangered species, it is well-settled that the ESA requires EPA to consult with the expert Wildlife Agencies before authorizing a pesticide for use. *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 (D.C. Cir. 2017). For decades, however, EPA has failed to comply with its legal duties when it registers new pesticides and re-registers old pesticides. *See id., Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1029 (9th Cir. 2005) (affirming orders to consult over the effects of pesticide registrations on ESA protected

species according to a schedule); *Defenders of Wildlife v. Admin.*, 882 F.2d 1294 (8th Cir. 1989) (affirming section 7's application to EPA's registration of pesticides).

To address agency disagreements concerning consultations, in 2011, EPA and the Wildlife Agencies requested that the National Academy of Sciences ("Academy") convene a committee of independent experts to evaluate the approaches for assessing the effects of pesticide registrations on ESA protected species. The Academy published its final report in 2013 and laid out scientific principles and a joint approach to govern pesticide consultations. National Academy of Sciences, *Assessing Risks to Endangered and Threatened Species from Pesticides*.[3] The Academy concluded that EPA's ecological risk assessment process is "not scientifically defensible for assessing the risks to listed species posed by pesticides . . . ." *Id.* at 15.

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[3] The final report of the Academy, *Assessing Risks to Endangered and Threatened Species from Pesticides*, is available from a link on EPA's website at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and (last visited Feb. 15, 2019). Pursuant to Fed. R. Evid. 201(b)(2), courts may take judicial notice of government reports and information posted on a government agency website. *Hope v. Pelzer*, 536 U.S. 730, 737 n.7 (2002) (citing with approval judicial notice taken by Court of Appeals of report issued by Department of Justice); *Cannon v. District of Columbia,* 717 F.3d 200, 205 n. 2 (D.C. Cir. 2013) (Court took judicial notice of District of Columbia's Retirement Board website page summarizing pension fund operations).

Following the Academy's final report, EPA and the Wildlife Agencies jointly published a guidance document outlining how they would conduct pesticide consultations going forward. *See Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*.[4] This guidance document commits to follow the recommendations of the Academy and includes a three-step process for pesticide consultations. In the first step, EPA determines whether the pesticide authorization "may affect" any species or critical habitat that overlaps with the action area. *Id.* at 2 (Figure 1) and at 4. The action area is determined by examining "potential [pesticide] use sites combined with the range of off-site transport to identify the area of potential effects in and around use sites." *Id.* at 4-5. Where there is "may affect", the guidance directs EPA to proceed to a second step to analyze the degree to which the pesticide may impact species. *Id.* at 7. Then the agencies proceed to the third step, either informal consultation or formal consultation and preparation of a biological opinion. *Id.* at 10.

[4] The "Interim Approaches," available at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf (last visited Feb. 15, 2019). Courts may take judicial notice of government reports and information posted on a government agency website. *See supra*, n. 3 (judicial notice allowed)..

II. FACTUAL BACKGROUND.

A. Flupyradifurone (Case No. 15-1054).

On May 29, 2013, EPA published a notice in the Federal Register that it had received an application to register pesticides containing the new active ingredient flupyradifurone and opened a docket. 78 Fed. Reg. 32247. Following opportunity for public comment, on January 14, 2015, EPA registered flupyradifurone and two pesticide products containing flupyradifurone. JA ___, [FL Doc. 103, Registration Decision]; JA ___, [FL Doc. 60, Public Participation Memo]. Flupyradifurone is a systemic pesticide that is taken up and distributed through the plant to control insects. JA ___, [FL Doc. 103 at 3]. EPA approved it for a wide range of uses on about twenty crop types from alfalfa to soybeans and citrus to tree nuts. JA ___, [FL Doc. 103 at 3, 11].

EPA authorized these uses of flupyradifurone without consulting with the expert Wildlife Agencies, despite finding they would likely harm numerous listed species. *See* JA ___, [FL Doc. 96, Ecological Risk Assessment at 120]. EPA concluded, yes, there are potential direct and indirect effects to federally listed taxa associated with all authorized uses of flupyradifurone. JA ___, [FL Doc. 96 at 120 (Table 47)]. EPA identified "direct and indirect effect concerns, by taxa, that are

triggered by exceeding listed species" Levels of Concern.[5] JA ___, [FL Doc. 96 at 120]. EPA determined that approved uses of flupyradifurone may cause direct effects to protected birds, mammals, reptiles, terrestrial-phase amphibians, and aquatic invertebrates (freshwater and marine/estuarine). JA ___, [FL Doc. 96 at 120 (Table 47)]. Because these species may serve as prey or habitat, EPA also concluded that approved uses of flupyradifurone may cause indirect effects to birds, mammals, reptiles, terrestrial-phase amphibians, fish (freshwater and marine/estuarine), aquatic-phase amphibians, mollusks, and aquatic invertebrates fish (freshwater and marine/estuarine). JA ___, [FL Doc. 96 at 120 (Table 47)]. EPA stated it was "uncertain" whether there is potential to affect dicotyledonous plants, but concluded risks of concern "cannot be ruled out" and that there would be indirect effects on terrestrial and semi-aquatic plants when other affected species, such as birds and mammals, are required for seed dispersal or pollination. JA ___, [FL Doc. 96 at 120 (Table 47) and at 14]. EPA's risk assessment concludes that approved uses of flupyradifurone may affect nearly every taxonomic group that is represented on the list of ESA protected species. JA ___, [FL Doc. 96 at 120].

[5] Effects that fall below EPA's "Levels of Concern" are not equivalent to "no effect" determinations. The Academy's recommendation was that authorization of pesticides "may affect" protected species when there is overlap between a species or its critical habitat and the places a pesticide might be used or might otherwise reach, such as through drift, runoff or water transport, regardless of whether a Level of Concern is exceeded. *Interim Approaches* at 4-5, *supra* note 4.

Notably, EPA states that it did not evaluate risk to terrestrial invertebrates, other than honeybees. JA ___, [FL Doc. 96 at 7]. As an insecticide, flupyradifurone is most likely to affect insects and other invertebrates. Flupyradifurone is "highly toxic to honeybees on an acute oral exposure basis." [FL Doc. 96 at 7]. EPA also states that toxicity studies indicate potential effects of flupyradifurone to non-target terrestrial arthropods, such as insects and spiders, at or below application rates. JA ___, [FL Doc. 96 at 7, 112]. Arthropods include species such as lady beetles (ladybugs), which are beneficial insects because they prey on pest insects and insect eggs.[6] JA ___, [FL Doc. 96 at 74, 76-77]. But, EPA does nothing further to protect these beneficial insects or other listed terrestrial invertebrates.

EPA's primary concern is for aquatic invertebrates because flupyradifurone is "very highly toxic" to freshwater insects and estuarine/marine crustaceans, is mobile in the environment, and is persistent in the aquatic environment. JA ___, [FL Doc. 96 at 6]. EPA states that "methodologies are not available to determine the distance that is needed to eliminate the risk of concern from transport in runoff," and, despite acute risk to ESA-listed species, EPA did not require any buffer between the application sites and aquatic environments. JA ___, [FL Doc.

[6] *See, e.g.*, Wash. State Univ. Ext., "Beneficial Insects, Spiders, and Other Mini-Creatures in Your Garden" at 2 (Table 1). Available at: http://cru.cahe.wsu.edu/CEPublications/EM067E/EM067E.pdf (last visited Feb. 28, 2019). *See supra*, n. 3 (judicial notice allowed).

96 at 6]; *see also* JA ___, [FL Doc. 57, Sivanto 200 SL label].[7] The Sivanto 200 SL product label warned "This product may have effects on endangered species." JA ___, [FL Doc. 57 at 5]. The label directed the user to the "Endangered Species Protection Bulletin" for endangered species protection requirements; however, flupyradifurone and Sivanto 200 SL are not included on the *EPA's Bulletins Live! Two* website.[8] JA ___, [FL Doc. 57 at 3].

Despite these unequivocal findings on the risks flupyradifurone pose to listed species, EPA did not consult with the Wildlife Agencies prior to authorizing nationwide uses.

B. Bicylopyrone (Case No. 15-1176).

On August 13, 2014, EPA published a notice in the Federal Register that it had received an application to register pesticides containing the new active ingredient bicyclopyrone and opened a docket. 79 Fed. Reg. 47454. Following opportunity for public comment, on April 24, 2015, EPA conditionally registered

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[7] The Sivanto label prohibits application directly to water, but it only warns that drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas, but does not prohibit its use adjacent to water at any distance. JA ___, [FL Doc. 57, Sivanto 200 SL label at 3 (p. 5 of the pdf)].

[8] EPA's website *Bulletins Live! Two* is intended to protect endangered and threatened species by creating Pesticide Use Limitation Areas for some pesticide products, but it is only effective if products that are harmful to species are included. Available at: https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins (last visited Feb. 11, 2019). *See supra*, n. 3 (judicial notice allowed).

bicyclopyrone and five pesticide products containing bicyclopyrone. JA ___, [BCP Doc. 77, Registration Decision]; JA ___, [BCP Doc. 14, Public Participation Memo]. Bicyclopyrone is a systemic herbicide that EPA approved for use on corn, generally for pre-emergent application to soil (before weeds sprout) although early post-emergent application is also allowed. JA ___, [BCP Doc. 77 at 2].

EPA authorized these uses of bicyclopyrone without consulting with the expert Wildlife Agencies, despite finding they would likely harm numerous listed species. *See* JA ___, [BCP Doc. 15, Ecological Risk Assessment at 2]. EPA concluded that approved use of bicyclopyrone "may result in risk to federally listed threatened and endangered . . . species of terrestrial and semi-aquatic dicotyledonous (dicot) plants," and vascular aquatic plants. JA ___, [BCP Doc. 15 at 2, 10]. Over half the species protected by the ESA in the U.S. are plants.[9] EPA also determined mammals are at risk from chronic exposure. JA ___, [BCP Doc. 15 at 2]. EPA considered the likelihood of "acute mortality" for fish, invertebrates, mollusks, amphibians, birds, and reptiles to be low. JA ___, [BCP Doc. 15 at 10]. But, the likelihood that these species may not die quickly does not preclude finding that bicyclopyrone may affect them because, as EPA concluded, "indirect effects to these taxa are possible given the potential for adverse effects" to plants and

[9] U.S. Fish and Wildlife Service, *Listed Species Summary (Boxscore). Available at*: https://ecos.fws.gov/ecp0/reports/box-score-report (last visited March 1, 2019). *See supra*, n. 3 (judicial notice allowed).

mammals. JA ___, [BCP Doc. 15 at 55]. These potential indirect effects "include, but are not limited to reduction in food resources, decrease in cover, change in water quality parameters, and loss of breeding/nesting habitat." JA ___, [BCP Doc. 15 at 55]. EPA also expects bicyclopyrone to be very highly mobile in soil, degrade slowly in water, and may move to surface water bodies via spray drift and runoff. JA ___, [BCP Doc. 15 at 9].

In addition, EPA registered the product, Acuron™, which contains the active ingredients atrazine, mesotrione, and s-metolachlor, in addition to bicyclopyrone. JA ___, [BCP Doc. 77, Registration Decision at 2]. Each ingredient presents a unique risk to listed species and may have additive or synergistic[10] effects when co-applied with other pesticides. The Center for Biological Diversity detailed the risk and concerns associated with each additional active ingredient in Acuron™. JA ___, [BCP Doc. 57, Center for Biological Diversity Comment Letter at 4-8]. EPA itself has determined that atrazine poses ecological risk to fish, amphibians, and aquatic invertebrates, and for "mammals, birds, reptiles, plants and plant communities across the country . . . ."[11] Yet, EPA limited its analysis "to the

[10] When two or more pesticides are co-applied, their combined effect can be greater than the sum of their separate effects.

[11] EPA, Refined Ecological Risk Assessment for Atrazine (April 2016), available on regulations.gov EPA Docket #EPA-HQ-OPP-2013-0266-0315. *See supra*, n. 3 (judicial notice allowed).

exposure associated with bicyclopyrone specifically and not the other compounds . . . ." JA ___, [BCP Doc. 15 at 11].

Despite these unequivocal findings on the risks bicyclopyrone and Acuron™ pose to listed species, EPA did not consult with the Wildlife Agencies prior to authorizing nationwide uses on corn.

C. Benzovindiflupyr (Case No. 15-1389).

On April 19, 2013, EPA published a notice in the Federal Register that it had received an application to register pesticides containing the new active ingredient benzovindiflupyr and opened a docket. 78 Fed. Reg. 23558. Following an opportunity for public comment, on August 28, 2015, EPA conditionally registered benzovindiflupyr and nine pesticide products containing benzovindiflupyr. JA ___, [BE Doc. 66, Registration Decision]; JA ___, [BCP Doc. 7, Public Participation Memo]. EPA approved these fungicides for wide range of uses from cereals and grapes to corn and various vegetables. JA ___, [BE Doc. 66 at 3].

EPA authorized these uses of benzovindiflupyr without consulting with the expert Wildlife Agencies, despite finding they would likely harm numerous listed species. *See* JA ___, [BE Doc. 66 at 11]; JA ___, [BE Doc. 9, Ecological Risk Assessment at 75]. EPA concluded that approved use of benzovindiflupyr has the potential for "direct effects to listed mammals, birds, terrestrial invertebrates, fish, and aquatic invertebrates on all of its registered use sites," and indirect effects on

species that rely on those species that are directly affected. JA ___, [BE Doc. 9 at 75]. EPA completed an "Addendum" to its Ecological Risk Assessment based on proposed mitigation measures. JA ___, [BE Doc. 21, Addendum ERA at 1]. EPA summarized that mitigation resolved some issues, but that "there are still broad risks of concern" indicated for fish and aquatic invertebrates because benzovindiflupyr builds up in water bodies due to runoff. JA ___, [BE Doc. 21 at 5]. For terrestrial organisms, "there is also still broad risks of concern indicated for mammals and birds" even accounting for mitigation measures. JA ___, [BE Doc. 21 at 6]. In addition, EPA maintained there are still uncertainties for terrestrial invertebrates and beneficial insects. JA ___, [BE Doc. 21 at 6].

EPA also registered pesticide products that contain active ingredients in addition to benzovindiflupyr, including difenoconazole, propiconazole, and azoxystrobin. JA ___, [BE Doc. 66, Registration Decision at 3]. Each ingredient presents a risk to listed species and may have additive or synergistic effects when co-applied with other pesticides. JA ___, [BE Doc. 47, Center for Biological Diversity Comment Letter at 2-3]. For example, difenoconazole is persistent in soil and the aquatic environment and a possible human carcinogen. JA ___, [BE Doc. 47 at 2-3]. In 2006, EPA concluded that propiconazole has potential adverse effects on species protected under the ESA, including terrestrial and aquatic species. *See* Reregistration Eligibility Decision (RED) for Propiconazole (July

2006) at 52-53.[12] And, azoxystrobin is classified as highly toxic to freshwater fish and invertebrates and very highly toxic to estuarine/marine invertebrates on an acute exposure basis. Azoxystrobin Summary Document (2009) at 11.[13]

Despite these unequivocal findings on the risks that benzovindiflupyr and other active ingredients pose to listed species, EPA did not consult with the Wildlife Agencies prior to authorizing nationwide uses.

D. Cuprous Iodide (Case No. 15-1462).

On October 30, 2013, EPA published a notice in the Federal Register that it had received an application to register a pesticide containing the new active ingredient cuprous iodide and opened a docket. 78 Fed. Reg. 64938. Following an opportunity for comment, on October 6, 2015, EPA conditionally registered cuprous iodide and one pesticide product containing cuprous iodide. JA ___, [CI Doc. 126, Registration Decision]; JA ___, [CI Doc. 290, Public Participation Memo]. EPA approved this antimicrobial for use in a wide range of consumer products including apparel (socks, undershirts, underwear), bedding (sheets, blankets, mattress pads), table cloths, napkins, and towels, among other uses. JA

[12] Available at https://archive.epa.gov/pesticides/reregistration/web/pdf/propiconazole_red.pdf (last visited Feb. 24, 2019). *See supra*, n. 3 (judicial notice allowed).

[13] Available at regulations.gov Docket #EPA-HQ-OPP-2009-0835-0002 (last visited Feb. 24, 2019). *See supra*, n. 3 (judicial notice allowed).

___, [CI Doc. 126 at 3]; JA ___, [CI Doc. 124, Cupron Cuprous Iodide Label at 3 (p. 6 of the .pdf)].

EPA authorized these uses of cuprous iodide without consulting with the expert Wildlife Agencies, despite finding they would likely harm numerous listed species. According to EPA, cuprous iodide will dissociate in water, therefore, species' exposure will be predominantly in the form of copper and iodine ions. JA ___, [CI Doc. 127, Human Health and Ecological Risk Assessment at 8 and 10]. Copper is "very highly toxic to aquatic organisms and can adversely impact reproduction and growth at concentrations 3-fold lower than acute values." JA ___, [CI Doc. 127 at 11]. EPA expects release to the environment via leaching down the drain when products such as socks and sheets are washed.[14] JA ___, [CI Doc. 127 at 9]. EPA states that, based on its probabilistic modeling, if the acute Concentration of Concern for any key aquatic receptor group "is exceeded for one day or more, based on results from the high-end scenario . . ., then potential acute risks to such receptors cannot be ruled out." JA ___, [CI Doc. 127 at 14]. For copper, assuming 84.2% of copper is removed by wastewater treatment,[15] EPA

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[14] EPA did not have information to determine the amount of copper and iodine ions that could potentially be present in manufacturing process water, therefore, environmental release from that pathway could not be estimated and is an uncertainty in the risk assessment. JA ___, [CI Doc. 127 at 9].

[15] The Bay Area Clean Water Agencies commented that copper is highly toxic to aquatic life at low concentrations, is persistent and bioaccumlative, and asked EPA to assess the total quantities of copper being used in products and the cumulative

predicted the acute Concentration of Concern would be exceeded 72 days for endangered/listed freshwater invertebrates, 2 days for endangered/listed freshwater fish, and 1 day for endangered/listed algae, under the high-end scenario. JA ___, [CI Doc. 127 at 13, 15]. EPA did not assess indirect effects, such as adverse effects on fish due to loss of invertebrates that are their prey. Nor does EPA's assessment consider that the cumulative addition of cuprous iodide into waterbodies that are already violating water quality standards for excess copper. At least 649 waters nationwide do not meet water quality standards for copper and are listed as impaired under Section 303(d) of the Clean Water Act.[16]

Despite these unequivocal findings on the risks cuprous iodide and copper pose to listed species, EPA did not consult with the Wildlife Agencies prior to authorizing nationwide uses. Registration Decision at 5 ("EPA is not consulting with the [Wildlife Agencies] on the cuprous iodide registration.").

E. Halauxifen-methyl (Case No. 16-1351).

On February 13, 2013, EPA published a notice in the Federal Register that it had received an application to register pesticides containing the new active ingredient halauxifen-methyl and opened a docket. 78 Fed. Reg. 10167. Following

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totals being released to wastewater treatment plants. JA ___, [CI Doc. 166, BACWA Comment letter at 1-2].

[16] Available at: http://iaspub.epa.gov/tmdl_waters10/ attains_nation_cy.cause_detail_303d?p_cause_group_id=706 (last visited Feb. 26, 2019). *See supra*, n. 3 (judicial notice allowed).

an opportunity for comment, on July 28, 2016, EPA registered halauxifen-methyl and three pesticide products containing halauxifen-methyl. JA ___, [HM Doc. 322, Registration Decision]; JA ___, [HM Doc. 310, Public Participation Memo]. EPA approved these herbicides for use on wheat, barley, and triticale. JA ___, [HM Doc. 322 at 2].

EPA authorized these uses of halauxifen-methyl without consulting with the expert Wildlife Agencies, despite finding they would likely harm numerous listed species. *See* JA ___, [HM Doc. 322 at 9 - 11]; JA ___, [HM Doc. 317, Ecological Risk Assessment at 75]. EPA concluded that use of halauxifen-methyl may pose a risk to terrestrial, aquatic, and semi-aquatic vascular plants. JA ___, [HM Doc. 317 at 3, 104]. For listed plants, EPA predicts that exposure to halauxifen-methyl from spray drift continues to be of concern 2500 feet or more from the application site for aerial applications using coarse-to-very coarse droplets. JA ___, [HM Doc. 317 at 3]. Yet, EPA did not include a buffer to reduce or eliminate risk to listed plants. JA ___, [HM Doc. 322, Registration Decision at 10]; JA ___, [HM Doc. 321, Proposed Registration Decision at 8]. EPA omits completely that the direct effects on all plants exposed to spray drift likely will cause indirect effects on any species that rely upon those plants for food, cover, or breeding or nesting habitat, as EPA disclosed related to herbicide bicyclopyrone. *See* JA ___, [BCP Doc. 15 at 55].

One product, Quelex™, contains the active ingredient florasulam, in addition to halauxifen-methyl and other ingredients. JA ___, [HM Doc. 322 at 2]. Each ingredient presents a unique risk to listed species and may have additive or synergistic effects when co-applied with other pesticides. For example, florasulam alone also has the potential to adversely affect sensitive terrestrial plant species at distances of greater than 900 feet from the edge of the field. EPA Florasulam Pesticide Fact Sheet at 14 (Sept. 2007).[17] "Indirect effects to terrestrial or aquatic wildlife cannot be ruled out due to the potential for florasulam to effect changes in plant populations which may lead to changes in food supply or habitat." *Id.*

Despite the unequivocal findings on the risks halauxifen-methyl and other active ingredients pose to listed species, EPA admitted that it "is not consulting with the [Wildlife Agencies] on the issuance of the halauxifen-methyl registration." JA ___, [HM Doc. 317 at 10].

III. PROCEDURAL HISTORY.

Petitioners Center for Biological Diversity, Center for Food Safety, and Defenders of Wildlife ("Conservation Groups") filed petitions for review of each of EPA's orders registering the new pesticides flupyradifurone, bicyclopyrone, benzovindiflupyr, cuprous iodide, and halauxifen-methyl, respectively. *Ctr. for*

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[17] Available at: https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-129108_01-Sep-07.pdf (last visited Feb. 28, 2019). *See supra*, n. 3 (judicial notice allowed).

Biological Diversity v. EPA, No. 15-1054, Doc. 1542423 (Mar. 13, 2015); No. 15-1176, Doc. 1558360 (June 18, 2015); No. 15-1389, Doc. 1580497 (Oct. 27, 2015); No. 15-1462, Doc. 1590365 (Dec. 18, 2015); No. 16-1351, Doc. 1640538 (Oct. 7, 2016). This Court held these cases in abeyance until the Court resolved the jurisdictional issue in *Ctr. for Biological Diversity v. EPA*, No. 14-1036 (D.C. Cir.). *See, e.g., Ctr. for Biological Diversity v. EPA*, No. 15-1054, Doc. 1592472 (Jan. 8, 2016). In Case No. 14-1036, this Court decided it has exclusive jurisdiction pursuant to Section 16(b) of FIFRA, 7 U.S.C. § 136n(b). *Ctr. for Biological Diversity v. EPA*, 861 F.3d at 187.

On EPA's motion, this Court consolidated these cases and ordered a schedule for filing the certified indices to the records and briefing, "without prejudice to a consent dispositive motion in any of these consolidated cases, to be filed before briefing has commenced." *Ctr. for Biological Diversity*, Case No. 15-1054 (Lead), Doc. 1736834 (June 20, 2018).

EPA moved to defer these deadlines to file a dispositive motion for remand without vacatur based on its admissions that it violated the Endangered Species Act, which this Court denied. *Center for Biological Diversity v. EPA*, No. 15-1054 (Lead), Doc. 1738576 (June 29, 2018) (motion to consolidate); *Id.*, Doc. 1742122 (July 24, 2018) (order).

All parties filed a joint consent motion to hold the consolidated cases in abeyance to engage in settlement discussions, based in part on the Conservation Groups' written settlement proposal dated October 2, 2018. *Id.*, Doc. 1754630 (Oct. 11, 2018). This Court granted the motion and ordered the Conservation Groups' opening brief due March 4, 2019. As of March 4, 2019, EPA had not provided any written counterproposal. The Conservation Groups now file this brief.

STANDARD OF REVIEW

The Conservation Groups' claims that EPA failed to comply with its nondiscretionary duty to consult presents a question of law that courts review *de novo*. *See Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1017 (9th Cir. 2012) (en banc); *Ctr. for Biological Diversity v. EPA*, 861 F.3d at 188 (holding EPA violated the ESA based on EPA's admission without expressly stating the standard of review).

FIFRA vests courts with the authority to "affirm or set aside" an invalid order in whole or in part. 7 U.S.C. § 136n(b). Under FIFRA section 16(b), a court may only uphold EPA's decision to register a new pesticide "if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Pollinator Stewardship Council*

v. EPA, 806 F.3d 520, 533 (9th Cir. 2015) (Smith, N.R., concurring) (*quoting Vasquez v. Astrue*, 572 F.3d 586, 591 (9th Cir. 2009)). "The substantial evidence standard affords an agency less deference than the arbitrary and capricious standard." *Id.* (*citing Universal Camera Corp. v. Nat'l Labor Relations Bd.*, 340 U.S. 474, 477 (1951)) (other citations omitted).

SUMMARY OF ARGUMENT

The EPA has admitted to this Court that it failed to engage in consultation requirements that Congress required to protect endangered and threatened species when it registered for use the pesticides that are in question in this case. Attempts to excuse EPA's failure to engage in the required ESA consultation based on limited resources, agency priorities, or otherwise have already been rejected by this Court. This Court has also found that the Conservation Groups have standing to challenge EPA's violation of the ESA because their members have concrete aesthetic and recreational interests in the ESA protected species that are harmed by the use of the pesticides approved by EPA. Therefore, the only issue before this Court is one of the appropriate remedy given EPA's repeated and ongoing violations of ESA mandates.

The presumptive and appropriate statutory remedy for a violation of the law in registering a pesticide for use under FIFRA is vacatur. The burden is on the EPA to show why equity requires anything less than vacatur of its unlawful agency

action. Unlike an earlier case before this Court, the pesticides in question here do not present a "reduced risk" to a range of ESA protected species and the registrations should be vacated. No unusual circumstances warrant a remand without vacatur.

EPA's intentional violations of the Endangered Species Act are serious. The consultation procedure is the heart of the ESA, designed to ensure EPA carries out the ESA's substantive mandate to protect endangered species. Yet, EPA intentionally disregarded its ESA duties and registered the pesticides for use. Upon remand, EPA cannot substantiate its decision to violate the law through a more thorough explanation. A remand without vacatur will simply continue to delay implementation of EPA's statutory obligations to prevent jeopardy to ESA protected species.

The disruptive consequences of vacatur are low. EPA cannot demonstrate that by registering these pesticides, which are toxic to a range of taxa, there will be a decrease in environmental harm because these pesticides do not reduce risks to the environment. Vacating these pesticide registrations do not rise to the level of high disruption of a regulatory scheme that generally is required for courts to remand without vacatur.

In the event this Court does not vacate the registration orders it has the authority to, and should, order EPA to comply with the ESA by a date certain to curtail EPA's indefinite delay in complying with the law.

STANDING

The Conservation Groups have associational standing to bring this claim because protection of the environment is germane to their interests and their members' interests in listed species will be harmed by EPA's failure to consult on its authorizations of flupyradifurone, bicyclopyrone, benzovindiflupyr, cuprous iodide, and halauxifen-methyl. *See Am. Trucking Ass'ns v. Fed. Motor Carrier Safety Admin.,* 724 F.3d 243, 247 (D.C. Cir. 2013). The Conservation Groups provide twelve declarations from members with strong personal and professional interests in dozens of species from over 15 states. *See* Addendum of Standing Declarations in Support of Petitioners Opening Brief at DEC0001-0069 (filed contemporaneously). For example, as this Court has already recognized, EPA's failure to engage in consultation creates a "demonstrable risk" to members of the Conservation Groups, such as John Buse and Jeffrey Miller, who have "concrete aesthetic and recreational interests" in the valley elderberry longhorn beetle and Mitchell's satyr butterfly. *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 182-85 (D.C. Cir. 2017); Addendum of Standing at DEC0217-0220 (Decl. of Jeffrey Miller ¶ 30-36) and at DEC0041-0043 (Decl. of John Buse ¶ 10-20). Pesticides,

such as flupyradifurone, bicyclopyrone, and benzovindiflupyr, cause adverse effects on terrestrial invertebrates such as the ESA protected valley elderberry longhorn beetle and Mitchell's satyr butterfly among other species and taxa referenced in the declarations. *Supra* at 12, 14-15, 16-17. These adverse effects result not only from direct application to habitat for ESA protected species, but also from spray drift, runoff, accumulation in soils, and contamination of water supplies. *Supra* at 15, 21-22, n. 5. EPA also anticipates that the pesticides in this case will be used heavily on many crops throughout the United States, such as California's central valley, where numerous endangered species are found. *Supra* at 10, 14, 16, 21.

Accordingly, EPA's authorization of flupyradifurone, bicyclopyrone, benzovindiflupyr, cuprous iodide, and halauxifen-methyl, without first consulting with the Wildlife Agencies is likely to injure the interests in ESA protected species of members of the Conservation Groups. *See, e.g.,* Addendum of standing at DEC0219-220 (Decl. of Jeffrey Miller ¶ 35) and at DEC0043-0044 (Decl. of John Buse ¶ 18-20). EPA's failure to consult on its authorization of these pesticides will also likely harm many other members' interests in specific species. *See generally* Addendum of Standing.

The Conservation Groups have organizational standing because EPA's failure to consult on pesticide approvals has frustrated the Conservation Groups'

missions to protect ESA protected species, which has caused the groups to divert substantial organizational resources to identify and counteract EPA's illegal activity. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 383 (1982). For example, the Center for Biological Diversity has had to submit at least 12 Freedom of Information Act requests seeking information on EPA's failure to consult on pesticide registrations. *See* Addendum of Standing at DEC0080 (Decl. of Brett Hartl ¶ 9), DEC0020-0021 (Decl. of Lori Ann Burd ¶ 13). The Center for Biological Diversity also provided over 175 comments from staff during open comment periods on new pesticide registrations, the reregistration of pesticides, pesticide ecological risk assessments, and interim reregistration decisions urging the EPA to comply with the ESA's consultation requirements. *See id.* at DEC0078 (Decl. of Brett Hartl ¶ 5) and at DEC0021-0022 (Decl. of Lori Ann Burd ¶ 14). These actions seeking information and resources counteracting the harm to endangered species would not have been necessary if EPA had been engaged in the consultation under the ESA when it approved pesticides. *See e.g.* DEC0079 (Decl. of Brett Hartl ¶ 7), DEC0021-0022, 0025 (Decl. of Lori Ann Burd ¶ 14-15, 21); *People for the Ethical Treatment of Animals v. United States Dep't of Agric.*, 797 F.3d 1087, 1094-95 (2015) (standing found from denial of access to animal related harm and organizational resources expended to counteract harm).

These injuries are caused by EPA's failure to consult, which allow these pesticides to be sold and used in the United States. 7 U.S.C. § 136a(a); *id.* § 136j(2)(G). Likewise, the Conservation Groups' members' injuries would be redressed by an order from this Court either vacating the registration decisions or ordering EPA to complete consultation. Endangered Species Act consultations would include a thorough assessment of the effects of these pesticides on listed species. If consultation shows that authorized uses of these pesticides would jeopardize listed species, EPA would ultimately be required to impose limits on those uses to prevent jeopardy. 16 U.S.C. § 1536(a)(2); *see also Bennett v. Spear,* 520 U.S. 154, 170 (1997).

ARGUMENT

I. EPA'S FAILURES TO CONSULT VIOLATE THE ESA.

A. EPA Admitted It Violated the ESA.

EPA admitted to this Court that the ESA "requires it to make a determination regarding the effects of each of the challenged registration actions on ESA-listed species and critical habitat" and that it has not done so, "nor has it initiated any consultation that might be triggered by such effects determinations." EPA Motion to Consolidate at 1, Case No. 15-1054, Doc. #1722049. Based on its admissions, EPA sought leave to file a dispositive motion for remand without vacatur. Motion to Defer or Extend Existing Deadlines at 1 and 4, Case No. 15-1054, Doc. #1738576. As a result of its failures to consult, EPA violated its

substantive duty to ensure that registrations of these pesticides are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify critical habitat. 16 U.S.C. § 1536(a)(2). EPA cannot now contest the merits of these consolidated cases.

B. EPA's Failure to Consult Is Not Excusable.

Should EPA or other parties attempt to circumvent EPA's clear admission, there is no legally valid basis to hold EPA has not violated the ESA. This Court already rejected arguments that EPA's failure to consult on registration of pesticides is excusable:

> In no uncertain terms, the ESA mandates that every federal agency "shall" engage in consultation before taking "any action" that could jeopardize the continued existence of any endangered species or threatened species." 16 U.S.C. § 1536(a)(2). Absent a formal exemption under 16 U.S.C. § 1536(h), an agency may not duck its consultation requirement, whether based on limited resources, agency priorities or otherwise. *Id.*

Ctr. for Biological Diversity v. EPA, 861 F.3d 174, 188 n. 10 (D.C. Cir. 2017).

EPA's registration of a pesticide is the necessary federal approval that authorizes its use. 7 U.S.C. § 136a(a); *id.* § 136j(a)(2)(G). It is an "action" under the plain language of the ESA triggering the consultation requirement. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.02. *Defenders of Wildlife*, 882 F.2d 1294 (affirming section 7's application to EPA's registration of pesticides); *see also Defenders of Wildlife*, 791 F. Supp. 2d 96.

EPA must consult on any action that "may affect" any listed species or critical habitat, regardless of whether the effect is "beneficial, benign, adverse or of an undetermined character." 50 C.F.R. §§ 402.14, 402.01; 51 Fed. Reg. 19,926, 19,949 (June 3, 1986). The authorized uses of the active ingredients[18] at issue here meet this low threshold:

1. Approved uses of flupyradifurone may have direct and indirect effects to federally listed taxa including direct effects to protected birds, mammals, reptiles, terrestrial-phase amphibians, and terrestrial and aquatic invertebrates (freshwater and marine/estuarine) and indirect effects to birds, mammals, reptiles, terrestrial-phase amphibians, fish (freshwater and marine/estuarine), aquatic-phase amphibians, mollusks, and aquatic invertebrates (freshwater and marine/estuarine). JA ___, [FL Doc. 96, Flupyradifurone Ecological Risk Assessment at 120 (Table 47), 7, 112, 114]. EPA could not rule out direct effects to dicotyledonous plants. JA ___, [FL Doc. 96 at 120]. EPA determined there would be indirect effects on terrestrial and semi-aquatic plants when other affected species, such as birds and mammals, are required for seed dispersal or pollination. JA ___, [FL Doc. 96 at 14 and 120].

[18] EPA's determinations of potential effects to listed species does not include consideration of the additive, synergistic, or cumulative effects of other ingredients included in the pesticide products or co-applied with those products.

2. Approved use of bicyclopyrone may result in direct risk to ESA protected plants and mammals, and risk of indirect effects to fish, invertebrates, mollusks, amphibians, birds, and reptiles given the potential for adverse effects to plants and mammals. JA ___, [BCP Doc. 15, Bicyclopyrone Ecological Risk Assessment at 2, 10, 55].

3. Approved use of benzovindiflupyr may have "direct effects to listed mammals, birds, terrestrial invertebrates, fish, and aquatic invertebrates on all of its registered use sites," and indirect effects on species that rely on those species that are directly affected. JA ___, [BE Doc. 9, Benzovindiflupyr Ecological Risk Assessment at 75]; JA ___, [BE Doc. 21, Benzovindiflupyr Addendum to Ecological Risk Assessment at 1-2].

4. Approved use of cuprous iodide results in copper being released in water, which is very highly toxic to aquatic organisms and can adversely impact reproduction and growth. JA ___, [CI Doc. 127, Cuprous Iodide Ecological Risk Assessment at 11]. Approved uses may result in concentrations of concern for endangered freshwater invertebrates for up to 72 days, endangered freshwater fish for up to two days, and endangered algae for one day. JA ___, [CI Doc. 127 at 13, 15]. EPA did not assess indirect effects, but such adverse effects on fish are likely due to loss of invertebrates that are their prey.

5. Approved use of halauxifen-methyl may affect terrestrial, aquatic, and semi-aquatic vascular plants up to 2500 feet or more from aerial application sites. JA ___, [HM Doc. 317, Halauxifen-methyl Registration Decision at 3, 104]. EPA did not assess indirect effects, but such adverse effects are likely for any species that relies upon affected plants for food, cover, or breeding or nesting habitat, as EPA disclosed related to bicyclopyrone. *See* JA ___, [BCP Doc. 15 at 55].

Knowing that registration of these pesticides had the potential to affect species on the brink of extinction, EPA went ahead and registered them without consulting with the Wildlife Agencies or ensuring these pesticides would not jeopardize protected species or destroy or adversely modify their critical habitat. EPA Motion to Consolidate at 1, Case No. 15-1054, Doc. #1722049 (Mar. 13, 2018) (EPA admissions that it violated the ESA when registering these pesticides).

EPA had the tools necessary to undertake consultation. EPA and the Wildlife Agencies agreed the first step of consultation would be based on the overlap between areas the pesticide may be present and the species' ranges and designated critical habitats. Interim Approaches, *supra* n.5, at 4. EPA already has data on the overlap of certain crop uses and listed species and critical habitats. For example, for cyantraniliprole, EPA determined whether pesticide use sites are geographically associated with known locations of federally-listed species using its LOCATES database, identifying 1377 listed species overlapping with areas where

cyantraniliprole was proposed for use on multiple crops at the county level. *Ctr. for Biological Diversity v. EPA*, No. 14-1036, Doc. 1629167 at 150-51 (Joint Appendix JA-0258 to JA-0259) (Aug. 8, 2016). *See also, e.g.*, Malathion Biological Evaluation, Attachment 1-6, Tabs "RangeOverlap" and "CHOverlap" (showing overlap of each species with corn, wheat, cotton, orchards and vineyard, other crops, golf courses, and other uses).[19] Knowing these pesticides may affect protected species, EPA simply stopped short in its assessments and did not initiate consultation it admits it is required to undertake.

EPA asserts that it is not consulting on these five pesticides because it claims to be consulting on other pesticides. The ESA does not allow EPA, or any agency, to bypass consultation simply because it might be consulting on other actions. The ESA requires EPA to consult on all of its actions that may affect listed species or critical habitat. 16 U.S.C. § 1536(a)(2) (agencies must consult on "any action"); *Rancho Viejo, LLC v. Norton*, 323 F.3d 1062, 1064 (D.C. Cir. 2003) (all federal agencies must "ensure that none of their activities, including the granting of licenses and permits, will 'jeopardize the continued existence of any endangered species'"). EPA cannot simply ignore its mandatory duties. *Ctr. for Biological*

[19] Link available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment (last visited Feb. 16, 2019). *See supra*, n. 3 (judicial notice allowed).

Diversity, 861 F.3d at 188 n. 10 ("an agency may not duck its consultation requirement, whether based on limited resources, agency priorities or otherwise.").

II. THE CONSERVATION GROUPS ARE ENTITLED TO VACATUR.

The Conservation Groups respectfully request that this Court set aside EPA's registration decisions and remand for EPA to comply with its duties to ensure, through consultation, that its pesticide registration actions do not jeopardize species already on the edge of extinction or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2).

A. Vacatur Is the Presumptive and Usual Remedy.

Congress prescribed vacatur in FIFRA as the statutory remedy for EPA's unlawful pesticide registrations. 7 U.S.C. § 136n(b) (court of appeals has exclusive jurisdiction "to affirm or set aside" invalid orders). As such, vacatur is the statutory and presumptive remedy.

In addition to the express language in FIFRA, vacatur also is the normal or usual remedy where, as here, a federal agency acted contrary to law. *Allina Health Servs. v. Sibelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) ("vacatur is the normal remedy"); *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) (court "[n]ormally" would vacate for clear violation of law); *NRDC v. EPA*, 489 F.3d 1250, 1261-62 (D.C. Cir. 2007) (vacating rule inconsistent with plain language of the Clean Air Act); *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d

989, 994 (9th Cir. 2012) (court orders remand without vacatur only in "limited circumstances"); *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165-66 (2010) (vacatur of an unlawful decision is the "less drastic remedy" than the "extraordinary relief of an injunction."). *See also* Administrative Conference of the United States, The Unusual Remedy of Remand Without Vacatur (Jan. 3, 2014) at 1 ("Remand without vacatur is an unusual remedy by several measures."); *id.*at 50 ("Where vacatur serves the interests of prevailing parties challenging the agency's action it is and should be the ordinary remedy."). [20]

Because vacatur is the presumptive, statutory remedy under FIFRA, the burden is on EPA to show why equity requires anything less than vacatur of its unlawful agency actions. *NRDC v. EPA*, 489 F.3d 1250, 1264 (D.C. Cir. 2007) (Randolph, J., concurring) (vacatur places "the burden where it should be—on the losing agency" to convince the court to grant a stay of its vacatur order with time limits); *Public Emples. For Envtl. Responsibility v. U.S. Fish & Wildlife Serv.*, 189 F.Supp.3d 1, 3-5 (D.D.C. 2016) (vacating agency decision based on presumptive remedy and agency failure to "make a strong showing" or "compelling case" for remand without vacatur); *Ctr. for Envtl. Health v. Vilsack*, No. 15-cv-01690-JSC, 2016 U.S. Dist Lexis 79984, at *41 (N.D. Cal. June 20, 2016) ("given that vacatur

[20] Available at https://www.acus.gov/sites/default/files/documents/Remand%20Without%20Vacatur%20Final%20Report.pdf (last visited February 22, 2019). *See supra*, n. 3 (judicial notice allowed).

is the presumptive remedy for a procedural violations such as this, it is Defendants' burden to show that vacatur is unwarranted"). EPA bears the burden to demonstrate the circumstances that may warrant equitable departure from the presumptive, statutory remedy of vacatur.

B. No Unusual Circumstances Warrant Remand Without Vacatur.

Equitable balancing should be disfavored where EPA intentionally violated a clear statutory mandate. Remand without vacatur, in effect, creates a statutory exemption to the ESA for however many years EPA takes to comply with it. It is not the role of courts to grant exemptions to congressional mandates. And, remand without vacatur, when there has been a clear statutory violation, provides the executive branch extraordinary power. *Olmstead v. United States*, 277 U.S. 438, 485 (1928) ("In a government of laws, existence of the government will be imperiled if it fails to observe the law scrupulously.") (Brandeis, J., dissenting).

In determining whether to remand without vacatur, courts evaluate whether to vacate depending on "the 'seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly)" and the disruptive consequences of vacatur. *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150 (D.C. Cir. 1993). In environmental cases, courts consider the effects on public health and the environment that would result from vactur or

remand without vacatur. *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008).

Although remand without vacatur may be appropriate in certain limited circumstances, EPA cannot demonstrate those circumstances here. First, EPA's unlawful action—intentional violation of its duties to protect endangered species—was serious and not readily curable. Second, this is not the type of case where vacatur will be highly disruptive. Leaving the pesticide registrations in place is likely to result in more environmental harm to the very endangered and threatened species that Congress mandated all federal agencies to protect. In contrast, vacatur will not be highly disruptive to a regulatory scheme intended to protect the environment. These equitable considerations counsel against remand without vacatur.

1. EPA's Intentional Violations of the ESA Are Serious.

EPA's blatant violations of its duties to ensure the protection of endangered species before it registers pesticides are serious. EPA cannot carry its burden to show otherwise, nor can it substantiate its decision on remand. *Allied-Signal, Inc.*, 988 F.2d at 150 (EPA must show "at least a serious possibility" that it will be able "to substantiate its decision on remand."); *see also NACS v. Bd. of Governors of Fed. Reserve Sys.*, 746 F.3d 474, 493 (D.C. Cir. 2014) (agency may be able "to cure a defect in its explanation of a decision").

There is little question that EPA's violations of the ESA are serious. Congress enacted the Endangered Species Act "to halt and reverse the trend toward species extinction, whatever the cost." *Tenn. Valley Auth.*, 437 U.S. at 184. Congress consciously chose to "give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185. EPA's decision to register pesticides in defiance of plain congressional mandates to ensure against jeopardy of endangered and threatened species is extremely serious. 16 U.S.C. § 1536(a)(2).

The ESA's consultation procedure—the procedure that EPA unlawfully avoided here—is the "heart of the ESA." *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 495 (9th Cir. 2011). It is the process by which agencies carry out the ESA's substantive mandate to protect endangered species from jeopardy. 50 C.F.R. §§ 402.13-402.14; *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("[T]he strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with the substantive provisions.") (emphasis in original), *abrogated on other grounds by Cottonwood Env. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). It is hard to overstate the importance of the consultation process. EPA's violations cut to the quick of the statute. *See, e.g.*, *Nat'l Parks Conservation Ass'n v. Jewell*, 62 F. Supp. 3d 7, 20-22 (D.D.C. 2014)

(holding a failure to consult violation to be a serious error for purposes of vacatur, and vacating the agency action).

Courts regularly vacate agency decisions for failures to comply with procedural requirements for notice and comment, which do not carry the weight of the ESA's substantive duties to protect the "incalculable" value of endangered species through the procedure of consultation. *TVA*, 437 U.S. at 187. *See also, e.g., Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (An agency's "[f]ailure to provide the required notice and to invite public comment ... is a fundamental flaw that 'normally' requires vacatur of the rule"); *AFL–CIO v. Chao*, 496 F. Supp. 2d 76, 91 (D.D.C. 2007) (failure to comply with notice-and-comment requirements is unquestionably a serious deficiency for purposes of vacatur). Vacatur is even more appropriate here given EPA's intentional disregard of its mandatory ESA duties.

The problem with EPA's registration decisions is not that EPA inadequately explained them, but rather that EPA intentionally registered pesticides knowing it has a mandatory duty to protect endangered and threatened species, knowing that the use of these pesticides may affect these species and their critical habitat, and yet proceeding anyway in flagrant disregard of its mandatory, statutory duties. There is no "serious possibility" that, on remand, EPA can substantiate its intentional and serious legal error not to comply with the ESA. *See NRDC v. U.S.*

EPA, 857 F.3d at 1040, 1042 (vacating pesticide registration due to EPA's failure to substantiate its finding that the pesticide's use was in the public interest).

2. Consideration of Disruptive Effects Favors Vacatur.

In environmental cases, courts consider the core purpose of the statute at issue and whether vacatur itself will defeat those purposes or cause environmental harm that Congress intended to protect. In contrast, EPA cannot show that vacatur herewill be highly disruptive of a complex regulatory scheme that, once implemented, cannot easily be undone, as is often the case where courts decide to vacate.

a. Pesticides Do Not Enhance Environmental Protection.

Here, vacating is the environmentally protective decision because the core purpose of the ESA is to protect endangered species through consultation, which EPA egregiously failed to do. *See, e.g., North Carolina,*, 550 F.3d at 1178 (remand without vacatur appropriate where EPA provided evidence that vacatur would at least temporarily defeat the enhanced environmental protection covered by the unlawful EPA rule) *citing Environmental Defense Fund v. EPA*, 898 F.2d 183, 190 (D.C. Cir. 1990) (remanding without vacatur because provisions of the Clean Air Act rule provided enhanced, if inadequate, protection of environmental values that petitioners sought, such that vacatur would "at least temporarily defeat" petitioner's interests); *Pollinator Stewardship Council*, 806 F.3d at 532 ("given the

precariousness of the bee population, leaving the EPA's registration of sulfoxaflor in place risks more potential environmental harm than vacating it."); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405–06 (9th Cir. 1995) (leaving in place unlawful decision to list a snail as an endangered species because setting it aside would risk potential extinction).

EPA cannot meet its burden to demonstrate that keeping registrations in place while it completes consultation is the more environmentally protective outcome. In an earlier case, a panel of this Court remanded EPA's unlawful registration of cyantraniliprole without vacating based, in part, on EPA's classification of cyantraniliprole as a "reduced risk"[21] pesticide because it was considered "generally less toxic" to mammals, birds, fish, and honey bees than the leading alternatives. *Ctr. for Biological Diversity*, 861 F.3d at 188-89 (citation omitted). The pesticide registrations at issue here are easily distinguishable.[22]

In sharp contrast to cyantraniliprole, EPA did not classify bicyclopyrone, benzovindiflupyr, cuprous iodide, or halauxifen-methyl as "reduced risk," and, on

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[21] Pesticide uses with reduced risk status receive an expedited time frame for review for FIFRA registration. 7 U.S.C. 136a(c)(10)(B).

[22] One distinction is that petitioners in the cyantraniliprole case did not request vacatur; therefore, the issue was not squarely before the court. *Ctr. for Biological Diversity*, Case Nos. 14-1036, Petitioners'/Appellants' Final Opening Brief at 48, Doc. 1631304 (Aug. 19, 2016) (asking the Court to order EPA to complete consultation and retain jurisdiction until consultation was complete); *see also Nat'l Lime Ass'n v. Envt'l Prot. Agency*, 233 F.3d 625, 635 (D.C. Cir. 2000) (court decided against vacatur at request of party challenging agency action).

that basis, remand without vacatur is not appropriate. EPA compared toxicity of bicyclopyrone to seven alternative active ingredients, which showed that bicyclopyrone is the second most toxic to mammals, third most toxic to vascular aquatic plants, and fourth most toxic to terrestrial plants. JA ___, [BCP Doc. 77 at 6-7]. In other words, bicyclopyrone is generally more toxic than alternative herbicides. For benzovindiflupyr, EPA asserted that it "may be an alternative" to several fungicides, but it did not conduct a reduced risk analysis. JA ___, [BE Doc. 66 at 9]. EPA does not claim that cuprous iodide is less risky than any other antimicrobials. EPA summarily states that halauxifen-methyl "may provide a better alternative" to comparable products, however, it does not conclude that halauxifen-methyl is a reduced risk. JA ___, [HM Doc. 322 at 7].

EPA's classification of some uses of flupyradifurone as reduced risk does not support a finding that remand without vacatur provides a net environmental benefit. First, EPA granted flupyradifurone reduced risk status for some, but not all, uses. JA ___, [FL Doc. 868, Reduced Risk Determination]. Reduced risk status uses include citrus, cotton, pome fruit, and vegetables. JA ___, [FL Doc. 868 at 1]. This leaves many approved uses without reduced risk status, including berries, grapes, wheat, alfalfa, and tree nuts. JA ___ [FL Doc. 103, Registration Decision at

3, 11]. Wheat, for example, is grown in many states,[23] as compared to oranges, which are primarily produced in California, Texas, and Florida.[24] The record does not show that EPA analyzed the overall net environmental benefit taking into consideration uses of flupyradifurone on widely grown crops, which are not reduced risk, and uses on more limited geographic areas that it considered to be reduced risk.

Second, EPA's reduced risk determination is not supported by its reduced risk analysis. More than a year prior to completion of the Ecological Risk Assessment, on February 5, 2013, EPA's Environmental Fate and Effects Division ("EFED") conducted a reduced risk analysis based on the registrant's submissions, but did not independently validate the information the registrant provided for accuracy. JA ___, [FL Doc. 865, Reduced Risk Analysis at 2, 3 (EFED also states the methodologies and data were "not fully in accord with standard EFED procedures")]. EFED compared flupyradifurone to available alternative pesticides for certain uses and determined that flupyradifurone:

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[23] *See, e.g.,* USDA, National Agricultural Statistics Service, "Winter Wheat 2017, Planted Acres by County for Selected States, available at https://www.nass.usda.gov/Charts_and_Maps/graphics/WW-PL-RGBChor.pdf (last visited Feb. 23, 2019). *See supra*, n. 3 (judicial notice allowed).

[24] *See, e.g.,* USDA, National Agricultural Statistics Survey "December 1, 2018 All Orange Production" available at https://www.nass.usda.gov/Charts_and_Maps/Citrus_Fruits/orgmap.php (last visited Feb. 23, 2019). *See supra*, n. 3 (judicial notice allowed).

- is *more* persistent than all but one alternative (imidacloprid);
- may accumulate in soils;
- is likely to move into surface and ground water due to rainfall/runoff;
- has a higher Estimated Environmental Concentration ("EEC") than all the alternatives except acephate.

JA ___, [FL Doc. 865 Reduced Risk Analysis at 2, 4]. Five of the alternative pesticides have similar or lower risk profiles across a range of aquatic and terrestrial organisms compared to flupyradifurone. JA ___, [FL Doc. 865 at 4]. Nonetheless, after meeting with the registrant's representatives, EPA classified flupyradifurone as reduced risk status for certain uses based on a favorable "mammalian toxicity risk profile" while ignoring available alternatives that have similar or lower risk profiles for a range of organisms or for aquatic animals, such as salmonids or freshwater mussels, which were EPA's primary concern in its Ecological Risk Assessment. JA ___, [FL Doc. 867, Sign-in sheet for Committee meeting]; JA ___, [FL Doc. 868, Reduced Risk Determination]; JA ___, [FL Doc. 96, Ecological Risk Assessment at 6]. In other words, EPA provided flupyradifurone a general "reduced risk" status for certain uses when, in fact, it is not less risky than nine or more of the other alternative pesticides that are already available for use on these crops.

Finally, it is fundamentally flawed to rely on new active ingredients as "less risky" than older pesticides to justify leaving in place registrations that increase the risk of harm to endangered and threatened species. EPA already has a duty to ensure all pesticides are safe, including older ones through ESA consultation[25] and the FIFRA reregistration, registration review, or cancellation processes. 7 U.S.C. § 136a-1 (reregistration of pesticides registered before November 1, 1984); 7 U.S.C. § 136a(g) (review of pesticide registrations at least every 15 years); 7 U.S.C. § 136d(b) (cancellation of registrations). For example, to the extent flupyradifurone may be less risky than an older pesticide like chlorpyrifos, instead of reducing or eliminating the use of chlorpyrifos, EPA is fighting to keep it on the market. *See League of United Latin Am. Citizens v. Wheeler*, 899 F.3d 814, 829 (9th Cir. 2018) (vacating EPA decision to maintain chlorpyrifos, based on EPA's own scientific assessment that chlorpyrifos residue on food did not meet safety standard), *vacated and rehearing en banc granted,* 914 F.3d 1189 (9th Cir. 2019) (granting EPA's petition for rehearing).

[25] Reregistration decisions also triggered ESA consultation duties, but EPA did not comply with the ESA when it took those actions to reregister pesticides. *See, e.g.,* EPA Motion to Consolidate at 2-3 (EPA acknowledged its ESA duties and that it approved "thousands of pesticides" still available for use without making ESA effects determinations), *Ctr. for Biological Diversity v. EPA*, Case No. 15-1054, Doc. 1722049 (filed Mar. 13, 2018 D.C. Cir.).

b. Other Consequences of Vacatur Are Not Highly Disruptive.

Remand without vacatur depends on EPA demonstrating that "the disruptive effect of vacatur is high . . . ." *NACS* , 746 F.3d at 493; *Allied-Signal, Inc.*, 988 F.2d at 151 (finding "the consequences of vacating may be quite disruptive"). Because the focus of the ESA is to protect endangered and threatened species and their habitats, non-environmental concerns should be given less weight. *Public Emples. For Envtl. Responsibility*, 189 F.Supp.3d at 4-5 (vacating orders to kill cormorants because obvious effect of inability to kill cormorants after vacatur is not disruptive). EPA cannot meet this high burden.

This is not a situation where "the egg has been scrambled" and there is no way to restore the status quo. *See Sugar Cane Growers*, 289 F.3d at 97. Here, the pesticide registrations are licenses to sell pesticides, not agency regulations or programs that, once implemented, have consequences that cannot later be undone if vacated. In *Allied Signal*, the consequences of vacating the rule were quite disruptive because the agency would have to refund fees it had collected, and it would not be able to recover them later. 988 F.2d at 151 (also finding "serious possibility" that agency would be able to substantiate its decision on remand). In contrast, the Ninth Circuit vacated a pesticide registration for sulfoxaflor because of the "precariousness of bee populations" affected by this insecticide, regardless of what disruption vacatur may have caused. *Pollinator Stewardship Council*, 806

F.3d at 532. The pesticide registration decisions at issue here also put at risk species in a precarious position – those that are protected as endangered or threatened under the ESA. The disruption here is to congressional mandates to protect species.

Leaving the registrations in place puts our most vulnerable wildlife, endangered and threatened species, at risk by allowing continued use of these pesticides before EPA has ensured that their use is not likely to jeopardize these species. This Court should vacate EPA's orders registering these pesticides.

III. IN THE ALTERNATIVE, THE COURT HAS EQUITABLE AUTHORITY TO ORDER EPA TO COMPLY WITH THE ESA BY A DATE CERTAIN.

If the Court were to exercise its equitable authority to remand without vacatur, it also has authority to order EPA to comply with the ESA by a date-certain deadline. *In re Core Communs., Inc.*, 531 F.3d 849, 861-62 (D.C. Cir. 2008) (ordering agency to respond to remand order within 90 days and ordering the rules vacated unless the agency notifies the court that it complied with the court's order before that date); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995); *Rodway v. U.S. Dep't of Agriculture*, 514 F.2d 809, 817 (D.C. Cir. 1975) (ordering 120-day deadline to complete a new rulemaking with notice and comment, based on the "critical importance" of the regulations to the entire food stamp system); *Concerned About Trident v. Rumsfeld*, 555 F.2d 817, 830 (D.C. Cir. 1976) (ordering 120-day deadline for revision of the U.S. Navy's

Environmental Impact Statement to remedy its good faith, but inadequate, attempt to comply with the National Environmental Policy Act); *Friends of the Earth, Inc. v. EPA*, 446 F.3d 140, 148 (D.C. Cir. 2006) (Court remanded case to district court to determine "the shortest reasonable timetable" for "an expedited schedule for further rulemaking").

