SUBJECT TO PROTECTIVE ORDER

No. 19-70115

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 petition seeks review of the October 31, 2018 decision by the United States Environmental Protection Agency (EPA) to continue the new uses registrations of the pesticide dicamba on dicamba-resistant cotton and soybean, Excerpts of Record (ER)0001-0024 ("Registration Decision for the Continuation of Uses of Dicamba on Dicamba Tolerant Cotton and Soybean"). 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] EPA's October 31, 2018 decision is a continuation of the new uses initially approved by EPA in 2016.[2] ECF 1-6 at 2-3; ER0003.[3] Petitioners timely filed this petition for review. 7 U.S.C. § 136n(b), 40 C.F.R. § 23.6.

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[1] *United Farm Workers of Am. v. Envt'l Prot. Agency*, 592 F.3d 1080, 1082-83 (9th Cir. 2010).

[2] Petitioners submitted comments to the agency in 2016, ER1238-1306; ER1325-1328; ER1329-1355; ER1226, and again prior to the 2018 continuation decision, along with hundreds of other stakeholders. ER0005, n.1; ER0006-7; ER0509-514.

[3] Petitioners have standing. *Friends of Earth, Inc. v. Laidlaw Envt'l Serv. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). The approval threatens to directly injure Petitioners' members' environmental,

ISSUES PRESENTED

1. Whether EPA violated FIFRA by authorizing the registrations without prerequisite findings and required data, and without supporting its decision with substantial evidence; and

2. Whether EPA violated 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 case concerns a pesticide Intervenor Monsanto developed, "XtendiMax with VaporGrip Technology" (XtendiMax), containing the weed-killing active ingredient, dicamba. ER0003-4.[4] While dicamba has existed since 1967, XtendiMax is a "new use" registration because it is

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vocational, agricultural, recreational, aesthetic, and economic interests. Bentlage Decl. ¶¶ 2-17; Buse Decl. ¶¶ 1-13; Crouch Decl. ¶¶ 2-14; Faux Decl. ¶¶ 1-17; Griffith Decl. ¶¶ 1-9 ; Ishii-Eiteman Decl. ¶¶ 1-11; Kimbrell Decl. ¶¶ 6-12; Newman Decl. ¶¶ 1-18; Pool Decl. ¶¶ 1-26; Suckling Decl. ¶¶ 2-11; Zulke Decl. ¶¶ 1-18. The declarations are contained within the attached Addendum of Declarations (A80-163).

[4] The registration also covers the competitor dicamba varieties approved by EPA for the same uses. ER0004-5, tbl.2; ER0121-ER0210. We use XtendiMax for simplicity.

an entirely novel use of dicamba: direct, "post-emergent" application to cotton and soybeans that Monsanto genetically engineered (GE) to survive being sprayed with dicamba. ER0005.

I. XTENDIMAX AND GENETICALLY ENGINEERED CROPS.

Dicamba is extremely toxic to conventional cotton and soybean. Its use was previously restricted to before planting ("preplant") to clear a field of early-season weeds, and once again at season's end (preharvest) for soybeans (and postharvest for cotton), but never sprayed during the critical crop growing periods. ER0005; ER0051-52, 0057. Genetically engineering soybean and cotton with resistance to dicamba enables "over-the-top" or "post-emergent" spraying much later in the season. ER0003; ER0059-61. Monsanto markets patented GE dicamba-resistant seeds, which are also resistant to its Roundup herbicide, together with XtendiMax, as the "Roundup Ready Xtend Crop System." ER1710-1711.

For 20 years, Monsanto sold Roundup and seeds genetically engineered to resist Roundup's active ingredient, glyphosate. This "Roundup Ready" crop system dramatically increased the overall pesticide output into our environment. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 841 (9th Cir. 2013); ER1754-1759. It also caused a related

problem: weed resistance. ER1066-1067; ER1296-1297; ER00014. As with overusing antibiotics, Roundup overuse generated an epidemic of glyphosate-resistant "superweeds" infesting about 100 million acres of U.S. cropland. ER1348-1349.

EPA and Monsanto (Respondents) touted XtendiMax's ability to kill glyphosate-resistant weeds as the approval's primary benefit, but after just two seasons of the approved use, weeds have developed resistance to dicamba, making them more intractable, as many experts predicted.[5] XtendiMax exacerbated the resistant-weed epidemic and massively increased use of dicamba, roughly *12-fold in just one year*.[6] This dicamba use has caused widespread damage to conventional crops and plants, potentially jeopardized hundreds of endangered and threatened species and their habitat, and significantly injured farmers and the environment.[7]

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[5] ER1160-1162; ER1155-1156; ER1157-1159; ER1346; ER1228-1237.

[6] In 2017, soybean and cotton dicamba use increased to nearly 10 million lbs., vs. the 2012-2016 average of 768,000 lbs., with "significantly more dicamba" expected in 2018. ER0477.

[7] *See infra* at pp.7-12.

II. THE 2016 APPROVAL.

EPA was well-aware of XtendiMax's potential to harm crops and other plants due to dicamba's spray drift and volatility.[8] ER1765-1766, 1771-1775; ER1714-1715, 1718; ER1573-1577; ER1229-1230, ER1233-1234; ER1307-1320; ER1748-1750; ER1760-1770. Farmers, scientists, and conservationists supplied EPA with studies, expert opinions, and practical evidence warning of devastating impacts from dicamba's notorious tendency to drift off-site. ER1226-1380. EPA knew the new uses could dramatically increase crop injury by sharply increasing and shifting dicamba use to later in the season, when hot conditions increase volatility and crops are more susceptible to damage. ER1309-1310; ER0753-757. These warnings were prophetic. *Infra* pp.7-12.

EPA was also informed the new use might harm hundreds of endangered species and their critical habitats and the environment

[8] Vapor drift is largely a function of the pesticide's volatility and weather conditions, beyond a farmer's control. ER1063-1064. Volatile pesticides like XtendiMax evaporate from soil and plant surfaces hours to days after application, forming vapor clouds that damage plants far from the application site. *See* ER0959-0963; ER1060; ER1309; ER0753-757. Spray drift (pesticide droplets blown by the wind during application) also cannot be entirely prevented. ER0753-757. "Drift" when used alone means either vapor drift, spray drift, or both.

generally. ER1329-1343; ER1245-1253. The registration allows application on millions of acres in 34 states, and EPA knew that ESA-protected animals, such as the whooping crane, feed in sprayed crop fields, ER1966-1975, and that hundreds of other endangered plants and animals found near those fields would be threatened by drift. ER1830-1835.

EPA nonetheless approved registration in November 2016, ER0211-246; ER0003, based on the supposition that XtendiMax is less volatile than prior dicamba formulations. EPA approved a lengthy label containing use restrictions, such as wind direction, buffers, spray boom height, and temperature and humidity adjustments, which the agency claimed would "effectively limit" any impacts. ER0240-246; ER0247-258; ER0259-269.

Tellingly, the Agency imposed a 2-year automatic expiration on the registration (Nov. 9, 2018) "because of the concerns about resistance and off-target movement," ER1072, "unless EPA determines before that date that off-site incidents are not occurring at unacceptable frequencies or levels." ER0245.

Instead of consulting the expert wildlife agencies about potential harm to endangered plants and animals and their critical habitats, EPA made the unprecedented finding the registration would have absolutely "no effect" on any of hundreds of species or habitats. ER0233-235; ER1960-1961; ER1796-1797; ER1581.

III. 2017-2018: TWO SEASONS OF CATASTROPHIC CROP DAMAGE.

Farmers began using XtendiMax in 2017. By the end of July 2017, 2.5 million acres of soybeans alone was officially reported as damaged by dicamba drift, ER1133; rising to over 3 million acres by August 2017, ER1061-1062, with numerous reports of ongoing extensive damage. ER1153; ER1149 (50% of the non-dicamba-resistant soybeans injured in Illinois).

Other crops and plants were also damaged, including grapes, tomatoes, melons, tobacco, vegetables, and fruit and nut trees and shrubs; the flower and nectar of many of these plants being vital food for pollinators. ER1106-1113; ER1114-1115; ER1146; ER0952; ER0958-963. According to expert Dr. Bradley, "[w]e have never seen anything like this before … in our agricultural history." ER1097.

Dicamba drift threatens farmers' livelihoods by slowing soybean growth and reducing yields, costing farmers millions. ER0887-889; ER0891-894; ER1148-1151; ER1061-1065; ER1100-1102. Farmers were pressured to purchase patented GE dicamba-resistant soybean seeds at a premium (ER1058; ER1063) just "to protect themselves" from dicamba drift. ER0768-0769; ER0667-669; ER0967; ER1120; ER1138. The damage tore apart rural communities. University of Tennessee's Dr. Steckel said dicamba damage has divided agriculture "like nothing I've seen," pointing to "angry" growers whose fields have suffered drift damage multiple times. ER1151.

University scientists affirmed volatility, or vapor drift, as "one of the major routes" of dicamba drift injury, based on "air sampling data, field volatility studies and field visits." ER1100. EPA received extensive test results showing that, contrary to Monsanto's claims, XtendiMax volatilized "for as many as 3 or 4 days following the application." ER0998-1050; ER1097-1100; ER1062-1065.

State and academic experts told EPA the label restrictions did not work because they did not address volatility. ER1148-1151; ER1136-1137; ER0998-1050; ER1114-1115; ER1080 (professional applicators

report drift damage common up to a mile from field); ER1066-1067 (similar, 3 to 5 miles); ER0686 ("vapor drift occurred in all directions from applied fields"). Experts opined that "there's nothing we can do for a volatile product as far as label changes," ER1093; ER1099-1100.[9]

Faced with unprecedented damage reports, in fall 2017 EPA briefly considered experts' recommendations to prohibit use after a spring "cutoff date" to mitigate vapor drift damage, but rejected it after Monsanto and the pesticide industry opposed it. ER1057; ER0971; ER0995.[10]

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[9] For more, *see National Family Farm Coalition v. Environmental Protection Agency*, No. 17-70196 (9th Cir., Jan. 20, 2017) (*Dicamba I*), ECF 70, at 5-11 and record citations therein.

[10] When EPA finally acted, it took its orders not from the states or their experts, but from Monsanto, repeatedly meeting with its representatives and letting them dictate what label changes EPA would make. ER1786-1788; ER0955-957; ER0953-954; ER0910 (EPA official to Monsanto: "like I said, no surprises."), ER0908-909; ER0905-907.

Faced with EPA's inaction and catastrophic losses, several states passed restrictions to address vapor drift, such as spray cut off dates and temperature limits. ER0884-886 ("Most of the state-by-state changes are being made, they stated, because the federal EPA labels do not address herbicide volatility."); ER0597-610.

Instead Respondents amended the registration and added Monsanto's proposed changes, which included more 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. *Dicamba I*, ECF 57-2; ER0282.

The 2018 season demonstrated the futility of EPA/Monsanto's 2017 label changes, as damage reports climbed throughout the planting season. ER0616 ("As we near the end of the 2018 growing season, many states continue to report significant complaints from the movement of dicamba from the target site."). Illinois and Indiana were once again "overwhelmed," Kansas "overrun" with dicamba drift complaints. ER0652-655; ER0612-614; ER0734.

In fact, the number of official dicamba damage reports *was even higher than 2017* in leading soybean-production states like Iowa, Illinois, Indiana, Ohio, Nebraska and North Dakota. ER0529-531. Although many soybean farmers were forced to prevent another disastrous season by switching to Monsanto's dicamba-resistant soybeans, growers of other plants and crops were left defenseless. ER0737-744 (damage to "cypress trees, tomatoes, gardens, a vineyard");

ER0751-752 (university scientists and states finding majority of dicamba damage to "specialty crops, vegetables, and ornamental, fruit and shade trees"); ER0628-636 (vineyards); ER0747-749 (trees); ER0717-723; ER0709-710; ER0737-744; ER0532-539. Dicamba drift damage to flowering plants is one suspected cause of beekeepers' dramatic decline in honey production. ER0515; ER0750; ER0777.

The damage was so severe that by late July 2018, the U.S.'s fourth largest soybean seed seller wrote to EPA urging prohibition of over-the-top applications of dicamba. ER0711. As one university expert told EPA, the 2018 season demonstrated "that minimizing the off target movement of dicamba to a reasonable level is NOT possible. … [The] level of [dicamba] movement is completely unacceptable." ER0724-25.

Volatility remained a major concern, both in new field tests and real-world farming experiences. ER0879 ("Volatility continues to be a significant contributor to off-target movement of dicamba during the summer months."); ER0619-620 (Illinois applicator association survey finds volatility is main cause of dicamba damage); ER0627 (South Dakota Department of Agriculture emphasized dicamba's volatility in soybean damage). Again university scientists, state pesticide regulators,

seed companies, and professional associations urged EPA to limit dicamba usage to pre-plant, or with early cutoff dates, to prohibit XtendiMax applications in volatility-enhancing heat. ER0617; ER0655; ER0643-649; ER0711-712; ER0528; ER0620, ER624-625.

Two years of XtendiMax use have proven disastrous: over 4,200 official complaints and more than 4.7 million acres of soybeans injured, as well as scores of other plants and crops, including valuable specialty crops. *See supra* pp.7-11; ER529-531 (total dicamba complaints in 2017 (2,708) and 2018 (1,526)); ER0890; ER0732; ER0751-752. And these figures are substantial underestimates, since only a small fraction of drift damage episodes are reported. ER0989 (likely only 1 in 10 incidents reported in Indiana).

IV. 2018 REGISTRATION DECISION.

Despite overwhelming evidence of unacceptable dicamba drift damage, and despite EPA's own assurance that it would not continue the registration beyond November 2018 in such instance, on October 31, 2018, EPA nonetheless continued the new use registration. ER0003, 24. And, despite public calls from experts demanding that EPA impose an early-season cut-off date, *supra* p.9, EPA did not, instead again adding

more meaningless conditions and continuing the registration to expire on December 20, 2020. EPA acknowledged that many of its latest label amendments "represent[] no change" or would have "minimal" impact, raising the question of how EPA reached it decision to continue the approved uses. ER00020-21.

While admitting "effects to non-target terrestrial plant offsite from the treated fields," ER00012, rather than complying with its ESA duty to consult the expert wildlife agencies, EPA once again proceeded on its own, using methods and assumptions contrary to the ESA, unilaterally declaring that a 57-feet buffer (in addition to pre-existing the 110-foot downwind buffer) would be sufficient to protect endangered species. ER00021-22.

V. PROCEDURAL HISTORY.

Petitioners challenged the 2016 registration in January 2017. *Dicamba I,* ECF 1-5. After EPA amended the registration in 2017, Petitioners amended their petition to encompass the amended EPA decision. *Id.,* ECF 62; 68; 70; 92; 102; 133 (briefing). On August 28, 2018, the parties presented oral argument to this Court. After EPA

continued the registration in 2018, this Court dismissed that petition as moot, but expedited this case. *Dicamba I*, ECF 157, 160-1, 173.

Dicamba I contains relevant facts, argument, and supporting materials, not all of which Petitioners had space to duplicate here, but which this Court may find informative. The entirety of the administrative record of that case is the record in this case, plus the additional 2018 materials added by the agency.

ARGUMENT

I. EPA VIOLATED FIFRA.

To uphold the registration, the Court must find that EPA supported its decision with "substantial evidence" in the record. 7 U.S.C. § 136n(b).[11] Judicial review must be "searching and careful, subjecting the agency decision to close judicial scrutiny." *Containerfreight Corp. v. United States*, 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. U.S. Envtl. Prot. Agency*, 806 F.3d 520, 532 (9th Cir. 2015) (quoting

[11] All pertinent statutory and regulatory provisions are included in the attached Statutory and Regulatory Addendum (A2-75). 9th Cir. R. 28-2.7.

Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 50 (1983)).

EPA violated FIFRA. The agency failed to make required findings and failed to meet data requirements to approve a conditional new use. Nor did it support the 2018 decision with substantial evidence. The 2018 changes will not fix the drift crisis; they still fail to address the crux of the issue: volatility. EPA hinged its decision on a flawed volatility assessment and on unrealistic and impossibly complex use directions, without analyzing their efficacy. Finally, the agency failed to weigh the true costs of its approval to farmers and the environment.

