Case Nos. 20-70787, 20-70801

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, ORGANIZACIÓN EN CALIFORNIA DE LÍDERES CAMPESINAS, FARMWORKER ASSOCIATION OF FLORIDA, BEYOND PESTICIDES, AND CENTER FOR FOOD SAFETY,

Petitioners,

v.

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

Respondents,

and

NATIONAL ASSOCIATION OF WHEAT GROWERS, *et al.*,

Respondent-Intervenors.

NATURAL RESOURCES DEFENSE COUNCIL, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,
NATIONAL ASSOCIATION OF WHEAT GROWERS, et al.,
Respondent-Intervenors.

On Petition for Review of an Order of the United States Environmental Protection Agency

---

PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

CENTER FOR FOOD SAFETY
George A. Kimbrell
Amy van Saun
Ryan D. Talbott
2009 NE Alberta St., Suite 207
Portland, OR 97211
T: (971) 271-7372
gkimbrell@centerforfoodsafety.org
avansaun@centerforfoodsafety.org
rtalbott@centerforfoodsafety.org
Counsel for Petitioners

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Page(s)

Federal Cases Cont'd

Page(s)

Federal Cases Cont'd

State Cases

Federal Statutes

Rules

Regulations

Page(s)

Regulations Cont'd

Other Authorities

Page(s)

Other Authorities Cont'd

Page(s)

Other Authorities Cont'd

Page(s)

Other Authorities Cont'd

GLOSSARY OF ACRONYMS AND TERMS

APA	Administrative Procedure Act
BE	Biological Evaluation
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
IARC	International Agency for Research on Cancer
NMFS	National Marine Fisheries Service
ORD	Office of Research and Development
SAP	Scientific Advisory Panel
USDA	U.S. Department of Agriculture

INTRODUCTION

Glyphosate is the most widely-used pesticide[1] in the country, indeed, likely in human history. For decades, Intervenor Monsanto—maker of glyphosate-containing "Roundup" pesticides—assured customers that glyphosate was safe. But significant evidence emerged showing serious health effects, including world health experts agreeing that glyphosate is probably carcinogenic. Congress requires the Environmental Protection Agency (EPA) to reassess the safety of pesticides every fifteen years under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration review provisions. Given the exponential increase in glyphosate use since its last registration, careful analysis of glyphosate's safety to people who use it and the environment is long overdue. Rather than rigorously assess the registration based on current science, EPA rubber-stamped Monsanto's assurance of safety, contrary to its statutory duties.

Petitioners' members include the people who everyday work to bring food to America's tables. They are the frontline of exposure and

[1] Pesticides used to kill weeds are known as herbicides, a subset of the broader pesticide category.

possible health effects from glyphosate. EPA failed these essential workers by concluding there are no health risks without even assessing workers' exposure to glyphosate and its formulations. When absorbed through the skin, glyphosate enters the bloodstream to cause further harms, such as increasing cancer risk.

The purpose of Congress's command to review pesticide registrations every fifteen years is to ensure EPA uses the latest science and data to assess whether that pesticide still meets FIFRA's safety standard. Over time science advances, more data is collected, and latent harms are revealed. But here, EPA completely fails to fulfill FIFRA's command to use the most current information, or to even assess at all, various vital aspects of glyphosate's health and environmental impacts.

To ensure that glyphosate does not cause "unreasonable adverse effects" to people or the environment, EPA weighs the costs of a pesticide against its benefits. Here, EPA's cost-benefit analysis consists of a single sentence, where EPA completely fails to weigh the substantial costs of registration: among them, costs to farmers from the epidemic of glyphosate-resistant weeds and costs to wildlife exposed to spraying, especially crucial pollinators and iconic Monarchs.

EPA premises its conclusion that the registration would not have unreasonable adverse effects on three vague and ineffective label amendments, forms of mitigation against harm. Yet EPA fails to provide any evidence, let alone substantial evidence, in support of these measures' efficacy, to show how and why they would reduce the known risks below the FIFRA safety standard.

Finally, in addition to meeting the FIFRA safety standard, the Endangered Species Act (ESA) requires that EPA ensure its pesticide registrations will not jeopardize the continued existence of protected species. Agencies accomplish this through the Section 7 consultation process with the expert wildlife agencies, called by this Court the heart of the statute. The ESA's overarching directive is that agencies undertake this review at the earliest possible time. Here, EPA knows with certainty that glyphosate will likely adversely affect no less than 1,676 species of birds, mammals, fish, plants, amphibians, insects, and more. Yet EPA still issued this registration without undertaking the necessary consultation, in flagrant violation of the ESA.

EPA's fatally flawed decision should therefore be vacated.

JURISDICTIONAL STATEMENT

This petition presents for review the January 22, 2020 decision by EPA to issue the "interim" registration review decision for the pesticide glyphosate. Rural Coalition Excerpts of Record (RC_ER) Vol.1-RC_ER-0003-38 ("Glyphosate—Interim Registration Review Decision Case Number 0178").

EPA's "interim" registration is a final agency action subject to judicial review because (1) it marks the consummation of EPA's decisionmaking process on the human health and ecological risk assessments and mitigation measures, and (2) it determined rights or obligations from which legal consequences flow, namely allowing the continued registration of glyphosate and its hundreds of formulations. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *United Farmworkers of America v. U.S. Envtl. Prot. Agency*, 2005 WL 7140333, *9 (W.D. Wash., Feb. 14, 2005).

This Court has jurisdiction under 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).[2] EPA's January 22, 2020 decision is a final determination in EPA's review of the glyphosate registration, a process that began in 2009.[3] Petitioners timely filed. 20-70801, ECF 1-5; 7 U.S.C. § 136n(b), 40 C.F.R § 23.6.

ISSUES PRESENTED

1. Whether EPA violated FIFRA by authorizing the registration (1) without the data required to fully assess glyphosate's effects to farmworkers' and other users' health and the environment, (2) without weighing the true costs, and (3) without supporting its decision to register glyphosate with minimal label changes with substantial evidence; and

2. Whether EPA violated the ESA by failing to consult the expert wildlife agencies concerning glyphosate'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.

---

[2] *Ctr. for Biological Diversity v. Envtl. Prot. Agency,* 847 F.3d 1075, 1089-90 (9th Cir. 2017).

[3] Petitioners submitted comments to the agency in 2009, 2016, 2018, and 2019. 7-RC_ER-1416; 5-RC_ER-0876; 3-RC_ER-0473; 2-RC_ER-0067. Petitioners have standing. *Friends of Earth, Inc. v. Laidlaw Envtl. 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, health, vocational, agricultural, recreational, aesthetic, and economic interests. *See* Addendum of Declarations, A106-209.

STATEMENT OF THE CASE

This case is about the most widely-used pesticide in the country: glyphosate, the active ingredient in hundreds of products, including Monsanto's Roundup brands. 1-RC_ER-0005-6.[4] EPA issued a registration decision for glyphosate early in 2020, allowing hundreds of millions of pounds of glyphosate to be sprayed on hundreds of millions of acres throughout the United States. 1-RC_ER-0011.

Glyphosate use has increased exponentially since the advent of Monsanto's genetically engineered "Roundup Ready" crops that resist glyphosate in the 1990s. Today, 280 million pounds of glyphosate are sprayed annually on 285 million acres of U.S. farmland.[5] For scale, that

---

[4] The registration covers glyphosate acid (PC Code 417300) and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, and 103613). ER0003. Petitioners use glyphosate for simplicity.

[5] EPA recently updated these figures. *See* EPA, *Draft National Level Listed Species Biological Evaluation for Glyphosate*, 1-4, https://www.epa.gov/endangered-species/draft-national-level-listed-species-biological-evaluation-glyphosate#executive-summary (hereinafter "BE"). Petitioners request judicial notice of this and other extra-record information cited throughout this brief. Fed. R. of Evid. 201(c)(2); 201(b) (because this information is "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," this Court can properly take notice). Government publications are frequently given judicial notice. *See, e.g.*, *Corrie v. Caterpillar*, 503 F.3d 974, 978 n.2 (9th Cir. 2007).

is nearly the size of three Californias. This is four times the amount of the second-leading conventional pesticide, atrazine. 4-RC_ER-0843. Over 21 million more pounds are sprayed by homeowners, on roadways, in forestry, and for other non-agricultural uses. BE at 1-4.

Despite Monsanto's assurance that glyphosate is safe, science emerged over the years showing that glyphosate may cause cancer. Currently in the courts are thousands of cases brought by over 100,000 plaintiffs alleging that their own or their loved ones' cancer developed after exposure to Monsanto's Roundup. This may only be the tip of the iceberg,[6] as more evidence emerges regarding the number of people whose risk of cancer was and is being increased by glyphosate exposure.

But even though EPA's registration review process began over a decade ago, in this decision EPA still fails to analyze glyphosate's health impacts to workers who are frequently exposed to glyphosate. This includes farmers and farmworkers like Petitioners' members, who

[6] While homeowners and groundskeepers brought early lawsuits, the vast majority of glyphosate users are farmers and farmworkers. *See* Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits,* NY TIMES (June 24, 2020), https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html#:~:text=Bayer%20faced%20tens%20of%20thousands,set%20aside%20for%20future%20cases.

are on the frontlines of nearly every health and environmental crisis, from the COVID-19 pandemic to climate change, and are particularly at risk of health impacts from glyphosate spraying at work.

And despite those many decades and billions of pounds of glyphosate sprayed on farms, public lands, and homes, EPA registered glyphosate without consulting with the expert wildlife agencies to ensure glyphosate is not jeopardizing the continued existence of protected species. The monumental scale of this failure is now evident, because EPA recently made public a draft evaluation that finds *100%* of the 1,795 endangered and threatened species exposed to glyphosate may be affected.[7] And of those species, 93% will likely experience adverse effects, meaning they may be harmed, perhaps enough to jeopardize their very existence. Yet this evaluation and subsequent expert consultation is required before an agency action is taken, not after the fact.

I. BACKGROUND OF THE GLYPHOSATE REGISTRATION.

EPA first registered the plant-killing pesticide glyphosate in 1974. 2-RC_ER-0297. For two decades, glyphosate spraying in farming was

[7] *Supra* n.5.

limited because it kills crops and other desirable plants along with weeds. Thus, glyphosate could only be sprayed to kill weeds before crops like corn sprouted ("preemergence"), shortly before or after harvest, or between rows in orchards. 5-RC_ER-0924, 933.

However, following EPA's reregistration of glyphosate in 1993, 1-RC_ER-0006, Monsanto created a significant new expansion: spraying over the top of commodity crops that Monsanto genetically engineered to be resistant to glyphosate. Glyphosate resistance enabled what was previously impossible: these "Roundup Ready" crops are sprayed directly, post-emergence, one to three times throughout the growing season. 5-RC_ER-0933.

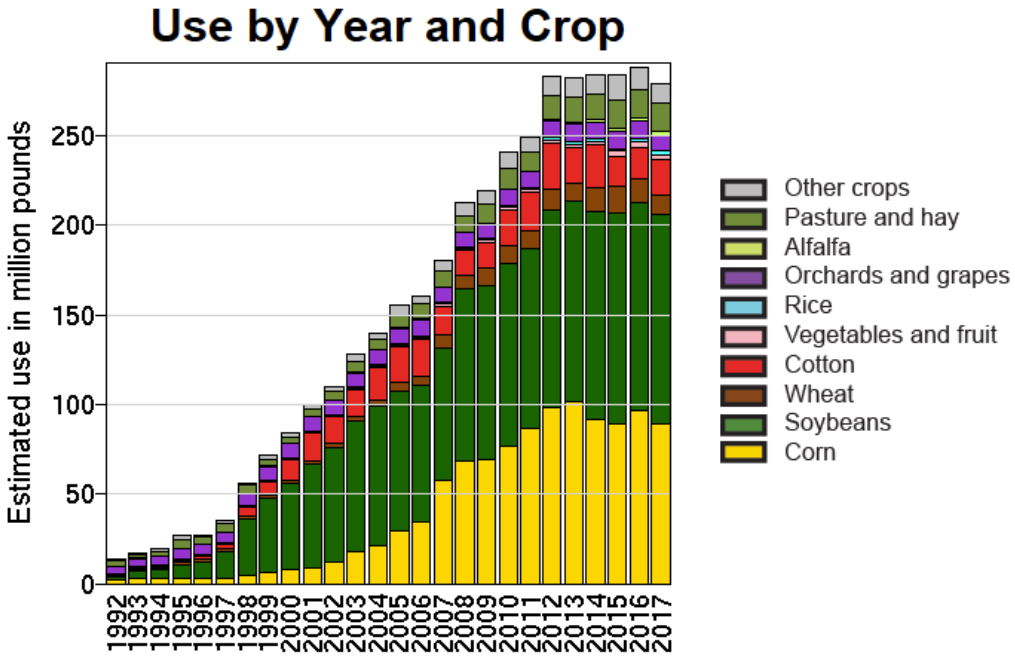
Near universal adoption of glyphosate-resistant soybeans, cotton, and corn since their introduction drove a massive increase in agricultural use of glyphosate, from less than 8 million pounds in 1990 to 280 million pounds today. 5-RC_ER-0928; 2-RC_ER-0267; 2-RC_ER-0074.[8] Home and other non-agricultural uses account for an additional 21-24 million pounds per year. 2-RC_ER-0282.[9] This U.S. Geological

[8] BE at 1-4.

[9] *Id.*

Survey graph shows the stark increase caused by introduction of genetically engineered, glyphosate-resistant crops:

Figure 1: Estimated Use of Glyphosate by Year and Crop (in million pounds).[10]



[10] USGS, *Pesticide National Synthesis Project—Estimated Annual Agricultural Pesticide Use Maps*, https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2017&map=GLYPHOSATE&hilo=L.

Health Impacts

Such intensive glyphosate use causes numerous harms. Regarding human health, EPA itself has found glyphosate to be a liver and kidney toxin, as well as a possible carcinogen. 3-RC_ER-0525; 2-RC_ER-0078-80; 3-RC_ER-0359-61; 2-RC_ER-0150-189; 6-RC_ER-1208-21; 11-RC_ER-2410-23. The World Health Organization's cancer experts classify glyphosate as "probably carcinogenic," and it is associated with increased risk of the cancer non-Hodgkin lymphoma in the pesticide's users. 5-RC_ER-1100-01; 3-RC_ER-336-58.

Currently, there are thousands of lawsuits against Monsanto/Bayer, by more than 100,000 plaintiffs alleging cancer from glyphosate exposure.[11] Monsanto has lost all three bellwether trials,[12] including one on appeal, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th

---

[11] U.S. Right to Know, *Monsanto Roundup & Dicabma Trial Tracker: Bayer backs away from plan to contain future Roundup cancer claims* (July 8, 2020), https://usrtk.org/monsanto-roundup-trial-tracker-index/#:~:text=More%20than%20100%2C000%20people%20in,covered%20up%20the%20cancer%20risks.

[12] *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Super. Ct. 2018); *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019).

Cir.) (Oral Argument heard Oct. 23, 2020). These cases involve people who used glyphosate at home or at work, with each plaintiff later developing non-Hodgkin lymphoma. Following extensive jury trials, these plaintiffs were awarded over $2 billion in compensatory and punitive damages because glyphosate was a "substantial factor" in causing their cancers and Monsanto failed to warn that its glyphosate-based pesticides could cause cancer.

To settle the remaining non-Hodgkin lymphoma cases, Bayer has agreed to a massive $10 billion settlement, one of the largest settlements ever in U.S. civil litigation.[13] The settlement does not cover at least 30,000 claims from plaintiffs who did not join the settlement. Monsanto/Bayer has not agreed to include a warning about increased risk of cancer on any glyphosate product labels. *Id.*

[13] Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits,* NY TIMES (June 24, 2020), https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html.