EPA will argue for a remand without vacatur and no deadlines for it to act to cure its violations of the ESA. An open-ended remand without vacatur and without time limits is "in effect, an indefinite stay of the effectiveness of the court's decision and agencies naturally treat it as such" because the agency has no incentive to act in a reasonable time. *NRDC v. EPA*, 489 F.3d 1250, 1264 (D.C. Cir. 2007) (Randolph, J., concurring) (citation omitted); *see also EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118, 132 (D.C. Cir. 2015) ("To be sure, remand without vacatur creates a risk that an agency may drag its feet and keep in place an unlawful agency rule."). For example, it took EPA fifteen years to respond to a remand of the rule in *Environmental Defense Fund, Inc. v. Administrator of United States EPA,* 898 F.2d 183 (D.C. Cir. 1990); 70 Fed. Reg. 59,582 (Oct. 12, 2005), and finally did so only after a petition for a writ of mandamus had been filed. This extensive timeframe is not speculative in these consolidated cases, where EPA has no intention of complying with the ESA until pesticide registration review, which, for these five pesticides, is fifteen years from the dates of registration. *See* 7 U.S.C.

§ 136a(g)(1)(iii)(II) (registration review 15 years after registration of first pesticide containing a new active ingredient); *see also, e.g.,* JA ___, [FL Doc. 103, Registration Decision at 11] (EPA focusing "most" resources for assessing impacts to listed species on registration review program). The practical effect of a remand without vacatur and without deadlines is to give EPA about two decades of delay to comply with a statute enacted to protect our most vulnerable wildlife.

A panel of this Court denied the Conservation Groups' request to establish a deadline for EPA to conduct its ESA consultation in the cyantraniliprole case. *Ctr. for Biological Diversity v. EPA*, 861 F.3d at 189 n. 12. However, as set forth above, the Court has the equitable authority to do so. Moreover, the case relied upon concerned a very different factual situation from the present case. *Id. citing Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952). In *Idaho Power*, the court of appeals held that conditions on a license for a hydroelectric project exceeded the Federal Power Commission's authority, then it entered a judgment that modified the license by striking the conditions and affirmed the license as thus modified. *Id.* at 19-20. The Supreme Court reversed, holding that when the court of appeals affirmed the license without the conditions, "it usurped an administrative function" to consider whether to issue the license at all. *Id.* at 20. Here, as an alternative, the Conservation Groups are asking for this Court to order a deadline to consult, which EPA was required to do *before* it issued the pesticide

registrations three or more years ago. Such an order does not overreach into EPA's functions, as set forth in the ESA or FIFRA.

CONCLUSION

EPA's failure to consult on its decisions to authorize nationwide uses of these new pesticides, violates the Endangered Species Act, 16 U.S.C. § 1536(a)(2). The Conservation Groups ask this Court to declare that EPA's failure to consult on the effects of these pesticides violates the ESA and to vacate the Registration Orders, or, in the alternative, to order EPA to initiate consultation by a date certain and to report back to this Court every six months until consultation is complete.

Respectfully submitted this 4th day of March, 2019.

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CERTIFICATE OF COMPLIANCE

In accordance with Circuit Rule 32(a) and Rule 32(a)(7) of the Federal Rules of Appellate Procedure, the undersigned certifies that the accompanying brief has been prepared using 14-point Time New Roman typeface, and is double-spaced (except for headings and footnotes).

The undersigned further certifies that the brief is proportionally spaced and contains 11,979 words, exclusive of the certificate required by Circuit Rule 28(a)(1), table of contents, table of authorities, glossary, signature lines, and certificates of service and compliance.

The undersigned used Microsoft Word 2010 to compute the word count.

Respectfully submitted this 4th day of March, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2019, I served the foregoing *Petitioners' Opening Brief (Addendum of Pertinent Statutes and Regulations attached)* and *Addendum of Standing Declarations in Support of Petitioners' Opening Brief* on Respondent Environmental Protection Agency and Intervenors Bayer CropScience LP, Syngenta Crop Protection LLC, and Dow AgroSciences LLC via electronic filing (CM/ECF) to the following:

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ORAL ARGUMENT NOT YET SCHEDULED

Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CENTER FOR BIOLOGICAL DIVERSITY, CENTER FOR FOOD SAFETY, and DEFENDERS OF WILDLIFE,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

and

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION LLC, and DOW AGROSCIENCES LLC,
Intervenor-Respondents.

Petition for Review of Order of U.S. Environmental Protection Agency (Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351)

ADDENDUM OF PERTINENT STATUTES AND REGULATIONS IN SUPPORT OF PETITIONERS' OPENING BRIEF

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"(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

"(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

"(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

"(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted."

SHORT TITLE OF 2012 AMENDMENT

Pub. L. 112–177, § 1, Sept. 28, 2012, 126 Stat. 1327, provided that: "This Act [amending sections 136a–1 and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136a–1 of this title] may be cited as the 'Pesticide Registration Improvement Extension Act of 2012'."

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110–94, § 1, Oct. 9, 2007, 121 Stat. 1000, provided that: "This Act [amending sections 136a, 136a–1, and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the 'Pesticide Registration Improvement Renewal Act'."

SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108–199, div. G, title V, § 501(a), Jan. 23, 2004, 118 Stat. 419, provided that: "This section [enacting section 136w–8 of this title, amending sections 136a, 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the 'Pesticide Registration Improvement Act of 2003'."

SHORT TITLE OF 1996 AMENDMENT

Pub. L. 104–170, § 1, Aug. 3, 1996, 110 Stat. 1489, provided that: "This Act [enacting sections 136i–2, 136r–1, and 136w–5 to 136w–7 of this title, amending this section, sections 136a, 136a–1, 136d, 136q, 136s, 136w, 136w–3, 136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i–2 of this title and sections 301 and 346a of Title 21] may be cited as the 'Food Quality Protection Act of 1996'."

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104–170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104–170, set out as a note under section 301 of Title 21, Food and Drugs.]

SHORT TITLE OF 1988 AMENDMENT

Pub. L. 100–532, § 1(a), Oct. 25, 1988, 102 Stat. 2654, provided that: "This Act [enacting section 136a–1 of this title, amending this section and sections 136a to 136d, 136f to 136q, 136s, 136v to 136w–2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136y of this title] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988'."

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95–396, § 29, Sept. 30, 1978, 92 Stat. 842, provided that: "This Act [enacting sections 136w–1 to 136w–4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136*l*, 136*o*, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136*o*, and 136w–4 of this title, and amending provisions set out as a note under this section] may be cited as the 'Federal Pesticide Act of 1978'."

SHORT TITLE

Pub. L. 92–516, § 1, Oct. 21, 1972, 86 Stat. 973, provided: "That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the 'Federal Environmental Pesticide Control Act of 1972'."

Act June 25, 1947, ch. 125, § 1(a), as added by Pub. L. 92–516, § 2, Oct. 21, 1972, 86 Stat. 973, provided that: "This Act [enacting this subchapter] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'."

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 136a. Registration of pesticides

(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 reg-

istration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

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

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

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

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

(C) Simplified procedures

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

(D) Exemption

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

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

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

(E) Minor use waiver

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

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

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

(3) Application

(A) In general

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

(B) Identical or substantially similar

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

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

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

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

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

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

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

(C) Minor use registration

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

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

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

(ii) For the purposes of clause (i)—

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

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

(D) Adequate time for submission of minor use data

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

(4) Notice of application

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

(5) Approval of registration

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

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

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

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

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

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

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide.

Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)—

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

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

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

(8) Interim administrative review

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

(9) Labeling

(A) Additional statements

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

(B) Requirements

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

(C) Notification and disapproval

(i) Notification

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

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

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

(ii) Disapproval

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

(iii) Restriction on sale

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

(iv) Objection

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

(v) Final action

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

(D) Use dilution

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

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

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

(10) Expedited registration of pesticides

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

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

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

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

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

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

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

(d) Classification of pesticides

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

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

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

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without addi-

tional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

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

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

(2) Change in classification

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

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

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

(e) Products with same formulation and claims

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

(f) Miscellaneous

(1) Effect of change of labeling or formulation

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

(2) Registration not a defense

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

(3) Authority to consult other Federal agencies

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

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of—

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

(B) 1 or more fertilizer products,

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

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

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

(iii) Initial registration review

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

(I) October 1, 2022; or

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

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is

completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

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

(B) Docketing

(i) In general

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

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

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

(ii) Protected information

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

(C) Limitation

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

(2) Data

(A) Submission required

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

(B) Data submission, compensation, and exemption

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

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

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

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

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

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

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

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

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

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

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

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

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

(ii) Requirements

Proposed regulations issued under clause (i) shall—

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

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

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

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

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

(iii) Comments

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

(B) Final regulations

(i) Issuance

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

(ii) Failure to meet goal

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

(iii) Requirements

In issuing final regulations, the Administrator shall—

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

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

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

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

(bb) revised procedures for application review; and

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

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

(C) Expedited review

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

(D) Alternative review periods

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

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

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

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

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

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

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

(E) Wood preservatives

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

(F) Notification

(i) In general

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

(ii) Final decision

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

(iii) Exemption

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

(iv) Limitation

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

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

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

(4) Annual report

(A) Submission

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

(B) Requirements

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

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

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

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

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

PRIOR PROVISIONS

A prior section 3 of act June 25, 1947, was classified to section 135a of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

2007—Subsec. (c)(3)(B)(ii)(I). Pub. L. 110–94, § 2(1), substituted "review the application in accordance with section 136w–8(f)(4)(B) of this title and," for "within 45 days after receiving the application, notify the registrant whether or not the application is complete and,".

Subsec. (c)(3)(B)(ii)(II). Pub. L. 110–94, § 2(2), substituted "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" for "within".

Subsec. (g)(1)(A). Pub. L. 110–94, § 3(1), designated first sentence as cl. (i) and inserted heading, designated second sentence as cl. (ii), inserted heading, and substituted "In accordance with this subparagraph, the Administrator" for "The Administrator", added cls. (iii) and (iv), designated fourth sentence as cl. (v) and inserted heading, and struck out third sentence which read as follows: "The goal of these regulations shall be a review of a pesticide's registration every 15 years."

Subsec. (g)(1)(B), (C). Pub. L. 110–94, § 3(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

2004—Subsec. (h)(2)(F). Pub. L. 108–199, § 501(b)(1), substituted "120 days" for "90 to 180 days".

Subsec. (h)(3)(D)(vi). Pub. L. 108–199, § 501(b)(2)(A), substituted "120 days" for "240 days".

Subsec. (h)(3)(F)(iv). Pub. L. 108–199, § 501(b)(2)(B), added cl. (iv).

1996—Subsec. (c)(1)(F)(ii) to (vi). Pub. L. 104–170, § 210(b), added cls. (ii), (v), and (vi), redesignated former cls. (ii) and (iii) as (iii) and (iv), respectively, and in cl. (iv) substituted "(i), (ii), and (iii)" for "(i) and (ii)".

Subsec. (c)(1)(G). Pub. L. 104–170, § 250(1), added subpar. (G).

Subsec. (c)(2)(A). Pub. L. 104–170, §§ 210(d)(1), 231, inserted heading, inserted "the public health and agricultural need for such minor use," after "pattern of use,", and substituted "potential beneficial or adverse effects on man and the environment" for "potential exposure of man and the environment to the pesticide".

Subsec. (c)(2)(B). Pub. L. 104–170, § 210(d)(2), inserted heading.

Subsec. (c)(2)(B)(vi). Pub. L. 104–170, § 210(c)(1), added cl. (vi).

Subsec. (c)(2)(B)(vii). Pub. L. 104–170, § 210(f)(2), added cl. (vii).

Subsec. (c)(2)(B)(viii). Pub. L. 104–170, § 222, added cl. (viii).

Subsec. (c)(2)(C). Pub. L. 104–170, § 210(d)(3), inserted heading.

Subsec. (c)(2)(E). Pub. L. 104–170, § 210(d)(4), added subpar. (E).

Subsec. (c)(3)(A), (B). Pub. L. 104–170, § 210(e)(1), (2), inserted headings.

Subsec. (c)(3)(C), (D). Pub. L. 104–170, § 210(e)(3), added subpars. (C) and (D).

Subsec. (c)(9). Pub. L. 104–170, § 223, added par. (9).

Subsec. (c)(10). Pub. L. 104–170, § 250(2), added par. (10).

Subsec. (f)(4). Pub. L. 104–170, § 105(b), added par. (4).

Subsec. (g). Pub. L. 104–170, § 106(b), added subsec. (g).

Subsec. (h). Pub. L. 104–170, § 224, added subsec. (h).

1991—Subsec. (c)(1)(D). Pub. L. 102–237, § 1006(a)(3)(B), (C), added subpar. (D) and redesignated former subpar. (D) as (F).

Subsec. (c)(1)(E). Pub. L. 102–237, § 1006(a)(3)(A), (C), added subpar. (E) and struck out former subpar. (E) which read as follows: "the complete formula of the pesticide; and".

Subsec. (c)(1)(F). Pub. L. 102–237, § 1006(a)(3)(A), (B), (D), redesignated former subpar. (D) as (F), in cl. (i) substituted "With" for "with" and a period for semicolon at end, in cl. (ii) substituted "Except" for "except" and a period for semicolon at end, in cl. (iii) substituted "After" for "after" and a period for semicolon at end, and struck out former subpar. (F) which read as follows: "a request that the pesticide be classified for general use, for restricted use, or for both."

Subsec. (c)(2)(A). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator" for "he" before "requires", "shall permit", "shall make", and "deems", and substituted "the Administrator's" for "his".

Subsec. (c)(2)(D). Pub. L. 102–237, § 1006(c), clarified amendment made by Pub. L. 100–532, § 102(b)(2)(A). See 1988 Amendment note below.

Subsec. (c)(3)(A). Pub. L. 102–237, § 1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(6). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator" for "he" before "shall notify" in two places and "the Administrator's" for "his" in four places.

Subsec. (d)(1). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "shall classify it for both" in subpar. (A), before "will classify" in subpar. (B), and before "shall classify" in subpar. (C).

Subsec. (d)(2). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

1990—Subsec. (c)(2)(A). Pub. L. 101–624 inserted after third sentence "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."

1988—Subsec. (a). Pub. L. 100–532, § 601(b)(1), substituted "Requirement of registration" for "Requirement" in heading and amended text generally. Prior to amendment, text read as follows: "Except as otherwise provided by this subchapter, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator."

Subsec. (c)(1)(D). Pub. L. 100–532, § 801(b)(1)–(4), in introductory provisions, substituted "paragraph (2)(D)" for "subsection (c)(2)(D) of this section", in cl. (i), substituted "(i) with" for "(i) With" and ", except that" for ": *Provided*, That", in cl. (ii), substituted "clause (i)" for "subparagraph (D)(i) of this paragraph", and in cl. (iii), substituted "clauses (i) and (ii)" for "subparagraphs (D)(i) and (D)(ii) of this paragraph".

Subsec. (c)(2)(A). Pub. L. 100–532, § 801(b)(5)(A), (B), substituted "(2) Data in support of registration.—

"(A) The"

for "(2)(A) Data in support of registration.—The", and directed that subpar. (A) be aligned with left margin of subsec. (d)(1)(A) of this section.

Subsec. (c)(2)(B). Pub. L. 100–532, §§ 102(b)(1), 801(b)(5)(C)–(F), substituted "(B)(i) If" for "(B) Additional data to support existing registration.—(i) If", directed that cls. (ii) to (v) be aligned with left margin of subpar. (A), in cls. (ii) and (iii), inserted "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.", in cl. (iv), substituted "title. The only" for "title: *Provided*, that the only", and in cl. (v), substituted "paragraph (1)(D)" for "subsection (c)(1)(D) of this section".

Subsec. (c)(2)(C). Pub. L. 100–532, § 801(b)(5)(G), (H), struck out "Simplified procedures" after "(C)" and directed that text be aligned with left margin of subpar. (A).

Subsec. (c)(2)(D). Pub. L. 100–532, § 102(b)(2)(A), and Pub. L. 102–237, § 1006(c), substituted "the pesticide that is the subject of the application" for "an end-use product".

Subsec. (c)(2)(D)(i). Pub. L. 100–532, § 102(b)(2)(B), struck out "the safety of" after "data pertaining to".

Subsec. (c)(3). Pub. L. 100–532, § 103, substituted "(A) The Administrator" for "The Administrator" and added subpar. (B).

Subsec. (c)(7). Pub. L. 100–532, § 801(b)(6), in introductory provisions, substituted "paragraph (5)" for "subsection (c)(5) of this section", in subpars. (A) and (B), substituted "paragraph (5). If" for "subsection (c)(5) of this section: *Provided*, That, if", and in subpar. (C), substituted "prescribe. A" for "prescribe: *Provided*, that a".

Subsec. (d)(1)(A). Pub. L. 100–532, § 801(b)(7), substituted "restricted use. If" for "restricted use, provided that if" and "restricted uses. The Administrator" for "restricted uses: *Provided, however*, That the Administrator".

Subsec. (f)(2). Pub. L. 100–532, § 801(b)(8), substituted "this subchapter. As" for "this subchapter: *Provided*, That as".

Subsec. (g). Pub. L. 100–532, § 801(b)(9), struck out subsec. (g) which read as follows: "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process."

1978—Subsec. (c)(1)(D). Pub. L. 95–396, § 2(a)(1), added subpar. (D), and struck out provisions which required the applicant for registration of a pesticide to file with the Administrator a statement containing "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970, in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 136h(b) of this title. This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If either party does not agree with said determination, he may, within thirty days, take an appeal to the Federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. Registration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court.".

Subsec. (c)(2). Pub. L. 95–396, §§ 2(a)(2)(A)–(D), 3, 4, designated existing provisions as subpar. (A), inserted in second sentence "under subparagraph (B) of this paragraph" after "kind of information", struck out from introductory text of third sentence "subsection (c)(1)(D) of this section and" after "Except as provided by", and inserted provisions relating to establishment of standards for data requirements for registration of pesticides with respect to minor uses and consideration of economic factors in development of standards and cost of development, and added subpars. (B) to (D).

Subsec. (c)(5). Pub. L. 95–396, § 5, provided for waiver of data requirements pertaining to efficacy.

Subsec. (c)(7), (8). Pub. L. 95–396, § 6, added pars. (7) and (8).

Subsec. (d)(1)(A). Pub. L. 95–396, § 7(1), authorized classification of pesticide uses by regulation on the initial classification and registered pesticides prior to reregistration.

Subsec. (d)(2). Pub. L. 95–396, § 7(2), substituted "forty-five days" for "30 days".

Subsec. (d)(3). Pub. L. 95–396, § 7(3), added par. (3).

Subsec. (g). Pub. L. 95–396, § 8, added subsec. (g).

1975—Subsec. (c)(1)(D). Pub. L. 94–140 inserted exception relating to test data submitted on or after January 1, 1970, in support of application, inserted provision that compensation for producing test data shall apply to all applications submitted on or after October 21, 1972, and provision relating to delay of registration pending determination of reasonable compensation, struck out requirement that payment determined by court not be less than amount determined by Administrator, and substituted "If either party" for "If the owner of the test data".

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110–94, § 6, Oct. 9, 2007, 121 Stat. 1007, provided that: "This Act [see Short Title of 2007 Amendment note set out under section 136 of this title] and the amendments made by this Act take effect on October 1, 2007."

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–199, div. G, title V, § 501(h), Jan. 23, 2004, 118 Stat. 434, provided that: "Except as otherwise provided in this section [enacting section 136w–8 of this title, amending this section and sections 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under sections 136 of this title and section 346a of Title 21, Food and Drugs] and the amendments made by this section, this section and the amendments made by this section take effect on the date that is 60 days after the date of enactment of this Act [Jan. 23, 2004]."

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–396, § 2(b), Sept. 30, 1978, 92 Stat. 824, provided that: "The amendment to section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [subsec. (c)(1)(D) of this section] made by [subsec. (a)(1) of] this section shall apply with respect to all applications for registration approved after the date of enactment of this Act [Sept. 30, 1978]."

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

BIOLOGICAL PESTICIDE HANDLING STUDY

Pub. L. 101–624, title XIV, § 1498, Nov. 28, 1990, 104 Stat. 3631, provided that:

"(a) STUDY.—Not later than September 30, 1992, the National Academy of Sciences shall conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency.

"(b) DEVELOPMENT OF PROCEDURES.—Not later than 1 year after the completion of the study under subsection (a), the agencies and offices described in such subsection shall develop and implement a common process for reviewing and approving biological control applications that are submitted to such agencies and offices that shall be based on the study conducted under such subsection and the recommendation of the National Academy of Sciences, and other public comment."

EDUCATION, STUDY, AND REPORT

Pub. L. 100–478, title I, §1010, Oct. 7, 1988, 102 Stat. 2313, provided that:

"(a) EDUCATION.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act [Oct. 7, 1988], shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements that may be imposed by the Administrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

"(b) STUDY.—The Administrator of the Environmental Protection Agency, jointly with the Secretary of Agriculture and the Secretary of the Interior, shall conduct a study to identify reasonable and prudent means available to the Administrator to implement the endangered species pesticides labeling program which would comply with the Endangered Species Act of 1973, as amended, and which would allow persons to continue production of agricultural food and fiber commodities. Such study shall include investigation by the Administrator of the best available methods to develop maps and the best available alternatives to mapping as means of identifying those circumstances in which use of pesticides may be restricted; identification of alternatives to prohibitions on pesticide use, including, but not limited to, alternative pesticides and application methods and other agricultural practices which can be used in lieu of any pesticides whose use may be restricted by the labeling program; examination of methods to improve coordination among the Environmental Protection Agency, Department of Agriculture, and Department of the Interior in administration of the labeling program; and analysis of the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.

"(c) REPORT.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate."

§ 136a–1. Reregistration of registered pesticides

(a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 136a(c)(5) of this title have been satisfied.

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) Phase one

(1) Priority for reregistration

For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) Reregistration lists

For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registration standards have been issued before such effective date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) Judicial review

The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) Notice to registrants

On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(d) Phase two

(1) In general

The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) Notice of intent to seek or not to seek reregistration

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) Missing or inadequate data

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 136a of this title, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) Time periods

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent

the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application 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 this section 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 this section; 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 subparagraph, 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) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, 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 subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph 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 written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(5) Cancellation and removal

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

(I) during the comment period a person acquires the rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by this section has been paid.

(6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. 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 sup-

port other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a 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 paragraph, 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 section 136a(c)(2)(B)(iv) of this title 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 this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph 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.

(e) Phase three

(1) Information about studies

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 136a of this title and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 136a of this title, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 136d(a)(2) of this title, indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing; and

(I) evidence of compliance with section 136a(c)(1)(D)(ii)[1] of this title and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this subchapter and shall be subject to the penalties prescribed by section 136*l* of this title.

(2) Time periods

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 12 months after the

[1] See References in Text note below.

date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application 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 this section 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 this section; 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 subparagraph, 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) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, 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 subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph 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 written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Cancellation

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. 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 subparagraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph 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 subparagraph, 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 section 136a(c)(2)(B)(iv) of this title 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 this subparagraph, 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.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall deter-

mine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title, except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) Guidelines

(A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section,

under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not be subject to judicial review.

(5) Monitoring

The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

(f) Phase four

(1) Independent review and identification of outstanding data requirements

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 136a(c)(2)(B) of this title for the submission of the additional data that are required to meet such requirements.

(2) Time periods

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application 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 this section 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 this section; 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 subparagraph, 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) of section 136a(c)(2)(B) of this title or other provisions

of this section, as appropriate, 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 subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph 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 written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. 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 paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a 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 paragraph, 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 section 136a(c)(2)(B)(iv) of this title 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 this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph 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.

(g) Phase five

(1) Data review

The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) and of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions

(A) IN GENERAL.—The Administrator shall make a determination as to eligibility for reregistration—

(i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and

(ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.

(B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 136a(c)(2)(B) of this title and shall review such data within 90 days after its submission.

(ii) TIMING.—

(I) IN GENERAL.—Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(II) EXTRAORDINARY CIRCUMSTANCES.—In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator

shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

(i) IN GENERAL.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(ii) TIMING FOR REGULATORY ACTION.—Regulatory action under clause (i) shall be completed as expeditiously as possible.

(E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—

(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);

(ii) determine whether such tolerance or exemption meets the requirements of that Act [21 U.S.C. 301 et seq.];

(iii) determine whether additional tolerances or exemptions should be issued;

(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and

(v) commence promptly such proceedings under this subchapter and section 408 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a] as are warranted by such determinations.

(h) Compensation of data submitter

If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 136a of this title, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 136a(c)(1)(D)[1] of this title. In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) Fees

(1) Maintenance fee

(A) IN GENERAL.—Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration, except that no fee shall be charged for more than 200 registrations held by any registrant.

(B) In the case of a pesticide that is registered for a minor agricultural use, the Administrator may reduce or waive the payment of the fee imposed under this paragraph if the Administrator determines that the fee would significantly reduce the availability of the pesticide for the use.

(C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017.

(D) MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.—The maximum annual fee payable under this paragraph by—

(i) a registrant holding not more than 50 pesticide registrations shall be $115,500 for each of fiscal years 2013 through 2017; and

(ii) a registrant holding over 50 registrations shall be $184,800 for each of fiscal years 2013 through 2017.

(E) MAXIMUM AMOUNT OF FEES FOR SMALL BUSINESSES.—

(i) IN GENERAL.—For a small business, the maximum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pesticide registrations shall be $70,600 for each of fiscal years 2013 through 2017; and

(II) a registrant holding over 50 pesticide registrations shall be $122,100 for each of fiscal years 2013 through 2017.

(ii) DEFINITION OF SMALL BUSINESS.—

(I) IN GENERAL.—In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) AFFILIATES.—

(aa) IN GENERAL.—In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.

(bb) AFFILIATED PERSONS.—For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.

(cc) INDICIA OF CONTROL.—For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees.

(F) FEE REDUCTION FOR CERTAIN SMALL BUSINESSES.—

(i) DEFINITION.—In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that—

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle,

had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

(III) holds not more than 5 pesticide registrations under this paragraph.

(ii) WAIVER.—Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.

(iii) LIMITATION.—The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(G) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(H) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(I) The authority provided under this paragraph shall terminate on September 30, 2017..[2]

(2) Other fees

Except as provided in section 136w–8 of this title, during the period beginning on October 25, 1988, and ending on September 30, 2019, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter except as provided in paragraph (1).

(j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(1)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 136a(c)(2)(D) of this title, the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) Reregistration and expedited processing fund

(1) Establishment

There shall be established in the Treasury of the United States a reregistration and expedited processing fund which shall be known as the Reregistration and Expedited Processing Fund.

(2) Source and use

(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the fund and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title. Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications. The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the Government Accountability Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title; and

(iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

(B) The Administrator shall also—

(i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (*l*)(2); and

(ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.

(3) Review of inert ingredients; expedited processing of similar applications

(A) The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2013 through 2017, between ⅛ and ⅛, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—

(i) to review and evaluate inert ingredients; and

(ii) to ensure the expedited processing and review of any application 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

[2] So in original.

would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment;

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

(III) proposes the initial or amended registration of an end use pesticide that, if registered as proposed, would be used for a public health pesticide.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on October 25, 1988.

(C) So long as the Administrator has not met the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title with respect to any application subject to section 136a(c)(3)(B) of this title that was received prior to August 3, 1996, the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject to section 136a(c)(3)(B) of this title that were received prior to August 3, 1996, have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 136a(c)(3)(B) of this title have been acted upon.

(4) Enhancements of information technology systems for improvement in review of pesticide applications

(A) In general

For each of fiscal years 2013 through 2017, the Administrator shall use not more than $800,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Activities

The Administrator shall use amounts made available from the Reregistration and Expedited Processing Fund to improve the information systems capabilities for the Office of Pesticide Programs to enhance tracking of pesticide registration decisions, which shall include—

(i) the electronic tracking of—

(I) registration submissions; and

(II) the status of conditional registrations;

(ii) enhancing the database for information regarding endangered species assessments for registration review;

(iii) implementing the capability to electronically review labels submitted with registration actions; and

(iv) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions.

(5) Unused funds

Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(6) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii)[1] are used only for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (*l*). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (*l*). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

(*l*) Performance measures and goals

The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 136a(c)(2)(B) of this title issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A)

and (B) in the current fiscal year and the succeeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

(m) Judicial review

Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title.

(n) Authorization of funds to develop public health data

(1) "Secretary" defined

For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) Consultation

In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 136a(c)(2)(B)(iv) of this title, or cancel a registration under section 136a–1, 136d(e), or 136d(f) of this title. In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

(3) Benefits to support family

The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 136a of this title or reregistration under this section.

(4) Additional time

If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 136a(c)(2)(B) of this title to specify additional reasonable time periods for submission of the data.

(5) Arrangements

The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organizations qualified by experience and training to conduct such studies.

(6) Support

The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act [42 U.S.C. 201 et seq.], or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) Authorization of appropriations

There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

(June 25, 1947, ch. 125, § 4, formerly § 3A, as added and renumbered § 4, Pub. L. 100–532, title I, § 102(a), title VIII, § 801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub. L. 101–624, title XIV, § 1493, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, § 1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895–1897; Pub. L. 104–170, title I, § 103, title II, §§ 210(c)(2), (f)(1), 232, 237, title V, § 501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub. L. 107–73, title III, [(1)–(4)], Nov. 26, 2001, 115 Stat. 686; Pub. L. 108–7, div. K, title III, [(1)–(4)], Feb. 20, 2003, 117 Stat. 513; Pub. L. 108–199, div. G, title V, § 501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub. L. 108–271, § 8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–94, § 4(a)–(d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub. L. 112–177, § 2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329.)

REFERENCES IN TEXT

The effective date of this section, referred to in subsecs. (a), (c)(1), (2), and (e)(4)(A), is 60 days after Oct. 25, 1988. See Effective Date note below.

Section 136a(c)(1)(D) of this title, referred to in subsecs. (e)(1)(I) and (h), was redesignated section 136a(c)(1)(F) of this title by Pub. L. 102–237, title X, § 1006(a)(3)(B), Dec. 13, 1991, 105 Stat. 1894.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(A)(1), (E)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Subsection (i)(1)(C)(ii) of this section, referred to in subsec. (k)(6), was previously a reference to subsec. (i)(5)(C)(ii), which was repealed and a new subsec. (i)(5)(C)(ii) was added by Pub. L. 108–199, § 501(c)(2). Subsec. (i)(5)(C) was amended by Pub. L. 110–94, § 4(a), and, as so amended, related to fees but no longer contained a cl. (ii). Subsec. (i)(5) was redesignated (i)(1) by Pub. L. 112–177, § 2(a)(1)(C).

The Public Health Service Act, referred to in subsec. (n)(6), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

PRIOR PROVISIONS

A prior section 4 of act June 25, 1947, which was classified to section 136b of this title was transferred to section 11(a)–(c) of act June 25, 1947, which is classified to section 136i(a)–(c) of this title.

Another prior section 4 of act June 25, 1947, was classified to section 135b of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

2012—Subsec. (d)(5)(B)(ii)(III). Pub. L. 112–177, § 2(a)(2)(A)(i), substituted "this section" for "subsection (i)(1)".

Subsec. (i)(1) to (4). Pub. L. 112–177, § 2(a)(1)(C), (D), redesignated pars. (5) and (6) as (1) and (2), respectively, and struck out former pars. (1) to (4) which related to initial fee for food or feed use pesticide active ingredients, final fee for food or feed use pesticide active ingredients, fees for other pesticide active ingredients, and reduction or waiver of fees for minor use and other pesticides, respectively.

Subsec. (i)(5). Pub. L. 112–177, § 2(a)(1)(D), redesignated par. (5) as (1).

Subsec. (i)(5)(C). Pub. L. 112–177, § 2(a)(1)(A)(i), substituted "aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017." for "aggregate amount of $22,000,000 for each of fiscal years 2008 through 2012".

Subsec. (i)(5)(D)(i). Pub. L. 112–177, § 2(a)(1)(A)(ii)(I), substituted "shall be $115,500 for each of fiscal years 2013 through 2017;" for "shall be $71,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(D)(ii). Pub. L. 112–177, § 2(a)(1)(A)(ii)(II), substituted "shall be $184,800 for each of fiscal years 2013 through 2017." for "shall be $123,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(E)(i)(I). Pub. L. 112–177, § 2(a)(1)(A)(iii)(I), substituted "shall be $70,600 for each of fiscal years 2013 through 2017;" for "shall be $50,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(E)(i)(II). Pub. L. 112–177, § 2(a)(1)(A)(iii)(II), substituted "shall be $122,100 for each of fiscal years 2013 through 2017." for "shall be $86,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(F). Pub. L. 112–177, § 2(a)(1)(A)(vi), added subpar. (F). Former subpar. (F) redesignated (G).

Pub. L. 112–177, § 2(a)(1)(A)(iv), substituted "this paragraph" for "paragraph (3)" and "Human" for "Humans".

Subsec. (i)(5)(G), (H). Pub. L. 112–177, § 2(a)(1)(A)(v), redesignated subpars. (F) and (G) as (G) and (H), respectively.

Subsec. (i)(5)(I). Pub. L. 112–177, § 2(a)(1)(A)(v), (vii), redesignated subpar. (H) as (I) and substituted "2017" for "2012".

Subsec. (i)(6). Pub. L. 112–177, § 2(a)(1)(D), redesignated par. (6) as (2).

Pub. L. 112–177, § 2(a)(1)(B), substituted "2019" for "2014" and "paragraph (1)" for "paragraphs (1) through (5)".

Subsec. (i)(7). Pub. L. 112–177, § 2(a)(1)(C), struck out par. (7) which related to apportionment of certain fees among registrants of pesticides.

Subsec. (j). Pub. L. 112–177, § 2(a)(2)(A)(ii), substituted "subsection (i)(1)" for "subsection (i)(5)".

Subsec. (k)(2)(A). Pub. L. 112–177, § 2(a)(4)(A)(i), inserted ", to enhance the information systems capabilities to improve the tracking of pesticide registration decisions," after "paragraph (3)" wherever appearing.

Subsec. (k)(2)(A)(i). Pub. L. 112–177, § 2(a)(4)(A)(ii), inserted "offset" before "the costs of reregistration" and struck out "in the same portion as appropriated funds" before semicolon at end.

Subsec. (k)(3)(A). Pub. L. 112–177, § 2(a)(4)(B), in introductory provisions, substituted "2013 through 2017, between 1/9 and 1/8" for "2008 through 2012, between 1/8 and 1/7"; in cl. (i), struck out "new" before "inert"; and, in cl. (ii), substituted "any application that—" for "any application that—".

Subsec. (k)(4). Pub. L. 112–177, § 2(a)(4)(C)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 112–177, § 2(a)(4)(C)(i), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 112–177, § 2(a)(2)(A)(iii), substituted "subsection (i)(1)(C)(ii)" for "subsection (i)(5)(C)(ii)" and "subsection (i)(1)(C)" for "subsection (i)(5)(C)" in two places.

Subsec. (k)(6). Pub. L. 112–177, § 2(a)(4)(C)(i), (iii), redesignated par. (5) as (6) and substituted "for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (*l*)" for "to carry out the goals established under subsection (*l*)".

2007—Subsec. (i)(5)(C). Pub. L. 110–94, § 4(a), which directed substitution of "amount of $22,000,000 for each of fiscal years 2008 through 2012" for "amount of" and all that follows through the end of clause (v), was executed by making the substitution for "amount of—

"(i) for fiscal year 2004, $26,000,000;
"(ii) for fiscal year 2005, $27,000,000;
"(iii) for fiscal year 2006, $27,000,000;
"(iv) for fiscal year 2007, $21,000,000; and
"(v) for fiscal year 2008, $15,000,000."

to reflect the probable intent of Congress. The words "amount of" appeared in the heading and twice in the text.

Subsec. (i)(5)(D)(i). Pub. L. 110–94, § 4(b)(1)(A), substituted "shall be $71,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(I) for fiscal year 2004, $84,000;
"(II) for each of fiscal years 2005 and 2006, $87,000;
"(III) for fiscal year 2007, $68,000; and
"(IV) for fiscal year 2008, $55,000; and".

Subsec. (i)(5)(D)(ii). Pub. L. 110–94, § 4(b)(1)(B), substituted "shall be $123,000 for each of fiscal years 2008 through 2012." for "shall be—

"(I) for fiscal year 2004, $145,000;
"(II) for each of fiscal years 2005 and 2006, $151,000;
"(III) for fiscal year 2007, $117,000; and
"(IV) for fiscal year 2008, $95,000."

Subsec. (i)(5)(E)(i)(I). Pub. L. 110–94, § 4(b)(2)(A), substituted "shall be $50,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(aa) for fiscal year 2004, $59,000;
"(bb) for each of fiscal years 2005 and 2006, $61,000;
"(cc) for fiscal year 2007, $48,000; and
"(dd) for fiscal year 2008, $38,500; and".

Subsec. (i)(5)(E)(i)(II). Pub. L. 110–94, § 4(b)(2)(B), substituted "shall be $86,000 for each of fiscal years 2008 through 2012." for "shall be—

"(aa) for fiscal year 2004, $102,000;
"(bb) for each of fiscal years 2005 and 2006, $106,000;
"(cc) for fiscal year 2007, $82,000; and
"(dd) for fiscal year 2008, $66,500."

Subsec. (i)(5)(H). Pub. L. 110–94, § 4(c), substituted "2012." for "2008".

Subsec. (i)(6). Pub. L. 110–94, § 4(d)(1), substituted "2014" for "2010".

Subsec. (k)(2)(A). Pub. L. 110–94, § 4(e)(1), inserted "and to offset the costs of registration review under section 136a(g) of this title" after "paragraph (3)" wherever appearing.

Subsec. (k)(3)(A). Pub. L. 110–94, § 4(e)(2), substituted "2008 through 2012" for "2007 and 2008".

2004—Subsec. (g)(2)(A). Pub. L. 108–199, § 501(c)(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (f) of this section, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year."

Subsec. (g)(2)(B). Pub. L. 108–199, § 501(c)(5)(B), inserted subpar. (B) and cl. (i) headings, designated first sentence of existing provisions as cl. (i), inserted cl. (ii) and subcl. (I) headings, designated second sentence of existing provisions as cl. (ii)(I), substituted "Subject to subclause (II), the Administrator" for "The Administrator" in subcl. (I), and added subcl. (II).

Subsec. (g)(2)(D). Pub. L. 108–199, § 501(c)(5)(C), inserted subpar. (D) and cl. (i) headings, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (i)(5)(A). Pub. L. 108–199, § 501(c)(1)(A), inserted subpar. (A) heading and substituted "for each registration" for "of—

"(i) $650 for the first registration; and
"(ii) $1,300 for each additional registration".

Subsec. (i)(5)(C). Pub. L. 108–199, § 501(c)(2), struck out cl. (i) designation before "The amount of each", inserted subpar. (C) heading, substituted "aggregate amount of—" for "aggregate amount of $21,500,000 for fiscal year 2003.", added cls. (i) to (v), and struck out former cl. (ii), which related to collection of additional fees in fiscal years 1998, 1999, and 2000.

Subsec. (i)(5)(D). Pub. L. 108–199, § 501(c)(1)(B), inserted subpar. (D) heading, substituted "shall be—" for "shall be $55,000; and" and added subcls. (I) to (IV) in cl. (i), and substituted "shall be—" for "shall be $95,000." and added subcls. (I) to (IV) in cl. (ii).

Subsec. (i)(5)(E)(i). Pub. L. 108–199, § 501(c)(1)(C), inserted subpar. (E) and cl. (i) headings, realigned margins of subcls. (I) and (II), substituted "shall be—" for "shall be $38,500; and" and inserted items (aa) to (dd) in subcl. (I), and substituted "shall be—" for "shall be $66,500." and inserted items (aa) to (dd) in subcl. (II).

Subsec. (i)(5)(E)(ii). Pub. L. 108–199, § 501(c)(3), inserted cl. (ii) heading, redesignated existing provisions as subcl. (I), inserted subcl. (I) heading, substituted "In" for "For purposes of" in subcl. (I), redesignated former subcls. (I) and (II) as items (aa) and (bb) respectively, and realigned margins, substituted "500" for "150" in item (aa), substituted "global gross revenue from pesticides that did not exceed $60,000,000." for "gross revenue from chemicals that did not exceed $40,000,000." in item (bb), and added subcl. (II).

Subsec. (i)(5)(H). Pub. L. 108–199, § 501(c)(4), substituted "2008" for "2003".

Subsec. (i)(6). Pub. L. 108–199, § 501(d)(1), substituted "Except as provided in section 136w–8 of this title, during" for "During", and substituted "2010" for "2003".

Subsec. (k)(2)(A)(i). Pub. L. 108–271 substituted "Government Accountability Office" for "General Accounting Office".

Subsec. (k)(3). Pub. L. 108–199, § 501(e)(1), substituted "Review of inert ingredients; expedited" for "Expedited" in par. heading.

Subsec. (k)(3)(A). Pub. L. 108–199, § 501(e)(2), substituted "2004 through 2006, approximately $3,300,000, and for each of fiscal years 2007 and 2008, between 1/8 and 1/7, of the maintenance fees" for "1997 through 2003, not more than 1/10 of the maintenance fees", substituted "resources" for "resources to assure the expedited processing and review of any application that", added cl. (i), inserted cl. (ii) designation and introductory provisions, and redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii).

2003—Pub. L. 108–7, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 108–7, [(1)], substituted "$21,500,000 for fiscal year 2003" for "$17,000,000 fiscal year 2002".

Subsec. (i)(5)(H). Pub. L. 108–7, [(2)], substituted "2003" for "2002".

Subsec. (i)(6). Pub. L. 108–7, [(3)], substituted "2003" for "2002".

Subsec. (k)(3)(A). Pub. L. 108–7, [(4)], substituted "2003" for "2002".

2001—Pub. L. 107–73, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 107–73, [(1)], substituted "$17,000,000" for "$14,000,000" and "fiscal year 2002" for "each fiscal year".

Subsec. (i)(5)(H). Pub. L. 107–73, [(2)], substituted "2002" for "2001".

Subsec. (i)(6). Pub. L. 107–73, [(3)], substituted "2002" for "2001".

Subsec. (k)(3)(A). Pub. L. 107–73, [(4)], substituted "2002" for "2001" and "1/10" for "1/7" in introductory provisions.

1996—Pub. L. 104–170, § 501, which directed amendment of section 4 without specifying the name of the Act being amended, was executed to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Subsec. (d)(4)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (d)(6). Pub. L. 104–170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (e)(2)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (e)(3)(A). Pub. L. 104–170, § 210(f)(1)(B), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (f)(2)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (f)(3). Pub. L. 104–170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (g)(2)(E). Pub. L. 104–170, § 103, added subpar. (E).

Subsec. (i)(4)(B) to (D). Pub. L. 104–170, § 232(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (i)(5)(C). Pub. L. 104–170, § 501(a)(2), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (i)(5)(F), (G). Pub. L. 104–170, § 232(2), added subpar. (F) and redesignated former subpar. (F) as (G).

Subsec. (i)(5)(H). Pub. L. 104–170, § 501(a)(1), substituted "2001" for "1997".

Pub. L. 104–170, § 232(2), redesignated subpar. (G) as (H).

Subsec. (i)(6). Pub. L. 104–170, § 501(a)(1), substituted "2001" for "1997".

Subsec. (i)(7)(B). Pub. L. 104–170, § 232(3), substituted ", to determine the registrant's eligibility" for "or to determine the registrant's eligibility" and inserted before period at end ", or to determine the volume usage for public health pesticides".

Subsec. (k)(1). Pub. L. 104–170, § 501(b), inserted "which shall be known as the Reregistration and Expedited Processing Fund" before period at end.

Subsec. (k)(2). Pub. L. 104–170, § 501(c), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "All fees collected by the Administrator under subsection (i) of this section shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications."

Subsec. (k)(3)(A). Pub. L. 104–170, § 501(d)(1), which directed the amendment of introductory provisions by substituting "for each of the fiscal years 1997 through 2001, not more than 1/7 of the maintenance fees collected in such fiscal year" for "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to 2 million each year", was executed by making the substitution for text which contained the phrase "$2 million", to reflect the probable intent of Congress.

Subsec. (k)(3)(A)(iii). Pub. L. 104–170, § 232(4), added cl. (iii).

Subsec. (k)(3)(C). Pub. L. 104–170, § 501(d)(2), added subpar. (C).

Subsec. (k)(5). Pub. L. 104–170, § 501(e), amended heading and text of par. (5) generally. Prior to amendment, text read as follows: "The Administrator shall—

"(A) provide an annual accounting of the fees collected and disbursed from the fund; and

"(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section."

Subsec. (*l*). Pub. L. 104–170, § 501(f), added subsec. (*l*). Former subsec. (*l*) redesignated (m).

Subsec. (m). Pub. L. 104–170, § 501(f), redesignated subsec. (*l*) as (m). Former subsec. (m) redesignated (n).

Pub. L. 104–170, § 237, added subsec. (m).

Subsec. (n). Pub. L. 104–170, § 501(f), redesignated subsec. (m) as (n).

1991—Subsec. (f)(3). Pub. L. 102–237, § 1006(a)(4), realigned margin.

Subsec. (i)(5). Pub. L. 102–237, § 1006(e), amended par. (5) generally, substituting, in subpar. (A), provisions relating to January 15 for provisions relating to March 1, in subpar. (A)(i), provisions relating to fee of $650 for first registration for provisions relating to fee of $425 for each registration for registrants holding not more than 50 registrations, and in subpar. (A)(ii), provisions relating to fee of $1,300 for each additional registration up to 200 registrations, with no fee thereafter, for provisions relating to fee of $425 for each registration up to 50, $100 for each registration over 50, with no fee after 200 registrations, redesignating provisions formerly set out in subpar. (A), following cl. (ii), as subpar. (B), and substituting provisions relating to fee under this par. for provisions relating to fee under this subpar., redesignating former subpar. (B) as (C), striking former subpar. (C), which set maximum annual fee for registrants under subpar. (A)(i) at $20,000, and for registrants under subpar. (A)(ii) at $35,000, adding subpars. (D) and (E), and redesignating former subpars. (D) and (E) as (F) and (G), respectively.

Subsec. (k)(3)(A). Pub. L. 102–237, § 1006(f), substituted "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to $2 million each year" for "each fiscal year not more than $2,000,000 of the amounts in the fund".

1990—Subsec. (i)(5)(A). Pub. L. 101–624 inserted sentence at end relating to reduction or waiver of fee where pesticide is registered for minor agricultural use.

EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112–177, § 2(c), Sept. 28, 2012, 126 Stat. 1407, provided that: "This section [amending this section, section 136w–8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] and the amendments made by this section take effect on October 1, 2012."

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of this title.

EFFECTIVE DATE OF 2004 AMENDMENT

Amendment by Pub. L. 108–199 effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108–199, set out as a note under section 136a of this title.

EFFECTIVE DATE

Section effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as an Effective Date of 1988 Amendment note under section 136 of this title.

RELATIONSHIP OF PUB. L. 112–177 TO OTHER LAW

Pub. L. 112–177, § 2(d), Sept. 28, 2012, 126 Stat. 1407, provided that: "In the case of any conflict between this section [amending this section, section 136w–8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] (including the amendments made by this section) and a joint resolution making continuing appropriations for fiscal year 2013 (including any amendments made by such a joint resolution), this section and the amendments made by this section shall control."

ADJUSTMENT OF MAXIMUM ANNUAL FEE PAYABLE BY PESTICIDE REGISTRANTS

Pub. L. 108–11, title II, Apr. 16, 2003, 117 Stat. 603, provided that: "Within 30 days of enactment of this Act [Apr. 16, 2003], the Administrator of the Environmental Protection Agency shall adjust each 'maximum annual fee payable' pursuant to 7 U.S.C. 136a–1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108–7 [see Tables for classification] shall be established in the same proportion as those maintenance fee collections authorized in Public Law 107–73 [see Tables for classification]."

§ 136b. Transferred

CODIFICATION

Section, act June 25, 1947, ch. 125, § 4, as added Oct. 21, 1972, Pub. L. 92–516, § 2, 86 Stat. 983; amended Nov. 28, 1975, Pub. L. 94–140, §§ 5, 11, 89 Stat. 753, 754; Sept. 30, 1978, Pub. L. 95–396, § 9, 92 Stat. 827; Oct. 25, 1988, Pub. L. 100–532, title VIII, § 801(c), (q)(1)(A), (B), 102 Stat. 2681, 2683, which related to use of restricted use pesticides and certification of applicators, was transferred to subsecs. (a) to (c) of section 11 of act June 25, 1947, by section 801(q)(1)(A) of Pub. L. 100–532 and is classified to section 136i(a) to (c) of this title.

§ 136c. Experimental use permits

(a) Issuance

Any person may apply to the Administrator for an experimental use permit for a pesticide. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data, the Administrator shall either issue the permit or notify the applicant of the Administrator's determination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 136a of this title. An application for an experimental use permit may be filed at any time.

(b) Temporary tolerance level

If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, the Administrator may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

(c) Use under permit

Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

(d) Studies

When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 136a of this title.

(e) Revocation

The Administrator may revoke any experimental use permit, at any time, if the Administrator finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment.

(f) State issuance of permits

Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as the Administrator may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 136i of this title relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

(g) Exemption for agricultural research agencies

Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require. Such pesticide may be used only by such research agency or educational institution for purposes of experimentation.

(June 25, 1947, ch. 125, § 5, as added Pub. L. 92–516, § 2, Oct. 21, 1972, 86 Stat. 983; amended Pub. L. 94–140, § 10, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, § 10, Sept. 30, 1978, 92 Stat. 828; Pub. L. 100–532, title VIII, § 801(d), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102–237, title X, § 1006(b)(1), Dec. 13, 1991, 105 Stat. 1895.)

PRIOR PROVISIONS

A prior section 5 of act June 25, 1947, was classified to section 135c of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1991—Subsecs. (b), (e), (f). Pub. L. 102–237 substituted "the Administrator" for "he" before "may" in subsec. (b), before "finds" in subsec. (e), and before "may" in subsec. (f).

1988—Subsec. (f). Pub. L. 100–532, § 801(q)(1)(D), substituted "136i" for "136b".

Subsec. (g). Pub. L. 100–532, § 801(d), substituted "require. Such pesticide" for "require: *Provided*, That such pesticide".

1978—Subsec. (a). Pub. L. 95–396, § 10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95–396, § 10(2), substituted in first sentence "shall" for "may" where first appearing.

1975—Subsec. (g). Pub. L. 94–140 added subsec. (g).

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136d. Administrative review; suspension

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a–1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or mak-

ing public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in ac-

cordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt

of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a–1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

(A) such possession,

(B) the quantity of such pesticide such person possesses, and

(C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, § 6, as added Pub. L. 92–516, § 2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94–140, § 1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95–251, § 2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95–396, §§ 11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98–620, title IV, § 402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title II, § 201, title IV, § 404, title VIII, § 801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101–624, title XIV, § 1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, § 1006(a)(5), (b)(1), (2), (3)(C)–(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104–170, title I, §§ 102, 106(a), title II, §§ 210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

CODIFICATION

"Subchapter II of chapter 5 of title 5", referred to in subsec. (c)(2), was in the original "subchapter II of Title 5", and was editorially changed to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104–170, § 106(a)(1), substituted "Existing stocks and information" for "Cancellation after five years" in heading.

Subsec. (a)(1). Pub. L. 104–170, § 106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: "The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect."

Subsec. (b). Pub. L. 104–170, § 233, inserted "When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides." before "The proposed action shall become final".

Subsec. (c)(1). Pub. L. 104–170, § 102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: "No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide."

Subsec. (c)(3). Pub. L. 104–170, § 102(b), inserted after first sentence "The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire." and substituted "In the case of an emergency order" for "In that case".

Subsec. (f)(1)(C)(ii). Pub. L. 104–170, § 210(g)(1), substituted "180-day" for "90-day" in two places.

Subsec. (f)(3)(A). Pub. L. 104–170, § 210(g)(2), substituted "180-day" for "90-day".

Subsec. (f)(4). Pub. L. 104–170, § 210(h), added par. (4).

1991—Subsec. (a)(1). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "may specify" and before "determines".

Subsec. (a)(2). Pub. L. 102–237, § 1006(b)(3)(C), substituted "the registrant" for "he" before "shall".

Subsec. (b). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator's" for "his" in introductory provisions and par. (1), and "the Administrator" for "he" before "shall publish" in last sentence.

Subsec. (c)(1). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator" for "he" before "may" and "the Administrator's" for "his" before "intention".

Subsec. (c)(3). Pub. L. 102–237, § 1006(b)(1), (3)(D), substituted "the Administrator" for "he" before "may" and "the Administrator" for "him" after "permit".

Subsec. (d). Pub. L. 102–237, § 1006(b)(2), (3)(E), in penultimate sentence substituted "the Administrator's" for "his" and "the Administrator" for "him" before "and issue".

Subsec. (f)(3)(B). Pub. L. 102–237, § 1006(a)(5), substituted "adverse effect" for "adverse affect".

1990—Subsec. (f)(1). Pub. L. 101–624, § 1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request."

Subsec. (f)(3). Pub. L. 101–624, § 1494(2), added par. (3).

1988—Subsec. (a)(1). Pub. L. 100–532, § 801(e)(1), substituted "effect. The Administrator" for "effect: *Provided*, That the Administrator".

Subsec. (c). Pub. L. 100–532, § 801(e)(2)–(4), in par. (1) directed that undesignated paragraph beginning "Except as provided" be run into sentence ending "of the pesticide." and substituted "before the Administrator" for "before the Agency", in par. (2) substituted "submitted to the Administrator" for "submitted to the Agency" and "and the Administrator" for "and the Agency", and in par. (3) substituted "(A)" for "(i)", "and the Administrator" for "and the Agency", and "(B)" for "(ii)".

Subsec. (e). Pub. L. 100–532, § 801(e)(5), (6), in par. (1), substituted "met. The Administrator" for "met: *Provided*, That the Administrator", and in par. (2), substituted "section. The only" for "section: *Provided*, That the only".

Subsec. (f). Pub. L. 100–532, § 201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100–532, § 801(q)(2)(B), made a technical amendment to the reference to section 136a–1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100–532, § 404, added subsec. (g).

Subsec. (h). Pub. L. 100–532, § 201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98–620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95–396, § 11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95–251 substituted "administrative law judge" for "hearing examiner".

Subsecs. (e), (f). Pub. L. 95–396, § 12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94–140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration, and established criteria for Secretary taking any final action.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136e. Registration of establishments

(a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) Registration

Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

(c) Information required

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past year; and

(C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 136k of this title, inform the Administrator of the name and address of any recipient of any pesticide produced in any registered establishment which the producer operates.

(d) Confidential records and information

Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 136h of this title.

(June 25, 1947, ch. 125, § 7, as added Pub. L. 92–516, § 2, Oct. 21, 1972, 86 Stat. 987; amended Pub. L. 95–396, § 13, Sept. 30, 1978, 92 Stat. 829; Pub. L. 102–237, title X, § 1006(b)(1), (3)(F), (G), Dec. 13, 1991, 105 Stat. 1895, 1896.)

PRIOR PROVISIONS

A prior section 7 of act June 25, 1947, was classified to section 135e of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1991—Subsec. (b). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "shall".

Subsec. (c)(1)(A) to (C). Pub. L. 102–237, § 1006(b)(3)(F), substituted "the producer" for "he".

Subsec. (c)(2). Pub. L. 102–237, § 1006(b)(3)(G), substituted "the Administrator" for "him" after "inform" and "the producer" for "he".

1978—Subsec. (a). Pub. L. 95–396, § 13(1), made requirement of registration applicable to production of active ingredient used in producing a pesticide subject to this subchapter.

Subsec. (c)(1). Pub. L. 95–396, § 13(2), required information pertaining to types and amounts of active ingredients used in producing pesticides where applicable.

Subsec. (d). Pub. L. 95–396, § 13(3), considered names of pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment as not being confidential information.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136f. Books and records

(a) Requirements

The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this subchapter and to make the records available for inspection and copying in the same manner as provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

(b) Inspection

For the purposes of enforcing the provisions of this subchapter, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this subchapter, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to,

Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental and agronomic purposes, but in no case may a government agency release data, including the location from which the data was derived, that would directly or indirectly reveal the identity of individual producers. In the case of Federal agencies, such access to records maintained under subsection (a) shall be through the Secretary of Agriculture, or the Secretary's designee. State agency requests for access to records maintained under subsection (a) shall be through the lead State agency so designated by the State.

(c) Health care personnel

When a health professional determines that pesticide information maintained under this section is necessary to provide medical treatment or first aid to an individual who may have been exposed to pesticides for which the information is maintained, upon request persons required to maintain records under subsection (a) shall promptly provide record and available label information to that health professional. In the case of an emergency, such record information shall be provided immediately.

(d) Penalty

The Secretary of Agriculture shall be responsible for the enforcement of subsections (a), (b), and (c). A violation of such subsection shall—

(1) in the case of the first offense, be subject to a fine of not more than $500; and

(2) in the case of subsequent offenses, be subject to a fine of not less than $1,000 for each violation, except that the penalty shall be less than $1,000 if the Secretary determines that the person made a good faith effort to comply with such subsection.

