No. 17-70196

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PETITIONERS' OPENING BRIEF (REDACTED)

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

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JURISDICTIONAL STATEMENT

This case is a petition for review of a pesticide approval by the United States Environmental Protection Agency (EPA). This Court has jurisdiction under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides for review in the courts of appeals of "any order issued by the [EPA] Administrator following a public hearing," 7 U.S.C. § 136n(b), [1] which this Court has interpreted to include holding public notice and comment, *United Farm Workers of Am. v. Envt'l Prot. Agency*, 592 F.3d 1080, 1082-83 (9th Cir. 2010). EPA solicited and responded to public comments prior to approving the challenged XtendiMax registration. *See infra* n.5. Petitioners were "a party" to the EPA proceedings, having submitted comments, and are "adversely affected" by EPA's approval of XtendiMax use on dicamba-resistant cotton and soybean. 7 U.S.C. § 136n(b); ER485-553; ER572-75; ER576-602; ER473.

Petitioners have standing. Parties have Article III standing if they are under threat of suffering an injury-in-fact that is concrete and particularized; the threat is actual and imminent, not conjectural or hypothetical; the injury is fairly traceable to the challenged action; and it is likely that a favorable decision will redress the injury. *Friends of Earth, Inc. v. Laidlaw Envt'l Serv. (TOC), Inc.*, 528 U.S. 167,

[1] All pertinent statutory provisions, regulations, and rules are included in the attached Statutory and Regulatory Addendum (A2-89). 9th Cir. R. 28-2.7.

180-81 (2000). Public interest organizations like the Petitioners have representational standing "when its members would otherwise have standing to sue in their own right, the interests it seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). EPA's challenged actions threaten to directly injure Petitioners' members' environmental, vocational, agricultural, recreational, aesthetic, and economic interests. *See* Bentlage Decl. ¶¶ 2-17; Buse Decl. ¶¶ 1-13; Crouch Decl. ¶¶ 2-14; Griffith Decl. ¶¶ 1-9 ; Ishii-Eiteman Decl. ¶¶ 1-11; Kimbrell Decl. ¶¶ 6-12; Newman Decl. ¶¶ 1-18; Suckling Decl. ¶¶ 2-11 (A93-147).[2]

Petitioners timely filed this petition for review. Order, ECF No. 23; ECF No. 12-1; 7 U.S.C. § 136n(b), 40 C.F.R § 23.6.

ISSUES PRESENTED

1. Did EPA violate FIFRA by approving XtendiMax:
   - using the wrong legal standard;
   - without quantifying, analyzing, or including in its analysis the socioeconomic costs of XtendiMax's drift impacts;

[2] The declarations are contained within the attached Addendum of Declarations (A92-147).

- without supporting the efficacy and feasibility of its drift mitigation measures with any data, analysis, or rationale;
- relying on Monsanto's assurances rather than EPA's own analysis; and
- in the face of significant yet unaddressed volatility risks?

2. Did EPA violate the Endangered Species Act (ESA) by failing to consult the expert wildlife agencies concerning XtendiMax's effects on threatened and endangered species and their critical habitats, despite ample evidence and the agency's admissions that its approval decision "may affect" them?

STATEMENT OF THE CASE

This action concerns a pesticide Intervenor Monsanto developed, M1768 or "XtendiMax with VaporGrip Technology" (XtendiMax), containing the weed-killing active ingredient, dicamba. *See* Excerpts of Record (ER) 002. While dicamba has been sold in other forms since 1967, ER742, XtendiMax is a "new use" registration, ER003-4, because Monsanto sought approval from EPA for an entirely novel use of it: direct, "post-emergent" application to cotton and soybean plants that Monsanto genetically engineered (GE) to survive dicamba spray. ER003-4.

I. XTENDIMAX AND GENETICALLY ENGINEERED CROPS.

Because dicamba is extremely toxic to natural cotton and soybean, the pesticide previously could be used only before these plants sprouted ("pre-emergent"), to clear a field of early season weeds. ER003-4. Genetically engineered dicamba resistance enables Monsanto's GE crops to be sprayed much later in the season, without harming the crop. ER003. Monsanto markets patented GE dicamba-resistant seeds, which are also resistant to Roundup herbicide, together with XtendiMax, as the "Roundup Ready Xtend Crop System."[3]

This crop system is Monsanto's "solution" to a problem it created. ER782-87; ER278-79. For 20 years, Monsanto has sold Roundup and seeds genetically engineered to resist Roundup's active ingredient, glyphosate. This "Roundup Ready" crop system has dramatically and controversially increased the overall pesticide output into our environment. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 841 (9th Cir. 2013); ER782-87. It also caused a related problem: Monsanto told farmers they could rely entirely on Roundup without weeds becoming resistant to glyphosate, contrary to weed science experts' warnings. ER552-53. But as with overusing antibiotics, Roundup overuse generated an

[3] *See* Roundup Ready® Xtend Crop System, https://www.roundupreadyxtend.com/Pages/default.aspx (last visited Feb. 8, 2018).

epidemic of glyphosate-resistant "superweeds" now infesting an estimated 100 million acres of U.S. cropland. ER595-96.

Monsanto's new business model consists of genetically engineering soybean and cotton to resist both dicamba and Roundup, enabling both to be sprayed freely without killing the crops. ER782-87. Although Monsanto presents the ability to kill glyphosate-resistant weeds with dicamba as a quick fix to the glyphosate-resistant weed epidemic, many experts predict its addition of dicamba resistance will massively increase dicamba use—nearly a 100-fold increase on soybean use alone (without glyphosate reductions)—and simply foster rapid evolution of still more intractable weeds, resistant to both.[4]

II. PROCEDURAL HISTORY: THE PROPOSED APPROVAL RAISES SIGNIFICANT DRIFT DAMAGE CONCERNS.

Monsanto first sought registrations for dicamba new use on GE soy and cotton in 2010 and 2012, ER003, originally seeking registration of a different dicamba pesticide, M1691. ER002. EPA held notice and comment several times from 2010 to 2016. ER002-3.[5] Commenters, including farmers, scientists, and conservationists supplied EPA with studies, expert opinion, and practical

[4] ER594; ER474-84; ER782-87; *see* ER635 (EPA's benefits assessment acknowledging continued use of glyphosate).

[5] ER627-28; 77 Fed. Reg. 75,153 (December 19, 2012); 77 Fed. Reg. 50,686 (August 22, 2012); 75 Fed. Reg. 51,045 (August 18, 2010).

experiential evidence warning of devastating impacts from dicamba's notorious tendency to drift off-site.[6]

The record contains copious evidence EPA knew XtendiMax posed serious risks of substantial harm to crops and other plants due to dicamba's long history of drift-related crop injury, its great volatility,[7] and many plants' extreme sensitivity to it. ER793-94, 799-803; ER742-43, 755-57; ER721-25; ER476-81; ER558-61; ER776-78. Volatile pesticides like XtendiMax evaporate from soil and plant surfaces hours to days after application, forming vapor clouds that drift and damage plants far from the application site. *See* ER347-51; ER358, 361-62; ER560. Thus the new use would dramatically increase crop injury from spray drift and vapor drift,[8] by sharply increasing dicamba use and promoting use later in the season, when it is warmer and crops are more susceptible to damage. ER560. The combination of these factors would lead to devastating consequences.

EPA was also informed the new dicamba uses might harm hundreds of endangered species and their critical habitats, as well as the environment generally.

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[6] *See* ER473-626.

[7] Vapor drift is largely a function of the pesticide's volatility and weather conditions, beyond a farmer's control. ER361-62; ER560. Spray drift (pesticide droplets blown by the wind during application) also cannot be entirely prevented. *See* EPA, *Pesticide Volatilization*, https://www.epa.gov/reducing-pesticide-drift/pesticide-volatilization (last visited Feb. 8, 2018).

[8] "Drift" as used alone means either vapor drift or spray drift or both.

ER576-90; ER492-500. The registration allows the pesticide's application on millions of acres in 34 states, and EPA knew that protected animals such as the whooping crane and grey wolf feed in sprayed crop fields, ER657, 666, and that hundreds of other endangered plants and animals are found near those fields, and will be threatened by drift. ER694-701. Others warned dicamba drift threatens flowering plants that provide nectar for pollinators and habitat for other species. ER500-01.

EPA nonetheless granted new use approval in November 2016, ER001-2, beginning a 2-year, 34-state field experiment, based on the supposition that XtendiMax is less volatile than prior dicamba formulations,[9] erroneously declaring that this, and detailed use instructions to mitigate spray drift, would "eliminate any offsite exposures." ER029; *See* ER035; ER368 ("The 2-year expiration was put in place because of the concerns about resistance and off-target movement"). EPA included a lengthy label containing use restrictions, such as tractor speed, wind

[9] M1768/XtendiMax itself was never subject to public comment (only M1691, an earlier formulation without the "VaporGrip" component). ER002. Moreover, despite that pesticide firms as a matter of course permit independent scientists to conduct tests on new products, Monsanto took the extraordinary step of prohibiting any XtendiMax drift testing by independent scientists, even though it allowed such independent testing for the pesticide's weed-killing efficacy. ER360.

direction, buffers, spray boom height, and temperature and humidity adjustments, which the agency claimed would "effectively limit" any impacts. *See* ER029-59.

Instead of consulting the expert wildlife agencies about potential harm to hundreds of endangered plants and animals and their critical habitats to "insure" none are jeopardized by the registration, as the ESA requires, EPA performed its own analyses. Using methods contrary to the ESA and assumptions lacking any scientific basis (and since proven grossly inaccurate)—*e.g.*, dicamba *would not drift at all*—EPA made the unprecedented finding the registration would have "no effect" on any of hundreds of species or habitats, leaving the expert agencies with no voice whatsoever.

Petitioners filed this petition for review on January 20, 2017. ECF No. 1-5. Petitioners moved to expedite, ECF No. 32-1, which the Court granted in part, ECF No. 61-1, while EPA took nearly a year to produce the administrative record, ECF No. 13-1 (EPA motion to extend deadlines, February 24, 2017), ECF No. 63-1 (Dec 6, 2017 filing of the initial record index).

III. THE 2017 FARMING SEASON: AN UNPRECEDENTED CATASTROPHE.

Farmers began using Monsanto's XtendiMax for the 2017 planting season. The results were disastrous. By early July, EPA's herbicide branch chief emailed EPA staff: "As I am sure all of you are aware, extremely large numbers of complaints of crop damage are being received by a number of states...." ER445. By

July 19, 2.5 million acres of soybean alone had been officially reported as damaged by dicamba drift, ER419; rising to over 3 million acres in 16 states by August, ER359-60. And these figures were substantial underestimates, as plant scientist Dr. Kevin Bradley told EPA: "[f]or every one incident case that is submitted, there are 5 that aren't." ER449. Weed scientist Aaron Hager informed EPA that an astounding 50% of the non-dicamba-resistant soybeans were injured in Illinois. ER442. Many other crops also have been damaged, including tomatoes, melons, fruit and nut trees, and vegetables, as well as residential gardens, shrubs and trees; the flower and nectar of many of these crops are vital food sources for pollinators. ER382-91; ER439, ER122; ER183-87. According to Dr. Bradley, "[w]e have never seen anything like this before … in our agricultural history." ER375.[10]

Dicamba drift threatens farmers' livelihoods, for instance by slowing soybean growth and reducing yields, costing farmers millions. ER449-50; ER442-44; ER358-61; ER372-73. Farmers were pressured to purchase patented GE dicamba-resistant soybean at a huge premium (ER356) just "to protect themselves" from dicamba drift. ER289; ER397-404; ER178 (customers switching to dicamba-resistant soybean "as a defensive measure"); ER424. The damage tore

[10] EPA was well aware of the unfolding crisis, sharing newspaper and wire reports, yet took no action. ER280-84; ER355-63; ER395-404; ER189-91; ER379-81; ER291-92; *see* ER369 (stating that EPA was "waiting on registrants to voluntarily [take action]").

apart rural communities, pitting farmer against farmer. University of Tennessee's Dr. Larry Steckel said dicamba damage has divided agriculture "like nothing I've seen," pointing to "angry" growers whose fields have suffered drift damage two or three times. ER444.

University scientists affirmed volatility, or vapor drift, as "one of the major routes" of dicamba drift injury, concluding that "our air sampling data, field volatility studies and field visits indicate that to be the case." ER378. Dr. Bradley called Monsanto's contrary claims "disingenuous at best," ER378, and shared with EPA extensive volatility test results, ER293-345, showing that, contrary to Monsanto's claims, XtendiMax volatilized "for as many as 3 or 4 days following the application." ER377-78, ER361-62 (university field test illustrating XtendiMax volatilization).

Numerous state agricultural departments reported to EPA ongoing extensive damage. ER454. University scientists expressed unanimous concern that dicamba is more volatile than manufacturers admitted. ER359-62. One of the chief messages from state and academic experts was that the label restrictions *do not work because they do not address volatility*. ER442-44; ER423 ("[B]uffers don't resolve the problem."); ER293-345 (45 pages of independent vapor drift testing by universities); ER390-91 (list of dicamba-sensitive species); *see also* ER90-91 (85 pages on how drift impacts yield). Experts visited many Missouri farmers "who

have done [dicamba application] right and still experienced" vapor drift off their fields. ER376.

At a late August meeting, EPA previewed label amendments for state officials, ER369, and the experts again responded the data "are pointing to volatilization. Many others have the same data" and "there's nothing we can do for a volatile product as far as label changes," *id.*

IV. EPA AND MONSANTO'S RESPONSE.

In August 2017, EPA briefly considered state experts' recommendations to prohibit dicamba applications after a spring "cutoff date" as the only sure means to mitigate vapor drift damage, but after Monsanto opposed it, ER355, EPA rejected this solution. ER284, ER288 (Dr. Hartzler: "Monsanto and BASF are fighting restrictions because they would 'greatly reduce the value' of their chemical and seed systems").[11]

When EPA finally acted months later, it took its orders not from the states or their experts but from Monsanto, repeatedly meeting with its lawyers and officials about how to quell the uproar. *See* ER352. [redacted]

[11] When EPA refused to require measures to address volatility, several states passed restrictions to address vapor drift, such as spray cut off dates and temperature limits. *See* AGFAX, *Dicamba, 2018: States Struggle with Application Restrictions*, http://agfax.com/2017/12/14/dicamba-2018-states-struggle-with-application-restrictions-dtn/ (December 14, 2017) ("Most of the state-by-state changes are being made, they stated, because the federal EPA labels do not address herbicide volatility.").

[redacted]; ER172-74, and Monsanto informed EPA what the "Terms and Conditions" of that new label would be, ER170-71. When EPA sent it back to Monsanto, EPA confirmed it was exactly what Monsanto had asked for. ER123 (EPA official to Monsanto: "like I said, no surprises."). In fact, when EPA tried to suggest changes to the terms and conditions, ER167-69, Monsanto dictated which suggestions would be acceptable. ER165-66.

Finally, on October 12, 2017, EPA and Monsanto amended the registration and added Monsanto's new label amendments—more applicator training, greater record-keeping burdens, and a ban on spraying dusk to dawn—none of which addressed the key issue numerous experts had pointed to: volatility and vapor drift. *See* ECF No. 57-2.

EPA declared this revised document "did not affect the conclusions in the supporting assessment of risk," and that, rather than provide *any* new data or analysis supporting the new measures' efficacy, EPA "continues to rely on all the assessments" supporting the original registration, and thus the decision "does not require a revised endangered species effects determination, nor any other new risk assessment." ECF No. 57-2 at 1; *see also* ECF No. 57-1 (same). Petitioners amended their petition for review to encompass this further EPA decision. ECF Nos. 62; 68.

SUMMARY OF ARGUMENT

In its rush to approve XtendiMax, EPA ignored and violated numerous FIFRA mandates. First, EPA applied the wrong legal standard, and never made the statutorily-mandated findings, for a conditional approval of a pesticide new use. EPA approved XtendiMax based on its conclusion that it would not cause unreasonable adverse effects on the environment, when it should have weighed simply whether the pesticide's new use would significantly increase the risk of such unreasonable adverse effects occurring. Second, EPA failed to analyze and weigh the significant socioeconomic and agronomic costs to farmers of destructive dicamba drift. Instead, and third, EPA relied solely on label conditions for mitigation, which was catastrophic, because the label conditions did not address vapor drift. In fact, and fourth, EPA removed the only initially-proposed label provision addressing vapor drift, relying on legally inadequate data. Fifth, EPA also unlawfully assigned to Monsanto EPA's statutory responsibility to approve XtendiMax's foreseeable use in tank mixes.

Finally, after the catastrophic 2017 farm season, EPA amended the label conditions with revisions, but without any data, analysis, or even rationale of why these additions would be successful where its initial conditions failed. Instead EPA continued to rely unlawfully on its prior analyses and determinations, even though they have now been proven tragically flawed. Worse, again EPA failed to address

the key problem: XtendiMax's volatility and consequent vapor drift. And even for the lengthy, non-vapor drift measures EPA did include, the agency never analyzed or supported with substantial evidence their efficacy or feasibility in real world farming conditions. The predictable result of EPA recklessly pushing to market a product well known to drift on to neighboring plants and damage them has been millions of acres of damaged crops, with tremendous costs, all avoidable had EPA followed the law.