A. EPA Failed to Make the Required "Unacceptable Frequencies or Levels" of Drift Finding.

In the 2016 registration, EPA set forth that the registration was required to "automatically expire on November 9, 2018, unless EPA determines before that date that off-site incidents are not occurring at unacceptable frequencies or levels." ER0245. That is, EPA hinged any further registration on the agency making an express finding that off-field drift harms were not happening at "unacceptable frequencies or levels." Amending the registration in 2017, EPA reiterated that same prerequisite. ER0282.

As explained above, XtendiMax drift harms are happening at levels and frequencies literally unprecedented in the history of American agriculture, on millions of acres, levels the agency could not rationally defend as "reasonable." *See supra*. Yet whether the agency could defend such a finding is not before the Court because in the 2018 extension decision*, there is not a single word* about this required prerequisite finding the agency set for itself as a condition of continuing registration. The agency does not attempt to conclude, let alone support with substantial evidence, that drift in 2017-2018 did not occur at "unacceptable frequencies or levels." *State Farm*, 463 U.S. at 50 ("courts may not accept appellate counsel's *post hoc* rationalizations for agency action.") (emphasis in original).

The only mention is to kick the can down the road: EPA predicates any future continuation of the 2018 registration on the same "off-site incidents are not occurring at unacceptable frequencies or levels" requirement. ER00024. That does not meet the agency's burden to make that finding in *this* extension. ER0245. EPA's failure to explain how it purports to meet this requirement is reason enough to set aside the registration. *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194,

196-97 (1947) ("If the administrative action is to be tested by the basis upon which it purports to rest, that basis must be set forth with such clarity as to be understandable.").

EPA's failure to make the required finding upon which the agency itself *predicated any further registration* renders the registration without substantial evidence in support. *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, 735 F.3d 873, 884 (9th Cir. 2013) ("Having established a rule of decision of less than *or equal* to 1,000, EPA cannot unmake it because its actual MOE is in the neighborhood. Nor can we revise EPA's assumptions, alter its rule of decision, or perform our own risk assessment. … EPA may wish to revisit its standards in the future, but it cannot ignore them.") (emphasis in original); *Pollinator Stewardship Council*, 806 F.3d at 531-32 ("EPA chose to set its level of concern at a measurement it now feels is overly conservative, but a court cannot alter the agency's own rule.").

B. EPA Failed to Meet the Conditional New Use Data Requirements.

FIFRA's unconditional registration standard applies unless one of three "special circumstances" for conditional registration applies. 7 U.S.C. §§ 136a(c)(5), 136a(c)(7); *Nat. Res. Def. Council v. U.S. Envtl.*

Prot. Agency, 857 F.3d 1030, 1036-37 (9th Cir. 2017). Here EPA applied the conditional "new use" exception in the 2018 continuation which permits EPA to register a new use "notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment." 7 U.S.C. § 136a(c)(7)(B); ER00016. EPA must make and support with substantial evidence 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 adverse effect on the environment." *Id.* § 136a(c)(7)(B); ER00016. In its rush to keep XtendiMax on the market before the existing registration expired, EPA failed to comply with either condition.

First, EPA granted the registration despite admitting it lacked multiple key data specific to the new use. While conditional new use can be registered to provide flexibility, the application cannot be missing data related new use's risks *specifically*. 7 U.S.C. § 136a(c)(7). EPA can issue such a registration "*only if*" the agency has determined that it has "*all data* necessary" as to the specific product, including "at a minimum,

data needed to characterize any incremental risk that would result from approval...” 40 C.F.R. § 152.113(a)(1)-(2) (emphases added).

Here, EPA did *not* determine it had “satisfactory data pertaining to the proposed additional use,” as required. 7 U.S.C. § 136a(c)(7)(B). EPA admitted it lacked key data in several crucial areas specific to the new use, and concluded “there is *uncertainty associated with the existing database* for the OTT [over-the-top] uses and how they relate to reported incidents in terms of species effects, field conditions, and primary and secondary off-site movement.” ER00019 (emphasis added). Thus, EPA concluded that multiple field studies “*are required* to address this uncertainty.” *Id.* (emphasis added). Similarly, EPA concluded that damage to perennials and enhanced volatility via tank mixing[12] also required further studies “to address this uncertainty.” *Id.*;

[12] Farmers rarely spray XtendiMax alone; they tank mix it with other herbicides, most often glyphosate, which the crops are also engineered to resist. ER1565-1567; ER1793; ER0289. EPA scientists recognized that tank mixing could exacerbate spray drift and volatility, and therefore EPA limited tank-mixing to “products that have been tested and found not to increase the likelihood of drift/volatility.” ER1566. However, the 2016 registration did not require any *testing* of XtendiMax tank mixtures for volatility. ER0273. Despite studies confirming that tank-mixing with glyphosate makes XtendiMax more volatile by lowering the pH, EPA once again failed in the 2018 registration

id. at 23 (requiring four types of studies). There is no way to square EPA's admission that it lacked required data with FIFRA's requirement that the agency have "satisfactory data pertaining to the proposed additional use" to issue a conditional registration under 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(1)-(2).

Second, EPA's failure to ensure it had key data pertaining to the specific proposed new use means it also failed the second step: without it, the agency could not meaningfully conclude that the registration "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). The missing data goes to critical aspects of the decision: off-site movement; temperature effects on volatility; ecological effects on non-target plants; and the effect of lower pH making XtendiMax "more prone to volatilization" in tank mixtures. ER00022-23. Without that data, EPA could have "no real idea," *Pollinator Stewardship*, 806 F.3d at 532, whether or not the 2018 registration will significantly increase the risk of any unreasonable adverse effects on the environment.

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continuation to require any testing of tank mixes for volatility. ER0471, 22, ER0353; ER0068, 72-75. EPA's failure to require volatility testing of tank mixtures of XtendiMax and glyphosate products violated FIFRA.

C. The 2018 Registration Is Not Supported By Substantial Evidence.

1. 2018 Changes Will Not Fix the Drift Crisis.

EPA again justified its 2018 XtendiMax registration—despite overwhelming evidence the last two seasons of off-site damage—on unanalyzed label restrictions. ER00016-18. EPA's conclusion that these changes will prevent unreasonable adverse effects off-site is not supported by substantial evidence. 7 U.S.C. § 136n(b).

First, all but one of the changes ignores the main culprit of off-field movement, volatility. ER00019-22; *supra* pp.5, 8-9, 11-12; *e.g.* ER0688 (volatility is primary factor for damage in Illinois applicators' survey). Second, EPA continues to presume that applicator error is to blame, not the pesticide, despite required training for nearly 95,000 applicators prior to the 2018 season. ER0588. Finally, EPA acknowledged the changes were "minimal" and would not eliminate the problem of XtendiMax moving off the fields. ER00020 ("These label changes are anticipated to result in a minimal reduction of the flexibility of growers … EPA recognizes the possibility that there may be additional factors which make it difficult to eliminate all off-target

movement of dicamba."). The record reveals how ineffective these amendments will be in real world conditions.

Certified Applicator Provision

The 2017 label restricted XtendiMax use to certified applicators or persons working under their supervision; the 2018 label allows only certified applicators to spray. ER00020. Even with XtendiMax-specific training, drift complaints continued in 2018. ER0588 (95,000 applicators underwent dicamba training prior to 2018 season); *see supra* pp.10-12. In Indiana, over 10,000 applicators were trained for 2018, but there was an *increase* in drift complaints: "Needless to say, the mandatory training was not successful in reducing drift complaints." ER0613-614; ER0529-531 (increase in complaints from 2017 to 2018). In Illinois, more than 11,000 applicators underwent training, but the number of complaints rose sharply from 245 in 2017, to 330 in 2018, ER0529-531, and the Illinois Fertilizer and Chemical Association told EPA "[dicamba] is very difficult to keep on target by even the most professional, experienced applicators." ER0662-665. EPA heard over and over from state and industry experts that training was ineffective in reducing off-field impacts. The American Association of Pesticide

Applicators told EPA that training was "only marginally successful" despite thousands of hours, the amount of off-target damage was "unacceptably high," and urged EPA to explore causes other than applicator training. ER0656. Iowa State University weed specialist Dr. Hartzler stated: "It is my opinion that the new label restrictions put into place by EPA following the 2017 growing season, and the training required for applicators of the new dicamba products, have failed to reduce off-target problems to an acceptable level." ER0621-626. The problem is not applicators; it is XtendiMax.

Days after Planting Spray Prohibition

EPA added a restriction on spraying 45 (soybean) or 60 (cotton) days or more after planting, ER00021, but the change was "expected to be minimal" as most spraying already occurs within these timeframes. *Id.* The problem with "days after planting" restrictions is that farmers may plant *later* than usual, such as when rain makes fields too muddy; hence, experts have always recommended clear calendar restrictions, rather than allowing over-the-top spraying late in the season when temperatures are high and drift more likely. ER0639-642 ("Date restrictions are viewed as more 'workable' than the current growth

stage restriction…"); ER0596 (showing efficacy and feasibility of state-specific cutoff dates); ER0655 (recommending cutoff date due to possibility of weather delays in planting and plant growth). The record does not support that this amendment will make any difference in later-season XtendiMax spraying or reduce drift damage.

Sunrise/Sunset Timing Restriction

EPA revised the 2017 instructions permitting spraying only from dawn to dusk—to "at least one hour after sunrise and two hours before sunset"—because temperature inversions happen most often at night, and contribute to off-target damage from dicamba, at farther distances. ER00021. EPA acknowledges this amendment does not address volatility, a main culprit of off-field damage. *Id.* EPA also included advisory language to avoid spraying during temperature inversions, but such weather conditions are frequent and hard to avoid, ER746, and the advisory language is unenforceable. ER0617 (EPA should "only include risk mitigation measures that are enforceable" as "states will have great difficulty enforcing" label prohibitions related to weather conditions); ER0522 (strongly recommending EPA "specify required

[documentation] to provide evidence than an inversion did not exist [when application is made]," because of this "unenforceability" issue).

Advisory Language/Best Management Practices

EPA also added advisory language on pH and identification of sensitive areas meant to reduce off-target movement. ER00022. Unenforceable advisory language has the effect of preventing states from effectively enforcing mitigation measures, while shifting liability for damage from Monsanto to applicators. ER0617; ER0522 (EPA should enact clear restrictions in place of unenforceable use language, which allows registrants to shift liability for drift to applicators). The changes EPA made to its 2016/2017 registration will not fix the problem, particularly of vapor drift, are not supported by substantial evidence, and render the authorization contrary to FIFRA.

2. The Volatility Assessment is Not Supported by Substantial Evidence.

EPA has known from the beginning that dicamba injures off-field plants via vapor drift. ER1574-1576 (in 2016, discussing incidents of dicamba vapor drift injury 2,800 feet and 2.2 miles from fields); ER1382; *supra* pp.5, 8-9, 11-12. Yet in the 2018 continuation, EPA still does not adequately assess or mitigate vapor drift. Two years of

massive, real-world drift damage contradict the Monsanto studies underlying EPA's 2016 volatility assessment, but it was on the basis of these studies that EPA eliminated the "110-foot omnidirectional buffer for volatilization" EPA had initially proposed to protect off-field plants. ER1213-1214; ER0228. Despite now admitting that the Monsanto study methods were deficient,[13] EPA has continued the new uses another two years based on similarly deficient studies.

Field volatility-flux studies and modeling were used to simulate XtendiMax "vapor drift" (the concentrations of dicamba vapor that drift beyond a sprayed field). Small plastic chambers ("humidomes") containing different dicamba vapor concentrations, together with soybean seedlings, were used to estimate the "plant harm threshold" (the minimum dicamba vapor concentration that harms sensitive plants). Monsanto relies on these studies to conclude that vapor drift at a field's edge is less than the plant harm threshold, making any volatilization buffer to protect off-field plants unnecessary. ER0345.

[13] ER0353-354 (Admitting the studies submitted—"flux-based vapor drift estimates using field flux data, the modeling and humidome studies"—do not account for observed harms during planting seasons).

However, fatal flaws in all three study types—field volatility-flux, modeling and humidome—invalidate the results.

First, *none* of Monsanto's field volatility-flux studies were conducted in major soybean-producing states (*e.g.* IL, IA, MN, ND, IN, MO, NE) where the bulk of XtendiMax is used, and non-dicamba-resistant soybeans were most injured, violating EPA test guidelines.[14] Because the environmental conditions that influence volatilization vary regionally, studies in areas where few soybeans were grown or injured—Georgia, Texas, Arizona and Australia (ER0345)—likely underestimated XtendiMax's volatilization potential where it matters most.[15]

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[14] U.S. Envtl. Prot. Agency, *Fate, Transport and Transformation Test Guidelines: OPPTS 835.8100 Field Volatility* (Oct. 2008), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0030 ("Field volatility studies should be conducted in areas considered representative of major areas where the pesticide is intended to be used.").

[15] EPA is only now seeking to gain a better understanding of volatilization in soybean-growing regions by requiring drift-focused studies *in 2019*, ER0070, in violation of registration standards. *Supra* pp.17-20.

Second, the studies were far too small to simulate actual vapor drift in much larger commercial fields. All but one U.S. study were under 10 acres, ER0345-348, ER0417, and as EPA concedes, "[l]arge field studies [are] more reflective of what occurs in the environment." ER0376. The model employed partly to scale up drift estimates modeled only a hypothetical [redacted] ER2095, still far too small to represent greater vapor drift from real-world farms many times this size.[16]

Finally, the humidome studies fail to establish a reliable harm threshold, which is influenced by environmental conditions. In 2015, EPA requested volatility tests using "different sets of conditions, including those likely to cause volatilization," such as "high temperature and humidity . . . (over 80 F and 90% RH [relative humidity])." ER1709. But Monsanto never undertook such studies: the humidome studies utilized only 40% relative humidity, ER0353; ER1163, leaving "the influence of the atmospheric conditions . . . on the amount of volatilized dicamba . . . and the observed phytotoxic and

[16] U.S. Dep't of Agric., Econ. Research Serv., *Farm Size and the Organization of U.S. Crop Farming*, at 12 tbl. 2 (2013), *available at* https://www.ers.usda.gov/webdocs/publications/45108/39359_err152.pdf (midpoint acreage of corn (600 acres), soybean (490 acres), and cotton (1,090) farms).

height response uncertain." ER1166. In the real world, professional applicators found "heat and humidity correlated with [dicamba] symptoms and complaints," "hot weather and humidity was a big problem," and conversely that "low temperature and humidity" reduced drift. ER1075, 1089-1090. None of the registrant volatility studies—old or new—provide substantial evidence that support the 2018 registration's failure to address or mitigate vapor drift. *Pollinator Stewardship*, 806 F.3d at 532.

3. EPA Hinged its Decision on An Impossible to Follow Label.

Not only are the 2018 revisions insufficient to mitigate harm, they add even more complexity to an already impossible-to-follow label. In addition to the changes outlined above, the label permits spraying within a narrow wind speed range of 3 to 10 mph, prohibits use when rainfall is forecast within 24 hours, bars application during temperature inversions, requires a 110-ft "downwind" buffer, and a 57-foot omnidirectional ESA-buffer in limited areas that requires an internet search to identify. ER0038, 42-44.

EPA based its registration determination on a label so complex and contradictory as to be impossible to follow for even a well-trained

certified applicator. The record is replete[17] with applicators and state weed and pesticide experts' reports of the label being "very complex," "unrealistic," "contradictory," and the impossibility of making an "on-label application as the label is written." ER713-714; ER0988-989; ER0684-685; ER0613 (Indiana State Chemist: "One of the more prominent observations by regulators and educators alike has been that both the 2017 and 2018 dicamba label directions have been extremely challenging for a trained applicator to comply with completely," explaining 93% violation rate in 2017); ER0758-761 (Agricultural Retailers Association to EPA: "There doesn't appear to be any way for an applicator to be 100% legal in their application. What is an applicator to do in this no-win situation?"); ER0637-638; ER1373. Indeed, in Indiana the weather data showed legal applications by-the-label could only occur during about 47 hours for the entire *month* of June, 2018, when most post-emergent applications to soybeans would normally occur. ER0614.

[17] For more, *see Dicamba I,* ECF 70, at 30-33 and citations therein; ER1103-1105.