Environmental Impacts

Glyphosate is sprayed on 285 million acres of farmland annually (plus 21 million pounds on lawns, parks, schoolgrounds, forests, and roadways), with massive impacts to plants, animals, and their habitats. Glyphosate is ubiquitous in water bodies, the atmosphere, and in rainfall. 4-RC_ER-0812-21; 8-RC_ER-1669-97; 6-RC_ER-1382. Pollinators, frogs, and numerous other organisms are exposed, their habitats overlapping with spraying, drift, and runoff. 3-RC_ER-0504-5; 2-RC_ER-0100-101. Glyphosate formulations are extremely toxic to aquatic-stage amphibians, and are implicated as a factor in their world-wide decline. 2-RC_ER-0100-101. Glyphosate spraying may also reduce soil health by harming microbes that play critical roles in plant health and disease control, effects EPA did not assess. 7-RC_ER-1431-33. And rampant glyphosate drift has made it a leading culprit in damage to neighboring plants. 6-RC_ER-1355; 5-RC_ER-1049; 3-RC_ER-0557, 563; 9-RC_ER-2008-10, 2018-30; 8-RC_ER-1734.

Glyphosate is also a signficiant driver of the precipitous decline in Monarch butterflies, by nearly eliminating their host plant and food source, milkweed, from Midwestern crop fields. 6-RC_ER-1355; 5-

RC_ER-1049; 3-RC_ER-0555; 3-RC_ER-0483-85.[14] So much so that FWS recently determined that ESA listing and its associated protections for Monarchs is warranted. *Id.* The Monarchs' multigenerational migration path goes from Mexico through much of the Eastern half of the Continental U.S.:

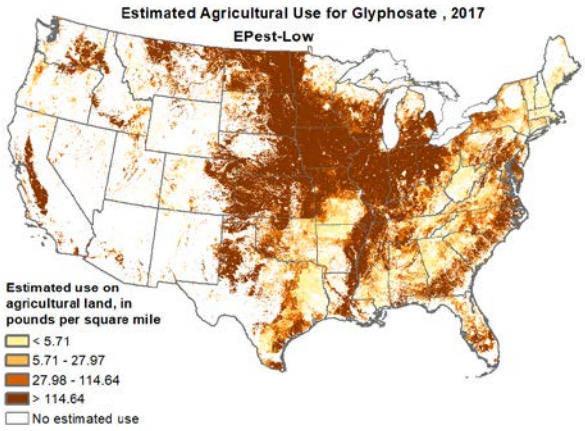
Figure 2: Monarchs Migratory Path[15]

[14] *See, e.g.*, FWS, Endangered and Threatened Wildlife and Plants; 90-Day Findings on Two Petitions, 79 Fed. Reg. 78775 (Dec. 31, 2014) (finding ESA protection for Monarchs "may be warranted" and initiating status review). On December 15, 2020 FWS announced that ESA protection for Monarchs is scientifically and legally warranted, but listing is precluded by other species at this time; listing for Monarchs is scheduled for 2024. FWS, *U.S. Fish and Wildlife Service Finds Endangered Species Listing for Monarch Butterfly Warranted but Precluded* (Dec. 15, 2020), https://fws.gov/news/ShowNews.cfm?ID=36817#:~:text=December%2015%2C%202020&text=After%20a%20thorough%20assessment%20of,on%20higher%2Dpriority%20listing%20actions.

[15] FWS, *Monarch Butterfly: Fall & Spring Migrations*, https://www.fws.gov/savethemonarch/pdfs/migration-map.pdf.

A map of glyphosate use shows the massive overlap with habitat:

Figure 3: Estimated Agricultural Use of Glyphosate in 2017 (in pounds per square mile).[16]



Superweeds

Exorbitant glyphosate use is also responsible for an epidemic of glyphosate-resistant "superweeds," which in just two decades have infested an astounding 120 million acres of cropland, causing severe harm to agriculture that agronomists have compared to the infamous boll weevil. 6-RC_ER-1354; 3-RC_ER-0509; 7-RC_ER-1447; 2-RC_ER-274. Just as excessive antibiotic use has fostered the evolution of

[16] USGS, *Pesticide National Synthesis Project – Estimated Annual Agricultural Pesticide Use Maps*, https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2017&map=GLYPHOSATE&hilo=L&disp=Glyphosate.

resistant bacteria, over-reliance on glyphosate—at Monsanto's direction and encouragement—created this crisis. 7-RC_ER-1456. Superweeds create substantial costs to farmers to control them, including increased expenditures on additional pesticides and increased use of soil-eroding tillage. 2-RC_ER-0104. This increase in tillage comes with a price tag of $450 million in damages to water quality and climate effects. 2-RC_ER-0041.

Monsanto recently introduced a new generation of crops genetically engineered for resistance to another pesticide, dicamba, as a "solution" to the glyphodate-resistant weed epidemic. 7-RC_ER-1102; 6-RC_ER-1367. In a repetition of the glyphosate debacle, dramatically increased spraying of dicamba to kill glyphosate-resistant weeds is already triggering a predicted rise in weeds resistant to both pesticides. *Id.*

Still worse, massive use of dicamba, a volatile chemical extremely prone to drift, has caused unprecedented drift damage to millions of acres of crops across the country. *See, e.g., Nat'l Family Farm Coal. (NFFC) v. U.S. Envtl. Prot. Agency*, 960 F.3d 1120 (9th Cir. 2020) (collecting extensive evidence of economic, environmental, and social

harms from dicamba use on resistant crops to control glyphosate-resistant weeds, including millions of acres of reported dicamba damage to crops and gardens, and a rupture in the social fabric of farming communities). EPA has done virtually nothing to rein in this toxic treadmill of pesticide use and weed resistance caused by glyphosate, despite being warned it would occur at the outset of the registration review process. 6-RC_ER-1371.

II. GLYPHOSATE REGISTRATION REVIEW PROCESS AND DECISION.

The Food Quality Protection Act of 1996 and the Pesticide Registration Improvement Renewal Act of 2007 amended FIFRA, requiring EPA to review all registered pesticide every 15 years and determine whether the pesticide still meets the FIFRA standard for registration: that the pesticide not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(a), (g); 40 C.F.R. § 155.40(a); 7-RC_ER-1480; 1-RC_ER-0005.

A. Registration Review

Registration review enables EPA to reassess a pesticide in light of evolving science, improved ability to detect risks, policy changes, and importantly here, changes in pesticide usage practices that have

occurred since the pesticide's last review. 7-RC_ER-1480. EPA must ensure that each pesticide's registration "is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment." 40 C.F.R. § 155.40(a)(1). Accordingly, EPA may identify and solicit data that it does not have, but would be useful to its review. *Id.* § 155.50(b)-(c). Among other things, EPA must "assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration." *Id.* § 155.53(a).

Registration review includes both the active ingredient and "all the products" containing it. *Id.* § 155.42(a). Here, that includes glyphosate and the 555 products containing glyphosate (like Roundup) that EPA identified. 2-RC_ER-0248. EPA also must assess the formulations' so-called "inert" ingredients, the different substances in a formulation that change how the pesticide product works. *Id.* § 155.53(a) (EPA must consider whether any new data is required for "an inert ingredient in the pesticide product...").

B. Glyphosate Registration Review

It has been nearly thirty years since EPA's last registration decision for glyphosate. 3-RC_ER-0516. In 2009, EPA began the glyphosate registration review process and anticipated it would take six years. 7-RC_ER-1485. Instead, it has taken nearly twice as long.

As part of its human health risk assessment, EPA says it evaluated the carcinogenic potential of glyphosate, concluding that glyphosate is "not likely to be carcinogenic to humans" in December 2017. 3-RC_ER-0499. This conclusion is at odds with EPA's own prior determination that glyphosate is a possible carcinogen, 11-RC_ER-2416, and with the World Heath Organization's International Agency for Research on Cancer's (IARC) 2015 determination that glyphosate is "probably carcinogenic to humans." 2-RC_ER-0217. IARC's conclusion is widely supported in the medical science community, as well as by the State of California, which listed glyphosate as a chemical known to cause cancer in July 2017. 3-RC_ER-0488. It also at odds with recent

court decisions that have found Monsanto's glyphosate-containing Roundup pesticides are a substantial factor in causing users' cancer.[17]

In February 2018, EPA opened its draft ecological and human health risk assessments to public comment. EPA received over 238,000 comments on the draft risk assessments. 2-RC_ER-0215. Astonishingly, EPA issued its public comment responses on the human health risk assessment *before the end of the comment period*, meaning the agency did not actually consider the comments submitted by Petitioner CFS or many thousands of others that filed their comments on the due date.[18] 83 Fed. Reg. 8476 (Feb. 27, 2018); 3-RC_ER-0498; 3_RC_ER-0473. Not surprisingly then, not one of the thousands of comments submitted on the drafts changed EPA's final risk assessments. 2-RC_ER-0215.

---

[17] *See Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Super. Ct. 2018); *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019).

[18] *See* NRDC Opening Br. at 56-58, *filed concurrently*, Case No. 20-70787 (EPA failure to respond to Petitioner comments regarding human health was unlawful).

C. "Interim" Registration and EPA Health and Environmental Conclusions

EPA's so-called "interim" registration actually finalized its human health and environmental risks assessments, its cost-benefit analysis, and its so-called mitigation measures. It did so while admitting several crucial sets of information were incomplete, including human health data, impacts on pollinators (bees), and effects to threatened and endangered species.

In 2019, EPA issued a "proposed interim" registration decision for glyphosate, stating that no further human health data (like on cancer) were required. 2-RC_ER-0229, 0235. EPA acknowledged that information on endocrine disruption, pollinator impacts, and endangered species was missing, but stated that it was not making any findings associated with these three missing categories of information. 2-RC_ER-0250.

In 2020, EPA issued the final "interim" registration challenged here. 1-RC_ER-0003. EPA did not say when reviews of glyphosate's impacts on pollinators (including bees), threatened and endangered species, and endocrine disruption would be completed. 1- RC_ER-0014, 22.

Human Health and Environmental Conclusions

EPA's decision "finalize[d]" the agency's proposed draft ecological and human health risk assessments, even though EPA still lacked critical human health and environmental reviews and determinations. 1- RC_ER-0022. Despite the medical science community's consensus on its health risks, 5-RC_ER-0916, the agency's own prior analysis, and several court decisions finding glyphosate pesticides were a substantial factor in causing cancers, EPA nonetheless claims that it "did not identify *any* human health risks from exposure to glyphosate." 1-RC_ER-0017 (emphasis added). EPA reached this conclusion after determining that "no occupational handler or occupational post-application assessments were required" for "the most commonly used herbicide in the United States." 3-RC_ER-0525; 2-RC_ER-0267. Thus, EPA came to its "no health risks" conclusion without conducting *any assessment* of the potential health effects to those most heavily exposed to glyphosate, including farmworkers, farmers, and other workers. 9-RC_ER-2048.

EPA admits that "risks to terrestrial invertebrates at higher application rates are uncertain" and that it "believes that additional

data may be necessary to fully evaluate risks to bees." 1-RC_ER-0014, 19. Rather than acquire these data, EPA finalized this registration with an ineffective warning on glyphosate labels that it hopes will "alert users" of impacts to non-target organisms, including pollinators. 1-RC_ER-0019. Similarly, although EPA admits there are "risk[s] to listed species whose range and/or critical habitat co-occur with the use of glyphosate," rather than complying with its ESA duty to consult the expert wildlife agencies before taking action, EPA relies instead on the same ineffective label warning that it "expect[s]" will "reduce the extent of environmental exposure" to listed species. 1-RC_ER-0022.

Cost-Benefit Analysis

While admitting ecological risks to mammals, birds, and plants, and the costs to farmers from glyphosate-resistant weeds, EPA's cost-benefit assessment consists of a one-sentence conclusion that "the benefits outweigh the potential ecological risks when glyphosate is used according to label directions." 1-RC_ER-0017.

Label Amendments

EPA's "interim" registration also finalizes its mitigation measures, supposedly reducing the harm from continued glyphosate spraying.

First, EPA included "information and recommendations" to slow the spread of superweeds, consisting of two older, non-binding guidance documents, which are not specific to glyphosate. 1-RC_ER-0026 (providing link to guidances without requiring any statements be added to pesticide labels). Second, EPA added a "non-target organism advisory," to "alert users" that glyphosate "is toxic to plants," and instructs users to follow the label instructions. 1-RC_ER-0019-20, Third, EPA added steps to "manage off-target spray drift," including maximum wind speeds for spraying and minimum droplet sizes. 1-RC_ER-0017-18. EPA offers no information as to how any of these three "mitigation" measures will reduce the known risks to plants, birds, fish, amphibians, or aquatic invertebrates.

Despite the absence of crucial data on human health (including worker exposure), pollinators, and endangered species, EPA finalized the glyphosate "interim" registration and its label amendments. 1-RC_ER-0005-6. "Interim" registration is not part of FIFRA, but a creation of EPA in its regulations. 40 C.F.R. § 155.56. EPA uses "interim" registrations to finalize parts of a registration, like mitigation measures, or identify needed data, like through a Data Call-In pursuant

to FIFRA Section 3(c)(2)(B). *Id.* Here, EPA "finalized" its mitigation measures, and the health and ecological risk assessments, announcing that "[it] concluded its regulatory review of glyphosate."[19] Whether called "interim" or not, this was a final registration that had to comply with the FIFRA safety standard of causing no unreasonable adverse effects on the environment. 7 U.S.C. § 136a. And it is final agency action under *Bennett v. Spear*, 520 U.S. 154 (1997) and the ESA. 16 U.S.C. § 1536(a)(2).

III. PROCEDURAL HISTORY

EPA issued a proposed decision in March 2019. 2-RC_ER-211. Petitioners submitted timely comments. 2-RC_ER-67. In their comments, Petitioners raised numerous significant issues concerning EPA's human health and ecological risk assessments, ESA compliance, and cancer assessment. In January 2020, EPA issued the registration decision. 1-RC_ER-0003. This challenge followed. Another group of petitioners also filed suit, *see Nat. Res. Defense Council, et al. v. U.S. Envtl. Prot. Agency*, No. 20-70787, and the Court consolidated the cases.

[19] *EPA Finalizes Glyphosate Mitigation* (Jan. 30, 2020), https://www.epa.gov/pesticides/epa-finalizes-glyphosate-mitigation.

SUMMARY OF ARGUMENT

The Court should grant the petition for review and vacate the registration for at least four reasons. First, EPA's registration failed to protect workers, including Petitioners' farmworker and farmer members, because EPA lacks substantial evidence to support its conclusion that there are no "occupational risks of concern" from glyphosate exposure, in violation of FIFRA. Second, EPA failed to consider and assess the true costs—economic, social, and environmental—of glyphosate, also in violation of FIFRA. Third, EPA failed to assess and support with substantial evidence the efficacy of its label mitigation measures on which its decision is based. And fourth, EPA violated the ESA by taking action without first completing Section 7 consultation, despite its knowledge that thousands of species may be affected, the vast majority of which will likely be adversely affected, requiring formal consultation and opinions by the expert wildlife agencies.

For any or all of these reasons, the Court should vacate the registration.

STANDARDS OF REVIEW

The Court may sustain EPA's glyphosate registration under FIFRA only if EPA's order is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). In reviewing for substantial evidence, the Court must consider the whole record and whether it "fairly detracts from its weight." *Universal Camera Corp. v. Nat'l Labor Relations Bd.,* 340 U.S. 474, 488 (1951). Judicial review must be "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal citations and quotations omitted).