(e) Federal or State provisions

The requirements of this section shall not affect provisions of other Federal or State laws.

(f) Surveys and reports

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall survey the records maintained under subsection (a) to develop and maintain a data base that is sufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use. The Secretary and Administrator shall enter into a memorandum of understanding to define their respective responsibilities under this subsection in order to avoid duplication of effort. Such reports shall be transmitted to Congress not later than April 1 of each year.

(g) Regulations

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency shall promulgate regulations on their respective areas of responsibility implementing this section within 180 days after November 28, 1990.

(Pub. L. 101–624, title XIV, § 1491, Nov. 28, 1990, 104 Stat. 3627; Pub. L. 102–237, title X, § 1006(d), Dec. 13, 1991, 105 Stat. 1896.)

CODIFICATION

Section was enacted as part of the Conservation Program Improvements Act, and also as part of the Food, Agriculture, Conservation, and Trade Act of 1990, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

AMENDMENTS

1991—Subsec. (a)(1). Pub. L. 102–237, § 1006(d)(1), inserted closing parenthesis after "section 136a(d)(1)(C) of this title".

Subsec. (d)(1). Pub. L. 102–237, § 1006(d)(2), inserted "of" after "fine".

§ 136i–2. Collection of pesticide use information

(a) In general

The Secretary of Agriculture shall collect data of statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables.

(b) Collection

The data shall be collected by surveys of farmers or from other sources offering statistically reliable data.

(c) Coordination

The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

(Pub. L. 104–170, title III, § 302, Aug. 3, 1996, 110 Stat. 1512.)

CODIFICATION

Section was enacted as part of the Food Quality Protection Act of 1996, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

PESTICIDE USE INFORMATION STUDY

Pub. L. 104–170, title III, § 305, Aug. 3, 1996, 110 Stat. 1512, provided that:

"(a) The Secretary of Agriculture shall, in consultation with the Administrator of the Environmental Protection Agency, prepare a report to Congress evaluating the current status and potential improvements in Federal pesticide use information gathering activities. This report shall at least include—

"(1) an analysis of the quality and reliability of the information collected by the Department of Agriculture, the Environmental Protection Agency, and other Federal agencies regarding the agricultural use of pesticides; and

"(2) an analysis of options to increase the effectiveness of national pesticide use information collection, including an analysis of costs, burdens placed on agricultural producers and other pesticide users, and effectiveness in tracking risk reduction by those options.

"(b) The Secretary shall submit this report to Congress not later than 1 year following the date of enactment of this section [Aug. 3, 1996]."

§ 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a–1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

(b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to—

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

(June 25, 1947, ch. 125, §12, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 989; amended Pub. L. 95–396, §16, Sept. 30, 1978, 92 Stat. 832; Pub. L. 100–532, title VI, §§601(b)(2), 603, title VIII, §801(g), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2677, 2678, 2682, 2683; Pub. L. 102–237, title X, §1006(a)(7), (b)(3)(L)–(O), Dec. 13, 1991, 105 Stat. 1895, 1896.)

PRIOR PROVISIONS

A prior section 12 of act June 25, 1947, was classified to section 135j of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1991—Subsec. (a)(2)(C). Pub. L. 102–237, §1006(b)(3)(L), substituted "the person's" for "his" and "the person" for "he" before "received".

Subsec. (a)(2)(D). Pub. L. 102–237, §1006(b)(3)(M), substituted "the person's" for "his".

Subsec. (a)(2)(F). Pub. L. 102–237, §1006(a)(7)(A), substituted "thereunder, except that it" for "thereunder. It".

Subsec. (a)(2)(O). Pub. L. 102–237, §1006(a)(7)(B), struck out "or" after semicolon at end.

Subsec. (a)(2)(P). Pub. L. 102–237, §1006(a)(7)(C), substituted a semicolon for period at end.

Subsec. (b)(1). Pub. L. 102–237, §1006(b)(3)(N), substituted "the person" for "he" after "from whom" and for "him" after "delivery to".

Subsec. (b)(3). Pub. L. 102–237, §1006(b)(3)(O), substituted "the official duties of the public official" for "his official duties".

1988—Subsec. (a)(1). Pub. L. 100–532, §601(b)(2)(A), in introductory provisions, substituted "distribute or sell to any person" for "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person".

Subsec. (a)(1)(A). Pub. L. 100–532, §603(1), added subpar. (A) and struck out former subpar. (A) which read as follows: "any pesticide which is not registered under section 136a of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(B). Pub. L. 100–532, §603(2)(A), added subpar. (B) and struck out former subpar. (B) which read as follows: "to refuse to keep any records required pursuant to section 136f of this title, or to refuse to allow inspection of any records or establishment pursuant to section 136f or 136g of this title, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 136g of this title;".

Subsec. (a)(2)(F). Pub. L. 100–532, §§601(b)(2)(B), 801(g), substituted "to distribute or sell, or to make" for "to make" and "thereunder, It" for "thereunder: *Provided*, That it".

Subsec. (a)(2)(J). Pub. L. 100–532, §801(q)(2)(B), made a technical amendment to the reference to section 136a–1 of this title to reflect the renumbering of the corresponding section of the original act.

Pub. L. 100–532, §603(2)(B), added subpar. (J) and struck out former subpar. (J) which read as follows: "to violate any suspension order issued under section 136d of this title;".

Subsec. (a)(2)(K). Pub. L. 100–532, §603(2)(B), added subpar. (K) and struck out former subpar. (K) which read as follows: "to violate any cancellation of registration of a pesticide under section 136d of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(M). Pub. L. 100–532, §603(2)(C), substituted "this subchapter" for "section 136f of this title".

Subsec. (a)(2)(Q), (R), (S). Pub. L. 100–532, §603(2)(D), added subpars. (Q), (R), and (S).

1978—Subsec. (a)(2)(F). Pub. L. 95–396 inserted proviso exempting from prohibition the sale, under regulations issued by the Administrator, of a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136k. Stop sale, use, removal, and seizure

(a) Stop sale, etc., orders

Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

(b) Seizure

Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 136a of this title;

(C) its labeling fails to bear the information required by this subchapter;

(D) it is not colored or discolored and such coloring or discoloring is required under this subchapter; or

"(1) SOURCE.—Any obligation of the Administrator to pay an indemnity arising under section 15 [this section], as it existed prior to the effective date of the amendment made by this section [see Effective Date of 1988 Amendment note above], shall be made from the appropriation provided under section 1304 of title 31, United States Code.

"(2) ADMINISTRATIVE SETTLEMENT.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code."

§ 136n. Administrative procedure; judicial review

(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.

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

AMENDMENTS

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), (3)(P), substituted "the Administrator" for "he" before "based", "the Administrator's" for "his", and "the Administrator" for "him" after "designated by".

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "may".

1988—Subsec. (a). Pub. L. 100–532 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "Except as is otherwise provided in this subchapter, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts."

1984—Subsec. (b). Pub. L. 98–620 struck out provisions requiring the court to advance on the docket and expedite the disposition of all cases filed pursuant to this section.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136*o*. Imports and exports

(a) Pesticides and devices intended for export

Notwithstanding any other provision of this subchapter, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this subchapter—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 136(p), 136(q)(1)(A), (C), (D), (E), (G), and (H), 136(q)(2)(A), (B), (C)(i) and (iii), and (D), 136e, and 136f of this title; and

(2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136d(a)(1) of this title, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) Cancellation notices furnished to foreign governments

Whenever a registration, or a cancellation or suspension of the registration of a pesticide be-

tion 669b of this title, and paid, transferred, or otherwise credited each fiscal year to the Sport Fishing Restoration Account established under 1016 of the Act of July 18, 1984.

(2) Amounts deposited into the special fund are authorized to be appropriated annually and allocated in accordance with subsection (d) of this section.

(Pub. L. 93–205, §6, Dec. 28, 1973, 87 Stat. 889; Pub. L. 95–212, Dec. 19, 1977, 91 Stat. 1493; Pub. L. 95–632, §10, Nov. 10, 1978, 92 Stat. 3762; Pub. L. 96–246, May 23, 1980, 94 Stat. 348; Pub. L. 97–304, §§3, 8(b), Oct. 13, 1982, 96 Stat. 1416, 1426; Pub. L. 100–478, title I, §1005, Oct. 7, 1988, 102 Stat. 2307.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original "this Act" or "This Act", meaning Pub. L. 93–205, Dec. 28, 1973, 81 Stat. 884, known as the Endangered Species Act of 1973, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of this title and Tables.

The Sport Fishing Restoration Account established under section 1016 of the Act of July 18, 1984, referred to in subsec. (i)(1), probably means the Sport Fish Restoration Account established by section 9504(a)(2)(A) of Title 26, Internal Revenue Code, which section was enacted by section 1016(a) of Pub. L. 98–369, div. A, title X, July 18, 1984, 98 Stat. 1019.

AMENDMENTS

1988—Subsec. (d)(1). Pub. L. 100–478, §1005(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "The Secretary is authorized to provide financial assistance to any State, through its respective State agency, which has entered into a cooperative agreement pursuant to subsection (c) of this section to assist in development of programs for the conservation of endangered and threatened species. The Secretary shall make an allocation of appropriated funds to such States based on consideration of—

"(A) the international commitments of the United States to protect endangered species or threatened species;

"(B) the readiness of a State to proceed with a conservation program consistent with the objectives and purposes of this chapter;

"(C) the number of endangered species and threatened species within a State;

"(D) the potential for restoring endangered species and threatened species within a State; and

"(E) the relative urgency to initiate a program to restore and protect an endangered species or threatened species in terms of survival of the species.

So much of any appropriated funds allocated for obligation to any State for any fiscal year as remains unobligated at the close thereof is authorized to be made available to that State until the close of the succeeding fiscal year. Any amount allocated to any State which is unobligated at the end of the period during which it is available for expenditure is authorized to be made available for expenditure by the Secretary in conducting programs under this section."

Subsec. (i). Pub. L. 100–478, §1005(b), added subsec. (i).

1982—Subsec. (d)(2)(i). Pub. L. 97–304, §3(1), substituted "75 percent" for "66⅔ per centum".

Subsec. (d)(2)(ii). Pub. L. 97–304, §3(2), substituted "90 percent" for "75 per centum".

Subsec. (i). Pub. L. 97–304, §8(b), struck out subsec. (i) which authorized appropriations to carry out this section of $10,000,000 through the period ending Sept. 30, 1977, $12,000,000 for the period Oct. 1, 1977, through Sept. 30, 1980, and $12,000,000 for the period Oct. 1, 1980, through Sept. 30, 1982. See section 1542(b) of this title.

1980—Subsec. (i). Pub. L. 96–246 in par. (2) substituted "$12,000,000" for "$16,000,000" and "1980" for "1981", and added par. (3).

1978—Subsec. (c). Pub. L. 95–632 designated existing provision as par. (1), and in par. (1) as so designated, redesignated pars. (1) to (5) as subpars. (A) to (E), respectively, and subpars. (A) and (B) of subpar. (E), as so redesignated, as cls. (i) and (ii), respectively, substituted "paragraph" for "subsection" in provision preceding subpar. (A), as so redesignated, "endangered or threatened species of fish or wildlife" for "endangered species or threatened species" in subpar. (D), as so redesignated, "subparagraphs (C), (D), and (E) of this paragraph" for "paragraphs (3), (4), and (5) of this subsection" in cl. (i) of subpar. (E), as so redesignated, "clause (i) and this clause" for "subparagraph (A) and this subparagraph" in cl. (ii) of subpar. (E), as so redesignated, and added par. (2).

1977—Subsec. (c). Pub. L. 95–212, §1(1), inserted provisions that States in which the State fish and wildlife agencies do not possess the broad authority to conserve all resident species of fish and wildlife which the Secretary determines to be threatened or endangered may nevertheless qualify for cooperative agreement funds if they satisfy all other requirements and have plans to devote immediate attention to those species most urgently in need of conservation programs.

Subsec. (i). Pub. L. 95–212, §1(2), substituted provisions authorizing appropriations of $10,000,000 to cover the period ending Sept. 30, 1977, and $16,000,000 to cover the period beginning Oct. 1, 1977, and ending Sept. 30, 1981, for provisions authorizing appropriations of not to exceed $10,000,000 through the fiscal year ending June 30, 1977.

COOPERATIVE AGREEMENTS WITH STATES UNAFFECTED BY 1981 AMENDMENT OF MARINE MAMMAL PROTECTION ACT

Nothing in the amendment of section 1379 of this title by section 4(a) of Pub. L. 97–58 to be construed as affecting in any manner any cooperative agreement entered into by a State under subsec. (c) of this section before, on, or after Oct. 9, 1981, see section 4(b) of Pub. L. 97–58, set out as a note under section 1379 of this title.

§ 1536. Interagency cooperation

(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).

(b) Opinion of Secretary

(1)(A) Consultation under subsection (a)(2) 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) 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), 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) and can be taken by the Federal agency or applicant in implementing the agency action.

(B) Consultation under subsection (a)(3), 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), 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), 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), 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), 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) 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. 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), the Secretary's opinion under subsection (b) indicates that the agency action would violate subsection (a)(2). 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) 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), 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) 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);

(ii) conducted any biological assessment required by subsection (c); 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); 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).

(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). The Committee shall grant an exemption from the requirements of subsection (a)(2) 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) 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); 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) 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) or was not identified in any biological assessment conducted under subsection (c), 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. 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) 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) 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) 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) 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) 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. 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. 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.

(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. 3741, 3742; Pub. L. 100–707, title I, § 109(g), Nov. 23, 1988, 102 Stat. 4709.)

REFERENCES IN TEXT

This chapter, referred to in subsecs. (a)(1), (i), and (j), was in the original "this Act", meaning Pub. L. 93–205, Dec. 28, 1973, 81 Stat. 884, known as the Endangered Species Act of 1973, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of this title and Tables.

The Privacy Act, referred to in subsec. (e)(7)(C), is probably a reference to section 552a of Title 5, Government Organization and Employees. See Short Title note set out under section 552a of Title 5.

The National Environmental Policy Act of 1969, referred to in subsec. (k), is Pub. L. 91–190, Jan. 1, 1970, 83 Stat. 852, as amended, which is classified generally to chapter 55 (§ 4321 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 4321 of Title 42 and Tables.

The Disaster Relief and Emergency Assistance Act, referred to in subsec. (p), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, as amended, known as the Robert T. Stafford Disaster Relief and Emergency Assistance Act, which is classified principally to chapter 68 (§ 5121 et seq.) of Title 42. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of Title 42 and Tables.

AMENDMENTS

1988—Subsec. (p). Pub. L. 100–707 substituted "the Disaster Relief and Emergency Assistance Act" for "the Disaster Relief Act of 1974" and "section 405 or 406 of the Disaster Relief and Emergency Assistance Act" for "section 401 or 402 of the Disaster Relief Act of 1974".

1986—Subsec. (b)(4)(C). Pub. L. 99–659, § 411(b)(1)–(3), added subpar. (C).

Subsec. (b)(4)(iii), (iv). Pub. L. 99–659, § 411(b)(4)–(6), added cl. (iii), redesignated former cl. (iii) as (iv), and in cl. (iv), as so redesignated, inserted reference to cl. (iii).

Subsec. (*o*). Pub. L. 99–659, § 411(c)(1), in introductory provisions, inserted ", sections 1371 and 1372 of this title,", and substituted "any" for "either" after "implement".

Subsec. (*o*)(2). Pub. L. 99–659, § 411(c)(2), substituted "subsection (b)(4)(iv)" for "subsection (b)(4)(iii)" and inserted "prohibited" before "taking of the species".

1982—Subsec. (a)(3), (4). Pub. L. 97–304, § 4(a)(1), added par. (3) and redesignated former par. (3) as (4).

Subsec. (b). Pub. L. 97–304, § 4(a)(2), incorporated existing provisions into pars. (1)(A) and (3)(A) and added pars. (1)(B), (2), (3)(B), and (4).

Subsec. (c)(1). Pub. L. 97–304, § 4(a)(3), inserted ", 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" after "agency" in parenthetical provision.

Subsec. (e)(10). Pub. L. 97–304, §4(a)(4), struck out provision that, except in the case of a member designated pursuant to paragraph (3)(G) of this subsection, no member could designate any person to serve as his or her representative unless that person was, at the time of such designation, holding a Federal office the appointment to which was subject to the advice and consent of the United States Senate.

Subsec. (g)(1). Pub. L. 97–304, §4(a)(5)(B), substituted "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) after a report is made pursuant to paragraph (5)" for "An application for an exemption shall be considered initially by a review board in the manner provided in this subsection, and shall be considered by the Endangered Species Committee for a final determination under subsection (h) after a report is made by the review board".

Subsec. (g)(2)(A). Pub. L. 97–304, §4(a)(5)(C)(i), substituted "An exemption applicant shall submit a written application to the Secretary, in a form prescribed under subsection (f), 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 "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; or, in the case of any agency action involving a permit or license applicant, not later than 90 days after the date on which the Federal agency concerned takes final agency action, for purposes of chapter 7 of title 5, with respect to the issuance of the permit or license" and inserted provision that, "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."

Subsec. (g)(2)(B). Pub. L. 97–304, §4(a)(5)(C)(ii), inserted "(i)" after "the Secretary shall promptly", struck out "to the review board to be established under paragraph (3) and" after "individuals to be appointed" in cl. (i) as so designated, and added cl. (ii).

Subsec. (g)(3). Pub. L. 97–304, §4(a)(5)(D), (E), redesignated par. (5) as (3) and substituted provisions directing the Secretary, 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, to (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), and providing that the denial of an application under subparagraph (B) shall be considered final agency action for purposes of chapter 7 of title 5, for provisions placing upon the review board appointed under former par. (3) the duty to make a full review of the consultation carried out under subsection (a)(2) of this section, and within 60 days after its appointment or within such longer time as was mutually agreed upon between the exemption applicant and the Secretary, to make a determination, by a majority vote, (A) whether an irresolvable conflict existed and (B) whether the Federal agency concerned and such exemption applicant had (i) carried out its consultation responsibilities as 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 of it by subsection (c) of this section, and (iii) refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d) of this section, and providing that any determination by the review board that an irresolvable conflict did not exist or that the Federal agency concerned or the exemption applicant had not met its respective requirements under subclause (i), (ii), or (iii) was to be considered final agency action for purposes of chapter 7 of title 5. Former par. (3), providing for the establishment and functions of a review board to consider applications for exemptions and to submit reports to the Endangered Species Committee, was struck out.

Subsec. (g)(4). Pub. L. 97–304, §4(a)(5)(D), (F), redesignated par. (6) as (4) and substituted "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)" for "If the review board determines that an irresolvable conflict exists and makes positive determinations under subclauses (i), (ii), and (iii) of paragraph (5), it shall proceed to prepare the report to be submitted under paragraph (7)". Former par. (4), directing the Secretary to submit the application to the review board immediately after its appointment under paragraph (3), and to submit to the review board, in writing, his views and recommendations with respect to the application within 60 days after receiving a copy of any application under paragraph (2), was struck out.

Subsec. (g)(5). Pub. L. 97–304, §4(a)(5)(G), redesignated par. (7) as (5) and substituted "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" for "Within 180 days after making the determinations under paragraph (6), the review board shall submit" in the provisions preceding subpar. (A), and added subpar. (D). Former par. (5) redesignated (3) and amended.

Subsec. (g)(6). Pub. L. 97–304, §4(a)(5)(H), redesignated par. (8) as (6). Former par. (6) redesignated (4) and amended.

Subsec. (g)(7). Pub. L. 97–304, §4(a)(5)(I), redesignated par. (10) as (7) and substituted "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" for "Upon request of a review board, the head of any Federal agency is authorized to detail, on a nonreimbursable basis, any of the personnel of such agency to the review board to assist it in carry out its duties under this section". Former par. (7) redesignated (5) and amended.

Subsec. (g)(8). Pub. L. 97–304, §4(a)(5)(J), redesignated par. (12) as (8) and substituted "records resulting from activities pursuant to this subsection" for "records of review boards". Former par. (8) redesignated (6).

Subsec. (g)(9). Pub. L. 97–304, §4(a)(5)(D), struck out par. (9) which had provided that the review board, in carrying out its duties, could (A) sit and act at such times and places, take such testimony, and receive such evidence, as the review board deemed advisable, (B) subject to the Privacy Act of 1974 [5 U.S.C. 552a], re-

quest of any Federal agency or applicant information necessary to enable it to carry out such duties, and upon such request the head of such Federal agency would furnish such information to the review board, and (C) use the United States mails in the same manner and upon the same conditions as a Federal agency.

Subsec. (g)(10). Pub. L. 97–304, §4(a)(5)(I), redesignated par. (10) as (7).

Subsec. (g)(11). Pub. L. 97–304, §4(a)(5)(D), struck out par. (11) which had provided that the Administrator of the General Services Administration provide to a review board, on a reimbursable basis, such administrative support services as the review board requested.

Subsec. (g)(12). Pub. L. 97–304, §4(a)(5)(J), redesignated par. (12) as (8).

Subsec. (h)(1). Pub. L. 97–304, §4(a)(6), substituted "within 30 days after receiving the report of the Secretary pursuant to subsection (g)(5)" for "within 90 days of receiving the report of the review board under subsection (g)(7)" in provisions preceding subpar. (A), substituted "report of the Secretary, the record of the hearing held under subsection (g)(4) and on such other testimony" for "report of the review board and on such other testimony" in subpar. (A) preceding cl. (i), and added cl. (iv).

Subsec. (*o*). Pub. L. 97–304, §4(a)(7), substituted "Notwithstanding sections 1533(d) and 1538(a)(1)(B) and (C) of this title or any regulation promulgated to implement either such section (1) any action for which an exemption is granted under subsection (h) 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)(iii) shall not be considered to be a taking of the species concerned" for "Notwithstanding sections 1533(d) and 1538(a) of this title or any regulations promulgated pursuant to such sections, any action for which an exemption is granted under subsection (h) of this section shall not be considered a taking of any endangered or threatened species with respect to any activity which is necessary to carry out such action".

Subsec. (q). Pub. L. 97–304, §8(b), struck out subsec. (q) which authorized appropriations of $600,000 for each of fiscal years 1979, 1980, 1981, and 1982 in carrying out functions under subsecs. (e), (f), (g), and (h) of this section. See section 1542(c) of this title.

1979—Subsec. (a). Pub. L. 96–159, §4(1), designated existing provisions as par. (1); struck out third sentence requirement that each Federal agency, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (referred to as "agency action") did not 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 was determined by the Secretary, after consultation as appropriate with the affected States, to be critical, unless the agency was granted an exemption for such action by the Committee pursuant to subsec. (h) of this section; and added pars. (2) and (3), incorporating former third sentence provisions.

Subsec. (b). Pub. L. 96–159, §4(2), (3), substituted "he believes would not violate subsection (a)(2) of this section and" for "he believes would avoid jeopardizing the continued existence of any endangered or threatened species or adversely modifying the critical habitat of such species, and which" before "can be taken" and introductory "subsection (a)(2) of this section" for "subsection (a) of this section".

Subsec. (c). Pub. L. 96–159, §4(3), (4), substituted "subsection (a)(2)" for "subsec. (a)" of this section, designated existing provisions as so amended par. (1), and added par. (2).

Subsec. (d). Pub. L. 96–159, §4(3), (5), substituted introductory words "subsection (a)(2)" for "subsection (a)" of this section and "alternative measures which would not violate subsection (a)(2)" for "alternative measures which would avoid jeopardizing the continued existence of any endangered or threatened species or adversely modifying or destroying the critical habitat of any such species".

Subsecs. (e)(2), (f). Pub. L. 96–159, §4(3), substituted "subsection (a)(2)" for "subsection (a)".

Subsec. (g)(1). Pub. L. 96–159, §4(3), (6), substituted in first sentence "subsection (a)(2)" for "subsection (a)" of this section and "agency action would violate subsection (a)(2)" for "agency action may jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify the critical habitat of such species".

Subsec. (g)(2)(A). Pub. L. 96–159, §4(7), required exemption applicant, to submit a written application, in the case of any agency action involving a permit or license applicant, not later than 90 days after the date on which the Federal agency concerned takes final agency action, for purposes of chapter 7 of Title 5, with respect to the issuance of the permit or license.

Subsec. (g)(3). Pub. L. 96–159, §4(8), added subpar. (B), and redesignated former subpar. (B) as (C).

Subsec. (g)(5). Pub. L. 96–159, §4(3), (9), substituted in introductory text and cl. (i) "subsection (a)(2)" for "subsection (a)" of this section; redesignated as cls. (A) and (B) former cls. (i) and (ii); inserted in cl. (B) "the Federal agency concerned and" before "such exemption applicant"; redesignated as subcls. (i) to (iii) former subcls. (A) to (C); substituted in subcl. (i) "agency action which would not violate subsection (a)(2) of this section" for "agency action which will avoid jeopardizing the continued existence of an endangered or threatened species or result in the adverse modification or destruction of a critical habitat"; and substituted in last sentence "the Federal agency concerned or the exemption applicant has not met its respective requirements under subclause (i), (ii), or (iii)" for "the exemption applicant has not met the requirements of subparagraph (A), (B), or (C)" preceding "shall be considered final agency action".

Subsec. (g)(6). Pub. L. 96–159, §4(10), substituted "subclauses (i), (ii), and (iii)" for "subparagraphs (A), (B), and (C)" of paragraph (5).

Subsec. (h)(1). Pub. L. 96–159, §4(3), substituted "subsection (a)(2)" for "subsection (a)" of this section.

Subsec. (h)(2). Pub. L. 96–159, §4(11), in subpar. (A), substituted "paragraph (1)" for "subsection (h) of this section", inserted cl. (i), incorporated existing provisions in text designated cl. (ii), inserting thereto "with respect to such agency action"; in subpar. (B), incorporated existing provision in cl. (i), inserted findings provision respecting the extinction of a species that was not: the subject of consultation or identified in any biological assessment under subsec. (a)(2) or (c) of this section, added cl. (ii), deleted prior requirement for a Committee determination within 30 days of the Secretary's finding that an exemption would result in extinction of the species whether to grant an exemption for the agency notwithstanding such finding, and superseded the same with requirement that the Committee meet with respect to the matter within 30 days after the date of such a finding.

Subsec. (m). Pub. L. 96–159, §4(3), substituted "subsection (a)(2)" for "subsection (a)" of this section.

Subsec. (q). Pub. L. 96–159, §4(12), authorized appropriations of $600,000 for fiscal years 1980 through 1982, and deleted appropriations authorization of $300,000 for period beginning Oct. 1, 1979, and ending Mar. 3, 1980, and requirement that the Chairman of the Committee report to the Congress before end of fiscal year 1979 with respect to adequacy of the budget authority.

1978—Subsec. (a). Pub. L. 95–632 designated existing provision as subsec. (a), inserted reference to agency action, substituted "adverse modification" for "modification", and provided for the grant of an exemption for agency action by the Endangered Species Committee pursuant to subsec. (h) of this section.

Subsecs. (b) to (q). Pub. L. 95–632 added subsecs. (b) to (q).

DEFERRAL OF AGENCY ACTION

Pub. L. 105–18, title II, §3003, June 12, 1997, 111 Stat. 176, provided that:

"(a) CONSULTATION AND CONFERENCING.—As provided by regulations issued under the Endangered Species Act (16 U.S.C. 1531 et seq.) for emergency situations, formal consultation or conferencing under section 7(a)(2) or section 7(a)(4) of the Act [16 U.S.C. 1536(a)(2), (4)] for any action authorized, funded or carried out by any Federal agency to repair a Federal or non-Federal flood control project, facility or structure may be deferred by the Federal agency authorizing, funding or carrying out the action, if the agency determines that the repair is needed to respond to an emergency causing an imminent threat to human lives and property in 1996 or 1997. Formal consultation or conferencing shall be deferred until the imminent threat to human lives and property has been abated. For purposes of this section, the term repair shall include preventive and remedial measures to restore the project, facility or structure to remove an imminent threat to human lives and property.

"(b) REASONABLE AND PRUDENT MEASURES.—Any reasonable and prudent measures specified under section 7 of the Endangered Species Act (16 U.S.C. 1536) to minimize the impact of an action taken under this section shall be related both in nature and extent to the effect of the action taken to repair the flood control project, facility or structure."

TRANSLOCATION OF CALIFORNIA SEA OTTERS

Pub. L. 99–625, § 1, Nov. 7, 1986, 100 Stat. 3500, provided that:

"(a) DEFINITIONS.—For purposes of this section—

"(1) The term 'Act' means the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.).

"(2) The term 'agency action' has the meaning given that term in section 7(a)(2) of the Act [16 U.S.C. 1536(a)(2)].

"(3) The term 'experimental population' means the population of sea otters provided for under a plan developed under subsection (b).

"(4) The phrase 'parent population' means the population of sea otters existing in California on the date on which proposed regulations setting forth a proposed plan under subsection (b) are issued.

"(5) The phrase 'prospective action' refers to any prospective agency action that—

"(A) may affect either the experimental population or the parent population; and

"(B) has evolved to the point where meaningful consultation under section 7(a)(2) or (3) of the Act [16 U.S.C. 1536(a)(2), (3)] can take place.

"(6) The term 'Secretary' means the Secretary of the Interior.

"(7) The term 'Service' means the United States Fish and Wildlife Service.

"(b) PLAN SPECIFICATIONS.—The Secretary may develop and implement, in accordance with this section, a plan for the relocation and management of a population of California sea otters from the existing range of the parent population to another location. The plan, which must be developed by regulation and administered by the Service in cooperation with the appropriate State agency, shall include the following:

"(1) The number, age, and sex of sea otters proposed to be relocated.

"(2) The manner in which the sea otters will be captured, translocated, released, monitored, and protected.

"(3) The specification of a zone (hereinafter referred to as the 'translocation zone') to which the experimental population will be relocated. The zone must have appropriate characteristics for furthering the conservation of the species.

"(4) The specification of a zone (hereinafter referred to as the 'management zone') that—

"(A) surrounds the translocation zone; and

"(B) does not include the existing range of the parent population or adjacent range where expansion is necessary for the recovery of the species.

The purpose of the management zone is to (i) facilitate the management of sea otters and the containment of the experimental population within the translocation zone, and (ii) to prevent, to the maximum extent feasible, conflict with other fishery resources within the management zone by the experimental population. Any sea otter found within the management zone shall be treated as a member of the experimental population. The Service shall use all feasible non-lethal means and measures to capture any sea otter found within the management zone and return it to either the translocation zone or to the range of the parent population.

"(5) Measures, including an adequate funding mechanism, to isolate and contain the experimental population.

"(6) A description of the relationship of the implementation of the plan to the status of the species under the Act and to determinations of the Secretary under section 7 of the Act [16 U.S.C. 1536].

"(c) STATUS OF MEMBERS OF THE EXPERIMENTAL POPULATION.—(1) Any member of the experimental population shall be treated while within the translocation zone as a threatened species for purposes of the Act, except that—

"(A) section 7 of the Act [16 U.S.C. 1536] shall only apply to agency actions that—

"(i) are undertaken within the translocation zone,

"(ii) are not defense-related agency actions, and

"(iii) are initiated after the date of the enactment of this section [Nov. 7, 1986]; and

"(B) with respect to defense-related actions within the translocation zone, members of the experimental population shall be treated as members of a species that is proposed to be listed under section 4 of the Act [16 U.S.C. 1533].

For purposes of this paragraph, the term 'defense-related agency action' means an agency action proposed to be carried out directly by a military department.

"(2) For purposes of section 7 of the Act [16 U.S.C. 1536], any member of the experimental population shall be treated while within the management zone as a member of a species that is proposed to be listed under section 4 of the Act [16 U.S.C. 1533]. Section 9 of the Act [16 U.S.C. 1538] applies to members of the experimental population; except that any incidental taking of such a member during the course of an otherwise lawful activity within the management zone, may not be treated as a violation of the Act or the Marine Mammal Protection Act of 1972 [16 U.S.C. 1361 et seq.].

"(d) IMPLEMENTATION OF PLAN.—The Secretary shall implement the plan developed under subsection (b)—

"(1) after the Secretary provides an opinion under section 7(b) of the Act [16 U.S.C. 1536(b)] regarding each prospective action for which consultation was initiated by a Federal agency or requested by a prospective permit or license applicant before April 1, 1986; or

"(2) if no consultation under section 7(a)(2) or (3) regarding any prospective action is initiated or requested by April 1, 1986, at any time after that date.

"(e) CONSULTATION AND EFFECT OF OPINION.—A Federal agency shall promptly consult with the Secretary, under section 7(a)(3) of the Act [16 U.S.C. 1536(a)(3)], at the request of, and in cooperation with, any permit or license applicant regarding any prospective action. The time limitations applicable to consultations under section 7(a)(2) of the Act apply to consultations under the preceding sentence. In applying section 7(b)(3)(B) with respect to an opinion on a prospective action that is provided after consultation under section 7(a)(3), that opinion shall be treated as the opinion issued after consultation under section 7(a)(2) unless the Secretary finds, after notice and opportunity for comment in accordance with section 553 of title 5, United States Code, that a significant change has been made with respect to the action or that a significant change has occurred regarding the information used during the initial consultation. The interested party may petition the Secretary to make a finding under the preceding sentence. The Secretary may implement any reasonable and pru-

dent alternatives specified in any opinion referred to in this subsection through appropriate agreements with any such Federal agency, prospective permit or license applicant, or other interested party.

"(f) CONSTRUCTION.—For purposes of implementing the plan, no act by the Service, an authorized State agency, or an authorized agent of the Service or such an agency with respect to a sea otter that is necessary to effect the relocation or management of any sea otter under the plan may be treated as a violation of any provision of the Act or the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361 et seq.)."

§ 1537. International cooperation

(a) Financial assistance

As a demonstration of the commitment of the United States to the worldwide protection of endangered species and threatened species, the President may, subject to the provisions of section 1306 of title 31, use foreign currencies accruing to the United States Government under the Food for Peace Act [7 U.S.C. 1691 et seq.] or any other law to provide to any foreign country (with its consent) assistance in the development and management of programs in that country which the Secretary determines to be necessary or useful for the conservation of any endangered species or threatened species listed by the Secretary pursuant to section 1533 of this title. The President shall provide assistance (which includes, but is not limited to, the acquisition, by lease or otherwise, of lands, waters, or interests therein) to foreign countries under this section under such terms and conditions as he deems appropriate. Whenever foreign currencies are available for the provision of assistance under this section, such currencies shall be used in preference to funds appropriated under the authority of section 1542 of this title.

(b) Encouragement of foreign programs

In order to carry out further the provisions of this chapter, the Secretary, through the Secretary of State, shall encourage—

(1) foreign countries to provide for the conservation of fish or wildlife and plants including endangered species and threatened species listed pursuant to section 1533 of this title;

(2) the entering into of bilateral or multilateral agreements with foreign countries to provide for such conservation; and

(3) foreign persons who directly or indirectly take fish or wildlife or plants in foreign countries or on the high seas for importation into the United States for commercial or other purposes to develop and carry out with such assistance as he may provide, conservation practices designed to enhance such fish or wildlife or plants and their habitat.

(c) Personnel

After consultation with the Secretary of State, the Secretary may—

(1) assign or otherwise make available any officer or employee of his department for the purpose of cooperating with foreign countries and international organizations in developing personnel resources and programs which promote the conservation of fish or wildlife or plants; and

(2) conduct or provide financial assistance for the educational training of foreign personnel, in this country or abroad, in fish, wildlife, or plant management, research and law enforcement and to render professional assistance abroad in such matters.

(d) Investigations

After consultation with the Secretary of State and the Secretary of the Treasury, as appropriate, the Secretary may conduct or cause to be conducted such law enforcement investigations and research abroad as he deems necessary to carry out the purposes of this chapter.

(Pub. L. 93–205, § 8, Dec. 28, 1973, 87 Stat. 892; Pub. L. 96–159, § 5, Dec. 28, 1979, 93 Stat. 1228; Pub. L. 110–246, title III, § 3001(b)(1)(A), (2)(N), June 18, 2008, 122 Stat. 1820.)

REFERENCES IN TEXT

The Food for Peace Act, referred to in subsec. (a), is act July 10, 1954, ch. 469, 68 Stat. 454, which is classified generally to chapter 41 (§ 1691 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 1691 of Title 7 and Tables.

This chapter, referred to in subsecs. (b) and (d), was in the original "this Act", meaning Pub. L. 93–205, Dec. 28, 1973, 81 Stat. 884, known as the Endangered Species Act of 1973, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of this title and Tables.

CODIFICATION

In subsec. (a), "section 1306 of title 31" substituted for "section 1415 of the Supplemental Appropriation Act, 1953 (31 U.S.C. 724)" on authority of Pub. L. 97–258, § 4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–246 substituted "Food for Peace Act" for "Agricultural Trade Development and Assistance Act of 1954".

1979—Subsec. (b)(1). Pub. L. 96–159, § 5(1), encouraged conservation of plants.

Subsec. (b)(3). Pub. L. 96–159, § 5(2), encouraged conservation practices for enhancement of plants taken for importation into the United States.

Subsec. (c)(1). Pub. L. 96–159, § 5(3), made personnel available for plant conservation.

Subsec. (e). Pub. L. 96–159, § 5(4), struck out subsec. (e) relating to Convention implementation.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–246 effective May 22, 2008, see section 4(b) of Pub. L. 110–246, set out as an Effective Date note under section 8701 of Title 7, Agriculture.

CONSERVATION OF SEA TURTLES; IMPORTATION OF SHRIMP

Pub. L. 101–162, title VI, § 609, Nov. 21, 1989, 103 Stat. 1037, provided that:

"(a) The Secretary of State, in consultation with the Secretary of Commerce, shall, with respect to those species of sea turtles the conservation of which is the subject of regulations promulgated by the Secretary of Commerce on June 29, 1987—

"(1) initiate negotiations as soon as possible for the development of bilateral or multilateral agreements with other nations for the protection and conservation of such species of sea turtles;

"(2) initiate negotiations as soon as possible with all foreign governments which are engaged in, or which have persons or companies engaged in, commercial fishing operations which, as determined by

If the Administrator determines that any such revised or new standard is not consistent with the applicable requirements of this chapter, he shall not later than the ninetieth day after the date of submission of such standard notify the State and specify the changes to meet such requirements. If such changes are not adopted by the State within ninety days after the date of notification, the Administrator shall promulgate such standard pursuant to paragraph (4) of this subsection.

(4) The Administrator shall promptly prepare and publish proposed regulations setting forth a revised or new water quality standard for the navigable waters involved—

(A) if a revised or new water quality standard submitted by such State under paragraph (3) of this subsection for such waters is determined by the Administrator not to be consistent with the applicable requirements of this chapter, or

(B) in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this chapter.

The Administrator shall promulgate any revised or new standard under this paragraph not later than ninety days after he publishes such proposed standards, unless prior to such promulgation, such State has adopted a revised or new water quality standard which the Administrator determines to be in accordance with this chapter.

(d) Identification of areas with insufficient controls; maximum daily load; certain effluent limitations revision

(1)(A) Each State shall identify those waters within its boundaries for which the effluent limitations required by section 1311(b)(1)(A) and section 1311(b)(1)(B) of this title are not stringent enough to implement any water quality standard applicable to such waters. The State shall establish a priority ranking for such waters, taking into account the severity of the pollution and the uses to be made of such waters.

(B) Each State shall identify those waters or parts thereof within its boundaries for which controls on thermal discharges under section 1311 of this title are not stringent enough to assure protection and propagation of a balanced indigenous population of shellfish, fish, and wildlife.

(C) Each State shall establish for the waters identified in paragraph (1)(A) of this subsection, and in accordance with the priority ranking, the total maximum daily load, for those pollutants which the Administrator identifies under section 1314(a)(2) of this title as suitable for such calculation. Such load shall be established at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality.

(D) Each State shall estimate for the waters identified in paragraph (1)(B) of this subsection the total maximum daily thermal load required to assure protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife. Such estimates shall take into account the normal water temperatures, flow rates, seasonal variations, existing sources of heat input, and the dissipative capacity of the identified waters or parts thereof. Such estimates shall include a calculation of the maximum heat input that can be made into each such part and shall include a margin of safety which takes into account any lack of knowledge concerning the development of thermal water quality criteria for such protection and propagation in the identified waters or parts thereof.

(2) Each State shall submit to the Administrator from time to time, with the first such submission not later than one hundred and eighty days after the date of publication of the first identification of pollutants under section 1314(a)(2)(D) of this title, for his approval the waters identified and the loads established under paragraphs (1)(A), (1)(B), (1)(C), and (1)(D) of this subsection. The Administrator shall either approve or disapprove such identification and load not later than thirty days after the date of submission. If the Administrator approves such identification and load, such State shall incorporate them into its current plan under subsection (e) of this section. If the Administrator disapproves such identification and load, he shall not later than thirty days after the date of such disapproval identify such waters in such State and establish such loads for such waters as he determines necessary to implement the water quality standards applicable to such waters and upon such identification and establishment the State shall incorporate them into its current plan under subsection (e) of this section.

(3) For the specific purpose of developing information, each State shall identify all waters within its boundaries which it has not identified under paragraph (1)(A) and (1)(B) of this subsection and estimate for such waters the total maximum daily load with seasonal variations and margins of safety, for those pollutants which the Administrator identifies under section 1314(a)(2) of this title as suitable for such calculation and for thermal discharges, at a level that would assure protection and propagation of a balanced indigenous population of fish, shellfish, and wildlife.

(4) LIMITATIONS ON REVISION OF CERTAIN EFFLUENT LIMITATIONS.—

(A) STANDARD NOT ATTAINED.—For waters identified under paragraph (1)(A) where the applicable water quality standard has not yet been attained, any effluent limitation based on a total maximum daily load or other waste load allocation established under this section may be revised only if (i) the cumulative effect of all such revised effluent limitations based on such total maximum daily load or waste load allocation will assure the attainment of such water quality standard, or (ii) the designated use which is not being attained is removed in accordance with regulations established under this section.

(B) STANDARD ATTAINED.—For waters identified under paragraph (1)(A) where the quality of such waters equals or exceeds levels necessary to protect the designated use for such waters or otherwise required by applicable

water quality standards, any effluent limitation based on a total maximum daily load or other waste load allocation established under this section, or any water quality standard established under this section, or any other permitting standard may be revised only if such revision is subject to and consistent with the antidegradation policy established under this section.

(e) Continuing planning process

(1) Each State shall have a continuing planning process approved under paragraph (2) of this subsection which is consistent with this chapter.

(2) Each State shall submit not later than 120 days after October 18, 1972, to the Administrator for his approval a proposed continuing planning process which is consistent with this chapter. Not later than thirty days after the date of submission of such a process the Administrator shall either approve or disapprove such process. The Administrator shall from time to time review each State's approved planning process for the purpose of insuring that such planning process is at all times consistent with this chapter. The Administrator shall not approve any State permit program under subchapter IV of this chapter for any State which does not have an approved continuing planning process under this section.

(3) The Administrator shall approve any continuing planning process submitted to him under this section which will result in plans for all navigable waters within such State, which include, but are not limited to, the following:

(A) effluent limitations and schedules of compliance at least as stringent as those required by section 1311(b)(1), section 1311(b)(2), section 1316, and section 1317 of this title, and at least as stringent as any requirements contained in any applicable water quality standard in effect under authority of this section;

(B) the incorporation of all elements of any applicable area-wide waste management plans under section 1288 of this title, and applicable basin plans under section 1289 of this title;

(C) total maximum daily load for pollutants in accordance with subsection (d) of this section;

(D) procedures for revision;

(E) adequate authority for intergovernmental cooperation;

(F) adequate implementation, including schedules of compliance, for revised or new water quality standards, under subsection (c) of this section;

(G) controls over the disposition of all residual waste from any water treatment processing;

(H) an inventory and ranking, in order of priority, of needs for construction of waste treatment works required to meet the applicable requirements of sections 1311 and 1312 of this title.

(f) Earlier compliance

Nothing in this section shall be construed to affect any effluent limitation, or schedule of compliance required by any State to be implemented prior to the dates set forth in sections 1311(b)(1) and 1311(b)(2) of this title nor to preclude any State from requiring compliance with any effluent limitation or schedule of compliance at dates earlier than such dates.

(g) Heat standards

Water quality standards relating to heat shall be consistent with the requirements of section 1326 of this title.

(h) Thermal water quality standards

For the purposes of this chapter the term "water quality standards" includes thermal water quality standards.

(i) Coastal recreation water quality criteria

(1) Adoption by States

(A) Initial criteria and standards

Not later than 42 months after October 10, 2000, each State having coastal recreation waters shall adopt and submit to the Administrator water quality criteria and standards for the coastal recreation waters of the State for those pathogens and pathogen indicators for which the Administrator has published criteria under section 1314(a) of this title.

(B) New or revised criteria and standards

Not later than 36 months after the date of publication by the Administrator of new or revised water quality criteria under section 1314(a)(9) of this title, each State having coastal recreation waters shall adopt and submit to the Administrator new or revised water quality standards for the coastal recreation waters of the State for all pathogens and pathogen indicators to which the new or revised water quality criteria are applicable.

(2) Failure of States to adopt

(A) In general

If a State fails to adopt water quality criteria and standards in accordance with paragraph (1)(A) that are as protective of human health as the criteria for pathogens and pathogen indicators for coastal recreation waters published by the Administrator, the Administrator shall promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in paragraph (1)(A) for coastal recreation waters of the State.

(B) Exception

If the Administrator proposes regulations for a State described in subparagraph (A) under subsection (c)(4)(B), the Administrator shall publish any revised or new standard under this subsection not later than 42 months after October 10, 2000.

(3) Applicability

Except as expressly provided by this subsection, the requirements and procedures of subsection (c) apply to this subsection, including the requirement in subsection (c)(2)(A) that the criteria protect public health and welfare.

(June 30, 1948, ch. 758, title III, § 303, as added Pub. L. 92–500, § 2, Oct. 18, 1972, 86 Stat. 846;

(b) Certain toxicological and exposure studies must be submitted simultaneously with the toxicology data submitted in a tiered system. Exposure data must be submitted along with first tier toxicology data. The requirement for additional second and third level toxicology testing will be determined by the Agency based on the results of the first tiered studies.

(1) The required first-tier toxicology studies consist of:

(i) Battery of acute studies.

(ii) A subchronic 90–day dermal study or a subchronic 90–day inhalation study.

(iii) An acute and subchronic neurotoxicity screening battery in the rat.

(iv) Prenatal developmental toxicity studies in both the rat and rabbit.

(v) Reproduction and fertility studies in rats.

(vi) Battery of mutagenicity studies.

(vii) Immunotoxicity study.

(2) The conditionally required second-tier studies include:

(i) Subchronic 90–day feeding studies in both the rodent and nonrodent.

(ii) Dermal penetration study.

(3) The conditionally required third-tier studies include:

(i) Chronic feeding studies in the rodent.

(ii) Carcinogenicity.

(iii) Metabolism study.

(iv) Additional mutagenicity testing.

Subpart G— Ecological Effects

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50}/EC_{50} studies -- fish, mollusk and invertebrate. All other outdoor residential uses, *i.e.*, gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) *Key.* R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = Pure active ingredient; EP = end-use product. Commas between the test substances (*i.e.*, TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) *Test notes.* The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96–hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} <1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water >4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are <1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is <5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥50.

B. The log Kow is ≥3.

C. The Koc ≥1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is >0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is >10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥50.

B. The log Kow is ≥3.

C. The Koc ≥1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of <11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 401.21 Patents and inventions.

Determination of the patent rights in any inventions or discoveries resulting from work under project agreements entered into pursuant to the Act shall be consistent with the "Government Patent Policy" (President's memorandum for Heads of Executive Departments and Agencies, August 23, 1971, and statement of Government Patent Policy as printed in 36 FR 16889).

§ 401.22 Civil rights.

Each application for Federal assistance, grant-in-aid award, or project agreement shall be supported by a statement of assurances executed by the Cooperator providing that the project will be carried out in accordance with title VI, Nondiscrimination in federally Assisted Programs of the Civil Rights Act of 1964 and with the Secretary's regulations promulgated thereunder.

§ 401.23 Audits.

The State is required to conduct an audit at least every two years in accordance with the provisions of Attachment P OMB Circular A–102. Failure to conduct audits as required may result in withholding of grant payments or such other sanctions as the Secretary may deem appropriate.

[49 FR 30074, July 26, 1984]

PART 402—INTERAGENCY COOPERATION—ENDANGERED SPECIES ACT OF 1973, AS AMENDED

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

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

Subpart A—General

§ 402.01 Scope.

(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.

§402.02 Definitions.

Act means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 *et seq.*

Action means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

(a) actions intended to conserve listed species or their habitat;

(b) the promulgation of regulations;

(c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or

(d) actions directly or indirectly causing modifications to the land, water, or air.

Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

Applicant refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

Biological assessment refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

Biological opinion is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Conference is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

Conservation recommendations are suggestions of the Service regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.

Critical habitat refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

Cumulative effects are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

Designated non-Federal representative refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

Director refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

Early consultation is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

Effects of the action refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.

Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

Framework programmatic action means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Incidental take refers to takings that result from, but are not the purpose of,

carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

Jeopardize the continued existence of means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

Listed species means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11–17.12.

Major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

Mixed programmatic action means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Preliminary biological opinion refers to an opinion issued as a result of early consultation.

Proposed critical habitat means habitat proposed in the FEDERAL REGISTER to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

Proposed species means any species of fish, wildlife, or plant that is proposed in the FEDERAL REGISTER to be listed under section 4 of the Act.

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director believes necessary or appropriate to minimize the impacts, *i.e.*, amount or extent, of incidental take.

Recovery means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

Service means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

[51 FR 19957, June 3, 1986, as amended at 73 FR 76286, Dec. 16, 2008; 74 FR 20422, May 4, 2009; 80 FR 26844, May 11, 2015; 81 FR 7225, Feb. 11, 2016]

§402.03 Applicability.

Section 7 and the requirements of this part apply to all actions in which there is discretionary Federal involvement or control.

[74 FR 20423, May 4, 2009]

§402.04 Counterpart regulations.

The consultation procedures set forth in this part may be superseded for a particular Federal agency by joint counterpart regulations among that agency, the Fish and Wildlife Service, and the National Marine Fisheries Service. Such counterpart regulations shall be published in the FEDERAL REGISTER in proposed form and shall be subject to public comment for at least 60 days before final rules are published.

§402.05 Emergencies.

(a) Where emergency circumstances mandate the need to consult in an expedited manner, consultation may be conducted informally through alternative procedures that the Director determines to be consistent with the requirements of sections 7(a)–(d) of the

likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

§ 402.13 Informal consultation.

(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.

[74 FR 20423, May 4, 2009]

§ 402.14 Formal consultation.

(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) through (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.

[51 FR 19957, June 3, 1986, as amended at 54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015]

§402.15 Responsibilities of Federal agency following issuance of a biological opinion.

(a) Following the issuance of a biological opinion, the Federal agency shall determine whether and in what manner to proceed with the action in light of its section 7 obligations and the Service's biological opinion.

(b) If a jeopardy biological opinion is issued, the Federal agency shall notify the Service of its final decision on the action.

(c) If the Federal agency determines that it cannot comply with the requirements of section 7(a)(2) after consultation with the Service, it may apply for an exemption. Procedures for exemption applications by Federal agencies and others are found in 50 CFR part 451.

§402.16 Reinitiation of formal consultation.

Reinitiation of formal consultation is required and shall be requested by the Federal agency or by the Service,

ORAL ARGUMENT NOT YET SCHEDULED

Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CENTER FOR BIOLOGICAL DIVERSITY, CENTER FOR FOOD SAFETY, and DEFENDERS OF WILDLIFE,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

and

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION LLC, and DOW AGROSCIENCES LLC,
Intervenor-Respondents.

Petition for Review of Order of U.S. Environmental Protection Agency (Nos. 15-1054 (LEAD), 15-1176, 15-1389, 15-1462, and 16-1351)

ADDENDUM OF STANDING DECLARATIONS IN SUPPORT OF PETITIONERS' OPENING BRIEF

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DECLARATION OF ILEENE ANDERSON, M.S.

I, Ileene Anderson, state and declare as follows:

1. The facts set forth in this declaration are based upon my personal knowledge. If called as a witness, I could and would testify to these facts. As to those matters which reflect an opinion, they reflect my personal opinion and judgment on the matter.

2. I am an adult citizen of the United States and reside in Los Angeles, California.

3. I am submitting this declaration on behalf of myself and the Center for Biological Diversity, a non-profit organization of good standing.

4. I am currently the Public Lands Deserts Director and a Senior Scientist with the Center for Biological Diversity (Center), where I have been employed since November 2005 and have been a member of the organization since 1999. In that capacity, my responsibilities include assessing various environmental impacts to public and private land resources primarily in southern California and other parts of the southwestern United States. I use my biological education and experience to evaluate effects on wildlife and wildlife habitat as well as to recommend necessary protections for wildlife.

5. I have a Masters of Science in Biology from the California State University at Northridge. I have studied and surveyed for native plants and animals in California for over 30 years.

6. I was born and raised in the southern and central San Joaquin Valley of California and regularly return there to visit family and friends, as well as for work purposes to evaluate the status of rare plants and animals and their habitats. When I was growing up, my family regularly went on vacations that included camping in some of the nearby wild places. On those trips and trips to see my relatives in Fresno, one of my educational pastimes was identifying the different crops that were growing along our travel routes because the San Joaquin Valley had been primarily converted to agriculture. In my childhood of the 1960's and 1970's, many of the crops were annual crops, mostly vegetables or cotton, with alfalfa as a cover crop. There were some fruit orchards as well. These days when I drive to see my relatives, I still pay attention to the crops grown in the San Joaquin valley and have noticed an increase in perennial crops including nuts and grapes.

7. I have also noticed a marked decrease in the number of insects. When I was a kid growing up in the southern San Joaquin Valley during the spring, summer and fall, we would need to clean the windshield of our car frequently because of the number of insects that got hit by the car, making the windshield harder to see through. Now when I drive along those same roads at the same time of year, often times, I do not need to clean my windshield at all. I worry about the lack of insects because of the vital role they play in supporting other species including birds. I am very concerned that the pesticides being used on the crops today are reducing the population of all insects including critical pollinators.

8. I now live in Los Angeles and regularly visit places to observe native plants and wildlife in central and southern California. While I personally

enjoy travelling to places to see rare plants and animals in central and southern California, I also do so to view rare species and evaluate habitat for rare plants and animals.

9. Because of the high number of endemic plant and animal species that are found nowhere else in the world, I enjoy targeting places where I might be able to see rare and endangered plants and animals, because it brings me great joy to be able to view these species, too many of which are teetering on the brink of extinction. I intend to continue visiting these areas regularly in the future.

10. The Center is committed to protecting endangered species and wild places. We recognize that rare species need habitat protection in order to recover and thrive at levels that assure non-extinction. I rely upon the Center to represent my interests in protecting threatened and endangered species.

11. I am very concerned about the impact of pesticides on numerous rare and threatened and endangered species that I have worked on both in the field and in securing conservation of their habitat for years.

12. I am very concerned about a suite of rare species that have virtually been extirpated from the San Joaquin Valley of California primarily due to habitat conversion to agriculture and only persist along the peripheries of their historic ranges. Along with their habitat conversion, they now are documented to suffer from pesticides. The mammal species include the federally and California state listed endangered giant kangaroo rat (*Dipodomys ingens*), and the federally

endangered and California state listed threatened San Joaquin kit fox (*Vulpes macrotis mutica*). The giant kangaroo rat is affected by pesticides primarily in and around their remaining habitat that is adjacent to agricultural fields. As granivores, these kangaroo rats eat seeds of plants that may be exposed to pesticides. I worry about the health impacts to these imperiled small mammals from toxic food, in addition to the fact that they have already lost over 90% of their habitat to conversion to agriculture.

13. The highly imperiled San Joaquin kit fox is one of my favorite animals because it is a smart and adorable mammal. I have visited habitat for the San Joaquin kit fox on many occasions and at many locations. Most recently in December 2018, I visited its habitat near the Kern River in Kern County. While I did not see any San Joaquin kit fox on that trip I saw its habitat and I searched for burrows that a San Joaquin kit fox would use, because they are very distinctive. I intend to visit San Joaquin kit fox habitat in the spring of 2019 to try to see this critically endangered species.

14. The preferred prey of the San Joaquin kit fox are kangaroo rats and other small rodents. If its prey are affected by pesticides directly the kit foxes will also be affected by consuming rodents that have been exposed to pesticides. The pesticides, then bioaccumulate in the San Joaquin kit foxes (and other predators) and causes illness, reduction of fitness and often mortality.

15. I have visited habitat for the giant kangaroo rat on many occasions and several locations. Most recently in May 2018, I visited its habitat in the Carrizo Plain area in San Luis Obispo County. While in the area, I located giant kangaroo rat territories, called precincts, which are obvious on the landscape because giant kangaroo rats clip the vegetation around their burrows. However, I did not see any giant kangaroo rats. I intend to visit giant kangaroo rat habitat in 2019 to view their precincts and try to view their nocturnal activities.