Something as common, likely, and impossible to predict as a shift in wind direction and/or speed can turn a legal application into an illegal one. The label limits applications to wind speeds between 3 and 10 mph, but experts demonstrated wind gusts *over* 10 mph with average wind speeds of just 5 mph. ER0715 (should limit applications to average wind speed of 3-5 mph "as long as wind gust over 10 is a label violation"); ER0684 (wind speeds/direction changes, weather constantly changing, a light breeze changes during application can "start a field on label, end[] off label"). Moreover, the spray prohibition when sensitive crops are downwind does not specify *distance* downwind. ER0044; ER0522. Thus, "there is really no way to use the products." ER0651.

The impossible-to-follow label use requirements, coupled with ambiguous directions, operate to place all the blame for drift harm on the farmer or applicator, not Monsanto. ER0522 ("registrants can continue to place blame on the applicator with the knowledge that state responders probably cannot piece together what actually occurred during application"); ER0560 ("The label is written to put all of the liability (both regulatory and civil) on the applicator"); ER0758-761; ER0691-692, 699 (mandatory training served to shift liability from

chemical companies to applicators). EPA cannot support its registration by placing blame for an infeasible label on applicators. And it cannot be the case that any imaginable restrictions on use—no matter how impracticable, infeasible, or complex—are sufficient for a label to pass muster and support a "not likely to cause unreasonable adverse effects" conclusion. Without a realistic assessment of mitigation measures' on-the-ground efficacy and practicability, risk cannot be predicted accurately and EPA's determination is not supported by substantial evidence. 7 U.S.C. § 136n(b); *Pollinator Stewardship*, 806 F.3d at 532.

4. EPA Failed To Weigh the True Costs and Inflated the Benefits.

The FIFRA "unreasonable adverse effects on the environment" definition 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. 7 U.S.C. § 136(bb) ("[U]nreasonable adverse effects 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."). Despite overwhelming evidence from the disastrous 2017-2018 seasons, EPA failed to support by substantial evidence that the

claimed benefits of XtendiMax outweigh its historic and catastrophic costs to agriculture and environment. *Id.* § 136n(b).

EPA's cost-benefit analysis ignores critical information and fails to provide even a rough estimate of the registration's harms, let alone a concrete, quantitative assessment of the costs. Despite acknowledging a "record number of complaints alleging damage from off-target dicamba movement" in 2017 and 2018, ER0475, 479 (a more than 65-fold increase from before over-the-top dicamba use), EPA ignored extensive evidence of yield and associated economic losses attributable to dicamba drift. *Supra* pp.7-8, 11-12 (millions in losses); ER0491; ER0887-889 (200 Minnesota farmers damaged by dicamba drift estimate $7 million in collective losses); ER0895-904 (North Dakota farmer loss of yield due to dicamba vapor drift). FIFRA requires more than avoiding analyzing costs by referring to "uncertainties." *Pollinator Stewardship*, 806 F.3d at 531-32.

EPA also entirely ignored the social costs, including strife among farmers and communities due to drift damage; forced adoption of dicamba-resistant GE crops by farmers to avert damage, annulling their right to buy and plant crops of their choice and imposing

additional costs for the dicamba-resistance trait; and the irreparable threat to growers of hundreds of "sensitive" crops, including virtually all vegetable and fruit trees, for which no dicamba-resistant trait is available. ER0667-669 (farmers growing Xtend soybeans "in defense" of drift); ER0768-769 (similar); ER0717-723 (South Dakota vegetable farm destroyed; Tennessee gardens destroyed); ER0747-749 (gardens destroyed, commercial vegetable growers crops may be condemned, truck crop growers going out of business; "industry [has] no choice but to plant 100% of the soybean acreage to this technology"); ER0762-767 (year of Missouri public soybean breeding research lost as a result of dicamba drift); ER1100-1102; ER1096-1100; ER0491 (naming but not assessing these costs). Finally, EPA ascribes no environmental costs to the new XtendiMax registration, despite evidence of harm to pollinators via impairment of flowering plants. ER0750; ER0777; ER0658-659; ER0515.

On the other hand, EPA accepts two Monsanto-claimed benefits: an additional herbicide for weed control and resistance management for

other herbicides. ER0485-489.[18] The first is true of any new use, which by definition provides an additional means of weed control. But EPA contradicts itself by admitting that 14 and 9 other post-emergence herbicides, 36 and 30 overall, are available to control broadleaf weeds in soybeans and cotton, respectively. ER00015; ER0486 n.4. Second, EPA presents no evidence that XtendiMax will delay weed resistance to other herbicides, but admits it "will increase selection pressure [for] resistance to dicamba," ER0488-489, a process that is already beginning. *Supra* p.4; ER0484: (two dicamba-resistant weeds "across millions of acres of soybeans and cotton"). Given these dubious benefits and complete lack of any real costs assessment, EPA's cost/benefit analysis cannot support EPA's 2018 continuation. 7 U.S.C. § 136(bb).

[18] EPA properly rejected Monsanto's claim that XtendiMax is beneficial to conservation tillage or reducing yield loss from resistant weeds more effectively than other weed control programs. ER0489.

II. EPA VIOLATED THE ESA.

Unlike most agency actions subject to Section 7, pesticides are toxic by design. They kill their targets, but also harm endangered species that happen to be exposed. In 2018, EPA continued its pattern of circumventing compliance with the ESA's mandates and unilaterally declared that hundreds of endangered plants, animals, and habitats would be completely unaffected by spraying a toxic weed killer across millions of acres.

By 2018, after continued damage and academic studies documenting that damage, EPA could not continue to pretend that XtendiMax does not move off fields in every direction. It put in place a 57-foot buffer only where a limited number of endangered plants survive adjacent to fields and a handful of species have critical habitat. The 57-foot buffer is not supported by the record, especially in the context of the low consultation bar of "any chance" of affecting endangered species. Having erred in its assumptions about dicamba damage off the field, EPA still did not revisit any of its earlier determinations of "no effect," continuing to act contrary to the

controlling ESA "may affect" legal standards, scientific standards, and the record.

EPA violated the ESA if its failure to consult the expert wildlife agencies in connection with its XtendiMax registration was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *Karuk Tribe of California v. U.S. Forest Serv.*, 681 F.3d 1006, 1017 (9th Cir. 2012).

EPA violated the ESA numerous ways. First, EPA applied an unlawful legal standard throughout: it imported a FIFRA standard and risk assessment process, which tolerate harm, to its ESA duties, which require consultation when there is any chance the authorization may affect ESA species or their habitats. Second, EPA manipulated the action area, to categorically eliminate hundreds of endangered species from any consideration despite overlap with dicamba-sprayed soybean and cotton fields. Third, the big reveal of 2018, a new 57-foot buffer, only applies to a small subset of ESA species, is eight-fold smaller than EPA scientists believed it should be, and still fails to consider multiple crucial impacts. Fourth, EPA applied an unlawful standard for potential impacts to designated critical habitat, improperly tying that

independent duty to species' effects as well as applying far too high a threshold.

A. EPA Applied the Wrong Standard.

The issue is whether EPA erred in concluding the dicamba use it authorized can have absolutely "no effect" on hundreds of species or their critical habitat or, conversely, whether EPA should have consulted because its registration of XtendiMax meets the low bar that it "may affect" species or habitat. By applying the FIFRA standards and assessment, EPA ignored the ESA's requirements and very low trigger for consultation, in violation of Section 7 of the ESA. 16 U.S.C. § 1536(a)(2).

1. ESA Standards Are Different from FIFRA Standards.

The ESA "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978). Unlike FIFRA's cost-balancing, in the ESA Congress made it "abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities." *Id.* at 194.

Section 7 is the "heart" of the ESA, one of its most crucial protections. *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). It mandates each federal agency "insure" its actions—here, the XtendiMax authorization—are not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C. § 1536(a)(2). Section 7 establishes a process to insure agencies like EPA meet their substantive ESA duties: evaluation of the authorization's effects "in consultation with and with the assistance of" the agencies Congress designated as having special expertise in determining effects on endangered species: the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (hereafter "FWS" for simplicity). *Id.* § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). Thus, the ESA grants action agencies like EPA no special authority: unlike FWS, they have no particular expertise in protected species' survival and recovery, nor in interpreting and applying the ESA's standards. *City of Tacoma, Washington v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006) ("This interagency consultation process reflects Congress's awareness that expert agencies (such as the Fisheries Service and the Fish and Wildlife Service) are far more knowledgeable

than other federal agencies about the precise conditions that pose a threat to listed species.").

EPA *must* consult with FWS if its authorization "may affect" any listed species or designated critical habitat. 50 C.F.R. §§ 402.14(a), 402.01(b). The "may affect" or "no effect" determination is known as "Step 1" in the Section 7 process. 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*, 681 F.3d at 1027 (emphasis added).

The agency must also apply the "best scientific and commercial data available." 16 U.S.C. § 1536(a)(2). That mandate "prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on." *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006).

FIFRA and the ESA have different legal standards that reflect different policies, and, consequently, assign different duties to EPA, but EPA must comply with the ESA using its standards, not FIFRA's. *Washington Toxics Coal. v. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005)

(EPA must separately comply with the ESA in pesticide registrations). The ESA "may affect" standard that triggers consultation to protect species on the brink of extinction is a low bar and legally distinct from the FIFRA registration standard of no "unreasonable adverse effects" that includes cost-benefit analysis. *Karuk Tribe*, 681 F.3d at 1027 ("*Any possible effect*, whether beneficial, benign, adverse or of an undetermined character.") (emphasis added and quotations omitted).[19] *See, e.g.*, *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011); *Lockyer*, 575 F.3d at 1018-19.

The ESA's intentionally very low threshold for consultation reflects the overarching congressional intent of "institutionalized caution." *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015) (quoting *Hill*, 437 U.S. at 194). Hence the

[19] In *Karuk Tribe*, the plaintiff challenged the Forest Service's failure to consult before issuing notices to conduct mining activities in ESA-protected salmon critical habitat. Mining interests argued the record contained no evidence "so much as a single endangered fish or fish egg [was] ever injured by this [mining] activity." *Id.* at 1028 (quotations omitted). This Court rejected the arguments to make the agency's procedural consultation duty dependent on actual harm evidence, ordering consultation and emphasizing that any risk triggers it. *Id.*

expert agencies' definition of the "may affect" threshold as "the appropriate conclusion when a proposed action *may pose any effects* on listed species or designated critical habitat . . . ." U.S. Fish & Wildlife Serv. & Nat'l Marine Fisheries Serv., *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act*, at E-13 (Mar. 1998) (hereinafter "*Consultation Handbook*")[20] (emphasis added); *accord* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986). And strict enforcement of the process is vital to meeting the substantive protection mandate: "[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." *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) (emphasis in original).

In sharp contrast to the ESA low "may affect" consultation trigger, the FIFRA pesticide registration standards ask whether the pesticide

[20] *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1113 (9th Cir. 2012) (repeatedly relying on the Handbook). FWS is entitled to deference, whereas EPA's ESA decisions, as merely an action agency, are entitled to none.

will "cause an unreasonable adverse effect," weighing costs and benefits. 7 U.S.C. § 136(ee). The courts resoundingly rejected an earlier EPA attempt to substitute its FIFRA standard and framework for its ESA duties:

> *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.

Washington Toxics Coal. v. U.S. Dep't of Interior, Fish & Wildlife Serv., 457 F. Supp. 2d 1158, 1184 (W.D. Wash. 2006) (quoting a NMFS scientist) (emphasis added); *see also id.* at 1185 ("EPA's risk assessment, designed to answer a question posed by FIFRA (*i.e.*, whether unreasonable adverse effects would result from use of the pesticide), was not designed to answer the question posed by the ESA (*i.e.*, whether an action may be considered 'not likely to jeopardize[.]'")).

2. EPA Unlawfully Applied Its FIFRA Standard and Risk Assessment Process to Arbitrarily Conclude "No Effect."

Instead of applying the ESA's "may affect/no effect" standard, as defined by this Court and the expert agencies, EPA unlawfully applied its FIFRA "unreasonable adverse effect" standard and risk interpretation tool, imported into the ESA context. ER0228-229.

Specifically, EPA concluded "no effect" whenever its "risk quotient" (RQ), which is the measure of harm or mortality when a species is exposed to a certain amount of pesticide, did not exceed its own "level of concern" (LOC), which represents an arbitrary level of harm or mortality acceptable to EPA. ER1960 [redacted] ER1777-1778, 1782-1783. EPA employs self-created RQs and LOCs in the FIFRA context to determine "when a pesticide use as directed on the label has the potential to cause *adverse effects* on non-target organisms." ER1782 (emphasis added). EPA describes its FIFRA RQ/LOC scheme as "interpretive policy" of a level of adverse harm EPA is willing to tolerate as a cost. *Id.*; ER1579-1580 (applying it in this case); ER00010

(maintaining previous determinations for vast majority of species). However, RQ/LOCs are levels of tolerable harm that were not designed to support compliance with the ESA, but rather contain "methodologies and protocols that are intended to provide data to inform regulatory decisions under . . . FIFRA."[21] ER1713 (citing toxicity tests upon which EPA relies); ER1777-1778.

The Whooping crane provides one example of EPA's misappropriation of the "may affect" standard. The iconic crane is among the world's most endangered animals and a "flagship species…symbolizing the struggle for survival [of] endangered species worldwide." [22] There were as few as twenty-one in 1954, and conservation efforts have led to only a limited recovery; there are now a few hundred in the wild.[23] EPA acknowledged Whooping cranes [redacted]

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[21] U.S. Envtl. Prot. Agency, *Ecological Effects Test Guidelines OCSPP 850.2100: Avian Acute Oral Toxicity Test*, at i (May 10, 2012), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0010.

[22] U.S. Fish & Wildlife Serv., *International Recovery Plan: Whooping Crane* (*Grus americana)*, at 1 (Mar. 2007), *available at* http://www.fws.gov/uploadedFiles/WHCR%20RP%20Final%207-21-2006.pdf.

[23] *Id*.

[redacted] ER1965. 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. *Id.*

EPA used this collection of guesses to calculate acute and chronic RQs, and compared these with EPA's internally-generated LOCs. ER1965-1968. Because EPA's numbers fell below its LOC, EPA declared there would be "no effect." *Id.* But the RQ/LOC does not equate to no effect, *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 v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994). EPA did not, violating Section 7.

EPA made the exact same error for multiple species, applying the LOC/RQ framework rather than consulting for every species it determined would be exposed in dicamba fields. ER1966-1982 ([redacted]

[redacted]); ER1407-1429 (8 species in 7 states); ER1584-1602 (6 species in 11 states); ER1174-1184 (4 species in 34 states); *e.g.*, ER1412 (Attwater's Greater Prairie Chicken: "An RQ of 0.08 does not exceed the acute LOC of 0.1; consequently a 'no effect' determination is concluded for the Attwater's greater prairie chicken."); ER1975-1977 (Gray Wolf); ER1977-1979 (similar, Indiana Bat); ER1979-1980 (Ozark Bat).

Nor did EPA change this fundamentally improper standard in any way in the 2018 assessment, discussed *infra*. That assessment was limited to some plant species surrounding fields, but otherwise offered nothing regarding the hundreds of species both in and surrounding the fields. ER00010 ("The conclusions from the previous listed species effects determinations made in the initial screening level risk assessments and the refined endangered species addenda…are maintained for all taxa except listed non-monocot plants that may exist near the treated field, where levels of exposure could potentially result in effects and any newly listed species of terrestrial animals that may be present on the treated field that were not previously assessed.").

Finally, FIFRA LOC's do not take into account all potential pesticide harms, including behavioral impacts, such as impairment of a fish's ability to escape predators. This mismatch means a "no effect" decision from EPA can actually have grave consequences. For example, EPA previously found "no effect" to listed salmon from pesticide exposures, but the expert agency found these pesticides could actually jeopardize the continued existence of the salmon.[24] This is why at least some consultation is required for "any chance" of effects. EPA has no authority to forgo consultation with FWS when the low "may affect" threshold is met, and its FIFRA processes, however elaborate and purportedly scientific, do not comply with the ESA.[25]

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[24] Nat'l Marine Fisheries Serv., ESA Section 7 Consultation Biological Opinion, EPA Registration of Pesticides Containing Azinphos methyl, Bensulide, Dimethoate, Disulfoton, Ethoprop, Fenamiphos, Naled, Methamidophos, Methidathion, Methyl parathion, Phorate and Phosmet (Aug. 31, 2010) (Item #3), *available at* https://www.fisheries.noaa.gov/national/consultations/pesticide-consultations.