The substantial evidence standard "affords an agency *less* deference than the arbitrary and capricious standard." *Pollinator Stewardship Council v. U.S. Envtl. Prot. Agency*, 806 F.3d 520, 533 (N.R. Smith, J., concurring) (citing *Universal Camera Corp.,* 340 U.S. at 477; *Union Oil Co. of Cal. v. Fed. Power Comm'n,* 542 F.2d 1036, 1040-41 (9th Cir. 1976)) (emphasis added). Therefore, if EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence. To avoid being arbitrary and capricious, EPA "must examine the relevant data and articulate a satisfactory explanation for its action

including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations and quotations omitted).

Under either standard, the Court's "review must not rubber-stamp . . . administrative decisions that [the court deems] inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1119 (9th Cir. 2004) (internal citations and quotations omitted). Any difference between these two standards is immaterial, however, because EPA's registration decision for glyphosate satisfies neither. If it finds EPA's actions violated FIFRA, this Court should set aside, or vacate, the registration. *Pollinator Stewardship,* 806 F.3d at 532-33.

EPA violated the ESA if its failure to consult the expert wildlife agencies in connection with its registration of glyphosate was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *see Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). The ESA requires that federal agencies consult the expert wildlife agencies before taking any action that "may affect" any protected species or critical habitat. 50 C.F.R. § 402.14(a); *see* 16 U.S.C.

§ 1536(a)(2). *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1020-21 (9th Cir. 2012) (en banc).

ARGUMENT

I. EPA VIOLATED FIFRA.

A. EPA Failed to Protect Workers and Lacks Substantial Evidence For Conclusion That There Are No "Occupational Risks of Concern."

First, EPA abysmally failed to protect farmworkers and other users when it concluded that there are no "occupational risks of concern" from glyphosate spraying. 1-RC_ER-0011. People who work around, handle, and apply pesticides like glyphosate are the most highly exposed, and therefore most at risk of suffering the negative health effects from these toxins. 2-RC_ER-0309-10. They are the proverbial canaries in the coal mine: through skin contact and other exposure, they are at greater risk of harm, such as cancer, than people whose primary exposure is dietary. *Id.*; 3-RC_ER-0424, 431-32.

Yet from the outset of registration review in 2009, EPA concluded it would not conduct an occupational risk assessment, and maintained this position throughout the review process. 7-RC_ER-1504. In EPA's view, glyphosate is not hazardous and thus will not harm workers no

matter how much they take in via skin contact or other means, so there is no need to assess exposure in order to quantify risk.

But EPA failed to consider signficiant evidence to the contrary, as explained in Petitioners' and others' comments. 2-RC_ER-0089-97; 3-RC_0448-65. Even after the World Health Organization's IARC classified glyphosate as "probably carcinogenic to humans" in 2015,[20] based in part on elevated incidence of cancer in *glyphosate applicators*, EPA doubled down in 2017, reiterating that it would not undertake a "quantitative exposure risk assessment" for those most highly exposed to glyphosate. 3-RC_ER-0518.

Accordingly in its 2020 registration decision, EPA concluded that there are no health risks from glyphosate, despite evidence of carcinogenicity and its failure to quantify occupational exposure. And EPA completely failed to assess any formulations of glyphosate, the real world products that users spray, which are known to increase injury. This failings are reversible error; EPA did not have substantial

[20] The IARC Working Group included scientists from the EPA, the U.S. Institute of Environmental Health Sciences, and the California EPA. 4-RC_ER-0687-89.

evidence for its conclusion that there are no occupational risks from glyphosate.

1. EPA Failed to Assess Skin Absorption of Glyphosate, the Main Way Workers Are Exposed.

EPA itself has explained that "[skin] absorption [of pesticides] is a significant factor in occupational or residential exposure risk assessments since these exposures occur most frequently via the dermal route." 9-RC_ER-2048. And yet from glyphosate's initial registration in 1974 to the present day, EPA has apparently never collected *even a single dermal absorption study* to determine how much glyphosate users absorb into their systems via skin contact. 3-RC_ER-0518, 25, 27, 43; 9-RC_ER-2055-68ER.

Unbelieveably, EPA's refusal to assess absorption of glyphosate via skin contact is based on a 21-day dermal toxicity study conducted on 20 rabbits in 1982. 3-RC_ER-0525, 27, 43; 10-RC_ER-2121. There are at least three major problems with EPA's reliance on this stale, Monsanto-sponsored study.

First, the EPA guideline for this type of study cautions that such studies are "not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life

shortening)."[21] It is unsurprising then that EPA further warns that "[e]xtrapolation from the results of this study to humans is valid *only to a limited degree*." *Id.* (emphasis added).

Whatever that "limited degree" is, EPA has far surpassed it, repeatedly pointing to this rabbit study decade after decade as its sole basis for not conducting a quantitative dermal exposure risk assessment for workers. 10-RC_ER-2121; 8-RC_ER-1715-16; 3-RC_ER-0525, 27, 43. Given that one of the hazards is cancer, and that this study was not capable of determining long-latency effects like those of cancer, EPA cannot rely on this study as substantial evidence for its conclusion that there are no occupational risks of concern. *Id.*

Second, the study is nearly 40 years old. The core point of registration review is to update "effects on human health" by using "current" science, to determine if the pesticide still meets FIFRA's safety standard. 40 C.F.R. § 155.40(a)(1). Indeed, Congress recognized the necessity in providing EPA with "sufficient authority to adjust pesticide evaluation and registration standards as scientific risk and

---

[21] EPA, *Series 870 - Health Effects Test Guidelines*, 1 (Aug. 1998), https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines.

benefit assessment technologies and methodologies advance." H.R. Rep. No. 104-669(I), at 37 (1996). Thus, the registration review amendments to FIFRA "establish[ed] ongoing scientific look-back procedures" to enable EPA to integrate "the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment" during registration review. *Id*. at 38. EPA's reliance on a 40-year-old rabbit study ignores this charge.

In other contexts, this Court has found agency reliance on outdated data is arbitrary and capricious. *Sierra Club v. U.S. Envtl. Prot. Agency*, 671 F.3d 955, 968 (9th Cir. 2012) (EPA approval of state implementation plan under Clean Air Act using old mobile source data, where newer data available, was arbitrary and capricious); *Lands Council v. Powell*, 379 F.3d 738, 748-49 (9th Cir. 2004) (data on habitat of trout "too outdated to carry the weight assigned to it" and rendered National Environmental Policy Act analysis inadequate); *see also Northern Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1086 (9th Cir. 2011) (similar).

The argument is even stronger here because, unlike in the National Environmental Policy Act context, EPA has broad authority to

require more data or studies as needed. 7 U.S.C. § 136a(c)(2)(B) (FIFRA gives EPA power to call in data from registrants); 40 C.F.R. § 155.40(c)(2) (EPA "will" require data via call in when it determines that new data or information are necessary for a pesticide's registration review). EPA has no administrative or resource-based excuse: it can and regularly does require the registrants to update studies.

For instance, here EPA should have required a "dermal penetration" study, for which EPA has specific test guidelines, to assess the critically important issue of how much glyphosate is taken up into a worker's system via dermal absorption of glyphosate. 9-RC_ER-2055-68. And there are many additional human health data needs. 2-RC_ER-0047-49; 2-RC_ER-0311-18. That Congress gave EPA this power underscores the need for EPA to use it rather than rely on stale data. 7 U.S.C. § 136a(c)(2)(B).

Finally, the rabbit study involved only the active ingredient (glyphosate) and not any of the hundreds of formulations of glyphosate, which contain numerous other ingredients that change how the pesticide works. 3-RC_ER-0542; 8-RC_ER-1730-33; 7-RC_ER-1392, 1399-1411. This flaw is explained further below. *Infra* 43.

This single study is nearly four decades old, assessed only the active ingredient and not the whole formulations, and cannot measure harms like cancer. Thus, EPA's reliance on it to claim no further data are needed does not comply with the FIFRA registration review requirements. There is no way EPA can know if glyphosate and its formulations continue to meet the FIFRA safety standard without updating its data. Because of EPA's failure to assess skin absorption of glyphosate, its conclusion that there are no occupational risks is not supported by substantial evidence.

2. EPA Ignored Increased Risk of Cancer to Workers from Glyphosate Exposure.

When workers are exposed to glyphosate, it can enter their bloodstream and cause harms, such as an increased risk of cancer. EPA's conclusion in the interim registration that there are no human health risks, and specifically no risk to people who work around glyphosate, is based in part on its erroneous conclusion that there is no risk of cancer from glyphosate. But given the significant evidence to the contrary, and dubious gaps in data, EPA's conclusion of no health risks is not supported by substantial evidence. *NFFC*, 960 F.3d at 1136-42 (EPA's failure to acknowledge some risks and understatement of other

risks demonstrated lack of substantial evidence for its registration of dicamba).

Scientists around the world, including many at EPA, regard glyphosate and its formulations as likely to be carcinogenic. Despite an earlier glyphosate classification as potentially carcinogenic, years of Monsanto interference and pressure led EPA's pesticide division to stick its head in the sand and accept Monsanto's erroneous conclusion to the contrary.[22] In this registration review, commenters pointed to ample evidence that glyphosate formulations cause cancer in farmers and other occupational users, but EPA failed to change or adequately explain its conclusion that there are no health risks to workers. Especially given that glyphosate is the most widely-used pesticide in the U.S., EPA cannot ignore this evidence under FIFRA.

In 2015, IARC determined that glyphosate is "probably carcinogenic to humans." 4-RC_ER-0797. This classification is just one

[22] In 1985, EPA classified glyphosate as a Category C oncogene, 11-RC_ER-2416, equivalent to today's "suggestive evidence of carcinogenic potential," Proposed Guidelines for Carcinogen Risk Assessment, 49 Fed. Reg. 46294, 46297 (Nov. 23, 1984), and the National Research Council estimated its carcinogenic risk to consumers from dietary exposure. 11-RC_ER-2387; *see also* 3-RC_ER-567; 5-RC_ER-0896-98.

step below known carcinogens (e.g., tobacco smoking) and is widely supported by medical scientists, as well as the State of California. 4-RC_ER-0714; 5-RC_ER-0918; 3-RC_ER-0566. IARC's conclusion has been cited in multiple court cases where plaintiffs who were occupational users of glyphosate—and thus regularly exposed through skin contact—were awarded hundreds of millions of dollars after being diagnosed with cancer linked to that exposure. *See supra* 11-12.

IARC is not the only body to rebut Monsanto's claim. Also in 2015, EPA's *own* scientists at the Office of Research and Development (ORD) reviewed the EPA pesticide division's draft cancer analysis finding glyphosate not likely to be carcinogenic. They noted that EPA failed to properly analyze data, deviated from the EPA's own Cancer Guidelines[23] by dismissing rodent tumors in in glyphosate feeding trials, and agreed with IARC that epidemiology studies showed a "credible" association between glyphosate exposure and non-Hodgkin lymphoma in farmers. 5-RC_ER-0939; 4-RC_ER-0735. Based on EPA's Cancer Guidelines, ORD scientists within EPA concluded that

[23] EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (Mar. 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

glyphosate should be classified as either "likely to be carcinogenic" or "suggestive evidence" of carcinogenicity, and that occupational user—like farmer—cancer data *alone* ruled out the pesticide division's "not likely to be carcinogenic" conclusion. 5-RC_ER-0941, 5-RC_ER-0944.

Further, in 2016 EPA convened a Scientific Advisory Panel (SAP) to review its glyphosate cancer evaluation according to EPA's Cancer Guidelines. 4-RC_ER-0586. Like the ORD, this Panel found EPA flouted its Cancer Guidelines in assessing glyphosate, including by downplaying evidence of cancer in both animal and human epidemiology studies in ways that were "flawed," "highly imbalanced," "contrary to," and "at odds" with its Guidelines, all of which "further reduces the credibility of the assessment." 4-RC_ER-0594, 596, 621, 624-28, 651, 657; 5-RC_ER-0884-87.

Despite its own scientists and expert advisory panel warning EPA that it's conclusion was unsupported and failed to comply with its own Cancer Guidelines, EPA nevertheless maintained its "not likely to be carcinogenic" determination and conclusion therefore that there are no human health risks to workers in this registration. 2-RC_ER-0217; 1-RC_ER-0009, 11. But like EPA's registration of sulfoxaflor in *Pollinator*

Stewardship Council, EPA cannot deviate from its own guidelines for pesticide risk assessment. 806 F.3d at 531-32 (EPA set its own level of concern and some pesticide residue measurements triggered testing threshold; EPA's failure to require those tests before registering the pesticide was not supported by substantial evidence).

Other evidence further exposes EPA's failure to consider this key aspect of human health risks from glyphosate. In 2019, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) published a "toxicological profile" of glyphosate, despite efforts by EPA's pesticide division and Monsanto to "kill" the report, which did delay it several years. 2-RC_ER-0049-0051; 2-RC_ER-0297-0318. This report found that the majority of epidemiological studies (which analyze the risk of illness in an exposed population) found glyphosate exposure increases the risk of non-Hodkin lymphoma. 2-RC_ER-0304-0307; *see also* 6-RC_ER-1235-45. Two subsequent meta-analyses confirmed that increased risk, one finding that more highly-exposed glyphosate users had a *41% elevated risk* of contracting non-Hodkin lymphoma. 3-RC_ER-0338-58; 2-RC_ER-0319-35.

EPA further failed to assess the cancer-causing potential of a contaminant found in glyphosate,[24] despite it being in a class of carcinogenic compounds. EPA's own testing policy requires carcinogenic testing if such contaminant levels exceed 1 part per million (ppm) in a pesticide product. 2-RC_ER-0092; 3-RC_ER-0505; *see also* 45 Fed. Reg. 42854 (June 25, 1980). Again, Petitioners raised this issue and EPA admitted that over 7% of glyphosate samples exceed the testing threshold, but dismissed the concern and collected no additional data. 2-RC_ER-0092; 3-RC_ER-0505. *Pollinator Stewardship Council*, 806 F.3d at 531-32.

Finally, as Petitioners commented to EPA, numerous studies that track glyphosate distribution in animal tissues demonstrate that it spreads to bone and bone marrow, one tissue where non-Hodgkin lymphoma begins. 2-RC_ER-0090-91; 11-RC_ER-2382; 8-RC_ER-1752-1759. Although these studies can "provide valuable insights into the likelihood of human cancer risk," and show how glyphosate may play a

[24] N-nitrosoglyphosate (or NNG), belonging to the N-nitrosamines.

role in triggering the cancer in farmers and farmworkers, EPA nowhere addresses this possibility in its risk assessment.[25]

EPA completely failed to analyze some aspects of glyphosate's cancer risk and understated others. EPA's failure to account for these gaps in data and evidence renders its conclusion of *no* risk to people who work around glyphosate arbitrary and capricious, and without substantial evidence. *See NFFC*, 960 F.3d at 1136-42; *State Farm*, 463 U.S. at 43 (agency action is arbitrary and capricious if EPA fails to consider an important aspect of the problem, or fails to articulate a satisfactory explanation for its action).