16. I am concerned about the federally and state listed endangered Buena Vista Lake ornate shrew (*Sorex ornatus relictus*) another animal endemic to the San Joaquin Valley. The Buena Vista Lake ornate shrew's habitat has also been significantly reduced from habitat conversion to agriculture and alteration of hydrological processes. The few acres of remaining habitat for the Buena Vista Lake ornate shrew is primarily surrounded by industrial agriculture, where pesticides used in agricultural practices could cause injury, harm and/or mortality to this already highly imperiled species. The shrew is a voracious feeder, requiring consumption of its own body weight in insects and invertebrates each day in order to survive. I worry about pesticides reducing the Buena Vista Lake ornate shrew's food sources which are necessary to sustain and recover the shrew. In addition, the Buena Vista Lake ornate shrew's habitat is moist soils commonly found near a reliable water source. Agricultural runoff areas are often times the best source of

reliable water in the agriculturally industrialized San Joaquin Valley where the Buena Vista Lake ornate shrew lives. Because agricultural runoff is frequently laden with pesticides, I worry about the direct exposure of the Buena Vista Lake ornate shrew to these pesticides and the effects of the direct exposure on the shrew particularly because many of these pesticides have known negative impacts on other animals.

17. I have visited habitat for the Buena Vista Lake ornate shrew on several occasions, including its habitat in a tributary to Buena Vista Lake in Kern County. While I enjoyed visiting Buena Vista Lake shrew's habitat, I was unable to see this rare animal. I intend to visit Buena Vista Lake shrew's habitat in 2019 to try to view their activities.

18. I am concerned about the federally listed endangered and state listed fully-protected and endangered blunt-nosed leopard lizard (*Gambelia sila*) another animal endemic to the San Joaquin Valley and adjacent areas. The blunt-nosed leopard lizard's habitat has been significantly reduced from habitat conversion to agriculture. The remaining habitat for the blunt-nosed leopard lizard is surrounded by or directly adjacent to industrial agriculture, where pesticides used in agricultural practices could cause injury, harm and/or mortality to this already highly imperiled species. The blunt-nosed leopard lizard is insectivorous and pesticides, which are often aerially applied and have been applied to areas set

aside for blunt-nosed leopard lizard conservation, reduce the primary food source (insects) for the lizard. In addition, the blunt-nosed leopard lizard relies on burrows dug by burrowing rodents as shelter. Pesticides that harm burrowing rodents could reduce the number of shelter sites for the blunt-nosed leopard lizard.

19. I have visited habitat for the blunt-nosed leopard lizard on numerous occasions. Most recently in May of 2018, I visited its habitat on the Carrizo Plain area in San Luis Obispo County. However I did not see any blunt-nosed leopard lizards although I did see a number of suitable burrows in appropriate habitat. I intend to visit blunt-nosed leopard lizard's habitat in the spring of 2019 to try to find these lizards as they are foraging or basking.

20. I am concerned about the federally listed threatened Kern primrose sphinx moth (*Euproserpinus euterpe*) another animal found only in the Walker Basin, in Kern County, the Carrizo Plain, in eastern San Luis Obispo County and the Cuyama Valley in Santa Barbara and Ventura Counties, all in Central California. The Kern primrose sphinx moth's habitat is disjunct and in some locations directly adjacent to agriculture, where pesticides used in agricultural practices could cause injury, harm and/or mortality to this already highly imperiled species. The Kern primrose sphinx moth can remain in extended diapause in its larval form for several years waiting for environmental cues (adequate precipitation) to ensure that its host plant, suncups (*Camissonia campestris*),

germinate and are present to complete the sphinx moth's lifecycle. Whether in its larval stage or as a moth, the Kern primrose sphinx moth is vulnerable to pesticides which are often aerially applied. It is also affected indirectly if herbicides eliminate its host plant, adversely modifying the essential habitat it needs to survive.

21. I have visited habitat for the Kern primrose sphinx moth several times. Most recently in May of 2018, I visited its habitat on the Carrizo Plain area in San Luis Obispo County and also in the Cuyama Valley. I looked for suncups along sandy washes which is the habitat for the Kern primrose sphinx moth and when I found the suncups, I looked carefully for larval or moth stages of the Kern primrose sphinx moth. However I did not find any Kern primrose sphinx moths. I intend to visit Kern primrose sphinx moth's habitat in 2019 to try to find these the moths or larval stages.

22. I am concerned about the federally listed threatened coastal California gnatcatcher (*Polioptila californica*), a non-migratory bird species that is only found along the coast of southern California and northern Baja, Mexico. The California gnatcatcher's habitat has been significantly reduced from habitat conversion to urban, suburban and agricultural development. The small amount of remaining California gnatcatcher habitat often lies directly adjacent to agriculture or urban/suburban development, where pesticides are used that could cause injury, harm and/or mortality to this already highly imperiled species. The California

gnatcatcher, as its name suggests, is insectivorous and pesticides, which are often aerially applied, reduce the primary food source (insects) for the gnatcatcher.

23. I have visited habitat for the California gnatcatcher numerous times, including implementing quantitative surveys on gnatcatcher habitat characteristics in Orange County, California for four years in the late 1990's after a fire in Crystal Cove State Park.

24. My most recent trip to view coastal California gnatcatchers was in the fall of2017 when I visited the Palos Verdes Peninsula. While there, I decided to wander down to the beach to see if I could spot a coastal California gnatcatcher—the Peninsula holds significant high-quality gnatcatcher habitat and has undergone significant efforts at habitat restoration that included herbicide use to eliminate non-native plants. After walking only a short way down the trail towards the beach I heard the gnatcatcher's distinctive mewing call and I was overjoyed to see a California gnatcatcher flitting around in a California sagebrush. Later in the day, when I returned to my car, another California gnatcatcher was "mewing" in some dense coastal sage scrub adjacent to the parking lot. I could see it best with my binoculars.

25. I intend to visit California gnatcatcher habitat in 2019 to try to see and hear these sweet singing little songbirds and assess the quality of their habitat, primarily in San Bernardino and Riverside Counties, where California gnatcatcher

habitat is being impacted by conversion to development and agriculture. I worry about the gnatcatcher's habitat that is adjacent to urban and suburban development and agriculture, because of the potential use of pesticides in such areas. My concern is that increasing use of pesticides adjacent to California gnatcatcher habitat will reduce the amount of insects that the gnatcatcher relies on as a food source, for itself and when raising its young. Depressed populations of insects from the nearby use of pesticides would decrease the populations of gnatcatchers which are already suffering from significant habitat losses.

26. I am concerned about the federally listed endangered and state listed threatened Stephen's kangaroo rat (*Dipodomys stephensi*), a highly localized endemic species that is only found in the western part of Riverside County and the northern part of San Diego County, California. The Stephen's kangaroo rat's habitat has been significantly reduced from conversion to urban, suburban and agricultural development. The little remaining Stephen's kangaroo rat habitat often lies directly adjacent to agriculture or urban/suburban development, where pesticides are used that could cause injury, harm and/or mortality to this already highly imperiled species.

27. The Stephen's kangaroo rat is very likely affected by pesticides that are in and around their remaining habitat adjacent to agricultural fields, urban/suburban areas and earthen dams where pesticides are used based on

documented impacts from pesticides on other burrowing species rodents. Stephen's kangaroo rats are primarily granivorous and I worry about the impact on the Stephen's kangaroo rat if they eat grains that have been sprayed with pesticides. I have visited habitat for the Stephen's kangaroo rat numerous times, visiting many of the reserves established for them. Most recently in 2018, I visited its habitat in Riverside County at the San Jacinto Wildlife Area. I looked for Stephen's kangaroo rats in the grassland habitat that they prefer. However I did not see any Stephen's kangaroo rats, although burrows were present that could have been dug by the burrowing Stephen's kangaroo rat. I intend to visit Stephen's kangaroo rat habitat in 2019 to try to view the nocturnal activities of this very rare species of kangaroo rat.

28. I am concerned about the federally listed threatened Santa Ana sucker (*Catostomus santaanae*), a native California fish endemic to only four southern California rivers – the upper portion of the Tujunga Wash, the San Gabriel River and the upper reaches of the Santa Clara River in Los Angeles County, and a less-than-five-mile stretch of the Santa Ana River between Riverside Drive and Mission Inn Drive, in Riverside and San Bernardino Counties. The Santa Ana sucker's habitat has been significantly reduced from alteration of hydrological regimes. The Santa Ana sucker habitat in the Santa Ana river is

primarily tertiarily treated wastewater, where the Santa Ana sucker is exposed to contaminants including new generation pesticides.

29. I have visited habitat for the Santa Ana sucker numerous times. I have participated in the Santa Ana Sucker Conservation Team since 2005. I have participated in characterizing Santa Ana Sucker habitat along the Santa Ana River spearheaded by the U.S. Fish and Wildlife Service for over ten years. I have assisted the U.S. Geological Survey to assess the population of the Santa Ana sucker in the Santa Ana river for three years. Most recently in August 2017, I helped monitor the Santa Ana sucker population along the Santa Ana River just downstream of the Rialto channel convergence with the River. I looked for Santa Ana Sucker in the river, and helped take measurements of Santa Ana suckers that were captured during the inventory. I will be visiting Santa Ana Sucker habitat in 2019 to try to see the habitat in the different river systems. I also plan continued participation in the Santa Ana Sucker Conservation Team in 2019.

30. I am also concerned about rare plants that have potential to be affected by pesticides including herbicides. I worry about numerous rare plant species that are found in very localized populations at sites known as vernal pools. Vernal pools are ephemeral water features that are typically located in topographically flat areas with less permeable, often clay soils. During winter rains, low points on the landscape fill with water and form shallow pools, which

through slow infiltration due to clay soils and evaporation, gradually shrink in size until they disappear by summer. While water is present, the vernal pools host very unique plants and animals that require the formation and persistence of these pools.

31. Critically imperiled endemic plants that rely on vernal pools include the but not limited to the federally and California endangered Orcutt grass (*Orcuttia californica var. californica*), the federally threatened and California endangered thread-leaved brodiaea (*Brodiaea filifolia*), the federally threatened and California endangered San Diego thorn-mint (*Acanthomintha ilicifolia*), the federally threatened spreading navarretia (*Navarretia fossalis*), the federally and California endangered San Diego button-celery (*Eryngium aristulatum* var.*parishii*) and the federally and California endangered San Diego mesa mint (*Pogogyne abramsii*) as well as unlisted but very rare plants.

32. Many of these species and much of their vernal pool habitat have been lost due to conversion to urban/suburban development and agriculture because of the relatively flat nature of the landscape. Now these species cling to existence in small set aside areas in the midst of urban/suburban development and agricultural areas, where pesticides and herbicides are in use, further threatening these unique and critically endangered plants. I worry that inadvertent drift or runoff of herbicides from adjacent urban/suburban properties and agricultural areas into the vernal pools, will negatively impact the rare plants.

33. Vernal pool plants are not the only species at risk from pesticides. Unique shrimp-like invertebrates known as fairy shrimp including but not limited to the federally endangered San Diego fairy shrimp (*Branchinecta sandiegonensis*) and the Riverside fairy shrimp (*Streptocephalus woottoni*) are also at risk from the local use of pesticides in and adjacent to the vernal pools in the small set aside areas in the midst of urban/suburban development and agriculture. I worry that unwittingly used pesticides will run off from the urban/suburban and agricultural areas into the vernal pool habitat and negatively affect the reproductive cycle of the fairy shrimp.

34. I have visited vernal pool habitats in southern California numerous times. For many years from approximately 1991-2004 I was involved in vernal pool surveys as a consulting biologist throughout southern and central California. I am very familiar with some of the areas that are important for vernal pool species because I have been there many times over the course of many years. Most recently I visited a vernal pool complex in Riverside County known as the "Stowe pool" in April of 2017 where I was able to see the Orcutt grass and the spreading navarretia. I intend to return to this area and other vernal pool complexes in 2019 to continue looking for rare and imperiled vernal pool species, including threatened and endangered plants and invertebrates.

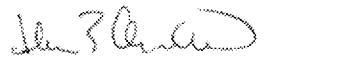
35. My scientific, educational, and wildlife preservation interests have been, are being, and will continue to be adversely and irreparably injured by EPA's failure to consider the impacts of its pesticide registrations on endangered and threatened species. These are actual, concrete injuries, and procedural injuries traceable to EPA's failure to consult with the U.S. Fish and Wildlife Service on impacts to these species under the Endangered Species Act in registering about 400 pesticides.

36. The legal violations alleged in this case cause direct injury to my aesthetic, conservation, recreational, scientific, educational, and wildlife preservation interests and will continue to be adversely affected and irreparably injured if EPA continues to fail to consult with the U.S. Fish and Wildlife Service on impacts to these species under the Endangered Species Act. These are actual, concrete injuries and procedural injuries caused by EPA's failure to comply with the ESA when registering pesticides.

37. My interest in maintaining viable populations of these very rare plants and animals has been sustained over a period of decades. I have provided comments on numerous development and land management plans both under the National Environmental Policy Act and the California Environmental Quality Act that involve all of these species.

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

Executed this 28th day of February, 2019.



Ileene Anderson

DECLARATION OF LORI ANN BURD

I, Lori Ann Burd, declare as follows:

1. I am over 18 years of age, have personal knowledge of the matters asserted in this declaration and if called upon to testify would state the same.

2. I am the director of the Environmental Health Program at the Center for Biological Diversity ("CBD").

3. CBD's mission is to ensure the preservation, protection, and restoration of biodiversity, native species, ecosystems, public lands and water, and public health through science, policy, and law. Based on the understanding that the health and vigor of human societies, plants and wildlife, and the natural environment are deeply intertwined, CBD works to protect and to secure a future for animals and plants hovering on the brink of extinction, for the ecosystems they need to survive, and for the people that interact with, depend on, and cherish these ecosystems. One of the primary mechanisms for wildlife conservation at CBD is citizen participation in species listing and protection under the Endangered Species Act. Through citizen petitions and citizen lawsuits CBD has helped secure protection for 621 species and 507 million acres of designated critical habitat under the Endangered Species Act ("ESA"). The Environmental Health Program is focused on protecting biodiversity and human health from toxic substances. I am also a member of CBD.

4. In my role at CBD, I am involved in strategic decision making and setting policy priorities for the work that CBD does to reduce the threats to the environment and public health from toxic substances, including pesticides.

5. CBD's Environmental Health program works to help reduce the threats posed by pesticides and other pollutants through scientific, legal, and policy mechanisms. I strive to represent the interests of our members and am concerned about how pesticides are impacting them, their families, and the environment that they reply upon. I am relieved that CBD works on my and our behalf to enforce standards that help reduce the threat of pollution and pesticides and help better inform the public of the dangers of pesticides.

6. CBD cannot, of course, work on every pesticide issue in the country. Thus, we set priorities for our pesticides work. One factor we consider in setting priorities for our pesticides work is determining the gravity and magnitude of the threats to the environment and wildlife, including species listed under the ESA. Our ability to effectively determine priorities is based on the analyses of experts, including the expert wildlife agencies of the U.S. Fish and Wildlife Service and National Marine Fisheries Service ("Services").

7. 16 U.S.C. § 1536 ("Section 7 Consultation") as provides that that the Services are required and able to determine whether pesticides adversely affect ESA listed species, jeopardize the continued existence of ESA listed species, or

adversely modify the critical habitat of ESA listed species.

8. CBD views Section 7 Consultation as also providing CBD and the public with information about what reasonable and prudent measures can be taken to avoid actions that can jeopardize the continued existence or adversely modify critical habitat for ESA listed species.

9. The information provided through Section 7 Consultation would be helpful to me, as the Director of CBD's Environmental Health Program, in determining whether our pesticides work is directed in the most efficient manner and to be effective in reducing the harms of pesticides to wildlife and the environment. This determination is a factor in my priority setting of CBD's pesticides work. The failure of the Environmental Protection Agency ("EPA") and U.S. Fish and Wildlife Service to effectively cooperate in completing the Section 7 Consultation for flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide is denying me and CBD this helpful information.

10. Combating the environmental harms posed by pesticides is an issue that is very important to me personally and CBD because I understand the environmental impacts of those pesticides. I am deeply troubled by the effects that they have on the environment and to human and animal health. I am aware of studies linking pesticides to a range of environmental impacts to wildlife and human health, such as the tendency of pesticides to cause reproductive harm,

cancer, neurological problems, and chronic effects.

11. I am further aware that pesticides can negatively affect the health of wildlife and plant life that I and CBD's other members appreciate viewing in the outdoors, my and CBD's other members experiences in nature and the outdoors, and can lead to broader ecosystem effects by adversely affecting water quality. For example, I am aware that the EPA determined that the pesticide malathion is likely to adversely affect 97% of ESA listed species and 98% of critical habitat.

12. CBD has a long history of work analyzing the harms of pesticides on ESA listed species, educating the public about those harms, and advocating for more effective means to reduce those harms. CBD has expended a great deal of resources for over a decade seeking to rectify the EPA's failure to engage in Section 7 Consultation through a series of reports, comments to public agencies, advocacy, and litigation.

13. The Section 7 Consultation process is a crucial mechanism to inform the public about the harm of federal agency actions on ESA listed species and the environment. When that process is not followed the public, including CBD, must seek other avenues to obtain that information. Because the EPA and Services are not conducting Section 7 Consultation CBD has used the Freedom of Information Act (FOIA) to obtain information from the EPA, Services, United States Department of Agriculture, and other federal agencies about the harm to

endangered species from pesticides and the failure to comply with the Section 7 Consultation process during pesticide registrations and re-registrations. CBD has submitted at least twelve FOIA requests specifically related to and because of the government's failure to complete Section 7 Consultations regarding pesticides. For example, CBD has received hundreds of records that we have to review to try to piece together harm to species that should have been in biological opinions related to pesticides that were supposed to be completed by the end of 2017. CBD has also sought information about what government agencies are doing pursuant to a Memorandum of Agreement that further delays pesticide ESA Section 7 Consultation. Despite producing some records, the agencies have not produced all of the records and are still producing records in several of these requests. The illegal failure to complete ESA Section 7 process results in a tremendous amount of time spent in the FOIA process that CBD, and the government itself, would not have been required to do if the government complied with the ESA. We would not have had to divert organizational time and resources to this information gathering effort if the government had completed the Section 7 process.

14. CBD has also had to divert a significant amount of staff resources to attempt to counteract the government's failure to engage in Section 7 Consultation for pesticides. For example, CBD has submitted over 175 comments from staff regarding EPA's failure to comply with the ESA during open comment periods.

The research for these comments was substantial and, among other things, required reviewing agency documents provided on regulations.gov, toxicity and exposure criteria for pesticides, and information regarding environmental effects, especially as it relates to ESA listed species. It also required drafting independent comment letters focusing on the harm to endangered species, the tools available to conduct a viable Section 7 Consultation, and emphasizing the need to comply with the ESA. CBD would not have expended such resources had EPA and the Services been complying with Section 7 Consultation.

15. In one example of lost organizational opportunities because of this diversion of resources, scientific staff employed by CBD have had to divert resources from researching and preparing publications and conducting public education because of the need to research, prepare, and draft comments to government agencies regarding the failure to comply with the ESA when registering pesticides. Time for scientific staff have been diverted from other scientific research in order to analyze studies provided by EPA and the pesticide industry, including Ecological Risk Assessments and Biological Evaluations, in order to analyze how pesticides affect endangered species, which should have been analyzed by the Services.

16. CBD has also dedicated time to outreach to our membership in emails, newsletters, and email action alerts informing them about the impacts to

endangered species from the government's failure to comply with ESA Section 7. CBD has also developed and sent out email action alerts to our members encouraging them to contact government officials directly regarding their concern about the impacts of EPA's failure to comply with Section 7 Consultation.

17. CBD has dedicated organizational resources to author a series of reports detailing the effects of pesticides on ESA listed species. In 2004, CBD released the report *Silent Spring Revisited: Pesticide Use and Endangered Species*, which analyzed the effects on endangered species of EPA's registration of pesticides.[1] The report analyzed EPA's continued failure to enforce the ESA's Section 7 Consultation requirements and how that illegal action affected ESA listed species. As noted in the report,

> Although the EPA by law is required to consult with the U.S. Fish and Wildlife Service on pesticide registration, it has failed to complete a single consultation in the last ten years despite repeated formal requests from the wildlife agency and the unambiguous requirements of the Endangered Species Act.

18. *Silent Spring Revisited* noted how pesticides often exceeded the aquatic life criteria set by the EPA to determine the risk to aquatic life from water contamination and specifically noted exceeded criteria values in the Willamette River of Oregon, the beautiful river that runs through Portland, where I have seen

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[1] https://www.biologicaldiversity.org/publications/papers/Silent_Spring_revisited.pdf

salmon and sea lions splashing and where I swim on hot days every summer. *Silent Spring Revisited* also detailed how pesticides were harmful to ESA listed species such as the California tiger salamander, California red-legged frog, blunt-nosed leopard lizard, coho salmon, chinook salmon, chum salmon, steelhead trout, delta smelt, barton springs salamander, and Illinois cave amphipod. I care deeply about the survival of all these imperiled species.

19. In 2006, CBD issued the report *Poisoning Our Imperiled Wildlife, San Francisco Bay Area Endangered Species at Risk from Pesticides*.[2] CBD was forced to divert its resources and expend resources beyond those that are normally expended to produce and analyze the outcome of EPA's illegal activity and educate the public about the impacts of EPA's failure to engage in consultation, which would have studied and mitigated the effects of pesticides on endangered species. The report repeatedly emphasized the systemic failure at EPA to engage in consultation and how that impacted ESA listed species. For example,

> By failing to consult with the USFWS and NMFS, which have the statutory authority and responsibility to cooperate with other agencies in assessing impacts of agency actions and authority on threatened and endangered species, the EPA neglects to comply with federal law or even develop the information base for making the wise and cautious decisions about our most endangered wildlife.

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[2] https://www.biologicaldiversity.org/publications/papers/bayareapesticidesreport.pdf

20. *Poisoning Our Imperiled Wildlife* examined the risk that toxic pesticides pose to endangered species in the nine Bay Area counties: Marin, Sonoma, Napa, Solano, Contra Costa, Alameda, Santa Clara, San Mateo and San Francisco. *Poisoning Our Imperiled Wildlife* also sought to analyze and highlight the dangers posed by EPA's violations of the ESA in registering pesticides. The report detailed how the use of pesticides in the Bay Area is of particular concern for the California red-legged frog, California tiger salamander, delta smelt and Pacific salmonid species. It further noted that pesticides have an endocrine disrupting effect and a wide range of long-term effects on mammals including damage to eyesight, abnormal brain waves, immunosuppression and delayed neurotoxicity; pesticides have a very high immediate toxicity for bees, amphibians and aquatic insects; levels of concern for pesticides are exceeded for acute hazard to endangered fish, aquatic invertebrates and insects; and chronic hazard levels of concern for pesticides are exceeded by most uses for endangered fish and invertebrates and are potentially exceeded for certain uses for threatened birds, mammals, amphibians and reptiles.

21. CBD had to divert substantial organizational resources to produce these reports, which would not have been required had EPA conducted the consultation analysis.

22. Beyond publishing reports CBD spends a significant amount of staff

time informing, and responding to, the media regarding the failure of the EPA and Services to comply with Section 7 Consultation. Independent of the time needed to review material and become adequately informed about information that should have been provided through the consultation process CBD has had to dedicate time from scientific staff to reviewing responding to inquiries from reporters related to the government's failure to comply with Section 7 Consultation related to pesticides. This is time that scientists and other program staff would have dedicated to other research and environmental health related matters. CBD also has dedicated at least ten percent of the staff time of a media specialist in order to inform the public and respond to requests regarding the government's failure to comply with Section 7 Consultation related to pesticides. For example, since 2002 CBD has issued over forty press releases related to EPA's failure to engage in Section 7 consultation. The time spent on media education and outreach has required a significant amount of staff resources that could have been dedicated to other issues if EPA had complied with the ESA.

23. CBD has also had to dedicate organizational resources or scientific, legal, administrative, and conservation staff to analyzing scientific research, agency data, proposed governmental and industry action, and submitting comments to public agencies in order to help reduce the threats of pesticide use on the environment or urge EPA to engage in Section 7 Consultation regarding pesticide

approvals. Scientific and legal staff were diverted to be deeply involved in the EPA's preparation of a Biological Evaluation related to malathion, chlorpyrifos, and diazinon. In 2016, Center staff traveled to and attended a two-day stakeholder workshop in EPA's offices in Washington DC regarding the draft Biological Evaluation for malathion, chlorpyrifos, and diazinon and submitted comments in June 2016 on the draft Biological Evaluation for those pesticides. When the EPA and FWS failed to produce Biological Opinions by the December 31, 2016 deadline they had agreed to and had assured us in previous months they were on track to do, Center staff had to divert more time in to developing an understanding as to why this failure occurred, including filing FOIA requests, reading legal filings and speaking with members of the media.

24. CBD has had to explore other avenues of relief in order to carry out its mission to minimize the threats to the ESA listed species and their habitat from pesticides. One example is our work on state regulatory efforts that may result in protection for endangered species. CBD has had to submitted comments to the California Office of Environmental Health and Hazard Assessment supporting its decision to list malathion, parathion, glyphosate, and tetrachlorvinphos as carcinogens, which may also reduce the overall exposure of those pesticides to the environment and ESA listed species. CBD has also submitted comments to the California Department of Pesticide Regulation urging greater restrictions on

rodenticides because of the adverse effects on non-target wildlife and, in particular, ESA listed species such as the San Joaquin kit fox (*Vulpes macrotis mutica*) and northern spotted owl (*Strix occidentalis caurina*). In Oregon, CBD worked on the successful ordinance banning the use of neonicotinoids by the city of Portland and has urged the state of Oregon to pass legislation to ban or restrict the use of neonicotinoid pesticides because of the effects of those systemic insecticides on imperiled pollinators such as the ESA listed Fender's blue butterfly.

25. CBD's environmental health program also monitors the latest data on the use of pesticides from the United States Geological Survey. By monitoring and reporting on pesticide use trends, we can attempt to evaluate the threats posed to ESA listed species, although this analysis would of course be much better done by the EPA and Services

26. Because of the dangers posed by pesticides to the environment and wildlife CBD has worked to inform the public and public agencies of the magnitude and risks of pesticide use. For example, CBD produced a report *No Refuge: How America's national wildlife refuges are needlessly sprayed with nearly half a million pounds of pesticides each year* that documents that found an estimated 490,000 pounds of pesticides were dumped on commodity crops like

corn, soybeans and sorghum grown in national wildlife refuges in 2016.[3] The analysis was conducted by analyzing an extensive volume of records obtained by the Center under the Freedom of Information Act. The report focused on national wildlife refuges, which are federal public lands dedicated to protecting wildlife and ESA listed species. Members of the public did previously commonly know that pesticides are used in private agricultural operations on these lands. Work such as this has required a diversion of tremendous amount of resources for CBD and will continue to require more resources into the future to work to try to analyze the scope of harm to ESA listed species. This work would not likely have been necessary had EPA engaged in Section 7 Consultation to provide an analysis of the scope of use and dangers of pesticide use on ESA listed species and subsequently followed reasonable and prudent measures to mitigate those harms by amending pesticide labels to ensure pesticide use does not harm listed species.

27. Through my work at CBD I am also involved in a range of activities to protect wildlife, especially pollinators, that are particularly threatened by pesticides. CBD's native pollinators campaign ties together issues in the context of pollinator conservation to provide relevant information and action opportunities to supporters who are rightfully concerned about the health of native pollinators. One

[3] https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/No-Refuge.pdf

of the biggest threats to pollinators is the use of pesticides, which would likely be reduced in key habitat if the EPA were to engage in Section 7 Consultation because reductions in harm to ESA listed species would provide benefits to other native pollinators that face the same or similar threats due to pesticides. In 2017, CBD produced the report *Pollinators in Peril: a systematic status review of North American and Hawaiian native bees*, which was the first-of-its-kind systematic review of the status of all 4,337 North American and Hawaiian native bees. One of the key findings of that report is that agricultural intensification, which includes habitat destruction and pesticide use, is a key driver in native bee declines. If EPA had engaged in Section 7 Consultation pesticide registrations it would have likely analyzed the effects on ESA listed pollinators that would have reduced the threats posed by pesticides for other native bee species. Native and imperiled bee species such as the yellow carpet solitary bee (*Andrena blennospematis*) and sunflower leafcutting bee (*Megachile fortis*) face key threats from pesticide exposure. Recently in 2018, CBD sent a petition to the U.S. Fish and Wildlife Service to list the Mojave poppy bee under the Endangered Species Act. The petition specifically noted that insecticides that are toxic to bees are used on grazing areas and pose a threat to the Mojave poppy bee.

28. In January of 2019, CBD petitioned the Services to prohibit nearly all uses of pesticides in areas designated as critical habitat for endangered species

because of EPA's failure to engage in Section 7 Consultation related to pesticides. The petition calls for the federal agencies to use their authority under the Endangered Species Act, independent of ESA Section 7, to put in place measures to protect endangered wildlife from harmful pesticides. The petition was submitted as a result of decades of intransigence by the EPA, which has refused to comply with the legal mandates of the Endangered Species Act to protect the nation's most imperiled species from highly toxic pesticides that are known to harm wildlife. This petition required over 230hours of staff time dedicated to research, analysis, drafting, laboriously developing critical habitat maps for 400 hundred species , and media outreach which would not have been required had EPA engaged in Section 7 Consultation. The total cost of producing this report, including salary and benefits, was over $8,300.

29. I live in Tucson, Arizona, and Portland, Oregon. Oregon and Arizona are two of the states where the EPA registered pesticides such as flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide for use on agricultural crops and ornamental uses.

30. A significant portion of my personal and professional life is dedicated to protecting wildlife and pollinators from the impacts of pesticides. I have been working on pollinator issues for the last eight years. I helped rediscover the rare western bumble bee (*Bombus occidentalis*) on Mt. Hood in Oregon. This species

has been experiencing an alarming decline, both range-wide and locally. I have also done surveys for a yellow butterfly called the Intermountain Sulphur (*Colias occidentalis pseudochristina*), which faces serious threats due to pesticide applications that has eliminated several populations in the Blue Mountains of eastern Washington. In addition, I am one of the authors of a petition to list the monarch butterfly under the ESA and am particularly aware of the inadequacy of existing regulatory mechanisms that have failed to protect the monarch from threats, such as pesticides, and put the species at risk of extinction. I am also generally aware of efforts to protect a broad range of pollinators, especially bumblebees, solitary bees, honey bees, bats, and butterflies.

31. I am very concerned about the effects of pesticides on species and their habitats—many that I enjoy viewing in the wild, would like to see in the wild, and that I have worked to protect. I regularly enjoy looking for species in their natural habitats wherever I am during my travels, and especially around where I live in Arizona and Oregon. I frequently tailor travel plans to try to see butterflies, native bees and other species. I have definite plans to continue to look for and enjoy these species in the states where I live and in my travels. I recently returned from a trip to Mexico. The purpose of this trip was to view overwintering monarch butterflies. I was fortunate to see thousands, if not millions, of monarchs. The experience of being surrounded by all these butterflies was one of the highlights of

my life. Pesticide use is a leading cause of monarch declines. I am now more concerned than ever about the impacts of pesticides on monarch butterflies, and the grave danger that if we don't reign in pesticide use in key habitats we could lose this incredibly migratory phenomenon.

32. In Oregon, I am specifically concerned about the effects of pesticides on the Fender's blue butterfly (*Icaricia icarioides fender*), Kincaid's lupine (*Lupinus oreganus*), and Oregon silverspot butterfly (*Speyeria zerene hippolyta*). The Fender's blue butterfly has a very limited range in the Willamette Valley. I frequently spend time in natural areas in the Willamette Valley, visiting vineyards, wildlife refuges and rivers. Whenever I am in the Willamette Valley, I hope to see a Fender's blue butterfly, and am extremely careful never to trample a lupine, it's host plant, in the Valley. One of my dear friends and colleagues dressed up as a Fender's blue butterfly for a Halloween endangered species costume contest and I was able to immediately identify the species she was dressed as. I am deeply concerned that pesticide use in the Willamette Valley may harm the Fenders blue butterfly and Kincaid's lupine. I am also concerned about threat pesticides might pose to the Oregon silverspot butterfly. This butterfly has an extremely limited distribution. I have visited two sites where it lives, Cascade Head and the Cummins Creek Wilderness, hoping to see it, but have never successfully seen one. I am concerned that pesticide spraying could harm this greatly imperiled butterfly. I

plan to continue to visit habitat for these threatened and endangered species when I travel in Oregon while living there in 2019.

33. In Arizona, I am specifically concerned about the effects of pesticides on the Chiricahua leopard frog (*Rana chiricahuensis*). I am aware that the EPA has determined that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide are likely to adversely affect all this species and am concerned about my personal, aesthetic, and professional ability to observe and enjoy these species.

34. CBD has a long history of protecting the Chiricahua leopard frog. In 1998, CBD submitted a citizen petition to list it as a federally endangered species and to designate critical habitat for it. CBD had to file lawsuits before the U.S. Fish and Wildlife Service listed the frog as threatened in 2002. In 2007, CBD became part of the stakeholders' group that developed the federal plan to recover the frog.

35. I regularly hike and recreate in southeast Arizona and have looked for, and possibly caught sign of the Chiricahua leopard frog at isolated ponds and watering holes in the San Pedro and Cienega creek river basins. If flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide are sprayed on fields in these areas and reaches the rivers through direct spraying, run off or drift, the Chiricahua leopard frog could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and

aesthetic interests. I intend to continue to look for and hope to see the frog in these and other places in southern Arizona while living there in 2019.

36. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be routinely applied on lettuce, cotton, corn, soybeans, hay, alfalfa, cabbage, cantaloupe, watermelons, wheat, and for home and garden treatments, among other uses, in Arizona in and around habitat for the Chiricahua leopard frog and have negative impacts on them and their habitat. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be routinely applied on pastures, hay, berries, hazelnuts, wheat, Christmas trees, grass fields, walnuts, cherries, blueberries, apples, homes and gardens, and for mosquito control in Oregon and around habitat for the Fender's blue butterfly, Kincaid's lupin, and Oregon silverspot butterfly and have negative impacts on them and their habitat. I am concerned and fear that these species will be harmed by use of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, cuprous iodide and other agricultural chemicals. If these species are further impacted and their populations reduced or extirpated, my enjoyment Oregon and Arizona's unique natural environment would be diminished.

37. My front and back garden in Portland is planted with all native plants in order to attract native birds and insects and I also have a garden plot designed to

attract pollinators down the street. Similarly, my garden in Tucson is designed to attract wildlife, specifically birds, bees, and butterflies, and is very successful in doing so. When I see that my neighbors have used pesticides I worry about how that will impact the wildlife that I am working to attract in my own gardens.

38. My parents live in suburban Chicago, immediately adjacent to the range of the Rusty patched bumble bee (*Bombus affinis*). I have looked for this endangered bumble bee in both northern Illinois and southern Wisconsin and intend to continue to look for it in 2019 while visiting my parents. The Rusty patched bumble bee is endangered due to pesticide use and habitat loss, and has experienced a massive decline in recent decades. It has a very large range and is a habitat generalist, so I look for it in any place that has flowers, including immediately adjacent to farm fields. When I was a teen in Illinois, I was once out on a late-night walk and was directly sprayed by a mosquito spraying truck. I have often wondered what the chemical was that they were using and whether it may have caused adverse effects on my health. After the Rusty patched bumble bee was listed as endangered, I also became very concerned that the routine mosquito spraying I know occurs there may harm this species. I have also observed residents of the area using insecticides on their gardens and am concerned about how this affects the Rusty patched bumble bee. And, given that there is a lot of agriculture, including commodity crops, vegetables, orchards, and tree farms, I am concerned

that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide may be used and are harming the Rusty patched bumble bee there.

39. I have professional, aesthetic, recreational, and spiritual interests in the preservation of the Fender's blue butterfly, Kincaid's lupin, Oregon silverspot, Chiricahua leopard frog, Rusty patched bumble bee and their habitats. I look for these species and I very much hope to see them. My interests in them are being harmed by the Environmental Protection Agency's failure to ensure that these species will not be put in jeopardy through consultation with the U.S. Fish and Wildlife Service on impacts of its registration of new uses of the flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide on ESA listed species and the implementation of reasonable and prudent measures to prevent jeopardy. The EPA's failure makes it more likely these species will further decline or become extinct. If that should happen, I will be deprived of my enjoyment of these species in the wild. Section 7 Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of this pesticide on this species, which is important to ensure that my interests in the species are preserved and remain free from injury.

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I declare under penalty of perjury that the foregoing is true and correct. Executed on February 26, 2018 in Tucson, Arizona.

Lori Ann Burd

DECLARATION OF JOHN BUSE

I, John Buse, declare as follows:

1. I have personal knowledge of the facts and statements contained herein and, if called as a witness, could and would competently testify thereto.

2. I submit this declaration in support of Petitioners' standing.

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

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.

7. As a 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 effects 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 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 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.

9. I am concerned about the harms to birds, bees, butterflies, beetles and other animals posed by the United States Environmental Protection Agency's decision to register flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide without consulting with the United States Fish and Wildlife Service or National Marine Fisheries Service on potential impacts to endangered and threatened species and their critical habitats. I understand that a broad range of crops will be sprayed with flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide and other pesticides involved in this case, including corn, hay, apples, wheat, beans, blueberries, and soybeans.

Mitchell's Satyr Butterfly

10.I am a periodic visitor to Michigan's Lake Michigan shore. In particular, during these trips, I 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.

11. 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.

12. 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 have an interest in maintaining the diversity of life.

13. 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 in 2019 and beyond to look for Mitchell's satyr butterflies.

14. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around Mitchell's satyr butterfly habitat without regard to the species' conservation and recovery. Killing of non-target insects by pesticides is well-documented, and I fear that Mitchell's satyr butterflies are being inadvertently killed and harmed by agricultural chemicals.

15. I am particularly concerned about the effects of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide because they can be toxic to terrestrial insects such as the Mitchell's satyr butterfly. Additionally, from reviewing the U.S. Fish and Wildlife Service's website, I learned that contamination of the Mitchell's satyr butterfly's habitat by agricultural pesticides is one of the primary threats to this endangered species.

16. On my visits to Michigan, I have frequently observed commercial blueberry cultivation. From visiting the U.S. Department of Agriculture website, I learned that Michigan is one of the top states in the country (ranked by acres in cultivation) for commercial blueberry production. And information available on the Michigan State University website shows that Van Buren County, Michigan is one of the top counties in Michigan for blueberry production.

17. I am also aware that EPA has found in its registration decision that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous

iodide is expected to be used heavily on blueberry crops to control a fruit fly, the spotted-wing Drosophila. EPA notes that it will provide blueberry growers with effective pesticides to combat spotted wing Drosophila and EPA anticipates its use to this end.

18. Because flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide are likely to be very toxic to the Mitchell's satyr butterfly, and is likely to be used extensively on blueberry crops in Van Buren County and other blueberry growing counties in Michigan where the butterfly is native, I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide could severely impact the already-imperiled Mitchell's satyr butterfly.

19. In addition, the Mitchell's satyr butterfly is native to Lagrange and La Porte counties in northern Indiana. Use of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide in 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.

20. 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. 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.

Hine's Emerald Dragonfly

21. 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.

22. 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 have an interest in maintaining the diversity of life.

23. On several occasions, including July 2018, I have attempted to observe Hine's emerald dragonflies in their known habitat in and around Chicago, but I have not experienced a confirmed Hine's emerald observation. I intend to return to

Chicago in 2019 and beyond to look for Hine's emerald dragonflies in their known habitat.

24. 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 flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around Illinois and elsewhere without regard to Hine's emerald dragonfly conservation and recovery. Killing of non-target insects by pesticides 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 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 and other locations in the Midwest were extirpated or reduced, my appreciation of the area's unique natural environment would be markedly diminished.

Indiana Bat

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

26. I regularly observe bats at or near my home in Indianapolis on summer and fall evenings and enjoy looking for the Indiana bat (*Myotis sodalis*). I have specifically observed Indiana bats 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.

27. 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 have an interest in maintaining the diversity of life.

28. I have hiked and recreated near this species' 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.

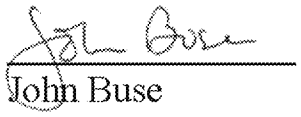
29. I hope to again see Indiana bats in the wild, but even if I fail to observe the species again, I am happy knowing that the species persists in the wild. I would be happier if the species can recover, and I look forward to the recovery of the Indiana bat throughout its native range. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide 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

species by pesticides is well-documented. Indiana bats are insectivores and may eat up to half their body weight in insects each night. I fear that Indiana bats will be harmed by the use of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide and other agricultural chemicals directly and because it will kill insects the bat needs to survive. 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.

30. 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 flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide 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.

DATED: February 26, 2019, in Indianapolis, Indiana.



John Buse

DECLARATION OF CHRISTINA R. CELANO

I, Christina R. Celano, declare as follows:

1. I am over the age of 18 and I currently reside in Florida where I have lived for nineteen years. I moved to Florida in large part because of its abundance of wildlife.

2. I work as a professional wildlife photographer in Florida. I stand or sit in my kayak, for hours at a time in the rivers, bays and mangroves to take images of birds or any living thing that catches my eye.

3. I have been a member of the Center for Biological Diversity since 2009. The Center is a non-profit organization committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend. As a member of the Center, I participate in action alerts and read the newsletters to be more informed. I rely upon the Center to represent my interests in protecting endangered species and their habitat.

4. I am concerned about pesticide impacts on endangered and threatened species. Pesticides harm ALL species. That is what they were designed to do . . . KILL. Whatever we put into the environment ends up in our bodies. If it affects any species in a negative manner it will eventually affect humans. I am concerned about the pesticides used on the major agricultural crops in Florida, including oranges, sugarcane, hay, and different kinds of fruits and vegetables. Because of the breadth of agriculture in Florida and

the number of pesticides used the effects on rare wildlife species are widespread.

5. I am particularly concerned about the impact of pesticides on the imperiled species that I regularly photograph and seek to photograph. These include:

Mammals

Florida panther (*Puma concolor coryi*)
Florida salt marsh vole (*Microtus pennsylvanicus dukecampbelli*)
West Indian manatee (*Trichechus manatus*)

Birds

Audubon's crested caracara (*Polyborus plancus audubonii*)
Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*)
Everglade snail kite (*Rostrhamus sociabilis plumbeus*)
Florida grasshopper sparrow (*Ammodramus savannarum floridanus*)
Florida scrub jay (*Aphelocoma coerulescens*)
Piping plover (*Charadrius melodus*)
Roseate tem (*Sterna dougallii dougallii*)
Wood stork (*Mycteria americana*)

Reptiles

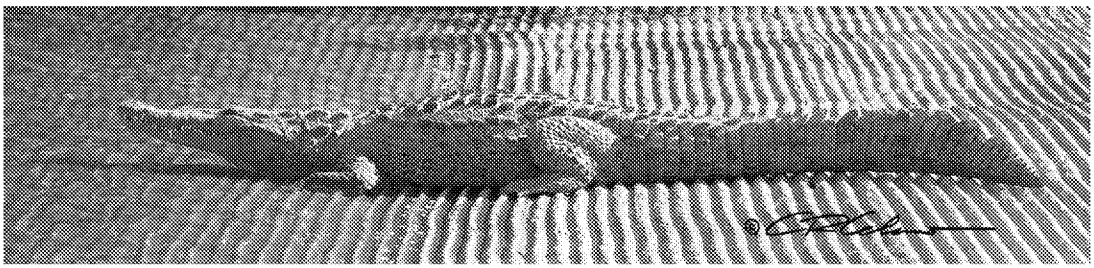
Atlantic salt marsh snake (*Nerodia clarkii taeniata*)
American crocodile (*Crocodylus acutus*)
Bluetail mole skink (*Eumeces egregius lividus*)
Eastem indigo snake (*Drymarchon corais couperi*)
Sand skink (*Neoseps reynoldsi*)

6. I have yet to see the seriously imperiled Florida panther, a very elusive animal with an incredibly low population. I travel to parts of Florida where the panther has been seen but its habitat is fractured or destroyed by

overdevelopment and agriculture. I am still hoping to see one but am very concerned about the threats of pesticides to the Florida panther because its food source, deer and other small mammals, feed in those agricultural areas.

7. I travel to the Everglades often, which is habitat for a range of endangered species,

8. The American crocodile



9. The Wood stork

10. The West Indian manatee

11. as well as the Northern Harrier with the endangered Florida Salt Marsh vole clutched in its talons.

12. The animals of the Everglades and Florida Bay provide me with an education, an income and more joy than anything else I have experienced in my 60 years of life.

13. I have snorkeled with, kayaked among, and photographed the West Indian manatee. The experience is always amazing and I look forward to future encounters with this imperiled mammal.

14. My photography focuses on birds, and I have had the pleasure of observing several imperiled bird species, including Audubon's Crested Caracara, Cape Sable Seaside sparrow, Everglades Snail kite, Florida Grasshopper sparrow, Florida Scrub jay, Piping plover, Roseate tern, and Wood stork.

15. I have also observed several endangered reptile species; including, the American crocodile, Bluetail mole skink, Eastern Indigo snake, and Sand skink. I have seen and photographed the Atlantic Salt Marsh snake on many occasions, sitting motionless on the bottom among mangrove roots, waiting for prey. Snakes are misunderstood and under appreciated by most of the human race. A great shame, as they are elegant in movement, fascinating to observe, beautiful in their simplicity of design and beneficial to the ecosystem; eating many insects, rodents and even other reptiles.

16. I spend 330 plus days per year outside to prepare for or take photographs for my living, and I travel to the habitat of the species listed in

this declaration on a daily basis. On these visits, I will continue to seek out opportunities to observe and photograph all of the species listed in this declaration.

17. The use of pesticides in and around habitat for these species is harmful and reduces the likelihood that I will be able to observe them in the future. Every species, including human, is part of a complex ecosystem. If we lose one species, others that depend on it for their survival will also disappear. Within the unique ecosystem of the peninsula we call Florida, indigenous species are in decline due to ignorance and unintentional or intentional poisoning from humans who do not understand how important they are to our continued existence on this planet.

18. The use of pesticides in 'wildlife habitat', or in agricultural areas that affect wildlife habitat, endangers all life forms and most certainly the recovery of threatened species. Additionally, I am concerned about the effects of pesticides on my health which is why, for the last 30 years, I have only purchased organically produced foods and personal care products and would be more comfortable photographing in some areas if pesticides were not used.

19. Because I work as a wildlife and nature photographer, I have a strong professional and economic interest in the preservation of imperiled wildlife and habitat, including the species listed in this declaration. I have been a

professional photographer for 14 years, and I depend upon intact and healthy ecosystems to provide subjects to photograph. If the species listed in this declaration or those species that depend on them suffer further declines or become extinct, I could lose my livelihood.

20. The loss of species in the ecosystem of Florida would also negatively affect the area as a tourist destination due to the fact that many people travel here to see wildlife. A reduction in tourism would impact my ability to sell my images to these visitors.

21. I have an aesthetic interest in protecting all of the species listed in my declaration. I find nature and all species to be stunningly beautiful. I am captivated by and joyful in viewing behaviors I am able to witness and ever hopeful in my efforts to view more secretive species and their behaviors.

22. I have a moral and spiritual interest in protecting these species. I find it unconscionable when animals—individuals or whole species—perish due to the ignorance and/or greed of a few human beings. I believe that all animals have a right to live and that they should be treated with the respect they have earned for survival despite humanity's detrimental interference. I also believe that the biodiversity of Earth is of the utmost importance to all its inhabitants.

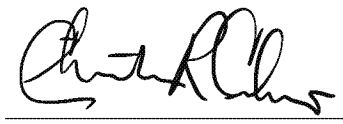
23. As someone who is deeply concerned about the fate of imperiled wildlife, I am upset that the Environmental Protection Agency has refused to

consult with the U S. Fish and Wildlife Service about the impacts of pesticide registrations on the rare species included in this declaration. It is another example, among many, of the US Government's failure to properly communicate between branches! Without consultation, the Environmental Protection Agency cannot understand the full environmental impacts. And as a result, the Environmental Protection Agency has not taken all available steps to ensure that use of pesticides does not harm or kill these species.

24. In sum, I have professional, economic, aesthetic, spiritual, and moral interests in the preservation of these species 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 pesticide registration on these species. Specifically, I believe that the Environmental Protection Agency's failure to follow the law makes these species more likely to suffer further population declines. If these species decline or become extinct, the loss would deprive me of the benefits I currently enjoy from the existence of these rare animals. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of pesticides on these species, and would ensure that my interests in these species and the species themselves are preserved.

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

Executed on February 25, 2019.



Christina R Celano

DECLARATION OF MARTHA L. CROUCH

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 am a member of the 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 in advocating for more stringent government oversight of food production and its work on reducing the amount of chemical inputs into U.S. agriculture. I have also been consulting for CFS since approximately 2009.

2. I am a resident of Bloomington, Indiana which is located in Monroe County. When I was a child, my father was a florist and maintained his own greenhouse in southwestern Michigan. I became interested in plants from playing and working in his greenhouse. In high school I worked at Fernwood Botanical Garden and Nature Center in Berrien County, Michigan, where I developed a lifelong interest in anything having to do with nature.

3. I earned a Bachelor of Science degree in Botany from Oregon State University, and a PhD in developmental biology from Yale University. I am a retired professor of biology at Indiana University, where for twenty 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 CFS regarding these issues.

4. Besides my professional work, I am an amateur naturalist and maintain a wildlife refuge in my yard. I grow native plants that attract birds and insects such as migrant warblers and pipevine swallowtail butterflies (*Battus philenor*). I grow plants that produce flowers and berries at different times throughout the year in order to provide good breeding and migration habitat for several species of animals. I know that many neotropical migrant warblers are experiencing a decline in population and I take immense pleasure from providing a habitat and sanctuary for these species as they are migrating.

5. I am concerned about the harm to birds, bees, butterflies, beetles and other animals posed by the United States Environmental Protection Agency (EPA)'s decision to register the new pesticides flupyradifurone and bicyclopyrone without consulting with the United States Fish and Wildlife Service or the National Marine Fisheries Service (collectively, "the Services") on potential impacts to endangered and threatened species and their critical habitats. I understand that a range of crops could be sprayed with flupyradifurone, bicyclopyrone, and the other pesticides involved in this case, including various citrus fruits, vegetables, blueberries, corn, wheat, cotton, and soybeans. I am also aware that this treatment

is systemic in the plants and am concerned that insects and other animals that use these plants, eating leaves, roots, and pollen, or sipping nectar, including non-target and non-pest insects, will be harmed. I am aware that many pesticides break down very slowly in the environment and accumulate in soil, potentially putting species throughout the affected ecosystem at risk of harm.

6. Blueberries are an important niche crop in Indiana. There are a lot of blueberries grown in northern Indiana near the Great Lakes region (north of Lafayette). The biggest blueberry region is just south of South Bend, in northern Indiana. There is a blueberry festival near South Bend every year that I used to go to when I was growing up. I frequently drive through northern Indiana and stop at various nature preserves along the way. There is also a blueberry farm in Daviess County, Indiana, which is in southern Indiana. I occasionally go there in order to pick fresh blueberries.

7. I am enthralled by the outdoors, nature, and its many environments. I sometimes go on organized outings by groups such as the Indiana Forest Alliance and the Sassafras Audubon Society, I personally conduct workshops identifying wild mushrooms and wildflowers, and belong to insect and bird listservs (electronic mailing lists) that allow members to report the various birds and insects that they have seen and observed. I also go out with friends with similar interests in nature to photograph various species, including going on night hikes to photograph

amphibians. I am, and have always been, the type of person who likes to experience as many different species in my environment as possible. I learn the names of plants, mushrooms, birds, insects, and other organisms, and go out specifically to find and observe new species that I have never seen before.

8. My personal and aesthetic interests are being, and will be, adversely affected by EPA's decision to register flupyradifurone and bicyclopyrone without consulting the Services because it may limit my opportunity to view threatened and endangered species if the use of these pesticides harm them. I know that the EPA is required to consult with the Services prior to registering a pesticide if the pesticide may harm threatened and endangered species. I am also aware that EPA found that flupyradifurone and bicyclopyrone may harm, directly or indirectly, federally-protected threatened and endangered species, but failed to consult. I know that pesticides may have devastating impacts on target and non-target wildlife, causing death or injury, adversely affecting food supplies and habitat, and impairing growth, immunity to disease, or reproduction.

9. Similarly, my recreational interests are being, and will be, adversely affected by EPA's failure to consult with the Services on potential impacts to endangered and threatened species and their critical habitats that may result from registration of pesticide products containing flupyradifurone, bicyclopyrone, and other pesticides. Endangered and threatened species are already under tremendous

stress to survive, and adding additional stresses, even if sub-lethal, can put these species on the brink of extinction over the edge, inhibiting my ability to see them while recreating in their natural habitat.

10. In addition to experiencing the natural environment in my yard every day, I visit other natural areas at least twice a month. Luckily, it is very easy for me to visit a lot of different kinds of habitats and environments as various state and national forests and parks can be reached within about an hour or less, such as the Hoosier National Forest, which is distributed in nine different counties in Indiana. I also visit wildlife areas a little further away, such as Jasper-Pulaski Fish and Wildlife Area. These areas are often surrounded by or have within them agricultural land that could be planted with crops that may be treated with flupyradifurone, bicyclopyrone, and other pesticides that have failed to go through the Endangered Species Act (ESA) consultation process. Jasper-Pulaski Fish and Wildlife Area is located in Jasper County, which contains over 200,000 acres of crops such as corn or soybeans that could be sprayed with fluypradifurone, bicyclopyrone, or other pesticides. The edges of these parks and forests are very important for viewing wildlife. Whether it is because wildlife prefers to congregate along the edges, or because it is simply easier to see species there, species certainly interact with, and may become exposed to, blueberries or other agricultural

products treated with flupyradifurone, bicyclopyrone, or other pesticides in areas where agricultural land runs alongside natural habitat.

11. Additionally, when I take vacations, they often revolve around nature and natural history experiences. Every month or two I visit my father in Goshen, a town in Elkhart County, located in northern Indiana near the border of Michigan. When I visit my father I sometimes go to various parks near Lake Michigan and return to the Fernwood Botanical Garden and Nature Preserve in Berrien County, Michigan, where I worked in high school, in order to go bird watching and find particular pollinators and insects. I know that Berrien County is a large fruit growing region. My Grandfather owned a raspberry farm there, which I worked on as a child. Our family also picked blueberries, apples, peaches, and other fruit at U-pick farms in Berrien County every year. There are hundreds of acres of blueberries grown in Berrien, County. A few years ago I took a trip with a friend to the Great Lakes region along the shores of Michigan from Berrien County to the Upper Peninsula, where we enjoyed hiking and looking for wildlife, and also bought blueberries and other locally-grown fruits at roadside stands.

12. I am aware that Berrien County, Michigan has critical natural habitat for the federally endangered Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*) and the Karner blue butterfly (*Lycaeides melissa samuelis*). I am also aware that Berrien County, Michigan has tens of thousands of acres of crops,

including corn and soybeans, that could be sprayed with flupyradifurone and bicyclopyrone. I have never seen the Mitchell's satyr butterfly or the Karner blue butterfly, but it is something I would like to do in the near future. I know that the Mitchell's satyr butterfly and Karner blue butterfly fly in that area in late June and early July. Since I visit my father every few months, and continue to plan to visit him every few months, I have the opportunity when I visit there in the summer to observe the Mitchell's satyr butterfly and Karner blue butterfly in their natural habitat when I visit Berrien County, Michigan. If the Mitchell's satyr butterfly or Karner blue butterfly is harmed or caused to go extinct because of new and increased exposure to pesticides formulated with flupyradifurone, bicyclopyrone, or other pesticides, my enjoyment of observing wildlife species would greatly suffer by never having the opportunity to observe these butterflies in their natural habitat.

13. I also consider myself a "Craniac," as those of us who follow the whooping crane (*Grus americana*) population often refer to ourselves.

14. 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.

15. I am aware that there are four populations of whooping cranes, two of which migrate, including a self-sustaining western population 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.

16. I am aware that crane conservationists, out of concern that having the entire whooping crane population overwintering in one location put the species at risk from a single adverse event, received permission to raise an experimental population to reduce the risk to the species. That experimental eastern population now summers in Wisconsin and winters in Florida, with the help of a dedicated whooping crane recovery team.

17. The western population does not migrate where I live, but I have some friends in Rockport, Texas, who live near 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 I saw two pairs of whooping cranes in the fields outside of the Aransas National Wildlife Refuge where they winter in Texas.

18. I plan to visit my friends in Texas again during the months when the whooping crane is wintering in the nearby wildlife refuge, so I can observe the western population. In addition to my following, observing, and interest in the western population, I have experience with the migrating eastern population, as well. This population migrates over Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida. The migration pattern of this population leads some to fly directly over my house, and on two occasions I have seen them going over in mixed flocks with sandhill cranes (*Antigone canadensis,* formerly *Grus canadensis*). 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, Indiana, where there are over 100,000 acres of corn and soybeans. I read news and blogs about both populations.

19. I am worried about how the registration of flupyradifurone, bicyclopyrone, and other pesticides may affect whooping cranes. The whooping cranes fly through Arkansas, Kansas, Nebraska, South Dakota, North Dakota, and Texas, and I am aware that these states contain tens of millions of acres of crops that could be sprayed with flupyradifurone, bicyclopyrone, and other pesticides that have not gone through the ESA consultation process. I am aware that corn, cotton, wheat, and soybeans are major crops in Texas covering over 14 million acres of land that could be sprayed with flupyradifurone, bicyclopyrone, and other

pesticides. I am also aware that citrus fruits are major crops in Florida, where the experimental whooping crane population winters, and individuals are sometimes found in parts of Florida where thousands of acres of citrus is produced.