The ESA required EPA to "insure" its XtendiMax registration would not jeopardize the existence of any of the hundreds of protected imperiled species it knew were in or near the areas across 34 states EPA approved for XtendiMax spraying, nor harm any of the hundreds of habitats designated as critical to their survival and recovery. 16 U.S.C. § 1536(a)(2). Similar to how it handled its FIFRA obligations, EPA approached this rigorous duty by disregarding well-settled law.

But while EPA administers FIFRA, it has no special role or authority when assessing risks to endangered species. The ESA required EPA, like every other agency whose action might have any effect whatsoever—even a beneficial one—on any such species or habitat to consult the federal agencies with wildlife expertise to insure their protection. 50 C.F.R. § 402.14(a). Instead, EPA made up its own rules. In its haste to get XtendiMax on the market with minimal oversight, EPA applied the wrong legal standards for whether to consult the expert agencies,

and employed a home-grown risk assessment process that conflicted with the ESA's requirements but allowed EPA to substitute its own uninformed guesses for those agencies' expertise. EPA not only failed to use the best available data as the ESA expressly requires, but based its assessments of potential harm to hundreds of endangered plant and animal species on grossly inaccurate factual assumptions—such as that XtendiMax would not drift at all beyond any sprayed fields, and therefore could not possibly any plants or animals beyond the fields' borders.

Following this reckless and uninformed course, EPA made the unprecedented finding that exposure to the potent chemical could not possibly affect, let alone harm, any of the many hundreds of plant and animal species at risk of extinction, nor any of their critical habitats—and that the expert wildlife agencies were not entitled to any input on the subject. This unlawfully exposed to harm vast numbers of protected species and the areas upon which they depend to survive, and continues to do so.

ARGUMENT

I. FIFRA STANDARD OF REVIEW.

To uphold this pesticide registration, the Court must find EPA supported its registration decision with "substantial evidence" in the record. 7 U.S.C. § 136n(b). Judicial review must be "searching and careful, subjecting the agency decision to close judicial scrutiny." *Containerfrieght Corp. v. U.S.*, 752 F.2d 419, 422 (9th Cir.

1985). The agency's action may be upheld only on the "basis articulated by the agency itself." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. vs. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). If it finds EPA's actions violated FIFRA, this Court should "set aside," or vacate, the registration. *Pollinator Stewardship,* 806 F.3d at 532-33.

II. EPA APPLIED THE WRONG STANDARD AND FAILED TO MAKE STATUTORILY REQUIRED FINDINGS.

EPA must approve, or "register," pesticides before they are used or sold. 7 U.S.C. § 136a(a). A registration can be unconditional, *id.* §§ 136a(c)(5) or conditional, *id.* §§ 136a(c)(7). *See Nat. Res. Def, Council v. EPA*, 857 F.3d 1030, 1036-37 (9th Cir. 2017). For unconditional registrations, EPA must conclude a pesticide will, *inter alia*, "not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D). But for a conditional "new use" registration, which EPA approved here,[12] the standard is different. EPA must make two findings: "(i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable

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

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

EPA initially proposed an unconditional approval of M1691—a different dicamba pesticide—but eventually approved a conditional new use of XtendiMax. *See* ER001, 029. However, EPA failed to find that either of the two conditional new use prerequisites were met. First, as discussed below, EPA readily admits that, with regard to XtendiMax vapor drift and tank mixtures containing XtendiMax, it lacked sufficient data to assess harm from XtendiMax's new use. *See* 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(2); *see infra* pp. 21-26.

Second, EPA applied the *unconditional* registration standard: that XtendiMax "will not generally *cause* unreasonable adverse effects." ER029 (emphasis added). But the approval bar for conditional new use is higher: "amending the registration … would not *significantly increase the risk* of any unreasonable adverse effect on the environment." 70 U.S.C. § 136a(c)(7)(B) (emphasis added); *see also* S. Rep. 95-334, 95th Cong., 2d Sess. 10-11 (1977) ("The subcommittee agreed that the Administrator in implementing this provision

should take necessary steps to assure that conditional registrations are granted only in circumstances in which the *risk* of unreasonable adverse effects *would be minimal*.") (emphases added). EPA based its assessment, and decision, on the wrong legal standard, and never made the required legal finding.

Petitioners need not show XtendiMax will cause unreasonable adverse effects, only that XtendiMax significantly *increases the risk* of such effects. Plainly, however, EPA's decision was fatally flawed and unsupported by substantial evidence under either standard: the record shows EPA's failure to analyze risks of using XtendiMax in the manner approved *has already caused* unreasonable adverse effects, and thus the approval significantly increased the risk of unreasonable adverse effects.

III. EPA FAILED TO ACCOUNT FOR XTENDIMAX'S MASSIVE COSTS TO U.S. AGRICULTURE.

"Unreasonable adverse effect on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). This standard requires EPA to analyze not just the pesticide's *benefits*, but also its environmental, economic, and social *costs*, and the agency must explain how any benefits outweigh those costs. *See id.* EPA failed to support with any—let alone substantial—evidence that it adequately considered and accounted for the

foreseeable, catastrophic costs to U.S. agriculture that XtendiMax's registration is causing.

EPA's approval set in motion a 2017 farm season like nothing American agriculture had before experienced, with uncontrollable drift damaging crops on millions of acres, proliferating farmer class action lawsuits against Monsanto, farmer-to-farmer violence, and state governments implementing emergency dicamba drift measures because EPA would not. *See supra* pp. 8-11 (and citations therein). Despite this predicted disaster, EPA's 36-page registration decision, where the agency must provide its rationale, is nearly silent on these significant costs. Instead, it one-sidedly promotes alleged benefits to U.S. agriculture, ER028-29, concluding EPA "finds these benefits important," ER029.[13]

Nowhere did EPA rigorously assess XtendiMax's *costs*, such as drift damage to neighboring crops, lost sales or land use from such damage, forced protective expenditures on GE seeds, farmer vs. farmer strife, and the costs of

[13] EPA's "Review of Benefits as Described by the Registrant…" is similarly framed to ignore costs and to review only a single Monsanto document described as a "statement of benefits claimed by Monsanto." ER633. EPA also violated FIFRA by ignoring the substantial evidence that belies these assumed benefits. ER502-12. Any agronomic benefits from XtendiMax are questionable and short-term. Here, what's past is also prologue: weeds will quickly develop resistance to dicamba, just as with glyphosate. ER476-80; ER523-48; ER614 (comment from agrichemical company employee warning "[i]t would be naïve to think widespread weed resistance to dicamba will not occur.").

controlling dicamba-resistant weeds. Nor does the decision show EPA weighed these costs against any alleged benefits. Indeed, only a single paragraph in the registration decision even mentions drift costs. FIFRA requires EPA do much more: analyze and weigh these costs and support its approval decision with substantial evidence. 7 U.S.C. § 136n(b).

EPA instead relied entirely on label instructions to prevent harm. Yet EPA knew these instructions might not stop drift. The registration decision vaguely claims the label instructions would "effectively limit" drift problems, ER029, and EPA's "Benefits" assessment acknowledged these restrictions "*may reduce* the potential for drift to off-target sites." ER637 (emphasis added). That EPA anticipated XtendiMax's potential to cause drift damage is further demonstrated by the limited two-year registration, which automatically expires absent EPA's determination "that off-site incidents are not occurring at unacceptable frequencies or levels." ER035; ER368 (*EPA Responds to Dicamba Complaints*, quoting EPA's Dan Kenny: "The 2-year expiration was put in place because of the concerns about resistance and off-target movement"). EPA's expectation that dicamba drift damage might occur at "unacceptable frequencies" obligated the agency to develop credible estimates of drift costs and factor them into its FIFRA assessment before approving XtendiMax. 7 U.S.C. § 136(bb); *Pollinator Stewardship*, 806 F.3d at 532. But it did not.

Finally, that EPA's label restrictions did *not* prevent massive and widespread harm to U.S. agriculture is undeniable. *See supra* pp. 8-11. EPA's reliance on the label to stop such costs was not supported by substantial evidence, 7 U.S.C. § 136n(b). By any measure, EPA's decision was proven tragically and catastrophically wrong.

IV. EPA DISREGARDED HARM FROM XTENDIMAX VAPOR DRIFT.

Experts agree that vapor drift later in the season, when temperature and humidity are higher, is one of the major causes of the extensive dicamba drift damage in 2017. *See supra* pp. 10-11. EPA itself knew all along that XtendiMax vapor could drift off-field and destroy neighboring plants and crops. Yet in approving XtendiMax's new use, including authorizing potential use in tank mixes with other pesticides, including glyphosate, EPA disregarded record evidence demonstrating XtendiMax vapor drift would harm plants off-field, and that tank mixtures containing XtendiMax and glyphosate would amplify XtendiMax's volatility. EPA's decision to allow XtendiMax to be used in tank mixes without EPA approval violated FIFRA.

A. The Record Shows XtendiMax Vapor Drift Would Harm Neighboring Plants.

EPA knew from the outset that dicamba vapor drift was a concern. *See* ER630 (describing "high vapor drift from soybean fields resulting in non-target plant injury). Unable to ascertain the real-word effect of XtendiMax's volatility,

EPA proposed an omnidirectional buffer strip to prevent vapor drift damage.[14] ER630; ER724-25. Yet when it approved XtendiMax's new use, EPA claimed, based on additional data from Monsanto, that vapor drift was not a concern, and eliminated the omnidirectional buffer. ER460-61; ER018.

Contrary to EPA's changed position, the additional data actually showed XtendiMax vapor *could* injure non-target plants outside a sprayed field. The additional data included laboratory studies (referred to as the humidome studies) and two field studies, and additional modeling projections of XtendiMax vapor air concentrations off-field based on the data obtained from the field studies. *See* ER463-65. Importantly, EPA determined, based on the first humidome study, that the maximum allowable dicamba vapor air concentration that would not adversely affect non-target plants (referred to as the No Observed Adverse Effect Concentration or NOAEC), is 0.0177 ug/m^3. ER463. EPA then compared modeling projections of peak XtendiMax vapor off-field air concentrations against the NOAEC to predict whether XtendiMax vapor drift would harm plants. ER463-64. Critically, one of the predicted peak air concentration five meters away from the edge of a treated field was 2.08 x 10^{-2} ug/m^3 (0.0208 ug/m^3), exceeding the

[14] EPA proposed a no-spray zone—extending from the last sprayed row of crops to the edge of the field in all directions—of 100- or 220- feet—for the 0.5 lb a.e./A and 1.0 lb a.e./A application rate, respectively. ER630.

NOAEC (0.0177 ug/m^3). ER464. But instead of acknowledging that XtendiMax could injure plants off-field and assessing the magnitude of that harm, EPA simply downplayed the projection as "essentially at or below [the NOAEC]," ER464, then falsely concluded "the expected exposure at field's edge is less than the NOAEC for plant risk." ER018.

EPA's cavalier dismissal of the modeling outcome is unlawful. EPA assessed XtendiMax's volatilization risk by "determin[ing] the distance from site of application to where the NOAEC *is not expected to be exceeded*," ER018 (emphasis added); it cannot conclude there is no harm to non-target plants when one of its models showed XtendiMax vapor levels above the NOAEC beyond the treated field. *See Pollinator Stewardship*, 806 F.3d at 531 ("We cannot allow the EPA to avoid its own regulations when actual measurements trigger risk concerns, even where the measurements were 'in the neighborhood' of measurements that would not trigger such concern.") (citing *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013)). Simply put, "essentially the same" is not good enough, when the livelihood of hundreds of thousands of farmers or, as discussed below, the survival and recovery of hundreds of endangered plants and animals, are at stake.

B. The Record Shows That Tank Mixing XtendiMax and Glyphosate Increased XtendiMax's Volatility.

EPA also failed to analyze the likelihood of increased volatility from mixing XtendiMax with other pesticides in tank mixtures.[15] EPA acknowledged dicamba was designed to be sprayed along with other pesticides and chemicals, including glyphosate, the active ingredient in Monsanto's flagship herbicide Roundup. *See, e.g.*, ER714 ("It is common for products like this to be tank mixed with other products and pesticide active ingredients."). As EPA recognized, dicamba is only effective at killing some broadleaf weeds, and other herbicides would still be needed to manage other weed types. *See* ER635. [redacted]

EPA also knew tank mixes may worsen XtendiMax's effects. *See* ER022 (tank mixing could result in "enhanced activity or synergistic effects."). Specifically, [redacted] Rather than analyzing that risk, EPA's proposed registration—and all of the agency's risk assessments—relied on prohibiting tank mixing until EPA affirms a particular tank

[15] Pesticides are commonly mixed with other pesticides and chemicals in a tank prior to application. *See* ER714; ER022.

mix will not increase dicamba's volatility. *See, e.g.*, ER714 (EPA would only allow tank mixing "with products that have been tested and found not to increase the likelihood of drift/volatility."); ER457-58 (EPA addressed tank mixing increasing XtendiMax's volatility by prohibiting tank mixing).

However, the final registration authorized tank mixing without assessing XtendiMax tank mixtures' increased volatility. Instead, EPA authorized *Monsanto* alone to approve tank mix components, so long as the tank mixture has been tested for increased *spray drift*—but *not vapor drift*. *See* ER063 (requiring only "testing of tank mix products for spray drift properties"). EPA failed to require independent EPA approval of proposed tank mixes, but merely required submission of test data. *See* ER060-61.

EPA cannot register a pesticide new use without ensuring that "amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). The statutory definition of "pesticide" broadly includes "*mixture of substances* intended for use as a plant regulator, defoliant, or dessicant." *Id.* § 136(u)(2) (emphasis added). Because EPA was aware tank mixes are commonly used, and that mixing XtendiMax and glyphosate could result in increased volatility, EPA was required to assess such tank mixes before allowing their use. It failed to require any such testing, or agency review. EPA's abdication of its

statutory duty to assess and consider increased harm risk from XtendiMax tank mixes violated FIFRA.

V. EPA'S OCT. 12, 2017 ACTION FURTHER PROVES THE XTENDIMAX DECISION WAS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.

The unprecedented damage forced EPA and Monsanto to act. But instead of vacating and remanding XtendiMax's registration, EPA accepted wholesale and incorporated into an amended XtendiMax registration, ECF Nos. 57-1; 57-2, [redacted]; ER394. EPA did so in response to the huge number of crop damage incidents to "further minimiz[e] [sic] off-field movement," ECF No. 57-2, at 1. This extraordinary action underscores that EPA grossly miscalculated its approval's actual costs. EPA cannot argue both 1) EPA's 2016 determination, based on the older mitigation measures alone, was supported by substantial evidence; and 2) these new 2017 revised measures are needed to address the action's consequences.

A. EPA Is Still Relying on Its Erroneous 2016 Assessments and Determinations.

While adding revised label restrictions, EPA doubled down on its original decision, underscoring it "continues to rely on all risk assessments and determinations that supported the November 9[, 2016] registration." ECF Nos. 57-1, at 1; 57-2, at 2 (claiming new measures "do not affect the conclusions in the supporting assessment of risk" and EPA "continues to rely" on that decision).

Thus, EPA did not revise its original rationale, in its November 2016 decision, despite now acknowledging its inadequacy for all practical purposes.

B. EPA Did Not Support the New Label Amendments with Any Data, Analysis, or Rationale.

At the same time, EPA conducted no analysis supporting the amended registration and new label measures it now claims will prevent recurrence of drift damage. EPA did not prepare a "revised endangered species effects determination, nor any other new risk assessment." ECF No. 57-2, at 1. Indeed, there is no new analysis of these measures' efficacy in the record: this new part of the registration is unsupported by any EPA analysis at all, only Monsanto's self-interested assurances. *See* ER355-57.[16] Empty, unanalyzed agency action is not supported by substantial evidence. Whether EPA relies on the unanalyzed and unsupported, hastily-enacted measures, or stands by its initial assessments that proved so egregiously deficient, or both, its decision-making is not supported by substantial evidence and violates FIFRA. 7 U.S.C. § 136n(b).

Further, for new use approvals, EPA must find "amending the registration *in the manner proposed by the applicant* would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(B) (emphasis added). EPA accepted Monsanto's proposed changes to the label

[16] [redacted] *Compare* [redacted] *with* ER075-121; *see* [redacted].

without new findings or analysis. EPA was required to analyze whether XtendiMax's use under the amended registration conditions, i.e., "in the manner proposed" now by Monsanto, would still significantly increase the risks of any unreasonable adverse effect. *Id.* § 136a(c)(7)(B). But in its determination to keep the product on the market and appease Monsanto while appearing to do something to address the problem, EPA simply slapped on the unanalyzed, Monsanto-drafted label additions. ER394 (EPA e-mail to Monsanto: "Our goal is to ensure these technologies are available to growers for the 2018 season" so EPA is "moving very quickly"). By relying solely on its prior analyses and determinations, analyzing a different Monsanto proposal and label, EPA violated FIFRA's plain language.