3. EPA Failed To Assess Health Threat From Glyphosate Formulations.

In the real world, pesticide products are not just the active ingredient, here "glyphosate technical." Rather, glyphosate formulations—like Roundup—are mixtures of glyphosate and various other ingredients that change the way the product works. 2-RC_ER-0077. By its plain language, FIFRA requires that EPA consider the whole pesticide and whether it will have unreasonable adverse impacts

[25] *Supra* n. 23 at 2-25.

when used in accordance with widespread and commonly recognized practice. 7 U.S.C. § 136a(c)(5)(D). FIFRA's definition of "pesticide" is "any substance or *mixture* of substances intended for preventing, destroying, repelling, or mitigating any pest," and plainly does not refer exclusively active ingredients. *Id.* § 136(u) (emphasis added). Thus, EPA's duty in registration review extends not just to the active ingredient *alone*, but also to *all* of the registered products containing glyphosate. *See also* 40 C.F.R. §§ 155.42(a), 155.53(a).[26]

Glyphosate formulations contain surfactants, confidential ingredients which can both: (1) cause skin and eye injuries in their own right, and (2) increase dermal absorption of glyphosate into the bloodstream. 2-RC_ER-0077-79, 85-91; 8-RC_ER-1730. But in registering glyphosate, EPA has apparently failed to assess *any* of the 555 glyphosate-containing formulations that contain surfactants that

[26] Petitioner Center for Food Safety (CFS) filed a petition with EPA to require safety testing of the whole pesticide formulations to capture impacts from surfactants and other "inert" ingredients, as well as tank mixes. EPA took public comment on the petition early in 2019 and has yet to respond. CFS, *Rulemaking Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration* (July 10, 2017), EPA-HQ-OPP-2018-0262.

increase dermal absorption and, thus, enhance glyphosate's cancer-causing potential.

EPA's reason for not conducting a quantitative assessment of skin exposure for workers was based on a single rabbit study that only involved the active ingredient. 3-RC_ER-0542; *supra* 31-35. Thus, the effects documented in the 1982 rabbit study, 10-RC_ER-2121, cannot be extrapolated to the risks from exposure to the many different glyphosate *formulations*—like Roundup—that workers actually use and regularly come into contact with.

First, the skin toxicity of some glyphosate formulations is plainly shown by documented injuries to skin that include "blisters, rash, pruritis, skin irritation, hives, welts, sores, burning skin, and peeling skin." 7-RC_ER-1504-1506, 1527-1573. These injuries are among the most frequent category (30%) of reported glyphosate adverse effect incidents. *Id.* EPA also describes "severe dermal effects," including extensive chemical burns, from accidental exposure to glyphosate formulations containing surfactants, including one known as POEA (polyethoxylated tallow amines or MON 0818). 6-RC_ER-1253. POEA is severly irritating to skin and positively corrosive to eye tissue. 2-

RC_ER-0087. Petitioners' farmworker members have suffered skin damage from exposure to Roundup. *See, e.g.,* Cordero Decl. at A121-23.

Second, surfactants increase the amount of glyphosate that penetrates the skin and enters the bloodstream, which disseminates it throughout the body. Assessing skin absorption of glyphosate formulations is critical for understanding glyphosate's systemic toxicity, including potential adverse effects on other organs and diseases like cancer. 8-RC_ER-1824-25; 2-RC_ER-0123-0126.[27]

As explained by Monsanto scientists, surfactants enhance skin absorption of glyphosate by, for instance, removing protective lipids (e.g. oils) from the skin's surface; spreading out droplets of glyphosate solution on the skin; and via their skin irritation effects, which increase blood flow in blood vessels just beneath the epidermis. 9-RC_ER-2000. Because of compositional differences, Monsanto's scientists recommend that: "[i]deally, all of the different glyphosate formulations would have

[27] *See also Hardeman v. Monsanto*, Case No. 19-16636 (9th Cir.), Direct Testimony of Dr. Weisenberger (Hardeman ER521, 524) (explaining that "surfactants . . . help[ ] the glyphosate penetrate through the walls of the plants into the actual plant cells" and "when you get Roundup on your skin, just like the Roundup will penetrate the plant cells, it will penetrate the cells of the skin and it will get into the tissues and it will get into the lymph system and into the blood . . .").

to be tested for dermal uptake." *Id*. Indeed, a Monsanto-commissioned dermal absorption study found a huge difference in the glyphosate penetration rate of the two glyphosate formulations tested (though it was never submitted to EPA), underscoring the need for formulation-specific testing. 9-RC_ER-1957-92; 2-RC_ER-0125. Yet as noted above, after nearly half a century, EPA still does not have a single dermal absorption study in its toxicity database for even one glyphosate formulation, much less all of them. 3_RC_ER-0525.

Not only did EPA fail to assess how much more glyphosate might enter a person's body based on differences in the formulations, EPA also did not assess the carcinogenic potential of these formulations and their various surfactants. The evidence before EPA, however, shows that both glyphosate and its formulations trigger cancer-causing (genotoxic) changes in cells, such as mutations. 5_RC_ER-1100-01; 3-RC_ER-424-39; 7_RC_ER-1464-76; 4-RC_ER-0764-92.[28]

Indeed, EPA permits glyphosate formulations to contain (at levels up to 25%) surfactants like POEA, despite finding substantial risks to

[28] Notably, these tests for cellular changes were far more likely to give positive results when conducted by independent scientists rather than glyphosate registrants. 3-RC_ER-424-39.

occupational users, and despite lack of animal studies on their carcinogenicity, chronic toxicity, and endocrine disruption potential, among other data gaps, as pointed out by Petitioners. 2-RC_ER-0086-87; 7-RC_ER-1578; 74 Fed. Reg. 28616, 28623 (June 17, 2009). In contrast, European regulators banned use of POEA in glyphosate formulations based on evidence of its cancer-causing changes in cells and other harms, and lack of animal data on its carcinogenicity and other effects. 6-RC_ER-1229; 5-RC_ER-0926.

Even if it were true that glyphosate alone is "not likely to be carcinogenic"—it is not, *see supra* 35-41—this conclusion is largely irrelevant to workers exposed to glyphosate *formulations* like Roundup. As Monsanto's chief toxicologist warned colleagues: "you cannot say that Roundup is not a carcinogen … we have not done the necessary testing on the formulation to make that statement." 8-RC_ER-1760-61.

In summary with regard to human health risks, EPA did not assess a key routes of exposure (skin) to the people most exposed to glyphosate. It failed to assess the effects of these exposures, in part, because it denies the reality that glyphosate is probably carcinogenic. But EPA's conclusion that there are no "occupational risks of concern"

for glyphosate is not supported by substantial evidence. Accordingly, by registering glyphosate and its formulations without crucial health information—including on those formulations that *increase* the risk of harm—EPA has abdicated its duty to prevent unreasonable adverse effects to human health.

B. EPA Failed to Weigh the True Costs of Glyphosate.

Pesticides are biocides, meaning they are toxic substances intended to kill living things. As such, they come with significant risks or harms, or "costs" in FIFRA's rubric; costs that EPA is required by law to evaluate alongside any purported benefits, before granting registration. 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.").

Here, there are significant costs to farmers and the environment from glyphosate drift and the plague of resistant weeds from glyphosate overuse, including the substantial increase in use of other toxic weed-killers in response. 4-RC_ER-0841; *NFFC*, 960 F.3d at 1120. And costs to the thousands of animal and plant species whose ranges and habitat

overlap with glyphosate spraying, including pollinators and Monarch butterflies. EPA must take these costs into consideration and assess them, because FIFRA does not allow it to register a pesticide with unreasonable adverse effects. That standard means EPA cannot blindly accept the purported benefits of glyphosate while ignoring the signficiant economic and environmental costs. But that is exactly what EPA did here.

1. EPA Failed to Weigh the Economic Costs of Glyphosate.

In evaluating whether a pesticide mets the FIFRA safety standard, EPA must take into account economic, social, and environmental costs and benefits of the use of any pesticide, as it is commonly used. 7 U.S.C. §§ 136(bb); 136a(c)(5)(D). Here EPA's cost-benefit "analysis" appears in a single sentence in its decision document and response to comments, concluding that the *ecological* costs are outweighed by the benefits. 1-RC_ER-0017; 2-RC_ER-0266-96. But EPA entirely failed to consider and assess the significant *economic* costs resulting from widespread glyphosate use. These costs include both glyphosate-resistant weeds and glyphosate drift damage.

First, the economic and social costs of the glyphosate-resistant weed epidemic are considerable and well-documented. EPA knows that pesticide-resistant weeds are "a widespread problem" that may "fundamentally change production practices in U.S. agriculture." 1-RC_ER-0019.

In fact, they already have. The U.S. Department of Agriculture (USDA) estimated over a decade ago that up to 25% of U.S. pest (weed and insect) control expenditures are attributable to managing pesticide resistance. 7-RC_ER-1437. EPA acknowledges that glyphosate applied to genetically-engineered (Roundup Ready) crops "has made glyphosate resistance the worst herbicide resistance problem." 2-RC_ER-0274.

Nonetheless, EPA nowhere assesses the extent, the explosive growth, or the astronomical costs of glyphosate-resistant weeds to farmers or U.S. agriculture. Glyphosate resistance first appeared in a Roundup Ready crop in 2001. 2-RC_ER-0291. Just five short years later, cotton agronomist Alan York described one such weed, glyphosate-resistant Palmer amaranth, as "potentially the worst threat [to cotton] since the boll weevil." 1-RC_ER-0019; 7-RC_ER-1447. The amount of agricultural land infested with glyphosate-resistant weeds

nearly *quadrupled* from 2010 to 2017, from 33 million to 120 million acres. 2-RC_ER-0104; 6-RC_ER-1354; 3-RC_ER-0509. In a 2017 survey of 4,000 growers, 73% reported glyphosate-resistant weeds in their fields. 2-RC_ER-0104; 3-RC_ER-0509.

Farmers incur substantial costs to control glyphosate-resistant weeds in the form of increased expenditures on additional toxic pesticides, while increased use of soil-eroding tillage is an environmental cost of resistance. 2-RC_ER-0104. In 2013, agronomists estimated that glyphosate-resistant weeds increased farmers' pesticide expenditures by six-fold in both Arkansas cotton (from $50-$75 to $370 per hectare) and Illinois soybeans ($25 to $160 per hectare). 2-RC_ER-0104; 6-RC_ER-1353. Georgia cotton growers saw their pesticide costs double by paying for additional pesticides to kill the rapidly spreading Palmer amaranth resistant to glyphosate. 2-RC_ER-0104; 6-RC_ER_1343. Even with these additional expenditures, for many farmers, it was insufficient to eradicate Palmer amaranth, so these farmers spent far more money on hand-weeding crews and for increased tillage operations. 2-RC_ER-0104-05; 6-RC_ER_1343.

Further, USDA found that glyphosate-resistant weeds reduced farmers' total returns by $67.29 per acre of planted corn, and a $22.53/acre loss for soybean farmers who reported declining effectiveness of glyphosate on weeds. 5-RC_ER-1085. Applied to the 120 million acres of farmland with glyphosate-resistant weeds, the costs borne by farmers amount to an enormous $5.4 billion.[29] Despite explicitly acknowledging these resistant weed costs elsewhere, EPA ignored all these costs when it concluded that glyphosate is "a relatively inexpensive herbicide in agricultural situations, with the cost of applications to most crops ranging from $1 to $13 per acre." 1-RC_ER-0016; 5-RC_ER-0858-59. EPA fails entirely to account for these substantial glyphosate-resistant weed costs.

Second, glyphosate has also caused extensive damage when it drifts or runs off of the fields to which it is applied and onto neighboring fields and crops. 5-RC_ER-1005-06; 6-RC_ER-1171-73. Glyphosate has ranked among the three top pesticides in drift episodes. 9-RC_ER-2008-10, 18-26; 8-RC_ER-1737. Organic farmers and conventional farmers

[29] Assuming corn and soybean fields are equally infested: (60 million x $67.29) + (60 million x $22.53).

who do not use pesticides often have to take measures to protect their crops from glyphosate drift, measures that cost time and money to implement. *See e.g.*, Shipman Decl. at A193-95; Walker Decl. at A205-208.

EPA's own spray drift analysis found that glyphosate spray drift causes plant damage exceeding its plant safety threshold many *hundreds* of feet from the edge of a sprayed field, depending on the application method and amount of glyphosate applied. 5-RC_ER-1036. While EPA recognized the "potential risk to terrestrial and aquatic plants from off-site spray drift" because glyphosate is an herbicide, it failed entirely to evaluate the economic costs that come from that drift. 1-RC_ER-0017.

Both glyphosate's drift costs and its weed resistance costs are analogous to the pesticide costs of dicamba, which this Court recently addressed in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020). In *NFFC*, EPA registered dicamba pesticide products for the first time to be sprayed over the top of crops genetically engineered with dicamba resistance. That approval caused several growing seasons of substantial off-field drift, damaging millions of acres

of neighboring soybean crops as well as other crops, vegetables, and ornamental, fruit and other trees. *Id.* at 1127-29, 1136-38. The Court held that EPA's "substantially understated" this cost, pointing to record evidence. *Id.* at 1136-39. EPA's failure to consider, assess, and quantify the drift harm costs rendered the registration unsupported by substantial evidence. *Id.* at 1138-39 (holding that EPA "refused to quantify or estimate the amount of damage costs"). The Court therefore vacated the registration. *Id.* at 1144-45.

As explained above, ironically the purported benefit EPA gave for registering this damaging use of dicamba was to address the resistant weed crisis *costs* caused by the chief use of glyphosate, on glyphosate-resistant crops. EPA should have assessed these sigificant costs long before the dicamba case. But at a minimum it absolutely had to do so in this registration and its failure rendered its decision without substantial evidence, in violation of FIFRA.

2. EPA Failed to Weigh the Environmental Costs of Glyphosate.

FIFRA requires EPA to weigh environmental costs. 7 U.S.C. § 136(bb). Yet in its cost-benefit analysis for the latest glyphosate registration decision, EPA failed to evaluate the significant

environmental costs of glyphosate, despite its bald conclusion that the benefits outweigh the ecological costs. 1-RC_ER-0011-17; 2-RC_ER-0266-96. EPA quanitifed neither ecological costs nor purported benefits. *Id.*

EPA dismissed environmental costs, including to pollinators and Monarchs, from continued glyphosate spraying. Effects identified in EPA's ecological assessment include impairment of growth and reproduction of mammals, growth of birds and terrestrial-phase amphibians, and imperiling the survival of both of terrestrial and various aquatic plants. 5-RC_ER-0946. Yet EPA's registration decision dramatically downplays these serious impacts, strangely concluding that it "did not identify any potential risks of concern for fish, aquatic invertebrates, or aquatic-phase amphibians" and "low or limited risks of concern" for mammals and birds. 1-RC_ER-0014.

EPA admits that there may be direct impacts to honey bees and other pollinators from higher application rates, and indirect impacts via spray drift killing off wild plants that provide them with critical nectar sources and habitat. 1-RC_ER-0014, 19. And EPA admits that it does not even have the data necessary to evaluate these impacts. 1-RC_ER-

0014 ("additional data may be necessary to fully evaluate risks to bees" from glyphosate). But EPA ignores the major negative impact of glyphosate on Monarchs: its near-eradication of milkweed in Midwest corn and soybean fields. *Id*. at 12.

But both bee and Monarch populations have precipitously declined over the last twenty years, the same time period that glyphosate use has exponentially grown. Scientists know that the vastly increased agricultural use of glyphosate is a major factor in the nearly 90% decline in migratory Monarch butterfly populations; glyphosate is a particularly potent killer of common milkweed, a "critical food source" for Monarch butterflies, in agricultural fields throughout the butterfly's Midwest breeding grounds. 3-RC_ER-0483; 1-RC_ER-0014. Populations of pollinators, including honey bees, and other beneficial insects are in dangerous decline, and glyphosate is implicated. 2-RC_ER-0101-02, 0190-0210. Many of these insects depend on habitat near agricultural fields that is vulnerable to offsite movement of glyphosate in drift and run-off. 2-RC_ER-0102.

Instead of evaluating impacts to pollinators and other beneficial insects, EPA says it may call for additional data on honey bees.