20. Around Thanskgiving, I usually visit the Jasper-Pulaski Fish and Wildlife Area in Jasper County, Indiana. That area is famous for sandhill cranes, which regularly stop at Jasper-Pulaski during their migration south. From time to time there are whooping cranes mixed in with the sandhill cranes. The best time to view sandhill cranes is during November to late December. This year there were close to 30,000 cranes reported to be staging there before migrating south. Sandhill cranes typically go as far south as Mississippi. I was able to see them this year, and plan to go again next year. I am particularly worried about the sandhill cranes that stage in Jasper County because I know there are over ten million acres of crops that could be sprayed with flupyradifurone, bicyclopyrone, and other pesticides grown there, including corn, soybeans, and wheat.

21. I have always been interested in the different roles that species play in nature. For instance, the role that carrion beetles play in decomposition of organic matter in the environment is fascinating to me. On one trip to the Deam Wilderness Area, in the Hoosier National Forest near Bloomington, I was thrilled to come across a dead rattlesnake that was covered with American carrion beetles (*Necrophila americana*). When I began to see these same American carrion beetles

in my yard, I was not only excited to observe them, but I also knew that I was doing a good job of maintaining a natural condition for them to thrive in my own yard.

22. I was very excited, then, when I heard that the Cincinnati Zoo recently reintroduced the largest carrion beetle in the United States, the critically endangered American burying beetle (*Nicrophorus americanus*), into its native habitat in southwest Ohio, with expectations that it will travel into parts of its original range in Kentucky and Indiana. I have not yet seen an American burying beetle, but I have since kept my eyes open for it during evening hikes, and am alert to any sightings in my area, because I know that Monroe County, Indiana is part of its original range. I am concerned however, because some of the land where these endangered species were released at Fernald Preserve in Southwestern Ohio contains crops that could be sprayed with flupyradifurone, bicyclopyrone, and other pesticides, such as Butler County. Nocturnal American burying beetles can travel a couple miles a night, and I am concerned that they will have to traverse agricultural land and be exposed to flupyradifurone, bicyclopyrone, and other pesticides in soil and water. I am particularly concerned that the beetles may not be able to disperse from the areas they were introduced into their original habitat if they come into contact with flupyradifurone, bicyclopyrone, or other pesticides,

and I may not be able to observe them in their natural habitat, including the various parks and forests I visit.

23. In sum, I am injured by EPA's decision to register flupyradifurone and bicyclopyrone without consulting with the Services regarding impacts to listed species and their critical habitats, particularly in light of the fact that EPA determined that federally-protected threatened and endangered species may be impacted, including nearly all the species that I have seen and plan to see listed above. This decision harms my personal, aesthetic, and recreational interest in being able to view threatened and endangered species in their native habitats, because the use of flupyradifurone, bicyclopyrone, and other pesticides where EPA has not consulted under the ESA may jeopardize species that I care about and intend to see.

I declare under penalty of perjury that the foregoing is true and correct to the best of my ability.

DATED: February 15, 2019, in Bloomington, Indiana.

Martha L. Crouch

Martha L. Crouch

DECLARATION OF JAYDEE R. HANSON

I, JAYDEE HANSON, 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 Policy Director of the Center for Food Safety (CFS). I submit this declaration in support of the opening brief of Petitioners Center for Biological Diversity, Center for Food Safety, and Defenders of Wildlife (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) registration of flupyradifurone, bicyclopyrone, and other pesticides without the required consultations with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively, Services) pursuant to the Endangered Species Act.

2. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; Hawaii and Washington, D.C. CFS represents more than 950,000 farmer and consumer members, in every state throughout the country. CFS and its members are being, and will be, adversely affected by EPA's decision to register flupyradifurone, bicyclopyrone, and other pesticides.

3. CFS was founded in 1997. Since its inception CFS's mission has been to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. Accordingly, CFS's program activities are

focused in several areas, including the environmental, public health, and economic impacts of the development and commercialization of agriculture and food processing technologies. A cornerstone of this mission is to advocate for thorough, science-based safety testing of new agricultural products and technologies. This includes major programs on both pesticides as well as genetically engineered crops.

4. CFS combines multiple tools and strategies in pursuing its mission, including public and policymaker education, outreach, and campaigning. For example, CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the effects of industrial food production, agricultural products, and pesticides, on human health and the environment. These educational and informational materials include, but are not limited to, news articles, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets. CFS often has provided expert testimony to policymakers on the potentially-harmful agrichemical impacts associated with industrial monoculture cropping systems, including the increased use of pesticides and chemical fertilizers. CFS has spent hundreds, if not thousands, of hours on policy, scientific, and legal staff time over many years of work address EPA's failure to consult with the Services in regards to registering dangerous pesticides. Over the last few years, CFS has issued over a half-dozen

press releases and blog posts regarding EPA's failure to consult with the Services before authorizing pesticide registrations.

5. Staff members also regularly monitor the Federal Register and submit comments to EPA and other regulatory agencies via the public notice-and-comment process. CFS staff has submitted dozens of comments to EPA regarding its obligation to consult with the Service before approving pesticide registrations. For example, CFS submitted comments to EPA regarding its duty to consult with the Services in the following pesticide registration proceedings:

a. Xtendimax (Docket No. EPA-HQ-OPP-2016-0187)
b. Enlist Duo (Docket Nos. EPA-HQ-OPP-2014-0195 and EPA-HQ-OPP-2016-0594)
c. Prothioconazole (Docket No. EPA-HQ-OPP-2015-0722)
d. Fluensulfone (Docket No. EPA-HQ-OPP-2015-0478)
e. Fluopyram (Docket No. EPA-HQ-OPP-2015-0707)
f. Cyprodinil, Mefenoxam, and Flutriafol (Docket Nos. EPA-HQ-OPP-2015-0180; EPA-HQ-OPP-2015-0014; and EPA-HQ-OPP-2015-0179)
g. Cyantraniliprole (Docket No. EPA-HQ-OPP-2011-0668)
h. Flonicamid (Docket No. EPA-HQ-OPP-2016-0452)
i. Chlorfenapyp (Docket No. EPA-HQ-OPP-2016-0452)

j. Bicyclopyrone and Bromoxynil Octanoate (Docket No. EPA-HQ-OPP-2015-0589)

k. Flupyradifurone (Docket No. EPA-HQ-OPP-2013-0226)

6. CFS also regularly sends out action alerts to its members, encouraging them to participate in the notice-and-comment process, or to submit letters to government officials related to the oversight of industrial agriculture, pesticide use, genetically engineered crops, and other issues affecting CFS's mission to build a sustainable food system. Over the last five years, CFS has issued several alerts regarding EPA's failure to consult with the Services before approving pesticide registrations.

7. CFS also engages at the state level on pesticide issues due, in part, to EPA's failure to consult with the Services before approving pesticide registrations. For example, CFS has worked on model bill drafting and supporting state legislation in Hawaii, California, and other states that would restrict pesticide spraying.

8. CFS would not have had to expend organizational resources focusing on EPA's failure to consult under the ESA in the form education and outreach generated by press releases and email action alerts, administrative comments to EPA on pesticide registrations and Endangered Species Act (ESA) compliance, and state level action to counteract EPA's illegal ESA activity if EPA had been

complying with the ESA's section 7 consultation requirements when it approved pesticides for use.

9. When necessary, and as here, CFS also engages in public interest litigation to address the impacts of industrial food production and pesticides on its members, the environment, and the public interest.

10. As a party to this proceeding, CFS and its members are injured by the approved use of flupyradifurone, bicyclopyrone, and other pesticides. CFS and its members are concerned by the detrimental impacts on farmers, the environment, including on endangered species and their habitat, and on the public health that will result from the approved use of flupyradifurone, bicylopyrone, and other pesticides.

11. CFS and its members are being, and will be, adversely affected by the challenged EPA's decision to register flupyradifurone, bicylopyrone, and other pesticides for use on the range of crops for which they are approved. Many members of CFS have substantial interests in maintaining a healthy environment for many species of animals for recreational, aesthetic, and personal reasons. The use of flupyradifurone, bicylopyrone, and other pesticides will negatively harm non-target organisms, injuring CFS members' recreational and aesthetic interests.

12. Many CFS members are farmers and/or live in rural areas where excessive amounts of pesticides are being applied to crops such as those for which

flupyradifurone, bicylopyrone, and other pesticides are approved for use. These members are especially susceptible to the environmental and health risks associated with EPA's approval of flupyradifurone, bicylopyrone, and the other pesticides at issue in this case. Moreover, the intensive use of flupyradifurone, bicylopyrone, and other pesticides 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.

13. CFS members' interests are also injured by EPA's decision to approve flupyradifurone, bicylopyrone, and other pesticides without consulting with the Services 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 Monarch butterfly 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 flupyradifurone, bicylopyrone, and other pesticides without consulting with the Services, as required under the Endangered Species Act.

14. CFS's organizational interests are being, and will be, adversely affected by EPA's decision to register flupyradifurone, bicylopyrone, and other pesticides. EPA's registration of these pesticides injures CFS's organizational

interests in addressing the environmental and human health impacts raised by increased pesticide use in industrial agriculture. CFS has also spent considerable staff time over many years commenting on and engaging with our members on EPA's failure to consult with the Services before approving pesticide registrations. Finally, CFS's procedural interests are being harmed by EPA's registration of flupyradifurone, bicylopyrone, and other pesticides without consulting with the Services.

15. In sum, EPA's decision to register flupyradifurone, bicylopyrone, and other pesticides for use on a wide range of crops injures CFS's organizational interests in protecting agriculture and the environment, as well as the aesthetic, recreational, economic, and personal health interest of CFS's hundreds of thousands of members. CFS has had to divert a substantial amount of staff time and resources to counteract EPA's failure to consult under section 7 of the ESA that it would not have had to otherwise expend. CFS and its members will be redressed if and when this Court vacates the registrations.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 27, 2019, in Washington, DC.

Jaydee R. Hanson

Jaydee Hanson
Policy Director, CFS

DECLARATION OF BRETT HARTL

I, Brett Hartl, declare as follows:

1. I am over 18 years of age, have personal knowledge of the matters asserted in this declaration and if called upon to testify would state the same.

2. I have an undergraduate degree in conservation biology from Prescott College, Arizona, and a law degree from Lewis and Clark Law School.

3. I have worked at the Center for Biological Diversity ("CBD") since 2013. From 2013 to 2016, I was CBD's Endangered Species Policy Director, and in 2017 was promoted to CBD's Government Affairs Director.

4. I have worked on the issue of endangered species consultations for pesticides since 2011, when I was a Legislative Fellow in the U.S. House of Representatives Committee on Natural Resources, which has oversight responsibilities on the Endangered Species Act. I was one of the primary staffers for the Minority for an oversight hearing on May 3, 2011, that examined the issue of endangered species consultations for pesticides. This hearing helped precipitate the request from the federal agencies to the National Academy of Sciences to study this issue and prepare recommendations for the agencies to implement. I closely followed the progress of the National Academy for the Minority staff in 2011 and provided comments on this to the Environmental Protection Agency ("EPA") in 2012 while I was the senior policy fellow at the Society for Conservation Biology. In 2013, the National Academy issued its report. National Research Council of the

National Academies of Sciences, *Assessing Risks to Endangered and Threatened Species from Pesticides* (2013) ("*Academy of Sciences Report*").[1]

5. I have been deeply involved in this issue at CBD, including providing testimony to the agencies on the *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report* ("*Interim Approaches*")[2] (discussed below). I have participated in every stakeholder meeting on this issue since 2014. In my former role as Endangered Species Policy Director, I submitted over one hundred comment letters to the EPA regarding new pesticide registrations, the reregistration of pesticides, pesticide ecological risk assessments, and interim reregistration decisions. Had the EPA and U.S. Fish and Wildlife Service ("FWS") or the National Marine Fisheries Service ("NMFS") (collectively, the "Services") been complying with the Endangered Species Act ("ESA")'s consultation requirements the substantial time spent on those efforts would have been unnecessary.

6. I was also a coauthor of a peer-reviewed paper entitled *Risk management decisions for pesticides and threatened and endangered species: The*

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[1] https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides.

[2] https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

role of uncertainty analysis in HUMAN AND ECOLOGICAL RISK ASSESSMENT: AN INTERNATIONAL JOURNAL.[3]

7. I have had to allocate a great deal of resources at CBD, including my staff time and time of other staff, in monitoring, tracking, testifying, submitting comments, and communicating with government agency staff on the importance of EPA's compliance with the ESA when it registers pesticides I estimate that over the past 5 years, I have allocated roughly 10% of my total work focus, or approximately 1000 hours, to the issue of EPA's failure to comply with the ESA's consultation requirements and promoting solutions to making these consultations a success. This allocation of my time and resources would not have been necessary if EPA was complying with the ESA because the main reason that CBD submitted comments on EPA pesticide decisions was to address the long-standing failure to comply with the ESA. Having to dedicate this amount of my time, and other staff time at CBD, has resulted in costs to CBD. It has reduced CBD's capacity to reduce other threats to threatened and endangered species, develop policies to strengthen protections for currently listed species, bring enforcement actions against violators of the ESA, and educate the public and decision makers about threatened and endangered species issues.

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[3]https://www.researchgate.net/publication/282352096_Risk_Management_Decisions_for_Pesticides_and_Threatened_and_Endangered_Species_The_Role_of_Uncertainty_Analysis.

8. I am generally familiar with this litigation. I submit this declaration to address responsibilities under the Endangered Species Act and how EPA's failure to comply with the ESA affects CBD and me, as a member. I am closely familiar with CBD cases relating to EPA's obligation under the ESA to address pesticides.

9. Since 2017, CBD has been compelled to submit at least a dozen Freedom of Information Act requests to obtain basic information regarding the progress — or lack thereof — in conducting ESA consultations on pesticides. Our experience since January 2017 has been that the only means of obtaining accurate information regarding pesticide consultations has been through FOIA requests, which take significant staff time to develop, and even more time to review records of. EPA has repeatedly provided information in confusing and difficult formats in responding to our FOIA requests, for example, including meaningless file titles such as "ED_001334_00000924_0_7792a2d5-eaae-476d-b5f0-ae1d8617702a.pdf" for nearly all FOIA records to slow down our review of our FOIA requests. This has drastically increased the time required to review FOIA records. I would estimate that over the past two years, review of FOIA records relating to EPA and the wildlife agencies efforts to consult on pesticides has required that 3-4 staffers at the Center have spent at least 3-5% of their total work time on review of records.

10. I am very familiar with the terms, circumstances, and results of the settlement actions that EPA has taken with respect to five pesticides — chlorpyrifos, malathion, diazinon, carbaryl, and methomyl — over the last several

years regarding EPA's obligation to engage in ESA section 7 consultations related to pesticides.

11. To the best of my knowledge, with the exception of the five currently-registered pesticides listed above that have been subject to settlement agreements with CBD and other non-profit organizations, since 2013 EPA has not taken any meaningful steps towards completing a useable assessment—through the completion of a Biological Evaluation or otherwise—that would allow FWS or NMFS to evaluate the impacts of any other pesticides on endangered species.

12. CBD's 2014 legal settlement required EPA to complete five Biological Evaluations. In turn, the settlement required the FWS to complete Biological Opinions based on those Biological Evaluations. Biological Opinions from FWS for the three organophosphate pesticides (malathion, diazinon, and chlorpyrifos) were due in December 2017. Biological Opinions for the two carbamate pesticides (carbaryl and methomyl) were due in December 2018. *See* Stipulation Amending Original Stipulated Settlement and Order, *Center for Biological Diversity v. U.S. Fish & Wildlife,* No. 11-cv-5108 (N.D. Cal. July 28, 2014), (attached as Exhibit 1).

13. The 2014 settlement was premised on a good-faith effort by EPA and FWS to develop new approaches to complete nationwide consultations. Pursuant to these settlements, EPA and FWS provided CBD with non-binding benchmark dates for the completion of the draft and final Biological Evaluations. For these

benchmarks, EPA stated it would attempt to complete the first three Biological Evaluations by March of 2016 and the remaining two March of 2017. *See* Tentative Milestone Dates for ESA Consultations, (attached as Exhibit 2).

14. To aid in completing these Biological Evaluations and Biological Opinions, EPA and the Services developed their *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report* ("*Interim Approaches*") discussed above.[4]

15. The goal of the *Interim Approaches* was to allow EPA and the Services to work together to develop new methodologies to complete the pilot consultations — as well as additional consultations — in an effective and efficient manner. The *Interim Approaches* was a "learn-as-you-go" process that was designed to allow the agencies to refine and improve the efficacy of consultations. During the past three and a half years, EPA and the Services have developed, among other things: (1) refined geospatial data of pesticide use patterns, (2) refined species distribution and range maps, (3) new models to estimate aquatic exposure to pesticides, and (4) sophisticated analyses of impacts to endangered species. Because of these advances, the EPA and the Services do not have to replicate the methods and data sets each time from scratch, and instead could apply them in any future Biological Evaluation, making future assessments potentially far more

[4] https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

efficient. For example, once the FWS completes refined species distribution maps, those maps can be used in other assessments without having to start over.

16. At its simplest, the goal of the *Interim Approaches* was to allow EPA — with the involvement of the Services throughout the process — to produce sufficient "initiation packages" for formal consultations and then for the Services to complete consultations in a timely manner. The Services currently require[5] that each consultation package include at a minimum (1) a description of the action being 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 or other analyses prepared on the proposal; and (6) any other relevant studies or other information available on the action.

17. Despite the progress made from 2014 to 2016 by the agencies to develop more refined methods via the *Interim Approaches*, events since 2017 have demonstrated that without a firm judicial deadline to complete consultations, any assessments of the impacts of pesticides on endangered species simply will not occur. EPA now appears to be embarking on a deliberate path to manipulate and

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[5] The Services have undertaken a rulemaking to change the existing consultation regulations found at 50 C.F.R. § 424. This declaration does not address those possible changes.

drag-out the consultation process rather than taking meaningful action to address the impacts of pesticides on endangered species.

18. The entire *Interim Approaches* now appears to be a dead letter, after being called into question by the political leadership of the EPA. For example, on January 31, 2018, former EPA Administrator Scott Pruitt stated that: "The current Endangered Species Act pesticide consultation process is broken,"[6] and that EPA and the Services were establishing a new "interagency working group" to reassess the entire premise of nationwide consultations, including an unnecessary review of the Endangered Species Act's legal framework, case-law, and past developments. *See* Memorandum of Agreement (MOA), (attached as Exhibit 3). This working group does not appear to be a good-faith effort to improve the *Interim Approaches* and the pilot consultations, but instead is a top-down effort by political appointees to block pesticide consultations from being completed. This action by former Administrator Pruitt followed a request by several pesticide registrants as well as CropLife America to reconsider the *Interim Approaches*. *See* Letter from Rachel Lattimor, Senior Vice President, CropLife America, to Scott Pruit, Administrator, EPA (April 19, 2017) (attached as Exhibit 4). These developments further

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[6] EPA Administrator Scott Pruitt Signs Endangered Species Act Memorandum with State Agriculture Commissioners (Jan. 31, 2018), https://www.epa.gov/newsreleases/epa-administrator-scott-pruitt-signs-endangered-species-act-memorandum-state.

underscore the inability to rely on any timetables or processes set by EPA without court-ordered schedules.

19. Even though the FWS and EPA have totally failed to meet any of the deadlines or benchmarks set forth in our good-faith settlement, the two agencies continue to refuse to provide CBD with any assurances that they will ever complete the chlorpyrifos, malathion, and diazinon Biological Opinions that were due at the end of 2017. Nor has EPA provided any indication or assurance that they will ever complete the carbaryl and methomyl Biological Evaluations. . Given that EPA has not completed the Biological Evaluations for carbaryl and methomyl, which were due in 2017, it is virtually impossible to conclude that a Biological Opinion can be initiated, let alone completed by the FWS.

20. Importantly, documents obtained via FOIA conclusively demonstrate that the Fish and Wildlife Service's Biological Opinions for chlorpyrifos, malathion and diazinon were nearly complete in 2017. Likewise, the Biological Evaluations for carbaryl and methomyl were also nearly complete in 2017, and that the primary reason the entire process has broken down was not due to technical or scientific challenges facing the career staff at the agencies, but instead that the process was by political pressure.

21. For example, on and around April 12, 2017, career staff indicated that the draft Biological Evaluations for carbaryl and methomyl were nearly complete, and that they were preparing the final paperwork in order to send a notice to the

Federal Register to announce a public comment period. *See* EPA interagency emails, (attached as Exhibit 5). Shortly thereafter, at the May 3, 2017 Pesticide Program Dialogue Committee ("PPDC") meeting, the EPA released a handout to the public, dated May 3, 2017, entitled ESA § 7 CONSULTATIONS & NEXT STEPS, which stated that the "Draft BEs for carbaryl and methomyl are expected to be released soon for 60-day public comment." *See* EPA, Endangered Species Act: Section 7 Consultations and Next Steps (May 3, 2017), (attached as Exhibit 6). In contemporaneous remarks, former assistant director of the Environmental Fate and Effects Division, Anita Pease stated to the public "Also, EPA has completed draft BEs for carbaryl and methomyl. Those have not yet been released for public comment yet. That's all tied up in consideration of the letter that we got from industry."[7]

22. The May 3, 2017 handout entitled ESA § 7 CONSULTATIONS & NEXT STEPS also stated that "EPA expects to release the Services' draft BiOps for chlorpyrifos, diazinon, and malathion for a 60-day public comment period in late May or early June 2017 with final BiOps by December 2017." *See* Exhibit 6 at 2. FWS career staff echoed this expectation. Gina Shultz, deputy assistant director of ecological services at the Fish and Wildlife Service stated to a reporter with InsideEPA news that the draft Biological Opinions were complete and "We are in

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[7] Transcript of PPDC Meeting (May 3, 2017), at 176, https://www.epa.gov/sites/production/files/2017-07/documents/may-3-2017-ppdc-meeting-transcript.pdf

the process of trying to brief our new policy leadership team" in order to "make sure that everybody understands and is comfortable with what this is and the science." *See* Dave Reynolds, Pesticide Reviews Advance But EPA Attainment Of Court Schedule Uncertain, InsideEPA, Oct. 2, 2017, (attached as Exhibit 7).

23. Two days later, May 5, 2017, Nancy Beck, the current Deputy Assistant Administrator in the Office of Chemical Safety and Pollution Prevention appointed by President Trump, sent an email to former Administrator Pruitt's top policy advisor Samantha Dravis and says "Because we think the Services are likely to release the BiOps in the end of May, we will need to engage quickly." *See* email from Nancy Beck to Samantha Dravis (May 5, 2017), (attached as Exhibit 8).

24. Similarly, on or around May 15, 2017, career staff at the Fish and Wildlife Service briefed the political leadership at Department of Interior on the draft biological opinions. Although redacted at a key point, the presentation document notes that the Biological Opinion will contain Reasonable and Prudent Alternatives — the legal requirement when a "jeopardy" finding is made in an opinion — that will include "buffers, equipment, no-spray zone/time." *See* "National Pesticide Consultations: An Overview" (attached as Exhibit 9).

25. Neither the Biological Opinions nor Biological Evaluations were released to the public for review as promised by the EPA and the Services at any point in 2017.

26. At the November 1, 2017 PPDC meeting, Marietta Echeverria (EPA's Director of the Environmental Fate and Effects Division in the Office of Pesticide Programs), stated that EPA did not meet its May time frame and was continuing to work on the Biological Evaluations.[8] EPA has provided no further detailed information to CBD regarding when, or even if, a Biological Evaluation for carbaryl and methomyl.

27. Similarly, at the PPDC meeting on November 1, 2017, the agencies were only willing to state that the "Draft BiOPs have not yet been released for chlorpyrifos, diazinon, or malathion. Once they are released, a public comment period is expected to occur before finalization of the BiOPs."[9] In 2018, the FWS requested an extension from EPA to complete the Biological Opinion for malathion until 2021. *See* FWS request for extension, (attachment as Exhibit 10). This extension does not mean that the Biological Opinion will be completed in 2021. All this ensures is that the Biological Opinion will not be completed prior to 2021, because the FWS is under no obligation to complete it under any court order. To the best of my knowledge, FWS has not requested an extension for chlorpyrifos

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[8] Transcript of PPDC Meeting (Nov. 1, 2017), at 78 https://www.epa.gov/sites/production/files/2018-01/documents/november-1-2017-ppdc-meeting-transcript.pdf.

[9] Transcript of PPDC Meeting (Nov. 1, 2017), at 77 https://www.epa.gov/sites/production/files/2018-01/documents/november-1-2017-ppdc-meeting-transcript.pdf.

or diazinon, but this only means that the consultations remain in limbo, it is not an indication of progress.

28. Additional records obtained via a Freedom of Information Act strongly suggest that by October, 2017, the Fish and Wildlife Service had completed a draft Biological Opinion on the effects of chlorpyrifos, diazinon and malathion. The draft Biological Opinion most likely included Reasonable and Prudent Alternatives designed to avoid jeopardy to species and destruction critical habitat. The Reasonable and Prudent Alternatives mostly likely recommended revising pesticide label language: to restrict pesticide usage in localized areas where certain listed species occur; to eliminate areas where pesticides are not anticipated to be used; to establish or increase buffers to reduce spray drift into areas where listed species may occur; and to improve required pesticide application equipment. *See* Full Communication Strategy, (attached as Exhibit 11). The Service provided a second briefing on its October 2017 draft Biological Opinion to Deputy Secretary of the Interior David Bernhardt in October 2017. *See* Overview of the National Pesticide Biological Opinions, (attached as Exhibit 12).

29. CBD's settlement with the Service was premised on a good-faith effort by the FWS and, as a result, we did not have a judicially enforceable mechanism to enforce this deadline. The FWS has requested an extension from EPA and the registrants to at least March 2021 to complete the Biological Opinion for malathion. However, the past failure to adhere to proposed deadlines and

refusal to agree to any enforceable deadline leaves the March 2021 timeframe essentially meaningless.

30. Based on my experiences and CBD's numerous past attempts to ensure compliance, only a binding Court order with enforceable deadlines will force the EPA to comply with the Endangered Species Act. Our experiences indicate that leaving pesticides on the market during the assessment process only continues to expose endangered species to continued harm. A Court order vacating the registrations until compliance with the Endangered Species Act is the only guarantee that EPA will have the proper incentive to comply with the law. Absent that, our experience shows that compelling Endangered Species Act compliance under a court-ordered timeline with retained court jurisdiction is the only way to ensure that this crucial work is completed.

31. CBD also entered into good faith settlements with the EPA and the Services to complete nationwide consultations regarding glyphosate (the key ingredient in Roundup) and the triazine class of pesticides, which includes atrazine, simazine and propazine. We agreed to similar, non-enforceable deadlines in good faith for EPA to complete Biological Evaluations for glyphosate in 2020 and the triazine class in 2021, with the Service completing a biological opinion a year after that.

32. We agreed to these deadlines over a year after the completion of the first Biological Opinions because EPA stated it would need additional time and

resources to implement mitigation measures — including label changes — and would not have the resources to do both at once. Because CBD approached these consultations in good faith, we consented to those deadlines. Even if one assumed that the Service will complete a Biological Opinion by 2021, EPA would need to spend at least one additional year to implement them, assuming good faith on the agencies parts. This is extremely unlikely given current efforts by the political leadership at the agencies to stall the process. In essence, a process that was expected to take five years to complete will now take at least double that amount of time assuming no additional delays or interference.

33. The deliberate delays by the EPA and Service harm me personally and harm CBD's ability to fulfill its mission. One of my personal passions when not working is to view wildlife at home, around the country and around the world. I have seen over 3300 species of birds and 360 species of mammals, and regularly travel to observe wildlife, which I photograph and take video of to post online.

34. Among the endangered birds that I have observed include the whooping crane (*Grus americana*), red-cockaded woodpecker (*Picoides borealis*), Florida scrub-jay (*Aphelocoma coerulescens*), least Bell's vireo (*Vireo bellii pusillus*), southwestern willow flycatcher (*Empidonax traillii extimus*), piping plover (*Charadrius melodus*), snowy plover (*Charadrius nivosus nivosus*), interior least tern (*Sterna antillarum*), light-footed clapper rail (*Rallus longirostris levipes*), Yuma clapper rail (*Rallus longirostris yumanensis*), and endangered species in

Hawaii like the Hawaiian duck (*Anas wyvilliana*), Hawaiian coot (*Fulica americana alai*), Hawaiian moorhen (Gallinula galeata sandvicensis), nene goose (*Branta sandvicensis*), and Hawaiian stilt (*Himantopus mexicanus knudseni*).

35. For example, I have seen endangered light-footed clapper rails in southern California and Yuma clapper rails along the Colorado River in the past. I visit southern California at least once a year and plan to visit habitat for the light-footed clapper rail and Yuma clapper rail in an attempt to see them. These rare marsh birds are likely harmed by pesticide spraying from nearby agriculture or other pest control activities. I am concerned by the impacts of pollution — including pesticides — and the direct and indirect impacts which are a documented threat to these species. Without consultations, these species are put at greater risk of becoming extirpated locally — meaning they disappear from certain marshes — and harder to observe in the future.

36. I visit Hawaii at least once a year, most recently in October 2018, and plan to return there in the fall of 2019. The birds from Hawaii discussed above are all found in lowland areas including ponds and wetlands. Many of their habitats are nearby to agricultural areas or are likely exposed to pesticides from mosquito control activities. Endangered species in Hawaii face many threats, but harmful exposure to pesticides makes it harder to not only stabilize populations but precludes their recovery. I would be greatly harmed if any of these species

becomes rarer or went extinct, because they are very important to me personally and I take great joy from seeing them.

37. I have also travelled widely to view whooping cranes on their wintering grounds on the Texas coast, most recently in the spring of 2014 and plan to return again in March of 2019 to take video of them. Seeing these iconic birds is always an incredible experience for me, and one of my life goals is to view all of the 15 species of cranes around the world. I have included a photo of a group of whooping cranes that I took during my most recent visit.

38. I am very concerned that the use of pesticides in Texas for agricultural and non-agricultural uses, could dramatically impact the food supply for whooping cranes. The entire wild population of this species survives in a small area of marsh

along the Texas coast, and cumulative impacts from pesticide worry me greatly given the precarious conservation status of this species. Furthermore, the migratory nature of these cranes means that they are potentially exposed to pesticides along their entire migratory route, causing further harm. The extinction of the whooping crane would directly harm my interests in seeing them in their natural habitat in the future and would be devastating to me.

39. As an organization whose mission is to protect endangered species from extinction, the Environmental Protection Agency's decades-long non-compliance with the Act harms the organization, and thousands of our members that — like me — derive enormous satisfaction and benefit from viewing animals in the wild as part of thriving, healthy environments. CBD's mission of preserving species from extinction is frustrated by EPA's failure to consult and comply with the ESA. Like many of our members, I have professional, recreational, aesthetic, and spiritual interests in the conservation and preservation of the endangered species discussed in this declaration.

40. I do not believe that the EPA and the government's representations regarding its actions with respect to endangered species is candid, accurate, or truthful. Science and knowledge, by definition, will always be refined over time. But decision-making for endangered species, by definition, always must occur based on incomplete knowledge based on the best information known at the present to avoid extinction. The government's years of inaction continues to cause

enormous harm to the environment and endangered species in particular in the meanwhile.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 27th day of February, in Prescott, Arizona.

Brett Hartl

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Center for Biological Diversity,

Plaintiff,

v.

United States Fish and Wildlife Service et al.,

Defendants,

and,

CropLife America,

Intervenor-Defendant.

Case No. 3:11-cv-5108-JSW

Stipulation Amending Original Stipulated Settlement and [~~Proposed~~] Order

Plaintiff Center for Biological Diversity (the "Center"), Defendants the United States Fish and Wildlife Service ("FWS"), Dan Ashe, in his official capacity as Director of the Fish and Wildlife Service, the United States Environmental Protection Agency ("EPA"), and Gina McCarthy, in her official capacity as Administrator of EPA (collectively, the "Parties"), by and through the undersigned counsel, state as follows:

Whereas, the Parties entered into a stipulated settlement that resolved the remaining disputed issues in this case, and the Court entered the terms of that settlement as an order and dismissed this case without prejudice (while retaining continuing jurisdiction to enforce its order), Docket No. 76 (Nov. 4, 2013) ("Original Stipulated Settlement");

Whereas, that settlement requires FWS to complete consultation with EPA under the Endangered Species Act ("ESA") (and pursuant to the applicable regulations) on the potential effects of seven pesticides on the California red-legged frog by November of 2015, Stipulated Settlement ¶¶ 1, 2;

Whereas, EPA, the United States Department of the Interior, the United States Department of Commerce, and the United States Department of Agriculture ("USDA") had previously asked the National Academy of Sciences ("NAS") to evaluate the differing risk assessment approaches used by these agencies to identify the potential effects of pesticides on threatened and endangered species;

Whereas, the NAS responded to that request on April 30, 2013 by issuing a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (the "NAS report");

Whereas, the NAS report suggests, *inter alia*, that EPA, FWS, and the National Marine Fisheries Service ("NMFS") take a common approach to assessing the potential effects of pesticides on threatened and endangered species to facilitate coordination among federal agencies;

Whereas, EPA, FWS, NMFS, and the USDA are now working in close cooperation to evaluate and implement the recommendations made by the NAS report;

Whereas, based on the findings in the NAS report and the work done so far by the agencies to implement the recommendations in that report, the Parties now agree that it would be more efficient for EPA and FWS to consult on the potential effects that pesticides at issue in this case have on threatened and endangered species nationwide, instead of limiting their consultation only to potential effects on the California red-legged frog;

Whereas, EPA and FWS are working to complete such nationwide consultations on five (5) of the pesticides at issue in this case as part of the nationwide endangered species assessments that EPA will be conducting in connection with registration review under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA");

Whereas, those five (5) pesticides are carbaryl, chlorpyrifos, diazinon, malathion, and methomyl;

Whereas, EPA and FWS currently expect to complete nationwide ESA consultations for three (3) of the five pesticides listed above by December 31, 2017 and for the remaining two (2) pesticides by December 31, 2018;

Whereas, the Parties agree that it would be more efficient to conduct nationwide consultations, instead of consultations limited to the California red-legged frog, but the agencies still face significant challenges in implementing the recommendations of the NAS report and completing such nationwide consultations;

Whereas, the Parties have now devised this stipulation to amend the Original Stipulated Settlement so that FWS will have an opportunity to attempt to complete the nationwide consultations described above, but which will still require FWS to complete the original consultations on the California red-legged frog if it is not able to complete nationwide consultations (although the schedule for such California red-legged frog consultations would be extended);

Whereas, the Parties reserved the right to ask this Court to modify the Original Stipulated Settlement "because of the Service's ongoing actions to comply with the ESA, to meet the requirements of other federal agencies or departments, or to deal with circumstances not presently anticipated."

Stipulated Settlement ¶ 5; and,

Whereas, Intervenor-Defendant CropLife America takes no position on the relief sought by this stipulation;

Now, therefore, the Parties stipulate to amend the Original Stipulated Settlement as follows:

1. The consultation schedule set out in paragraph 2 of the Original Stipulated Settlement is hereby suspended to allow the Federal agencies to engage in the nationwide consultations described above in the "whereas" clauses.

2. No provision of this Stipulation requires (or shall be construed to require) FWS or EPA to conduct the nationwide consultations described above in the "whereas" clauses, and no provision of this Stipulation requires (or shall be construed to require) FWS or EPA to complete any such nationwide consultations on the schedule set out above in the "whereas" clauses.

3. While it is not obligated to do so, if FWS completes nationwide consultations on the effects of the five (5) pesticides listed above on the schedule set out above in the "whereas" clauses, then FWS shall be deemed to have discharged its obligations under the terms of the Original Stipulated Settlement in full.

4. Alternatively, if:

(a) FWS does not complete nationwide consultations on the five (5) pesticides listed above on the schedule set out above in the "whereas" clauses;

(b) FWS concludes (based on further review of these issues) that nationwide consultations are no longer appropriate; or,

(c) FWS does not complete the interim benchmarks on the

estimated schedule described below in Paragraph 5,

then:

(1) at the request of either the Center or the Federal Defendants, the Parties shall meet and confer at the earliest available opportunity to discuss whether it is appropriate for FWS to complete the consultations "on the potential effects of seven pesticides on the California red-legged frog" described in Paragraph 1 of the Original Stipulated Settlement and, if so, to discuss an appropriate revised schedule for those consultations based on the schedule set out in Paragraph 2 of the Original Stipulated Settlement; and,

(2) if the Parties are unable to reach agreement on that revised schedule within thirty (30) days of any such meeting and conference, either party may petition the Court to resolve the dispute and set a schedule for the remaining consultations "on the potential effects of seven pesticides on the California red-legged frog" described in Paragraph 1 of the Original Stipulated Settlement.

5. Within 30 days of the Court's approval of the Amended Stipulated Settlement, FWS and EPA shall provide the Center (and Intervenor-Defendant) with an estimated schedule, including interim benchmarks, for completing the nationwide consultations described above in the "whereas" clauses. That schedule will include estimated dates for EPA's preliminary risk assessments (which include the draft biological evaluation ("BE")), EPA's submittal of the BE to FWS, FWS's draft biological opinions, and FWS's final biological opinions for each of these pesticides. The parties recognize that this schedule will be a good faith estimate as of the date that it is provided, but that the schedule may be subject to change (based on factors including, but not limited to, variations in the estimated dates for data

submission, the volume of public comments, and unanticipated legal obligations), and that, as stated above in Paragraph 2, this schedule will not be binding or enforceable by the Court.

6. FWS shall provide the Center (and Intervenor-Defendant) with an update by conference call every four (4) months describing the status of these consultations.

7. Within 30 days of the Court's approval of the amended Stipulated Settlement, FWS shall issue a press release that alerts the public to the amended Stipulated Settlement and shall make the following modifications to the webpage created pursuant to the first paragraph in Section 3 ("Web-site Content") of the Original Stipulated Settlement: i) summarize the principal terms of this amended Stipulated Settlement; and ii) include a hyperlink to the full text of this amended Stipulated Settlement. As for the webpage created pursuant to the second paragraph in Section 3 ("Web-site Content") of the Original Stipulated Settlement, FWS shall work with EPA to include on an appropriate, easily accessible Federal government website publicly-available documents associated with the nationwide consultation processes for the pesticides that are the subject of this stipulation, as well as the pesticides that are subject to this case, including preliminary risk assessments, biological evaluations, draft biological opinions, and proposed decisions that are subject to public comment. The webpage shall post the documents or links to websites containing the documents within 14 days of the date they become publicly available.

8. The first and second sentences of Paragraph 15 of the Original Stipulated Settlement are amended to read, in their entirety: "Upon entry of this Stipulated Settlement, Plaintiff's complaint shall be dismissed without prejudice. Plaintiff resolves its Complaint as to the five active ingredients

carbaryl, chlorpyrifos, diazinon, malathion, and methomyl, but Plaintiff reserves the right to bring a new Complaint regarding the 59 other active ingredients." This Stipulation does not amend the third sentence of Paragraph 15 of the Original Stipulated Settlement, which remains in effect.

9. Provisions of the Original Stipulated Settlement that are not directly amended by this Stipulated Settlement shall remain in effect.

10. This Stipulation has no precedential value and shall not be used as evidence in litigation or in any other context.

PURSUANT TO STIPULATION, IT IS ORDERED that the Settlement executed by the Parties is hereby incorporated into this Order; and

IT IS FURTHER ORDERED that this Court shall have continuing jurisdiction to enforce this Order and the terms of the Settlement herein consistent with the terms of that agreement; and

IT IS FURTHER ORDERED that this case is hereby **DISMISSED** without prejudice.

Dated: July 28, 2014

Jeffrey S. White
United States District Judge

Respectfully submitted July 25, 2014,

SAM HIRSCH,

Acting Assistant Attorney General
United States Department of Justice
Environment & Natural Resources Division

SETH M. BARSKY, Section Chief
S. JAY GOVINDAN, Assistant Section Chief

/s/ James A. Maysonett

JAMES A. MAYSONETT, Senior Trial Attorney

Wildlife & Marine Resources Section
P.O. Box 7611, Washington D.C. 20044
(202) 305-0216, facsimile (202) 305-0275
james.a.maysonett@usdoj.gov

COUNSEL FOR FEDERAL DEFENDANTS

/s/ Collette Adkins Giese

COLLETTE ADKINS GIESE (MN Bar # 035059X)
JUSTIN AUGUSTINE (CA Bar # 235561)

CENTER FOR BIOLOGICAL DIVERSITY
351 California Street, Suite 600
San Francisco, CA 94104
Telephone: (415) 436-9682
Facsimile: (415) 436-9683
jaugustine@biologicaldiversity.org
cadkinsgiese@biologicaldiversity.org

ATTORNEYS FOR PLAINTIFF

Exhibit 2

Tentative Milestone Dates for ESA Consultations

Pesticide Active Ingredient	Registration Review Docket Opening	Date of Data Call-In Notice	Start of Comment Period on Preliminary Risk Assessment	BE Submitted to Services	Draft BiOp Available for Public Comment	Issuance of Final BiOp
EPA, FWS, and NOAA Fisheries – Nationwide Consultation						
Carbaryl	September 2010	October 2011	August 2016	March 2017	May 2018	December 2018
Chlorpyrifos	March 2009	September 2010	August 2015	March 2016	May 2017	December 2017
Diazinon	June 2008	December 2009	August 2015	March 2016	May 2017	December 2017
Malathion	June 2009	August 2010	August 2015	March 2016	May 2017	December 2017
Methomyl	September 2010	November 2011	August 2016	March 2017	May 2018	December 2018

Exhibit 3

MEMORANDUM OF AGREEMENT

between

the Environmental Protection Agency, the Department of the Interior, and the Department of Commerce

on

Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review

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I. PURPOSE

This Memorandum of Agreement (MOA) establishes an interagency working group ("Working Group") comprised of representatives from the Environmental Protection Agency (EPA), the Department of the Interior (DOI), which includes the Fish and Wildlife Service (FWS), and the Department of Commerce (DOC), which includes the National Marine Fisheries Service (NMFS) (collectively, "the Signatory Agencies"). The Working Group will provide recommendations to EPA, FWS, and NMFS leadership on improving the Endangered Species Act (ESA)[1] consultation process for pesticide registration and registration review ("pesticide consultation process") and will ensure that the new process is recorded and formalized as appropriate.

II. BACKGROUND

Statutory Framework and Pending Reviews

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[2] governs pesticide registration, distribution, and use. EPA implements FIFRA, while consulting with the Department of Agriculture (USDA) on pesticide-related rulemakings. Most pesticides distributed or sold in the United States must obtain a registration from EPA prior to their use. FIFRA additionally requires that EPA review pesticide registrations every 15 years. As of July 1, 2017, EPA has been processing 725 registration review cases that cover approximately 1,140 pesticide active ingredients.

The ESA seeks to conserve threatened and endangered species and the ecosystems upon which they depend. Pursuant to ESA section 7(a)(2), federal agencies shall "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence" of any listed species or result in adverse modification of critical habitat.[3] Section 7(a)(2) further requires agencies to consult with FWS, NMFS, or both (collectively, "the Services") when contemplating an agency action subject to ESA. Courts have found specific

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[1] 16 U.S.C. § 1531 *et seq.*
[2] 7 U.S.C. § 136 *et seq.*
[3] 16 U.S.C. § 1536(a)(2).

registrations and registration reviews of pesticides under FIFRA to be agency actions subject to ESA's consultation requirements.

Status of Pesticide Consultations

America's 3.2 million farmers operate over 2 million farms and annually produce billions of pounds of food. Responsible pesticide use is an essential tool for managing America's estimated 915 million acres of farmland. At the same time, pesticides may impact non-target organisms, including fish and wildlife.

For decades, EPA and the Services have worked to determine how best to fulfill ESA's consultation requirements when registering and reregistering pesticides:

- Initially, EPA and FWS conducted ESA consultations on individual pesticides but ended this practice after it was deemed too lengthy and ineffective in protecting listed species.[4]
- In 1981, EPA in cooperation with FWS adopted a "cluster" approach pursuant to which all pesticides registered for the same use pattern were examined concurrently. At that time, EPA received biological opinions from the Services for four clusters and began drafting implementation plans for the biological opinions. However, the implementation plans proved to be unworkable because they were "far more complex and time-consuming than originally anticipated," and as a result, the cluster approach was abandoned in 1998.[5]
- In 1989, after collaboration among EPA, the Services, and USDA, and the conclusion of a notice-and-comment period, the agencies published a revised Endangered Species Protection Plan and returned to species-based assessments. Under this approach, EPA identified species most vulnerable to pesticides, the Services identified the counties where those species lived, and USDA provided information on crop growth and pesticide application.
- In 2001, a non-government organization successfully challenged EPA's failure to consult with NMFS on 54 pesticide active ingredients and their effect on 25 listed species of salmon and steelhead.[6] Partially in response to this challenge, in 2004, EPA and the Services issued counterpart regulations, which created a number of different procedures to conduct informal and formal ESA pesticide consultations.[7] The implementation of one such procedure for informal consultation, the alternative consultation procedure, was challenged and, in 2006, held to be arbitrary and capricious.[8]

In an effort to address issues between federal agencies related to identifying and implementing appropriate scientific and technical approaches, EPA, the Services, and USDA requested the

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[4] ENVIRONMENTAL PROTECTION AGENCY, REPORT TO CONGRESS ON THE ENDANGERED SPECIES PROTECTION PROGRAM AS IT RELATES TO PESTICIDE REGULATORY ACTIVITIES, at 6 (1991), *available here*.
[5] *Id.* at 8.
[6] Wash. Toxics Coal. v. EPA, 413 F.3d 1024 (9th Cir. 2005), *cert. denied*, 546 U.S. 1090 (2006).
[7] 50 C.F.R. § 402.40-48 (2016).
[8] Wash. Toxics Coal. v. United States Dep't of the Interior, 457 F. Supp. 2d 1158 (W.D. Wash. 2006).

National Research Council (NRC) "to examine scientific and technical issues related to determining risks posed to listed species by pesticides."[9] In 2013, the NRC released a report that identified categories of issues the agencies should seek to resolve and strategies to improve interagency coordination. As a result of the NRC report, EPA and the Services developed and are implementing a set of "interim agreements" and a "stakeholder engagement process."

The pesticide consultation process that has evolved since the NRC report remains highly challenging. For example, although EPA is required to complete registration review of more than 700 cases by 2022, it has taken EPA and the Services several years to address the three active ingredients in the first pesticides covered using the most recent approach. This experience has shown that the NRC report did not foresee the challenges associated with implementing its recommendations in view of the statutory requirements and associated regulations that the EPA and the Services must follow. In addition, the pesticide consultation process continues to be subject to litigation and various consent decrees.

III. ACTIONS

Creation of Interagency Working Group

This MOA establishes a Working Group to support EPA and the Services in meeting their obligations related to the pesticide consultation process. The Working Group shall consist of the Signatory Agencies to this memorandum. In addition, the Signatory Agencies request that USDA, the Council on Environmental Quality (CEQ), and the Office of Management and Budget (OMB) join the Working Group, and that CEQ serve as Chair of the Working Group. The Signatory Agencies may also request the participation of other federal agencies or offices in the Working Group as appropriate.

Action Plan

Federal agency coordination and support is necessary to meet ESA obligations with regard to pesticide consultations. The Working Group will (1) outline a legal and regulatory framework by analyzing the relevant statutes, regulations, and case law, (2) review past pesticide consultation practices to learn from those experiences, (3) develop scientific and policy approaches that will increase the accuracy and timeliness of the pesticide consultation process, and (4) memorialize the proposed approach through a memorandum of understanding, revised regulations, or another legal mechanism:

1. ***Analyze relevant statutes, regulations, and case law.*** The Working Group will review (1) the statutory requirements under ESA and FIFRA, (2) the case law that has developed on the intersection of ESA and FIFRA, and (3) existing regulations for the pesticide consultation process. For example, the Working Group will review 50 C.F.R. § 402.46-47 (the optional formal consultation procedure) and determine whether its application would improve the pesticide consultation process. The Working Group should also provide advice on how best to define the scope of the agency action subject to consultation, and on how to properly identify and classify direct and indirect effects of

[9] ASSESSING RISKS TO ENDANGERED AND THREATENED SPECIES FROM PESTICIDES, at 3 (2013) available here.

the agency action. The Working Group will identify statutory obligations and limitations, providing a legal and regulatory framework to guide the Working Group as it develops its scientific and policy recommendations for the pesticide consultation process.

2. ***Review past ESA pesticide consultation practices to learn lessons from recent experience.*** The Working Group will review current and previous pesticide consultation practices to identify problems and areas for improvement, as well as best practices that should be used in future pesticide consultations.

3. ***Prepare recommendations to improve scientific and policy approaches.*** The Working Group will provide recommendations on how to improve scientific and policy approaches to ESA pesticide consultations. For example, the Working Group will develop a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation. The Working Group will also help provide clarity as to what constitutes the "best scientific and commercial data available" in the fields of pesticide use and ecological risk assessment, which EPA and the Services are required to use under ESA section 7(a)(2).

4. ***Document the approach.*** To the extent that current authorities and practices do not allow for the timely and accurate review of pesticides consistent with governing authorities, the Working Group may memorialize its recommendations for a revised regulatory framework, including addressing agency responsibilities, recommended technical approaches, and recommendations for new regulations, a memorandum of understanding, or other appropriate documentation. Documenting the new approaches would promote lasting cooperation between the agencies.

IV. OTHER PROVISIONS

1. ***Period of Agreement.*** The term of this MOA will commence upon full execution by the Signatory Agencies, and shall remain in effect until such time as the MOA is terminated by any Signatory Agency or its successor.

2. ***Modification.*** This MOA, or subsequent annexes, may only be modified by mutual agreement of the Signatory Agencies or their successors. Such modifications shall be in writing and will take effect upon execution by the Signatory Agencies or their successors.

3. ***Rights and Benefits.*** Nothing in this MOA is intended to diminish or otherwise affect the authority of any agency to carry out its statutory, regulatory, or other official functions, nor does it create any right or benefit, substantive or procedural, enforceable at law by any party against the United States, its agencies or officers, State agencies or officers carrying out programs authorized under Federal law, or any other person.

4. ***Agreement Does Not Involve Funding.*** This MOA, in and of itself, does not result in the transfer of funds or other financial obligations between the Signatory Agencies. No provision of this MOA shall be interpreted to require obligation or payment of funds in

violation of the Anti-Deficiency Act, 31 U.S.C. § 1341. Funding arrangements, if any, shall be the subject of separate agreements that will be subject to the availability of funds.

5. ***Stakeholder Input.*** In carrying out Section III of the MOA, the Working Group is not prohibited from seeking or receiving stakeholder expertise, experience, input, information, or other items deemed appropriate, consistent with the requirements of the Federal Advisory Committee Act (FACA).

V. SIGNATORIES

Date: 1/31/2018

Ryan K. Zinke
Secretary
U.S. Department of the Interior

Date: JAN 31 2018

Wilbur Ross
Secretary
U.S. Department of Commerce

Date: 1/31/2018

Scott Pruitt
Administrator
U.S. Environmental Protection Agency

Exhibit 4

April 19, 2017

The Honorable Scott Pruitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

The Honorable Ryan Zinke
Secretary
U.S. Department of the Interior
1849 C Street, NW
Washington, DC 20240

The Honorable Wilbur Ross
Secretary
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Via E-mail

Re: OP Registrants' Request That Services Return Biological Evaluations to EPA

Dear Administrator Pruitt, Secretary Zinke and Secretary Ross:

CropLife America (CLA) writes in support of the requests from our members Dow AgroSciences, LLC, FMC Corporation, and Makhteshim Agan of North America, Inc. (d/b/a ADAMA) that the Environmental Protection Agency (EPA) withdraw from the National Marine Fisheries Services and U.S. Fish & Wildlife Services three organophosphate (OP) "biological evaluations" (BEs) that EPA sent to the Services on January 18, 2017. We understand that request was filed on April 13.

Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber, and fuel. CLA members support science based regulation of pesticides to ensure that these

Representing the Crop Protection Industry
1156 15th St. N.W., Suite 400 Washington, D.C. 20005 • 202.296.1585 phone 202.463.0474 fax
www.croplifeamerica.org

products can be used without causing unreasonable adverse effects to either human health or the environment, including threatened and endangered species.

The case for the withdrawal of the BEs, and for the related actions the registrants have requested, is compelling. As the registrants have explained, the analysis the BEs present does not represent "the best scientific and commercial data available" that the Endangered Species Act (ESA) requires.

Equally important from CLA's perspective, taking the requested actions will help to assure that EPA and the Services have adequate time to reconsider the "interim approaches" that preparation of the BEs have tested. It is time to call a halt to further efforts to implement those "interim approaches" and work together towards a sustainable approach to our common concerns.

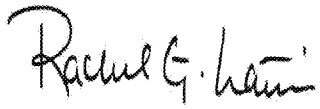
The "interim approaches" were developed by the prior Administration as a purported test of the recommendations of the 2013 report of the National Academy of Sciences ("NAS") *Assessing Risks to Endangered and Threatened Species from Pesticides*. But as applied to these BEs, the approaches ignored many of the NAS's recommendations and were flawed from the start.

The interim approaches have failed to provide a meaningful path towards a tiered risk assessment that will lead to an efficient, effective means to fulfill EPA's statutory obligations. Instead, they have created a process that does not screen and does not meaningfully assess risk, but instead threatens to remove from use valuable tools needed for production agriculture and public health, all while diverting resources away from more meaningful efforts towards species protection.

The initial release of the draft BEs confirmed these flaws, as many commenters (including CLA) told EPA. Yet, rather than responding to those comments and fundamentally revisiting the drafts (or the propriety of those approaches), two days before the prior Administration left office, EPA sent final versions of the BEs to the Services.

There likely are few better examples than this situation of the illogical and wasteful regulatory approaches that President Trump has committed to reform. The actions requested by the three OP registrants thus will not only allow these products to be evaluated under a far more appropriate regulatory approach, but demonstrate the seriousness of the Administration's commitments. CLA and its member companies continue to advocate for an ESA review process that works towards protecting species from potential adverse effects of agricultural operations.

Sincerely,



Rachel G. Lattimore
Senior Vice President,
General Counsel and Secretary

Representing the Crop Protection Industry
1156 15th St. N.W., Suite 400 Washington, D.C. 20005 • 202.296.1585 phone 202.463.0474 fax
www.croplifeamerica.org

cc:
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance
Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Richard P. Keigwin, Jr., Acting Director, Office of Pesticide Programs, Environmental Protection Agency

Exhibit 5

To: Jakob, Avivah[Jakob.Avivah@epa.gov]
From: Perry, Tracy
Sent: Wed 4/12/2017 4:22:56 PM
Subject: FW: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)
17P-0055 version dated 4.5.17 final for signature.docx

Avivah – here the final version of the carbaryl/methomyl BE FR – it was signed by Yu-Ting.

From: Nguyen, Khue
Sent: Thursday, April 06, 2017 11:06 AM
To: Travers, Mary-F <travers.mary-f@epa.gov>
Cc: Perry, Tracy <Perry.Tracy@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Subject: RE: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)

Hi Mary,

There were minor editorial edits to this FR from a couple of the managers. We are sending the revised encoded version—this is the version that was signed this morning by our DD.

The signed version will be sent over to RCS today, with the typesetting request form, docket verification, and action information form.

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Travers, Mary-F
Sent: Thursday, March 30, 2017 2:36 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Perry, Tracy <Perry.Tracy@epa.gov>; Walsh, Linsey <Walsh.Linsey@epa.gov>
Cc: Hofmann, Angela <Hofmann.Angela@epa.gov>; Lanier, Minnie <Lanier.Minnie@epa.gov>; Green, Teresa <Green.Teresa@epa.gov>; Pastor, Justo <Pastor.Justo@epa.gov>
Subject: FW: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)

Hi Khue,

Great job!!! If you need to make any other changes, follow the same procedure that we discussed earlier today, and everything looks just fine!

Mary F. Travers

Regulatory Coordination Staff (7101M)

Office of Chemical Safety and Pollution Prevention

United States Environmental Protection Agency

202 566-1588 (Office)

240 210-2318 (Cell)

202 566-2068 (Fax)

Travers.mary-f@epa.gov

From: Nguyen, Khue
Sent: Thursday, March 30, 2017 2:13 PM
To: Travers, Mary-F <travers.mary-f@epa.gov>
Cc: Grable, Melissa <Grable.Melissa@epa.gov>; Perry, Tracy <Perry.Tracy@epa.gov>; Walsh, Linsey <Walsh.Linsey@epa.gov>
Subject: FW: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)

Hi Mary,

Here is the revised word encoded version of FR 17P-0055. It has the shortened summary, but also additional changes as we discussed this morning, including a new table.

So in terms of next steps: we will complete the typesetting request form, the docket verification/certification form, the action information form, and route this version of the FR for signature.

Let me know if there are additional changes to the FR that is required before we print and route for signature over here. The other forms are not finished, so we will not route for signature until they are ready.