C. The New Label Still Fails to Address Vapor Drift.

Not only are EPA's supplemental label instructions lacking any analysis of their efficacy, or even any explanatory rationale, but no reason exists to believe the new measures will stop dicamba drift. Crucially, the revised label lacks any provision even purporting to address volatility or vapor drift, the harm's main wellspring according to farmers and experts. *See supra* pp. 6-11 (and citations therein); *see also supra* pp. 21-26.

As the disaster of the 2017 planting season unfolded, weed scientists confirmed to EPA that volatility was a major source of the problem and repeatedly pleaded with EPA to address it. *See supra* pp. 10-11 (and citations therein);

ER358-62; ER300-45; ER346-48; ER422. Their chief recommendation was to address volatility, such as by prohibiting use during warm-weather summer months when volatilization is more likely, as numerous states eventually did. ER369-70. Yet EPA amended the label without any measures to address it. *See* ER072-21.

Instead of addressing vapor drift/volatilization, the amended label added new peripheral use instructions, as though farmers were the problem. ER116 (the new label is "incorporating certain additional training and record keeping requirements and certain other amplifications."). These included: classifying XtendiMax as restricted use "to facilitate compliance with appropriate training and recordkeeping practices," ER116; clarified use instructions, including graphics showing buffer requirements, ER093-94; and small changes—unstudied as to efficacy—in spray volume, ER092 (compared to ER043; ER055); wind speed restriction, ER092 (compared to ER043-44; ER055-56); and time of day restriction, ER092, intended to reduce spray drift during temperature inversions, ER092-93. None of these measures even purports to address vapor drift damage, let alone stops it. At root is Monsanto's insistence that its product is flawless and farmers' errors caused the harm, so merely improving label compliance will solve everything.

D. No Evidence Supports the Changes EPA and Monsanto Did Make.

EPA not only failed to address volatility, but violated FIFRA by failing to support with substantial evidence its assumption that the byzantine measures it did include in the label will effectively prevent XtendiMax's off-field movement under real-world conditions. 7 U.S.C. § 136n(b). EPA failed to consider and analyze applicators' ability to follow the label instructions, or their effectiveness if followed. *Pollinator Stewardship*, 806 F.3d at 532.

In approving XtendiMax's new use, EPA imposed use instructions of unprecedented scope and complexity—"unlike anything that's ever been seen before," ER379 (weed scientist Bob Hartzler); for context, the 16,000-plus word revised 2017 label[17] (ER075-115) is *longer than this entire brief*. Weather restrictions permit spraying only within a narrow wind speed range of 3 to 10 mph; prohibit use when rainfall is forecast within 24 hours; bar applications dusk to dawn, and during frequently-occurring "temperature inversions" during summer days. ER377 (in Missouri, one-half to two-thirds of summer). A Missouri farmer stated: "You have to be a meteorologist to get it exactly right." ER380. A commercial applicator told EPA, "[w]e only have a very limited amount of proper

[17] *See* Monterey Language Servs., *Free Online PDF Word Count Tool*, http://www.montereylanguages.com/pdf-word-count-online-free-tool.html. This excludes a continually changing Monsanto website (part of the label) with still more requirements that must be checked within 7 days of application.

days to, by label, make applications," adding: "No matter how hard we try to do things right, there will be off target issues." ER618. Other requirements include 110ft/220ft in-field buffer zones, special spray nozzles, spray pressure limits and tractor speed restrictions. *See* ER092-94. The November 2017 additions only made the unworkable label more lengthy and complex. ER370 (state experts to EPA regarding proposed revisions, eventually adopted: the "label is too complicated now, and people are never going to comply if we make it even more complicated.").

The instructions also are contradictory. Notwithstanding explicit permission to spray at wind speeds from 3 to 10 mph with buffer zones, the label demands: "DO NOT APPLY this product when the wind is blowing toward adjacent non-dicamba tolerant susceptible crops."[18] ER094. "The applicator must also consult applicable sensitive crop registries," and not spray if he "identif[ies] any commercial specialty or certified organic crops that may be located near the application site," "near" being undefined. *Id.*

No record evidence shows EPA considered and analyzed applicators' ability to follow the incredibly lengthy and complex label instructions, or their

[18] "Susceptible crops include, but are not limited to," thirteen specific crops or crop groups; "[s]evere injury or destruction could occur if any contact between this product and these plants occurs." ER094.

effectiveness if followed. For example, despite record evidence that the ultra-low 24-inch boom height requirement to reduce spray drift is "impractical" and that "at least 3 feet" is needed because otherwise "booms break too often," ER444 (Tennessee), ER430-31 (Iowa), the record fails to show EPA analyzed the measure's feasibility. Despite expert evidence that "buffers don't resolve the problem" of drift in Iowa and "[n]o buffer size seems feasible" in Missouri, ER443, no record evidence shows EPA conducted any practical, field-level assessment of buffer zones' ability to prevent dicamba drift damage. EPA also does not account for applicators' behavior in changing weather conditions, and whether farmers could reliably abstain from XtendiMax use "if rain is expected in the next 24 hours" to prevent runoff, as the label requires. ER087. The feasibility of following the label's wind speed restrictions also was unassessed.

Thus, even for the issues the revised instructions purport to address, the record is devoid of documentation, studies, or other assessments supporting efficacy or feasibility. In fact, EPA fails even to explain its own rationale for imagining the label amendments will work. This cannot withstand judicial review. *Pollinator Stewardship*, 806 F.3d at 538 (Smith, J., concurring) ("Unless I am provided with evidence of the EPA's basis for its judgment and knowledge, I can only assume it acted with none."); *id.* at 533 ("I simply ask the EPA to explain the analysis it conducted, the data it reviewed, and how the EPA relied on the data in

making its final decision."). EPA's failings mirror those in *Pollinator Stewardship*, where it also relied on mitigation measures it failed to analyze. 806 F.3d 520. Without a realistic assessment of mitigation measures' efficacy and feasibility, risk cannot be predicted accurately and EPA's determination is not supported by substantial evidence. 7 U.S.C. § 136n(b).

VI. EPA VIOLATED THE ENDANGERED SPECIES ACT.

EPA authorized spraying XtendiMax on millions of acres across 34 states, home to hundreds of ESA-protected species, and hundreds of their designated critical habitat areas. The ESA required EPA to comply with specific processes to prevent harm to them, including, most importantly, seeking guidance from the agencies with wildlife expertise. However, EPA doggedly avoided complying with the ESA's requirements, instead applying either processes that do not apply in the ESA context, or rules it invented that apply in no context at all. By doing so, EPA circumvented ever consulting the expert wildlife agencies, before unilaterally declaring that hundreds of plants, animals, and habitats would be completely unaffected by spraying them with a toxic weed killer. EPA's unprecedented, wholesale disregard of the ESA must be reversed.

A. The ESA's Consultation Process and Standards.

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437

U.S. 153, 180 (1978). Congress spoke "in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities." *Id*. at 194. "[T]he plain language of the [ESA] … shows clearly that Congress viewed the value of endangered species as 'incalculable.'" *Id*. at 187 (citation omitted).

Section 7 is the "heart" of the ESA, one of the statute's most important protections for endangered species. *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). It mandates that each federal agency "insure" its action (here, registering an XtendiMax new use) is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C. § 1536(a)(2).[19] EPA's duty to insure against jeopardy and adverse modification is "rigorous." *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987).

Section 7(a)(2) and its implementing regulations establish a process requiring EPA to evaluate its XtendiMax registration's effects "in consultation

[19] "Jeopardize" means taking an action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution…." 50 C.F.R. § 402.02. Critical habitat means "the specific areas within the geographical area occupied by the species, at the time it is listed … on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

with and with the assistance of" the agencies Congress designated as having special expertise in determining effects on endangered species: the United States Fish and Wildlife Service (FWS) (for terrestrial and freshwater species) and the National Marine Fisheries Service (NMFS) (for marine species).[20] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). This consultation process to assess the registration's effects is integral to "insuring" EPA implements the ESA's substantive protections. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("[T]he strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with the substantive provisions.") (emphasis in original).

First, Section 7(a)(2) requires EPA to determine whether the registration "may affect" any listed species or designated critical habitat. If so, EPA then *must* consult FWS. 50 C.F.R. § 402.14(a).

Importantly, the "may affect" standard is extremely low: "[A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (emphasis added). "*Any possible effect*,

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

whether beneficial, benign, adverse or of an undetermined character" triggers the requirement. *Id.* (quoting *Lockyer*, 575 F.3d at1018–19 (quotation omitted)) (emphasis in *Lockyer* in part, added in part). *See also W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2010) (same).

If its action meets the "may affect" threshold, EPA has only two alternatives: formally or informally consulting FWS. In formal consultation, FWS issues a Biological Opinion, containing FWS's expert opinion whether EPA's action is likely to jeopardize the continued existence of any species or adversely modify any critical habitat, and authorizing any incidental harm, or "take." 50 C.F.R. § 402.14(h)(3), (i).

"Informal consultation" is an exception to formal consultation. EPA may avoid formal consultation through informal consultation *only* if during informal consultation FWS *concurs in writing* that while EPA's action "may affect" a species or habitat, the action is "not likely to adversely affect" them. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994) ("The consulting agency [FWS] must issue a written concurrence in the determination…."). In all of these analyses, EPA must "give the benefit of the doubt to the species," *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988), and use the best scientific and commercial data available, 16 U.S.C. § 1536(a)(2).

B. EPA Violated the ESA's Consultation Mandates.

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

EPA ignored the ESA's requirements and instead applied processes appropriate only for determining whether to register a pesticide under FIFRA. *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005) (EPA must separately comply with the ESA in pesticide registrations). However, FIFRA and the ESA reflect different policies, address different issues, apply different legal standards, and consequently assign different duties to EPA. EPA's fundamental legal error was substituting FIFRA's less protective standards and processes for the ESA's, and refusing to consult the expert wildlife agencies.

First, FIFRA permits—indeed, requires—EPA to weigh the costs and benefits of a pesticide when considering whether to register it, *see* 7 U.S.C. § 136(bb); *supra* p. 18, but the ESA emphatically prohibits any such cost-benefit balancing: "The plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, whatever the cost." *Hill*, 437 U.S. at 184; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008) ("ESA's no-jeopardy mandate applies to every discretionary agency action—regardless of the expense or burden its application might impose.") (quotation omitted). While pesticide regulation is among EPA's many missions, the ESA affords endangered species "the highest of priorities," *Hill*, 437 U.S. at

174, and "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185.

Second, the ESA grants EPA no special authority. It has no particular expertise in protected species' survival and recovery, nor in interpreting and applying the ESA's standards. Congress therefore explicitly demanded that EPA, like every other federal agency, seek FWS's expertise when dealing with ESA-protected species and habitats. 16 U.S.C § 1536(a)(2). "This interagency consultation process reflects Congress's awareness that expert agencies (such as the Fisheries Service and the Fish and Wildlife Service) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species." *City of Tacoma, Washington v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006).

Third, EPA uses a risk assessment methodology, produced at record identifier I.1 (excerpts at ER804-12), for its FIFRA pesticide registrations that evaluates not whether the pesticide registrations "may affect" a species or habitat, but whether exposing them to a pesticide exceeds EPA's self-determined "level of concern" (LOC). An LOC is a term EPA created for the FIFRA context, and has no ESA analogue or applicability. Instead of determining whether the exposure meets

the ESA's low "may effect" standard triggering consultation, an LOC measures "adverse effects."[21]

EPA erroneously claimed the right to use this same FIFRA procedure to assess effects on ESA-protected species: instead of consulting FWS about harm risks, it simply consulted itself, using its own methodology designed to administer a very different statute. Specifically, as long as EPA's calculations yielded an acute risk quotient of >0.1 (or >.05 for aquatic animals), and a chronic risk quotient of >1, ER810-11, the agency concluded its own LOC had not been exceeded, declared "no effect," and thus excluded FWS from the process. ER651 ("EPA determines that there is 'no effect' on listed species if, at any step in the screening level assessment, no levels of concern are exceeded."). EPA has no such authority.

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[21] According to EPA:

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

ER810 (emphases added); *see* ER703-04 (showing EPA used this risk assessment process in this case).

2. EPA's Application of Its FIFRA Process to Determine Whether to Consult Under ESA § 7(a)(2) Violates the ESA.

EPA's process, however elaborate and purportedly scientific, does not comply with the ESA. The court in *Washington Toxics Coalition v. U.S. Department of Interior*, 457 F. Supp. 2d 1158, 1179-80 (W.D. Wash. 2006), resoundingly rejected an earlier EPA attempt (even with FWS's cooperation that time) to bypass the mandated consultation process similar to the self-consultation EPA attempts now. The court explained the critical disconnect between EPA's risk assessment process and the ESA's requirements:

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

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

Following *Washington Toxics*, the National Academy of Sciences (NAS) recommended how EPA should perform the consultation process in the context of pesticide registrations, in its report *Assessing Risks to Endangered and Threatened Species from Pesticides*.[22] EPA incorporated this advice in interim protocols EPA agreed to follow during its FIFRA-mandated registration review process.[23] But EPA deviated greatly from the *Interim Protocols* in this case, reverting to the self-consultation the court in *Washington Toxics Coalition* rejected.

EPA circumvented the consultation process by applying its internal methodologies to the ESA instead of limiting them to the FIFRA context for which they were designed. In so doing, EPA raised the consultation bar high above the ESA's "may affect" standard (as this Court and FWS have long interpreted that term) to exceeding EPA's "level of concern," which merely measures the impact

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[22] *See* National Research Council, Committee on Ecological Risk Assessment under FIFRA and ESA, *Assessing Risks to Endangered and Threatened Species from Pesticides* 10, National Academies Press (2013), https://www.nap.edu/read/18344/chapter/1.

[23] EPA, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report* (*Interim Protocols*), https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf (last visited Feb. 8, 2018). EPA assesses each registered pesticide at least once every 15 years to determine whether it continues to meet FIFRA registration standards. The ESA applies identically to EPA's registration review process and the registration at issue in this case. *Ctr. for Biological Diversity v. EPA*, 847 F.3d 1075, 1086 (9th Cir. 2017).

EPA itself considers acceptable in the FIFRA context. Instead of undergoing informal consultation and obtaining FWS's written concurrence that EPA's action is "not likely to adversely affect" any listed species or critical habitat, 50 C.F.R. §§ 402.13(a), 402.14(b)(1), EPA arrogated to itself FWS's prerogative, deciding *unilaterally* that if the registration's effects on endangered species do not exceed EPA's own "level of concern," those effects equate to "no effect," obviating any need to consult, even informally.

But those two metrics differ significantly, and as this Court has recognized, EPA lacks authority to impose its own interpretation of when consultation is triggered. ESA § 7(a)(2) does not require consultation only when an action's effects exceed EPA's "level of concern," *will adversely affect* a listed species or critical habitat, or *will affect* them at all. Instead, under the "may affect" standard, "actions that have *any chance of affecting* listed species or critical habitat—*even if it is later determined that the actions are 'not likely' to do so*—require at least some consultation under the ESA." *Karuk Tribe*, 681 F.3d at 1027 (emphases added).

In *Karuk Tribe*, the plaintiff challenged the Forest Service's failure to consult before issuing notices of intent to conduct mining activities in ESA-protected salmon critical habitat. Mining interests argued the record contained no evidence "'that even a single member of any listed species would be "taken" by

reason' of the mining activities," and that the plaintiff had not identified "so much as a single endangered fish or fish egg ever injured by this [mining] activity." *Id.* at 1028 (citation omitted). This Court sitting *en banc* rejected industry's efforts to make the agency's procedural duty to consult the expert agencies dependent on evidence of actual harm, emphasizing that any risk triggers consultation. *Id.* The miners argued that mitigation "assured" there would be "no impact whatsoever on listed species." *Id.* The Court observed that the argument "cuts against, rather than in favor of" the agency having no duty to consult, since the perceived need to reduce potential effects underscored that effects were possible, compelling consultation. *Id*.

EPA's risk assessment methodology, which seeks to determine the "likelihood of *adverse* ecological effects on non-target species," ER810 (emphasis added), thus is fundamentally and inescapably at loggerheads with the ESA's mandate to consult FWS whenever EPA's action may produce "[a]ny possible effect, *whether beneficial, benign, adverse or of an undetermined character*." *Karuk Tribe*, 681 F.3d at 1027 (emphasis added). FWS and NMFS's *Endangered Species Consultation Handbook*[24] underscores the distinction between "no effect"

[24] FWS & NMFS, *Endangered Species Consultation Handbook* (Mar. 1998) (*Consultation Handbook*), http://www.nmfs.noaa.gov/pr/pdfs/laws/esa_section7_handbook.pdf. This Court

and the "not likely to adversely affect" standard EPA effectively applied here, while calling it "no effect":

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

Consultation Handbook, *supra* n.24, at *xv-xvi* (italics and formatting added).