[25] EPA's application of RQs/LOCs also violates the ESA's best science mandate. 16 U.S.C. § 1536(a)(2); *Kern Cty. Farm Bureau*, 450 F.3d at 1074. In 2013, the National Academy of Sciences addressed the outmoded "level of concern/risk quotient" (RQ/LOC) FIFRA process and metrics EPA applied here, concluding that it is "*not scientifically*

B. The Record Shows XtendiMax "May Affect" Hundreds of Endangered Species, Requiring Consultation.

EPA record statements repeatedly acknowledged there were potential effects that met the low "may affect" threshold and should have triggered consultation on hundreds of ESA-protected species and their critical habitats. But by transposing the FIFRA RQ/LOC risk assessment framework 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 risk assessments, ER1712-1745, admitted dicamba, applied at the allowed rate, may harm many protected plant and animal species. EPA admitted its screening analysis found "potential direct risk concerns could not be excluded for" any birds,

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defensible for assessing the risks to listed species posed by pesticides . . ." Nat'l Acad. of Sci., *Assessing Risks to Endangered and Threatened Species from Pesticides*, Nat'l Acad. Press (2013), at 15, *available at* https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides (emphasis added); *id.* at 148-150 (criticizing the use of RQ/LOCs at length, as making assumptions that are "not reliable;" with "unpredictable performance outcomes;" and as "not appropriate for assessments for listed species"); *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (agency documents available on U.S. government websites are judicially noticeable).

mammals, or terrestrial plants. ER1959; ER0336-337. And, "indirect effect risk concerns for all taxa were possible for any species that have dependencies (e.g., food, shelter, and habitat) on mammals, birds, reptiles, terrestrial-phase amphibians, or terrestrial plants." ER0337. This list included 322 ESA-protected species within 11 states, ER1583-1584, [redacted], ER1960, [redacted], totaling hundreds across the 34 states. ER0336-337.

In the 2018 decision EPA revised its Action Area because it found that off-field drift "*may have resulted in effects*" to species off-field. ER0340. EPA found that the "new information" from the 2017-2018 seasons showed that XtendiMax drift "*has resulted in effects*" to non-target plants offsite. ER00012. This should have led the agency to finally consult, but instead EPA "maintained" its previous "no effect" determinations "for all taxa except listed non-monocot plants that may exist near the treated field." ER0341; ER00012-13. Unsurprisingly, as discussed further below, EPA again unilaterally determined no effect.

These repeated EPA admissions of potential risk are more than sufficient alone to show that the low "may affect" bar was breached. In

Karuk, while the Forest Service did not dispute "may affect," the Intervenor Miners vigorously did, arguing that the record was " 'devoid of any evidence' that the mining activities may affect coho salmon" and placing the issue squarely before the Court. *Karuk Tribe*, 681 F.3d at 1027-28. This Court rejected the Miners' arguments, holding that there was "ample evidence" of "may affect" in the record: just like here, agency admissions of potential risk to endangered salmon were alone sufficient, as a "textual matter," to resolve the issue and make a "may affect" conclusion. *Id.* at 1028-29; *id.* at 1027 ("If the phrase 'might cause' disturbance of fisheries habitat is given an ordinary meaning, it follows *almost automatically* that mining pursuant to the approved NOIs 'may affect' critical habitat of the coho salmon.") (emphasis added).[26]

[26] *Kraayenbrink*, 632 F.3d at 496 (the "sheer number of acres affected" by agency decision can "alone suggest" it "may affect" listed species).

C. EPA's Action Area Machinations Violated the ESA.

EPA determined that hundreds of species are "within the action area . . . ." ER1960, 1986-1989 ([redacted]); ER1796, 1828-1835 ([redacted]); ER1580, 1606-1613 (322 species in 11 states); ER1170 (70 additional species). However, instead of consulting EPA took several unlawful and unscientific steps to reduce the action area and eliminate species from further consideration.

1. EPA Unlawfully Restricted the 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). ESA regulations define "action area" to be "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(d) (emphasis added). EPA violated this by unlawfully constricting the registration's "action area."

In the 2016 decision, despite initially finding overlap with hundreds of species and despite knowing dicamba was singularly infamous for drifting off fields, *see supra* pp. 5-7, EPA reduced the action area to just the crop fields themselves, eliminating hundreds of

species from ESA consideration. ER1962. Relying on mitigation, EPA concluded that "exposures that could potentially trigger risk concerns would be limited to the treated field." ER1169. In other words, EPA applied its FIFRA RQ/LOC "level of concern" approach to reduce the action area and conclude "no effect" for species outside the action area.

That decision violated the ESA definition of "action area," as well as sound science, farming realities, and the record evidence. And it was exposed as erroneous: EPA grossly miscalculated XtendiMax's vapor drift, thus exposing countless endangered plants and animals beyond field boundaries to the potent chemical. *See supra* pp.5-7.

EPA acknowledged that "new information" from the 2017-2018 seasons shows that drift "*has resulted in effects* to non-target terrestrial plants offsite." ER00012 (emphasis added). So EPA has tried again, now expanding the action area to a "reasonable distance" from field edges "which is reasonably protective of listed plant species." ER0380. EPA's action is improper as a matter of law because it is still based EPA's FIFRA thresholds of harm that EPA considers "reasonable" or tolerable.

Moreover, even based on the new 57-foot infield buffer, which is arbitrary and capricious and not supported by the record, *see infra*, EPA

admits that it has not eliminated effects off-field. The XtendiMax label mitigation would only effectively *reduce*—not eliminate—the likelihood of off-field impacts. ER0003 (new label restrictions will "further minimize the potential for off-sight movement" not eliminate); ER0005 (same "further minimize" language); ER0017 (mitigation will "limit any exposures beyond the treated field *to levels below thresholds that would trigger risk concerns,*" i.e., LOC); ER0020 (new label changes "are expected to further minimize the potential for off-site movement" and recognizing "possibility that there may be additional factors which make it difficult to eliminate all off-target movement of dicamba."). It is undisputed that some amount of XtendiMax will escape the fields through spray drift and runoff, despite the label mitigation and buffer.

Again, EPA was looking through the wrong lens: the Step 1 "no effect/may affect" standard is not just what EPA thinks is an "adverse," "toxic," "acute," "chronic," or "reasonable," but "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe*, 681 F.3d at 1027 (emphasis in original). EPA did not look for these effects based on a limited action area and thus its "no effect" determinations were arbitrary and capricious.

2. EPA Arbitrarily and Capriciously Eliminated Most Species from the Crop Field "Action Area."

After unlawfully applying the FIFRA RQ/LOC approach to limit the action area to just the crop fields, many species ranges still overlapped with those crop fields.[27] Instead of consulting FWS as the expert agency, EPA looked at FWS's Recovery Plans "to determine whether listed species in these states would be *expected to occur in an action area encompassing the treated soybean and corn fields*." *See, e.g.* ER1581 (emphasis in original). Using this, EPA eliminated hundreds of species from this action area and categorically concluded "no effect," based on its unilateral, inexpert review of each species' habitat needs. ER1990-2056; ER1836-1939; ER1614-1697.

EPA does not have the expertise to reduce FWS's species' range information. For example, EPA eliminated Karner blue butterfly from the action area, even though EPA reports its habitat includes "open areas . . . along old fields, highway and powerline rights-of-way" with

[27] EPA's decision to not consult despite overlap was also contrary to the ESA's best science mandates. The National Academy of Sciences determined that because of pesticides' inherent toxicity, any spatial overlap between pesticide use and listed species' ranges or habitat should lead to a "may affect" determination and requires at least informal consultation with FWS. *See supra* n.25 at 9, 29, 32.

wild lupines. ER1615 (citing FWS Karner Blue Butterfly Recovery Plan (2003)). The Recovery Plan expressly states that "some Karner blue sites are near agricultural fields where insecticide or herbicide application could affect the butterfly."[28] Not only is the butterfly near fields, but Karner adults rely on nectar to survive, which may be growing on the fields. *Id.* at 1. Yet EPA said it did not expect overlap, eliminated it from the action area, and concluded "no effect."

In the 2018 assessment, EPA purported to include "any newly listed species of terrestrial animals that may be present on the treated field that were not previously assessed." ER0341. However, EPA does not identify the newly listed species, much less explain its rationale for concluding that they will not be present on the field. ER0385 ("No additional animal species were found to overlap with the treated field."). For example, FWS listed the rusty patched bumble bee as endangered in 2017. 82 Fed. Reg. 3186 (Jan. 11, 2017). Bumble bees are "generalist foragers," gathering pollen and nectar from a wide variety of flowering

[28] EPA relies on the Recovery Plan but did not include it in the record. U.S. Fish & Wildlife Serv., *Karner Blue Butterfly Recovery Plan*, at 90 (Sept. 2003), *available at* https://ecos.fws.gov/docs/recovery_plan/030919.pdf.

plants, and the rusty patched is "one of the first bumble bees to emerge early in the spring and the last to go into hibernation, so to meet its nutritional needs, the species requires a constant and diverse supply of blooming flowers." *Id.* at 3187. EPA's failure to discuss the bumble bee or any other newly listed species is arbitrary.[29]

Using this approach, EPA eliminated nearly all species from the action area and concluded "no effect." ER1963 (eliminating all but 10 of 183 listed species); ER1800-1801 ([redacted]); ER1584-1589 (eliminating all but 6 of 322 listed species); ER1171-1173 (overall only 27 species within the action area); ER0341, ER0385 (unknown number of newly listed terrestrial species not found to overlap treated field). EPA's sweeping elimination of hundreds of species from the action area based on its subjective review of species habitats is not within EPA's expertise or statutory mandate, is contrary

[29] EPA's inexpert conclusions are based on qualitative and subjective descriptions of habitat, which is also contrary to the ESA's best science mandate: the Academy concluded that qualitative descriptions of habitat are not as reliable as objective and quantitative "statistical characterization and delineation of habitat . . . ." *See supra* n.25 at 57, 79. EPA's focus on habitat ignores that some species may be present in fields for a considerable amount of time, either on the move from nesting to foraging habitat or traveling to find a mate.

to, let alone based on, the best available science, and fails to give the benefit of doubt to species on the brink of extinction, *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

3. Reliance on Mitigation Means Consultation Should Be Compelled.

In the new 2018 assessment and decision, EPA candidly admits that, but for the new 57-foot buffer, its conclusion for all of the new species it analyzed in the 2018 addendum and new action area would have been "may affect." ER00013 ("69 species *would be may-affect with no additional mitigation*.") (emphasis added); *Id.* ("12 critical habitats would be "modification" with no additional mitigation"); ER0442-450 (listing all species as "May Affect" absent the new 57-foot buffer).

So EPA has predicated its no effect determination for nearly 70 plants—that it knows were at grave risk from its 2016 decision—on the efficacy of its new 57-foot buffer. What happened in 2017-2018 plainly shows that "may affect" is easily surpassed surrounding the fields and that drift is more than possible; it *has just occurred* in unprecedented amounts. This is exactly the type of decision that EPA must consult over, and cannot decide unilaterally.

Karuk Tribe held that agency reliance on mitigation like this "cuts against, rather than in favor of" having no duty to enter consultation and proceed to Step 2. 681 F.3d at 1028. As in *Karuk Tribe*, EPA's perceived need to reduce potential effects here with the 57-foot buffer underscores that effects are *possible* to off-field species, which is *all that is required* to compel consultation. *Id.* In fact the Court zeroed in on the exact same agency language as here as showing its misinterpretation of the standard. *Id.* (miners' compliance with agency "criteria should *'reduce' – not eliminate* – 'the impacts to anadromous fisheries' . . .") (emphasis added). *Compare supra* p.54 & citations; ER0003, 5, 17, 20.

4. EPA's 57-Foot Buffer as "Mitigation" to Limit the Action Area and Conclude "No Effect" is Unsupportable.

The new buffer reliance proves that EPA was required to consult as a matter of law, but even if it did not, it is arbitrary and capricious, rendering EPA's decision unlawful.

EPA continues to err by relying on "mitigation measures" that EPA wrongly assumes will prevent exposure to dicamba above LOCs outside of the fields. In 2016, EPA initially proposed to limit the action area to treated fields by relying on mitigation that included an in-field,

downwind buffer for spray drift, plus an omnidirectional buffer for volatility, both 110 feet. ER1169. Monsanto then submitted volatility studies (discussed *supra* pp.25-29) that convinced EPA to eliminate the volatilization buffer, which had been based on university research (ER1213-1214), and instead rely entirely on the downwind-only buffer to mitigate spray drift to "a level where effects are expected only within the confines of the treated field."
ER1583; ER1169.

In 2018, EPA had to admit this error and included a 57-foot, omnidirectional, in-field buffer, but only for a limited number of plant species found within 30 meters of field edges as the action area, again arriving at "no effect" determinations. ER0385. EPA's 57-foot buffer does not support its no effect determinations because: 1) EPA ignored injury to plants documented hundreds of feet, *supra* pp.25-26, from fields and overrode its own scientists' conclusions that a much greater buffer distance was necessary; and 2) EPA ignored effects on endangered species that rely on plants for habitat, food, or cover.

EPA assessed twelve academic field studies conducted between 2016 and 2018 showing dicamba spray and volatility "may affect"

susceptible off-field plants based on visual signs of injury, a widely used rating system for herbicidal damage (0 = no injury to 100 = plant death). ER0355-376, 416-418. Two of the field studies recorded injury at distances greater than 440 feet (168m and 136m). ER0368, 370-71, 373, 417-18. More than half the studies identified injury to plants at distances greater than 130 feet (39.6 m). *Id*. This evidence of harm meets the low bar of "may affect" to require an expansion of the action area and consultation.

Based on these studies, on October 3, 2018, EPA scientists recommended expansion of the action area *to 196 feet* (60 meters) around fields where overlap would be possible with endangered species' range, contingent on further evaluation of the 2018 Norsworthy study. ER0523. Following discussions with Dr. Norsworthy, EPA scientists concluded the Norsworthy study is valid and recommended expansion of the action area *to 443 feet* (135 meters) beyond the fields. ER0525.

But, following "management" review, EPA ignored data showing harm to plants and its scientists' recommendations of a 443-foot buffer. ER0526 (scientists drafted "one-pager for our management" on Norsworthy study). On October 11, 2018, EPA conveyed to Monsanto

that "with all of the uncertainty on the Endangered Species side, there is still a lot of work left." ER0521. However, less than two weeks later, on October 31, 2019, EPA concluded a 57-foot buffer was adequate.

EPA reached the 57-foot buffer by disregarding reported visual injury and relying only on four studies that measured plant height, despite their deficiencies, and third-party "Crystal Ball" simulation software. ER0379-81, 411. EPA ignored visual injury to plants because it believed it must show effects on plant growth or reproduction, EPA-approved endpoints in the FIFRA context.

EPA concluded that the 57-foot buffer mitigation provides no more than "*reasonable*" protection (ER0380-81), a *FIFRA* rather than ESA standard, and made its "no effect" determinations on this faulty basis. However, the "may affect" threshold encompasses "any possible effect," including "reasonable" visual injury, not just effects that are related to growth or reproduction. Ignoring visual injury harms misinterprets this standard and violates the ESA.

Assuming, *arguendo*, that EPA must link visual injury to growth or reproduction for its effects determination, EPA did so. EPA concluded that conversion from visual injury to growth/reproduction endpoint

could be achieved using a simple conversion factor compiled from nine studies. ER0409 (all levels of visual injury "were related to thresholds of height or yield effects" using "multiple published effects studies . . ."). EPA scientists found that "at 10% visual injury, a 5% reduction in yield would be expected." ER523. EPA also identified considerable advantages to using all of the twelve field studies in this manner because it provides a "larger pool of data . . . under more variable environmental conditions and performed in more geographic locations." ER0409. But, EPA scrapped these studies to arrive at the unsupportable 57-foot buffer and reach unlawful "no effect" determinations.