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Walsh, Linsey
Sent: Thursday, March 30, 2017 10:26 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: FW: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)

Linsey Walsh

Chemical Review Manager

OCSPP/OPP/PRD/RMIB3

U.S. Environmental Protection Agency

(703) 347-8030

From: Travers, Mary-F
Sent: Monday, March 20, 2017 5:11 PM
To: Walsh, Linsey <Walsh.Linsey@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>; Perry, Tracy <Perry.Tracy@epa.gov>; Schroeder, Carolyn <Schroeder.Carolyn@epa.gov>
Cc: Hofmann, Angela <Hofmann.Angela@epa.gov>; Lanier, Minnie <Lanier.Minnie@epa.gov>; Green, Teresa <Green.Teresa@epa.gov>
Subject: Typeset FR Document Ready for Signature Package (17P-0055; FRL-9960-24)

Hello All!

I have completed my review. Attached are the typeset FR documents for your signature package. Please follow the instructions in this Email to avoid delays and complications. PLEASE make sure when you fill out the typesetting request form, in the large empty block, in the left top corner, you insert, my initials (MT) and 17P -0055.

What am I providing you?

1) FR Document – The final signature ready copy in Word.

Important Note:

You must print a SINGLE-SIDED copy of the FR document to use as the original for inclusion in the signature package that will be given to the official who must sign the FR document. *** IF you can find out who will be signing the document, PLEASE, insert their name on the signature page******** The Office of the Federal Register (OFR) requires the original signature to be on a single-sided FR document. If the original signature is on a double-sided document, the OFR will NOT accept it and you will have to get your manager to sign a single-sided version. The other documents can be double sided.

Process for Correcting the FR Document:

I've attached the word version, in the event of needed changes. Email the corrected version directly to me BEFORE you get the document signed. That way paper and electronic version match. **Also, when you print your document for signature, please make sure it's in Times New Roman, 12 pt. and single sided. Make sure the signature page is on a separate page.**

2) **Concurrence Sheet** - Include this sheet in your signature package to document the reviewer's concurrences for your records. You do NOT need to return this to us – it is for YOUR records.

3) **Typesetting Request Form** – Follow the attached guidance document that was sent on June 16, 2015 that provides detailed instructions for staff and managers in OCSPP that must obtain the required publication funding commitment for an FR document. In addition to explaining how the form should be completed, this guidance document describes the typical process used to get the necessary funding commitment.

Remember that you MUST complete the TSRF and get your funding commitment BEFORE the FR document is signed. You MUST submit a completed and funded TSRF to the RCS when you

submit the signed FR Document to RCS for publication processing. (see attached pdfs)

4) **Docket Verification and Certification Form -** Use the electronically fillable and signature enabled pdf form that is available through FDMS. The completed form will be used to satisfy the "proof of docket" requirement because it shows that the docket manager has verified that the docket you cited has indeed been established for your action, and that you have or are in the process of submitting all of the relevant documentation that must be in the docket. You will need to provide completed form to us when you submit the signed FR Document for publication processing (see below).

5) **Action Information Sheet** – Required information from OP for all documents going to the OFR. Please fill out the information and return the form or else your document will not be processed for publication by OP.

AFTER signature, deliver the following to RCS in WJC East Rm 3139:

1) FR Document – The original signed & dated FR Document.

Remember: The original must be SINGLE-SIDED!

2) Typesetting Request Form – The original signed, funded & dated form.

Remember: Include documentation of the funding commitment.

3) Docket Verification and Certification Form – The signed & dated form.

4) Action Information Sheet – send back the paper copy!

If you have questions, let me know.

THANKS,

Mary F. Travers

Regulatory Coordination Staff (7101M)

Office of Chemical Safety and Pollution Prevention

United States Environmental Protection Agency

202 566-1588 (Office)

240 210-2318 (Cell)

202 566-2068 (Fax)

Travers.mary-f@epa.gov

Exhibit 6

- The EPA has continued to work closely with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS) (collectively referred to as the Services) to develop shared interim scientific methods for use in pesticide consultations, based on recommendations from the 2013 National Academy of Sciences' report "Assessing Risks to Endangered and Threatened Species from Pesticides".

- Given consultation deadlines and existing resources, the EPA will continue to address stakeholder recommendations in a phased and iterative approach.

- EPA released final Biological Evaluations (BEs) for three pilot chemicals including chlorpyrifos, diazinon, and malathion in January 2017.
    - Revisions to the final BEs based on stakeholder feedback include refined aquatic modeling, error corrections, improved transparency specifically related to the Terrestrial Effects Determination (TED) tool and the Weight of Evidence (WoE) matrices, and additions/deletions to the list of endangered and threatened species.
    - Posted documents include Response to Comments received during the 60-day public comment period for the draft BEs.
    - On April 13, 2017, Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc.; and FMC Corporation sent letters to the political leadership of EPA, FWS, and the NMFS making a number of requests. The letter requested that EPA withdraw the BEs for chlorpyrifos, diazinon, and malathion; that the Services stop work on their Biological Opinions (BiOps) for these pesticides; and that the Services modify various ESA-related settlement agreements to allow more time for the agencies to complete pesticide consultation. CropLife America voiced support for the request in a subsequent April 19, 2017, memorandum to EPA, FWS, and NMFS. EPA is considering the request.

- Draft BEs for carbaryl and methomyl are expected to be released soon for 60-day public comment.

- Based on previous public comments, the EPA is exploring the following additional revisions for future BEs:
    - reducing the size and complexity of the BEs;
    - a move toward more probabilistic approaches;
    - refinements in geospatial data used to define species ranges and potential use sites;
    - use of watershed-level aquatic exposure models;
    - improved methods for estimating exposures in riverine and estuarine/marine habitats;
    - improved characterization and consideration of magnitude of effects; and
    - a consideration in the timing and duration of potential pesticide exposures (e.g., linking exposure with life-history variables).

- EPA is also exploring ways to use species-specific toxicity data earlier in the first step of the BE process to refine, and still maintain a protective screening process.

- The EPA continues to work with the Services on interim methods for Step 3 (i.e., the Services' determination of "jeopardy/adverse modification" or "no jeopardy/no adverse modification") in the Biological Opinion (BiOp).

- The EPA expects to release the Services' draft BiOps for chlorpyrifos, diazinon, and malathion for a 60-day public comment period in late May or early June 2017 with final BiOps by December 2017. The EPA expects to release final BiOps for methomyl and carbaryl by December 2018.

Exhibit 7

USCA Case #15-1054 Document #1775923 Filed: 03/04/2019 Page 131 of 270

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Pesticide Reviews Advance But EPA Attainment Of Court Schedule Uncertain

October 02, 2017

Trump administration officials are reviewing staff-level draft biological opinions of the first pesticides to undergo a new process for assessing risks to endangered species but it is unclear whether they will complete their reviews and forward them to EPA in time to meet a year-end court deadline for issuing the final versions.

Gina Shultz, deputy assistant director of ecological services at the U.S. Fish and Wildlife Service (FWS), tells *Inside EPA* in a recent interview that the service has completed drafts of the first three biological opinions (BiOps) and is currently seeking Trump administration review before forwarding the documents to EPA.

"We are in the process of trying to brief our new policy leadership team" on the fist three draft BiOps completed under an Obama-era framework for assessing pesticide risks to listed species. "We want to make sure that everybody understands and is comfortable with what this is and the science behind" the new process and the initial reviews.

Federal officials face a court-ordered year-end deadline for reviewing the first three chemicals -- chlorpyrifos, malalthion and diazinon -- to undergo a new inter-agency process for assessing pesticides' risks under the Endangered Species Act (ESA).

But some environmentalists fear the Trump administration will fail to complete the reviews after Dow AgroSciences and other industry officials urged the Trump administration to scrap the process largely crafted during the Obama administration, though they warn that scrapping the process will result in additional work for the agencies, which face later deadlines for a host of additional substances.

Shultz said she did not know whether federal agencies would meet the year-end deadline for evaluating the first three pesticides. She said FWS next step is to send the draft final BiOps to EPA after Trump administration officials in the Interior Department and its Solicitor's Office complete their review.

Shultz also said she is not aware of any Trump administration response to the industry request to scrap the so-called interim approaches, and that FWS continues to improve the process both internally and through meetings with EPA, the U.S. Department of Agriculture and the National Marine Fisheries Service.

"We are continuing to improve and refine the process," she said, noting that federal officials have improved maps of species ranges to better focus on the species that are likely to be affected by pesticide use. "The four agencies do continue to meet periodically and share information and discuss lessons learned" and areas for improvement.

Shultz' assurance that federal officials are seeking to advance reviews of the first pesticides to undergo the new federal review process comes as some environmentalists are raising alarms that the Trump administration will heed Dow's request to scrap the process.

EPA recently sidestepped state pesticide regulators' request for an update on the reviews.

A source with the Center for Biological Diversity (CBD), which won legal deadlines for federal agencies to complete the ESA reviews, says EPA Administrator Scott Pruitt, along with Commerce Secretary Wilbur Ross and Interior Secretary Ryan Zinke, who lead federal wildlife agencies, appear willing to heed pesticide producers' call to scrap the Obama-era process.

But a second environmentalist, who has negotiated with industry in an effort to revise the new process, says that federal officials face a significant workload in completing the novel reviews. Although the source called it concerning that federal agencies have not released draft final BiOps for public comment, the source says work is advancing.

ESA Section 7 requires that EPA consult with FWS and/or the National Marine Fisheries Service, collectively known as the services, on pesticides' potential risks to listed species. After an EPA biological evaluation, the services craft a BiOp of the product's potential for jeopardizing listed species and lay out reasonable and prudent alternatives that EPA must implement to protect the species.

But EPA and the services have long failed to conduct the required consultations on pesticides' risks to listed species, resulting in numerous environmentalist lawsuits that have set legal deadlines for the agencies to consult on risks of certain commonly-used pesticides.

In November 2013, EPA and federal wildlife officials rolled out the "interim approaches" process based on National Academy of Sciences advice for complying with the ESA in Federal Insecticide, Fungicide and Rodenticide Act registrations.

Since then, EPA officials have acknowledged that the current process is overly conservative but said they are working to improve it and make it more efficient. Nevertheless, on Jan. 18, days before Trump's inauguration, the Obama EPA forwarded the first biological evaluations to the services, in support of final BiOps due out by December 2017.

During a Sept. 18-19 meeting of the State FIFRA Issues Research and Evaluation Group in Washington, DC, EPA officials sidestepped a request from state pesticide regulators for a status update on reviews of the first three pesticides to undergo the new federal process, saying the agency would provide a response in the future.

Uncertainty over the status of inter-agency consultation on the first three chemicals comes after Dow and two other registrants in an April 13 letters, urged top officials at EPA and federal wildlife agencies to scrap the Obama administration ESA pesticide assessment process, charging the interim approaches are "fundamentally flawed and should be set aside."

The companies urged the Trump administration to halt the first three reviews under the new process, and adopt a new approach, though former Obama-era EPA toxics chief Jim Jones has publicly doubted that the Trump administration will be able to adopt "sustainable" long-term changes to the framework.

The CBD source says that should the Trump administration heed the industry call to scrap the new process and miss the court-ordered deadline for the first three reviews it would only create more work for federal agencies.

"I don't understand what they think they're endgame is. They're just digging themselves into a deeper hole," the source says, noting that federal agencies face deadlines for completing similar future reviews of numerous pesticides, including methomyl, carbarly, and glyphosate.

"If they had just moved forward with consultation, they would have far more clarity" on what steps are needed to protect species from various pesticides and to complete the required for reviews, the source adds.

Should EPA miss the deadline for the first reviews, the source says, the Trump administration would have to show the court that agencies either lacked the resources or expertise to complete the consultations, a high hurdle given progress agencies made under the Obama administration in developing the process and conducting the reviews.

The second environmentalist, who has negotiated with industry in hopes of preserving the Obama-era process, says despite the tight window for seeking public input on the first draft BiOps and issuing the final versions by year-end, federal agencies are continuing the effort.

The source said federal officials face a significant workload, noting that EPA's first draft biological evaluations completed under the new process found the first pesticides are likely to adversely affect an overwhelming majority of listed species and critical habitat, requiring federal wildlife officials to weigh risks to numerous species.

"I think these BiOps are still going to move forward," the second environmentalist source said. "My understanding is it's a lot of work." -- *Dave Reynolds* (dreynolds@iwpnews.com)

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Exhibit 8

To: Dravis, Samantha[dravis.samantha@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Mclean, Kevin[Mclean.Kevin@epa.gov]; Minoli, Kevin[Minoli.Kevin@epa.gov]
Cc: Keigwin, Richard[Keigwin.Richard@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
From: Beck, Nancy
Sent: Fri 5/5/2017 11:55:12 AM
Subject: ESA issue bubbling up
ESA Issue Paper_industry letters_5-5-17v2.docx

Samantha and Kevin,

Under the Endangered Species Act (ESA), EPA develops Biological Evaluations (BEs) for pesticides which are then the backbone of Biological Opinions (BiOps) issued by the services (FWA, NMFS). There is a court ordered settlement deadline for the services to complete 3 BiOps by December 2017. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Further details are in the attached. Because we think the Services are likely to release the BiOps in the end of May, we will need to engage quickly.

Perhaps we can chat next week?

Thanks,

Nancy

****

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

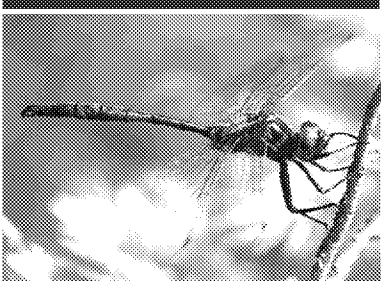
Ex. 6 - Personal Privacy

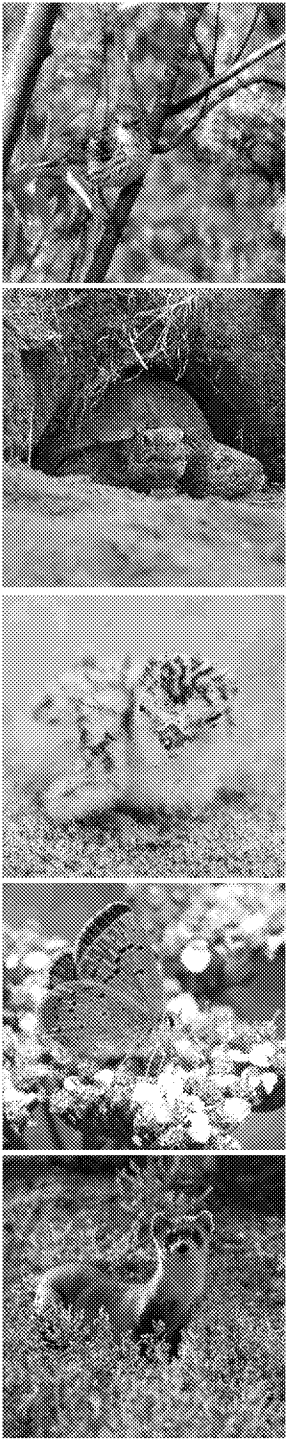
beck.nancy@epa.gov

Exhibit 9

National Pesticide Consultations: An Overview

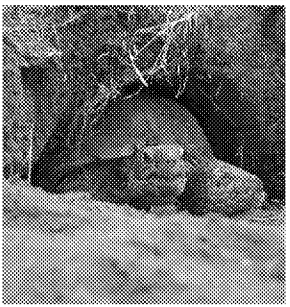
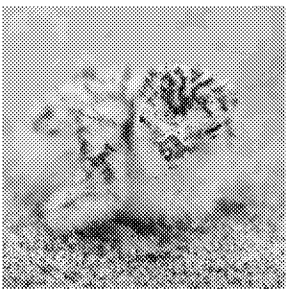
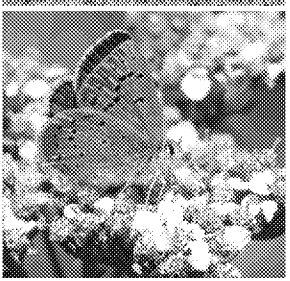
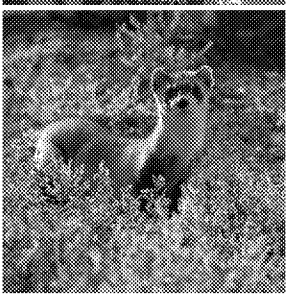
May 15, 2017





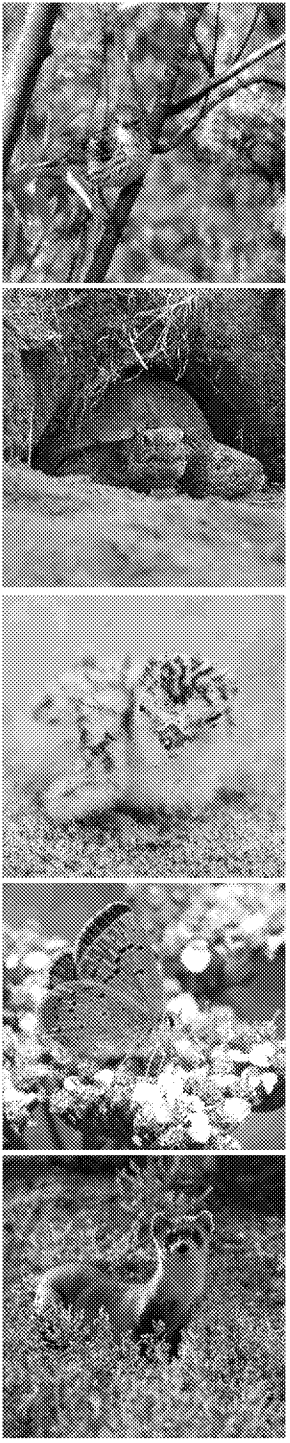
Pesticide Registration Review

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires registration of pesticide products
- FIFRA requires review of registered pesticides every 15 years
- Section 7 of the ESA requires all federal agencies ensure – in consultation with FWS – actions they authorize are not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat

History of FIFRA ESA Section 7 Consultations

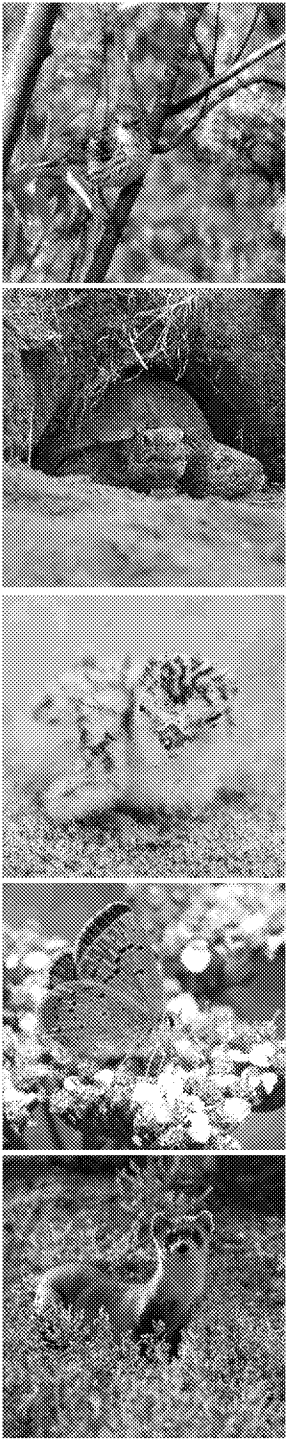
- 1970s: case-by-case consultations began
  (Endrin, Creosote, Compound 1080, Strychnine)
- 1980s: crop-based "cluster consultations"
  (Corn, Sorghum, Cotton, Forestry uses, Mosquitos)
- 1990s: consultation on 31 pesticides
  (Greatest risk to aquatic/terrestrial species)
- 1996 – 2013: agencies unable to agree on risk assessment approach



Pesticides Litigation - EPA

- 2002 – *CBD v. Johnson*: CBD filed suit against EPA for failure to consult on the effects of 66 pesticides on the California red-legged frog
  - Settlement in 2006 – EPA agreed to make effect determinations on 66 pesticides
  - Oct 2007 – Oct 2008 EPA requested initiation of formal consultation on effects of > 30 pesticides on red-legged frog
  - Jan 2009 – FWS informed EPA insufficient information to consult

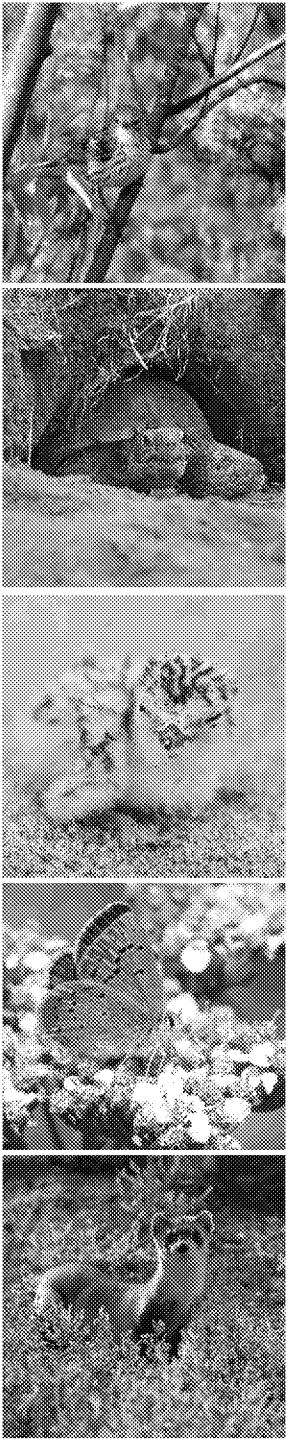
- 2007 – *CBD v. EPA*: CBD filed suit to compel EPA to initiate consultation on the effects of 75 pesticides on 11 listed species in San Francisco Bay area
  - Settlement in 2010 – EPA complete effect determinations on the 75 pesticides and initiate ESA consultation on those that may affect listed species
  - July 2013 EPA completed effects determinations for 69 of the 75
  - Settlement Amended 2015 – Effect determinations on 4 pesticides (atrazine, simazine, propazine and glyphosate) for all listed species



Pesticides Litigation - FWS

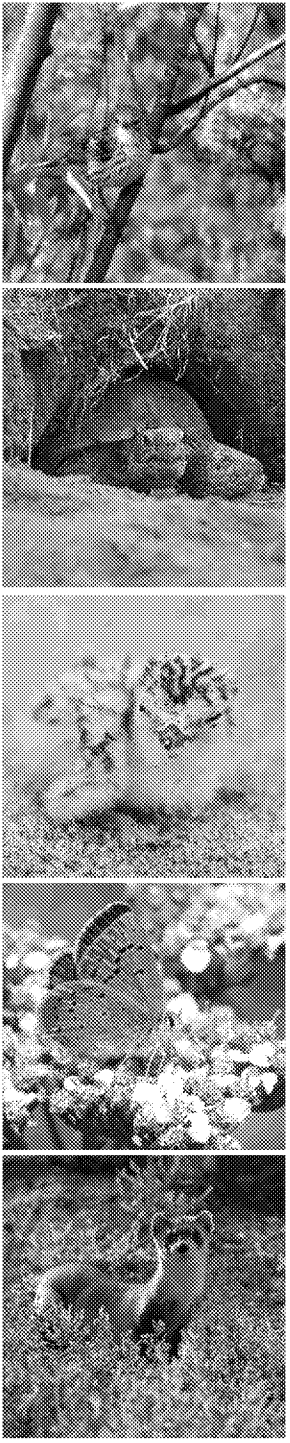
- 2011 – *CBD v. FWS*: CBD filed suit against FWS and EPA for failure to consult on the effects of 64 pesticides on red-legged frog
  - Settlement Nov 2013 - FWS and EPA agreed to complete consultation on effects of 7 pesticides on red-legged frog within 3 years
  - Settlement Amended July 2014 – Nationwide consultations on 5 pesticides (3 OPPs, 2 Carbamates)

- 2015 – *CBD v. FWS*: CBD filed a lawsuit against FWS for failure to complete consultation on effects of 2 pesticides on delta smelt and 1 pesticide on Alameda whipsnake
  - Settlement Feb 2016 – Nationwide consultations on 4 pesticides from EPA's 2015 settlement



Settlement Agreement Summary

- December 2017 – chlorpyrifos, diazinon and malithion
- December 2018 – carbaryl and methomyl
- December 2022 – atrazine, simazine, propazine and glyphosate

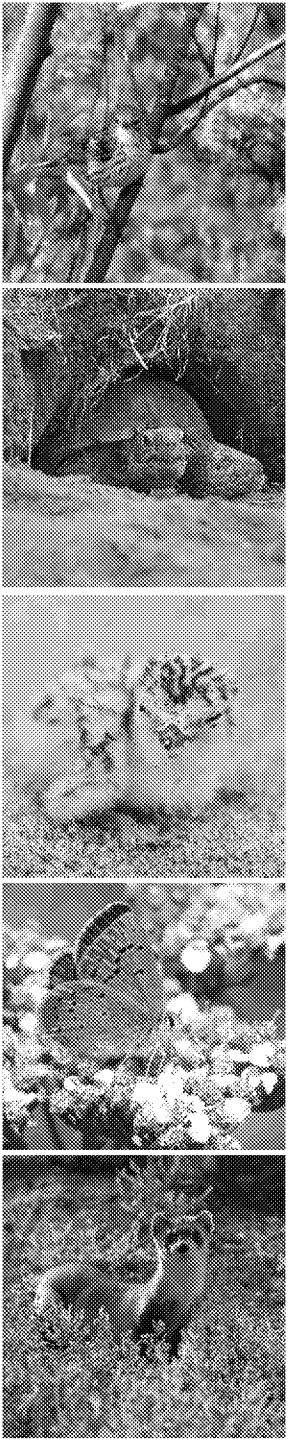


National Academy of Sciences

Assessing the Risks to Endangered and Threatened Species from Pesticides

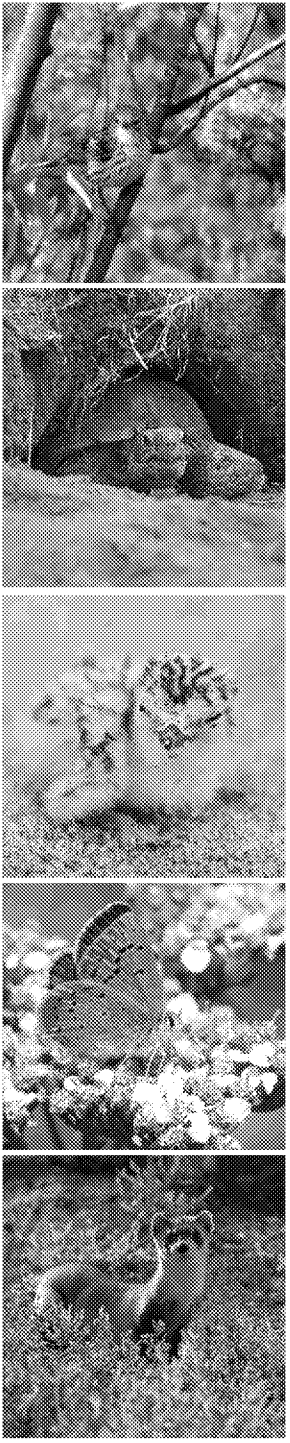
- EPA, FWS, NMFS, and USDA asked National Academy of Sciences to provide recommendations for a path forward

- NAS report recommendations:
  - Common approach
  - Best available data
  - Uncertainty
  - Exposure analysis
  - Effects analysis
  - Risk characterization



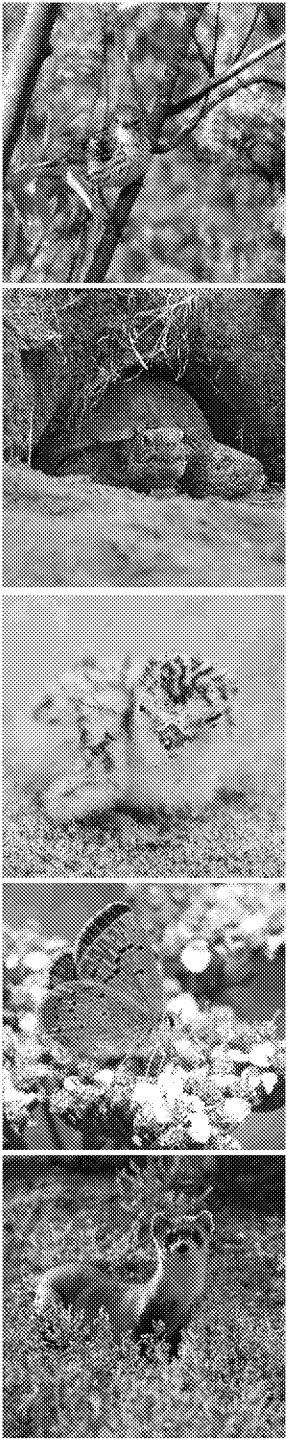
3-Step Process

- NAS suggested using a phased, iterative process that incorporates stakeholder engagement throughout
  - Phase 1: May affect/no affect
  - Phase 2: Likely to adversely affect/not likely to adversely affect (Biological Evaluations by EPA)
  - Phase 3: Jeopardy/no jeopardy (Biological Opinions by FWS and NMFS)
- All agencies agreed to pilot the 9 pesticides through December 2022
- All agencies recognize this process is currently not sustainable, working together to streamline



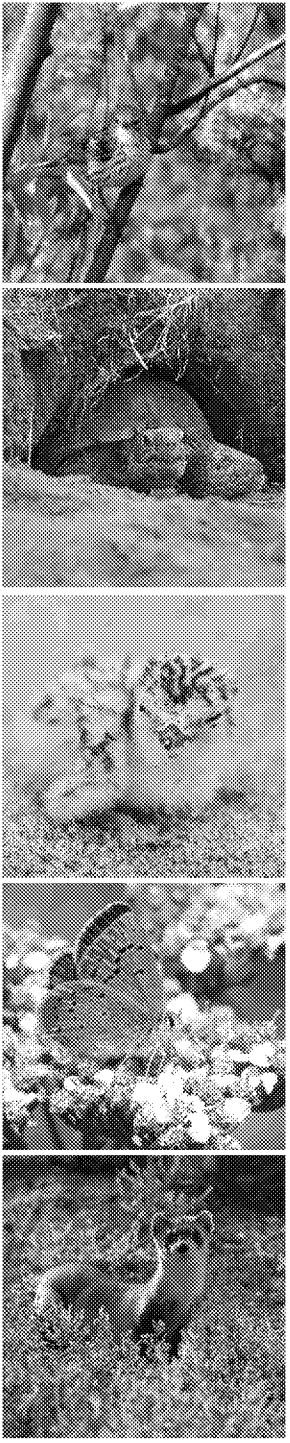
Biological Evaluations Steps 1 & 2

- EPA, in conjunction with FWS, NMFS, and USDA completes BEs:
  - Chlorpyrifos, diazinon, and malathion
    - Final BEs published January 2017
  - Carbaryl and methomyl
    - Final BEs due December 2017
  - Atrazine, simazine, propazine, and glyphosate
    - Final BEs due December 2020



Biological Opinions Step 3

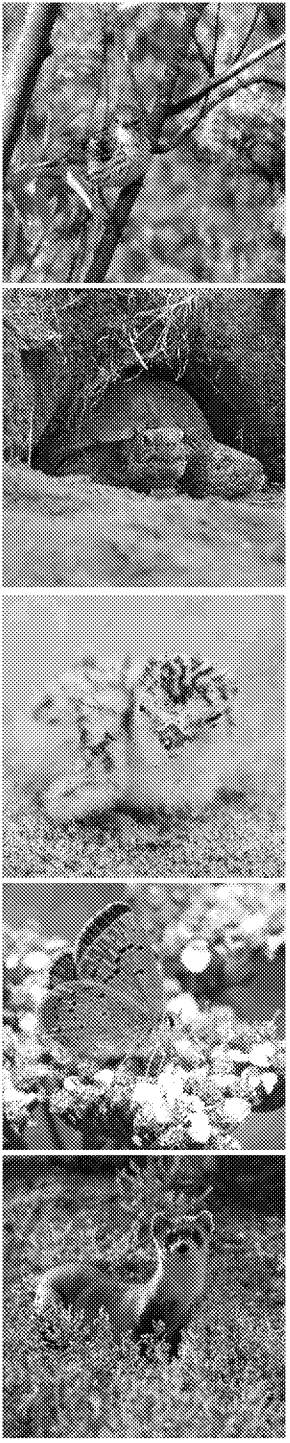
- FWS and NMFS in consultation with EPA and USDA complete BOs:
  - Chlorpyrifos, diazinon, and malathion (OPPs)
    - Final BOs due December 2017
  - Carbaryl and methomyl
    - Final BOs due December 2018
  - Atrazine, simazine, propazine, and glyphosate
    - Final BOs due December 2022



OPP Consultations

- Chlorpyrifos, diazinon, and malathion
  - Widely used insecticides
  - Highly toxic nerve agents
- Preliminary Draft BO May 2017

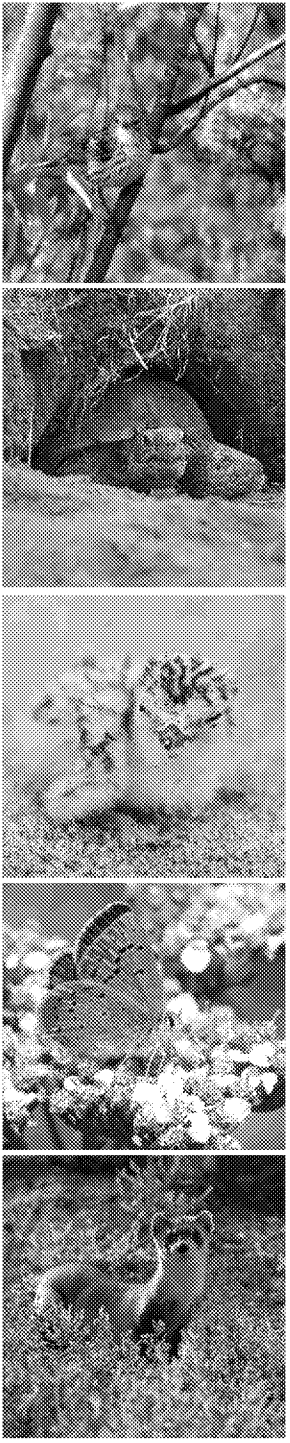
  b5-DP [redacted]
  - RPAs – buffers, equipment, no-spray zone/time.
  - Brief Leadership before release to EPA
- Draft BOs to EPA June 2017
  - 60-day comment period



Interaction with Congress

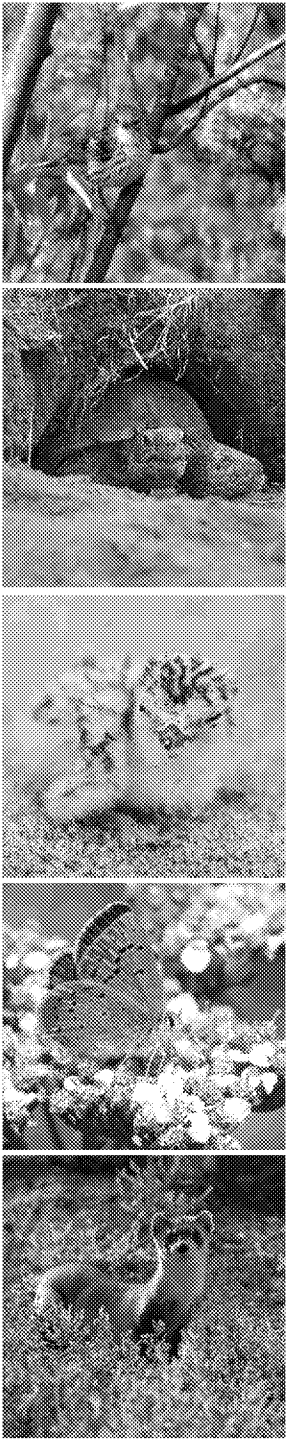
- Provided numerous briefings for Senate Agriculture Committee and Staff

- Reports to Congress on Endangered Species Act Implementation in Pesticide Evaluation Program
  - Update on implementation of NAS recommendations and stakeholder engagement
  - Written by EPA, FWS, NMFS, and USDA
  - Interim Report provided November 2014
  - Final Report pending clearance



Industry Letters

- Dow AgroSciences, Makhteshim Agan of North America, and FMC Corporation
  - Asking EPA to withdraw BEs and FWS/NMFS to return BEs to EPA
- Crop Life America
  - Support for Dow et al. letter
- FWS Recommendations
  - Complete OPP BOs unless EPA withdraws BEs
  - Continue nationwide consultations on the 9 pilot pesticides covered by settlement agreements
  - Continue to streamline consultation process



Next Steps

- Clear Final Report to Congress
- Resolve response to Industry letters
- Brief on preliminary draft OPP BOs
- Transmit draft BOs to EPA for release
- Work with registrants and pesticide users on RPAs and RPMs
- Implement lessons learned for next BEs/BOs

Exhibit 10

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Washington, D.C. 20240

OCT 15 2018

Ms. Marietta Echeverria
Director, Environmental Fate and Effects Division
Office of Pesticide Programs
Division Mail Code 7507P
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Dear Ms. Echeverria:

On March 29, 2018, the U.S. Fish and Wildlife Service (Service) received the U.S. Environmental Protection Agency's (EPA) "National and State Use and Usage Summary for Malathion" in response to the Service's request for additional information to complete formal consultation under section 7(a)(2) of the Endangered Species Act (ESA) involving EPA's re-registration of this pesticide. Since that time, we have worked with EPA, the U.S. Department of Agriculture (USDA), and the National Marine Fisheries Service (NMFS) to evaluate use and usage data for incorporation into the consultation. In addition, we have continued to work with the EPA, USDA, and NMFS to identify and obtain additional sources of data that could inform the consultation. We anticipate that these efforts will help improve the consultation and result in a biological opinion (BO) that more accurately reflects those effects that are reasonably certain to occur to ESA-listed species and critical habitat as a result of re-registering malathion.

As we have discussed, additional time is required to review the available use and usage data, assess whether it can be further refined at a more granular scale, and incorporate such data in our effects analysis. Therefore, we are requesting an extension of the consultation period in accordance with 50 C.F.R. 402.14(e) and ESA Section 7(b). The Service estimates that a draft biological will be released to EPA for its review and release for public comment by April 2020 and that the final biological opinion will be issued by March 2021.

To complete this process in the timeframe specified, we assume collaboration between the Federal Agencies will continue, with specific assistance from EPA in refining the action area, calculating the area of overlap for each species, familiarizing Service staff with the mechanics, structure, and function of the MagTool, and compiling public comments on the draft BO.

The Service will also continue to work with the malathion technical registrants that EPA has identified as the "applicants" for purposes of this consultation and as defined in the ESA's implementing regulations at 50 CFR 402.02. Pursuant to section 7(b) of the ESA, the Service and EPA may agree to this extension, provided that the consent of the applicants is obtained. Accordingly, we are also be seeking the applicants' consent to this extension.

We look forward to receiving your response to this request for an extension. If you have any questions or concerns about this request or the consultation process in general, please feel free to call me at 202-208-4646 or Deputy Assistant Director Gina Shultz at 703-358-1985.

Sincerely,

Gary Frazer
Assistant Director - Ecological Services

Exhibit 11

FULL COMMUNICATIONS STRATEGY

FOR HIGH-PROFILE OR CONTROVERSIAL ANNOUNCEMENTS

SECTION I: GENERAL INFORMATION

1. **Plan title** National Pesticide Draft Biological Opinions on Chlorpyrifos, Malathion and Diazanon

2. **DTS number** 066537

3. **What is the action triggering this communications plan?** *(Please explain in no more than three sentences. Additional background information may be included in the appendix)*

The Service will be transmitting to the Environmental Protection Agency (EPA) our draft biological opinions on the effects of three pesticides (chlorpyrifos, diazinon and malathion) on all Endangered Species Act (ESA) candidate, proposed and listed species, and all proposed and designated critical habitats in the U.S. and its territories. By transmitting these biological opinions to the EPA, we are meeting our obligations under section 7 of the ESA for the re-registration of the three pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act.

4. **What is the proposed date for this action? Why has it been selected? Is it flexible?**

The Service is under a court-ordered settlement agreement to finalize its consultations on these three pesticides by December 31, 2017. This deadline was jointly agreed upon by the Center for Biological Diversity (CBD), EPA and the Service. We are seeking to transmit the draft biological opinions to the EPA by mid- to late October 2017. The EPA will release the draft biological opinions for a 60-day comment period before they are finalized.

5. **Which office is leading this communications effort and which other programs, regions or groups are involved?**

External Affairs in Headquarters office will lead this communications effort, in close collaboration with Ecological Services. We will coordinate with EPA on timing and messaging, and share outreach with all FWS regions, given that species and critical habitats in every region are involved.

NOAA-NMFS is submitting separate BiOps to EPA on the same pesticides. As such, we will coordinate with their EA office on this action.

SECTION II: GOALS

6. **What is our ultimate goal here beyond simply informing people of this action?** *(How do we want audiences to regard the Service as a result of this action?)*

We want target audiences to regard the Service as not only having fully met its ESA consultation requirements through this action, but that our draft findings are entirely based on science. We want target audiences to fully understand this action and what jeopardy and adverse modification findings mean and that adverse effects to every listed species and critical habitat can be minimized.

Finally, we want target audiences to understand that we are committed to working with industry and stakeholders to protect America's imperiled wildlife while helping industry and landowners avoid jeopardizing listed species and destroying or adverse modifying critical habitats. Importantly, every jeopardy and adverse modification finding can be avoided through Reasonable and Prudent Alternatives between now and the final biological opinions.

7. **What story do we want to tell?** *(What should audiences understand, appreciate or connect with emotionally?)*

The Service remains committed to working with diverse partners to conserve America's imperiled wildlife based on science. [redacted]

SECTION III: ASSESSING STAKEHOLDER INTEREST AND POSITION

8. **External audiences** *(Please name up to five target audiences to inform the messages, tactics and stakeholder contact lists below. Be as specific as possible. Only list media if there are issue-specific outlets that merit targeting. General "media" and "the public" should not be used)*

Partner agencies, including EPA, NMFS, USDA

Agricultural groups and pesticide users

Pesticide registrants

Members of Congress

Conservation groups and petitioners, including CBD and Xerces Society

9. **Internal audiences** *(Please note any audiences within the Fish and Wildlife Service or Department of the Interior)*

Regional External Affairs offices, HQ Ecological Services

10. **Which groups or individuals may publicly oppose this action? What are their primary concerns?** *(This may include any or all of those described in Target Audiences and/or additional ones. Write "none" if no opposition is expected)*

Pesticide manufacturers, registrants, agriculture groups, farmers/ranchers – may oppose the findings as overly conservative and burdensome restrictions that will prevent them from using pesticides and hurt their bottom lines. May also take issue with science and methodology of the biological opinions.

USDA – may oppose our biological opinions on grounds that they do not represent best available or robust science. (USDA has already make these arguments internally and has avoided engaging the Service throughout much of consultation process.)

EPA – may argue that our biological opinions are not based upon the best available science.

Members of congress, especially in agriculture districts – they will likely hear from industry and agricultural constituencies that restrictions are unfair, overly burdensome and harmful to agricultural production.

11. What stakeholder groups or third-party validators might be leveraged for a statement, quote or other supportive action?

The Service should contact Defender of Wildlife, to see if they have recommendations regarding which pesticide registrants and other stakeholders would be most appropriate to give a statement.

SECTION IV: KEY MESSAGES

12. What are our topline, big picture messages? *(These should be top concepts that readers should take away, including an understanding of why this action matters and why they should care, not a list of facts, which should be placed in the appendix. List no more than three!)*

The Service has completed three draft biological opinions, analyzing the effects, of three pesticides (chlorpyrifos, diazinon and malathion) on all ESA-listed, and proposed, and candidate species (1,653 species) and designated and proposed critical habitats. (These are the first such national consultations on pesticides for all ESA-listed species and critical habitats of their kind.)

[redacted]

Importantly, jeopardy and destruction or adverse modification can be avoided through reasonable modifications to how and where the three pesticides are used. We will work with registrants, industry, pesticide users, and others in the coming months to develop measures that allow for the responsible use of these chemicals in a manner that avoids jeopardy and destruction or adverse modification of species and critical habitats.

See appendix for definitions of all terms and concepts.

13. What secondary messages are there? *(Again, these are messages, not facts. Divide these by audience if appropriate)*

The findings are based on usage of each pesticide as defined by its label. For pesticides registered for use in the U.S. with EPA, the label is the law.

With the transmittal of the draft biological opinions to the EPA, we anticipate that EPA will request public comment on the draft biological opinions for 60 days. During this time, we will work with pesticide registrants, agricultural groups, Federal agencies and conservation groups to refine our effects analyses and identify measures to minimize impacts and avoid jeopardy and destruction or adverse modification determinations.

Examples of measures for avoiding jeopardy and minimizing impacts include restricting pesticide usage in localized areas; clarifying and revising label-language to eliminate areas where pesticides are not anticipated to be used (such as areas of high elevation and deserts); establishing or increasing buffers to reduce spray drift into areas where listed species may occur; improving pesticide application equipment.

See appendix for additional messaging, background and table of all jeopardy and adverse modification findings each pesticide.

SECTION V: IMPLEMENTATION

14. What is the overarching plan for reaching specified audiences with our key messages?
(Explain the strategic approach and list key tactics)

The outreach strategies for this action are still under consideration. We will closely coordinate with EPA and NOAA-NMFS on both messaging and strategies, which will likely include one of the following:

1. **Joint proactive**: Issue a joint news release with EPA (and possibly NMFS) when EPA posts the biological opinions and opens the comment period.
2. **Service-only:** Issue a solo Service news release. If EPA decides to issue a news release as well, coordinate on timing and messaging.
3. **Hybrid:** Provide a notification on our website but do not put out a news release. Prepare and use if-asked only talking points for incoming inquiries.
4. **Reactive only:** No web posting, prepare and use if-asked only talking points.

Media and stakeholder webinar? Could go a long way to clarifying for all involved exactly what the draft biops, jeopardy findings and discussion over RPAs/RMAs are and are not, helping ensure informed public discourse.

Commented [AC1]: Gina, I left this one for u.

15. **How will internal audiences be informed and engaged?** *(Be specific! External communications plans will not be approved unless internal communications are adequately addressed)*

TBD

16. **Which communications tools are needed to support these strategies and tactics?** *(Be as specific as possible about the products identified and who will produce them)*

Tool	Responsible	Due Date
TBD		

17. **Implementation timeline** *(If not known, put TBD or the number of days/hours before/after the announcement)*

Date and Time	Tactic	Responsible
All times are in the time zone		
Afternoon before transmittal	Notify members of congress and other VIP stakeholders, including EPA, NMFS and USDA	EA-Haussman, EA-Partners,
Mid to late October 2017?	Transmit biological opinions consultation to EPA.	HQ ES
Mid-November?	ANY OUTREACH SHOULD TIE TO EPA POSTING OF DOCKET **NOT** FWS TRANSMITAL OF BIOPS	HQ ES/HQ EA

Day of transmittal	News release or bulletin to media and stakeholders?	HQ EA-Hires
Day of Transmittal	Congressional notification to key committee staff	HQ-CLA Hausman
Days following transmittal	Offer Congressional briefing for key committee staff (in conjunction with EPA, USDA, and NMFS)	HQ-CLA Hausman

Commented [AC2]: Is this actually the date EPA posts to docket?

18. VIP Call List *(Who needs to be called in person by a senior staff member and who will that senior staff member be? Note: not all plans will require such in-person calls)*

EPA - Marietta Echeverria USDA – Sheryl Kunickis NOAA-NMFS - Cathy Tortorici

19. Stakeholder contacts *(For each, paste in a table that provides organization name, contact person, contact information as appropriate, and the name of the person responsible for making contact)*

Internal

External Pro

External Neutral

Organization:	**Name:**	**Email:**	**Contacted by:**
American Bird Conservancy	Steve Holmer Cynthia Palmer	sholmer@abcbirds.org cpalmer@abcbirds.org	DPIA
Association of Fish & Wildlife Agencies	Jen Mock-Schaeffer	jenmock@fishwildlife.org	DPIA
American Fisheries	Tom Bigford	tbigford@fisheries.org	DPIA

Society			
American Rivers	Chris Williams	cwilliams@americanrivers.org	DPIA
Bat Cons. Int'l	Mike Daulton	mdaulton@batcon.org	DPIA
Center for Biological Diversity	Brett Hartl	bhartl@biologicaldiversity.org	DPIA
Defenders of Wildlife	Bob Dreher Ya-Wei Li	rdreher@defenders.org yli@defenders.org	DPIA
Endangered Species Coalition	Leda Huta	lhuta@stopextinction.org	DPIA
Friends of the Earth	Erich Pica	epica@foe.org	DPIA
National Wildlife Refuge Association/CARE	David Houghton Desiree Sorenson-Groves	dhoughton@refugeassociation.org dgroves@refugeassociation.org	DPIA
National Wildlife Federation	Naomi Edelson Jim Lyon	edelson@nwf.org lyon@nwf.org	DPIA
Natural Resources Defense Council	Andrew Wetzler	awetzler@nrdc.org	DPIA
The Wildlife Society	Keith Norris	Keith.norris@wildlife.org	DPIA
WildEarth Guardians	John Horning	jhorning@wildearthguardians.org	DPIA
Xerces Society	Matthew Shepherd	Matthew.shepherd@xerces.org	DPIA

External Anti

20. Congressional contacts

CLA will contact authorizing committee staff. Division of budget will contact appropriations committee staff

Senate Appropriations Interior S/C – Majority	Chris_Tomassi@appro.senate.gov	(202) 224-7233
Senate Appropriations Interior S/C – Minority	ryan_hunt@appro.senate.gov	(202) 228-0774
Senate EPW – Majority	Matt_Leggett@epw.senate.gov Andrew_Harding@epw.senate.gov James_Willson@epw.senate.gov	(202) 224-6176
Senate EPW – Minority	Gabrielle_Batkin@epw.senate.gov Christophe_Tulou@epw.senate.gov Elizabeth_Mabry@epw.senate.gov	(202) 224-8832
Senate EPW W&W S/C – Majority	Joe_Brown@boozman.senate.gov	(202) 224-4843
Senate EPW W&W S/C – Minority	Radha_Adhar@duckworth.senate.gov	(202) 224-2854
Senate ENR – Majority	chuck_kleeschulte@energy.senate.gov lucy_murfitt@energy.senate.gov Colin_hayes@energy.senate.gov	(202) 224-4971
Senate ENR – Minority	david_brooks@energy.senate.gov	(202) 224-4971
House Appropriations Interior S/C – Majority	darren.benjamin@mail.house.gov	(202) 225-3081
House Appropriations Interior S/C – Minority	rita.culp@mail.house.gov Jocelyn_hunn@mail.house.gov	(202) 225-3481
House Natural Resources – Majority	erica.rhoad@mail.house.gov william.ball@mail.house.gov todd.ungerecht@mail.house.gov parish.braden@mail.house.gov Christopher.Santini@mail.house.gov Brandon.Miller@mail.house.gov Melissa.Beaumont@mail.house.gov SYi@mail.house.gov	(202) 225-2761
House Natural Resources – Minority	Matt.Strickler@mail.house.gov brandon.bragato@mail.house.gov sarah.lim@mail.house.gov daniel.torrez@mail.house.gov	(202) 225-6065
Senate Agriculture Committee – Majority	Andrew_Vlasaty@ag.senate.gov; DaNita_Murray@ag.senate.gov; James_Glueck@ag.senate.gov	
Senate Agriculture Committee – Minority	Sean_Babington@ag.senate.gov mary_olive@ag.senate.gov	

House Agriculture Committee – Majority	Stacy.Revels@mail.house.gov; patricia.straughn@mail.house.gov	
House Agriculture Committee – Minority	Anne.Simmons@mail.house.gov; keith.jones@mail.house.gov	

SECTION VI: SOCIAL MEDIA PLAN

21. How will social media be used to help in messaging to target audiences and achieve communications goals?

N/A

SECTION VII: PRIMARY POINTS OF CONTACT

22. Media coordinators *(For national-level plans, list at least one person from HQ Public Affairs and others from region/program if appropriate. For regional-level plans, only regional coordinators are required. Enter name, email and phone)*

Public Affairs, FWS HQ, Brian Hires, brian_hires@fws.gov, 703-358-2191

23. Congressional coordinators (*For national-level plans, list at least one person from HQ Public Affairs and others from region/program if appropriate. For regional-level plans, only regional coordinators are required. Enter name, email and phone)*

Alyssa Hausman, HQ CLA, Alyssa_Hausman@fws.gov, 703-358-2275

24. Social media coordinators *(Enter name, email and phone)*

N/A

25. Program communications POCs *(Enter name, email and phone)*

Gina Shultz, gina_shultz@fws.gov, 703-358-1985

26. Subject matter experts available for interview *(Must be approved by HQ Public Affairs for an HQ-led announcement or by Regional Public Affairs for region-led announcement. Enter name, email and phone)*

Gina Shultz, gina_shultz@fws.gov, 703-358-1985

27. Additional technical experts for reference *(Enter name, email and phone)*

Gina Shultz, gina_shultz@fws.gov, 703-358-1985

28. Are there any non-FWS points of contact for this action? *(Enter name, organization, role, email and phone)*

SECTION VIII: DOCUMENT INFO

29. Created by **Date created**

Brian Hires	8/31/2017

30. Edited by **Date edited**

Gavin Shire	9/8/17
Alyssa Hausman	9/14/17
D.L. Hobbs	09/20/2017
Craig Aubrey	10/10/2017

APPENDIX: ADDITIONAL BACKROUND INFORMATION AND MATERIALS

DO NOT PUT OTHER MATERIALS SUCH AS FAQs, NEWS RELEASE OR TALKING POINTS IN THIS SECTION. KEEP THOSE AS SEPARATE DOCUMENTS.

(Consider the following: What is the historical context? Does this relate to other issues that may not immediately be apparent (consider other programs and regions)? Is there a scientific basis to this issue? If so what is it?)

The Service will work with registrants to identify labeling and use modifications such as:

- Modify pesticide use for more localized applications
- Clarify pesticide use areas by eliminating places not sprayed, such as high elevation, desert ecosystems, etc.
- Increase buffers to reduce spray drift
- Equipment improvements
- No spray zones for highly endangered and endemic species
- Clarify adulticide (pesticide uses targeting adult mosquitos) and wide area use areas
- create partnerships for maintaining or increasing natural areas near agriculture
- Work with Industry to set up some field monitoring and collection of usage data

Primary Use and Effects of Three Insecticides Studied

Chlorpyrifos

- USES – Agricultural crops, orchards and vineyards, pasture, managed forests, and non-agricultural uses including right of ways and developed areas (e.g. public parks, golf courses). Also used, with no geographic and few temporal restrictions for, adult mosquito control and wide area use as ant bait and foliar spray. Other uses: cattle ear tags, seed treatment, granular formation, bait
- EFFECTS –
  - High overlap between chlorpyrifos use sites and species' ranges.
  - Can result in mortality, sublethal effects and/or indirect adverse effects to listed, proposed and candidate species.
  - Can remain in the environment for weeks to months after application, resulting in continuing effects after application

Malathion

- USES - Various agricultural and non-agricultural uses including crops, orchards and vineyards, pasture, and developed areas (e.g. residential, public parks). Can be purchased by the public for home use. Used for adult mosquito control with no geographic restrictions.
- EFFECTS –
  - High overlap between malathion use sites and species' ranges. Can result in mortality, sublethal effects and/or indirect adverse effects to listed, proposed and

candidate species.

- For all taxa, exposure to malathion could result in indirect effects to prey resources, particularly for species that consume invertebrates.
- Similarly, listed plants would experience indirect effects from loss of pollinators.
- For mosquito adulticide, high mortality to invertebrates over 100% of range based on lack of label restrictions. For other taxa, direct effects were more limited, but indirect effects for insectivorous species expected.
- Can remain in the environment up to a month after application, resulting in continuing effects to species post application.

Diazinon

USES - Due to risk to human health and the environment, use of diazinon was severely restricted in 2004. Remaining uses are limited to select crops, orchards, vineyards and nurseries. Can also be used in cattle ear tags.