As a matter of law, therefore, an effect EPA deems insignificant (or even beneficial) *cannot be classified as "no effect."* The ESA classifies such effects as "not likely to adversely affect" the species—but only if FWS concurs in writing after informal consultation. 50 C.F.R. §§ 402.13(a), 02.14(b)(1). By conflating the two standards and claiming that an effect below its self-determined "level of concern" or lacking "adverse effects" has "no effect," EPA unlawfully cut FWS out of the process. The Court must set the registration aside as not in accordance with law. *See* 7 U.S.C. § 136n; *Pollinator Stewardship*, 806 F.3d at 532.

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has relied on the *Consultation Handbook*. *See, e.g.*, *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1113 (9th Cir. 2012).

3. The Record Shows Xtendimax "May Affect" Hundreds of Endangered Species, Requiring Consultation.

EPA admitted the XtendiMax registration "may effect" hundreds of ESA-protected species and their critical habitats, but by misapplying the risk assessment framework EPA developed under FIFRA for determining whether impacts on non-target organisms are *"of concern" to EPA*, EPA erased all of these findings and converted them to "no effect" findings to avoid consultation.

Specifically, EPA in its March 8, 2011 risk assessment, ER740-73, admitted dicamba, applied at the allowed rate, may harm many protected plant and animal species; it expressly found its calculated risk quotients exceeded its own "level of concern" for all types of plants and animals. ER758-59. EPA admitted its screening analysis found "potential direct risk concerns could not be excluded for" any birds, mammals, or terrestrial plants. ER650. This list included 322 ESA-protected species within 11 states, ER708, 183 ESA-protected species within 16 additional states, ER688, and 307 ESA-protected species in 7 more states, ER684, for a total of 812 species in 34 states. Based on these admissions alone, the Court must find that, as in *Karuk Tribe*, the "record in this appeal includes ample

evidence" that the action in question "may affect" endangered species. *Karuk Tribe*, 681 F.3d at 1028.[25]

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

EPA began the process of erasing these hundreds of "may affect" findings by unlawfully redefining the registration's "action area." When evaluating whether its action "may affect" any listed species or critical habitat, EPA must examine all effects within the registration's "action area." 50 C.F.R. §§ 402.02, 402.12; *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 901 (9th Cir. 2002). EPA violated this by unlawfully constricting the registration's "action area" to just the sprayed crop fields themselves, excluding completely all surrounding environments.

However, "action area" is defined as "all areas to be affected *directly or indirectly* by the Federal Action and *not merely the immediate area involved in the action*." 50 C.F.R. § 402.02 (emphases added). EPA initially found 812 listed species were within the registration's action area. *See, e.g.*, ER704 ("322 species in the 11 states proposed for registration were identified as *within the action area*….") (emphasis added). This was appropriate, since EPA knows pesticides commonly travel well beyond sprayed fields, with harmful effects.

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

As discussed extensively above, *see supra* pp. 6-7, 21-26, EPA also knew before this amended registration that XtendiMax is extremely drift prone, and knew even before the original registration that dicamba is: "Multiple literature studies show that there is a high vapor drift [of dicamba] from soybean fields resulting in non-target plant injury." ER746; *see* ER757 (incident data).

Yet because Monsanto purported to address this serious problem by adding "VaporGrip" to its dicamba formulation, and EPA added extraordinarily elaborate label restrictions discussed above, EPA concluded the registration would have "no effect" on any of the hundreds of species it had already identified as at-risk (except the handful expected to occur in crop fields), conclusively assuming there would be *no drift whatsoever*. EPA therefore attempted to restrict the registration's "action area" to only the fields themselves. ER653.

This culling violated the ESA definition of "action area," as well as sound science, farming realities, and the record evidence. It now is undeniable that EPA grossly miscalculated XtendiMax's vapor drift, thus exposing countless endangered plants and animals beyond field boundaries to the potent chemical. *See supra* pp. 8-11. But EPA knew before it registered XtendiMax that its laundry list of restrictions would not completely eliminate off-site drift. *See, e.g.*, ER028 (measures "*reduce the likelihood* of spray drift and volatilization" beyond fields) (emphasis added); *id*. ("if further refinements that included more realistic exposure

scenarios were conducted, these risks *would likely fall below the agency's levels of concern*.") (emphasis added); ER637 (label instruction "*may reduce* the potential for drift to off-target sites") (emphasis added).

Even before EPA's miscalculation became obvious, EPA admitted its label restrictions would only reduce drift beyond the fields' borders "to where the [No Observed Adverse Effect Concentration (NOAEC)] is not expected to be exceeded." ER018. Thus, even had EPA's drift conclusions not turned out to be so disastrously wrong, EPA's redefinition of the action area was erroneous as a matter of law. EPA defines the NOAEC as "[t]he highest level of a chemical stressor in a toxicity test that did not cause *harmful effect* in a plant or animal."[26] But the ESA mandates consultation not only when EPA's action causes "harmful effects," but when an action may cause "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe*, 681 F.3d at 1027. This repeats the overarching theme of EPA's legal error: trying to jam a FIFRA square peg into an ESA round hole to avoid consultation.

Even if it were not so obvious that dicamba escapes the crop fields' borders, ESA-protected species in surrounding areas consume prey—insects, rodents,

[26] EPA, *Ecological Risk Assessment Glossary of Terms*, https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=Eco%20Risk%20Assessment%20Glossary (emphasis added) (last viewed March 1, 2017).

reptiles—that are in the fields when they are sprayed, before moving out of the fields. EPA never considered this risk, let alone received FWS's input in consultation, and this alone renders EPA's "action area" deficient. *See Wilderness Soc. v. Wisely*, 524 F. Supp. 2d 1285, 1305 (D. Colo. 2007) (rejecting failure to consult regarding effects in broader action area); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 254 F. Supp. 2d 1196, 1212 (D. Or. 2003) (same). In sum, the record is overwhelming that EPA's no-drift assumption and action-area manipulations were completely wrong, leaving hundreds of species and habitats on millions of acres vulnerable to the weed-killer's effects. Accordingly, EPA violated the ESA by failing to consult.

5. EPA's Conclusion that Dicamba Will Have "No Effect" Even on Protected Species Within Sprayed Fields Also was Unlawful.

Even had EPA not erred by excluding the hundreds of potentially-affected species and habitats *surrounding* dicamba-sprayed crop fields, EPA erred by then declaring the registration will have "no effect" even on the species it admitted are *in* those fields.

EPA's initial risk assessment found the proposed dicamba new use potentially harms *all* ESA-listed species that might come in contact with the pesticide. ER759 ("no species currently listed as federally threatened or endangered can be excluded from the potential for adverse effects from the

proposed new use of dicamba."). EPA was required to consult FWS at that point, and if it concluded the registration was "not likely to adversely affect" any species or habitat, it had to obtain FWS's written concurrence. Instead, EPA gerrymandered the registration's "action area" to include only the sprayed fields themselves, and thus exclude most species. But EPA admitted no drift mitigation could prevent some of America's most iconic and critically endangered animals—such as the California condor, Florida panther, and whooping crane—from ingesting dicamba, because they are "reasonably expected to occur on soybean and cotton fields." ER708-09. Again, once EPA realized listed species will be exposed to dicamba, ESA § 7(a)(2) demanded it stop and consult FWS.

In fact, the Interim Protocols EPA agreed to follow (mirroring the ESA's own requirements) unequivocally requires that EPA consult FWS regarding any listed species within the action area: "For species and critical habitats that do overlap with the action area, the call *will be 'May Affect,'* and the analysis *will proceed* with" determining whether the action is "likely to adversely affect" or "not likely to adversely affect" the species, the latter requiring FWS's written concurrence. Interim Protocols, *supra* n.23, at 7 (emphases added); *see also* 50 C.F.R. §§ 402.13(a), 402.14(b)(1).

Instead, EPA unlawfully consulted only itself, and decided the risk of harm to these protected species was not sufficiently severe to warrant consultation.

Because the "may affect" threshold is so low, to Petitioners' knowledge no court has ever upheld an action agency's "no effect" determination where endangered species are found in the action area. This Court must vacate and remand.

6. EPA's Process for Species-Specific Analysis Violated the ESA.

EPA's next step to avoid making what the ESA defines as "may effect" determinations was continuing to analyze its registration's impacts using more and more tenuous assumptions, until declaring the effects did not exceed EPA's "levels of concern"—the FIFRA-based concept at odds with the ESA. EPA then characterized these "may effect" circumstances as "no effect," sidestepping the required consultation altogether. EPA did this with many species found in crop fields, ER659-73, but its analysis of the registration's effect on whooping cranes is typical of its contortions.

a. Whooping Crane (*Grus Americana*)

The iconic whooping crane is among the world's most endangered animals. There were as few as twenty-one in 1954,[27] and conservation efforts have led to only a limited recovery; there are now a few hundred in the wild.[28] As FWS observed: "The whooping crane is a flagship species for the North American

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

[28] *Id*. at 1.

wildlife conservation movement, symbolizing the struggle for survival that characterizes endangered species worldwide."[29]

EPA acknowledged whooping cranes "could be feeding on arthropod prey in treated cotton and soybean fields during its migration from March to May." ER656. But rather than make the required "may affect" finding and consult FWS, EPA estimated the crane's field metabolic rate, guessed the amount of prey it was likely to consume, and guessed the amount of dicamba in hypothetical prey a hypothetical crane might consume. ER656.

EPA used this collection of guesses to calculate acute and chronic risk quotients, and compared these with EPA's internally-generated "levels of concern" (LOC). ER656-57. Because EPA's numbers fell below its LOC, EPA declared there would be "no effect." *Id.* But the risk quotients were not zero, *id*., and therefore required a "may effect" determination as a matter of law. If EPA believed the exposure was nonetheless "not likely to adversely affect" the cranes, the ESA required EPA to engage in informal consultation and obtain FWS's written concurrence with this conclusion. 50 C.F.R. § 402.14(b); *Pac. Rivers Council*, 30 F.3d at 1054 n.8. EPA did not, violating Section 7.

[29] *Id.*

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

The ESA imposes the additional, independent statutory mandate that EPA, like all federal agencies, use the "best scientific and commercial information available" when assessing effects on ESA-listed species and habitats. 16 U.S. C. § 1536(a)(2). In addition to its other ESA violations, EPA violated this mandate in assessing impacts on whooping cranes and other species. For example, EPA relied on its 1993 Wildlife Exposure Factors Handbook (Exposure Handbook), produced at document identifier I.3 (excerpts at ER813-824), for critical data. *See* ER656. (In contrast, FWS's latest version of its 160 page recovery plan for whooping cranes, which EPA ignored, is from 2007.[30]) The Exposure Handbook nowhere mentions whooping cranes, nor any other endangered species, because EPA never intended it to be used for assessing effects on any endangered species, nor for any purpose after screening assessments show species may be affected.

On the contrary, the Exposure Handbook is designed for a narrow purpose: "to provide a convenient source of information and an analytic framework for *screening-level* risk assessments for *common* wildlife species." ER815 (emphases added). The Exposure Handbook also emphasizes the need to obtain data for the particular species being assessed. ER816 ("Exposure varies between different

[30] *See id.*

species and even between different populations of the same species….") The Exposure Handbook contains no data about any type of crane.

As discussed, once the "may affect" threshold is reached, EPA must consult FWS, not perform more refined, site-specific analyses to avoid consultation. Instead, EPA persisted in its consultation avoidance, purporting to fill the data gaps with an Exposure Handbook that instructs EPA to obtain data about local populations—specifically, *by consulting FWS*. ER818-19. Relying on this inappropriate source of critical data and its own FIFRA-based assessment methodology, EPA concluded that because the total load of dicamba it guesstimated a crane would consume was less than its own "level of concern," spraying a toxic chemical on their food would have "no effect" on any whooping cranes. ER657-58. EPA's use of patently inappropriate information and guesswork instead of even attempting to obtain the best available information independently violated Section 7(a)(2).

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

ESA § 7(a)(2) imposes an independent, additional duty on EPA to "insure" its XtendiMax registration will not destroy or adversely modify any habitat FWS designated pursuant to ESA § 4(a)(3)(A) as "critical" to a listed species' survival or recovery. EPA's duty to consult FWS regarding potential effects on critical habitat is separate from, but identical to the low bar controlling its duty regarding

effects on listed species themselves: EPA *must* consult FWS if its registration "may affect" a listed species' designated critical habitat.

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

EPA perfunctorily dismissed its duty to consult FWS to insure spraying millions of acres with a toxic chemical does not affect any critical habitat, falling far short of the ESA's requirements. First, EPA acknowledged FWS had designated critical habitat for 499 species in and around fields in 34 states where EPA authorized XtendiMax spraying: ER685 (for 118 listed species found in 7 states); ER705 (for 322 species in 11 additional states); and ER674 (for 59 species in another 16 states). Yet EPA then invented rules from whole cloth about when its action will trigger consultation with respect to critical habitat, and substituted them for the ESA's "may affect" standard, leading EPA to unlawfully circumvent consultation for *every single one* of 499 critical habitats. Here is the rule EPA created for itself:

> The Agency will conclude 'modification' of designated critical habitat if the range of designated critical habitat co-occurs with the states subject to the Federal action and one or more of the following conditions exist:
>
> 1. … *cotton or soybean fields are habitat for the species and there is a "may affect" determination for the species* associated with exposure to dicamba ….

> 2. … *the species uses cotton or soybean fields* and one or more effects on taxonomic groups predicted for dicamba … on cotton and soybean fields *would modify one or more of the designated PCEs.*
>
> If neither of the above conditions are met, EPA concludes "no modification."

ER692-92 (emphasis added); ER711 (emphases added).

EPA thus decided for itself that XtendiMax spraying could not cause "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character" on critical habitat, triggering consultation, *Karuk Tribe*, 681 F.3d at 1027, unless EPA first found its action "may affect" *the listed species* for which a sprayed field was part of designated critical habitat. Otherwise, the listed species for which FWS designated critical habitat that includes agricultural fields must be shown to actually use those fields, *and* EPA must find that spraying XtendiMax on the fields reduces their value as critical habitat.

This made-up formula is riddled with legally erroneous assumptions. Initially, overlap between protected species or critical habitat and the action area virtually mandates consultation because "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character," *id.*, is almost unavoidable under such circumstances.[31] EPA not only ignored this, but contradicted it.

[31] The Interim Protocols EPA developed with input from the NAS and committed to using in its reregistration program provides "*any species or critical habitat that overlaps with the action area will be considered a 'May Affect'*)."

First, echoing the above myriad instances, EPA again awarded itself authority it does not have—here, to decide whether critical habitat is "modified." ESA § 7(a)(2) does not mandate consultation with FWS only where EPA's action "modifies" critical habitat, nor may EPA forego consultation if it finds "no modification." 16 U.S.C. § 1536(a)(2). The law requires consultation for all "actions that have *any chance of affecting* … critical habitat." *Karuk Tribe,* 681 F.3d at 1027 (emphasis added). EPA again applied the wrong legal standard.

Second, EPA's assertion it will consult if "there is a 'may affect' determination for the species" for which critical habitat has been designated (if the species also uses agricultural fields) is a *non sequitur*. EPA conflates risks to species with risks to habitat, and attempts to restrict its habitat consultation duties to only situations where it has already found direct species risks. But the ESA imposes on EPA independent duties for each risk. Critical habitat may be affected regardless of whether an action may directly affect the species itself. *See Greenpeace v. NMFS*, 55 F. Supp. 2d 1248, 1265 (W.D. Wash. 1999) (effects on species and habitat distinct and independent).

Interim Protocols, *supra* n.23, at 4 (emphasis added). *See Defenders of Wildlife v. Zinke*, 856 F.3d 1248, 1258-59 (9th Cir. 2017) (concluding FWS, in formal consultation, not required to assess adverse modification of critical habitat within action area because FWS, in informal consultation, had already agreed the projects at issue were unlikely to affect the critical habitat.).

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

b. EPA Unlawfully Excluded from Consideration All Critical Habitats Not Containing Sprayed Fields Occupied by Listed Species.

EPA's erroneous conclusion that consultation is not triggered unless a listed species "use[s] cotton or soybean fields" caused it to categorically circumvent—unlawfully—consultation on almost all of the hundreds of designated critical habitats in the action area. *See* ER711 (If any listed species is "judged to not use cotton or soybean fields," the critical habitat "assessment" for such species is automatically "no modification."); *e.g.*, ER692 ("One-hundred thirteen (113) species with critical habitat were judged to not use cotton or soybean fields and so the critical habitat determination for these was 'no modification.'"). This is not how critical habitat or the ESA works.

Whether members of an endangered species physically occupy a part of a designated critical habitat (here, cotton and soybean fields) is irrelevant to whether spraying pesticide on those fields "may affect" the habitat, triggering consultation.

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

> A physical or biological feature essential to the conservation of a species for which its designated or proposed critical habitat is based on, such as space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the species' historic geographic and ecological distribution.[32]

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

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

[32] FWS, *Endangered Species Glossary*, https://www.fws.gov/nc-es/fish/glossary.pdf (last visited Feb. 8, 2018).

the species." *Id.* § 1532(5)(A)(ii) (emphasis added). *See Consultation Handbook*, *supra* n.24, at xix ("Some designated, unoccupied habitat may never be occupied by the species, but was designated since it is essential for conserving the species because it maintains factors constituting the species' habitat.").