Finally, EPA compounded its errors by failing to address species' exposure to dicamba from runoff in irrigation water *as well as* the aggregate of runoff with spray and vapor drift. ER0335-337 (relying on hard-to-follow label direction not to spray within 24 hours of rainfall to mitigate initial LOC exceedance). Not only should reliance on mitigation itself compel consultation, *supra*, the 24-hour rainfall

mitigation does not account for exposure to dicamba from runoff via irrigation water or in the *aggregate* with spray drift and volatilization.[30]

But EPA knew that exposure to dicamba in irrigation water could cause effects because EPA required future additional studies examining the effects of dicamba-containing irrigation runoff water in its 2018 continuation. ER0498, 502-503; ER0519; ER0070; ER0504-508. And data provided to EPA showed how harmful combined exposure can be. ER0356-57, ER0463; ER0843 (showing 40% injury from runoff and drift combined extended *five times* farther off-field than drift alone). EPA arbitrarily ignored potential aggregate effects to species, 900 feet or more from fields. *Id.* For all these reasons, EPA's 57-foot buffer is arbitrary and capricious and contrary to law.

5. Even Applying a 57-foot Buffer, EPA Ignored Effects.

In updating its effects determinations in 2018 because of extensive off-field dicamba injury, EPA limited the assessment to 69 ESA-protected "non-monocot plants that may exist near the treated field" and "newly listed species of terrestrial animals that may be present on

[30] Nor is 24-hours temporally effective. ER0682 (applicator saw runoff with rainfall 4 days after application).

the treated field that were not previously assessed." ER0341; ER0385 (Identifying 69 listed dicot plants species within the "expanded" action area (treated field+30m) and concluding "no effect" based on 57-foot buffer where those species are thought to occur). However, EPA failed to consider the effects on any species *that relies on plants* (any plants, not just endangered or threatened plants) for habitat, including food, shelter/cover, or nesting. ER0009 (indirect effect risks were possible for any species with dependencies).

For example, the rusty patched bumble bee requires pollen and nectar from a variety of flowering plants from spring to fall. 82 Fed. Reg. at 3187. The bee is found near soybean fields, yet EPA ignored the effects of injury to any flowering plants the bee needs, ER0750; ER0777, because those plants are not protected under the ESA, and, therefore, were not included in the expanded action area. Another example is the yellow-billed cuckoo, which relies on riparian trees, including willow and cottonwoods. 79 Fed. Reg. 59992, 60000 (Oct. 3, 2014) (listing rule); 79 Fed. Reg. 48548, (Aug. 15, 2014) (proposed designation of critical habitat, optimal habitat has "dense canopy closure and high foliage volume" of willows and cottonwoods). The cuckoo's habitat is near

Arizona cotton fields, but EPA did not evaluate effects on trees that the cuckoo relies on for habitat. *Supra* p.7, 10-11; ER0727-731 (drift damage to trees).

D. EPA Failed to Comply with the ESA on Designated Critical Habitat.

ESA § 7(a)(2) imposes an independent duty on EPA to "insure" its registration will not result in "destruction or adverse modification" of habitat FWS designated as "critical" to a listed species' survival or recovery. 16 U.S.C. §§ 1533(a)(3)(A), 1536(a)(2). EPA must consult if its registration "may affect" a listed species' critical habitat.

For critical habitat, EPA compounded the legal and scientific errors it made with regards to listed species. In 2016, EPA concluded "no modification" for any species' critical habitat that EPA had already concluded would have "no effect" on the species based on: 1) EPA's unlawful FIFRA RQ/LOC standard and inadequate mitigation, which constrained the action area to the crop fields, 2) EPA's inexpert reduction of species' ranges to conclude most species will not be on the fields; and 3) EPA's inexpert conclusions that species that use the fields will not be affected, again based on RQ/LOC. This allowed EPA to

unlawfully circumvent consultation on *every single* critical habitat in and around the fields in 34 states where EPA authorized dicamba.

In 2018, EPA could not continue to ignore that XtendiMax leaves the fields, but did not revisit its 2016 critical habitat determinations. Instead, EPA required the 57-foot buffer for the limited number of designated critical habitats that exist within 30 meters of field edges if a "primary constituent element"[31] of the critical habitat includes plants likely to be damaged by dicamba. The 57-foot buffer is inadequate for the reasons discussed *supra* pp.59-64. Nonetheless, EPA concluded "no modification."

1. EPA Applied the Wrong Standard.

First, EPA failed to apply the low "may affect" standard that triggers consultation. EPA purported to analyze "modification" of critical habitat. ER0388. The law requires consultation for all "actions that have *any chance of affecting* … critical habitat—even if it is later

[31] 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).

determined that the actions are 'not likely' to do so." *Karuk Tribe,* 681 F.3d at 1027 (emphasis added).

Second, EPA conflated risks to species with risks to critical habitat, tiering its habitat duties to its species "no effect" determinations, but critical habitat may be affected regardless of whether an action may affect the species itself. *Greenpeace v. Nat'l Marine Fisheries Serv.*, 55 F. Supp. 2d 1248, 1265 (W.D. Wash. 1999).

Here is the rule EPA created:

> 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 [d]icamba ….
>
> 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 the above conditions are not met, EPA concludes 'no modification.'

ER1602; ER1173 (emphases added); ER2057; ER1822-1823. EPA applied the same unlawful rule in 2018 to the "fields or areas within 30

meters (spatial estimate of the EPA established 57-foot buffer)." ER0388.

Application of this unlawful standard, relying on unlawful species' effects determinations, resulted in "no modification" for hundreds of critical habitats. For example, EPA determined "no modification" for 59 critical habitats designated within 16 states because 53 has species "judged to not use cotton or soybean fields," none of remaining 6 were "at risk for direct adverse effects," and 5 of those 6 PCEs were "not relatable" to fields. ER2057. For Whooping crane, EPA found use on soybean "could affect" its critical habitat "by making waste soybean grain potentially toxic." *Id.* But, based on EPA's "direct effects assessment for this species" being below levels of concern, EPA concluded "no modification" for Whooping crane habitat too. ER2057-2058; ER1823 ([redacted]); ER1602-1603 (no modification for 122 critical habitats within 11 states); ER1173, 1180-1182, 1208-1209 (no modification for 11 additional critical habitats). In 2018, EPA only revisited 14 critical habitats located within the expanded action are of treated field + 30 meters and

concluded 12 would have "modification," but that the 57-foot buffer excluded these from the action area, resulting in "no modification" for all. ER0388.

2. 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" allowed it to avoid consultation, but a species' physical occupation of part of a critical habitat (here, cotton and soybean fields) is irrelevant to the trigger for consultation (whether dicamba use "may affect" the habitat) 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]

[32] U.S. Fish & Wildlife Serv., Endangered Species Glossary, *available at* https://www.fws.gov/nc-es/fish/glossary.pdf

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

Crucially, 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 the species." 16 U.S.C. § 1532(5)(A)(ii) (emphasis added); *Consultation Handbook* 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, including sprayed fields, regardless of whether members of species are likely to be present in them, because the habitat nonetheless may be important for the species' survival or recovery. *Nat'l 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); *Gifford Pinchot Task Force v. U.S. Fish & Wildlife Service*, 378 F.3d 1059, 1070 (9th Cir. 2004), *amended*, 387 F.3d 968 (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.").

Despite the millions of acres devastated by dicamba drift EPA was 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 meaningfully consider whether spraying the fields "may affect" critical habitats, violating the ESA by assuming effects on unoccupied critical habitat *cannot* trigger consultation.

E. EPA's Scope Was Unlawfully Narrow, Failing to Consider All of the Pesticide.

EPA's assessment also violates the ESA because of its narrowness: EPA focused solely on the dicamba component of XtendiMax. ER0336 (scope limited to the dicamba ingredient); ER0233 (same). Yet EPA

approved the *entire* pesticide product, not just the dicamba ingredient. The "may affect" determination requires determining the scope of what an "effect" is, that "may affect" any protected species or habitat. "Effects of the action" are defined very broadly, as "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." 50 C.F.R. § 402.02; *Karuk Tribe*, 681 F.3d at 1020 ("Congress intended agency action to have a broad definition in the ESA"). The rest of the product formulation, its "inerts," including surfactants, also may affect endangered species, either alone or in combination with the rest of the product. *Washington Toxics,* 457 F. Supp. 2d at 1183 (discussing inerts, surfactants, degradates). EPA has also approved XtendiMax to be "tank mixed" with other pesticides, without any further ESA assessment; any risks to ESA species from that use were also not considered. *See supra* n.12. EPA's overly narrow review was arbitrary and capricious and contrary to law. *State Farm*, 463 U.S. at 43 (failure to consider an important part of the problem).

III. THE COURT SHOULD VACATE THE REGISTRATION.

The Court should set aside EPA's approval. *All. for the Wild Rockies v. U.S. Forest Serv.,* 907 F.3d 1105, 1121-22 (9th Cir. 2018) ("presumption of vacatur," unless defendants meet their burden to show otherwise); *Pollinator Stewardship*, 806 F.3d at 532 (remand without vacatur permitted only in "limited circumstances"); *Humane Soc. of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("rare circumstances"); *Idaho Farm Bureau v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) ("Ordinarily" vacatur applies unless "equity demands" otherwise).

In *Pollinator Stewardship*, this Court held that "given the precariousness of bee populations, leaving the 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.

The XtendiMax registration is an experiment, the novel use of a volatile pesticide underwritten by great risks. At every opportunity, the agency re-shuffled the approval cards slightly for the coming season,

blaming farmers and requesting more Monsanto studies, while doubling down on its registration rubberstamp, unsupported by substantial evidence. EPA's gambles have busted; the agency's approval strategy and Monsanto's product are both broke, causing unprecedented agricultural harm and placing hundreds of endangered species, already on the brink of extinction, at continued risk. XtendiMax has already been unlawfully registered for three disastrous seasons. A year ago, Respondents wriggled away at the last moment, before this Court could decide these crucial issues. Enough is enough: Their game must end here.

CONCLUSION

For the reasons stated above, Petitioners request the Court vacate the registration, and remand for further proceedings consistent with this Court's decision.

Respectfully submitted this 13th day of August, 2019.

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STATUTORY AND REGULATORY ADDENDUM

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5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

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

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

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

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

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

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

(D) without observance of procedure required by law;

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

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

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

CREDIT(S)

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

Notes of Decisions (4338)

5 U.S.C.A. § 706, 5 USCA § 706
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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 (11)

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. 116-38.

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. § 136a

§ 136a. Registration of pesticides

Effective: December 20, 2018
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).

(11) Interagency working group

(A) Definition of covered agency

In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) Duties

The interagency working group established under subparagraph (B) shall--

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including--

(I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of--

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including--

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports

(i) Progress reports

(I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results

(I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate--

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Federal Advisory Committee Act

The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group established under this paragraph.

(G) Savings clause

Nothing in this paragraph supersedes any provision of--

(i) this subchapter; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(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; Pub.L. 115-334, Title X, § 10115, Dec. 20, 2018, 132 Stat. 4914.)

Notes of Decisions (104)

7 U.S.C.A. § 136a, 7 USCA § 136a
Current through P.L. 116-38.

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. 116-38.

End of Document

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 (110)

16 U.S.C.A. § 1532, 16 USCA § 1532
Current through P.L. 116-38.

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).

(b) Opinion of Secretary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Biological assessment

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

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

(d) Limitation on commitment of resources

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

(e) Endangered Species Committee

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

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

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

(A) The Secretary of Agriculture.

(B) The Secretary of the Army.

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

(D) The Administrator of the Environmental Protection Agency.

(E) The Secretary of the Interior.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Not later than 90 days after November 10, 1978, the Secretary shall promulgate regulations which set forth the form and manner in which applications for exemption shall be submitted to the Secretary and the information to be contained in such applications.

Such regulations shall require that information submitted in an application by the head of any Federal agency with respect to any agency action include, but not be limited to--

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

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

(g) Application for exemption; report to Committee

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) Grant of exemption

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) Exemption for national security reasons

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

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

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

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

(1) If the Committee determines under subsection (h) that an exemption should be granted with respect to any agency action, the Committee shall issue an order granting the exemption and specifying the mitigation and enhancement measures established pursuant to subsection (h) which shall be carried out and paid for by the exemption applicant in implementing the agency action. All necessary mitigation and enhancement measures shall be authorized prior to the implementing of the agency action and funded concurrently with all other project features.

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

(m) Notice requirement for citizen suits not applicable

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

(n) Judicial review

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

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

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

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

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

(p) Exemptions in Presidentially declared disaster areas

In any area which has been declared by the President to be a major disaster area under the Disaster Relief and Emergency Assistance Act, 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, 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 (780)

16 U.S.C.A. § 1536, 16 USCA § 1536
Current through P.L. 116-38.

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.

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 August 8, 2019; 84 FR 39173.

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.

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

Notes of Decisions (4)

Current through August 8, 2019; 84 FR 39173.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart A. General

50 C.F.R. § 402.01

§ 402.01 Scope.

Currentness

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

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

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

Notes of Decisions (308)

Current through August 8, 2019; 84 FR 39173.

End of Document

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

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]

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

Notes of Decisions (245)

Current through August 8, 2019; 84 FR 39173.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.12

§ 402.12 Biological assessments.

Currentness

(a) Purpose. A biological assessment shall evaluate the potential effects of the action on listed and proposed species and designated and proposed critical habitat and determine whether any such species or habitat are likely to be adversely affected by the action and is used in determining whether formal consultation or a conference is necessary.

(b) Preparation requirement.

(1) The procedures of this section are required for Federal actions that are "major construction activities"; provided that a contract for construction was not entered into or actual construction was not begun on or before November 10, 1978. Any person, including those who may wish to apply for an exemption from section 7(a)(2) of the Act, may prepare a biological assessment under the supervision of the Federal agency and in cooperation with the Service consistent with the procedures and requirements of this section. An exemption from the requirements of section 7(a)(2) is not permanent unless a biological assessment has been prepared.

(2) The biological assessment shall be completed before any contract for construction is entered into and before construction is begun.

(c) Request for information. The Federal agency or the designated non-Federal representative shall convey to the Director either (1) a written request for a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area; or (2) a written notification of the species and critical habitat that are being included in the biological assessment.

(d) Director's response. Within 30 days of receipt of the notification of, or the request for, a species list, the Director shall either concur with or revise the list or, in those cases where no list has been provided, advise the Federal agency or the designated non-Federal representative in writing whether, based on the best scientific and commercial data available, any listed or proposed species or designated or proposed critical habitat may be present in the action area. In addition to listed and proposed species, the Director will provide a list of candidate species that may be present in the action area. Candidate species refers to any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule. Although candidate species have no legal status and are accorded no protection under the Act, their inclusion will alert the Federal agency of potential proposals or listings.

(1) If the Director advises that no listed species or critical habitat may be present, the Federal agency need not prepare a biological assessment and further consultation is not required. If only proposed species or proposed critical habitat may be present in the action area, then the Federal agency must confer with the Service if required under § 402.10, but preparation of a biological assessment is not required unless the proposed listing and/or designation becomes final.

(2) If a listed species or critical habitat may be present in the action area, the Director will provide a species list or concur with the species list provided. The Director also will provide available information (or references thereto) regarding these species and critical habitat, and may recommend discretionary studies or surveys that may provide a better information base for the preparation of an assessment. Any recommendation for studies or surveys is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

(e) Verification of current accuracy of species list. If the Federal agency or the designated non-Federal representative does not begin preparation of the biological assessment within 90 days of receipt of (or concurrence with) the species list, the Federal agency or the designated non-Federal representative must verify (formally or informally) with the Service the current accuracy of the species list at the time the preparation of the assessment is begun.

(f) Contents. The contents of a biological assessment are at the discretion of the Federal agency and will depend on the nature of the Federal action. The following may be considered for inclusion:

(1) The results of an on-site inspection of the area affected by the action to determine if listed or proposed species are present or occur seasonally.

(2) The views of recognized experts on the species at issue.

(3) A review of the literature and other information.

(4) An analysis of the effects of the action on the species and habitat, including consideration of cumulative effects, and the results of any related studies.

(5) An analysis of alternate actions considered by the Federal agency for the proposed action.

(g) Incorporation by reference. If a proposed action requiring the preparation of a biological assessment is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may fulfill the biological assessment requirement for the proposed action by incorporating by reference the earlier biological assessment, plus any supporting data from other documents that are pertinent to the consultation, into a written certification that:

(1) The proposed action involves similar impacts to the same species in the same geographic area;

(2) No new species have been listed or proposed or no new critical habitat designated or proposed for the action area; and

(3) The biological assessment has been supplemented with any relevant changes in information.