EFFECTS -

- Compared to the other two pesticides, less overlap between diazinon use sites and species' ranges
- High toxicity for all taxa. In general, regardless of use site, exposure from diazinon to listed animal species often resulted in mortality and indirect effects to food sources.
- Similarly, listed plants would experience indirect effects from loss of pollinators.
- Due to high toxicity, effects predicted from spray drift onto adjacent use sites for many terrestrial species.
- Can remain in the environment for weeks to months after application, resulting in potential effects to species post application

Effects of Three Pesticides on Plants

- Most significant impact on plants is the indirect loss of pollinators. (The vast majority of listed plants are pollinated by insects.)
- Substantial overlap for chlorpyrifos and malathion uses, especially 100% overlap for adulticide and wide area use
- [redacted]

Summary of Draft Biological Opinion Conclusions for Three Pesticides

	Species			Critical Habitat		
	Jeopardy	No Jeopardy	NLAA*	Ad Mod	No Ad Mod	NLAA*
Chlorpyrifos	[redacted]					
Malathion						
Diazinon						

* *Not Likely to Adversely Affect*

DEFINITION OF TERMS AND CONCEPTS

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.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

Reasonable and prudent alternatives - recommended 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 are economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or the destruction or adverse modification of designated critical

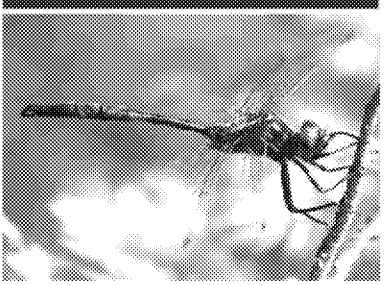
habitat. [50 CFR §402.02]

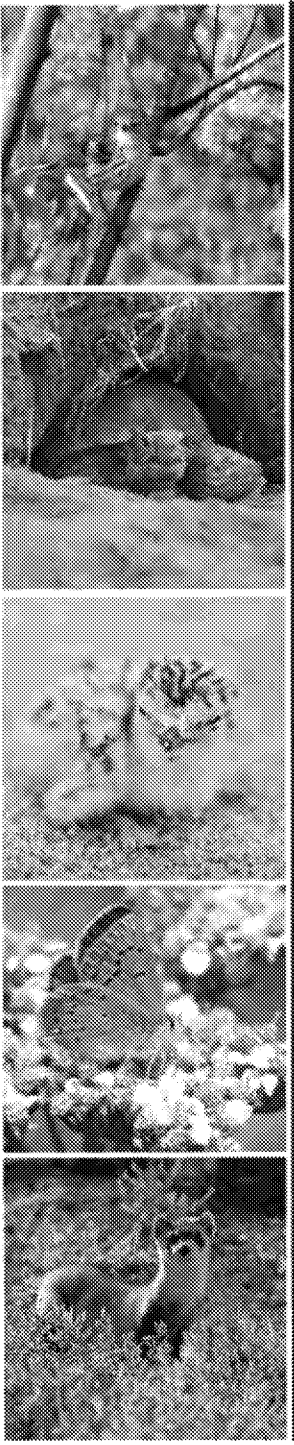
Reasonable and prudent measures - actions the Director believes necessary or appropriate to minimize the impacts, i.e., amount or extent, of incidental take. [50 CFR §402.02]

Exhibit 12

Overview of the National Pesticide Biological Opinions on Chlorpyrifos, Malathion and Diazinon

October, 2017

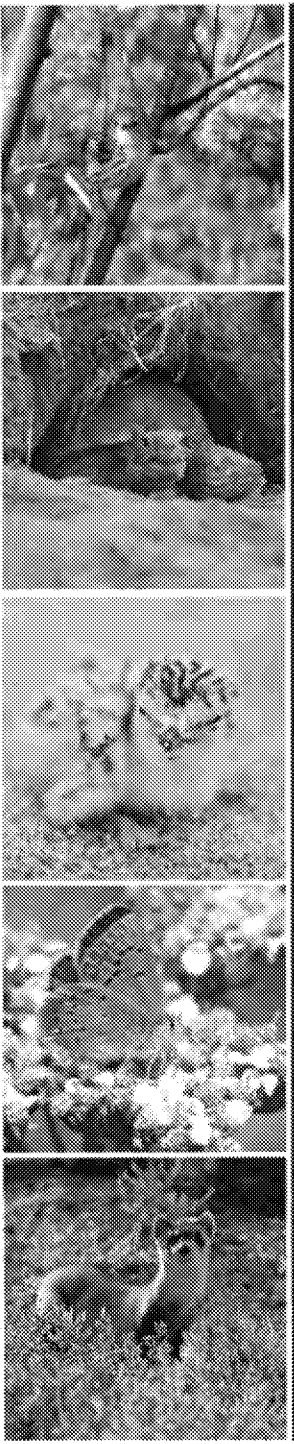


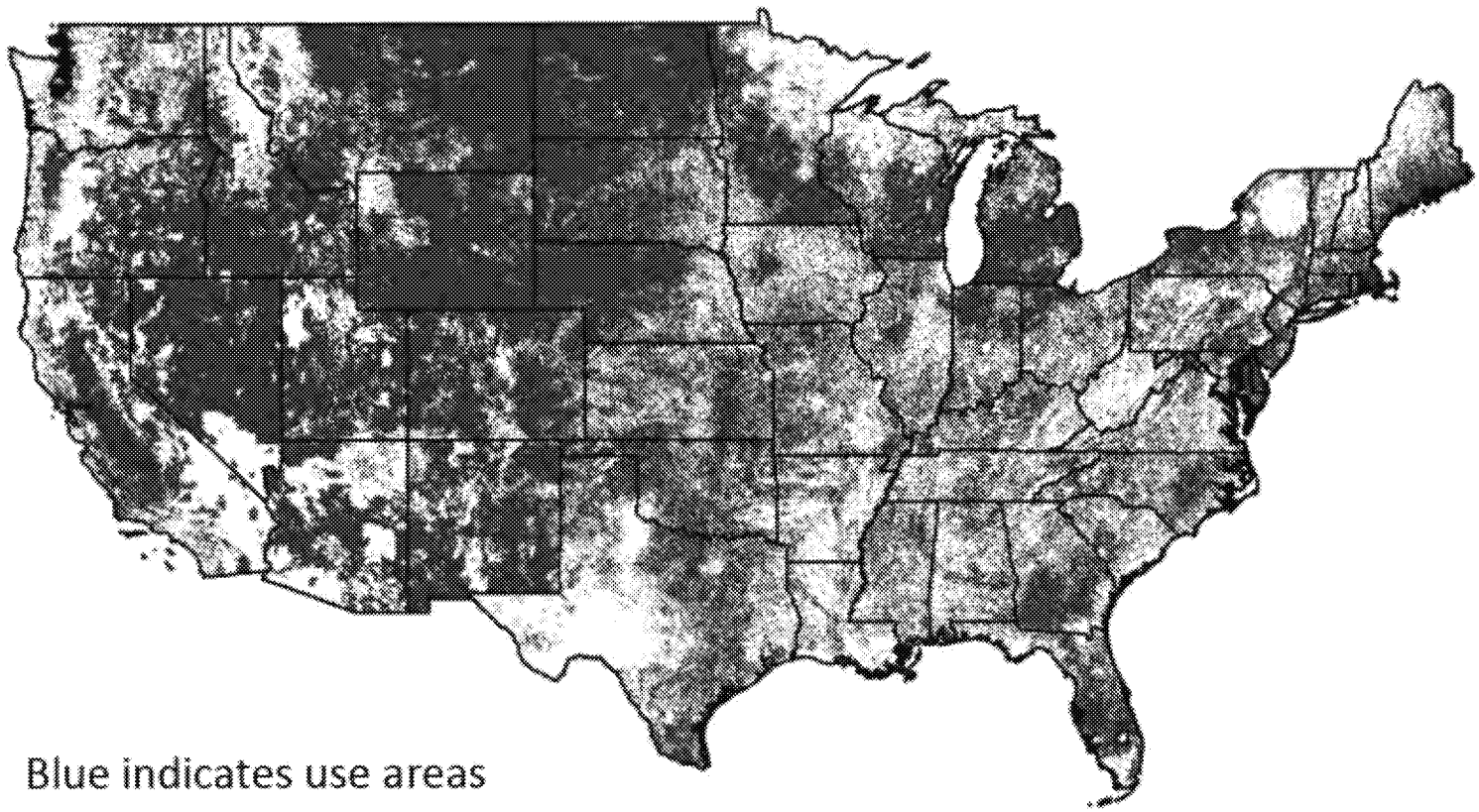


Chlorpyrifos, Diazinon and Malathion

- Broad spectrum insecticides (i.e., kill all insects)
- Organophosphates, work by inhibiting the enzyme acetylcholinesterase (AChE)
- All animals have this enzyme, so effects are not limited to target species
- Highly toxic across taxa
- Few limits on labels for when and where these pesticides can be used so exposure can be widespread (some restrictions for use near residential areas for human health concerns)
- These pesticides have been found far from sites of application, indicating transport via air

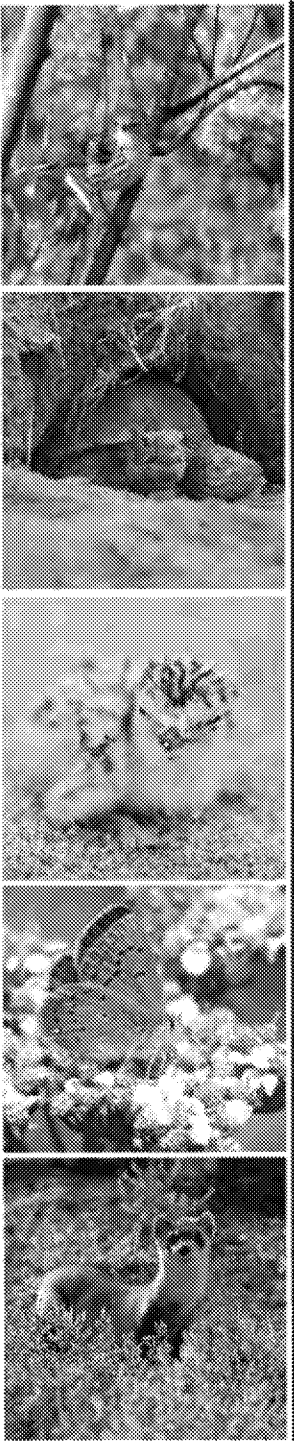
Diazinon Action Area - Labeled Uses





Action area for diazinon (this figure does not include the parts of the action area associated with Alaska, Hawaii, or the U.S. territories).

Biological Opinions – Our Approach



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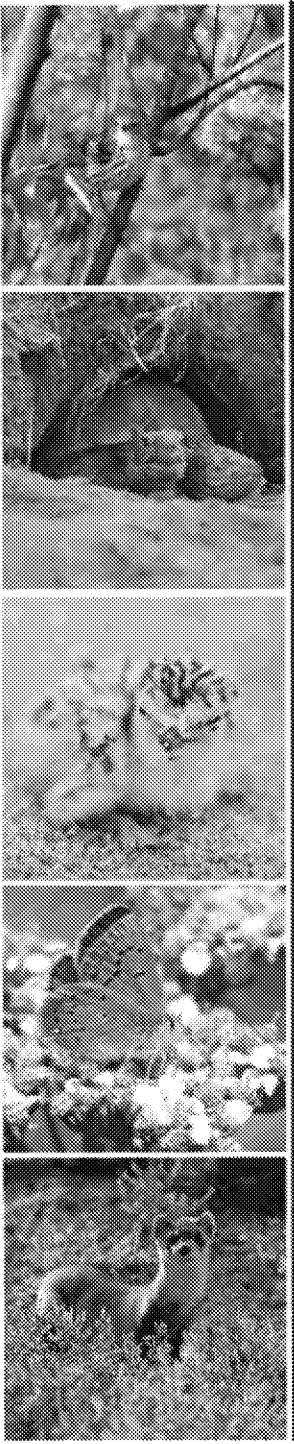

Tools used for the Effects Analysis

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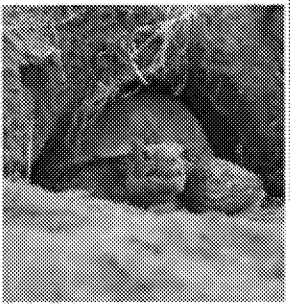
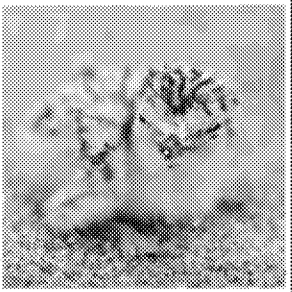
Island and Alaskan Species

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[redacted]

Critical Habitat Assessments

Steps for our assessment of the action to CH:

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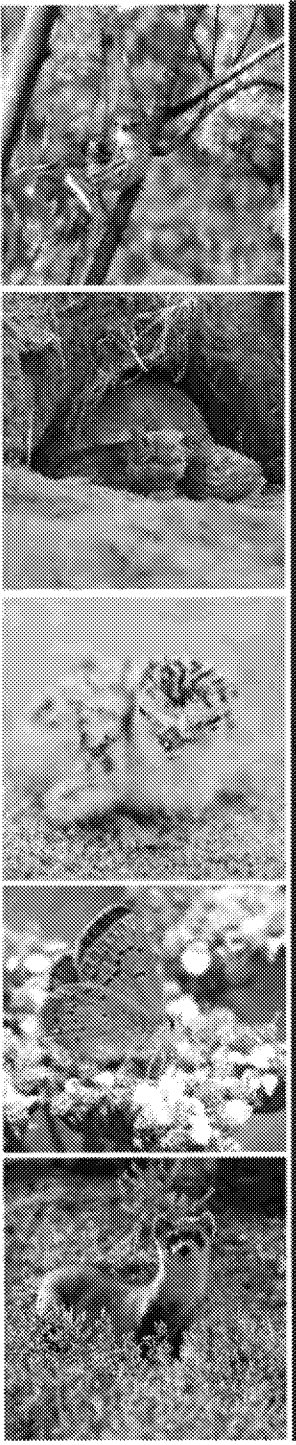
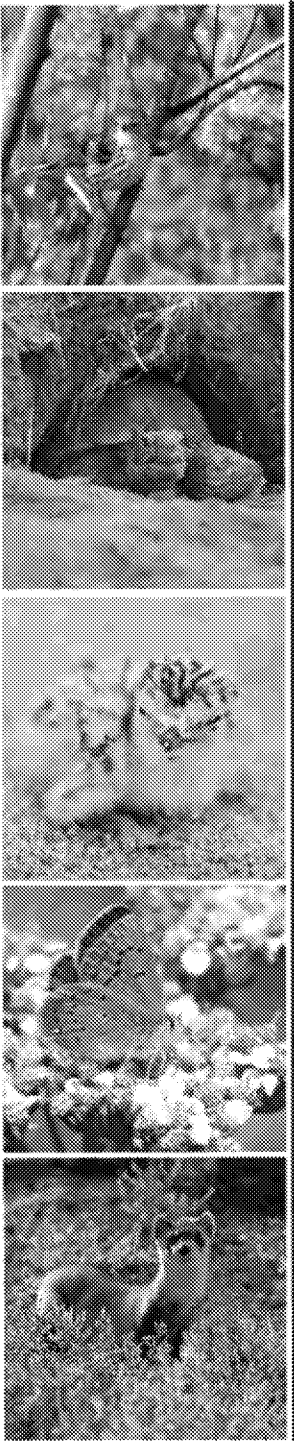


Chemical Overview – Chlorpyrifos and Malathion

- Various agricultural and non-agricultural uses including: crops, orchards and vineyards, pasture, managed forests, right of ways, and developed areas (e.g. public parks, golf courses, home use).
- Also used for the following with no geographic and few temporal restrictions
  - mosquito adulticide control
  - wide area use (ant bait and foliar spray)
- Other uses: cattle ear tags, seed treatment, granular formation, bait
- Can remain in the environment for weeks to months after application, resulting in potential effects to species after application



Chlorpyrifos and Malathion - Effects

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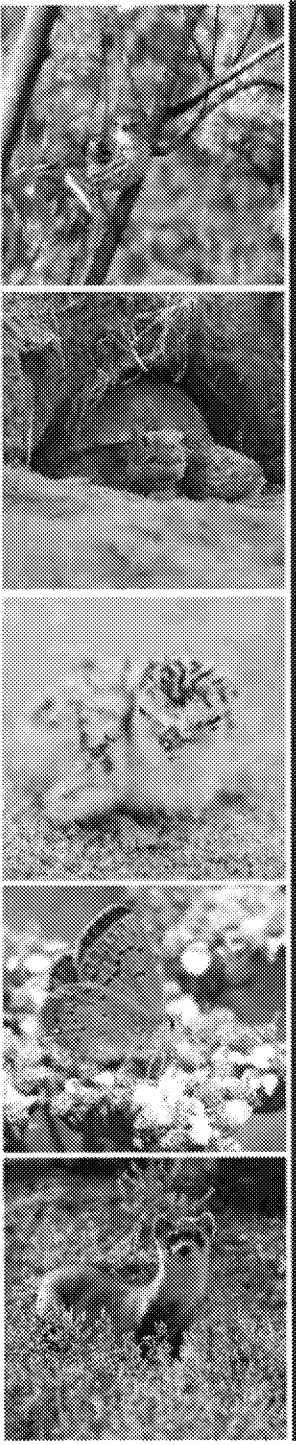
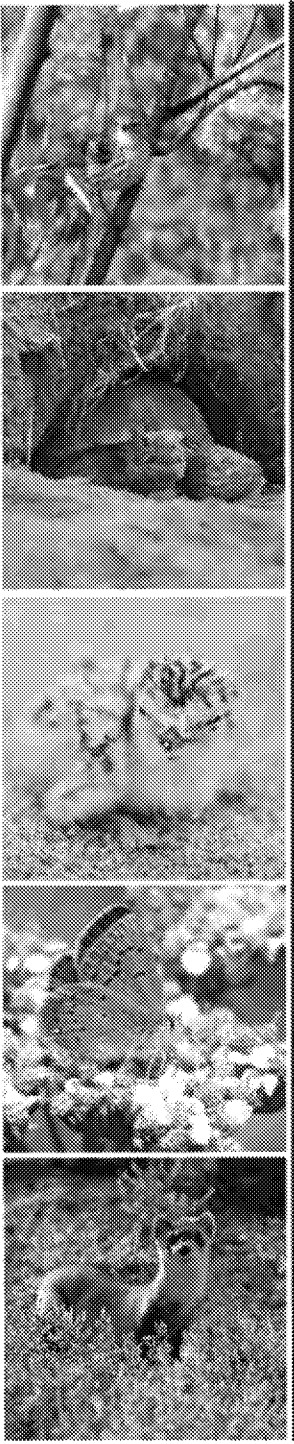


Chemical Overview – Diazinon

- Due to risk to human health and the environment, use of diazinon was severely restricted in 2004
- Remaining uses are limited to select crops, orchards, vineyards and nurseries
- Can also be used in cattle ear tags
- Can remain in the environment for weeks to months after application, resulting in potential effects to species post application

Diazinon - Effects



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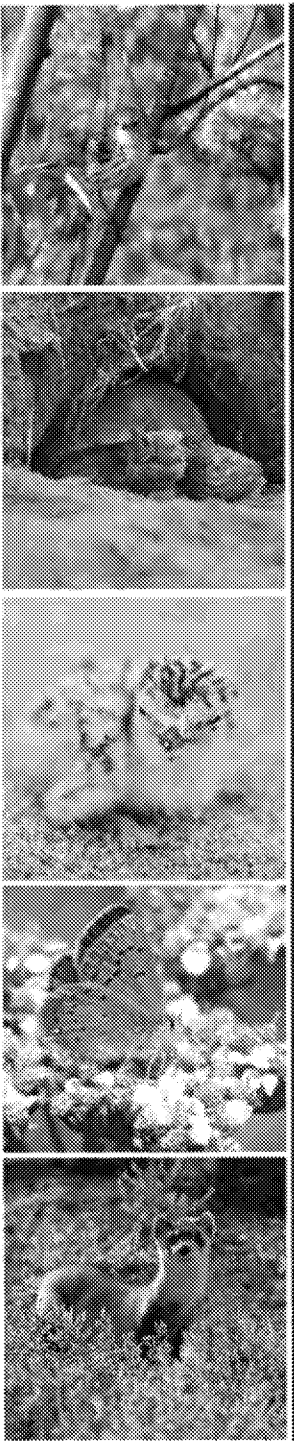
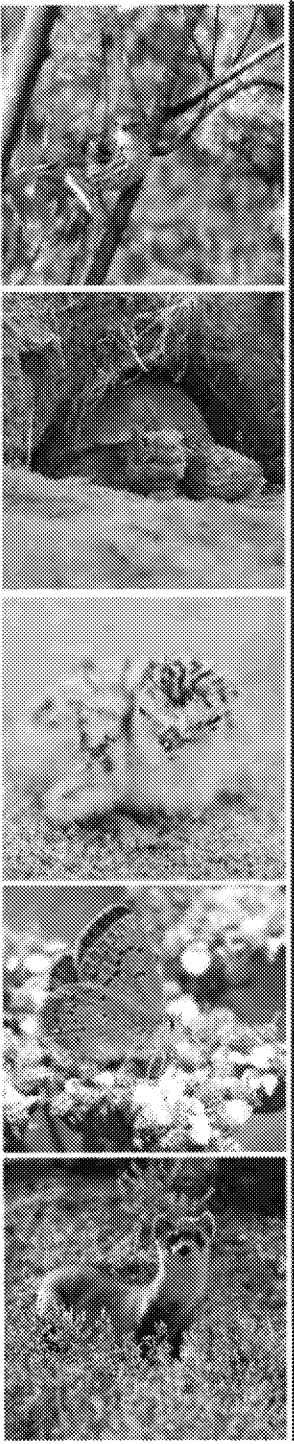


Draft Biological Opinion Conclusions

	Species			Critical Habitat		
	Jeopardy	No Jeopardy	NLAA	Ad Mod	No Ad Mod	NLAA
Chlorpyrifos	b5-DP					
Malathion						
Diazinon						

Notes:
Does not include no effect call determinations or determinations for experimental populations.

Effects for Plants



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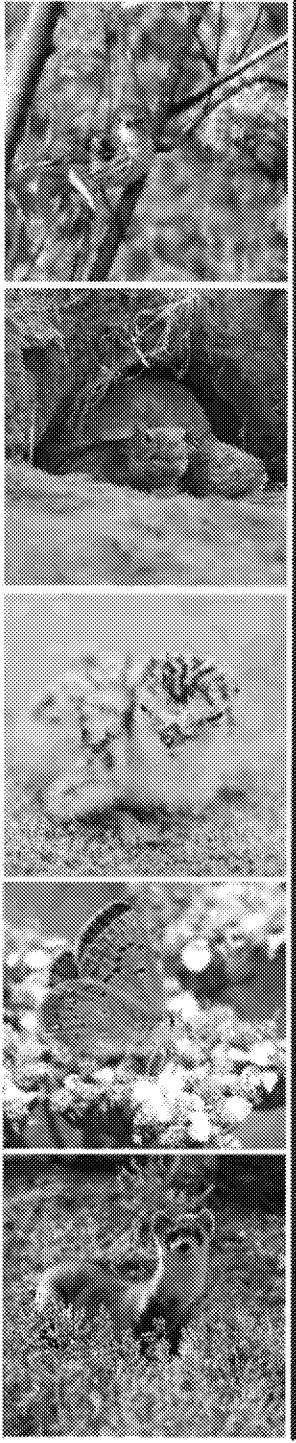
Contra Costa Goldfields

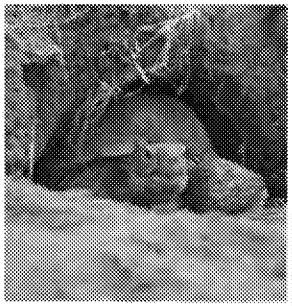


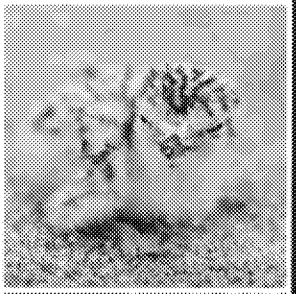
Example: Birds

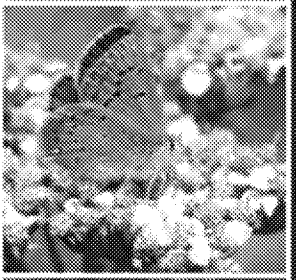
Cape Sable seaside sparrow - chlorpyrifos

Photo credit: Lori Oberhofer, NPS

b5-DP



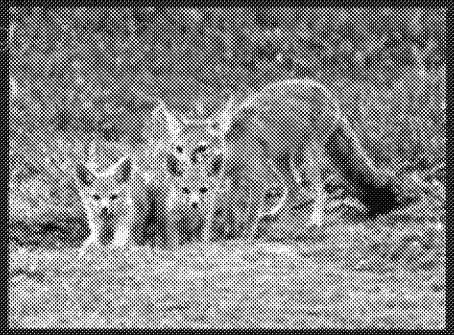




Example: Mammals

San Joaquin kit fox- Diazinon

Photo credit: USFWS



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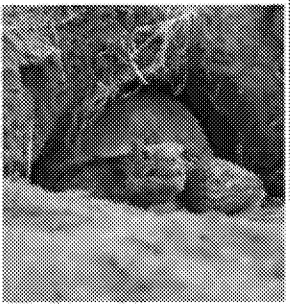
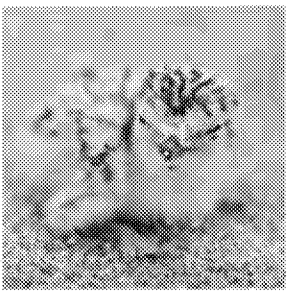
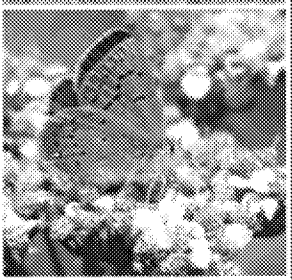

Example: Fish

Moapa dace

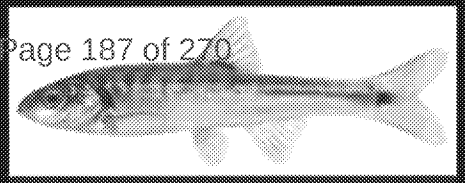

Illustration by Joseph R. Tomelleri

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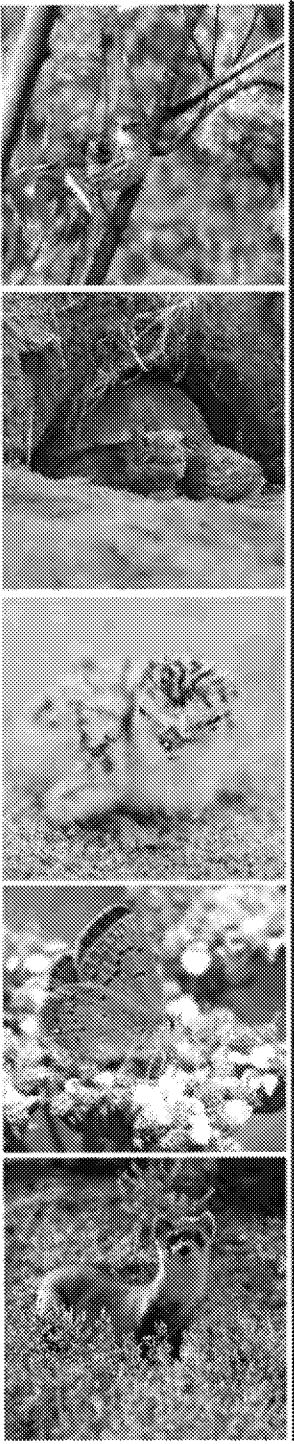

Path Forward

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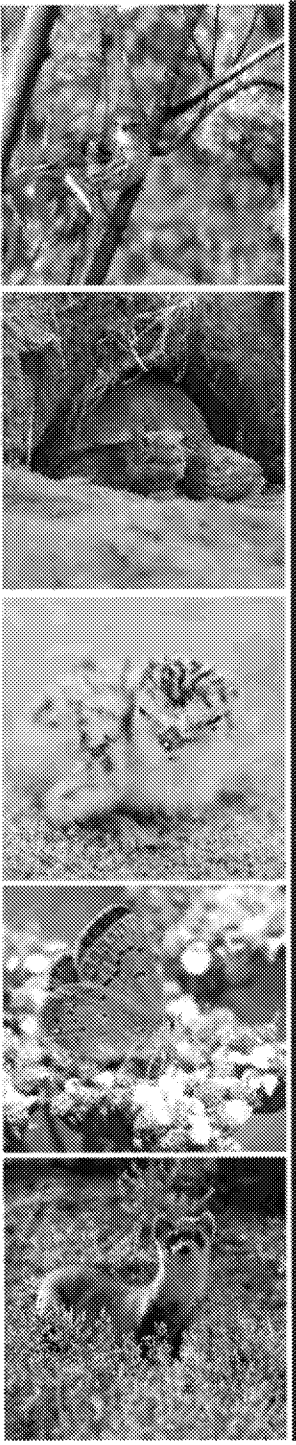


Questions?

DECLARATION OF JOHN HESS

I, John Hess, 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 member of the Center for Food Safety (CFS), and I support the organization's efforts to avoid adverse effects of pesticides on native wildlife. I joined CFS because I am concerned with agricultural and environmental issues and feel responsible for the welfare of native wildlife.

2. I reside in the city of Warrensburg, located in Johnson County, Missouri. I am a professor emeritus of biology; I have taught courses on ecology, evolutionary biology, and ornithology. I also have taught courses on scientific and technical photography that included components of wildlife photography, and particularly photography of small animals, such as insects; in that role, I trained professional photographers, among others. In addition to my academic work, I am an avid wildlife photographer, and I travel around the country taking photos and lecturing. I also sell my photos and author a blog about wildlife.

3. My professional, economic, aesthetic, and recreational interests are being, and will be, adversely affected by the United States Environmental Protection Agency (EPA)'s decision to register flupyradifurone, bicyclopyrone, and other pesticides without consulting with the United States Fish and Wildlife

Service or the National Marine Fisheries Service (collectively, "the Services") on potential impacts to endangered and threatened species and their critical habitats.

4. I understand that a range of crops could be sprayed with flupyradifurone, bicyclopyrone, and the other pesticides involved in this case, including various citrus fruits, vegetables, blueberries, corn, wheat, cotton, and soybeans. I am aware that some of the pesticides involved in this case are systemic in the plants and am concerned that insects and other animals that use these plants, including non-target and non-pest insects, will be harmed. I am also aware that the negative effects of pesticides are magnified as they move up the food chain, such as when threatened and endangered birds forage for insects. I am extremely concerned that flupyradifurone, bicyclopyrone, and other pesticides might have adverse effects on threatened and endangered species.

5. I am particularly worried about threatened and endangered species of birds that depend on invertebrates for their food source. Since flupyradifurone, bicyclopyrone, and the other pesticides involved in this case kill both target pests and non-target invertebrates, I am concerned that these pesticides will have detrimental impacts on food supplies for threatened and endangered birds due to the loss of terrestrial insects. In addition, I fear that birds will be exposed to flupyradifurone, bicyclopyrone, and other pesticides when foraging for insects that consumed plants with these pesticides or contain residues of these pesticides on

their bodies. I am aware that many pesticides persist in the environment for many years and may bioaccumulate in the tissues of living organisms, such as threatened and endangered birds.

6. I frequently recreate in areas where citrus is grown. Every spring I travel to south Texas and every winter I travel to the west coast of Florida. In both states I see massive growths of citrus and other crops that could be sprayed with flupyradifurone, bicyclopyrone, and other pesticides in areas that I visit for recreational and aesthetic enjoyment. I visit Texas and Florida because I have an aesthetic interest in threatened and endangered species of birds that live and migrate through those states. I also take photographs of species in those states and I am concerned that the use of flupyradifurone, bicyclopyrone, and the other pesticides at issue in this case will harm threatened and endangered species, which will diminish my opportunity to enjoy and photograph species in the future.

7. I regularly visit natural areas, such as rivers and local, state, and national parks, all over the country in order to photograph wildlife. For example, I often visit the Ding Darling National Wildlife Refuge in western Florida. I specifically travel to the gulf coast of Florida every winter to photograph different species of birds. I have photographed a variety of endangered species, including the Audubon's crested caracara (*Polyborus plancus audubonii*); piping plover (*Charadrius melodus*); red-cockaded woodpecker (*Picoides borealis*); whooping

crane (*Grus americana*); and wood stork (*Mycteria americana*). I also have seen (but not photographed) the California gnatcatcher (*Polioptila californica*). In addition to those endangered species, I have sought, but not yet seen, many others, including the California condor (*Gymnogyps californianus*) and northern spotted owl (*Strix occidentalis caurina*). To view and photograph endangered species, I visit their natural habitats; for example, to see the red-cockaded woodpecker, I visited the Ochlocknee River, near Tallahassee, Florida, where a colony of red-cockaded woodpeckers reside. I plan to continue visiting the natural habitats of endangered species to view and photograph them.

8. I have seen and photographed the Audubon's crested caracara in both Texas and Florida. I have gone to Texas every spring for the last thirteen years to get a cancer screen at MD Anderson, in which I make frequent stops to take photographs for my personal and professional interests.

9. In addition, I travel to Florida every winter to photograph threatened and endangered species at various wildlife refuges, including the Ding Darling National Wildlife Refuge and occasionally the Everglades National Park. Ding Darling National Wildlife Refuge is in Lee County, where thousands of acres of citrus fruit and other crops that could be sprayed with flupyradifurone, bicyclopyrone, and other pesticides are grown. The Everglades National Park is located throughout Dade, Monroe, and Collier Counties, which also contain

thousands of acres of citrus orchards and other crops that could be sprayed with flupyradifurone, bicyclopyrone, and the other pesticides. I will be traveling to Florida in the winter of 2019 for two weeks and I plan to take more photographs of the Audubon's crested caracara, the piping plover, and the red-cockaded woodpecker. I plan on seeing the red-cockaded woodpecker in Florida on my way to the gulf coast because there is a colony near the Ochlocknee River that I visit when passing through Tallahassee, Florida. The Ochlocknee River runs through Leon, Wakulla, and Gadsden Counties, where many acres of citrus fruit are grown. Once in the Ding Darling National Wildlife Refuge, I intend to see and photograph the piping plover, which is a small shorebird that nests and feeds along the coast. Every winter when I go to Florida, I have the opportunity to see and photograph the wood stork and whooping crane.

10. I have not yet seen the northern spotted owl despite all of my attempts to see it. The northern spotted owl is native to the Pacific Northwest, particularly Oregon. Two of my brothers will soon live in Oregon and I plan to visit them periodically. While there, I hope to photograph the northern spotted owl. I will be traveling through the coastal grove forests near Tillamook State Forest and the forest ranges east of Portland, including Mount Hood National Forest. Tillamook State Forest spans through Washington, Tillamook, Yamhil, and Clatstop Counties, where thousands of acres of blueberries are grown. Mount Hood National Forest is

located in the Counties of Clackamas, Hood River, Wasco, Multnomah, Marion, and Jefferson, which also contain thousands of acres of blueberries that could be sprayed with flupyradifurone.

11. I have also not yet seen the California condor, which maintains colonies both in and outside of California. I plan to travel to Grand Canyon National Park soon in order to see and photograph the California condor, which has habitat in the Grand Canyon. I know that a range of crops are grown in Arizona and California where the California condor's habitat may be impacted, such as Santa Barbara, Tulare, and Ventura Counties, California.

12. Taking photographs of threatened and endangered species is important to me from a personal, aesthetic, recreational, and professional level. I take photographs for my own personal and aesthetic enjoyment as well as sell photographs and train young photographers. Through photography, I am able to engage these animals on a personal level and can connect other people to them so that they will be valued intrinsically. It is important for me to teach future generations about the importance of threatened and endangered species, and to lose a personal connection to these animals would be a major loss for any attempt to encourage the concern and care of threatened and endangered species.

13. If the Audubon's crested caracara; piping plover; red-cockaded woodpecker; whooping crane; wood stork; California gnatcatcher; California

condor; northern spotted owl, or any other endangered species, is harmed or caused to go extinct because of new and increased exposure to flupyradifurone, bicyclopyrone, and other pesticides, my enjoyment of viewing and photographing wildlife would greatly suffer by never again seeing those animals in their native habitats. I am especially concerned that these pesticides may harm invertebrates that these species of birds depend on for their food source, which may result in a depleted food supply. Furthermore, I am concerned that these species of birds will be exposed to flupyradifurone, bicyclopyrone, and other pesticides by eating invertebrates that contain residues of these pesticides or have consumed plants containing these pesticides. The adverse effects that flupyradifurone, bicyclopyrone, and other pesticides have on endangered species injure my professional and recreational interests in viewing and photographing wildlife.

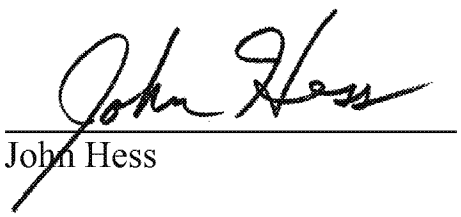
14. I feel discouraged that EPA failed to consult with the Services despite finding that federally-protected threatened and endangered species could potentially be harmed either directly or indirectly from the use of flupyradifurone, bicyclopyrone, and other pesticides including all the species I have plans to observe and photograph listed above. The EPA is required to ensure that the use of flupyradifurone, bicyclopyrone, and other pesticides will not jeopardize the continued existence of listed species, adversely affect their critical habitat, or

otherwise cause harm to listed species that could be avoided or reduced with appropriate mitigation.

15. In sum, I am injured by EPA's decision to register the extensive uses of flupyradifurone, bicyclopyrone, and the other pesticides at issue in this case without consulting with the Services despite finding that federally-protected threatened and endangered species may be impacted. If any threatened or endangered species is jeopardized or goes extinct, I will be harmed economically if I am unable to photograph and sell images of those species. Additionally, the EPA's failure to consult with the Services on the impacts to listed species and their critical habitats harms my aesthetic, recreational, and professional interests in, among other things, viewing and photographing wildlife, including threatened and endangered species, and their native habitats.

I declare under penalty of perjury that the foregoing is true and correct to the best of my ability.

Executed on February 20, 2019, in Warrensburg, Missouri.



John Hess

DECLARATION OF CHRISTOPHER SCOTT IRWIN

I, CHRISTOPHER SCOTT IRWIN, do hereby declare as follows:

1. I am over the age of eighteen, have personal knowledge of the following, and could competently testify thereto if called as a witness.

2. I currently live in Knoxville, Tennessee and am the past President of United Mountain Defense - where I worked also work as a staff attorney on watershed issues.

3. I have extensive training in watershed work. I have worked on a project regarding mussel populations in the Clinch river watershed. I have also worked as a Peace Corp volunteer where I did natural resources management in Africa. Much of the erosion control work I did in the Peace Corp revolved around water and how it interacted with soil. I also worked for the Watersheds Stewards Project in northern California doing watershed restoration and Chinook salmon restoration work, including underwater video. My work on salmon restoration further informed me on the dangers of pesticides for aquatic life. Additionally, I have experience as a white water guide on the Nolichucky and French Broad Rivers. Healthy watersheds are about stream health. All of these experiences have helped me understand and relate as to my interest in the importance of aquatic ecosystems and in mussel populations in particular.

4. I am a member of the Center for Biological Diversity, and I follow

its work closely. As a member of the Center I assisted in the Endangered Species Mural Project. As part of that project I coordinated with Gerald Dinkins, Curator of Malacology (the study of mussels) at the McClung Museum of Natural History and Culture at the University of Tennessee, who helped with an endangered species mural focused on the freshwater mussel life cycle in Knoxville Tennessee. I am particularly proud of my work on this mural, which has been well documented.[1]

5. I live next to the Tennessee River on Riverside Drive. Our river is a toxic, muddy industrial drainage ditch. I suspect pesticide run off has impacted the health of the river from both run off and manufacturers of pesticides. Even on the hottest day in July, people are afraid to swim in it because we all know how toxic and nasty it is. The polluted status of the Tennessee River, including contamination from pesticides, is very troubling to me because it affects my ability to enjoy the river and the ecosystem that is provides.

6. I am very concerned about the use of pesticide in agriculture in Tennessee. I know that agriculture has played a major role on the environment in Tennessee. The importance of agriculture is even represented on the state seal of

[1] Mike Blackerby, Knoxville News Sentinel, "A mural with mussel: New greenway artwork highlights area's biodiversity", July 11, 2016, http://archive.knoxnews.com/news/local/a-mural-with-mussel-new-greenway-artwork-highlights-areas-biodiversity-374bb65a-c91f-2aa4-e053-01000-386216471.html/

Tennessee. I am concerned that crops that are heavily grown in Tennessee, such as soybeans, corn, cotton, and hay for livestock forage, will rely on pesticides that will harm threatened and endangered species.

7. Even though the Tennessee River is highly polluted, the Tennessee Basin as a whole in one of the most biologically diverse river systems for aquatic organisms in the United States. It harbors a high number of imperiled species with many fish and mussel species considered to be at-risk.

8. I have a long-standing interest in mussels. In addition to collecting and looking for them, I have been to the mussel population exhibit at the University of Tennessee, and years ago I interviewed one of their scientists at the mussel lab.

9. I have an intense interest in the impacts of pesticides on mussel populations as they are interesting species as well as indicator species for stream health. I grew up as a child collecting and studying mussel populations on the Tennessee River and surrounding tributaries. I would bring home dead shells to my family several times a week. My Grandfather lived on the banks of the Tennessee River. Growing up I spent countless hours collecting dead mussel shells and observing them in streams flowing into the River. I lost many a shoe deep in the muck wading out to find my shells.

10. I have successfully observed mussels in the wild countless times. I

live right next to the Tennessee River, so I visit these areas weekly, sometimes daily. My family has been in East Tennessee for at least six generations and we have fished, swum, and waded all over. One of the very first things I look for when on the water are the shells of mussels. I like getting on river banks during low water and during that time I'm always looking to see if I can find mussel shells. The Clinch River, where I was involved in a project involving mussels, has more species of endangered freshwater mussels than any other river in North America. I also enjoy visiting the Holsten and French Broad rivers in Tennessee.

11. Additionally, I have looked for point source discharges of pollution into waterways and done conductivity testing with a YSI meter to test for water quality and water pollution all over east Tennessee. When I conduct water quality monitoring mussel populations are one of the things I look for. I did this as both a volunteer and past staff attorney for United Mountain Defense (UMD).

12. I intend to keep visiting waterways in Tennessee for years to come, for both professional and personal reasons. I am the past President and a staff attorney for the UMD. The UMD's mission is to protect Tennessee waters, so I anticipate with certainty that I will continue to visit these areas for months, if not years to come. Additionally, I live next to the Tennessee River, and my Aunt lives on the Tennessee River and owns marshland where I look for mussels.

13. Mussel populations are very important to me. I think they are neat.

The history of mussels and the history of this region fascinate me. I have seen the specialized hook traps that used to be used to drag the sediment to capture them a hundred years ago. I have watched videos on the mussels describing how they used to make buttons out of them and I enjoy visiting the mussel exhibit at the University of Tennessee Museum. I have visited with Gerald Dinkens at the University of Tennessee many times and have viewed most, if not all, of the mussel species in the state as a result of those visits. I hope to see many of those mussels in the wild in their natural habitat as well.

14. I encounter mussels on at least a monthly basis and I look for them everywhere. I always get a little nervous when I do not see them in a stream. It makes me happy when I see them recovering in a stream or creek. Every time I find only dead small ones, I know the stream is sick and it makes me feel ill inside.

15. I am very concerned about threatened and endangered species living in Tennessee watersheds, especially mussels, and enjoying looking for them. For example, I like to look for the pink mucket (*Lampsilis abrupta*), and Cumberlandian combshell (*Epioblasma brevidens*), which are two of the species depicted on the mussel endangered species mural in Knoxville that I helped create.

16. I believe all life has equal validity and when I see yet another

example of humans taking priority over all other life, like with the contamination of rivers with pesticides, I am saddened. I believe all species, including mussels, have the right to exist.

17. As an indicator species, mussels tell me how well we are doing at being stewards of the earth and what kind of planet we are handing off to the next generation. The loss of mussels is one of the indicators as to how contaminated the river is. If it were cleaner, if it had healthier mussel populations, it would be a sign that the river is not as filthy as it looks.

18. In sum, I have environmental, recreational, and aesthetic interests in viewing federally protected wildlife, especially mussels that are negatively affected by the Environmental Protection Agency's failure to follow the Endangered Species Act and protect imperiled wildlife. My ability to freely visit waterways is harmed by the failure of our federal government to protect aquatic wildlife from pesticide pollution. I am less able to see wildlife that is rarer because of pesticide use and I would be likely to visit waterways in Tennessee more often if they were less polluted with pesticides and I was more likely to see endangered species, such as mussels there.

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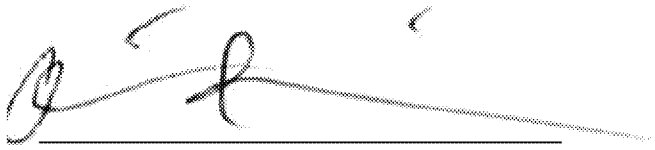
I declare under penalty of perjury that the foregoing is true and correct.

Dated this February 22, 2019



Chris Irwin

DECLARATION OF JEFFERY MILLER

I, Jeffrey K. Miller, declare as follows:

1. I declare under penalty of perjury that the following is true and correct. The facts set forth in this declaration are based on my personal knowledge and if called as a witness, I could and would competently testify thereto under oath. As to those matters which reflect a matter of opinion, they reflect my personal opinion and judgment upon the matter.

2. I am a resident of Morro Bay, California.

3. I have been a member of the Center for Biological Diversity ("CBD") since 1995 and have been employed on the staff of CBD since 1998. I am currently employed full-time by CBD based out of the Oakland, California office. My duties include, among other things, research, assembling endangered species listing petitions, community organizing, assisting with various conservation campaigns, educational presentations, writing press releases, contacting media, and other work to protect and restore endangered and threatened species and their habitats, primarily in California.

4. As an employee of CBD, I have personally been involved in CBD's Pesticides Reduction Campaign. Because of EPA's failure to consult, much of my time and CBD's resources have been diverted towards authoring a series of reports detailing the effects of pesticides on Endangered Species Act ("ESA") listed

species. In the absence of the ESA consultation analysis CBD has had to analyze on its own the harmful effects of pesticides on endangered species, including, but not limited to, determining what species were most harmed by pesticides, which pesticides posed the greatest harm to ESA listed species, what steps could be taken to educate the public and decision-makers about the threats posed by pesticides to ESA listed species, and what steps could be taken to counteract the environmental harms posed to ESA listed species from EPA's failure to consult.

5. In 2004, CBD released the first of two reports I helped publish on pesticide use and endangered species. *Silent Spring Revisited: Pesticide Use and Endangered Species* analyzed the effects on endangered species of EPA's registration of pesticides.[1] The report analyzed EPA's continued failure to enforce the ESA's Section 7 Consultation requirements and how that illegal action affected ESA listed species. As noted in the report,

> Although the EPA by law is required to consult with the U.S. Fish and Wildlife Service on pesticide registration, it has failed to complete a single consultation in the last ten years despite repeated formal requests from the wildlife agency and the unambiguous requirements of the Endangered Species Act.

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1 https://www.biologicaldiversity.org/publications/papers/Silent_Spring_revisited.pdf.

6. *Silent Spring Revisited* analyzed the effects pesticides have on ESA listed species so that the public was more aware of these issues, something the EPA was supposed to do. For example, the report discusses kit fox poisoning by rodenticides approved by the EPA and the effects rat poisons could have on the species. The report also analyzed the effects of pesticides on the southwestern willow flycatcher (*Empidonax traillii extimus*) noting that pesticides pose a threat to the species' food base. The report also discusses the biological effects of pesticides on imperiled species , including endocrine disruption, sexual deformities and other reproductive anomalies. The report acts as a replacement to the public for the Biological Opinion they were denied when EPA failed to consult under the ESA.

7. In 2006, CBD issued the report *Poisoning Our Imperiled Wildlife: San Francisco Bay Area Endangered Species at Risk from Pesticides*.[2] CBD was forced to divert its resources and expend resources beyond those that are normally expended to analyze the outcome of EPA's illegal activity and educate the public about the impacts of EPA's failure to engage in consultation, which would have studied and mitigated the effects of pesticides on endangered species. The report

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2 https://www.biologicaldiversity.org/publications/papers/bayareapesticidesreport.pdf

repeatedly emphasized the systemic failure at EPA to engage in consultation and how that impacted ESA listed species. For example,

> By failing to consult with the USFWS and NMFS, which have the statutory authority and responsibility to cooperate with other agencies in assessing impacts of agency actions and authority on threatened and endangered species, the EPA neglects to comply with federal law or even develop the information base for making the wise and cautious decisions about our most endangered wildlife.

8. *Poisoning Our Imperiled Wildlife* examined the risk that toxic pesticides pose to endangered species in the nine Bay Area counties: Marin, Sonoma, Napa, Solano, Contra Costa, Alameda, Santa Clara, San Mateo and San Francisco. *Poisoning Our Imperiled Wildlife* analyzed and highlighted the dangers posed by EPA's violations of the ESA in registering pesticides. The report detailed how the use of pesticides in the Bay Area is of concern for the California red-legged frog, California tiger salamander, Delta smelt, valley elderberry longhorn beetle and Pacific salmonid species. It further studied the Bay Area's use of pesticides by County and areas where that use was occurring. The report compared that usage data to critical habitat of ESA listed species. After analyzing the exposure to and effects on species the report made a list of recommendations to the public. For example, the report encouraged the public to use bio-pesticides to control insect pests and to hand weed and mulch their gardens.

9. In addition to helping to write and publish the two pesticide reports, I have been forced to spend my time doing extensive advocacy, outreach and public education around the harmful effects of pesticides on imperiled wildlife. CBD, the public, and myself have all been denied the important scientific and informational reports that come along when agencies consult under the ESA. Thus, CBD diverted resources, so I could write and distribute nearly 20 press releases on CBD pesticide actions, resulting in nearly 150 newspaper articles, and TV and radio interviews on CBS,KQED and others. I also helped organize public comments to the EPA on pesticides and pesticide registrations through CBD action alerts.

10. From 2003-2008, approximately 25% of my time was dedicated to addressing the impacts of pesticides on endangered species and providing information to the public about these impacts, due to the EPA's failure to consult.

11. I am also the founder and Director of the Alameda Creek Alliance, a community watershed group dedicated to protecting and restoring the natural ecosystems of the Alameda Creek watershed. To restore the Alameda Creek watershed's native wildlife, plants, habitats, and ecosystems, the Alameda Creek Alliance focuses its efforts on restoring steelhead trout and salmon, indicator species of watershed health.

12. I have worked on conservation campaigns for a wide array of imperiled wildlife species in California, including native fish, birds, raptors,

amphibians, reptiles, carnivores, ungulates, rodents, insects and plants. I have written or co-written many federal Endangered Species Act listing petitions, including petitions for the mountain yellow-legged frog (*Rana muscosa*), green sturgeon (*Acipenser medirostris*), Pacific lamprey (*Entosphenus tridentatus*), Delta smelt (*Hypomesus transpacificus*), longfin smelt *(Spirinchus thaleichthys*), Clear Lake hitch (*Lavinia exilicauda chi*), foothill yellow-legged frog (*Rana boylii*), and Siskiyou Mountains salamander (*Plethodon stormi*). I have also written, or co-written state California Endangered Species Act listing petitions for the western burrowing owl (*Athene cunicularia hypugaea*), Delta smelt, longfin smelt, mountain yellow-legged frog, Clear Lake hitch, foothill yellow-legged frog, and Cascades frog (*Rana cascadae*).

13. Personally, I am an avid amateur naturalist and birdwatcher and frequently visit habitat for rare and endangered birds and other wildlife throughout California. To look for and observe such wildlife, I often visit habitat throughout the Central Valley, San Francisco Bay Area and Bay-Delta, the central California coast, and Southern California. I also enjoy searching for and observing other species while birdwatching. In 2018 I took up wildlife and bird photography, in order to be able to better share the beauty and importance of California's native and imperiled bird and wildlife species with others.

14. I go birdwatching almost every day somewhere in California. In the last decade, I have seen 531 different species of birds in California alone. I lead annual birdwatching trips for the public at the Point Reyes Birding and Nature Festival in Marin County, and at the California Bird Festival at Morro Bay in San Luis Obispo County. I also participate annually in several Christmas bird counts, volunteer-based citizen science survey efforts coordinated by the Audubon Society to promote bird conservation and assess long-term trends in winter bird populations. I have been the co-compiler for the Eastern Alameda County Christmas Bird Count since 2009; and also regularly participate in the Point Reyes Peninsula, Western Sonoma County, Morro Bay and Carrizo Plain Christmas bird counts.

15. Through my professional work and personal hobbies, I have become very concerned about the impacts of pesticides on endangered and threatened species. With many endangered species already suffering from habitat loss, the effects of climate change, low population numbers, and other threats, harm from inappropriate use of toxic pesticides in and near habitat for imperiled species could push these species closer to extinction or impede their recovery. I am concerned that the effects of the pesticides flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will pose a significant threat to the recovery and continued existence of threatened and endangered species.

16. I am aware that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide and other pesticides have been approved to be sprayed on crops in California including but not limited to: alfalfa, cotton, corn, wheat, hay, strawberries, stone fruits, grapes, and nut trees. I know that species I enjoy and look for live where these pesticides are going to be sprayed. Their habitats overlap with where the spaying is going to occur. I understand that these pesticides are likely to degrade their habitat and put their existence at risk. These pesticides will also runoff into waterways and drift into nearby areas further affecting species I have professional, recreational, aesthetic, and spiritual interests in.

Salmon and Steelhead Trout

17. I have been involved in the restoration of salmon and steelhead trout (*Onchorhynchus mykiss*) throughout California since 1996. I worked for and continue to volunteer with the Salmon Protection and Watershed Network in Marin County, which protects and restores coho salmon (*Oncorhynchus kisutch*) and steelhead trout and their habitat in Lagunitas Creek and Olema Creek. I am a member of the Russian Riverkeeper, which works to protect chinook salmon (*Oncorhynchus tshawytscha*), coho salmon and steelhead trout in the Russian River in Sonoma County. I am the founder and Director of the Alameda Creek Alliance, and for the past 21 years have worked to protect steelhead trout and restore their

habitat in Alameda Creek in Alameda County. I am on the Board of Directors of Beyond Searsville Dam, an organization working to protect steelhead trout in San Francisquito Creek in San Mateo and Santa Clara counties. Since 1998 I have worked for CBD on numerous campaigns throughout California to protect coho salmon, chinook salmon, steelhead trout, green sturgeon, and native Bay-Delta fishes and their habitats. In 2007 and 2009 I received the Fishsniffer's "Leaping Steelhead" conservation awards for grassroots efforts to restore Alameda Creek and efforts to protect the San Francisco Bay-Delta and California's fisheries. In 2011 the East Bay Express voted me "Best Environmentalist" for my work with CBD and Alameda Creek Alliance, as part of their annual Best of the East Bay awards.

18. I have visited Central Valley rivers and waterways to look for and view spring run chinook salmon and steelhead trout, including areas that are designated as critical habitat for these salmonids, such as lower Sacramento River, Feather River, Yuba River, Deer Creek, Yolo Bypass, and the San Francisco Bay-Delta. In 2009 I visited Butte Creek, an important spawning area for Central Valley spring run chinook salmon. I have rafted down the Tuolumne River several times, an important spawning river for Central Valley steelhead. I plan to continue to visit these places to look for and view spring run chinook salmon and steelhead

trout. I have plans to visit the Sacramento River and SF Bay-Delta in spring and summer of 2019.

19. I have visited numerous California coastal rivers and creeks to look for and view coastal chinook salmon and steelhead trout, including areas that are designated as critical habitat for these salmonids. These include Redwood Creek, Mattole River, Eel River, Albion River, and Russian River which harbor the California coastal chinook salmon population. I have visited Usal Creek, Albion River, Navarro River, Gualala River, Russian River, and Lagunitas Creek where the central California coast coho salmon population occurs. I have visited Redwood Creek, Mattole River, Eel River, and Gualala River where the Northern California coast steelhead trout population occurs. I have visited many streams that contain the central California coast steelhead trout population, including the Russian River, Lagunitas Creek, Olema Creek, Pine Gulch Creek, Pilarcitos Creek, Pescadero Creek, San Gregorio Creek, San Francisquito Creek, and Alameda Creek. I have also visited streams that contain the south-central California coast steelhead trout population, including the Carmel River, Big Sur River, Salinas River, Arroyo Seco, San Carpoforo Creek, Santa Rosa Creek, Morro Creek, Chorro Creek, SLO Creek, and Arroyo Grande Creek. I plan to visit these places again this year and for years to come to view coastal chinook salmon and steelhead trout. I have plans to visit the Russian River, Eel River and Lagunitas Creek in

spring of 2019; I live nearby all of the San Luis Obispo County creeks, and plan to visit them regularly in the spring of 2019.

20. I have lived along the Albion River, Russian River, Pine Gulch Creek, and Lagunitas Creek and currently live near Morro Creek and Chorro Creek. I have kayaked on the Albion River, Navarro River, Russian River, Gualala River, and Lagunitas Creek, and I regularly raft down the Eel River. I will continue to visit these places in hopes to see salmon and steelhead trout. I have plans to raft down the Eel River in April 2019; and to visit my former home along the Russian River the same month.

21. In my capacity at CBD and personally I have worked on numerous campaigns to protect these salmonids and streams which are their critical habitat from impacts from logging, urban development, water withdrawals, pesticides, dams, and livestock grazing. These efforts included working with other conservation, fishing, and tribal groups, and scientists, writing press releases, submitting comments on projects and permits, and preparing web materials and action alerts.

22. This year Alameda Creek Alliance and I helped capture and tag adult steelhead in lower Alameda Creek and helped transfer them to suitable spawning habitat. This is a part of an effort to help construct a fish ladder in the lower creek to connect wild steelhead with former spawning and resring habitat areas. The

Alliance is helping restore wild steelhead spawning population in the largest local tributary to San Francisco Bay. I plan on continuing to work in Alameda Creek to restore habitat and ensure a safe fish passage.

23. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around chinook salmon and steelhead trout habitats without regard to the species' recovery. Chinook salmon and steelhead trout habitats are in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide. I am aware of the problem of pesticide runoff in watersheds in the Central Valley and other locations. I am concerned that the use of these and similar pesticides will harm and kill chinook salmon and steelhead trout directly and inadvertently.