1-RC_ER-0015. That does not amount to a consideration of the costs of continued glyphosate spraying and does not give EPA substantial evidence for its conclusion that glyphosate will not cause unreasonable adverse effects. *See Nat'l Family Farm Coal. v. U.S. Envtl. Prot. Agency,* 966 F.3d 893, 917 (9th Cir. 2020) (holding EPA's registration of the glyphosate-based pesticide Enlist Duo lacked substantial evidence because of failure to "consider[] how the destruction of milkweed on target fields would affect monarch butterflies.").

C. EPA Lacks Substantial Evidence For Conclusion That Label Will Prevent Harms.

Pesticide label use directions are a form of mitigation and EPA will most likely argue that it mitigated any environmental or economic costs with its label changes in this "interim" registration. However, just as with the rest of EPA's FIFRA determination, any such reliance on any mitigation measures must be supported by substantial evidence. That includes evidence that any mitigation measures will actually be *effective*—including that they can actually be followed—to ensure glyphosate spraying does not cause unreasonable adverse effects. That means the measures will work in the real world.

This Court in *NFFC* also explained this FIFRA requirement, when it comes to label mitigation. In that case, EPA had relied on a very complex list of use directions in the dicamba registration and "no unreasonable adverse effect" determination, but EPA had never analyzed how those measures would work in real world farming conditions, or if farmers could actually follow them. The record evidence showed the label was "difficult if not impossible" to follow. *NFFC,* 960 F.3d at 1124. Accordingly the Court held that EPA violated FIFRA by failing to acknowledge and consider the problems of users inability to follow the label instructions, despite the agency's heavy reliance on it as mitigation. *Id.* at 1139-40.

Here, EPA concluded that "the benefits outweigh the potential ecological risks when glyphosate is used according to label directions." 1-RC_ER-0017. Yet despite finding many risks of concern, EPA's label mitigation measures in its decision—which address pesticide resistance, non-target organisms, and spray drift—differ little from those on current glyphosate product labels. 1-RC_ER-0017-20.

Moreoever, at no point did EPA *actually assess the efficacy* of these mitigation measures on which it predicated its determination. Thus,

EPA lacks substantial evidence to support its conclusion that label directions will ensure that the alleged benefits of glyphosate outweigh the costs and that glyphosate meets the FIFRA safety standard.

First, EPA claims that "implementation of herbicide resistance measures" will help "slow the development and spread of herbicide resistant weeds." 1-RC_ER-0019. This is based on two pesticide registration notices (PRNs 2017-1 and 2017-2) that EPA incorporates into its registration decision. 1-RC_ER-0019, 26. Both notices are toothless "guidance" documents that suggest pesticide-resistance management language that pesticide registrants might choose to put on their product labels, but are entirely non-binding. 5-RC_ER-0871 ("pesticide applicants may assert that the guidance is not appropriate generally or not applicable a specific pesticide").

In any case, experience has taught that such label recommendations are wholly insufficient to actually slow the development and spread of glyphosate-resistant weeds. First, glyphosate product labels have for over 13 years listed very similar

"weed resistance management" measures,[30] but glyphosate-resistant weeds still dramatically spread over this time. *See supra* 15-16, 23. Second, the PRN recommendations reflect a pesticide-intensive approach to resistant weed management that serves the interest of chemical industry, fosters even more damaging weeds resistant to multiple pesticides, and is inferior to an integrated approach that lessens both pesticide use and resistance. 6-RC_ER-1365-75; 7-RC_ER-1435-41. EPA just assumed these *voluntary* measures would be sufficient to stop the weed resistance crisis. It did not support their efficacy with any evidence, let alone substantial evidence. *NFFC*, 960 F.3d at 1139.

Second, EPA added a "non-target organism advisory" to "alert users of potential impact to non-target organisms." 1-RC_ER-0019-20. This "advisory" states:

> This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift.

[30] *See e.g.*, 2007 Roundup Pro label, Sections 5.1 & 5.2, at https://natseed.com/pdf/Roundup%20Pro%20Label.pdf.

1-RC_ER-0019. With this vague advisory to "[p]rotect the forarge and habitat of non-target organisms," EPA assumes that glyphosate applicators know which non-target organisms to look for and what their forage and habitat requirements are. EPA does not explain *how* users can follow this directive. And again, at no point does EPA assess whether users can actually *comply* with this advisory in real world farming conditions, and the effects to non-target organisms if those directions are not able to be followed. 9-RC_ER-1993-96. *NFFC*, 960 F.3d at 1139.

Moreover, the advisory only instructs users to comply with "label directions intended to minimize spray drift," something they are already required to do. And it only slightly differs from an existing advisory on some product labels.[31] It is entirely unclear how this "mitigation measure" will do *anything at all* to protect the thousands of wild species at risk of harm from glyphosate use.

Third, EPA claims that language added to the glyphosate label to manage spray drift "will reduce the extent of environmental exposure

[31] *See* 2007 Roundup Pro label, Section 7.1, at https://natseed.com/pdf/Roundup%20Pro%20Label.pdf.

and risk to non-target plants and animals." 1-RC_ER-0017. This language tells applicators the maximum wind speed and minimum droplet size for spraying glyphosate, and prohibits spraying during temperature inversions. *Id.* While EPA claims that the spray drift language "is intended to be mandatory, enforceable statements," *id.*, it provides no assessment of their efficacy or ability to be followed.

As stated above, glyphosate has ranked among the three top pesticides in spray drift episodes and EPA well knows that pesticide applications are often made when it is too windy. 9-RC_ER-1993-96. That is why it is critical that EPA assess the efficacy of the new spray drift mitigation. Instead, EPA only "assessed the potential impact on growers of the required spray drift management restrictions" and whether the restrictions would "substantially reduce the benefits of glyphosate to users." 1-RC_ER-0018. EPA's failure to assess the other side of the coin—the risks of non-compliance in real world conditions and the harm to that would occur—violated FIFRA. "Non-compliance with the restrictions, of course, will result in [glyphosate] damage" to non-target organisms, which "EPA entirely failed to acknowledge." *NFFC*, 960 F.3d at 1139.

In sum, the flaw in EPA's conclusion is that it assumes all of these mitigation measures are effective without any assessment of their efficacy. EPA's failure renders its decision without substantial evidence. *Pollinator Stewardship*, 806 F.3d at 532.

II. EPA VIOLATED THE ESA.

By issuing a glyphosate registration decision before completing ESA Section 7 consultation with expert wildlife agencies, EPA violated the ESA. EPA has indeed never completed a nationwide ESA consultation in the 46-year history of this pesticide, despite being the most widely-used in the country.

This violation is glaring: 1,795 species—100% of the species exposed and 100% of their critical habitats—may be affected, 1,676 of which will likely be adversely affected by EPA's own assessment. BE at 4-3. These include iconic birds like the whooping crane and endangered pollinators critical to our food sytem. And hundreds of plants, insects, and aquatic invertebrates, the abundance and diversity of which are crucial to intact ecosystems. For some of these species, their continued existence may be jeopardized by glyphosate spraying allowed by EPA's latest decision. These numbers are now publicly known, because EPA

has started its ESA duties, enough to know that formal consultation is required for 93% of exposed species, but is far from completion. *See infra* 70-71.

EPA knows that its registration action triggers the low "may affect" threshold requiring consultation, but went forward regardless. But before EPA can register glyphosate—including this final "interim" registration—it must consult with and obtain biological opinions from the FWS and NMFS ("Services"). The ESA's regulations require consultation at the "earliest possible time." 50 C.F.R. § 402.14(a). EPA started its registration review over a decade ago: whatever the earliest possible time to consult may be, that time has plainly passed.

Under EPA's latest decision, 306 million pounds of glyphosate will be sprayed, without any effective or enforceable mitigation, on over 285 million acres every year. To the detriment and possible extinction of thousands of protected species. The ESA, which prioritizes species' continued existence over the primary missions of agencies, does not allow such a result.

A. The Endangered Species Act and ESA Section 7 Consultation.

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). Congress spoke "in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution.'" *Id.* at 194.

Section 7(a)(2) is the "heart" of the ESA, and one of the statute's most important protections. *California ex rel. Lockyer v. U.S. Dept. of Agric.,* 575 F.3d 999, 1018 (9th Cir. 2009). It mandates that "[e]ach federal agency" "insure" its action—here, registration of glyphosate—is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C. § 1536(a)(2).[32]

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

To do this, action agencies like EPA must consult the Services to determine if their actions may cause jeopardy, and if so, how to modify the action to avoid that result. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14. This procedure must be rigorouly adhered to because it is the only way to ensure compliance with the ESA's substantive protections. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

Every federal agency, using the "best scientific and commercial information available," 16 U.S.C. § 1536(a)(2), must review its action "at the earliest possible time" to determine whether it "may affect" any listed species or designated critical habitat. 50 C.F.R. § 402.14(a).[33] The threshold for a "may affect" determination triggering the required ESA Section 7(a)(2) consultation process is very low. 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) (codified at 50 C.F.R. pt. 402) ("Any possible effect, whether beneficial, benign, adverse, or an an undetermined

---

the species and (II) which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

[33] As the expert agencies, FWS and NMFS adopted joint regulations governing the Section 7(a)(2) consultation process.

character, triggers the formal consultation requirement.").[34] As this Court has explained, "actions that have *any chance of affecting listed species or critical habitat*—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Karuk Tribe*, 681 F.3d at 1027 (emphasis added).

If the action "may affect" listed species or habitats, the agency *must* initiate and complete Section 7 consultation with FWS or NMFS before taking action. *Id.* It is "critical that ESA review occur early in the process to avoid piecemeal chipping away of habitat." *Conner*, 848 F.2d at 1453-55 (consultation required before sale of any leases, and biological opinion could not be put off until later stage of agency action); *Lane Cty. Audubon Soc. v. Jamison*, 958 F.2d 290, 294 (9th Cir. 1992) (agency must consult on initial actions that may affect listed species before implementing later actions).

---

[34] *See also* FWS and NMFS, *Endangered Species Consultation Handbook*, xvi (1998) (defining "may affect" as "the appropriate conclusion when a proposed action may pose *any* effects on listed species or designated critical habitat") (emphasis in original); *id.* at 3-13, 4-26, https://www.fws.gov/ENDANGERED/esa-library/pdf/esa_section7_handbook.pdf.

ESA consultation may in some cases be informal, if the Service concurs in writing with a finding that that the action is "not likely to adversely affect" any listed species or critical habitat. 50 C.F.R. §§ 402.13(a); 402.14(b). Otherwise, formal consultation is required, which culminates with the Service's issuance of a biological opinion as to whether the action will likely jeopardize the continued existence of any species or adversely modify any critical habitat. *Id.* §§ 402.14(h)(3), (i); 402.02; 402.14(a). If there is a jeopardy finding for any species, the Service must include "reasonable and prudent alternatives," if any, to the action. *Id.* § 402.14(h)(2). A no-jeopardy biological opinion will include an incidental take statement for "take" of species that will not violate Section 7(a)(2) and any reasonable and prudent measures, along with the terms and conditions that implement them. *Id.* § 402.14(i). Thus, formal consultation is crucial to shaping the action to comply with the ESA and hence must be completed prior to the action happening.

B. EPA's "Interim" Registration is an "Agency Action" Under the ESA.

Under the ESA and its implementing regulations, EPA has a duty to consult with the Services prior to registering glyphosate, regardless of whether the agency calls it "interim" or anything else.

Respondents may attempt to argue that this decision is not a cognizable agency action triggering Section 7 duties. The ESA defines "agency action" as "any action authorized, funded, or carried out by [a federal] agency." 16 U.S.C. § 1536(a)(2). Congress intended "agency action" to have a broad definition in the ESA. *Karuk Tribe*, 681 F.3d at 1020. The Ninth Circuit established a two-part test for determining ESA "agency action" that triggers the duty to consult. EPA's glyphosate registration meets both parts.

First, the court asks whether a federal agency affirmatively authorized, funded, or carried out the underlying activity. *Id.* Pesticide registrations undoubtedly meet this standard. *Id.* (citing *Wash. Toxics Coal. v. U.S. Envtl. Prot. Agency*, 413 F.3d 1024, 1031-33 (9th Cir. 2005) (holding the ESA applies to FIFRA pesticide registrations). That EPA calls this registration "interim" makes no difference; it completed the health, ecological, and cost-benefit assessments and registered

glyphosate with the label "mitigation" measures. 1-RC_ER-0005, 17. *See Lane Cty. Audubon Soc'y*, 958 F.2d at 294 (interim management strategy designed to be implemented immediately constitutes agency action triggering consultation).

Second, the court determines whether the agency had some discretion to influence or change the activity for the benefit of a protected species. *Karuk Tribe*, 681 F.3d at 1024. EPA's decision to register a pesticide is discretionary because EPA can "influence a private activity [pesticide use] to benefit a listed species," *id.* at 1025, through label amendments, restricting the pesticides' uses, or not registering it. 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(a). EPA's glyphosate registration is plainly an cognizable agency action under the ESA, triggering Section 7 duties.

C. Because Glyphosate "May Affect" Listed Species, EPA Must Complete Consultation Before Registration.

Because EPA's "interim" registration of glyphosate is an agency action under the ESA that "may affect" thousands of listed species and hundreds of critical habitats, EPA must consult before registering

glyphosate.[35] Strict adherence to the ESA's procedural commands is required to guarantee compliance with its substantive provisions, which require that EPA ensure registering glyphosate (including all of its formulations) will not cause jeopardy to any protected species or habitat. EPA has abjectly failed to do that here.

First, there is absolutely no doubt that EPA's issuance of the registration "may affect" literally thousands of listed species and hundreds of critical habitats, because *EPA itself has already come to this conclusion*. In late November 2020, EPA released a draft "Biological Evaluation" (BE) assessing risks to listed species from labeled uses of glyphosate.[36] This is the "effects determination" that EPA, as action agency, must make before taking an action. 50 C.F.R. § 402.14(a). If

[35] Based on FWS's announcement that Monarch butterflies are a candidate for listing, EPA should now also consider impacts to them in its ESA consultation. *See* FWS and NMFS, *Consultation Handbook* at 1-5, 3-7, *supra* n.31.

[36] EPA, BE, *supra* n.5. While this draft was released in November 2020, EPA clearly began work on this assessment earlier, overlapping with its January 2020 interim registration decision. For example, the draft BE considers listed species and designated critical habitats that were listed as of January 30, 2019, suggesting EPA started this assessment around that time. BE at 1-5.

EPA determines that its action "may affect" any listed species or critical habitat, it *must* consult with FWS and/or NMFS.

Not only did EPA find "may affect" for 100% of species it determined would be exposed to glyphosate—1,795 species—it went to the second step and found that 93% of those—1,676 species—*would likely be adversely affected*. BE at 4-3. A likely adverse effect call requires formal consultation, concluding with biological opinions. 50 C.F.R. §§ 402.02; 402.14(a); 402.14(h)(3), (i). Thus, EPA itself admits that there will likely be adverse effects to 75 mammals, 88 birds, 36 amphibians, 33 reptiles, 179 fish, 940 plants, 185 aquatic invertebrates, and 140 terrestrial invertebrates. And to 759 critical habitats. BE at 4-3. Given that glyphosate is an herbicide, it is not surprising that it is highly toxic to plants, with endangered plants making up a large portion of the species affected. BE at 4-11. Glyphosate's toxicity to plants also contributes to its toxic effects to listed species that rely on those plants for food and shelter. BE at 4-13.

Accordingly, formal consultation is required for all of these species and critical habitats *before* EPA moves forward with glyphosate registration. *Conner*, 848 F.2d at 1453-55; *Karuk Tribe*, 681 F.3d at

1020 ("Section 7 imposes on all agencies a duty to consult with either the Fish and Wildlife Service or the NOAA Fisheries Service *before* engaging in any discretionary action that may affect a listed species or critical habitat.") (emphasis added).