(h) Permit requirements. If conducting a biological assessment will involve the taking of a listed species, a permit under section 10 of the Act (16 U.S.C. 1539) and part 17 of this title (with respect to species under the jurisdiction of the FWS) or parts 220, 222, and 227 of this title (with respect to species under the jurisdiction of the NMFS) is required.

(i) Completion time. The Federal agency or the designated non- Federal representative shall complete the biological assessment within 180 days after its initiation (receipt of or concurrence with the species list) unless a different period of time is agreed to by the Director and the Federal agency. If a permit or license applicant is involved, the 180–day period may not be extended unless the agency provides the applicant, before the close of the 180–day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why such an extension is necessary.

(j) Submission of biological assessment. The Federal agency shall submit the completed biological assessment to the Director for review. The Director will respond in writing within 30 days as to whether or not he concurs with the findings of the biological assessment. At the option of the Federal agency, formal consultation may be initiated under § 402.14(c) concurrently with the submission of the assessment.

(k) Use of the biological assessment.

(1) The Federal agency shall use the biological assessment in determining whether formal consultation or a conference is required under § 402.14 or § 402.10, respectively. If the biological assessment indicates that there are no listed species or critical habitat present that are likely to be adversely affected by the action and the Director concurs as specified in paragraph (j) of this section, then formal consultation is not required. If the biological assessment indicates that the action is not likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

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

Notes of Decisions (58)

Current through August 8, 2019; 84 FR 39173.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.14

§ 402.14 Formal consultation.

Effective: June 10, 2015
Currentness

(a) Requirement for formal consultation. Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) Exceptions.

(1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) Initiation of formal consultation. A written request to initiate formal consultation shall be submitted to the Director and shall include:

(1) A description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statement, environmental assessment, or biological assessment prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat.

Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12. Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area or a segment of a comprehensive plan. This does not relieve the Federal agency of the requirements for considering the effects of the action as a whole.

(d) Responsibility to provide best scientific and commercial data available. The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) Duration and extension of formal consultation. Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

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

(3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) Additional data. When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) Service responsibilities. Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Formulate its biological opinion as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)–(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45–day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45–day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10–day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

(h) Biological opinions. The biological opinion shall include:

(1) A summary of the information on which the opinion is based;

(2) A detailed discussion of the effects of the action on listed species or critical habitat; and

(3) The Service's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy biological opinion"); or, the action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(i) Incidental take.

(1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, i.e., the amount or extent, of such incidental taking on the species (A surrogate (e.g., similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinitiate consultation immediately.

(5) Any taking which is subject to a statement as specified in paragraph (i)(1) of this section and which is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(6) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) Conservation recommendations. The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) Incremental steps. When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(l) Termination of consultation.

(1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

Credits

[54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015]

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

Notes of Decisions (252)

Current through August 8, 2019; 84 FR 39173.

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) Critical habitat shall be specified to To the maximum extent prudent and determinable at the time a species is proposed for listing , 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 will be stated in the publication of proposed and final rules listing a species. A The Secretary will make a final designation of critical habitat shall be made on the basis of the best scientific data available, after taking into consideration the probable economic, 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 one or both 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) Critical Designation of critical habitat is not determinable when one or both of the following situations exist:

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

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat. identify any area that meets the definition of "critical habitat."

(b) In determining what areas are critical habitat Where designation of critical habitat is prudent and determinable, the Secretary shall consider those physical and biological features that are essential to the conservation of a given species will identify specific areas within the geographical area occupied by the species at the time of listing and that may require special management considerations or protection. Such requirements include, but are not limited to the following: any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat.

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

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements; (i) Identify the geographical area occupied by the species at the time of listing.

(3) Cover or shelter; (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.

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

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

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

(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 may be designated as critical habitat.

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

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

(f) Critical habitat (e) The Secretary may be designated 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.

(g) Existing critical habitat may be revised (f) The Secretary may revise existing designations of critical habitat according to procedures in this section as new data become available to the Secretary .

(h) Critical habitat shall (g) The Secretary will not be designated designate critical habitat within foreign countries or in other areas outside of United States jurisdiction 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]

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

Notes of Decisions (43)

Current through August 8, 2019; 84 FR 39173.

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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 Petition for Review of the Environmental Protection Agency's (EPA) registration decision for the herbicide dicamba filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America.

1. 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.

2. I have been a member of Missouri Rural Crisis Center for more than ten years. I currently serve as a board member of the Missouri Rural Crisis Center. Since 2017, I have also been serving as a board member of NFFC's executive committee.

3. I am a resident of Golden City, Missouri 64748.

4. I farm grain, including soybean, corn, and wheat, and I also raise cattle. I currently farm 1,200 acres—about 55%, or 650 acres are maintained as row crops for grain, while the other 45%, 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 650 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.

5. 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.

6. I am aware that in 2016, the United States Environmental Protection Agency granted approval of the pesticide XtendiMax, containing the active ingredient dicamba, for use on dicamba-resistant, genetically engineered cotton and soybean in thirty-four states, including my home state of Missouri. While dicamba has traditionally been used as a pre-emergent application to kill weeds in soybean fields early in the planting season, EPA had approved XtendiMax to be

applied both for pre- as well as post-emergent use, or "over-the top" 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.

7. Prior to EPA's approval, grain farmers that grow soybean in my town could only 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, many of the farmers in my locality switched over to planting dicamba-resistant soybeans and spraying dicamba 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.

8. I am aware that as a result of EPA's approval, many soybean farmers in Missouri and other states experienced devastating levels of crop damage to their soybean crops in the 2017 planting season.

9. I was one of the many farmers who was injured by EPA's approval of dicamba use on dicamba-resistant soybeans. In August of 2017, I experienced significant damage to one of my soybean fields that likely resulted from over-the-top dicamba 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. As a result of the crop damage I suffered in 2017, that same year, I traveled multiple times to Jefferson City, the capital of the State of Missouri, to educate state representatives and government officials about the dangers of over-the-top dicamba 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 also cost me my time and money, and took me away from my family. Yet, I had no choice but to continue these efforts in order to protect my farm.

14. I am aware that as a result of the devastating losses suffered by soybean farmers in Missouri, the Missouri Department of Agriculture took measures to limit the use of dicamba before the 2018 growing season, prohibiting over-the-top applications of dicamba on soybean crops in my county after July 15, 2018.

15. Despite the cutoff date for over-the-top applications of dicamba, I still observed crop damage on about 120 acres of my soybean plants in late June of last year. The soybean plants exhibited the curling of leaves that is typical of soybean exposure to dicamba. A photograph of the cupped and curled leaves typical of soybean damage by dicamba from that year is attached to my declaration as Exhibit C.

16. Because the injured soybean plants were not in bloom yet, I cannot say for certain whether I suffered a decrease in yield as a result of their exposure to dicamba. However, as a farmer, I can say that damaging a growing crop is never ideal, and the threat of such exposure from over-the-top dicamba use on nearby farms introduces significant economic uncertainties into my ability to plan as a farmer. It is particularly distressing to me because the damaged soybean field was actually adjacent to about roughly 100 yards, or 300 feet of pastureland as a buffer between my field and the neighboring field, but my soybean crops still got exposed to dicamba. The potential crop damage, loss in yield, and concerns of economic

shortcomings also weigh on me heavily emotionally, at a time when the margin of profit for farmers is razor thin.

17. I am also aware that, despite widespread reports of significant crop damage and economic loss from soybean farmers, in the winter of 2018, EPA nonetheless extended the registration of over-the-top dicamba for another 2 years. I understand that the extended registration included some additional measures limiting over-the-top applications on soybeans after a certain amount of time.

18. EPA's decision to continue the registration of over-the-top dicamba injures my livelihood as a farmer. As my own experience demonstrates, even with the cut-off date for over-the-top application of dicamba in place in Missouri in 2018, a portion of my soybean crops suffered physical damage from dicamba drift. So long as over-the-top dicamba remains approved for use on dicamba-resistant soybean, I will continue to be injured by the risk of drift damage to my soybean crop.

19. As a result of the threat of dicamba damage to conventional soybean crops, it seems to me that, more and more farmers near me are converting to planting and growing dicamba-resistant soybean. This means that more and more farmers in my town are likely to spray dicamba later in the season, 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 harder 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.

20. EPA's approval of over-the-top dicamba for use on dicamba-resistant soybean also puts my personal health at risk. As a farmer, I have seen time and time again when EPA and multinational agrichemical companies assure rural communities that the uses of pesticides like dicamba are safe. Yet, it is often after long-term exposure to these chemicals do we see the real long-term health effects.

21. Over the years, I have suffered health issues relating to my lung and respiratory health. I am also a hepatitis C survivor, so being exposed to pesticides like dicamba really concerns me. EPA's approval of over-the-top dicamba has enabled dicamba applications later in the season, which lengthens the time period when I may be exposed to dicamba. I am especially concerned since dicamba is known to volatilize in warm weathers over an extended amount of time. 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.

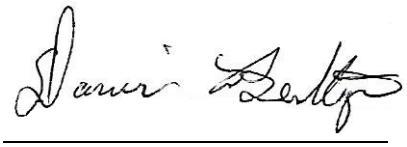
22. Additionally, EPA's approval of over-the-top dicamba for use on dicamba-resistant soybean has injured my personal relationships with my neighbors, as the source of yet another quarrel over the drift of chemicals and

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 over-the-top dicamba 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.

23. In sum, my personal health, social, economic interests and livelihoods have, and will continue to be, injured by EPA's decision to approve over-the-top dicamba for use on dicamba-resistant soybean. Without a court finding that EPA violated its duties in issuing the conditional registration of over-the-top dicamba 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 31st day of July, 2019, in Golden City, Missouri.



DARVIN BENTLAGE

Exhibit A

Exhibit B

Exhibit C

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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 Environmental Protection Agency's (EPA) registration decision for 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 Counsel and the General Counsel 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. I plan on returning to observe known Indiana bat colonies near Indianapolis in the late summer of 2019.

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. I frequently observe native insects in their natural habitats. In particular, I enjoy seeking out, observing, and photographing native butterflies and their host plants. In August 2019, I intend to visit Indiana Dunes National Park to attempt to view Karner blue butterflies (*Lycaeides Melissa samuelis*) and their habitat.

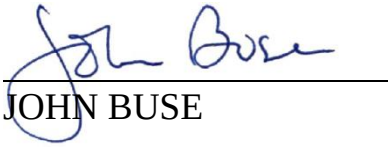
14. I am concerned that dicamba will be applied in Indiana and elsewhere on crops in close proximity to Karner blue butterfly habitat, including their host plants and plants that provide nectar, without regard to the species' conservation and recovery. As with Indiana bats, I fear that Karner blue butterflies are being inadvertently killed and harmed by agricultural chemicals. If the remaining populations of Karner blue butterflies were extirpated or reduced, my appreciation of the areas currently occupied by Karner blue butterflies, including the Indiana Dunes, would be diminished.

15. In summary, I have professional, aesthetic, and recreational interests in the preservation of the Indiana bat, the Karner blue butterfly, and their 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 these species. Specifically, I believe that the Environmental Protection Agency's failure to follow the law makes the species more likely to suffer further population declines. And if Indiana bats or Karner blue butterflies decline or become extinct, this loss would deprive me of the benefits I currently enjoy from their existence. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of this pesticide on these species, which is important to ensure that my interests in the species are preserved and remain free from injury.

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

Executed on this 9th day of August, 2019 at Indianapolis, Indiana.



JOHN BUSE

No. 19-70115

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 MARTHA L. CROUCH

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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 Petition for Review of the Environmental Protection Agency's (EPA) registration decision for 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 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 four 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 migrating population to reduce the risk to the species. That experimental eastern population now summers in Wisconsin and winters in Florida and in states along the migratory route, 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. My next trip would be in the spring of 2020, 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 over-the-top dicamba 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 over-the-top dicamba 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 over-the-top dicamba 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 over-the-top dicamba.

13. I am aware that, based on the instructions and guidelines for over-the-top dicamba 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 over-the-top dicamba 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 over-the-top dicamba 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 6th day of August, 2019, in Bloomington, Indiana.

MARTHA L. CROUCH, Ph.D.

No. 19-70115

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 ROB FAUX

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Counsel for Petitioners

I, ROB FAUX, 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 Environmental Protection Agency's (EPA) registration decision for 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 am an organic farmer and owner of Genuine Faux Farm.

3. I am a resident of Tripoli, Iowa with a population of around 2,000 residents. I own and operate Genuine Faux Farm, a diverse crop farm with 15 acres focused on a wide range of produce and poultry.

4. I am currently a member of Pesticide Action Network North America (PANNA). I joined PANNA a few years ago to be part of a larger community of likeminded farmers and advocates working towards sustainable agriculture.

5. I completed a doctoral degree in Computer Science and Adult Education at Union Institute and University in Cincinnati and I taught Computer Science at the University of Minnesota – Morris for two years. In 2004, we moved to Tripoli so my wife Tammy could take a position as a professor at Wartburg College. We decided to open up a farm when we noticed the lack of local foods, namely diverse vegetables, being served in the area, which is dominated by

soybean and corn farms. In 2005, Genuine Faux Farm began serving the Tripoli area with organic, diverse vegetables and poultry.

6. Since 2005, I have owned and operated Genuine Faux Farm with a focus on local distribution. We are a Community Supported Agriculture (CSA) operation, with shareholders who make our farming possible. Our cooperative shareholder approach to farming cultivates a sense of community, connecting our shareholders to the crops that we grow. As a CSA, we rely on being able to project the quantity of crops we will produce each season, not only for ourselves but for our shareholders.

7. Genuine Faux Farm is committed to a sustainable approach to agriculture. We are certified organic through the Iowa Department of Agriculture and Land Stewardship (IDALS). We do not use any synthetic fertilizers or sprays as we firmly believe that organic agricultural practices are the key to maintaining environmental health and long-term farm productivity. We are proud of our sustainable approach to agriculture and our commitment to farming a diverse production of crops. We consistently choose approaches to agriculture by including costs to the environment and community as part of our decision making process. For example, instead of plastic mulch, which is less expensive, we use locally sourced straw mulch or paper mulch which allows us to support local producers, and reduce any negative impact on the environment.

8. Farming and operating an organic farm is extremely challenging, especially since the majority of the surrounding farmlands grow soybeans and corn and rely heavily on herbicides, such as over-the-top dicamba, to produce higher yield. Although we do not rely on herbicides at Genuine Faux Farm, we have no control over the use of herbicides like dicamba by our neighboring farmers. We continue to be impacted by dicamba drift, which has grown notably more prevalent since 2017.

9. I am aware that the U.S. Environmental Protection Agency (EPA) has approved the use of over-the-top dicamba on genetically engineered, dicamba-resistant soybean and cotton crops. I am also aware that as a result of EPA's approval, farmers in my area can spray dicamba on their dicamba-resistant soybean crops later in the growing season.

10. I am aware that dicamba is drift-prone and volatile and can only be sprayed during certain times of the growing season, dependent on the climate. Because of where my farm is located, I have experienced damage to my crops from dicamba use by neighboring farms. Specifically, I have noticed the most susceptibility in my peppers, tomatoes, eggplants, and potatoes. While I have tried over the years to protect my crops by creating buffer zones, changing planting times, altering our crop rotation and moving crops to different locations on the farm each year, a higher percentage of crops are damaged by dicamba drift.

11. Over the years, I have come to recognize damage from dicamba on my plants, and am able to tell them apart from other types of pesticide damage. The signs of dicamba exposure manifest distinctly and rapidly once I notice them. Plant growth is inhibited and the crops are unable to reach healthy maturity or produce marketable fruit.

12. EPA's approval of dicamba for use on dicamba-resistant soybean injures me economically. Many of the farmers near me grow genetically engineered, herbicide-resistant soybean crops. I know that many farmers in the area have switched over to planting dicamba-resistant soybean crops after EPA's approval. As a farmer, I closely track the yields on my plants. Before 2018, Genuine Faux Farm produced between 10-14 tons of produce annually. However, in 2018, which has been my farm's lowest production year, we only yielded 7 tons of produce, and specifically only seven bell pepper fruit, out of 275 plants that were planted. In comparison, we produced 140 bell pepper fruit in 2017, and 1,333 in 2016.