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

Even considering the millions of acres of devastation already caused by dicamba drift that EPA was erroneously certain would never occur, whether EPA's registration will *adversely affect* (or "modify") any of the hundreds of critical

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

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

For its assessment of critical habitats where listed species occupy agricultural fields, EPA relied on its previous listed species' effects determinations "to ascertain if any [species] were determined to be at risk for direct adverse effects." ER674. Since EPA had already made erroneous "no effect" determinations for virtually all species, this had a foregone conclusion. But EPA's assessment methodology violated the ESA, since as noted above, an action "may affect" critical habitat regardless of whether it directly affects any members of the species.

EPA eventually looked at the critical habitats' PCEs, but only for those very few species actually occupying the sprayed fields found within their critical habitats. ER674. Even for those, EPA's assessment was inadequate: EPA summarily dismissed any possibility that spraying XtendiMax on fields within

critical habitat "may affect" them by declaring that, with the single exception of the whooping crane, which feeds in agricultural fields, "the PCE's are not relatable to agricultural fields." ER674. Whatever this might mean, EPA did not meet its duty to consult FWS to "insure" against adverse modification of critical habitat that includes or borders an agricultural field by declaring, without any record support or meaningful analysis, that the PCEs for those habitats are "not relatable to agricultural fields."

VII. THE COURT SHOULD VACATE THE REGISTRATION.

The Court should set aside, or vacate, EPA's approval. Vacatur is the express statutory remedy provided by FIFRA. 7 U.S.C. § 136n(b). Indeed, remand without vacatur is only permitted in "limited circumstances," *Pollinator Stewardship*, 806 F.3d at 532, *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("rare circumstances"), and only when the agency can show that "equity demands" a departure from this presumptive remedy, *Pollinator Stewardship Council*, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed.'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)).

This Court considers whether such "rare circumstances" for remand without vacatur are met by "weigh[ing] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *Pollinator Stewardship*, 806 F.3d at 532 (internal quotation marks and citation

omitted). As to the first factor, the FIFRA violations delineated above are serious legal errors, and have caused unprecedented damage to U.S. farmers. *See*, *e.g.*, *id.* at 532-33 (vacating pesticide registration); *Nat. Res. Def. Council v. EPA*, 857 F.3d 1030, 1042 (9th Cir. 2017) (vacating the pesticide registration).

As to the ESA violations, Congress has made clear those ESA duties are even more important than EPA's FIFRA duties, weighing even more heavily in favor of vacatur. *See Karuk Tribe*, 681 F.3d at 1020 (the ESA's "consultation requirement reflects a 'conscious decision by Congress to give endangered species priority over the "primary missions" of federal agencies.'") (quoting *Hill*, 437 U.S. at 173).

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

CONCLUSION

For the reasons stated above, Petitioners respectfully request the Court declare that EPA has violated FIFRA and ESA, vacate EPA's approval, and remand for further proceeding consistent with this Court's decision.

Respectfully submitted this 9th day of February, 2018.

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STATEMENT OF RELATED CASES

There are no other related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points or more and contains 13,980 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: February 9, 2018.

/s/ George Kimbrell
George Kimbrell

STATUTORY AND REGULATORY ADDENDUM

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

7 U.S.C.A. § 136

§ 136. Definitions

Effective: August 3, 1996
Currentness

For purposes of this subchapter--

(a) Active ingredient

The term "active ingredient" means--

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

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

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

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

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

(b) Administrator

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

(c) Adulterated

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

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

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

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

(d) Animal

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

(e) Certified applicator, etc.

(1) Certified applicator

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

(2) Private applicator

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

(3) Commercial applicator

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

(4) Under the direct supervision of a certified applicator

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

(f) Defoliant

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

(g) Desiccant

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

(h) Device

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

(i) District court

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

(j) Environment

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

(k) Fungus

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

(l) Imminent hazard

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

(m) Inert ingredient

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

(n) Ingredient statement

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

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

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

(o) Insect

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

(p) Label and labeling

(1) Label

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

(2) Labeling

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

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

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

(q) Misbranded

(1) A pesticide is misbranded if--

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

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

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

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

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

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

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

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

(2) A pesticide is misbranded if--

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

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

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

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

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

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

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

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

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

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

(i) the skull and crossbones;

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

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

(r) Nematode

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

(s) Person

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

(t) Pest

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

(u) Pesticide

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

(v) Plant regulator

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

(w) Producer and produce

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

(x) Protect health and the environment

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

(y) Registrant

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

(z) Registration

The term "registration" includes reregistration.

(aa) State

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

(bb) Unreasonable adverse effects on the environment

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

(cc) Weed

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

(dd) Establishment

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

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

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

(ff) Outstanding data requirement

(1) In general

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

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

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

(2) Factors

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

(gg) To distribute or sell

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

(hh) Nitrogen stabilizer

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

(1) dicyandiamide;

(2) ammonium thiosulfate; or

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

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

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

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

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

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

(kk) Service technician

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

(ll) Minor use

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

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

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

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

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

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

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

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

(mm) Antimicrobial pesticide

(1) In general

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

(A) is intended to--

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

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

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

(2) Excluded products

The term "antimicrobial pesticide" does not include--

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

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

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

(nn) Public health pesticide

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

(oo) Vector

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

CREDIT(S)

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

Notes of Decisions (9)

Footnotes

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

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

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

7 U.S.C.A. § 136, 7 USCA § 136

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

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

Currentness

(a) Requirement of registration

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

(b) Exemptions

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

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

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

(c) Procedure for registration

(1) Statement required

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

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

(B) the name of the pesticide;

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

(D) the complete formula of the pesticide;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Data in support of registration

(A) In general

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

(B) Additional data

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Simplified procedures

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

(D) Exemption

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

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

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

(E) Minor use waiver

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

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

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

(3) Application

(A) In general

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

(B) Identical or substantially similar

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

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

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

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

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

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

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

(C) Minor use registration

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

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

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

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

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

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

(D) Adequate time for submission of minor use data

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

(4) Notice of application

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

(5) Approval of registration

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

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

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

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

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

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

(6) Denial of registration

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

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)--

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

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

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

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

(8) Interim administrative review

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

(9) Labeling

(A) Additional statements

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

(B) Requirements

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

(C) Notification and disapproval

(i) Notification

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

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

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

(ii) Disapproval

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

(iii) Restriction on sale

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

(iv) Objection

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

(v) Final action

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

(D) Use dilution

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

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

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

(10) Expedited registration of pesticides

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

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

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

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

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

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

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

(d) Classification of pesticides

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

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

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

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

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

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

(2) Change in classification

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

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

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

(e) Products with same formulation and claims

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

(f) Miscellaneous

(1) Effect of change of labeling or formulation

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

(2) Registration not a defense

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

(3) Authority to consult other Federal agencies

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

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of--

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

(B) 1 or more fertilizer products,

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

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

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

(iii) Initial registration review

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

(I) October 1, 2022; or

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

(iv) Subsequent registration review

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

(v) Cancellation

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

(B) Docketing

(i) In general

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

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

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

(ii) Protected information

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

(C) Limitation

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

(2) Data

(A) Submission required

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

(B) Data submission, compensation, and exemption

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

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

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

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

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

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

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

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

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

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

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

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

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

(ii) Requirements

Proposed regulations issued under clause (i) shall--

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

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

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

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

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

(iii) Comments

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

(B) Final regulations

(i) Issuance

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

(ii) Failure to meet goal

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

(iii) Requirements

In issuing final regulations, the Administrator shall--

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

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

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

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

(bb) revised procedures for application review; and

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

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

(C) Expedited review

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

(D) Alternative review periods

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

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

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

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

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

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

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

(E) Wood preservatives

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

(F) Notification

(i) In general

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

(ii) Final decision

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

(iii) Exemption

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

(iv) Limitation

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

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

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

(4) Annual report

(A) Submission

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

(B) Requirements

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

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

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

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

CREDIT(S)

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

Notes of Decisions (100)

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

End of Document

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

7 U.S.C.A. § 136n

§ 136n. Administrative procedure; judicial review

Currentness

(a) District court review

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

(b) Review by court of appeals

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

(c) Jurisdiction of district courts

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

(d) Notice of judgments

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

CREDIT(S)

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

Notes of Decisions (70)

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

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

16 U.S.C.A. § 1532

§ 1532. Definitions

Currentness

For the purposes of this chapter--

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) between persons within one foreign country;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CREDIT(S)

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

Notes of Decisions (94)

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

End of Document

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

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

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

16 U.S.C.A. § 1533

§ 1533. Determination of endangered species and threatened species

Effective: November 24, 2003
Currentness

(a) Generally

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

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

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

(C) disease or predation;

(D) the inadequacy of existing regulatory mechanisms; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Basis for determinations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) a final regulation to implement such determination,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Lists

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

(2) The Secretary shall--

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

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

(i) be removed from such list;

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

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

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

(d) Protective regulations

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

(e) Similarity of appearance cases

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

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

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

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

(f) Recovery plans

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

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

(B) incorporate in each plan--

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

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

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

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

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

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

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

(g) Monitoring

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

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

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

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

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

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

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

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

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

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

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

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

CREDIT(S)

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

Notes of Decisions (403)

Footnotes

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

16 U.S.C.A. § 1533, 16 USCA § 1533

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

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

16 U.S.C.A. § 1536

§ 1536. Interagency cooperation

Currentness

(a) Federal agency actions and consultations

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

(2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

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

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

(b) Opinion of Secretary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Biological assessment

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

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

(d) Limitation on commitment of resources

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

(e) Endangered Species Committee

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

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

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

(A) The Secretary of Agriculture.

(B) The Secretary of the Army.

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

(D) The Administrator of the Environmental Protection Agency.

(E) The Secretary of the Interior.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) Application for exemption; report to Committee

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) Grant of exemption

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) Exemption for national security reasons

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

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

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

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

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

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

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

(m) Notice requirement for citizen suits not applicable

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

(n) Judicial review

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

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

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

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

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

(p) Exemptions in Presidentially declared disaster areas

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

CREDIT(S)

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

Notes of Decisions (697)

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

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter A. General
Part 23. Judicial Review Under EPA—Administered Statutes (Refs & Annos)

40 C.F.R. § 23.6

§ 23.6 Timing of Administrator's action under Federal Insecticide, Fungicide and Rodenticide Act.

Currentness

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of entry of an order issued by the Administrator following a public hearing for purposes of section 16(b) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after it is signed.

SOURCE: 50 FR 7270, Feb. 21, 1985; 53 FR 29322, Aug. 3, 1988; 70 FR 33359, June 8, 2005, unless otherwise noted.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

Current through February 1, 2018; 83 FR 4604.

End of Document

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

40 C.F.R. § 152.3

§ 152.3 Definitions.

Effective: February 10, 2009
Currentness

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

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

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

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

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

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

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

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

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

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

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

End use product means a pesticide product whose labeling

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

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

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

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

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

(1) Hospitals and nursing homes.

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

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

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

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

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

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

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

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

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

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

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

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

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

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

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

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Released for shipment. A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where finished products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment unless subsequent activities, such as relabeling or repackaging, constitute production.

Residential use means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

Credits
[66 FR 37814, July 19, 2001; 73 FR 64224, Oct. 29, 2008; 73 FR 75594, Dec. 12, 2008]

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15975, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Notes of Decisions (4)

Current through February 1, 2018; 83 FR 4604.

End of Document

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

40 C.F.R. § 152.113

§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

Currentness

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15980, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Notes of Decisions (4)

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Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart A. General

50 C.F.R. § 402.01

§ 402.01 Scope.

Currentness

(a) This part interprets and implements sections 7(a)–(d) [16 U.S.C. 1536(a)–(d)] of the Endangered Species Act of 1973, as amended ("Act"). Section 7(a) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical ("critical habitat"). Section 7(a)(1) of the Act directs Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or of Commerce, as appropriate, to utilize their authorities to further the purposes of the Act by carrying out conservation programs for listed species. Such affirmative conservation programs must comply with applicable permit requirements (50 CFR parts 17, 220, 222, and 227) for listed species and should be coordinated with the appropriate Secretary. Section 7(a)(2) of the Act requires every Federal agency, in consultation with and with the assistance of the Secretary, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat. Section 7(a)(3) of the Act authorizes a prospective permit or license applicant to request the issuing Federal agency to enter into early consultation with the Service on a proposed action to determine whether such action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Section 7(a)(4) of the Act requires Federal agencies to confer with the Secretary on any action that is likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat. Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat Biological assessments are required under section 7(c) of the Act if listed species or critical habitat may be present in the area affected by any major construction activity as defined in § 404.02. Section 7(d) of the Act prohibits Federal agencies and applicants from making any irreversible or irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternatives which would avoid jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Section 7(e)–(o)(1) of the Act provide procedures for granting exemptions from the requirements of section 7(a)(2). Regulations governing the submission of exemption applications are found at 50 CFR part 451, and regulations governing the exemption process are found at 50 CFR parts 450, 452, and 453.

(b) The U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) share responsibilities for administering the Act. The Lists of Endangered and Threatened Wildlife and Plants are found in 50 CFR 17.11 and 17.12 and the designated critical habitats are found in 50 CFR 17.95 and 17.96 and 50 CFR Part 226. Endangered or threatened species under the jurisdiction of the NMFS are located in 50 CFR 222.23(a) and 227.4. If the subject species is cited in 50 CFR 222.23(a) or 227.4, the Federal agency shall contact the NMFS. For all other listed species the Federal Agency shall contact the FWS.

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

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

Notes of Decisions (305)

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End of Document

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedPrior Version Held Invalid Cape Hatteras Access Preservation Alliance v. U.S. Dept. of Interior, D.D.C., Nov. 01, 2004

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Subchapter A
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Subpart A. General

50 C.F.R. § 402.02

§ 402.02 Definitions.

Effective: March 14, 2016
Currentness

Act means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 et seq.

Action means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

(a) actions intended to conserve listed species or their habitat;

(b) the promulgation of regulations;

(c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or

(d) actions directly or indirectly causing modifications to the land, water, or air.

Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

Applicant refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

Biological assessment refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

Biological opinion is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Conference is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

Conservation recommendations are suggestions of the Service regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.

Critical habitat refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

Cumulative effects are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

Designated non-Federal representative refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

Director refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

Early consultation is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

Effects of the action refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.

Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

Framework programmatic action means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

Jeopardize the continued existence of means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

Listed species means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11–17.12.

Major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

Mixed programmatic action means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Preliminary biological opinion refers to an opinion issued as a result of early consultation.

Proposed critical habitat means habitat proposed in the Federal Register to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

Proposed species means any species of fish, wildlife, or plant that is proposed in the Federal Register to be listed under section 4 of the Act.

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director believes necessary or appropriate to minimize the impacts, i.e., amount or extent, of incidental take.

Recovery means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

Service means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

Credits

[73 FR 76286, Dec. 16, 2008; 74 FR 20422, May 4, 2009; 80 FR 26844, May 11, 2015; 81 FR 7225, Feb. 11, 2016]

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

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

Notes of Decisions (234)

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Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.12

§ 402.12 Biological assessments.

Currentness

(a) Purpose. A biological assessment shall evaluate the potential effects of the action on listed and proposed species and designated and proposed critical habitat and determine whether any such species or habitat are likely to be adversely affected by the action and is used in determining whether formal consultation or a conference is necessary.

(b) Preparation requirement.

(1) The procedures of this section are required for Federal actions that are "major construction activities"; provided that a contract for construction was not entered into or actual construction was not begun on or before November 10, 1978. Any person, including those who may wish to apply for an exemption from section 7(a)(2) of the Act, may prepare a biological assessment under the supervision of the Federal agency and in cooperation with the Service consistent with the procedures and requirements of this section. An exemption from the requirements of section 7(a)(2) is not permanent unless a biological assessment has been prepared.

(2) The biological assessment shall be completed before any contract for construction is entered into and before construction is begun.

(c) Request for information. The Federal agency or the designated non-Federal representative shall convey to the Director either (1) a written request for a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area; or (2) a written notification of the species and critical habitat that are being included in the biological assessment.

(d) Director's response. Within 30 days of receipt of the notification of, or the request for, a species list, the Director shall either concur with or revise the list or, in those cases where no list has been provided, advise the Federal agency or the designated non-Federal representative in writing whether, based on the best scientific and commercial data available, any listed or proposed species or designated or proposed critical habitat may be present in the action area. In addition to listed and proposed species, the Director will provide a list of candidate species that may be present in the action area. Candidate species refers to any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule. Although candidate species have no legal status and are accorded no protection under the Act, their inclusion will alert the Federal agency of potential proposals or listings.

(1) If the Director advises that no listed species or critical habitat may be present, the Federal agency need not prepare a biological assessment and further consultation is not required. If only proposed species or proposed critical habitat may be present in the action area, then the Federal agency must confer with the Service if required under § 402.10, but preparation of a biological assessment is not required unless the proposed listing and/or designation becomes final.