North American Green Sturgeon – Southern Population

24. In my capacity at CBD I wrote a formal listing petition for protection of green sturgeon under the federal Endangered Species Act in 2001. Because of the petition, the National Marine Fisheries Service listed the southern green sturgeon population as a federally threatened species in 2006. I assisted in CBD campaigns and a lawsuit which led to designation of critical habitat for southern green sturgeon in 2009; ESA "take" regulations in 2010; and a formal recovery plan for southern green sturgeon, finalized in 2018. CBD intervened and

successfully fought off legal efforts by developers and water agencies to strip critical habitat protections for southern green sturgeon. I was involved in writing comments, working with scientific experts on the species, organizing other conservation groups, and writing 11 press releases, web site materials and action alerts for these protective efforts.

25. I frequently visit river habitat for the southern population of green sturgeon in the Sacramento River and also visit northern green sturgeon spawning habitat in the Rogue River and Klamath River in late spring and early summer to attempt to see green sturgeon in the wild. I regularly raft along the Rogue and Klamath Rivers in areas where green sturgeon are known to occur. Specific locations I have visited to attempt to see southern green sturgeon spawning include Balls Ferry, Red Bluff Diversion Dam, Todd Island, Woodson Bridge State Recreation Area and Hamilton Bend on the Sacramento River, and along the lower Feather and Yuba Rivers. Unfortunately, I have yet to encounter the rare green sturgeon in the wild and have only seen green sturgeon at the Monterey Bay Aquarium. I plan to continue to return to these rivers annually.

26. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around green sturgeon's habitat without regard to the species' recovery. These pesticides are likely to adversely affect the species' recovery and frustrate all the

work CBD and myself have done to help preserve the species. The North American green sturgeon's habitat is in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide. I am concerned that the use of these and similar pesticides will harm and kill North American green sturgeon directly and inadvertently.

Delta Smelt

27. In my capacity at CBD I helped prepare petitions to increase federal and state Endangered Species Act protections for Delta smelt. In 2006 we submitted a petition to uplist Delta smelt from threatened to endangered under the federal Endangered Species Act. In 2007 we submitted a petition to uplist Delta smelt from threatened to endangered under the California state Endangered Species Act. In 2009 our petition was granted, and Delta smelt was protected as endangered under the California state Endangered Species Act. I was involved in working with other conservation groups, and writing 13 press releases, web site materials and action alerts for these protective efforts. My recent visits to the Delta included Bethel Island, Brannan Island State Recreation Area, Isleton, lower Mokelumne River, Woodbridge Ecological Reserve, and Suisun Slough in 2016; and Cosumnes River Preserve and Rio Vista in 2018. I plan to make future trips to the Delta to view and look for Delta smelt, including in spring of 2019.

28. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around Delta smelt's habitat without regard to the species' recovery. These pesticides are likely to adversely affect the species recovery and frustrate all the work CBD and myself have done to help preserve the species. The Delta Smelt's habitat is in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide. I am concerned that the use of these and similar pesticides will kill and harm the Delta Smelt directly and inadvertently.

Valley Elderberry Longhorn Beetle

29. The valley elderberry longhorn beetle (*Desmocerus californicus dimorphus*) is listed as a threatened species under the federal Endangered Species Act.

30. The valley elderberry longhorn beetle is an attractive red and black beetle that lives in riparian zones throughout California's Central Valley, from Redding to Fresno. The valley elderberry longhorn beetle's entire life cycle is associated with elderberry trees. Females lay eggs in the bark of the tree, and the larvae hatch and burrow into the stems. For the first one-to-two years of their lives, the larvae eat the elderberry tree's interior wood as their sole source of food.

Adults emerge in the spring through distinctive exit holes and feed on the foliage until they mate.

31. Elderberry trees can be found in riparian forests along rivers and streams in the Sacramento Valley and San Francisco Bay-Delta. Over ninety percent of such riparian forests have been cleared in the last century for agricultural and urban development. Pesticide use on otherwise undisturbed areas has also degraded the quality of riparian habitat.

32. I have seen the related and more common California elderberry longhorn beetle on several occasions. While birdwatching in the Central Valley in 2009, I found longhorn beetle drill holes in elderberry trees that were likely made by valley elderberry longhorn beetles, based on their location, specifically along the American River Parkway adjacent to the lower American River. I subsequently began looking for longhorn beetle drill holes in elderberry trees while birdwatching within other suitable habitat for the valley elderberry longhorn beetle in the Central Valley, along the Cosumnes River, Putah Creek, the Llano Seco Unit of the North Central Valley Wildlife Management Area and the Colusa National Wildlife Refuge.

33. I have also visited the Sacramento River in April 2016; Cosumnes River Preserve in February 2018; Yolo Bypass in April 2018; and the American River in February 2019 in search of the valley elderberry longhorn and plan on to

continue to search for the beetle in future planned trips. I regularly visit Central Valley rivers and riparian areas with valley elderberry longhorn beetle habitat, about three-to-four times a year and plan to continue doing so in the future for birdwatching and salmon restoration activities. Additionally, I regularly attend an annual birdwatching festival in the Central Valley that involves spending time in the valley elderberry longhorn beetle's habitat.

34. In 2014, I submitted regulatory comments for CBD and helped put out two press releases to publicize the threatened removal of Endangered Species Act protections for the valley elderberry longhorn beetle. CBD's advocacy and publicity with the Xerces Society for Invertebrate Conservation prevented the premature delisting of this beetle species, which is still an imperiled species. Successful recovery of the valley elderberry longhorn beetle will inspire and promote similar efforts for other imperiled native species.

35. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around the valley elderberry longhorn beetle's habitat without regard to the beetle's recovery. The beetle's habitat is in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide to control other insects. I am concerned that the use of these and similar pesticides will harm or kill valley

elderberry longhorn beetles directly or inadvertently, as the killing of non-target insects by insecticides is a common phenomenon.

36. I plan to look for the valley elderberry longhorn beetles in the wild, but even if I do not observe the beetle, I am happy knowing that it exists in the wild. I enjoy knowing that the beetle is recovering as a listed species and I look forward to its full recovery. If the remaining populations of the valley elderberry longhorn beetle were extirpated because of pesticides, the ecological value of the Central Valley's riparian habitat and my appreciation of these areas would be diminished.

San Joaquin Kit Fox

37. The San Joaquin kit fox (*Vulpes macrotis mutica*) is listed as an endangered species under the federal Endangered Species Act.

38. The San Joaquin kit fox is the smallest fox in North America, and is an adorable creature with distinctive large ears and long legs.

39. The kit fox once ranged throughout the San Joaquin Valley, but now resides only at the edges, from southern Kern County in the south to Alameda, Contra Costa, and San Joaquin counties in the north.

40. I was lucky enough to see a San Joaquin kit fox out in the open during daylight hours on a memorable occasion near Tracy, California in 2011. A San Joaquin kit fox was running across an open field next to a road I was driving on. In

my 56 years in California, I have seen hundreds of foxes (including native gray foxes, introduced red foxes and endemic island foxes), but I could immediately tell this was a San Joaquin kit fox. I noticed its oversized ears, small size, long bushy tail and distinctive way of moving, and knew I was in the kit fox's restricted habitat area. Seeing this kit fox was an amazing experience given how rare the species is. It was exciting to see one of California's signature endemic species in the wild.

41. I also recently got to see three San Joaquin kit foxes at Carrizo Plain, once in June 2018 and twice in December 2018. I had a close encounter with a San Joaquin kit fox at Carrizo in June 2018, and got close-up photos included below.

42. I have visited Carrizo Plain in February 2016, June 2018, and twice in December 2018. I have trips planned to return to Carrizo Plain in March 2019 and April 2019. I have also looked for kit foxes in suitable habitat recently in Kern County (Lost Hills and Kern National Wildlife Refuge) in March and December 2018; and at Camp Roberts in July 2016 and May 2018.

43. I often visit San Joaquin kit fox habitat while birdwatching in the Central Valley, San Joaquin Valley, Carrizo Plain, Camp Roberts and Fort Hunter Liggett. I plan to continue regularly visiting such habitat in the future. I also regularly visit kit fox habitat in eastern Alameda County in Altamont Pass and Corral Hollow, up to ten times each year and will continue to do so.

44. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around the San Joaquin kit fox's habitat without regard to its recovery. The kit fox's habitat is in and nearby many agricultural operations that are likely to apply these pesticides to control insects.

45. I plan to look for San Joaquin kit fox in the wild again, but even if I do not observe the kit fox, I am happy knowing that these animals exist in the wild. I look forward to the kit fox's full recovery under the protections of the Endangered Species Act. If the small number of remaining kit foxes were reduced or extirpated because of the use of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide, the ecological value of the Central Valley's natural environment and my appreciation of these areas would be diminished.

Western Yellow-Billed Cuckoo

46. I recently was lucky enough to see the elusive yellow-billed cuckoo (*Coccyzus americanus*) - in October 2016 in Florida and in May 2018 in Texas. These sightings made me want that much more to see the western, or California, subspecies of yellow-billed cuckoo. I have been birdwatching in suitable western yellow-billed cuckoo habitat searching for this bird at the Kern River Preserve in July 2017 and July 2018; and along the Sacramento River in February 2019. I plan

to return to the Kern River Preserve and Sacramento River this spring and summer to look again for the cuckoo.

Least Bell's Vireo

47. I first became interested in the least Bell's vireo (*Vireo bellii*) and southwestern willow flycatcher (*Empidonax trailii extimus*) in 1998, when I was part of CBD's campaign to force the U.S. Forest Service to amend its management plans for Southern California's four national forests to better protect riparian habitat for Bell's vireo and willow flycatcher. From 2010 to 2014 I was involved in CBD's successful campaign to reverse an Army Corps of Engineers policy that would require stripping levees of vegetation that provides important habitat for imperiled California species, including the least Bell's vireo and southwestern willow flycatcher.

48. I saw my first least Bell's vireo in 2010. I have searched for least Bell's vireo in San Diego and the Tijuana River Valley area (September 2016, September 2017, and April 2018); in the Salton Sea area (February 2016, September 2016, September 2017, and April 2018); and in the Kern River drainage (July 2017 and July 2018). I have now seen least Bell's vireo four times. I plan to return to the Tijuana River Valley, Salton Sea, and Kern River drainage in 2019 to look for this bird.

Southwestern Willow Flycatcher

49. I saw my first southwestern willow flycatcher in 2009. I have since seen this species on 35 occasions while birdwatching in Mono County, the Kern River drainage, the central California coast, Salton Sea area, and Imperial Valley area. I recently looked for southwestern willow flycatcher in Inyo County and Mono County in 2017. I plan to look for this bird in 2019 along the eastern slope of the southern Sierras.

50. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around western yellow-billed cuckoo, least Bell's vireo, and southwestern willow flycatcher habitat without regard to the species' recovery. These pesticides are likely to adversely affect these species' recovery. These species live in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide. They eat insects that will be killed by these pesticides, lessening their ability to find food and increase their chances of getting poisoned themselves. I am concerned that the use of these and similar pesticides will kill and harm these species directly and inadvertently. If the small number of these remaining species were reduced or extirpated because of the use of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide, the ecological value of the natural environment and my appreciation of these areas would be diminished.

California Tiger Salamander

51. I have a conservation and personal interest in the California tiger salamander (*Ambystoma californiense*). I have been involved in CBD's campaigns to secure protections under the state and federal Endangered Species Acts for California tiger salamander populations, and worked on press releases, reports, and securing public and expert comments to protect the species and educate the public about the decline of California tiger salamanders and the loss of their vernal pool habitats. I have also worked on many CBD and Alameda Creek Alliance efforts to stop or reduce urban development in tiger salamander habitat in the East Bay and in Sonoma County.

52. In 2009 I went out with a tiger salamander researcher at night to participate in surveys for the California tiger salamander at Jepson Prairie Preserve in Solano County. I have also seen tiger salamander larvae on several occasions in ponds in Sunol and Ohlone Regional Parks in Alameda County. I plan to return to look for California tiger salamander when I visit eastern Alameda County for the Eastern Alameda County Christmas Bird Count and as part of my work with the Alameda Creek Alliance.

53. I am concerned that flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide will be applied in and around California tiger salamander habitat without regard to the species' recovery.

These pesticides are likely to adversely affect tiger salamander recovery since these salamanders live in and nearby many agricultural operations that are likely to apply flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, or cuprous iodide.

54. In summary, I have professional, recreational, aesthetic, and spiritual interests in the conservation and preservation of many imperiled native species in California, such as the valley elderberry longhorn beetle, San Joaquin kit fox, Delta smelt, North American green sturgeon, chinook salmon, coho salmon, steelhead trout, western yellow-billed cuckoo, least Bell's vireo, southwestern willow flycatcher, California tiger salamander, and their habitats. I derive benefits from visiting, observing, and restoring intact natural riparian ecosystems which are habitat for some of these species, and my enjoyment of these habitat areas for recreational, professional, and spiritual purposes is dependent upon healthy ecosystems and wildlife populations.

55. As a lifetime conservationist, I have aesthetic, spiritual and moral interests in these species. It is important to me that these and other species survive and thrive in their natural habitat, whether or not I am able to encounter them. It is my belief that no wildlife species should be allowed to be driven extinct by the actions of humans and that no species should be allowed to go extinct if it can be prevented. My spiritual fulfillment comes from interacting with nature and

protecting wild places, wildlife, and intact native ecosystems. The loss of these species will injure my aesthetic and spiritual enjoyment of native habitats in my home state. I believe that biodiversity has inherent value and it would be a moral and spiritual failure of our society to not protect our most vulnerable wildlife.

56. As a conservationist, I have a professional interest in protecting and recovering these species. The protection and recovery of these and other species are essential to my work to promote funding, take regulatory action, advocate, and organize citizen involvement in efforts to protect endangered species.

57. These interests are being harmed by the Environmental Protection Agency's failure to consult with the U.S. Fish and Wildlife Service on the impacts of flupyradifurone, bicyclopyrone, benzovindiflupyr, halauxifen methyl, and cuprous iodide, which could poison, harm, kill, and further imperil these species and other endangered and threatened species. The agency's failure to consult before registering these pesticides is contrary to federal law and contrary to the conservation and stewardship values of CBD and our society. The Environmental Protection Agency's failure to follow the law makes these species more vulnerable to habitat destruction, injury, death, and population declines. If these species decline or become extinct, the loss would deprive me of all the benefits I currently enjoy from their existence and recovery. Consultation could have resulted in more

protective measures to ensure the conservation and recovery of these species, ensuring that my interests would be free from injury.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on February 26, 2019 at Morro Bay, California.

By: _____
Jeffrey Miller

DECLARATION OF ALIXANDRA MULLINS

I, Alixandra Mullins, 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 member of the Center for Food Safety (CFS). I joined CFS shortly after my first child was born in 2009 because I was concerned about the safety of the food he was consuming, particularly in regards to pesticide residues. When my first child started eating solid food at around six months of age, I began avoiding conventionally grown food with pesticides to ensure that my children eat the healthiest and most nutritious food available. I actively seek out organic food to reduce the amount of chemicals me and my family eat. I am also concerned about the environmental impacts that pesticides have on threatened and endangered species, particularly butterflies and other pollinators. I support CFS for actively trying to reduce the amount of harmful pesticides used in industrial agriculture and to protect threatened and endangered species.

2. I am a resident of Aptos, California which is located in Santa Cruz County. My home is located in the forest of Nisene Marks State Park, which is known for its beautiful hiking and large redwood trees. There are numerous redwood trees on my property that create a shaded environment that ferns and other grasses and weeds thrive in. I do not use pesticides on my property nor do I

cut back the weeds because the natural flora attracts various species of butterflies and other pollinators that I enjoy photographing.

3. I earned a Bachelor of Arts degree in Communication Studies at California State University, Sacramento.

4. I am a professional artist, as well as a photographer, children's book author, and graphic designer. Using digital media and fine art tools, I create a wide variety of digital media projects and mixed media art pieces including art for greeting cards, art for puzzles, cover art for books and CDs, and canvas art, which is sold world-wide. In order to create my images, I combine my original paintings, drawings, graphics, and photography using a form of collage. My final images are printed on canvas, stretched, and then coated with a variety of acrylic mediums and painted glazes. Traveling throughout California where I take photographs of butterflies, other pollinators, and their habitat inspires me. I also sell some of the photographs that I take.

5. One of the central themes in my art is butterflies. When I began doing graphic design and photography in 2001, I was drawn to butterflies. Seeing a butterfly next to a flower reminds me of a fairytale. When I was in a photography class and I was told to find a subject matter, I gravitated towards butterflies because I think they are beautiful. Various traditions around the world view the butterfly as a spirit guardian. In Greek mythology, butterflies symbolized the

human soul; in Ireland, butterflies are known for their ability to shift between worlds; and Native American tribes believed butterflies carried wishes and prayers to the Great Spirit. Butterflies are also symbolic of transformation; the caterpillar's greatest power is to transform into a butterfly. I sell photographs, artwork, greeting cards, and puzzles of butterflies around the world. Most of my income comes from images I've created of butterflies and their landscapes.

6. I am concerned about the harm to butterflies and other pollinators posed by the United States Environmental Protection Agency (EPA)'s decision to register the new pesticides flupyradifurone, bicyclopyrone, and other pesticides without consulting with the United States Fish and Wildlife Service or the National Marine Fisheries Service (collectively, "the Services") on potential impacts to endangered and threatened species and their critical habitats. I understand that a variety of crops could be sprayed with flupyradifurone, bicyclopyrone, and the other pesticides involved in this case, including various citrus fruits, vegetables, strawberries, corn, wheat, cotton, and soybeans. I am also aware that this treatment is systemic in the plants and am concerned that butterflies that use these plants for food or come into contact with the plants will be harmed.

7. Aptos, the city I live in, is just Northwest of Watsonville. Watsonville is a large agricultural community where farmers grow mostly strawberries, but they also grow artichokes, berries, chard, spinach, and lemons. I am concerned that

flupyradifurone, bicyclopyrone, and the other pesticides involved in this case will be used on crops around Watsonville, which may harm threatened and endangered species of butterflies in Santa Cruz County.

8. I am an outdoor enthusiast who loves to go hiking and take pictures with my family. I drive down to Monterey County one to four times a month to hike and take photographs of butterflies and landscapes. My usual destination is Point Lobos State Natural Reserve, which is a scenic coastal area that features a variety of wildlife and hiking. I also frequently travel to Big Sur, Andrew Molera State Park, and Carmel, which are all in Monterey County. Whenever I go hiking and camping with my family, I bring my camera to take photographs of butterflies and landscapes. I mostly recreate in spring and summer because there are more opportunities to photograph butterflies during those seasons.

9. I have taken thousands of photographs of butterflies. I believe that I have seen many threatened and endangered species of butterflies, both near my home in Nisene Marks State Park, as well as when I take photographs in Point Lobos and Big Sur. One species of butterfly that I am particularly concerned about is the Bay Checkerspot butterfly (*Euphydryas editha bayensis*), whose habitat is limited to California and includes Monterey County and Santa Cruz County. The Bay Checkerspot butterfly has a similar orange color to the Monarch butterfly (*Danaus plexippus plexippus*), but its patterns are slightly different. I have seen

and photographed the Bay Checkerspot butterfly on my property. My property contains natural thistles and purple plants that the Bay Checkerspot butterfly feeds upon. I have also seen the Bay Checkerspot butterfly in Big Sur in 2012, when I went hiking and photographing for the day. There is one turnoff in Big Sur along the side of the road that is unmarked that I visit frequently because there are a lot of wild flowers that attract butterflies. I went to Big Sur each July in 2016-2018 and made three trips in the fall of 2018. There were hardly any butterflies in their usual wildflower location, which was very unusual.

10. I am also aware that there is a population of Bay Checkerspot butterflies between San Jose and Gilroy in the area around Coyote Valley. Because that is close to where I live in the neighboring county I often visit the area and I hope to see Bay Checkerspot butterflies when I visit. I plan to return to hopefully find and take more photographs of the Bay Checkerspot Butterfly in Santa Cruz, Monterrey, and Santa Clara Counties but I am concerned that EPA's registration of flupyradifurone, bicyclopyrone, and the other pesticides at issue in this case without consulting the Services will lead to further declines in Bay Checkerspot Butterfly. I frequently travel in the counties surrounding where I live and intend to continue visiting those areas for personal and professional visits into the future. I especially enjoy visiting those areas when I am able to see butterflies and often look for butterflies on my visits there.

11. I am also particularly concerned about the Monarch butterfly. The Monarch butterfly is currently under review to obtain a federal listing as threatened or endangered. I have seen and taken many photographs of monarch butterflies. The monarchs get the most attention because there is a monarch grove at Natural Bridges State Beach in Santa Cruz that provides monarch tours, and children go there on fieldtrips. Monarch butterflies used to swarm the plants and redwoods where I live, but every year I see less and less of the butterflies. We recently visited the Monarch Preserve in the fall of 2018 and there were a noticeably smaller number of butterflies. I was unable to photograph a large number of butterflies because they simply were not present.

12. As someone who creates artwork and photography for worldwide use in the greeting card and puzzles industries, with featured greeting card collections of butterfly photographs, the lack of available butterflies to photograph in their usual habitats along the central coast of California is very concerning and will impact my sales revenue and licensed artwork product placements in the retail industry. In October 2018, I had planned a photoshoot for a butterfly gown retailer and we were supposed to go to a wildflower field in Natural Bridges State Park and photograph the models surrounded by butterflies. The butterfly habitats here are very important and I know of several photographers who rely on seeing the butterflies in the park so they can photograph their clients (family, children, and

brides) in these beautiful locations with these beautiful creatures. Unfortunately, we had to cancel the photoshoot because there were no butterflies. We will try the photoshoot again this spring.

13. My personal, aesthetic, and recreational interests are being, and will be, adversely affected by EPA's decision to register flupyradifurone, bicyclopyrone, and the other pesticides involved in this case without consulting the Services because it may limit my opportunity to view the Bay Checkerspot butterfly and other threatened and endangered species of butterflies in the wild. I am aware that the EPA is required to consult with the Services prior to registering a pesticide if the pesticide may harm threatened and endangered species. I am also aware that EPA found that flupyradifurone and bicyclopyrone, and other pesticides may harm, directly or indirectly, federally-protected threatened and endangered species, but failed to consult. If the Bay Checkerspot butterfly, or any other species of butterflies, became extinct, I would not be able to observe and photograph them, which would injure my recreational, aesthetic, and personal interests.

14. Similarly, my professional and economic interests are being, and will be, adversely affected by EPA's failure to consult with the Services on potential impacts to endangered and threatened species and their critical habitats that may result from registrations of pesticide products containing flupyradifurone, bicyclopyrone, and the other pesticides involved in this case. I photograph and

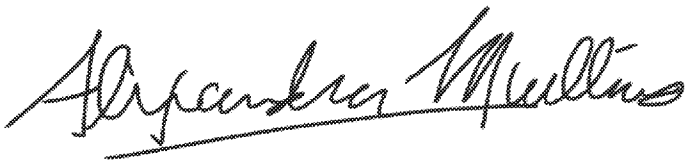
create images of butterflies to sell because it is a central theme in my artwork. If I go hiking and there are no butterflies, it impacts my business in a large way because I am unable to take new photographs of butterflies to sell. If any threatened or endangered species of butterfly were go to extinct, including the Bay Checkerspot butterfly, I would not be able to photograph and sell images of that butterfly, which would injure my business. In a substantial way, I rely on fashion photo-shoots of families in fields of wildflowers surrounded by butterflies in order to create and capture saleable images which will bring income to my small, locally owned photography studio: Alixandra Art & Photography Studios.

15. In sum, I am injured by EPA's decision to register flupyradifurone, bicyclopyrone, and the other pesticides involved in this case without consulting with the Services regarding impacts to listed species and their critical habitats, particularly in light of the fact that EPA determined that federally-protected threatened and endangered species may be impacted, including the Bay Checkerpsot butterfly and other species of butterflies. This decision harms my personal, aesthetic, recreational, professional, and economic interest in being able to observe and photograph threatened and endangered species of butterflies in their native habitats because the use of flupyradifurone, bicyclopyrone, and the other pesticides involved in this case may jeopardize species that I care about and intend

to see again. I am truly passionate about butterflies and other pollinators and I think the world will be in grave danger if these animals are not protected.

I declare under penalty of perjury that the foregoing is true and correct to the best of my ability.

DATED: February 21, 2019, in Aptos, California.



Alixandria Mullins

Declaration of Michael P. Senatore

I, Michael P. Senatore, declare as follows:

1. I am the Vice President for Conservation Law at Defenders of Wildlife ("Defenders"). I am also a member of Defenders. The facts set forth in this declaration are based on my personal knowledge. If called as a witness, I could and would testify competently thereto under oath.

2. Founded in 1947, Defenders is a non-profit membership organization with more than 1.8 million members and supporters. Defenders is headquartered in Washington, D.C., with field offices in Alaska, California, Colorado, Florida, New Mexico, North Carolina, Idaho, Montana, Oregon, Washington, and Mexico. Through my employment at Defenders over more than 20 years, I am familiar with nearly all aspects of its activities and organizational interests.

3. Defenders is dedicated to protecting native animals and plants in their natural communities. Defenders accomplishes its goals with partners at local, state, regional and national scales through demonstrated on-the-ground conservation, research, policy development, advocacy, and, when necessary, litigation. Defenders advocates sound, scientifically-based approaches to wildlife conservation that are geared to restoring imperiled species and preventing others from becoming threatened or endangered.

4. Defenders has long been concerned with the impacts of pesticides on wildlife and the ecosystems on which they depend. Through my own professional work, I have also been concerned with the impacts of conventional agricultural practices – including the widespread use of pesticides – on threatened and endangered species, water quality and human health.

5. Defenders involvement in pesticide issues goes back decades. In 1988, Defenders brought suit against the Administrator of the Environmental Protection Agency (EPA) and the Secretary of the Interior, challenging the continued registration of strychnine pesticides and rodenticides for above-ground uses. The U.S. Court of Appeals for the Eighth Circuit issued a decision in Defenders' favor. *Defenders of Wildlife v. Adm'r, E.P.A.*, 882 F.2d 1294 (8th Cir. 1989).

6. In 2004, Defenders expressed concerns about Bush administration proposals that would have essentially cut the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) out of the loop on EPA decisions regarding pesticide use. Defenders filed detailed comments opposing these Section 7 counterpart regulations, worked to generate public interest in and opposition to those proposals, and ultimately went to court to challenge those regulations. *Defenders of Wildlife v. Kempthorne,* No. 04-1230(GK), 2006 WL 2844232 (D.D.C. Sept. 29, 2006).

7. In 2006, Defenders published a report on "Pesticides and Endangered Wildlife." The report was offered to the press, made available to our members and supporters, and used to highlight both the impacts of pesticides on wildlife and the importance of the Endangered Species Act (ESA)'s Section 7 consultation provisions for protecting wildlife. https://defenders.org/sites/default/files/publications/pesticides_and_endangered_wildlife.pdf.

8. In 2010, Defenders brought suit over the use of Rozol prairie dog bait, an anti-coagulant rodenticide that EPA had approved without the required consultation under the Section 7 of the ESA. Our suit was aimed particularly at protecting the endangered black-footed ferret, a species which Defenders helped to reintroduce into the wild and which requires ongoing conservation and management. EPA's authorization of Rozol in black-footed ferret habitat threatened to undo much of that on the ground conservation work. The district court for the District of Columbia sided with Defenders, ruling that EPA had indeed violated the ESA by approving Rozol without first consulting with the FWS over the potential impacts of Rozol on ferrets and other threatened and endangered species. *Defenders of Wildlife v. Jackson*, 791 F. Supp. 2d 96 (D.D.C. 2011). The final order in the case barred use of Rozol in Montana, New Mexico, North Dakota, and South Dakota, required that Rozol's manufacturer notify its

distributors not to sell the product in those areas, and prohibited the manufacturer from selling or distributing existing stocks in its possession without relabeling it to reflect the ban in those four states. EPA also agreed to complete consultation with FWS over Rozol use in 10 states to prevent accidental injury to other listed species in the West.

9. Defenders has been particularly involved in efforts to protect salmon from the impacts of toxic pesticides. In 2010, Defenders joined the Northwest Center for Alternatives to Pesticides and the Pacific Coast Federation of Fishermen's Associations to defend a National Marine Fisheries Service (NMFS) biological opinion that required no-spray buffer zones and other measures to protect imperiled salmon from exposure to the organophosphate pesticides chlorpyrifos, diazinon, and malathion. These pesticides are known to contaminate waterways throughout California and the Pacific Northwest. Our intervention resulted in a ruling in 2011 upholding the biological opinion. https://defenders.org/press-release/judge-upholds-best-science-protect-endangered-salmon-pesticide-peril. The Fourth Circuit later vacated that opinion and remanded the biological opinion to NMFS for further consideration. *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462 (4th Cir. 2013). Defenders continues to advocate for implementation of a scientifically-rigorous biological opinion to protect salmon from pesticide impacts. We recently attempted to intervene in

another case related to this biop, but the court denied the motion. *Makhteshim Agan of N. Am., Inc. v. Nat'l Marine Fisheries Serv.*, No. 8:18-CV-00961-PWG, 2018 WL 5846816, at *1 (D. Md. Nov. 8, 2018).

10. Most recently, Defenders has been heavily involved in administrative efforts to improve interagency cooperation and make the ESA's Section 7 consultation process more efficient and effective in reviewing pesticides. Starting around 2012, and as described further below, Defenders began talking with industry leaders and Obama administration officials about ways to improve the consultation process and harmonize interagency approaches to reviewing pesticides.

11. Defenders was also instrumental in urging the National Academy of Sciences to review ongoing scientific disputes between the EPA and the FWS and NMFS. Defenders staff testified before the National Academy during public comment and ultimately issued a statement on the report's release. https://defenders.org/press-release/pesticide-report-leaves-tough-questions-unanswered. We also published a blog on the report on dotWild, the experts' blog for Defenders of Wildlife, in April 2013 to inform the public about the report and the questions that still needed to be resolved. http://experts.defendersblog.org/2013/04/new-report-on-pesticides-and-endangered-species-a-milestone-but-much-work-remains/.

12. In March 2014, Defenders joined with other conservation and food safety groups in alleging that EPA had failed to protect hundreds of endangered fish, butterflies and other species from a new toxic pesticide called cyantraniliprole. https://www.biologicaldiversity.org/news/press_releases/2014/pesticides-03-24-2014.html. The groups filed suit in June 2014, https://earthjustice.org/news/press/2014/groups-fight-to-protect-endangered-species-from-dangerous-new-pesticide, and ultimately won a decision that requires EPA to complete consultation for that pesticide. That consultation is ongoing.

13. In November 2017, Defenders drew public attention to an industry-driven effort that would have gutted federal safeguards for protecting threatened and endangered species from toxic pesticides. After obtaining a leaked copy of a draft bill the pesticide industry was shopping to members of Congress, Defenders prepared an analysis of the bill and generated news coverage that helped to stop the effort in its tracks. https://newsroom.defenders.org/industry-driven-bill-guts-federal-safeguards-protecting-endangered-species-from-toxic-pesticides/. This is not the first time Defenders has had to work to prevent efforts by pesticide manufacturers that could have undermined the ESA's consultation requirements. We routinely work to prevent riders to the Farm Bill on pesticide issues, attend congressional hearings on ESA and pesticide matters, and prepare materials for

members of Congress, their staff, and the public on the importance of the ESA's protections. *See, e.g.*, this fact sheet from 2011. https://defendersblog.org/wp-content/uploads/2011/05/ESA-pesticides-fact-sheet-FINAL.pdf.

14. On January 31, 2018, Defenders president Jamie Rappaport Clark issued a statement on a new memorandum of agreement setting up an interagency working group to develop recommendations for improving the consultation process for pesticides. https://newsroom.defenders.org/federal-agencies-launch-process-to-improve-evaluations-for-pesticides-and-endangered-species/. As was reported in the press in February 2018, Defenders staff have been and continue to work behind the scenes with pesticide manufacturers and the Trump administration to try to resolve concerns around the pesticide registration process and ensure adequate protections for wildlife. https://www.eenews.net/stories/1060073435.

15. As a result of those discussions, in April 2018, Defenders joined CropLife America and other agricultural interests in writing to the Secretaries of Interior, Agriculture, Commerce, and the Administrator of EPA outlining six key points of agreement for the interagency working group to consider. Specifically, we recommended that the working group: 1) Develop interagency processes on pesticide consultations that enable the EPA, services, and USDA to make the best use of each agency's expertise and limited resources; 2) Use more refined species location maps and better pesticide use data; 3) Adopt better endangered species

exposure assessments; 4) Take advantage of avoidance and minimization opportunities to improve the efficiency and effectiveness of pesticide consultations; 5) Support opportunities to use voluntary conservation in pesticide evaluations; and 6) Prioritize species-use combinations for formal consultation.

16. Defenders has expended considerable time and resources on finding ways to improve pesticide consultations while minimizing conflict with agricultural interests. These ongoing efforts to work with industry and the Trump administration demonstrate Defenders' deep commitment to finding common ground on pesticide issues to advance conservation outcomes for species without resort to litigation.

17. Increasingly, Defenders has had to bring its own science to bear on pesticide issues because of our concerns about the EPA's failure to complete pesticide consultations and adopt to the recommendations of the wildlife agencies. Through Defenders' Center for Conservation Innovation, which employs both GIS analysts and scientists, we are improving the effectiveness and efficiency of species threats analyses. https://defenders.org/maps. Our refined range mapping work will identify more precisely where pesticide use and species habitat areas overlap, which will both improve avoidance of pesticide application and help develop more precise recommendations for pesticide use. This work will result in both mapping tools and publications that can help policy-makers, scientists, and

the public to better conserve threatened and endangered species. https://home.cci-dev.org/#publications. We have undertaken this work at our expense to assist EPA and the wildlife agencies with tools that improve the effectiveness and efficiency of consultations and result in more scientifically-robust biological opinions.

18. Defenders has had to divert a significant amount of organizational resources in an attempt to counteract EPA's failure to engage in ESA section 7 consultations when it approves pesticides for use. If EPA had been engaging in the ESA consultation process Defenders would not have had to expend these organizational resources in a range of activities in an attempt to address EPA's illegal activity. Researching and analyzing pesticide use, its effects on endangered species, and legal obligations of EPA and pesticide registrants, among other things, has required a substantial amount of staff resources. Actions taken to educate and inform the public and decision makers on these issues in the form of press releases, educational materials, reports, communications, and other actions has further been a drain on limited organization resources that could have been dedicated to other conservation related actions.

19. Defenders brought the current case because EPA continues to unlawfully register pesticides for public use without complying with its consultation requirements under the ESA. EPA specifically noted that flupyradifurorne could harm wildlife protected under the ESA, including

butterflies, amphibians and birds, but nonetheless failed to complete consultation with the expert wildlife agencies.

20. Flupyradifurone is part of a new class of systemic insecticides that are taken up by the plant and transported to all plant tissues including leaves, flowers, roots, pollen and nectar. Systemic insecticides also include neonicotinoids, which numerous scientific studies have shown are one of the key factors driving the collapse of America's bee populations. *See, e.g.*, http://www.tfsp.info/worldwide-integrated-assessment/.

21. Defenders brings this case to further vindicate its organizational interests and the interests of its members around the country in protecting threatened and endangered species from the harmful impacts of pesticide use. Defenders' organizational interests and its members' interests in the conservation of threatened and endangered species will be injured if EPA fails to consult and implement reasonable and prudent measures to protect species from the harmful impacts of flupyradifurorne.

22. Defenders members have professional, aesthetic, recreational, and spiritual interests in the preservation of threatened and endangered species that could be imperiled by EPA's failure to ensure that its pesticide registration decisions do not jeopardize the survival of rare bees, butterflies, amphibians, and other species. EPA's failure to comply with the ESA increases the likelihood that

already imperiled species may further decline or even go extinct. Such a result directly impacts Defenders' mission to preserve such species for their own sake and for the sake of present and future generations.

23. EPA's failure to consult has also denied Defenders and its members important information that might have resulted from a scientifically-rigorous consultation process, including preparation of a biological opinion. Defenders uses that information to educate the public and inform its work with stakeholders to improve the pesticide registration process.

24. These concerns and injuries would be remedied if this court ruled in favor of Plaintiffs in this matter.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27th day of February 2019 in Washington, D.C.

MICHAEL P. SENATORE

DECLARATION OF JAMES D. WILLIAMS

I, James D. Williams, declare as follows:

1. I am over the age of 21 and currently reside in Gainesville, Florida, where I have lived for 31 years.

2. I have a PhD in Biology from the University of Alabama. I am retired from the U.S. Department of the Interior, U.S. Geological Survey, Biological Resources Division, and the Florida Fish and Wildlife Conservation Commission where my much of my work involved the biological research of aquatic species in the southeastern United States, especially as it related to the population and conservation status of those species. Previously, when I was a biologist for the U.S. Fish and Wildlife Service, I worked in the Endangered Species Office in Washington, DC, from 1974–1987 and was responsible for researching, evaluating, and proposing freshwater fishes for endangered and threatened status. I also served as the chief of the Biodiversity Branch, U.S. Fish and Wildlife Service and U.S. Geological Survey, in Gainesville, Florida. For approximately nine years I taught an annual workshop on freshwater mussels of the Apalachicola basin, Alabama, Florida, and Georgia. I have also received the Freshwater Mollusk Conservation Society Lifetime Achievement Award in recognition for singular accomplishments and long-term contributions that have advanced the conservation and science of

freshwater mollusks at a national and international level. I am currently a research associate in the Florida Museum of Natural History.

3. I have authored over 175 publications, reports, presentations, or books with a primary focus on mussels and fishes of the southeastern United States. For example, I was recently an author on articles of the conservation status of freshwater mussels in the United States and Canada. I was also primary author of the book "Freshwater Mussels of Florida" and "Freshwater Mussels of Alabama and the Mobile Basin in Georgia, Mississippi and Tennessee."

4. I have been a member of the Center for Biological Diversity since 2009. The Center is a nonprofit organization committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend. As a member of the Center, I participate in activities pertaining to endangered species issues. I helped organize the review of southeastern fishes and mussels included in a petition to the U.S. Fish and Wildlife Service to list those fishes and mussels under the Endangered Species Act. I also reviewed all the mussel taxa included in the petition, as well as some of the fishes. I rely upon the Center in part to represent my interests in protecting endangered species and their habitat, especially the aquatic species found in the United States.

5. I am particularly interested in the conservation of these aquatic species in the southeastern United States including the following:

Fishes

Percina antesella, Amber Darter
Cyprinella caerulea, Blue Shiner
Etheostoma wapiti, Boulder Darter
Etheostoma scotti, Cherokee Darter
Percina aurolineata, Goldline Darter
Acipenser oxyrinchus desotoi, Gulf Sturgeon

Mussels

Medionidus acutissimus, Alabama Moccasinshell
Elliptio chipolaensis, Chipola Slabshell
Medionidus parvulus, Coosa Moccasinshell
Amblema neislerii, Fat Threeridge
Hamiota altilis, Finelined Pocketbook
Medionidus penicillatus, Gulf Moccasinshell
Pleurobema taitianum, Heavy Pigtoe
Medionidus simpsonianus, Ochlockonee Moccasinshell
Pleurobema pyriforme, Oval Pigtoe
Elliptoideus sloatianus, Purple Bankclimber
Fusconaia rotulata, Round Ebonyshell
Hamiota subangulata, Shinyrayed Pocketbook
Pleurobema decisum, Southern Clubshell
Epioblasma penita, Southern Combshell
Ptychobranchus jonesi, Southern kidneyshell
Pleurobema georgianum, Southern Pigtoe
Ptychobranchus greenii, Triangular Kidneyshell
Epioblasma metastriata, Upland Combshell

6. I have worked in the southeastern United States, where these species occur, for the past 50 years. During this time I have sampled, studied, and published papers on most of the species listed in this declaration. I have observed these species and continue to participate in research projects involving most of them. I described or named 2 (*Etheostoma wapiti* and *Percina antesella*) of the 8 fishes listed in this declaration. As a research biologist I have participated in professional

meetings evaluating conservation status of southeastern freshwater mussels and fishes, including all taxa listed in this declaration.

7. I also have an aesthetic interest in these species and take joy in knowing that we have incredible aquatic biological diversity in the southeastern United States. The fact that many of these species are declining and we have lost forever numerous species does detract from my enjoyment of our aquatic biodiversity.

8. I believe very strongly that we have a moral obligation to pass on to future generations the incredible diversity that we have. Our aquatic biological diversity has inherent value and we have the responsibility to protect these species. Humankind does not have the right to eliminate or drive to extinction any living species.

9. The use of pesticides in and around watersheds inhabited by these species is harmful and reduces the likelihood that I will be able to observe and study them in the future. The broad application of chemicals on agricultural lands and the subsequent runoff into aquatic systems inhabited by these species exposes them to various levels of these chemicals. I think the impacts of pesticides are generally underestimated due to the pervasiveness and accumulative nature of some of the chemicals used. The fact that the Environmental Protection Agency has not thoroughly analyzed the chemicals and surfactants used in the application process for pesticides, how those pesticides affect ESA listed species, or consulted with the

U.S. Fish and Wildlife Service and National Marine Fisheries Service is also of great concern.

10. I will return to the habitats of these species in the coming years as I complete various research projects on the biology, evolution, and conservation of these taxa. In 2014 I completed a book on the freshwater mussels of Florida, which involved visiting the habitats of 8 of the mussel species included this declaration (*Medionidus acutissimus*, Alabama Moccasinshell; *Elliptio chipolaensis*, Chipola Slabshell; *Amblema neislerii*, Fat Threeridge; *Medionidus penicillatus*, Gulf Moccasinshell; *Medionidus simpsonianus*, Ochlockonee Moccasinshell; *Pleurobema pyriforme*, Oval Pigtoe; *Elliptoideus sloatianus*, Purple Bankclimber; and *Hamiota subangulata*, Shinyrayed Pocketbook; *Fusconaia rotulata*, Round Ebonyshell; and *Ptychobranchus jonesi*, Southern kidneyshell). The remaining species (*Medionidus parvulus*, Coosa Moccasinshell; *Hamiota altilis*, Finelined Pocketbook; *Pleurobema taitianum*, Heavy Pigtoe; *Pleurobema marshalli*, Flat Pigtoe; *Pleurobema decisum*, Southern Clubshell; *Epioblasma penita*, Southern Combshell; *Pleurobema georgianum*, Southern Pigtoe; *Ptychobranchus greenii*, Triangular Kidneyshell; and *Epioblasma metastriata*, Upland Combshell) will be included as part of a study of the impacts of impoundments on freshwater mussels in the southeastern United States. In addition to these mussels, 2 fishes in this declaration (*Cyprinella caerulea*, Blue Shiner and *Acipenser oxyrinchus desotoi*,

Gulf Sturgeon) will also be included in this study. Rivers inhabited by these species will be visited to evaluate existing habitat and impacts of dams. Streams inhabited by the remaining fishes in this declaration (*Percina antesella*, Amber Darter; *Etheostoma wapiti*, Boulder Darter; *Etheostoma scotti*, Cherokee Darter; and *Percina aurolineata*, Goldline Darter) will be visited during the next year as part of a long-term conservation evaluation of endangered and threatened fish habitat.

11. Because my research work has included these species, any further decline of any of these taxa would affect my current and future research.

12. My interests in these species have been, and will continue to be, harmed by the Environmental Protection Agency's failure to consult with the U.S. Fish and Wildlife Service on pesticide impacts. As a federal agency, EPA is required to consult with the U.S. Fish and Wildlife Service on any federal actions that might affect federally listed species and their critical habitat. Their failure to do so is a violation of the Endangered Species Act.

13. Without consultation with the U.S. Fish and Wildlife Service, the Environmental Protection Agency cannot understand the full environmental impacts of the pesticides that it authorizes. As a result, the Environmental Protection Agency has not taken all available steps to ensure that pesticides do not harm or kill endangered and threatened species.

14. In sum, my interest in these species ranges from purely aesthetic to research and conservation. I also believe that we have a moral obligation to protect these species from further decline and extinction. My interests are being harmed by the Environmental Protection Agency's failure to consult with the U.S. Fish and Wildlife Service on impacts of pesticide registrations on these species. Specifically, I believe that the Environmental Protection Agency's failure to follow the law makes these species more likely to suffer further population declines. If these species decline or become extinct, this loss would deprive me of the benefits I currently receive from the existence of these rare animals. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of pesticides on these species, which is important to ensure that my interests in these species are preserved and remain free from injury.

I declare under penalty of perjury that the foregoing is true and correct. Executed on 20 Feb 2019 in Gainesville, Florida.

James D. Williams PhD

DECLARATION OF ANDY WOOD

I, Andy Wood, declare as follows:

1. I am over eighteen and currently reside in Hampstead, NC, where I have lived for 13 years.

2. I have a Bachelor's of Science degree in Wildlife management from Texas A&M University (1981). From 1987-2000, I served as the Curator of education for the North Carolina Aquarium at Fort Fisher and subsequently worked for 11 years as the Education Director for Audubon North Carolina. I am now director of the Coastal Plain Conservation Group, a North Carolina non-profit organization established to provide ecosystem research and habitat management, with special attention to protecting threatened and endangered species in southeastern North Carolina's longleaf pine, pocosin, and bottomland swamp forests.[1] Coastal Plain Conservation Group also purchased and manages a 10.5 acre tract of longleaf pine habitat, previously threatened with being converted entirely into horse pasture, to benefit hundreds of plant and wildlife species that comprise the community of life sharing the biodiverse longleaf pine habitat, including the red-cockaded woodpecker (*Picoides borealis*), and Carolina gopher frog (*Rana capito capito*).

[1] Coastal Plain Conservation Group, https://coastalplaincg.org/

3. I am also Landscape Ecologist and Community Conservation Consultant with Habitats Gardens, LLC, an environmental conservation consulting company that provides services to business and industry involved in developing and maintaining our built environments and the infrastructures that support them. In addition to my professional career I have provided nature commentaries for public radio station WHQR for more than 25 years, which were compiled into the book "Backyard Carolina: Two Decades of Public Radio Commentary" published in 2008.[2]

4. Part of my research has involved research into pollution and the impacts on wildlife. For example, I led an exhaustive study of derelict fishing gear with emphasis on impacts of ghost crab pots on diamondback terrapins, a small saltmarsh turtle. One of my first assignments in the environmental field in 1970, helped document pollution from a chemical plant discharging raw waste into a Connecticut stream.

5. Since 1992, I have also led research and protection efforts to prevent the extinction of imperiled species of invertebrates and in particular, freshwater snails once found in streams and beaver ponds in southeastern North Carolina. Specifically I have studied and worked to protect the last living members of two

[2] https://www.whqr.org/people/andy-wood

freshwater species of snails: the magnificent ramshorn (*Planorbella magnifica*) and a related species called the Greenfield ramshorn (*Helisoma eucosmium*).

6. I have been a member of the Center for Biological Diversity since 2010. The Center is a non-profit organization committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend. As a member of the Center, I respond to action alerts and keep up with North Carolina activities. I rely in part upon the Center to represent my interests in protecting endangered species and their habitat, especially North Carolina species. I appreciate the Center's work to get wildlife protected under the federal Endangered Species Act because it provides crucial tools for the protection and recovery of endangered species.

7. I am concerned about the impacts of pesticides on endangered and threatened aquatic species, including the Cape Fear shiner (*Notropis mekistocholas*), and magnificent and Greenfield ramshorn snails. In addition to my concern about the impacts of pesticides to aquatic species, I am also concerned about land-based pesticide impacts to endangered plants and wildlife such as the red-cockaded woodpecker, rough-leaved loosestrife (*Lysimachia asperulaefolia*), wood stork (*Mycteria americana*), rare skipper (*Problema bulenta*), southern hognose snake (*Heterodon simus*), and Carolina gopher frog (*Lithobates capito capito*). Pesticides pose an insidious and often poorly understood threat to people,

wildlife, and the habitats we share. Many pesticides are used without full understanding of their long-term impacts. Pesticides have been proven to have endocrine disrupting impacts on wildlife and people, especially when different pesticides are used in the same area or mix in a waterbody such as a retention pond, river or lake.

8. I have a deep personal and professional appreciation for all wildlife, but especially for aquatic wildlife. My work studying and protecting some of the last known populations of the magnificent and Greenfield ramshorn snail has been recognized by the United States Fish and Wildlife Service for its importance in saving the species from extinction.[3] These rare snails are on the brink of extinction – pushed out of its natural habitat by the loss of its freshwater habitat from intrusion of salt water and loss of beaver ponds. During the storm brought by Hurricane Fran that hit North Carolina's coast in 1996, I rescued as many of the magnificent ramshorn as possible from the refuge I had built in my backyard—the last place on earth the rare snail was known to exist at the time. I have created a snail sanctuary, now consisting of several 300 gallon tank ecosystems, and learned how to maintain a population of ramshorns snails in captivity. While the snails have been successfully breeding in captivity, the wild population, if one still exists,

[3] One Man's Mission to Save a Magnificent Mollusk, Sarah McRae, U.S. Fish and Wildlife Service, https://www.fws.gov/endangered/news/episodes/bu-Spring-Summer2014/story1/index.html

has continued a slow and steady decline. A magnificent ramshorn has not been observed in the wild since 2004 and it is now believed that the snail may now only exist in captivity.

9. I live in the lower Cape Fear River basin located in the coastal plain of southeast North Carolina. I conduct research in and around the lower Cape Fear River focusing on birds, diamondback terrapins, and two critically rare freshwater endemic snails: the magnificent ramshorn and Greenfield ramshorn.

10. My work involves diligent sampling of aquatic and terrestrial habitats to confirm population presence/absence of expected or predicted species. My interest with wildlife includes the study of how species use habitats during all or part of their full life cycle, including salamanders and frogs that require aquatic habitat as nursery for eggs and larvae, and terrestrial habitat for juvenile and adult life stages. I also study the interactions of predators and their prey, including fishes and the invertebrates they eat, and birds and the fishes they eat. My work also includes study of anadromous American eels (*Anguilla rostrata*) and an eel-eating snake called the rainbow snake (*Farancia erytrogramma*) a reptile in decline due to habitat loss and decline of eels; the snake's primary prey.

11. Because I live and research in the Cape Fear River basin, I have explored many areas of the Cape Fear River, including much of the intact bottomland swamps extending from the piedmont to the coast, and intend to

continue visiting those areas in the future for my personal enjoyment and professional work. I sometimes travel to the Cape Fear shiner's habitats, and I consider their habitats crucial to the integrity of the Cape Fear River and its associated plants and wildlife they support. In addition to being important to the Cape Fear Shiner, riverine swamps provide essential habitat for the wood stork that uses Cape Fear river swamps during all or part of their full life cycle. As predators of aquatic animals negatively impacted by pesticide biomagnification, storks are especially vulnerable to consequences of pesticide biomagnification.

12. I would love to see the Cape Fear Shiner, and I have tried to observe the species. I searched for the species in its natal habitats during the early 1990s, while I was developing the storyline for an Aquarium exhibit. I knew the species was known from the areas I explored but its scarcity prevented me from finding any specimens. I intend to continue looking for the Cape Fear shiner and wood stork on my future travels in the Cape Fear river basin.

13. In addition, I regularly visit North Carolina State parks that have property in and around the range of the Cape Fear shiner, wood stork, and ramshorn snails. My visits to those parks are enriched by my knowledge that the species dwells there and I will continue to return to them in the future.

14. I am aware that agricultural activities have contributed to the decline of many native wildlife species. Agricultural activities have led to the conversion

of natural habitat and resulted in elevated nutrient and pesticide levels in streams and ground water from runoff or infiltration of manure, fertilizer, or pesticides. I know that corn, soy, wheat, cotton, peanut, sweet potatoes, and hay are major crops in North Carolina and that the pesticides used on those crops can harm wildlife, including threatened and endangered species. I am concerned with the amount of pesticides used in North Carolina and the negative effects it has on wildlife and the recovery of threatened and endangered species.

15. In the future, I will continue to seek out opportunities to observe native wildlife in North Carolina, including species such as the Cape Fear shiner ramshorn snails, wood stork, red-cockaded woodpecker, rough-leaved loosestrife, rare skipper, and southern hognose snake. My work as a conservation educator requires me to explore and observe habitats and the plants and wildlife they support in many areas in North Carolina, to help me write articles for popular and scientific journals, along with educational programs for other media including television and radio. I also lead outdoor explorations for organized groups, to introduce people to the habitats and ecosystem services they provide to the benefit of people, plants and wildlife. In short, my livelihood depends on having access to intact and healthy habitats that support wild species in their natural environments and I plan to continue visiting those natural areas in North Carolina for personal and professional benefit.

16. I am interested in threatened and endangered species from many perspectives, especially as an ecologist and educator. Much of my work as a professional ecologist and educator has to do with the lower reaches of the Cape Fear River. It is my belief that the future of endangered species, such as the Cape Fear Shiner, portends the future of species inhabiting the lower reaches river systems in North Carolina. This especially applies to Wood Stork, American Alligator (*Alligator mississippiensis*), and Bald Eagle (*Haliaeetus leucocephalus*), a species protected by the Bald and Golden Eagle Protection Act, and an apex riverine predatory species. As an educator, I lead numerous guided treks on the Cape Fear River and its tributaries Northeast Cape Fear River and Black River. Participants in these trips are enthralled by the sighting of Bald Eagle, Wood Stork, and American Alligator.

17. As an ecologist I am interested in the smaller and less glamorous species, including obscure snails and fishes. The lower trophic level species are the first indicators of health and stability of ecosystems. The Cape Fear Shiner and ramshorn snails are in a sense, "canaries in the coal mine." They are also keystone species that, combined with other related species, provide ecosystem services from nutrient cycling in aquatic habitats, to being in turn, food for larger species that people pursue and capture for food or recreation. As an indicator of environmental health, we need to assure their long-term perpetuity if only to be sure the same

environment that sustains endangered species is also healthy enough to sustain people. As an example, the plight of imperiled ramshorn snails and Cape Fear shiner tells us there is something wrong with riverine swamps that support them and us. In the case of the Cape Fear shiner, evidence suggests a direct correlation between chemical contaminants, including pesticides and fertilizers, and decline of shiner health. Other Cape Fear River keystone species include American Alligator, an apex aquatic predator of fishes, amphibians, other reptiles (turtles especially), and mammals.

18. I believe people have a responsibility to minimize our negative impacts on the environment and when our activities are shown to be detrimental to the environment we inhabit, it is an ethical responsibility for people to correct the problems we create. I feel I am as beholden to the magnificent ramshorn as the Cousteau Society is to the blue whale.

19. My spiritual connection to the environment is very personal. I have spent a lifetime exploring the natural world around me as a source of wonderment and knowledge. When species or habitats are lost, I feel the loss as a librarian might feel the loss of a book, or a reader might feel the loss of a chapter. Regardless of considerations pertaining to a Creator, as a species itself, thinking, sentient humans are smart enough to know we must protect the integrity of our planet's natural systems if we hope to survive into the future.

20. I find joy in knowing that endangered species, such as the Cape Fear Shiner, ramshorn snails, red-cockaded woodpecker, rough-leaved loosestrife, rare skipper, and southern hognose, snake still exist even when I don't have the opportunity to observe one. But if I see one in the wild, I know I will be moved, in both a scientific and spiritual manner. As a conservation educator working to introduce people to nature outdoors, my programs are highlighted and made more meaningful when my program participants observe Bald Eagle, Wood Stork, American Alligator, and endangered species.

21. I believe humans are the single greatest change agent in respect to habitats and the ecosystem services they provide to our benefit. I believe the future of humanity is tied to the future of biodiversity because we are at the top of all major multi-trophic ecosystem food chains. We depend on wild plants and animals for our continued survival; few, if any, wild species are inextricably dependent on humans for their survival. Protecting the health and well being of ecosystems and the plants and animals that inhabit them is only a moral obligation if we have a moral obligation to protect humanity. Endangered species are an essential part of this biodiversity, and its loss would be both a moral and ethical loss.

22. For these reasons, I would be deeply saddened and harmed if the Cape Fear shiner, ramshorn snails, red-cockaded woodpecker, rough-leaved loosestrife, rare skipper, bald eagle, wood stork, American alligator, Carolina gopher frog, and

southern hognose snake were to suffer further declines or even become extinct because of pesticide impacts or other threats.

23. As someone who is deeply concerned about the fate of imperiled wildlife, I am upset that the Environmental Protection Agency has refused to consult with the U.S. Fish and Wildlife Service about the impacts of pesticide registrations on endangered species. I believe that the EPA has a regulatory responsibility to investigate impacts of pesticides to the fullest of their abilities, including consulting with other agencies and organizations to learn what is known about pesticide impacts. Without consultation, the Environmental Protection Agency cannot understand the full environmental impacts of its actions or inactions. As a result of their inaction, the Environmental Protection Agency has not taken all available steps to ensure that use of pesticides does not, or will not, harm or kill species of ecological value and human benefit.

24. In sum, I have professional, aesthetic, spiritual, and scientific interests in the preservation of the Cape Fear Shiner, ramshorn snails, red-cockaded woodpecker, rough-leaved loosestrife, rare skipper, bald eagle, wood stork, American alligator, Carolina gopher frog, and southern hognose snake, 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 regarding impacts of pesticide registration 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 the species declines or becomes extinct, this loss would deprive me of the benefits I currently enjoy from the mere existence of these very rare animals. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of pesticides on this species, which is important to ensure that my interests in the species are preserved and remain free from injury, as well as ensuring the interests of human health are considered and held to account.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21 2019, in Hampstead, NC.

ANDY WOOD

Andy Wood