13. EPA's approval of dicamba use on dicamba-resistant crop also hurts me financially because it hurts my farm's ability to attract and retain CSA shareholders, who put a deposit at the beginning of each year in return for my farm produce. These shareholders provide resources upfront at the beginning of each year so that we may be able to grow the crops they are invested in. Genuine Faux

Farm has an obligation to fulfill these investments; however, EPA's approval of dicamba makes it increasingly difficult to produce the crops that our shareholders funded.

14. As a direct result of EPA's approval of the expansion of dicamba use, I will need to scale back the resources put into my production by half next year. As long as EPA continues to allow dicamba use on dicamba-resistant soybean crops, I will not be able to maximize my crop variety and will continue to plant on reduced acreage, rather than replanting or investing in new fields.

15. EPA's approval of dicamba injures my vocation by limiting my ability to produce crops sustainably, and to protect my crops from drift. Though I have buffer zones in place, which are required to receive organic certification, I continue to increase these buffer zones with higher vertical walls, wider windbreak crop zones, and taller grasses on the edges of my property. These investments cost me money by requiring investment to set up these buffer zones, and also by reducing my ability to fully utilize my land for food production, However, because dicamba drift is so widespread, these efforts are often futile as my crops continue to suffer dicamba-related damage. During wet springs, soybeans are planted later and Dicamba is applied later, increasing the risk of volatilization and lift. Without being able to predict these factors, I am unable to better protect my crops and ensure their integrity under the organic certification.

16. The damage caused by dicamba drift from other farms in the surrounding area has also hurt my personal relationships with my neighbors. Because I do not use herbicides, nor plant herbicide-resistant crops, many of my neighbors see me as a "hobby-farmer" rather than a vocational farmer. Therefore, many of them do not take me seriously when I try to talk with them about the impact of dicamba drift on my crops. I have attempted to speak candidly with neighbors about how their use of dicamba affects the surrounding farms, but they refuse to engage with me. Now, many of my neighbors are reluctant to speak with me because they think I am threatening their own livelihoods.

17. In sum, EPA's approval of Dicamba use has injured, and will continue to injure, my economic and social interests. Without a court finding that EPA violated its duties in expanding Dicamba use, the well-being of my farm and my personal relationships with my neighbors will continue to be adversely affected by the use of Dicamba.

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

Executed on this 9th of August, 2019, in Tripoli, Iowa.

Rob Faux
Owner, Genuine Faux Farm

No. 19-70115

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 LISA GRIFFITH

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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 submit this declaration in support of the Petition for Review of the Environmental Protection Agency's (EPA) registration decision for 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 am the National Program Coordinator of Petitioner National Family Farm Coalition (NFFC). NFFC is a Washington, D.C.-based, nonprofit corporation that serves as a national link for a coalition of family farm and rural groups on the challenges facing family farms and rural communities. Founded in 1986, NFFC today represents farmers and ranchers from 30 grassroots member organizations in 42 states, including farmers and ranchers from Georgia, Mississippi, Missouri, North Carolina, North Dakota, Ohio, South Dakota, Texas and Wisconsin, where the U.S. Environmental Protection Agency has approved the use of over-the-top dicamba 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 help to determine NFFC's campaigns. Working with organizational, rather than individual, members offers a broader base of support and outreach for implementing national organizing strategies.

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 2016 to EPA regarding the agency's initial proposal to register the new uses of over-the-top dicamba on dicamba-resistant cotton and soybean. NFFC was one of the petitioners in *National Family Farm Coalition v. Environmental Protection Agency*, No. 17-70196, ECF No. 1-5 (9th Cir., Jan. 20, 2017) (*Dicamba I*), which challenged EPA's earlier registration decisions of the same pesticide product and proposed uses.

7. The approved uses of over-the-top dicamba 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

[1] *Available at* http://www.farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf.

where over-the-top dicamba 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 over-the-top dicamba use in cotton and soybean states for in-season use, NFFC's farmer members may have to adjust their planting season and choice of seed or crop, or impose costly measures such as buffer zones, in an attempt to avoid crop damage by over-the-top dicamba.

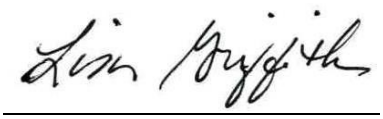
8. Many of NFFC's members are heavily involved with reducing the use of pesticides and preserve the use of non-patented seed crops. They see the use of conventional, non-genetically engineered seeds and the ability to save their seeds as vital components of rural life and their way of farming. Because EPA's approved new uses of over-the-top dicamba on dicamba-resistant cotton and soybean creates a longer period of time whereby farmers may suffer drift damage from over-the-top dicamba, 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 over-the-top dicamba 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 over-the-top dicamba for use on dicamba-resistant cotton and soybean adversely injures NFFC's organizational interests, as well as the economic and personal interests of our members.

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

Executed on 2nd day of August, 2019, in Washington, D.C.



Lisa Griffith
National Program Coordinator

No. 19-70115

UNITED STATES COURT OF APPEALS
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ON PETITION FOR REVIEW FROM THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DECLARATION OF MARCIA ISHII-EITEMAN

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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 submit this declaration in support of the Petition for Review of the Environmental Protection Agency's (EPA) registration decision for 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 am a Senior Scientist of Pesticide Action Network North America (PANNA).

3. 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 regulatory approval of the use of the herbicide over-the-top dicamba.

4. 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.

5. 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 over-the-top dicamba has been approved for use, including the Iowa Farmers Union, Iowa Organic Association and Practical Farmers of Iowa.

6. 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.

7. PANNA previously submitted organizational comments in 2016 to EPA regarding the agency's initial proposal to register over-the-top dicamba, the pesticide product and uses at issue in the present petition for review. PANNA was one of the petitioners in *National Family Farm Coalition v. Environmental Protection Agency*, No. 17-70196, ECF No. 1-5 (9th Cir., Jan. 20, 2017) (*Dicamba I*), which challenged EPA's earlier registration decisions of the same pesticide product and proposed uses.

8. 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.

9. 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 over-the-top dicamba 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 over-the-top dicamba.

10. PANNA's members are deeply concerned that EPA's registration of over-the-top dicamba will harm their farm productivity, livelihoods and environment, to the detriment of their economic and recreational interests.

11. 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 over-the-top dicamba will harm sensitive, threatened and endangered species, which will injure PANNA's

members' aesthetic interest in protecting natural ecosystems and wildlife and maintaining biodiversity.

12. EPA's decision to register over-the-top dicamba 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 6th day of August, 2019, in Berkeley, California.

MARCIA ISHII-EITEMAN, Ph.D.
Senior Scientist, PANNA

No. 19-70115

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 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 submit this declaration in support of the Petition for Review of the Environmental Protection Agency's (EPA) registration decision for 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 am the Legal Director of the Center for Food Safety (CFS) and counsel in this case. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; and Washington, D.C. CFS represents more than 970,000 farmer and consumer members, in every state throughout the country, including over 300,000 in the 34 states covered by the over-the-top dicamba approval challenged in this case. CFS and its members are being, and will be, adversely affected by EPA's decision to register the 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 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.

7. CFS submitted organizational comments in 2010, 2012, and 2016 to the EPA docket on the proposed registration of over-the-top dicamba, for use on dicamba-resistant cotton and soybean, the pesticide product and uses at issue in this petition for review. CFS also submitted comments to the EPA prior to the 2018 continuation decision. CFS was one of the petitioners in *National Family Farm Coalition v. Environmental Protection Agency*, No. 17-70196, ECF No. 1-5 (9th Cir., Jan. 20, 2017) (*Dicamba I*), which challenged EPA's earlier registration decisions of the same pesticide product and proposed uses.

8. As a party to this proceeding, CFS and its members are injured by the EPA's approval of novel and increased use of over-the-top dicamba 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 approval of over-the-top dicamba.

9. CFS and its members are being, and will be, adversely affected by the challenged EPA's decision to register over-the-top dicamba. 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 over-the-top dicamba will negatively harm non-target organisms, injuring CFS members' recreational and aesthetic interests.

10. 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 over-the-top dicamba for use on cotton and soybean fields. Moreover, the intensive use of over-the-top dicamba 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.

11. CFS members' interests are also injured by EPA's decision to approve over-the-top dicamba use 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 over-the-top dicamba without consulting with FWS, as required under the Endangered Species Act.

12. 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 over-the-top dicamba. EPA's registration of over-the-top dicamba use 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 over-the-top dicamba this year, making it more likely that CFS's farmers and gardeners members who cultivate crops near areas of over-the-top dicamba 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 over-the-top dicamba use near their crops. The livelihood and economic interests of CFS members who cultivate and farm such crops are injured by the EPA approval.

13. In sum, EPA's decision to register over-the-top dicamba 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 interests 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 12th day in August, 2019, in Portland, OR.

George Kimbrell
Legal Director, CFS

No. 19-70115

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 Environmental Protection Agency's (EPA) registration decision for 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. 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. For example, I rented a cabin in central Wisconsin in August and will look for whooping cranes en route to the cabin.

13. In the spring of 2017, I drove to Tennessee and looked for whooping cranes. I plan to continue making road trips to Tennessee and look for whooping cranes and other wildlife along the way.

14. 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.

15. 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.

16. These exposures to dicamba may have adverse effects on the whooping cranes.

17. 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.

18. In addition, I have strong aesthetic, recreational, and scientific interests in the rusty patched bumble bee. Near my home in Blaine, Minnesota, I look for the bees on a weekly basis in the summer. My partner and I have planted native prairie plants in our yard, including bee balm, which attract lots of bees. I have bee identification guides, and I know how to recognize the rusty patched bumble bee. We have wooded wetlands adjacent to our home and native prairie with lots of wildflowers, and I remain hopeful that someday I will see a rusty patched bumble bee in this bee habitat near my home.

19. I have done several "citizen science" surveys for bumble bees in the Twin Cities metropolitan area, where I have worked with scientific professionals to capture and identify numerous bee species.

20. Last summer, I walked along the shore of Como Lake in St. Paul, Minnesota, with the goal of seeing a rusty patched bumble bee, as I had heard that the species had been found near there. I was thrilled to find one as I observed dozens of bees of various species buzzing from flower to flower in this beautiful area.

21. With the recent Endangered Species Act listing of the rusty patched bumble bee, I began to learn about the status and threats facing the bee. I was fascinated to learn that the bee is found primarily in urban areas, which suggests that the bee may be susceptible to pesticides used in agricultural areas.

22. My home is in an outer-ring suburb and large agricultural fields can be found within just a few miles of my home. I'm concerned that survival and recovery of the bee in these areas will continue to be impacted by use of pesticides, including dicamba.

23. I try to quickly identify any bee that I notice when I'm out and about and talking a walk. I will continue to look for the rusty patched bumble bee whenever I'm out walking and observing potential bee habitat such as patches of wildflowers.

24. If the bee were to make progress toward recovery, I would have hope of seeing the bee in additional areas, such as near my home and during my travels in central Wisconsin.

25. I do not believe that EPA properly assessed the risks of this dicamba registration on the rusty patched bumble bee through consultation with the U.S. Fish and Wildlife Service. It concerns me that dicamba will harm flowering plants near soybean fields that the bee relies on for pollen and nectar. The rusty patched bumble bee already has lost much of its natural habitat and is likely exposed to insecticides in addition to herbicides like dicamba. Allowing use of dicamba over the top of soybean fields is another serious stress that can and will severely harm their recovery.

26. In summary, I have aesthetic and recreational interests in the preservation of whooping cranes, rusty patched bumble bees 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 29th day of July 2019, in Anoka County, Minnesota.

BRYAN P. NEWMAN

No. 19-70115

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 ERIC POOL

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Counsel for Petitioners

I, ERIC POOL, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the Environmental Protection Agency's (EPA) registration decision for 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 am a resident of 300 N. Elm Street, Claremont, Illinois. I farm at 1955 N. Praireton Road, Claremont, Illinois 62421.

3. I am currently a member of Center for Food Safety (CFS). I joined CFS in 2012 because CFS promotes sustainable agricultural practices and advocates on behalf of family farms and rural communities. I grew up near the small town of Berryville, Illinois. I was raised helping my father on his farm cultivating grain crops such as corn and beans.

4. I received a Bachelor's of Science in Business Administration with a concentration in Entrepreneurship from the University of Illinois in 1998. During the spring prior to my graduation, I decided to plant a vineyard. My father owned a parcel of land just three miles north of Berryville, Illinois, which was ideal for growing grapes. In 2001, I began harvesting trees around the vineyard to build a winery. After honing my winemaking skills in my basement with the first few

crops, the 2002 vintage was the first crop commercially crafted in my winery, Berryville Vineyards.[1]

5. I currently farm about 10 acres of wine grapes and small amounts of various fruits, including blackberries and strawberries. Berryville Vineyards is nestled amongst a mixture of land used for raising grain crops, as well as pasture and woods. The vineyard is comprised of over twenty varieties of wine grapes. Our main cultivars of grape are Vignoles, Vidal, Cynthiana, Chambourcin, and Diamond. The Vignoles, Vidal, and Chambourcin are all French hybrids meaning these varieties are a hybrid of European and American varieties of wine grapes. While the Cynthiana and Diamond varieties, are considered American varieties of wine grapes, which are more susceptible to dicamba. During my first year of farming, in 1998, I planted two acres of wine grapes on land that belonged to my father at that time. I spent all the money I had planting those 2 acres, but was able to obtain loans from the U.S. Department of Agriculture to continue planting and purchasing land. At my peak acreage, I was farming 12.7 acres.

6. All wines at Berryville Vineyards are a hundred percent estate grown and bottled in my winery. I am proud of my winery's many sustainable farming methods. For example, in our effort not to contribute to erosion and the release of

[1] *About Us*, Berryville Vineyards, http://buunyd.wixsite.com/berryvillevineyards (last visited July 23, 2019).

carbon dioxide, we do not till at Berryville Vineyards. We mainly use organic fertilizer and no pre-emergent herbicides. Our winery also uses a number of sustainable practices, including not using plastic; never tilling our vineyard; using only geothermal heating and cooling for the winery; and having a wood stove for heat in the tasting room.[2]

7. Farming and operating a sustainable winery is extremely challenging, especially since my vineyard is near farmlands growing grain crops like soybean, corn, and wheat, and using farming methods that rely heavily on herbicides. In fact, growing up and seeing the amount of chemical inputs in grain farming was a significant factor in my decision to grow grapes, instead of grain, because I did not see it as a sustainable way of farming. Throughout the years, I was able to negotiate and convince my father, who farms grain crops in some of the plots of land surrounding my vineyard, not to use herbicides that are particularly harmful to my grapes and fruits. However, I have no control over the use of such herbicides by my other neighbors.

8. I am aware that in 2016, the U.S. Environmental Protection Agency (EPA) approved the new uses of dicamba on genetically engineered cotton and soybean in thirty-four states, including Illinois. I am also aware that, despite

[2] *Going Green*, Berryville Vineyards, http://buunyd.wixsite.com/berryvillevineyards/going-green (last visited July 23, 2019).

reports of dicamba drift damage, EPA recently approved the continuation of the pesticide registration.

9. I am aware that dicamba is drift-prone and volatile, and can only be sprayed during certain times of the growing season, dependent on the climate. I am also aware that grapes are extremely sensitive to dicamba. Because of where my vineyard is located I have experienced damage to my grapevines from dicamba-use by neighboring farms.

10. EPA's decision to authorize dicamba use on dicamba-resistant soybean injures me economically. When I first began farming grapes, Roundup Ready crops dominated the agricultural landscape near me, and I had little to no problems with my crops. As the weeds became resistant to glyphosate, the active ingredient in Roundup, chemical representatives started telling farmers to apply dicamba. While I have tried over the years to protect my grapevines against dicamba drift by placing buffer strips around my fields, no matter what I do, I always end up with some percentage of my grapevines damaged by drift. Over the years, I have learned to identify the damage caused by dicamba to my grapevines and other plants.

11. I know that farmers in the area have switched over to planting dicamba-resistant soybean, and applying dicamba on their soybean crops later in the year, because I noticed them spraying later in the season when their soybean

crops are beginning to bloom, which they could not do with conventional soybean varieties without causing damage to their soybean crop.