(2) If a listed species or critical habitat may be present in the action area, the Director will provide a species list or concur with the species list provided. The Director also will provide available information (or references thereto) regarding these species and critical habitat, and may recommend discretionary studies or surveys that may provide a better information base for the preparation of an assessment. Any recommendation for studies or surveys is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

(e) Verification of current accuracy of species list. If the Federal agency or the designated non-Federal representative does not begin preparation of the biological assessment within 90 days of receipt of (or concurrence with) the species list, the Federal agency or the designated non-Federal representative must verify (formally or informally) with the Service the current accuracy of the species list at the time the preparation of the assessment is begun.

(f) Contents. The contents of a biological assessment are at the discretion of the Federal agency and will depend on the nature of the Federal action. The following may be considered for inclusion:

(1) The results of an on-site inspection of the area affected by the action to determine if listed or proposed species are present or occur seasonally.

(2) The views of recognized experts on the species at issue.

(3) A review of the literature and other information.

(4) An analysis of the effects of the action on the species and habitat, including consideration of cumulative effects, and the results of any related studies.

(5) An analysis of alternate actions considered by the Federal agency for the proposed action.

(g) Incorporation by reference. If a proposed action requiring the preparation of a biological assessment is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may fulfill the biological assessment requirement for the proposed action by incorporating by reference the earlier biological assessment, plus any supporting data from other documents that are pertinent to the consultation, into a written certification that:

(1) The proposed action involves similar impacts to the same species in the same geographic area;

(2) No new species have been listed or proposed or no new critical habitat designated or proposed for the action area; and

(3) The biological assessment has been supplemented with any relevant changes in information.

(h) Permit requirements. If conducting a biological assessment will involve the taking of a listed species, a permit under section 10 of the Act (16 U.S.C. 1539) and part 17 of this title (with respect to species under the jurisdiction of the FWS) or parts 220, 222, and 227 of this title (with respect to species under the jurisdiction of the NMFS) is required.

(i) Completion time. The Federal agency or the designated non- Federal representative shall complete the biological assessment within 180 days after its initiation (receipt of or concurrence with the species list) unless a different period of time is agreed to by the Director and the Federal agency. If a permit or license applicant is involved, the 180–day period may not be extended unless the agency provides the applicant, before the close of the 180–day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why such an extension is necessary.

(j) Submission of biological assessment. The Federal agency shall submit the completed biological assessment to the Director for review. The Director will respond in writing within 30 days as to whether or not he concurs with the findings of the biological assessment. At the option of the Federal agency, formal consultation may be initiated under § 402.14(c) concurrently with the submission of the assessment.

(k) Use of the biological assessment.

(1) The Federal agency shall use the biological assessment in determining whether formal consultation or a conference is required under § 402.14 or § 402.10, respectively. If the biological assessment indicates that there are no listed species or critical habitat present that are likely to be adversely affected by the action and the Director concurs as specified in paragraph (j) of this section, then formal consultation is not required. If the biological assessment indicates that the action is not likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

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

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

Notes of Decisions (56)

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Subpart B. Consultation Procedures

50 C.F.R. § 402.13

§ 402.13 Informal consultation.

Effective: May 4, 2009
Currentness

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non–Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required. If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

Credits
[73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009]

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

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

Notes of Decisions (16)

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Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.14

§ 402.14 Formal consultation.

Effective: June 10, 2015
Currentness

(a) Requirement for formal consultation. Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) Exceptions.

(1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) Initiation of formal consultation. A written request to initiate formal consultation shall be submitted to the Director and shall include:

(1) A description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statement, environmental assessment, or biological assessment prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat.

Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12. Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area or a segment of a comprehensive plan. This does not relieve the Federal agency of the requirements for considering the effects of the action as a whole.

(d) Responsibility to provide best scientific and commercial data available. The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) Duration and extension of formal consultation. Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

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

(3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) Additional data. When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's

request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) Service responsibilities. Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Formulate its biological opinion as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)–(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45–day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45–day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10–day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

(h) Biological opinions. The biological opinion shall include:

(1) A summary of the information on which the opinion is based;

(2) A detailed discussion of the effects of the action on listed species or critical habitat; and

(3) The Service's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy biological opinion"); or, the action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(i) Incidental take.

(1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, i.e., the amount or extent, of such incidental taking on the species (A surrogate (e.g., similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinitiate consultation immediately.

(5) Any taking which is subject to a statement as specified in paragraph (i)(1) of this section and which is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(6) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) Conservation recommendations. The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) Incremental steps. When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(l) Termination of consultation.

(1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

Credits

[54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015]

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

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

Notes of Decisions (206)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 424. Listing Endangered and Threatened Species and Designating Critical Habitat (Refs & Annos)
Subpart B. Revision of the Lists

50 C.F.R. § 424.12

§ 424.12 Criteria for designating critical habitat.

Effective: March 14, 2016
Currentness

(a) To the maximum extent prudent and determinable, we will propose and finalize critical habitat designations concurrent with issuing proposed and final listing rules, respectively. If designation of critical habitat is not prudent or if critical habitat is not determinable, the Secretary will state the reasons for not designating critical habitat in the publication of proposed and final rules listing a species. The Secretary will make a final designation of critical habitat on the basis of the best scientific data available, after taking into consideration the probable economic, national security, and other relevant impacts of making such a designation in accordance with § 424.19.

(1) A designation of critical habitat is not prudent when any of the following situations exist:

(i) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species; or

(ii) Such designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Services may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of “critical habitat.”

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

(i) Data sufficient to perform required analyses are lacking; or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of “critical habitat.”

(b) Where designation of critical habitat is prudent and determinable, the Secretary will identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat.

(1) The Secretary will identify, at a scale determined by the Secretary to be appropriate, specific areas within the geographical area occupied by the species for consideration as critical habitat. The Secretary will:

(i) Identify the geographical area occupied by the species at the time of listing.

(ii) Identify physical and biological features essential to the conservation of the species at an appropriate level of specificity using the best available scientific data. This analysis will vary between species and may include consideration of the appropriate quality, quantity, and spatial and temporal arrangements of such features in the context of the life history, status, and conservation needs of the species.

(iii) Determine the specific areas within the geographical area occupied by the species that contain the physical or biological features essential to the conservation of the species.

(iv) Determine which of these features may require special management considerations or protection.

(2) The Secretary will identify, at a scale determined by the Secretary to be appropriate, specific areas outside the geographical area occupied by the species that are essential for its conservation, considering the life history, status, and conservation needs of the species based on the best available scientific data.

(c) Each critical habitat area will be shown on a map, with more-detailed information discussed in the preamble of the rulemaking documents published in the Federal Register and made available from the lead field office of the Service responsible for such designation. Textual information may be included for purposes of clarifying or refining the location and boundaries of each area or to explain the exclusion of sites (e.g., paved roads, buildings) within the mapped area. Each area will be referenced to the State(s), county(ies), or other local government units within which all or part of the critical habitat is located. Unless otherwise indicated within the critical habitat descriptions, the names of the State(s) and county(ies) are provided for informational purposes only and do not constitute the boundaries of the area. Ephemeral reference points (e.g., trees, sand bars) shall not be used in any textual description used to clarify or refine the boundaries of critical habitat.

(d) When several habitats, each satisfying the requirements for designation as critical habitat, are located in proximity to one another, the Secretary may designate an inclusive area as critical habitat.

(e) The Secretary may designate critical habitat for those species listed as threatened or endangered but for which no critical habitat has been previously designated. For species listed prior to November 10, 1978, the designation of critical habitat is at the discretion of the Secretary.

(f) The Secretary may revise existing designations of critical habitat according to procedures in this section as new data become available.

(g) The Secretary will not designate critical habitat within foreign countries or in other areas outside of the jurisdiction of the United States.

(h) The Secretary will not designate as critical habitat land or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to a compliant or operational integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a) if the Secretary determines in writing that such plan provides a conservation benefit to the species for which critical habitat is being designated. In determining whether such a benefit is provided, the Secretary will consider:

(1) The extent of the area and features present;

(2) The type and frequency of use of the area by the species;

(3) The relevant elements of the INRMP in terms of management objectives, activities covered, and best management practices, and the certainty that the relevant elements will be implemented; and

(4) The degree to which the relevant elements of the INRMP will protect the habitat from the types of effects that would be addressed through a destruction-or-adverse-modification analysis.

Credits

[45 FR 13022, Feb. 27, 1980; 45 FR 64195, Sept. 29, 1980; 77 FR 25622, May 1, 2012; 81 FR 7439, Feb. 11, 2016]

SOURCE: 45 FR 13022, Feb. 27, 1980; 49 FR 38908, Oct. 1, 1984; 78 FR 53076, Aug. 28, 2013, unless otherwise noted.

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

Notes of Decisions (43)

Current through February 1, 2018; 83 FR 4604.

ADDENDUM OF DECLARATIONS

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*.,

Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF DARVIN BENTLAGE

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Counsel for Petitioners

I, DARVIN BENTLAGE, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, and Center for Biological Diversity (collectively Petitioners) in their Petition for Review of the registration of new uses of the herbicide XtendiMax.

2. I am a member of the Missouri Rural Crisis Center, a statewide farming and rural membership organization dedicated to preserving family farms, promoting sustainable land stewardship, and advocating on behalf of family farms and rural communities to achieve economic and social justice. Missouri Rural Crisis Center is a membership organization of Petitioner National Family Farm Coalition (NFFC). As a member organization, Missouri Rural Crisis Center participates directly in NFFC's executive committee, and helps direct NFFC's agenda and priority.

3. I have been a member of Missouri Rural Crisis Center for ten years. I currently serve as a board member of the Missouri Rural Crisis Center. Since last year, I have also been serving as a board member of NFFC's executive committee.

4. I am a resident of Golden City, Missouri 64748.

5. I farm grain, including soybean, corn, and wheat, and I also raise

cattle. I currently farm 1,200 acres—about 50%, or 650 acres, are maintained as row crops for grain, while the other 50%, or 500 acres, are used to raise cattle. I also keep about 50 acres of prairie and wetlands as conservation and wildlife habitat. Of the acreage set aside for row crops, I farm about 538 acres, and I rotate planting soybean, corn and wheat crops. I grow conventional, non-genetically engineered varieties of my crops. I go out of my way to purchase non-genetically engineered soybean seeds, and I also save seeds for replanting. I make roughly $200,000 annually. In 2017, I made approximately $80,000 in income from my crops, $80,000 from cattle, and $20,000 in conservation payments.

6. I am a fourth-generation farmer and a second-generation landowner. My great-grandfather migrated to the United States from Germany in 1867. My grandfather farmed as a sharecropper. My father bought the land that became our farm with the help of the G.I. Bill in 1948. When my father originally bought our farm, it was only 240 acres. Over his lifetime and mine, we have continued to expand our operations.

7. I am aware that the United States Environmental Protection Agency (EPA) has granted approval of XtendiMax, containing the active ingredient dicamba, for use on dicamba-resistant, genetically engineered cotton and soybean in thirty-four states, including Missouri. While dicamba has traditionally been used as a pre-emergent application to kill weeds in soybean fields early in the planting

season, EPA approved XtendiMax to be applied both for pre- as well as post-emergent use on dicamba-resistant soybean and cotton. As a result of the approval dicamba can be used directly on dicamba-resistant soybean later in the season.

8. Prior to EPA's approval of XtendiMax, grain farmers that grow soybean in my town would spray dicamba early in the planting season in the spring before planting their soybean plants. They would never spray dicamba during the summer because doing so would injure their crop. As a result of EPA's approval of XtendiMax, many of the farmers in my locality switched over to planting dicamba-resistant soybeans and spraying XtendiMax later in the growing season, when the temperature is higher, and the pesticide is able to volatilize for a longer period of time, thus extending the period when my soybean crop may potentially be damaged by dicamba.

9. EPA's approval of XtendiMax for use on dicamba-resistant soybean has injured me economically. In August of 2017, I experienced significant damage to one of my soybean fields that likely resulted from XtendiMax use from a neighboring farm. Specifically, I had a 58-acre soybean field that was adjacent to a dirt road, with another farmer's soybean field on the other side. The remaining sides of that 58-acre field are adjacent to my own pasture, where I raise cattle, and which I do not spray. About half of my soybean crop on the side of that 58-acre plot adjacent the dirt road was damaged by dicamba drift from in-season

application by my neighbor of dicamba on his dicamba-resistant soybean crop.

10. Prior to the drift damage incident, the 58-acre soybean field was looking to be one of my most productive plots. I had noticed my neighbor out spraying his field a few days prior to observing damage to soybean plants on that plot. A few days after seeing my neighbor spray his field, I noticed that roughly half of the soybean plants on that field (the half that is closer to my neighbor's farm) showing one of the classic signs of dicamba damage—shriveled leaves that curled upward like little cups. I documented the damage by taking pictures of the damaged plants, which are attached as Exhibit A to my declaration.

11. Since I had previously read about what farmers should do if they experience crop damage from dicamba drift, I called the local extension office of the Missouri Department of Agriculture. I then took a couple of the damaged plants and sent them to our local office. The Department sent the damaged plants to Dr. Kevin Bradley, a University of Missouri plant pathologist. Dr. Bradley concluded that the damage to half of my soybean crop on that field was either caused by dicamba or pasture spray damage. I did not spray any of my pastures adjacent to that plot, so the damage to my soybean field came from the use of dicamba late in the season from the neighboring farm.

12. The damaged soybean plants never bounced back. In fact, their growth was stunted by the drift damage. As a result, I suffered a major decrease in

yield from the damaged soybean plants, producing only half the yield size of soybeans I would typically harvest. Each of the affected plants produced approximately thirty-four pods, whereas the soybean plants that were unaffected produced an average of sixty-three pods. I also took pictures comparing a healthy soybean plant against the stunted soybean plant from that field. A photograph of me comparing the two soybean plants is attached to this declaration as Exhibit B. I believe that the loss in yield resulted in a loss in income of approximately $7,500.

13. So long as XtendiMax remains approved for use on dicamba-resistant soybean, I will continue to be injured by the risk of drift damage to my soybean crop. Thus, I have also been travelling to Jefferson City, the capital of the State of Missouri, to educate state representatives and government officials about the dangers of XtendiMax use on dicamba-resistant soybean, in the hope of convincing the State to do something to protect and compensate farmers like myself. These public outreach and lobbying efforts to prevent the likelihood of future damage to my crop from the use of dicamba formulations such as XtendiMax later into the season and on dicamba-resistant crops cost me my time and money, and take me away from my family. Yet, I have no choice but to continue these efforts in order to protect my farm.

14. I am aware that, in light of the significant crop damage caused by dicamba formulations like XtendiMax, the local seed bank where I buy my seeds is

considering phasing out sale of conventional and Roundup Ready soybean seeds, and switching to offering only dicamba-resistant soybean seeds. This means that more and more farmers in my town will likely switch over to planting dicamba-resistant soybean and spraying dicamba formulations like XtendiMax, which will further increase the likelihood of damage to my soybean crop, putting me at risk for additional economic losses. It also means that it will be impossible for me to buy non-genetically engineered soybean seeds from a local source, and I will have to spend additional time and money to locate such seeds.

15. EPA's approval of XtendiMax for use on dicamba-resistant soybean also puts my personal health at risk. I was recently diagnosed with a spot on my lung. I am also a hepatitis C survivor, so being exposed to pesticides like dicamba really concerns me. EPA's approval of XtendiMax has enabled dicamba applications later in the season, which lengthens the time period when I may be exposed to dicamba. I am concerned about the long-term effects that such exposure will have on my health. Despite having made the personal decision to not spray dicamba on my fields, I will have to continue to live with the risk of being exposed to dicamba from neighboring farms.

16. Additionally, EPA's approval of XtendiMax for use on dicamba-resistant soybean has injured my personal relationships with my neighbors, as the source of yet another quarrel over the drift of chemicals and pesticides onto my

farm. My wife and I are disgusted and exhausted by the amount of time and energy we have spent fighting with our neighbors to protect our health and livelihood. Fighting with my neighbors about dicamba-drift damage to my soybeans is not how I had envisioned I would farm. If my neighbors continue to spray dicamba formulations like XtendiMax on their soybean crop, I will not be able to maintain the way I farm. If XtendiMax continues to be approved for use on dicamba-resistant soybean, I will likely consider retiring early, and just sell my farm and move. It saddens me to think that I will sell the farm that my farther bought and handed down to me.

17. In sum, my personal health, social, and economic interests have, and will continue to be, injured by EPA's decision to approve XtendiMax for use on dicamba-resistant soybean. Without a court finding that EPA violated its duties in issuing the conditional registration of XtendiMax, my livelihood, personal health, and my relationships with my neighbors will continue to be adversely impacted.

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

Executed on this 4th day of February, 2018, in Golden City, Missouri.

DARVIN BENTLAGE

Exhibit A


08.11.2017 21:14


08.11.2017 21:15

Exhibit B

No. 17-70196

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*.,

Petitioners,

v.