Second, EPA should have come to this conclusion years ago. EPA reregistered glyphosate in 1993 and started the review process in 2009. Now, after all this time, EPA finds that 100% of species and habitats exposed may be affected and "[n]o species or critical habitats met [the "no effect"] criteria for glyphosate" in the massive action area ("pesticide footprint based on all labeled uses ….and offsite transport due to spray drift"). BE at 4-4, 4-5.

Indeed, EPA admits that "[t]he number of and strength of [likely to adversely affect] determinations found for glyphosate is *expected* given the action area of the chemical and the toxicity profile." BE at 4-12 (emphasis added). In plain terms, it means that EPA knew this result was coming because it was self-evident: glyphosate has extremely widespread spraying and every species that overlaps with that spraying may be impacted, mostly adversely impacted.

The massive spraying footprint and the obvious overlap of spraying and the habitat of thousands of listed species should have triggered consultation. But twelve years into the glyphosate registration review process, EPA is just *now* taking the first step. Before registering glyphosate, EPA must first finish the formal consultation it should have started years ago.

Listed Species Examples

Some of the listed species likely to be adversely affected are the whooping crane, Indiana bat, and rusty-patched bumble bee, species important to Petitioners' members.[37]

The iconic whooping crane is among the world's most endangered animals. In 1954, there were as few as twenty-one whooping cranes left.[38] In the decades since, conservation efforts have led to only a limited recovery; there are now a few hundred in the wild,[39] about 4% of

---

[37] *See* Crouch Decl. A125-132; Limberg Decl. A161-171; Shistar Decl. A196-201.

[38] *See* FWS, INTERNATIONAL RECOVERY PLAN: WHOOPING CRANE (GRUS AMERICANA) 1 (Mar. 2007), http://www.fws.gov/uploadedFiles/WHCR%20RP%20Final%207-21-2006.pdf.

[39] *Id*. at 13-14.

its historic numbers. Significant portions of the range of the two remaining whooping crane populations overlap with agricultural areas where there is extensive application of glyphosate.[40] EPA found the whooping crane is likely adversely affected by glyphosate. BE Appendix 4-1.

Indiana bats play a critical role in maintaining the balance of an ecosystem. A significant source of natural insect control, Indiana bats typically consume up to half their body weight in insects each night.[41] Their population has continued to decline despite conservation and recovery efforts; only half of those that existed when the species was listed as endangered remain.[42] FWS's Indiana bat recovery team specifically identified pesticide contamination of the bats' food supply as a reason for their continued decline.[43] Significant portions of the range of Indiana bat overlaps with with agricultural areas where there is

---

[40] Compare *id*. at 4 with Figure 2.

[41] U.S. Fish & Wildlife Service, *Midwest Region Endangered Species: Indiana Bat (Myotis Sodalis)*, https://www.fws.gov/midwest/endangered/mammals/inba/inbafctsht.html.

[42] *Id*.

[43] *Id*.

extensive application of glyphosate, and EPA found the Indiana bat is likely adversely affected. BE Appendix 4-1.

The rusty-patched bumble bee was the first bumble bee listed in the continental U.S. under the ESA.[44] Before the mid- to late-1990s, the bumble bee was considered abundant across a broad geographic range that included the District of Columbia, 28 states, and two Canadian provinces.[45] Since 2000, however, it has been reported in only a few places in 13 states and one province and its current distribution is only 13% of its historical extent. *Id*. Pesticides are considered one of the leading threats that have contributed to the rapid decline in rusty patched bumble bee populations.[46] Unsurprisingly, EPA found the rusty-patched bumble bee is likely adversely affected by glyphosate. BE Appendix 4-1.

These species are just examples of the 1,676 species likely adversely affected by glyphosate use. Before approving any registration

---

[44] FWS, *Rusty Patched Bumble Bee*, https://www.fws.gov/midwest/endangered/insects/rpbb/FAQsFinalListing.html#:~:text=These%20were%20the%20first%20bees,3.

[45] FWS, *Rusty patched bumble bee (Bombus affinis)*, https://ecos.fws.gov/ecp0/profile/speciesProfile.action?spcode=I0WI.

[46] *Supra* n.42 (FWS Rusty Patched Bumble Bee).

of glyphosate—including the so-called final "interim" registration—EPA needed to finish consultation to determine if any of these species are jeopardized with the Services. The FWS and NMFS have expertise on wildlife biology that EPA lacks, and that is why the ESA requires their expert opinions before an action is taken.

ESA Consultation Leads to Protective Measures

As explained above, if some species are jeopardized, the Services will provide EPA with reasonable and prudent alternatives to the registration, which could, for example, include prohibiting use in regions with these species. 50 C.F.R. § 402.14(h)(2). Even if *none* of the 1,676 species will be put in jeopardy, the Services still provide reasonable and prudent measures, along with the terms and conditions that implement them, to prevent any harm to species or habitats beyond what the Services find is incidental and will not cause jeopardy. *Id.* § 402.14(i). Given the sheer number of species and habitat impacted, it is beyond the pale that EPA would not have to modify the registration is some way to prevent harm and comply with the ESA.

EPA's "Advisory" Label Amendment Is Not ESA Compliance

Finally, instead of consulting, here EPA issued the "interim" registration with a new "advisory" label statement. 1-RC_ER-0019. Even if this "advisory" language can be followed, the command is simply to *follow the label directions*, which users are already bound to do. So this advisory changes nothing about how glyphosate will continue to be used, which as EPA admits is likely to adversely affected thousands of listed species. As explained above, EPA provides no evidence of the efficacy of this vague advisory language or whether glyphosate users can even identify the "forage and habitat of non-target organisms" that are supposed to be protected. *Supra* 23-24.

To comply with the ESA, mitigation measures must be the result of "specific and binding plans" and "reasonably certain to occur." *Nat'l Family Farm Coal.*, 966 F.3d at 923 (quoting *Defs. of Wildlife v. Zinke*, 856 F.3d 1248, 1258 (9th Cir. 2017) and *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 936 n.17 (9th Cir. 2008)). EPA has not shown that this advisory language regarding harm to non-target plants instructing users to follow the label is specific, binding, or at all reasonably certain to occur.

Nor have the Services had a chance to weigh in, as required by the ESA. Instead of this ineffective "advisory" language, EPA needs to complete consultation and determine what changes must be made to *ensure* that no species or habitats are jeopardized. The ESA, its regulations, and the Ninth Circuit's own cases require EPA to finish assessing the impacts to listed species and tailor its action to avoid jeopardy, *before* issuing any registration. 50 C.F.R. §§ 402.14(a) (Agencies shall review actions "at the earliest possible time"); 402.14(c)(4) (even consultation on a segment of a larger action does "not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole."); *Conner*, 848 F.2d at 1454-55 (holding that agency could not put off biological opinion until later stage of oil and gas lease approvals, since it is "critical that ESA review occur *early in the process* to avoid piecemeal chipping away of habitat."); *Lane Cty. Audubon Soc.*, 958 F.2d at 294 (consultation required on interim strategy that may affect spotted owl before it could be implemented through individual timber sales); *Karuk Tribe*, 681 F.3d at 1020.

EPA has now spent over ten years reviewing glyphosate's registration but has not completed the ESA consultation it knows is required. Because EPA issued a registration without first completing consultation, EPA violated the ESA and the Court should vacate the registration.

III. THE COURT SHOULD VACATE THE REGISTRATION.

Because EPA violated FIFRA and ESA, the Court should set aside EPA's approval. Vacatur is the presumptive remedy for unlawful pesticide registrations. *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 burden to show otherwise); *Pollinator Stewardship*, 806 F.3d at 532 (remand without vacatur permitted only in "limited circumstances"); *Idaho Farm Bureau v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) ("[o]rdinarily" vacatur applies unless "equity demands" otherwise).

This Court "weigh[s] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *NFFC*, 960 F.3d at 1144 (quoting *Pollinator Stewardship*, 806 F.3d at 532). In these environmental circumstances, the only cognizable

disruptive consequences are those environmental harms that flow from vacatur. *Id.* at 1145; *Pollinator Stewardship*, 806 F.3d at 532; *see also All. for the Wild Rockies*, 907 F.3d at 1122 (vacatur "appropriate when leaving in place an agency action risks more environmental harm than vacating it").

Just like in recent pesticide cases *NFFC* and *Pollinator Stewardship Council*, EPA here substantially understated or entirely failed to acknowledge the health risks to glyphosate users, and the environmental risks to pollinators and other wild species, including thousands of ESA-protected species. EPA's errors are serious: human health and environmental risks are core considerations of FIFRA. Violating ESA's Section 7 goes to the "heart" of that statute. *Lockyer,* 575 F.3d at 1018. And while there may be disruptive economic consequences alleged, the environmentally-safer result is vacatur. *Pollinator Stewardship*, 806 F.3d at 532.

Vacatur here means that glyphosate use would be unlawful, including the individual glyphosate-based products, because they all rest on EPA's unlawful determination that glyphosate does not cause unreasonable adverse effects on the environment. *See* 7 U.S.C.

§§ 136a(c)(5)(C), (D); 136a(a). This is the correct result because continued use of glyphosate formulations comes with serious, unexplored risks to workers, including of cancer. Given the serious error here, precarious populations of endangered species and pollinators, and the signficiant but long-term health impacts, this Court should vacate EPA's unlawful glyphosate registration.

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 17th day of December, 2020.

/s/ Amy van Saun
Amy van Saun
George A. Kimbrell
Ryan D. Talbott
2009 NE Alberta St., Suite 207
Portland, OR 97211
T: (971) 271-7372
avansaun@centerforfoodsafety.org
gkimbrell@centerforfoodsafety.org
rtalbott@centerforfoodsafety.org

Counsel for Petitioners

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

PAGE(S)

FEDERAL STATUTES

FEDERAL REGULATIONS

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

5 U.S.C.A. § 702

§ 702. Right of review

Currentness

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub.L. 94-574, § 1, Oct. 21, 1976, 90 Stat. 2721.)

Notes of Decisions (1324)

5 U.S.C.A. § 702, 5 USCA § 702
Current through P.L. 116-193.

End of Document

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

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

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

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

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

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

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

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

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

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

(D) without observance of procedure required by law;

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

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

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

CREDIT(S)

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

Notes of Decisions (4865)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 116-193.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

7 U.S.C.A. § 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 (12)

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. 116-193.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

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 (120)

7 U.S.C.A. § 136a, 7 USCA § 136a
Current through P.L. 116-193.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

7 U.S.C.A. § 136a-1

§ 136a-1. Reregistration of registered pesticides

Effective: March 8, 2019
Currentness

(a) General rule

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

(1) there are no outstanding data requirements; and

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

(b) Reregistration phases

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

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

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

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

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

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

(c) Phase one

(1) Priority for reregistration

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

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

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

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

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

(2) Reregistration lists

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

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

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

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

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

Each list shall be published in the Federal Register.

(3) Judicial review

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

(4) Notice to registrants

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

(d) Phase two

(1) In general

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

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

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

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

(3) Missing or inadequate data

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

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

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

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

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

(B) either--

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

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

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

(4) Time periods

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

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

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

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

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

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if--

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(5) Cancellation and removal

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

(B)(i) If--

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

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

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

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

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

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

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

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

(6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(e) Phase three

(1) Information about studies

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

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

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

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

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

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

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

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

(H) either--

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

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

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

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

(2) Time periods

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

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

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

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

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if--

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance,

the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Cancellation

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

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

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

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

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

(4) Guidelines

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

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

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

under paragraph (1).

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

(5) Monitoring

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

(f) Phase four

(1) Independent review and identification of outstanding data requirements

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

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

(2) Time periods

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

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

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

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

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if--

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Suspensions and penalties

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

(g) Phase five

(1) Data review

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

(2) Reregistration and other actions

(A) In general

The Administrator shall make a determination as to eligibility for reregistration--

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

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

(B) Product-specific data

(i) In general

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

(ii) Timing

(I) In general

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

(II) Extraordinary circumstances

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

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) Determination to not reregister

(i) In general

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

(ii) Timing for regulatory action

Regulatory action under clause (i) shall be completed as expeditiously as possible.

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

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

(ii) determine whether such tolerance or exemption meets the requirements of that Act;

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

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

(v) commence promptly such proceedings under this subchapter and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.

(h) Compensation of data submitter

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

(i) Fees

(1) Maintenance fee

(A) In general

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

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

(C) Total amount of fees

The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an average amount of $31,000,000 for each of fiscal years 2019 through 2023.

(D) Maximum amount of fees for registrants

The maximum annual fee payable under this paragraph by--

(i) a registrant holding not more than 50 pesticide registrations shall be $129,400 for each of fiscal years 2019 through 2023; and

(ii) a registrant holding over 50 registrations shall be $207,000 for each of fiscal years 2019 through 2023.

(E) Maximum amount of fees for small businesses

(i) In general

For a small business, the maximum annual fee payable under this paragraph by--

(I) a registrant holding not more than 50 pesticide registrations shall be $79,100 for each of fiscal years 2019 through 2023; and

(II) a registrant holding over 50 pesticide registrations shall be $136,800 for each of fiscal years 2019 through 2023.

(ii) Definition of small business

(I) In general

In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that--

(aa) has 500 or fewer employees; and

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

(II) Affiliates

(aa) In general

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

(bb) Affiliated persons

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

(cc) Indicia of control

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

(F) Fee reduction for certain small businesses

(i) Definition

In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that--

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

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

(ii) Waiver

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

(iii) Limitation

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

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

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

(I) The authority provided under this paragraph shall terminate on September 30, 2023.

(2) Other fees

Except as provided in section 136w-8 of this title, during the period beginning on March 8, 2019, and ending on September 30, 2025, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter or any other action covered under a table specified in section 136w-8(b)(3) of this title, except as provided in paragraph (1).

(j) Exemption of certain registrants

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

(k) Reregistration and expedited processing fund

(1) Establishment

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

(2) Source and use

(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the Reregistration and Expedited Processing Fund and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to offset the costs of registration review under section 136a(g) of this title, including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions. The Administrator shall, prior to expending any such moneys derived from fees--

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the Government Accountability Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely for the purposes specified in the first sentence of this subparagraph;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve the purposes specified in the first sentence of this subparagraph; and

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

(B) The Administrator shall also--

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

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

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

(A) For each of fiscal years 2018 through 2023, the Administrator shall use between $^{1}/_{9}$ and ⅛ of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources--

(i) to review and evaluate inert ingredients; and

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

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

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

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

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

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

frames specified in clause (ii) of section 136a(c)(3)(B) of this title on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 136a(c)(3)(B) of this title have been acted upon.

(4) Expedited rulemaking and guidance development for certain product performance data requirements

(A) Set-aside

For each of fiscal years 2018 through 2023, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Products claiming efficacy against invertebrate pests of significant public health or economic importance

The Administrator shall use amounts made available under subparagraph (A) to develop, receive comments with respect to, finalize, and implement the necessary rulemaking and guidance for product performance data requirements to evaluate products claiming efficacy against the following invertebrate pests of significant public health or economic importance (in order of importance):

(i) Bed bugs.

(ii) Premise (including crawling insects, flying insects, and baits).

(iii) Pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips).

(iv) Fire ants.

(C) Deadlines for guidance

The Administrator shall develop, and publish guidance required by subparagraph (B), with respect to claims of efficacy against pests described in such subparagraph as follows:

(i) With respect to bed bugs, issue final guidance not later than 30 days after March 8, 2019.

(ii) With respect to pests specified in clause (ii) of such subparagraph--

(I) submit draft guidance to the Scientific Advisory Panel and for public comment not later than June 30, 2018; and

(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than September 30, 2019.