12. The damage to my grapevines from dicamba use on dicamba-resistant soybean have occurred despite my efforts to utilize buffer zones around my vineyards. Additionally, many of my plots are surrounded by my father's soybean fields, who has stopped using dicamba on his soybean crops later in the season out of consideration for my vineyards. Nonetheless, my grapevines still get exposed to dicamba drift from other nearby farms.

13. The damage to my grapevines from dicamba has been the worst this year, which was a particularly rainy and wet spring in Illinois. The wet season delayed the planting of soybeans and limited the number of days farmers near me could spray their fields. As a result, farmers in the area were forced to delay planting of their soybean crops this year, and were limited to spray on the same days in late spring and early summer, thus concentrating the amount of dicamba in the air on those days.

14. Around the middle of June of this summer, when I noticed soybean farmers near me out in the fields spraying their soybean crops, I noticed that my entire vineyard got hit by dicamba and many of my grapevines got stunted due to exposure to dicamba. My ten acres of grapes are spread out in one to two acre patches on the crest of hills. The Traminette variety of wine grape exhibited some

of the greatest symptoms from exposure to dicamba. The stunted grapevines did not start growing again until one month later. This is very problematic as I started putting on bird netting at the end of July to protect my grapes from loss to birds. Ideally, growth would have started to slow by now as all the energy is directed toward ripening the fruit. Instead, the grapevines are taking off with a new flush of growth and are growing through the bird netting, making it very difficult and labor intensive to remove the bird netting in a month. When removed, many of the leaves and shoots get knocked off, giving the plant less strength going into winter and increasing "winter kill."

15. The stunted grapevines and delayed growth due to dicamba damage hurt me economically, and cost me a lot of my time. Because I typically work with seasonal workers from the area, whose job during the season is to train the grapevines into forms that are ideal for winemaking. The stunted grapevines meant that I did not have work for my seasonal workers, and I lost money in labor costs because I could not utilize my team as efficiently. I also incurred additional time and energy trying to reorganize the team, and lost some workers who left because I was unable to give them timely work.

16. The stunted grapevines also cost my time and money later in the season. Even when the grapevines began growing again, the stunted shoots put their new growth on the laterals, which is undesirable from a winemaking

perspective, since the new lateral growth shades the fruit. As a result, I incurred extra labor costs later in the season to remove the lateral growth.

17. EPA's approval of dicamba use on dicamba-resistant soybean later in the season also injures my vocation. As someone who tries to grow grapes sustainably, I try to utilize as much natural forms of weed control as possible. One of the ways I control weeds in my vineyards is by encouraging grapevines to grow vertically, forming a canopy to suppress weed growth. The stunted grapevines never reached that growth, which cost me labor expense and time to remove those weeds later in the season.

18. As a result of EPA's approval, my vineyard will continue to be threatened by exposure from dicamba use on nearby farms. The dicamba damage causes stunted growth in my grape plants for extended periods of time, disrupting my growing schedule significantly. I am unable to anticipate my labor needs and, therefore, unable to schedule workers because of the uncertainty of the future level of dicamba damage. This injures me economically and vocationally, as it introduces significant economic uncertainties into my ability to plan as a farmer.

19. EPA's approval of dicamba has also injured my ability to meet consumer demand and grow the wine grapes that they desire. Because of EPA's approval of dicamba to be sprayed for a longer period of time during the growing season, and due to my past experience with unavoidable dicamba drift damaging

my wine grapes, I have been forced to remove grapevines and decrease the variety of grape species I am able to plant. I have been operating on a handicapped basis since the implementation of dicamba use and have been unable to grow certain grape varieties, some of which are the most popular amongst my customers, because of their known susceptibility to dicamba damage.

20. Over the years, I have filed multiple complaints with the Illinois Department of Agriculture to report such drift damage, but generally the Department's investigation comes back with an inconclusive finding of where the dicamba drift came from. On one occasion, I felt threatened by a field inspector, who insinuated that voicing my concerns could pose a threat to my farm. This has not stopped me from continuing to voice my concerns, as I plan to file a complaint with the Illinois Department of Agriculture again this year.

21. As a direct result of EPA's approval of the expansion of dicamba usage, I will continue to be limited in my ability to grow different wine grapes, and suffer economic and labor costs due to damage caused to my grapevines from dicamba. As long as dicamba use on dicamba-resistant soybean later in the season continues, I will not be able to maximize my acreage for wine grape production, and will continue to plant on reduced acreage, rather than investing in replanting or planting out new fields and new grape varieties, to reduce the cost of planting and growing grapevines that will only be damaged by dicamba drift.

22. My ability to expand my vineyard and grow my business has been injured by EPA's decision to approve dicamba. It is difficult to make "best practice" decisions on where and how to plant my grapevines when I know they will be affected by volatile chemicals like dicamba. I am unable to invest further in my business's growth due to the realistic threat of dicamba drift wiping out my vineyard.

23. EPA's approval of dicamba also injures my vocation by limiting my ability to grow wine grapes and produce wine sustainably. I chose to farm wine grapes sustainably because I believe in a different way of life than being beholden to farming with pesticides. Yet as long as dicamba use later in the season continues, I am beholden to a future where I have to plan my farming practices and business around the risk of dicamba drift damage.

24. The damage caused by dicamba drift from other farms in the surrounding area has also hurt my personal relationships with my neighbors and my local reputation. Many of my neighbors no longer want to connect with me because they see me as a troublemaker who might report them to the Illinois State Department of Agriculture. Neighboring farms see drift damage to my grapevines from spraying dicamba on their soybean on their crops as my problem for planting a vineyard in that area, because they were farming first. These farmers do not see it as their responsibility to keep their chemicals to themselves, and certain farmers

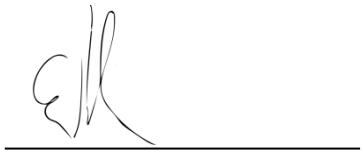
whom I have never met blame me for lawsuits I have nothing to do with, damaging my reputation amongst the farming community. To me, as the pesticide makers also now are often the companies producing the herbicide-resistant seeds, farming around me seems to require more chemicals, not less. My concern is that the policies surrounding pesticides will continue to allow more spraying of dicamba, increasing the risk of dicamba-related damage to farmers like myself.

25. Managing my business and protecting it from potential damage from pesticide use like dicamba has become the biggest stressor in my life. I could have taken over my father's farm and farmed corn, soybean, and other grains using pesticides, but I chose not to do so because I did not see it as a sustainable way of farming. Although I chose to farm grapes, instead of grain, now, as a result of the availability of pesticides such as dicamba and their companion genetically engineered corn and soybean, grain farming still continues to control and affect how I farm my vineyard.

26. In sum, EPA's approval of dicamba use on dicamba-resistant soybean has injured, and will continue to injure, my economic and social interests. Without a court finding that EPA violated its duties in expanding dicamba use, the growth of my winery and my relationships with my neighbors will continue to be adversely affected by EPA's registration decision.

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

Executed on this 7th day of August 2019, in Claremont, Illinois.



ERIC POOL

No. 19-70115

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 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 Environmental Protection Agency's (EPA) registration decision for 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 the lead author 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, but the Service has not yet finalized the cuckoo's critical habitat designation.

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.

11. On the Lower Colorado River in La Paz County, Arizona, I have seen yellow-billed cuckoos within the critical habitat area proposed for them by the U.S. Fish and Wildlife Service between the Cibola National Wildlife Refuge and the unincorporated town of Blue Water to the north. There are substantial cotton fields adjacent to the river and proposed yellow-billed cuckoo critical habitat,

especially on the west side of the river in the southern segment and the east side in the northern segment. On the Lower Gila River in Yuma County, Arizona, I have seen yellow-billed cuckoos within the critical habitat area proposed for them by the U.S. Fish and Wildlife Service between the town of Ligurta and the Quigley Wildlife Management Area to the east. There are substantial cotton fields adjacent to the river and proposed yellow-billed cuckoo critical habitat, especially on the south side of the river in the western segment and the north side in the eastern segment. On the Gila River in Maricopa County, Arizona, I have seen yellow-billed cuckoos within the critical habitat area proposed for them by the U.S. Fish and Wildlife Service between the river's confluences with the Agua Fria and Hassayampa rivers. There are substantial cotton fields adjacent to the river and proposed yellow-billed cuckoo critical habitat on the north side of the Gila River in this area.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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 12th day of July, 2019 at Portland, Oregon.

KIERÁN SUCKLING

No. 19-70115

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 JOHN ZUHLKE

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Counsel for Petitioners

I, JOHN ZUHLKE, 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 Environmental Protection Agency's (EPA) registration decision for 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 am an organic farmer and owner of Little Shire Farm.

3. I am a member of Dakota Rural Action, a regional farming membership organization committed to supporting local food and farmers with an activist approach to changing policy. Dakota Rural Action is a member organization of Petitioner National Family Farm Coalition (NFFC). As a member organization, Dakota Rural Action participates directly in NFFC's executive committee, and helps direct NFFC's agenda and priority.

4. I joined Dakota Rural Action as a member in 2010 to be part of a larger community of likeminded farmers and advocates working towards sustainable agriculture. I have previously served as the President of the Black Hills chapter.

5. I am a resident of Aurora, South Dakota, with a population of approximately 500 residents. Most of the residents of Aurora work with the

agriculture sector, many of whom are farmers of soybeans. Aurora is east of Brookings, South Dakota, where South Dakota State University is located. Recent growth in Brookings has caused the sudden expansion of Aurora's housing development.

6. I have spent more than a decade in rural economic development and urban planning. I decided to move away from the politics of urban planning to work in sustainable agriculture and local foods. I have studied agroecology and agronomy at the University of Nebraska. I began farming with a Community Supported Agriculture (CSA) operation in Lincoln, Nebraska and eventually decided to open my own farm in South Dakota.

7. I founded Little Shire Farm in 2017. Our focus is on providing locally grown food to our community. Little Shire Farm is a CSA, and bookkeeping operation. We sell our produce and products in farmers markets, grocery stores, and restaurants. I have five acres on the Little Shire Farm property and two additional acres south of Brookings, in an agricultural area surrounded by wetlands and pastures. We grow over 500 varieties of vegetables and fruit which we direct market to consumers and wholesale restaurants. We support producer and consumer education about sustainable practices. We are proud of our sustainable approach to agriculture and our commitment to farming a diverse production of crops. We consistently choose sustainable approaches to agriculture over short-

sighted, potentially more lucrative methods, such as using synthetic fertilizers or sprays.

8. Farming and operating an organic farm is extremely challenging in South Dakota because the majority of the surrounding farmlands grow herbicide resistant crops and rely heavily on herbicides, such as over-the-top dicamba, to produce higher yield. As an organic farm, we do not use herbicides. However, we have no control over the use of herbicides like dicamba by our neighboring farmers. We continue to be impacted by dicamba drift since opening Little Shire Farm in 2017.

9. I am aware that the U.S. Environmental Protection Agency has approved the use of over-the-top dicamba on genetically engineered, dicamba-resistant soybeans and cotton crops. I am also aware that as a result of EPA's approval, farmers in my area can spray dicamba on their dicamba-resistant soybean crops later in the growing season.

10. I am aware that dicamba is drift-prone and volatile and can only be sprayed during certain times of the growing season, dependent on the climate. Because of where my farm is located, I have experienced damage to my crops from dicamba use by neighboring farms. Because I opened Little Shire Farm in 2017, the year of EPA's approval of dicamba, we have experienced significant damage from dicamba drift every year of production, including 2018 and 2019.

11. I have come to recognize damage from dicamba on my plants, and am able to tell it apart from other types of pesticide damage. The signs of dicamba exposure manifest distinctly and rapidly once I notice them. As soon as my crops begin to show signs of damage, the necrosis inhibits normal progress, and plants begin to grow abnormally. Eventually the crops are no longer able to resist the herbicide and they die, do not fruit properly, or form deformed fruit.

12. The plants we grow on Little Shire Farm, which include many varieties of tomatoes, peppers, green beans, and summer squash, experience damage distinct to dicamba, while the plants grown on our two acres south of Brookings experience no such damage because they are not surrounded by any other conventional agricultural operations. The dicamba-related damage has become obvious as the leaves of my plants begin to cuff, distort, and extra tails begin to grow off of them as the abnormal growth progresses. I documented the damage by taking pictures of the damaged plants, which are attached as Exhibits A, B, C, and E.

13. EPA's approval of over-the-top dicamba for use on dicamba-resistant crops injures me economically. In 2017, our first year of production, we anticipated a much higher yield because of how much money we had initially invested, a $14,000 investment, in opening up our farming operation. However, it was our lowest production year for Little Shire Farm because of yield loss from

dicamba-related damage in August. In 2018, we anticipated a yield of $60,000 to $80,000. However, because of dicamba damage, we only yielded $20,000 worth of crops, losing $40,000 to $80,000 worth of sales.

14. Tomatoes are our most susceptible crop to dicamba-related damage. This year, 2019, all of our tomato fruits were significantly affected by dicamba drift. Not only was our produce affected, but the trees on our property were also damaged by dicamba, manifesting abnormal growth spurts. A photograph of the dicamba damage to a maple tree on Little Shire Farm is attached to this declaration as Exhibit D.

15. I have filed an official complaint with the South Dakota Department of Agriculture every year that Little Shire Farm has been in operation. In 2018, I filed two reports. Field inspectors visited the farm and confirmed the significant levels of dicamba on our property.

16. I am aware that in 2017 a neighboring farmer to Little Shire Farm sprayed dicamba. After I began to notice abnormal growth on my crops, I confronted the neighboring farmer, who informed me that he had used dicamba resistant seeds and dicamba on his crops that year. The following year I spoke with the adjacent land owners regarding dicamba use but they assured me that they had not used dicamba on their crops. In both 2018 and 2019, none of the adjacent properties sprayed dicamba but our crops still tested positive with dicamba. During

2018 and 2019, it has been difficult to know where the dicamba drift comes from and how to protect the integrity of my crops. My buffer zones and windbreak crops prove unhelpful because I cannot pinpoint where the dicamba drift is coming from. There has been significant damage to them from the dicamba drift.

17. The damage caused by dicamba drift from other farms in the surrounding area has also hurt my personal relationship with my neighbors. I have a very contentious relationship with the neighboring farmer who sprayed dicamba in 2017. He has even threatened to take legal action if we step on his property. We participated in a Drift Watch campaign and put up a sign warning about dicamba drift. In response, several neighbors put up signs mocking the campaign.

18. In sum, EPA's approval of dicamba use has injured, and will continue to injure, my economic and social interests. We cannot continue to have a viable farm operation with such heavy losses. Without a court finding that EPA violated its duties in expanding dicamba use, the well-being of my farm and my personal relationships with my neighbors will continue to be adversely affected by the use of dicamba.

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

Executed on this 9th day of August, 2019, in Aurora, South Dakota.

John Zuhlke
Owner, Little Shire Farm

Exhibit A

Exhibit B

Exhibit C

Exhibit D

Exhibit E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 19-70115

I am the attorney or self-represented party.

This brief contains 13,989 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- (•) complies with the word limit of Cir. R. 32-1.
- ( ) is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ( ) is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ( ) is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ( ) complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ( ) it is a joint brief submitted by separately represented parties;
  - ( ) a party or parties are filing a single brief in response to multiple briefs; or
  - ( ) a party or parties are filing a single brief in response to a longer joint brief.
- ( ) complies with the length limit designated by court order dated _____.
- ( ) is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/George A. Kimbrell **Date** Aug 13, 2019

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 15. Certificate of Service for Electronic Filing

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9th Cir. Case Number(s) 19-70115

I hereby certify that I electronically filed the foregoing/attached document(s) on this date with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate Electronic Filing system.

Service on Case Participants Who Are Registered for Electronic Filing:

☐ I certify that I served the foregoing/attached document(s) via email to all registered case participants on this date because it is a sealed filing or is submitted as an original petition or other original proceeding and therefore cannot be served via the Appellate Electronic Filing system.

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☐ I certify that I served the foregoing/attached document(s) on this date by hand delivery, mail, third party commercial carrier for delivery within 3 calendar days, or, having obtained prior consent, by email to the following unregistered case participants *(list each name and mailing/email address)*:

Description of Document(s) *(required for all documents)*:

Petitioners' Opening Brief (Redacted)

Signature s/ George A. Kimbrell **Date** Aug 13, 2019

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