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Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF JOHN BUSE

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Counsel for Petitioners

I, JOHN BUSE, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the registration of new uses of the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

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

3. I live in Indianapolis, Indiana. Indiana is one of the states where the EPA registered dicamba for use on genetically engineered soybean that have been engineered to resist dicamba. The state of Indiana is one of the largest producers of soybean, and much of the agricultural land in and around Marion County where I live is used for soybean production

4. I am a 1985 graduate of the University of Chicago, with a degree in the History, Philosophy and Social Studies of Science and Medicine. I also have a master's degree in Biological Chemistry from the University of Illinois–Chicago Medical Center. I am a 1992 graduate of the University of California–Davis School of Law, where I focused on environmental law and related topics.

5. Thanks to my educational background and personal experience, I have a deep professional and personal interest in evolutionary biology and the diversity of life on earth.

6. As a member and staff member of the Center, I count on the Center to represent my interest in protecting biodiversity and conserving threatened and endangered species and their habitats through legal advocacy, public education, and other means.

7. Through my professional work and personal observation, I have become very concerned about the effect of conventional agriculture on threatened and endangered species. I have become aware of the enormous quantities of pesticides used to support conventional agricultural operations in Indiana and other Midwestern states, and have followed with interest the reports that agricultural chemicals disrupt endocrine activity in amphibians. I am concerned that the effects of commonly used pesticides and herbicides extend beyond impacts on amphibians, and may pose a significant threat to the wellbeing and recovery of many other threatened and endangered species, as well as to water quality and human health.

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

9. I regularly observe bats at or near my home in Indianapolis on summer and fall evenings. I have specifically observed Indiana bats (*Myotis sodalis*) at a known colony south of Indianapolis International Airport as part of a bat count. I watched and counted the bats as they emerged from their tree colony at twilight.

10. I appreciate the Indiana bat and its continued existence in the wild for its quiet but persistent presence, for its stealthy hunting of insects, and for the valuable habitat it maintains in close proximity to urban centers. I also believe that all species, including the Indiana bat, have inherent value, and I have an interest in maintaining the diversity of life.

11. I have hiked and recreated near Indiana bat's habitat on numerous occasions while attempting to observe wildlife. I will continue to seek out and observe bats, including Indiana bats, as long as I live here.

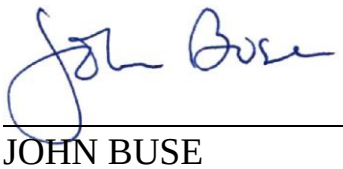
12. I hope to again see an Indiana bat in the wild here in Indiana and elsewhere, and I look forward to the recovery of the Indiana bat throughout its native range. I am concerned that dicamba will be routinely applied in Indiana and elsewhere in and around Indiana bat habitat without regard to the species' conservation and recovery. Killing of non-target insects and plants by pesticides and herbicides is well-documented, and I fear that Indiana bats are being inadvertently killed and harmed by agricultural chemicals. If the remaining

populations of Indiana bats in Indiana were extirpated or reduced, my appreciation of the area's unique natural environment would be diminished.

13. In summary, I have professional, aesthetic, and recreational interests in the preservation of the Indiana bat and its habitat. 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 new uses of the herbicide dicamba on this 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 Indiana bats 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 this species, which is important to ensure that my interests in the species are preserved and remain free from injury.

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

Executed on this 1st day of February, 2018 at Indianapolis, Indiana.



JOHN BUSE

No. 17-70196

UNITED STATES COURT OF APPEALS
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NATIONAL FAMILY FARM COALITION, *et al*.,

Petitioners,

v.

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Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF MARTHA L. CROUCH, PhD

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Counsel for Petitioners

I , MARTHA L. CROUCH, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, and Center for Biological Diversity (collectively Petitioners) in their Petition for Review of the registration of new uses of the herbicide XtendiMax.

2. I am a member of Center for Food Safety (CFS). I joined CFS because I am concerned about the environmental, health, and public safety impacts of food and agriculture. I support CFS's efforts to advocate for more stringent government oversight of food production and its work on reducing the amount of chemical inputs into U.S. agriculture.

3. I am a resident of Bloomington, Indiana which is located in Monroe County. The state of Indiana is one of the largest producers of both corn and soybean. The majority of agricultural land in and around Monroe County is used for corn and soybean production.

4. I earned a Bachelor of Science degree in botany from Oregon State University, and a Ph.D. in developmental biology from Yale University. I am a retired professor of biology at Indiana University, where for 20 years I conducted research on plant molecular biology and taught courses such as Introduction to

Biology, Biology for Elementary School Teachers, Plant Physiology, Plant Molecular Biology, and Biology of Food. I am currently a consultant on issues of agriculture and technology, focusing specifically on pesticide-related issues. I primarily consult for the Center for Food Safety regarding these issues.

5. Besides my professional work, I am an amateur naturalist and I consider myself a "Craniac," as those of us who follow the whooping crane (*Grus americana*) populations often refer to ourselves.

6. I first became interested in whooping cranes about fifty years ago, when my mother gave me the book "North With the Spring," by Edwin Way Teale. In the book, Teale visited a lone whooping crane in a zoo in New Orleans in 1947, where he thought he might be experiencing the same feeling as those who viewed the last passenger pigeon experienced. I have been fascinated by and interested in whooping cranes ever since, and I will continue to be for the foreseeable future.

7. I am aware that there are three populations of whooping cranes, two of which migrate, including a self-sustaining western population that overwinters in Texas, and migrates up through Oklahoma, Kansas, Nebraska, South Dakota, North Dakota and northeastern Montana to northeastern Alberta and the southern Northwest Territories in Canada where it summers and raises chicks, before migrating back.

8. I am aware that crane conservationists, out of concern that having the entire whooping crane population overwintering in one location put the species at risk from a single adverse event, received permission to raise an experimental population to reduce the risk to the species. That experimental eastern population now summers in Wisconsin and winters in Florida, with the help of a dedicated whooping crane recovery team.

9. The western population does not migrate where I live, but I have some friends in Rockport, Texas, whose house is near to the Aransas National Wildlife Refuge where the western population winters. I purposefully time my visits to my friends 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 many years ago I saw two pairs of whooping cranes in the fields outside of the Aransas National Wildlife Refuge where they winter in Texas.

10. I plan to continue visiting my friends in Texas during the months when the whooping crane is wintering in the nearby wildlife refuge, so I can observe the western population. I am making plans to visit my friends and stay with them in the spring of 2019 so that I may attend the festival again and observe the western population of whooping cranes there.

11. In addition to my following, observing, and interest in the western population, I have experience with the eastern population, as well. This population migrates over Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida. The migration pattern of this population leads some to fly directly over my house, and on two occasions I have seen them going over in mixed flocks with sandhill cranes. I have visited the wildlife refuges here in Indiana where many whooping cranes spend quite a bit of time, such as the Goose Pond Fish and Wildlife Area in Greene County, near Linton, Indiana. I read news and blogs about both populations.

12. I am worried about how the registration of XtendiMax may affect whooping cranes because they frequent agricultural fields. The flyway of the western population goes right through parts of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma and Texas, where XtendiMax has been approved for use on dicamba-resistant soybeans and cotton. The eastern flock migrates through the states of Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida where XtendiMax has been approved for use on dicamba-resistant soybeans and cotton. Many photos taken by birdwatchers of whooping cranes show them foraging in crop fields in the fall, including soybean and cotton fields, and I am aware that they also stop over in crop fields in the spring, where they have the potential to be exposed to toxic agricultural chemicals. During the spring

migration north, whooping cranes may stop over in soybean and cotton fields that have been prepared for planting or recently planted, and sprayed with herbicides, including XtendiMax.

13. I am aware that, based on the instructions and guidelines for XtendiMax use in dicamba-resistant soybean and cotton production, it is possible that food and water sources used by whooping cranes in these fields could or will have very high residues of dicamba on them, the exposure to which may have adverse effects on the whooping cranes.

14. I do not believe that the risks of registering XtendiMax have been properly assessed in regards to the whooping crane populations that I care about so deeply. It concerns me that given the stresses the cranes already have to endure, allowing XtendiMax to be used on dicamba-resistant soybeans and cotton in the agricultural fields which they migrate through and spend considerable time in, will be another serious stress that can and will severely harm their recovery.

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

Executed this 5th day of February, 2018, in Bloomington, Indiana.

MARTHA L. CROUCH, Ph.D.

No. 17-70196

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and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

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Counsel for Petitioners

I, LISA GRIFFITH, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am the Interim Executive Director of Petitioner National Family Farm Coalition (NFFC). I submit this declaration in support of the Petition for Review of the registration of new uses of the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

2. NFFC is a Washington, D.C.-based, nonprofit corporation that serves as national link for a coalition of family farm and rural groups on the challenges facing family farms and rural communities. Founded in 1986, NFFC today represents farmers and ranchers from 25 grassroots member organizations in 32 states, including farmers and ranchers from Georgia, Mississippi, Missouri, North Carolina, North Dakota, Ohio, Oklahoma, South Dakota, Texas and Wisconsin, where the U.S. Environmental Protection Agency (EPA) has approved the use of XtendiMax on dicamba-resistant cotton and soybean, the challenged new uses at issue in the present petition for review. The combination of our member groups' grassroots strength and NFFC's experience working on the national level enables us to play a unique role in securing a sustainable, economically just, healthy, safe and secure food and farm system.

3. NFFC chooses its projects based on the potential to empower family farmers by reducing the corporate control of agriculture and promoting a more socially just farm and food policy. NFFC's member organizations contribute to NFFC financially, participate in NFFC's executive decision-making, and help NFFC set its priorities. NFFC staff collaborate with NFFC members — family farmers and ranchers, community-based fishermen and rural advocates — who comprise the Trade, Farm and Food Policy, and Credit committees that determine NFFC's campaigns. Working by committee enables farm groups of differing commodities and in various regions to develop national organizing strategies and directly participate in issue work.

4. NFFC and its members are being, and will be, adversely affected by EPA's decision to register XtendiMax herbicide for new uses on dicamba-resistant cotton and soybeans.

5. Since the mid-1990s, NFFC has devoted significant resources to addressing the harms stemming from the use of pesticides on genetically engineered, pesticide-resistant crops. NFFC's Farmer to Farmer Campaign on Genetic Engineering sought to build a nationwide campaign focused on the risks of genetic engineering to agriculture. As part of the campaign, NFFC published educational materials on the liabilities of genetic engineering, and conducted trainings to develop farmer leaders on various genetically engineering issues,

including the agronomic, human health, and environmental harms of pesticide use on such crops. In 2009, Farmer to Farmer also published the *Out of Hand Report*[1] to outline the problems farmers have faced through concentration in the seed industry, including diminished options, higher costs and the increased use of toxic herbicides.

6. Between 2012 and 2017, NFFC participated in bi-weekly calls with allied organizations, farmers and media to oppose the deregulation of new herbicide-resistant crops, including dicamba-resistant crops and the expected increase in the spraying of those herbicides. On behalf of the farmers and ranchers NFFC represents, NFFC submitted organizational comments in May 2015 to EPA regarding the agency's initial proposal to register the new uses of XtendiMax on dicamba-resistant cotton and soybean.

7. The approved new uses of XtendiMax injure NFFC members' farm productivity, livelihoods and environment, to the detriment of their economic and personal interests. NFFC's members live, farm and recreate in many locations where XtendiMax has been sprayed or will be sprayed. Many of NFFC's farmer members who grow vulnerable crops, such as tomatoes, grapes and non dicamba-resistant soybeans, are at risk of dicamba damage. Because EPA's approval authorizes XtendiMax use in cotton and soybean states for in-season use, NFFC's

[1] http://www.farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf

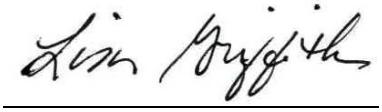
farmer members may have to adjust their planting season and choice of seed or crop, or impose costly measures such as buffer zones, in an attempt to avoid crop damage by XtendiMax.

8. Many of NFFC's members are heavily involved with reducing the use of pesticides and preserve the use of non-patented seed crops. They see the use of conventional, non-genetically engineered seeds and the ability to save their seeds as vital components of rural life and their way of farming. Because EPA's approved new uses of XtendiMax on dicamba-resistant cotton and soybean creates a longer period of time whereby farmers may suffer drift damage from XtendiMax, many farmers in localities where NFFC farmers reside have no choice but to switch to planting dicamba-resistant soybean and cotton in order to avoid economic losses due to drift damage to their crops. This, in turn, reduces the local availability of non-genetically engineered seeds as local seed banks have no incentive to sell such varieties due to reduced demand. Thus, the registration of XtendiMax has, and will continue to, injure NFFC's members' interest and ability to obtain and plant non-genetically engineered seeds, costing them additional time and money in order to locate such seeds.

9. In sum, EPA's decision to register XtendiMax for use on dicamba-resistant cotton and soybean adversely injures NFFC's organizational interests, as well as the economic and interests of our members.

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

Executed on 5th day of February, 2018, in Washington, D.C.



Lisa Griffith
Interim Executive Director

No. 17-70196

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF MARCIA ISHII-EITEMAN, PhD

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Counsel for Petitioners

I, MARCIA ISHII-EITEMAN, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am a Senior Scientist of Pesticide Action Network North America (PANNA). I submit this declaration in support of Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, and Center for Biological Diversity (collectively Petitioners)'s opening brief.

2. PANNA is a Berkeley, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. PANNA has more than 125,000 members across the United States. Many of our members are farmers or residents of rural communities. PANNA also has offices in Minneapolis, Minnesota and Des Moines, Iowa; states directly affected by the U.S. Environmental Protection Agency (EPA) regulatory approval of the use of the herbicide XtendiMax.

3. PANNA was founded in 1982 to combat the proliferation of chemical-intensive, mono-crop agriculture. PANNA's mission is to advance a post-industrial vision of agriculture that replaces the use of hazardous pesticides with healthier, ecologically-sound pest management. The costs of industrial food production and the increased use of pesticides now touch every aspect of our lives, from residues on our produce, to increased chronic disease, to biodiversity loss. In

order to meet its objectives, PANNA links local and international consumer, labor, health, environment and agriculture groups into an international citizens' action network. Through this network, PANNA challenges the global expansion of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable food system.

4. To protect our health and restore our ecosystems, PANNA shares information and builds alliances with numerous partners and coalitions across the United States and globe. PANNA works together with these groups to reduce reliance on toxic chemicals, promote food democracy, and move toward a healthy, resilient system of food and farming for all. PANNA's partners include the California Climate and Agricultural Network, Californians for Pesticide Reform, National Coalition for Pesticide-Free Lawns, National Family Farm Coalition, National Pesticide Reform Coalition, Rural Coalition and many more. We also work closely with food and farming groups to reduce the negative health and livelihood impacts of pesticide drift in the states where XtendiMax has been approved for use, including the Iowa Farmers Union, Iowa Organic Association and Practical Farmers of Iowa.

5. In addition to coalition building, we bring our strength in grassroots science and strategic communications to tackle a multitude of pesticide-related problems. PANNA provides scientific expertise, public education and access to

pesticide data and analysis, policy development, and coalition support to more than 100 affiliated organizations in North America.

6. PANNA submitted organizational comments in May 2015 to EPA regarding the agency's initial proposal to register XtendiMax, the pesticide product at issue in the present petition for review.

7. Dicamba, the active ingredient in XtendiMax, is a highly volatile chemical that easily turns to vapor, especially in warm summer temperatures, enabling it to drift for miles. In 2017 alone, weed scientists reported over 3.6 million acres of soybeans damaged by dicamba drift, in 23 states, representing over 2,700 individual reports of injury. Due to lack of reporting mechanisms, their figures do not include likely damage to other vulnerable crops (e.g., any broadleaf plants such as cotton, fruits, vegetables, vineyards, trees, or found in home gardens), plant habitat critical to pollinators and other wildlife, and organic farm businesses that may lose organic certification as a result of dicamba contamination.

8. PANNA and its members are being, and will be, adversely affected by EPA's decision to register XtendiMax herbicide for new uses on Monsanto's Xtend cotton and soybeans. PANNA's members live, farm, and recreate in many locations where XtendiMax has been sprayed or will be sprayed. PANNA's farmer members who grow vulnerable crops, residents who have home gardens and

community members who enjoy the benefits of pollinators, birds and other wildlife that rely on vulnerable plants for food, nesting or breeding, are at risk of dicamba damage to their crops, hedgerows, gardens and surrounding ecologically important flora. PANNA's farmer members may have to adjust their planting season and choice of seed or crop, or impose costly measures such as buffer zones, in an attempt to avoid crop damage by XtendiMax.

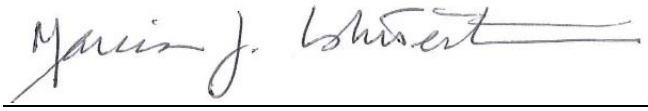
9. PANNA's members are deeply concerned that EPA's registration of XtendiMax will harm their farm productivity, livelihoods and environment, to the detriment of their economic and recreational interests.

10. PANNA's members are heavily involved with reducing the use of pesticides to protect various species of plants and animals and enhance biodiversity. Biodiversity is essential to a healthy and thriving ecosystem and successful agriculture. The registration of XtendiMax will harm sensitive, threatened and endangered species, which will injure PANNA's members' aesthetic interest in protecting natural ecosystems and wildlife and maintaining biodiversity.

11. EPA's decision to register XtendiMax for use on Xtend cotton and soybean adversely injures PANNA's organizational interests, as well as the aesthetic, recreational, economic and personal health interests of our members.

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

Executed on this 2nd day of January, 2018, in Berkeley, California.



MARCIA ISHII-EITEMAN, Ph.D.
Senior Scientist, PANNA

No. 17-70196

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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ON PETITION FOR REVIEW FROM THE UNITED STATES
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DECLARATION OF GEORGE KIMBRELL

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Counsel for Petitioners

I, GEORGE KIMBRELL, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am the Legal Director of the Center for Food Safety (CFS) and counsel in this case. I submit this declaration in support of the Petition for Review of the registration of new uses of the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

2. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; and Washington, D.C. CFS represents more than 950,000 farmer and consumer members, in every state throughout the country, including over 400,000 in the 34 states covered by the XtendiMax approval challenged in this case. CFS and its members are being, and will be, adversely affected by EPA's decision to register XtendiMax herbicide for new uses on dicamba-resistant cotton and soybeans.

3. CFS was founded in 1997. Since its inception CFS's mission has been to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. Accordingly, CFS's program activities are focused in several areas, including the environmental, public health, and economic impacts of the development and commercialization of agriculture and food processing technologies. A cornerstone of this mission is to advocate for thorough,

science-based safety testing of new agricultural products and technologies. This includes major programs on both pesticides as well as genetically engineered crops.

4. CFS combines multiple tools and strategies in pursuing its mission, including public and policymaker education, outreach, and campaigning. For example, CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the effects of industrial food production, agricultural products, and pesticides, on human health and the environment. These educational and informational materials include, but are not limited to, news articles, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets. CFS often has provided expert testimony to policymakers on the potentially-harmful agrichemical impacts associated with industrial monoculture cropping systems, including the increased use of pesticides and chemical fertilizers.

5. Staff members regularly monitor the Federal Register and submit comments to the U.S. Environmental Protection Agency (EPA) and other regulatory agencies via the public notice-and-comment process. CFS also regularly sends out action alerts to its members, encouraging them to participate in the notice-and-comment process, or to submit letters to government officials related to

the oversight of industrial agriculture, pesticide use, genetically engineered crops, and other issues affecting CFS's mission to build a sustainable food system.

6. When necessary, and as here, CFS also engages in public interest litigation to address the impacts of industrial food production and pesticides on its members, the environment, and the public interest. CFS submitted organizational comments in 2010, 2012, and 2016 to the EPA docket on the proposed registration of XtendiMax, the pesticide product at issue in this petition for review.

7. As a party to this proceeding, CFS and its members are injured by the approved novel and increased use of XtendiMax on herbicide-resistant cotton and soybean specifically engineered to withstand its application. CFS and its members are concerned by the detrimental impacts on farmers, the environment, including on endangered species and their habitat, and on the public health that will result from the approved use of XtendiMax.

8. CFS and its members are being, and will be, adversely affected by the challenged EPA's decision to register XtendiMax's new use. Many members of CFS are heavily involved with maintaining a healthy environment for many species of animals for recreational, aesthetic, and personal reasons. The use of XtendiMax will negatively harm non-target organisms, injuring CFS members' recreational and aesthetic interests.

9. Many of CFS's members are farmers and/or live in rural areas where excessive amounts of pesticides are being applied to cotton and soybeans crops genetically engineered with resistance dicamba. These members are especially susceptible to the environmental and health risks associated with EPA's approval of XtendiMax for use on cotton and soybean fields. Moreover, the intensive use of XtendiMax on crops compromises our members' enjoyment of their local environment, and injures the aesthetic and recreational interests of our members in maintaining biodiversity and protecting sensitive species.

10. CFS members' interests are also injured by EPA's decision to approve XtendiMax without consulting with the expert U.S. Fish and Wildlife Service (FWS) on the potential harm to federally endangered and threatened species and their critical habitats, as required under the Endangered Species Act. Many of CFS's members have significant recreational interests in observing these sensitive species, including the Indiana bat and whooping crane, and preserving their habitats. CFS's members' aesthetic interest in biodiversity and protection of these sensitive species are injured by EPA's decision to register XtendiMax without consulting with FWS, as required under the Endangered Species Act.

11. Similarly, members of CFS include farmers and gardeners who live and grow crops that have already been damaged or are likely to be damaged by drift and vaporization of XtendiMax. EPA's registration of XtendiMax has already

caused unprecedented damage to farmers and gardeners's crops and plants across millions of acres. Continued approval will lead to increased use and more frequent applications of XtendiMax this year, making it more likely that CFS's farmers and gardeners members who cultivate crops near areas of XtendiMax application will suffer crop or land use damage. Such members may have to adjust their planting season, or impose costly measures such as buffer strips, or forego the planting of certain crops, in order to try to reduce the negative impacts of XtendiMax use near their crops. The livelihood and economic interests of CFS members who cultivate and farm such crops are injured by the EPA approval.

12. In sum, EPA's decision to register XtendiMax for use on cotton and soybean injures CFS's organizational interests in protecting agriculture and the environment, as well as the aesthetic, recreational, economic, and personal health interest of CFS's hundreds of thousands of members. CFS and its members will be redressed if and when this Court vacates the registration.

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

Executed on this 8th day in February, 2018, in Portland, OR.

George Kimbrell
Legal Director, CFS

No. 17-70196

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF BRYAN P. NEWMAN

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Counsel for Petitioners

I, BRYAN P. NEWMAN, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the registration of new uses of the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

2. I have been a member of the Center for Biological Diversity since June of 2016.

3. I live in Blaine, Minnesota. Minnesota is one of the states where the EPA registered dicamba for use on genetically engineered soybean that have been engineered to resist dicamba.

4. I am an amateur naturalist, avid bird watcher and I look for wildlife wherever I go or travel.

5. I first became interested in whooping cranes (*Grus Americana*) as a child reading about endangered wildlife. I recall being fascinated by all the efforts people have made to save these amazing birds from extinction.

6. For many years, the only cranes I saw were in zoos. I vowed to one day see the birds in the wild. That dream came true when I was in my thirties, and I saw whooping cranes in the wild at Aransas National Wildlife Refuge near Rockport, Texas.

7. The next time I saw whooping cranes was on my annual road trip from Minnesota to visit family in Tennessee. That encounter was very special to me. I saw a flock of sandhill cranes fly over the road and noticed that two whooping cranes were included in the flock. I had been reading about people using ultralights to help whooping cranes migrate, and I took great joy in seeing the birds making their journey on their own and knowing that the recovery efforts were making a difference.

8. After that I made three visits to the International Crane Foundation in Baraboo, Wisconsin, and I saw whooping cranes on each visit.

9. The next time that I saw the cranes in the wild was fall of 2013, when I travelled to Necedah National Wildlife Refuge in Necedah, Wisconsin with the specific purpose of seeing the cranes in the wild. I was thrilled to see several flocks at the refuge.

10. In the fall of 2014, my partner and I went to the Necedah National Wildlife Refuge in Necedah, Wisconsin. I saw and heard whooping cranes on several occasions during that visit. I photographed the beautiful birds, and shared the photos with my family and friends. We also visited the nearby International Crane Foundation.

11. In the fall of 2016 and 2017, I took trips to central Wisconsin. I travel there several times a year for vacations and to see family, and I look for wildlife

every time I go. East of the city of Tomah, I saw a whooping crane standing in an agricultural field along with several sandhill cranes. It was great to see the cranes but I know about the threats to birds from agricultural pesticides, and I was concerned about how their feeding on agricultural residue could hurt them. Wisconsin is one of the states where EPA registered dicamba for use on genetically engineered soybean.

12. This spring I have plans to again return to Necedah National Wildlife Refuge, and we plan to make this an annual tradition. I will look for whooping cranes and other wildlife during each one of these visits.

13. In addition, I plan to visit central Wisconsin again this summer and fall, and I will again look for whooping cranes in the agricultural fields during my travels.

14. In the spring of 2017 I drove to Tennessee and looked for whooping cranes. I plan to continue my annual road trip to Tennessee and look for whooping cranes and other wildlife.

15. As an avid bird watcher, I follow posts from the birding community, where birders share rare bird sightings in Minnesota and adjacent states. I'd make every effort to try to find any whooping cranes posted near where I live or travel.

16. I am worried about how the registration of dicamba may affect whooping cranes because they frequent agricultural fields. The flyway of the

western flock goes right through parts of North Dakota, South Dakota, Nebraska, Kansas, and Texas, where dicamba has been approved for use on genetically engineered soybeans. The eastern flock migrates through the states of Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Georgia, and Florida where dicamba has been approved for use on genetically engineered soybeans and cotton. Many of the "crane cam" views of whooping cranes show them foraging in soybean fields in the fall and I am aware that they also stopover in soybean fields in the spring, where they have the potential to be exposed to toxic agricultural chemicals. During the spring migration north, whooping cranes may stopover in soybean fields that have been recently planted and sprayed with herbicides, including dicamba. Cranes are also often seen in corn fields grown near each other where they could be exposed to dicamba drift.

17. These exposures to dicamba may have adverse effects on the whooping cranes.

18. I do not believe that the risks of registering dicamba for use on soybean and cotton genetically engineered to resist dicamba have been properly assessed by the EPA through consultation with the U.S. Fish and Wildlife Service. It concerns me that given the stresses the cranes already have to endure, allowing the pesticide to be used in the agricultural fields frequented by the cranes will be another serious stress that can and will severely harm their recovery.

19. In summary, I have aesthetic and recreational interests in the preservation of whooping cranes and their habitats. These interests are being harmed by the EPA's failure to consult with the U.S. Fish and Wildlife Service on impacts of its registration of dicamba uses on this species. Specifically, I believe that the EPA'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 this species, which is important to ensure that my interests in the species are preserved and remain free from injury.

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

Executed on this 26th day of January, 2018, in Anoka County, Minnesota.

/s/ Bryan Newman
BRYAN P. NEWMAN

No. 17-70196

UNITED STATES COURT OF APPEALS
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ON PETITION FOR REVIEW FROM THE UNITED STATES
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DECLARATION OF KIERÁN SUCKLING

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Counsel for Petitioners

I, KIERÁN SUCKLING, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the registration of new uses of the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

2. I have been a member of the Center for Biological Diversity since 1989. I am a co-founder and the Executive Director.

3. I live in Tucson, Arizona. Arizona is one of the states where the EPA registered dicamba for use on genetically engineered cotton that have been engineered to resist dicamba. Cotton is one of Arizona's major agricultural commodities. Along with cattle, copper and citrus, cotton makes up the "Four Cs" dominating Arizona's resource economy. Cotton is grown primarily in Graham, Maricopa, Pima, Pinal, Cochise, Greenlee, La Paz, Mohave and Yuma counties.

4. The Center for Biological Diversity (the "Center") is a tax-exempt, nonprofit membership organization headquartered in Arizona with offices in Florida, Indiana, and Minnesota, among other places. I helped found the Center (formerly the Southwest Center for Biological Diversity) in 1989 to fight the growing number of threats to biodiversity. Our mission is to secure a future for all species, great and small, hovering on the brink of extinction through science,

policy, education, and environmental law. As a result of groundbreaking petitions, lawsuits, policy advocacy and outreach to media, hundreds of species have gained protection. The Center has a full-time staff of scientists, lawyers and other professionals who work exclusively on campaigns to save species and their habitat. Our members rely on the Center to represent their interests in protecting biodiversity and conserving threatened and endangered species and their habitats.

5. I have dedicated my life to protecting rare and imperiled wildlife, fish, and plants. I believe all of nature's living organisms, from beetles to polar bears, are equal, have inherent value, and are necessary for a healthy environment, including for humans. I have long been concerned about the widespread toxic contamination in our environment and the impacts these chemicals are having on biodiversity and human health. We developed the Environmental Health Program within the Center to address the adverse effects of pesticides and other toxic substances.

6. I am very concerned about the effects of pesticides on species and their habitats—many that I enjoy viewing in the wild and that I have worked to protect. I regularly enjoy looking for species in their natural habitats wherever I am during my travels, and especially in my home state of Arizona. I have definite plans to continue to look for and enjoy these species. In Arizona, I am specifically

concerned about the potential effects of the use of dicamba on the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog.

7. The Southwestern willow flycatcher (*Empidonax traillii extimus*) is a small migratory bird that was formerly common along desert rivers from Texas to California. It is now very rare, but maintains a few important stronghold populations in Arizona. I was one of the authors of the 1992 citizen petition to list it as a federally endangered species and to designate critical habitat for it. The Center had to file numerous lawsuits from 1995 through 2010 to protect the flycatcher: first, to get the U.S. Fish and Wildlife Service list it as endangered, then to designate critical habitat, including numerous lawsuits over the adequacy of the critical habitat. The Center also sued US Animal and Plant Health Inspection Service (APHIS) and the US Department of Agriculture (USDA) for violating the Endangered Species Act when it allowed the release of the tamarisk-defoliating leaf beetle within Southwestern willow flycatcher nesting areas and critical habitat.

8. I regularly hike and recreate along Arizona's rivers and have seen the Southwestern willow flycatcher on the San Pedro River, Santa Cruz River, Gila River, Bill Williams River and Colorado River. I have seen cotton fields in the uplands adjacent to each of these rivers. If dicamba is sprayed on these or new fields and reaches the rivers through direct spraying, run off or drift, the flycatcher could be harmed, killed or even locally extirpated. This would dramatically harm

my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the flycatcher in these and other places in southern Arizona.

9. The yellow-billed cuckoo (*Coccyzus americanus*) was formerly common along rivers from Arizona to Washington State. Today, the cuckoo is found in a mere handful of locations, including several critically important strongholds in southern and western Arizona. In 1998, the Center submitted a citizen petition, primarily written by myself, to list the yellow-billed cuckoo as a federally endangered species and to designate critical habitat for it. Again, the Center had to file lawsuits before the U.S. Fish and Wildlife Service listed the western populations as threatened in 2014. The Service has also proposed critical habitat, including in southern Arizona.

10. I regularly hike and recreate in southern Arizona and have seen the yellow-billed cuckoo on the San Pedro River, Bill Williams River, Colorado River, Gila River, Verde River, Sonoita Creek and Cienega Creek. If dicamba is sprayed on these or new fields and reaches the rivers through direct spraying, run off or drift, the yellow-billed cuckoo could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the cuckoo in these and other places in southern and western Arizona.

11. The Chiricahua leopard frog (*Rana chiricahuensis*) was once found at more than 400 sites along rivers in Arizona and New Mexico, but it is now found at fewer than 80. In southeast Arizona, it has declined more than any other leopard frog. In 1998, the Center submitted a citizen petition, primarily written by myself, to list it as a federally endangered species and to designate critical habitat for it. Again, the Center had to file lawsuits before the U.S. Fish and Wildlife Service listed the frog as threatened in 2002. In 2007, the Center became part of the stakeholders' group that developed the federal plan to recover the frog.

12. I regularly hike and recreate in southeast Arizona and have seen the Chiricahua leopard frog at isolated ponds and watering holes in the San Pedro, Santa Cruz, Brawley and Cienega creek river basins. If dicamba is sprayed on these or new fields and reaches the rivers through direct spraying, run off or drift, the Chiricahua leopard frog could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the frog in these and other places in southern Arizona.

13. I am concerned that dicamba will be routinely applied on cotton in Arizona in and around habitat for the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog and have negative impacts on them and their habitat. I am concerned and fear that these species will be harmed by use

of dicamba and other agricultural chemicals. If these species are further impacted and their populations reduced or extirpated, my enjoyment Arizona's unique natural environment would be diminished.

14. I have professional, aesthetic, and recreational interests in the preservation of the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog and their habitat. My interests are being harmed by the Environmental Protection Agency's failure to ensure that these species will not be put in jeopardy through consultation with the U.S. Fish and Wildlife Service on impacts of its registration of new uses of the herbicide dicamba on this species. The EPA's failure makes it more likely these species will further decline or become extinct. If that should happen, I will be deprived of my enjoyment of these species in the wild. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of this pesticide on this species, which is important to ensure that my interests in the species are preserved and remain free from injury.

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

Executed on this 5th day of February, 2018 at Tucson, Arizona.

KIERÁN SUCKLING

9th Circuit Case Number(s) 17-70196

NOTE: To secure your input, you should print the filled-in form to PDF (File > Print > *PDF Printer/Creator*).

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CERTIFICATE OF SERVICE
When All Case Participants are Registered for the Appellate CM/ECF System

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) February 9, 2018 .

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Signature (use "s/" format) s/ George A. Kimbrell

****

CERTIFICATE OF SERVICE
When Not All Case Participants are Registered for the Appellate CM/ECF System

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) .

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that some of the participants in the case are not registered CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, or have dispatched it to a third party commercial carrier for delivery within 3 calendar days to the following non-CM/ECF participants:

Signature (use "s/" format)