(iii) With respect to pests specified in clauses (iii) and (iv) of such subparagraph--

(I) submit draft guidance to the Scientific Advisory Panel and for public comment not later than June 30, 2019; and

(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than March 31, 2021.

(D) Revision

The Administrator shall revise the guidance required by subparagraph (B) from time to time, but shall permit applicants and registrants sufficient time to obtain data that meet the requirements specified in such revised guidance.

(E) Deadline for product performance data requirements

The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance specified in clauses (i) through (iv) of subparagraph (B).

(5) Good laboratory practices inspections

(A) Set-aside

For each of fiscal years 2018 through 2023, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Activities

The Administrator shall use amounts made available under subparagraph (A) for enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations), with respect to laboratory inspections and data audits conducted in support of pesticide product registrations under this subchapter. As part of such monitoring program, the Administrator shall make available to each laboratory inspected under such program in support of such registrations a preliminary summary of inspection observations not later than 60 days after the date on which such an inspection is completed.

(6) Unused funds

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

(A) maintained on hand or on deposit;

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

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

(7) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) are used only for the purposes described in paragraphs (2), (3), (4), and (5) and to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of Title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

(l) Performance measures and goals

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

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

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

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

(m) Judicial review

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

(n) Authorization of funds to develop public health data

(1) "Secretary" defined

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

(2) Consultation

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

(3) Benefits to support family

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

(4) Additional time

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

(5) Arrangements

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

(6) Support

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

(7) Authorization of appropriations

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

CREDIT(S)

(June 25, 1947, c. 125, § 4, formerly § 3A, as added and renumbered § 4, Pub.L. 100-532, Title I, § 102(a), Title VIII, § 801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub.L. 101-624, Title XIV, § 1493, Nov. 28, 1990, 104 Stat. 3628; Pub.L. 102-237, Title X, § 1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895 to 1897; Pub.L. 104-170, Title I, § 103, Title II, §§ 210(c)(2), (f)(1), 232, 237, Title V, § 501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub.L. 107-73, Title III, [(1) to (4)], Nov. 26, 2001, 115 Stat. 686; Pub.L. 108-7, Div. K, Title III, [(1) to (4)], Feb. 20, 2003, 117 Stat. 513; Pub.L. 108-199, Div. G, Title V, § 501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub.L. 108-271, § 8(b), July 7, 2004, 118 Stat. 814; Pub.L. 110-94, § 4(a) to (d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub.L. 112-177, § 2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329; Pub.L. 116-8, §§ 2(a), (b), 3, Mar. 8, 2019, 133 Stat. 484, 485.)

Notes of Decisions (5)

7 U.S.C.A. § 136a-1, 7 USCA § 136a-1
Current through P.L. 116-193.

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 (74)

7 U.S.C.A. § 136n, 7 USCA § 136n
Current through P.L. 116-193.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

16 U.S.C.A. § 1532

§ 1532. Definitions

Currentness

For the purposes of this chapter--

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) between persons within one foreign country;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CREDIT(S)

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

Notes of Decisions (117)

16 U.S.C.A. § 1532, 16 USCA § 1532
Current through P.L. 116-193.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

16 U.S.C.A. § 1536

§ 1536. Interagency cooperation

Currentness

(a) Federal agency actions and consultations

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

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

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

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

(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 (844)

16 U.S.C.A. § 1536, 16 USCA § 1536
Current through P.L. 116-193.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.40

§ 155.40 General.

Effective: February 10, 2009
Currentness

(a) Purpose. These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

(1) Among other things, FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment. Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.

(2) If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA.

(b) Applicability. This subpart applies to every pesticide product registered under FIFRA section 3 as well as all pesticide products registered under FIFRA section 24(c). It does not apply to products whose sale or distribution is authorized under FIFRA section 5 or section 18.

(c) Limitations.

(1) At any time, the Agency may undertake any other review of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing, scheduled, or not yet scheduled registration review.

(2) When the Agency determines that new data or information are necessary for a pesticide's registration review, it will require such data under FIFRA section 3(c)(2)(B).

Credits
[73 FR 75595, Dec. 12, 2008]

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through December 3, 2020; 85 FR 78189.

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.42

§ 155.42 Registration review cases.

Effective: October 10, 2006
Currentness

(a) Establishing registration review cases. A registration review case will be composed of one or more active ingredients and all the products containing such ingredient(s). The Agency may group related active ingredients into a registration review case when the active ingredients are so closely related in chemical structure and toxicological profile as to allow common use of some or all required data for hazard assessment.

(1) Existing pesticides. The Agency will assign each pesticide registered on or before the effective date of this regulation to a registration review case.

(2) New pesticides. The Agency will assign each pesticide registered after the effective date of this regulation to an existing registration review case or to a new registration review case.

(3) A pesticide product that contains multiple active ingredients will belong to the registration review cases for each of its active ingredients.

(b) Modifying registration review cases. New data or information may suggest that a registration review case should be modified. The Agency may modify a registration review case in the following ways:

(1) Add a new active ingredient to a registration review case. The Agency may determine that a new active ingredient is chemically and toxicologically similar to active ingredients in an existing registration review case and should be grouped with the ingredients in the existing registration review case.

(2) Split a registration review case into two or more registration review cases. For example, new data or information may suggest that active ingredients in a registration review case are not as similar as previously believed and that they belong in two or more separate registration review cases.

(3) Move an ingredient from one registration review case to another. For example, new data or information might suggest that an ingredient should not be grouped with the other ingredients in the registration review case and that it belongs in a different registration review case.

(4) Merge two or more registration review cases into a single registration review case. For example, new data or information might suggest that the active ingredients in two or more registration review cases should be grouped together for registration review.

(5) Delete an active ingredient from a registration review case. For example, the Agency will remove the ingredient from the case if the registrations of all products containing an active ingredient in a registration review case are canceled.

(c) Closing a registration review case. The Agency will close a registration review case if all products in the case are canceled.

(d) Establishing a baseline date for a registration review case. For the purpose of scheduling registration reviews, the Agency will establish a baseline date for each registration review case. In general, the baseline date will be the date of initial registration of the oldest pesticide product in the case or the date of reregistration, whichever is later. For the purpose of these procedures, the date of reregistration is the date on which the Reregistration Eligibility Decision or Interim Reregistration Decision was signed, whichever date the Agency determines to be more appropriate based on the comprehensiveness of the review.

(1) The Agency generally will not change the baseline date for a registration review case when it modifies a case by adding or deleting ingredients or products.

(2) When the Agency splits a registration review case into two or more cases, the new case(s) generally will have the baseline date of the original registration review case.

(3) When the Agency merges two or more registration review cases into a single case, the Agency generally will use the earliest baseline date as the baseline date for the new case.

(e) Announcing registration review cases and baseline dates. The Agency will maintain a list of registration review cases, including baseline dates, on its website.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through December 3, 2020; 85 FR 78189.

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.50

§ 155.50 Initiate a pesticide's registration review.

Effective: October 10, 2006
Currentness

The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under § 155.46, and opening it for public review.

(a) Contents of the registration review case docket. The Agency will place in this docket information that will assist the public in understanding the types of information and issues that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any Federal Register notices regarding pending registration actions, and current or pending tolerances;

(3) Risk assessment documents;

(4) Bibliographies concerning current registrations;

(5) Summaries of incident data; and

(6) Any other pertinent data or information.

(b) Public review of the registration review case docket. The Agency will publish a notice in the Federal Register announcing the availability for public review of the information described in paragraph (a) of this section and establishing a comment period of at least 60 days. During this comment period, interested persons may identify any additional information they believe the Agency should consider in the course of the registration review.

(c) Submission of data and other information during the comment period. The Agency may identify, either in the notice published under paragraph (b) of this section, or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review. Any person may submit data or information in response to such identification. In order to be considered during a pesticide's registration review, the submitted data or information must meet the requirements listed below.

(1) In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section. The Agency may, at its discretion, consider data or information submitted at a later date.

(2) The data or information must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through December 3, 2020; 85 FR 78189.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.53

§ 155.53 Conduct of a pesticide's registration review.

Effective: October 10, 2006
Currentness

The Agency will review data and information described in § 155.50(a), (b), and (c) or submitted in response to a Data Call–In notice that it believes should be considered in the pesticide's registration review.

(a) Assess changes since a pesticide's last review. The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted under § 155.50 or in response to a Data Call–In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under § 155.50 or in response to a Data Call–In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) Conduct new assessments as needed.

(1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it can base the new assessment on available data or information, including data or information submitted under § 155.50 or in response to a Data Call–In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call–In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call–In notice under FIFRA section 3(c)(2)(B).

(c) Public participation during a pesticide's registration review. The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the Federal Register announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the Federal Register announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment.

(1) The Agency might not request comments on a draft risk assessment in cases where the Agency's initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, poses low risk, and/or requires little or no risk mitigation. In such cases, the Agency will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case.

(2) If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in § 155.58.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through December 3, 2020; 85 FR 78189.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.56

§ 155.56 Interim registration review decision.

Effective: October 10, 2006
Currentness

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through December 3, 2020; 85 FR 78189.

End of Document

50 C.F.R. § 402.02

§ 402.02 Definitions.

Effective: October 28, 2019
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 as a whole for the conservation of a listed species.

Director refers to the Assistant Administrator for Fisheries for the National Marine Fisheries Service, or his or her authorized representative; or the Director of the U.S. Fish and Wildlife Service, or his or her authorized representative.

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 are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. (See § 402.17).

Environmental baseline refers to the condition of the listed species or its designated critical habitat in the action area, without the consequences to the listed species or designated critical habitat caused by the proposed action. 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. The consequences to listed species or designated critical habitat from ongoing agency activities or existing agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.

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.

Programmatic consultation is a consultation addressing an agency's multiple actions on a program, region, or other basis. Programmatic consultations allow the Services to consult on the effects of programmatic actions such as:

(1) Multiple similar, frequently occurring, or routine actions expected to be implemented in particular geographic areas; and

(2) A proposed program, plan, policy, or regulation providing a framework for future proposed actions.

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; 84 FR 45016, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

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

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

Notes of Decisions (256)

Current through December 3, 2020; 85 FR 78189.

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. § 402.03

§ 402.03 Applicability.

Effective: May 4, 2009
Currentness

Section 7 and the requirements of this part apply to all actions in which there is discretionary Federal involvement or control.

Credits
[73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009]

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

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

Notes of Decisions (39)

Current through December 3, 2020; 85 FR 78189.

End of Document

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

50 C.F.R. § 402.13

§ 402.13 Informal consultation.

Effective: October 28, 2019
Currentness

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non–Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

(c) If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(1) A written request for concurrence with a Federal agency's not likely to adversely affect determination shall include information similar to the types of information described for formal consultation at § 402.14(c)(1) sufficient for the Service to determine if it concurs.

(2) Upon receipt of a written request consistent with paragraph (c)(1) of this section, the Service shall provide written concurrence or non-concurrence with the Federal agency's determination within 60 days. The 60–day timeframe may be extended upon mutual consent of the Service, the Federal agency, and the applicant (if involved), but shall not exceed 120 days total from the date of receipt of the Federal agency's written request consistent with paragraph (c)(1) of this section.

Credits
[73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 84 FR 45016, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

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

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

Notes of Decisions (16)

Current through December 3, 2020; 85 FR 78189.

End of Document

50 C.F.R. § 402.14

§ 402.14 Formal consultation.

Effective: October 28, 2019
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.

(1) A written request to initiate formal consultation shall be submitted to the Director and shall include:

(i) A description of the proposed action, including any measures intended to avoid, minimize, or offset effects of the action. Consistent with the nature and scope of the proposed action, the description shall provide sufficient detail to assess the effects of the action on listed species and critical habitat, including:

(A) The purpose of the action;

(B) The duration and timing of the action;

(C) The location of the action;

(D) The specific components of the action and how they will be carried out;

(E) Maps, drawings, blueprints, or similar schematics of the action; and

(F) Any other available information related to the nature and scope of the proposed action relevant to its effects on listed species or designated critical habitat.

(ii) A map or description of all areas to be affected directly or indirectly by the Federal action, and not merely the immediate area involved in the action (i.e., the action area as defined at § 402.02).

(iii) Information obtained by or in the possession of the Federal agency and any applicant on the listed species and designated critical habitat in the action area (as required by paragraph (c)(1)(ii) of this section), including available information such as the presence, abundance, density, or periodic occurrence of listed species and the condition and location of the species' habitat, including any critical habitat.

(iv) A description of the effects of the action and an analysis of any cumulative effects.

(v) A summary of any relevant information provided by the applicant, if available.

(vi) Any other relevant available information on the effects of the proposed action on listed species or designated critical habitat, including any relevant reports such as environmental impact statements and environmental assessments.

(2) A Federal agency may submit existing documents prepared for the proposed action such as NEPA analyses or other reports in substitution for the initiation package outlined in this paragraph (c). However, any such substitution shall be accompanied by a written summary specifying the location of the information that satisfies the elements above in the submitted document(s).

(3) 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.

(4) 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, a programmatic consultation, or a segment of a comprehensive plan. The provision in this paragraph (c)(4) does not relieve the Federal agency of the requirements for considering the effects of the action or actions 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 and environmental baseline 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) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action 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 as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) Biological opinions.

(1) The biological opinion shall include:

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

(ii) A detailed discussion of the environmental baseline of the listed species and critical habitat;

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

(iv) The Service's opinion on whether the action is:

(A) 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

(B) 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).

(2) A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(3) The Service may adopt all or part of:

(i) A Federal agency's initiation package; or

(ii) The Service's analysis required to issue a permit under section 10(a) of the Act in its biological opinion.

(4) A Federal agency and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service's biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. The Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat, and other relevant factors to determine whether an action or a class of actions is appropriate for this process. The Federal agency and the Service may develop coordination procedures that would facilitate adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service, if appropriate, as the Service's biological opinion in fulfillment of section 7(b) of the Act.

(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) Expedited consultations. Expedited consultation is an optional formal consultation process that a Federal agency and the Service may enter into upon mutual agreement. To determine whether an action or a class of actions is appropriate for this type of consultation, the Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat and other relevant factors. Conservation actions whose primary purpose is to have beneficial effects on listed species will likely be considered appropriate for expedited consultation.

(1) Expedited timelines. Upon agreement to use this expedited consultation process, the Federal agency and the Service shall establish the expedited timelines for the completion of this consultation process.

(2) Federal agency responsibilities. To request initiation of expedited consultation, the Federal agency shall provide all the information required to initiate consultation under paragraph (c) of this section. To maximize efficiency and ensure that it develops the appropriate level of information, the Federal agency is encouraged to develop its initiation package in coordination with the Service.

(3) Service responsibilities. In addition to the Service's responsibilities under the provisions of this section, the Service will:

(i) Provide relevant species information to the Federal agency and guidance to assist the Federal agency in completing its effects analysis in the initiation package; and

(ii) Conclude the consultation and issue a biological opinion within the agreed-upon timeframes.

(m) 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; 84 FR 45016, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

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

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

Notes of Decisions (270)

Current through December 3, 2020; 85 FR 78189.

End of Document

ADDENDUM OF DECLARATIONS

TABLE OF CONTENTS

PAGE(S)

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70787 (consolidated)

DECLARATION OF STEPHANIE BISHOP IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

I, STEPHANIE BISHOP, declare that if called to witness in this action I would competently testify of my own personal knowledge, as follows:

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

2. I have been a member of the Center for Food Safety (CFS) for about 5 years. I joined because I am very concerned for our environment and pollinators and do everything in my power to address these issues. I appreciate CFS's work to support organic farming and oppose industrial agriculture, and am thankful that CFS keeps its members informed about what they can do to help these issues. I have battled pesticide use for over 10 years: I joined the March Against Monsanto, I have written senators, signed petitions, gone to protests, and educated my neighbors on the dangers of pesticides.

3. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This includes being mixed with other chemicals for specific formulations like Roundup.

4. I live in Stevens Point, Wisconsin, which is a small university town, home of University of Wisconsin Stevens Point. I bought a property here—an urban forest—with the goal to get it certified organic and restore the chem-lawn to native plants and plants to encourage biodiversity. I wanted to create a wildlife sanctuary with the urban forest and prairie land for pollinators, but it has been a constant struggle.

5. I bought my property 10 years ago. It is a historic property with ancient trees, over 200 years old. I have planted for habitat and biodiversity, I got rid of the lawn, and registered it as a climate victory garden. Nothing has been sprayed here for the 10 years I have had it. I grow organic foods in my gardens including tomatoes, basil, zucchini, pumpkins, squash, beans, cucumbers, and berries.

6. I had to relocate my garden beds away from my property line because my neighbors were using glyphosate spray and granules. Once I moved my food beds, I began to reclaim the lawn to make it a prairie so my property has varying ecosystems with rich biodiversity. Birds and wildlife are abundant here because it is an oasis for them. This can be difficult at times, because they eat everything I plant.

7. I enjoy watching the birds and wildlife that visit, and pay special attention to the pollinators that come here. I have gone on bee walks every day for the last 10 years, where I watch and count the numbers and types of pollinators I see. I observe many insects, and have noticed that Monarchs, lightening bugs, and grasshoppers are all declining in population. I have observed less than 10 Monarchs this year, where in the past I have counted 50 in one afternoon.

8. The loss of pollinators affects me personally, not only by the reduced enjoyment from watching them as their population declines, but also due to the issues I have had with non-producing plants. I have ordered brand new vegetable seeds that bloom beautiful flowers but never produce fruit. Zucchini and squash used to be so bountiful, you had more than you could handle, but now that is not the case. These are

plants that require pollinators to produce fruit. Something is wrong with our pollinators, and it is extremely troubling when you can actually watch their populations decline and the impacts this has on food crops.

9. I have to actively protect my property from my neighbors' use of chemicals, especially along the property line. I have started to build a barrier of logs and other items along the fence line to keep the granular pesticide out, and have to be diligent that my neighbors do not get their lawn clippings in my yard. I am concerned for my health due to the use of glyphosate nearby, and took special precautions to protect my dog from the spray.

10. I have personal, economic, aesthetic, and recreational interests in protecting pollinators and wildlife from population decline due to glyphosate, and these interests are harmed by EPA's registration of glyphosate. Should these populations decline further, I would no longer enjoy my oasis and would be extremely disturbed by their absence. I rely on pollinators to produce food and maintain my wildlife sanctuary: the whole reason I purchased this land and want to spend my time here.

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

Executed on this 30th day of November 2020, in Stevens Point, Wisconsin.

STEPHANIE BISHOP

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF ELVIRA CARVAJAL IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. I speak Spanish and worked with a translator in the drafting of this declaration in English.

3. I am a member of Rural Coalition and have worked actively with Rural Coalition since 2008 to support better lives for both farmworkers and small farmers, including farmworkers trying to enter agriculture as producers.

4. I am also a founder of and an organizer for Grupo Amor de Homestead, which is a member organization of Rural Coalition.

5. I live in Homestead, Florida and worked at various nurseries for twenty years where orchids and various bromeliads are grown. Through my work at these nurseries, I have been exposed to glyphosate on numerous occasions. Neither I nor anyone I worked with was ever provided any kind of protective gear to prevent or reduce the amount of exposure to glyphosate when it was sprayed at these nurseries. I also never received any trainings.

6. Glyphosate is everywhere in south Florida where I live. Even if you do not work at the farms and nurseries where glyphosate is sprayed, these farms and nurseries are near housing, schools, and services so you can still be impacted by the spraying if it drifts offsite.

7. In 1987, I lost my six-month-old baby girl. I was never given an explanation as to what caused her death but I suspect that it is because of chemicals like glyphosate that I have been exposed to through my work at the nursery. I know another woman who works at the nursery and was four months pregnant when she experienced complications with her pregnancy. She had an emergency C-section and her baby was dead. She, like me, has been exposed to glyphosate on numerous occasions.

8. I and other women who have worked and continue to work at the nursery are afraid to complain about working conditions and health effects from spraying because anyone who speaks up for themselves will likely be replaced. If that happened, it would be very difficult to find other work.

9. Even if you report incidents and you are not replaced, there is often nothing done to address any harm. For example, I know one woman who suffered facial paralysis after she was sprayed in the field. However, when the supervisor was told what happened, he claimed there was nothing wrong her and her injuries were never addressed.

10. In addition to losing my six-month-old baby, my health has deteriorated since I started working at the nursery. I now struggle with arthritis. I believe that it is the exposure to pesticides like glyphosate that has caused the deterioration of my health, including my arthritis. It is awful to be put in a position to have to choose between your health and your job.

11. I do not believe that it has to be this way, though. There are alternative methods of weed control that do not require using toxic pesticides like glyphosate. I believe the use of glyphosate and other

chemicals is harming soil health in the region, in addition to harming the health of the workers who are exposed to these chemicals.

12. I am aware that EPA recently registered glyphosate again, allowing it to be continued to be used throughout the country, including the nursery where I work. I am also aware that as part of EPA's registration decision, the agency concluded that there are no occupational risks of exposure from glyphosate. It is disturbing that EPA could reach such a conclusion since glyphosate is known to be a toxic pesticide and workers like myself are exposed to high levels of the pesticide.

13. In sum, exposure to glyphosate has already affected my health and quality of life. EPA's recent registration decision that permits glyphosate to continue to be used further injures me from continued exposure in the community. Without a court finding the EPA violated its duties in issuing the current registration for glyphosate, my health interests will continue to be adversely impacted.

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

Executed on this 11th day of December 2020, in Homestead, Florida.

ELVIRA CARVAJAL

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF ELIZABETH CORDERO IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. I live in Oxnard, California.

3. I am member of Rural Coalition and joined the organization because I support its mission to protect farmworkers and their families by demanding fair and safe working conditions and dignity for farmworkers and food chain workers.

4. I am also an auxiliary Board Member and Delegate of Organización en California de Líderes Campesinas in California, which is a member of Rural Coalition. We represent farmworker women and provide them with the opportunity to coordinate their work statewide.

We build collectives so that *campesinas*, farmworker women, may become agents of change and be a more effective and unified voice.

5. I am also the co-founder and Board President of Alianza Nacional De Campesinas, which is a member of Rural Coalition. Our national organization is comprised of farmworker women and women from farmworker families. We work to ensure these women have a place at decision-making tables and lead the charge to set agendas for issues that are most important to them and their communities.

6. I am a nurse who works in rural clinics across thirteen locations in the agricultural fields of southern California. Many of the patients that come to our clinics for services have Alzheimer's disease, Parkinson's disease, and other chronic nervous system conditions resulting from agricultural chemical exposures in their places of work. These are serious conditions that alter farmworkers long-term health, quality of life, and occupational ability.

7. I personally know farmworkers who have spent long careers working with grapes, which are often sprayed with glyphosate, who now suffer from dementia. This affects their family, their quality of life, and deteriorates their health.

8. Other patients come to the clinics with symptoms of dermatitis, allergies, psoriasis, and eczema. These conditions are caused by exposure of agricultural chemicals, including glyphosate, to the skin, eyes, nose, and mouth. There are high risks to workers for long-term exposure to agricultural herbicides like glyphosate.

9. I have also seen the effects of glyphosate on children whose families live close to the agricultural fields or attend school near the fields. About fifty percent of these children experience allergies, asthma, attention-deficit/hyperactivity disorder, anxiety or depression. These are chronic conditions that will affect these children for the rest of their lives, harming their quality of life and health outcomes.

10. I am aware that EPA recently registered glyphosate again, allowing its continued use around the country, including the fields of southern California where I work and organize with farmworker women who are chronically affected by this issue. I am also aware that as part of that decision, EPA concluded that there are no occupational risks of exposure to glyphosate. As a nurse who has seen and treated numerous agricultural workers exposed to glyphosate, it is upsetting that the

agency charged with protecting public health and our environment could reach such a conclusion.

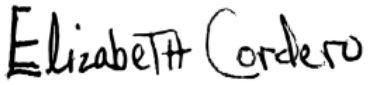
11. I am concerned that the continued registration of glyphosate will result in additional exposure through spray will worsen and expand the conditions of allergies, asthma, eczema, psoriasis, Parkinson's, dementia, Alzheimer's, for farmworkers in the fields of southern California.

12. I am also concerned that children who live or attend school near these agricultural fields will be disproportionately affected by allergies, asthma, anxiety, depression, or attention-deficit/hyperactivity disorder. These conditions will hamper their quality of life and result in chronic health conditions they will battle for the rest of their lives.

13. In sum, exposure to glyphosate has already significantly affected the health of the farmworkers we see in our rural clinics. EPA's recent registration decision that allows glyphosate to continue to be used further injures these farmworkers from continued exposure whenever they go to work in the fields. Without a court finding that EPA violated its duties in issuing the current registration for

glyphosate, the health interests of agricultural field workers in southern California will continue to be adversely impacted.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 11th day of December 2020, in Oxnard, CA.



ELIZABETH CORDERO

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF MARTHA CROUCH, PH.D. IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

I, MARTHA L. CROUCH, declare that if called as a witness in this action I would competently testify of my own personal knowledge, as follows:

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

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 soybeans. 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 CFS regarding these issues.

5. Besides my professional work, I am an amateur naturalist and I consider myself a "Craniac," as those of us who follow the whooping crane (*Grus americana*) populations often refer to ourselves.

6. I first became interested in whooping cranes about fifty years ago, when my mother gave me the book "North with the Spring," by Edwin Way Teale. In the book, Teale visited a lone whooping crane in a zoo in New Orleans in 1947, where he thought he might be experiencing the same feeling as those who viewed the last passenger pigeon experienced. I have been fascinated by and interested in

whooping cranes ever since, and I will continue to be for the foreseeable future.

7. I am aware that there are three populations of whooping cranes, two of which migrate, including a self-sustaining western population that overwinters in Texas, and migrates up through Oklahoma, Kansas, Nebraska, South Dakota, North Dakota and northeastern Montana to northeastern Alberta and the southern Northwest Territories in Canada where it summers and raises chicks, before migrating back.

8. I am aware that crane conservationists, out of concern that having the entire whooping crane population overwintering in one location put the species at risk from a single adverse event, received permission to raise an experimental population to reduce the risk to the species. That experimental eastern population now summers in Wisconsin and winters in Florida, with the help of a dedicated whooping crane recovery team.

9. The western population does not migrate where I live, but I have some friends in Rockport, Texas, whose house is near to the Aransas National Wildlife Refuge where the western population

winters. I purposefully time my visits to my friends who reside in Rockport, Texas to coincide with the "Whooping Crane Festival" in Port Aransas, Texas and nearby islands, so that I may see, watch, and observe the western flock of whooping cranes while they winter in Texas. On my last visit I saw two pairs of whooping cranes in the fields outside of the Aransas National Wildlife Refuge where they winter in Texas.

10. I plan to continue visiting my friends' residence in Rockport, Texas during the months when the whooping crane is wintering in the nearby wildlife refuge, so I can observe the western population. I am a senior citizen and cannot travel during the ongoing COVID-19 pandemic, but I intend to plan my next visit as soon as it is safe to do so.

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 visit these refuges every few months, and will continue to do so when it is safe to travel. I read news and blogs about both populations.

12. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This includes being mixed with other chemicals for specific formulations like Roundup.

13. I am worried about how EPA's registration of glyphosate may affect whooping cranes because they frequent agricultural fields where glyphosate is applied. The flyway of the western population goes right through parts of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas, where glyphosate is used on resistant corn, soybeans, and cotton. The eastern flock migrates through the states of Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida where glyphosate is used on resistant corn, soybeans, and

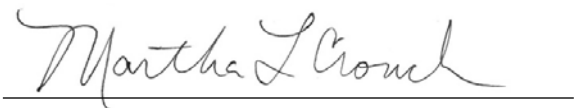
cotton. Many photos taken by birdwatchers of whooping cranes show them foraging in crop fields in the fall, including corn, soybean, and cotton fields, and I am aware that they also stop over in crop fields in the spring, where they have the potential to be exposed to toxic agricultural chemicals. During the spring migration north, whooping cranes may stop over in corn, soybean, and cotton fields that have been prepared for planting or recently planted, and sprayed with herbicides, including glyphosate. Cranes, including whooping cranes, are known to uproot corn seedlings and eat them, and thus they could be exposed to high levels of glyphosate residues.

14. I am aware that, based on the instructions and guidelines for glyphosate-containing herbicides on resistant corn, soybean, and cotton production, it is possible that food and water sources used by whooping cranes in these fields could or will have very high residues of glyphosate on them, the exposure to which may have adverse effects on the whooping cranes. EPA's registration of glyphosate thus injures my aesthetic and recreational interest in both the eastern and western flocks.

15. I do not believe that the risks of registering glyphosate 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 glyphosate to be used on corn, soybeans, and cotton in the agricultural fields which they migrate through and spend considerable time in, will be another serious stress that can and will severely harm their recovery.

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

Executed on this 12th day of November 2020, in Bloomington, Indiana.



MARTHA L. CROUCH, PH.D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF JEANNIE ECONOMOS IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I am the Coordinator of the Farmworker Association of Florida's Pesticide Safety and Environmental Health Project. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. The Farmworker Association of Florida (FWAF) is a state-wide, community-based, non-profit, farmworker membership organization with over 10,000 Haitian, Hispanic, and African American members. FWAF is headquartered in Apopka, Florida, and has four other offices in Fellsmere, Homestead, Immokalee, and Pierson, Florida.

3. Formed in 1983, FWAF's longstanding mission is to build power among farmworker and rural low-income communities, to

respond to and gain control over the social, political, economic, workplace, health, and environmental justice issues that impact their lives. FWAF's guiding vision is a social environment where farmworkers' contribution, dignity, and worth are acknowledged, appreciated, and respected through economic, social, and environmental justice. This includes farmworkers being treated as equals, and not exploited and discriminated against based on race, ethnicity, gender, or immigrant or socioeconomic status.

4. FWAF's core strategy is to help farmworkers realize and build upon their power to be effective agents of social and personal change. This includes validating and strengthening the experiences, knowledge, and understanding of farmworkers; building farmworkers' capacity to participate in decision-making processes that affect their lives; building multiracial coalitions with other farmworker organizations promoting civic engagement and better working conditions; organizing around community and labor issues; and raising consciousness about and advocating for farmworkers' rights and justice.

5. Toward this goal, FWAF's programs and activities build leadership, civic engagement, and activist skills among low-income

communities of color who are disproportionately affected by pesticide exposure and health problems related to that exposure, environmental contamination, institutional racism, harassment and intimidation, exploitation, and political under-representation.

6. When necessary, and as here, FWAF also engages in public interest litigation to protect the interests of rural farmworkers and communities. FWAF submitted organizational comments in 2019 to the EPA docket during its registration review of glyphosate, the pesticide product at issue in this petition for review.

7. As a party to this proceeding, FWAF and its members are injured by the interim registration review decision for glyphosate. FWAF and its members are concerned by the detrimental impacts on farmworkers, landscapers, and on the public health of rural farm communities that will result from the continued registration and use of glyphosate.

8. Many of FWAF's members are farmworkers and landscapers who live and work in rural areas where excessive amounts of glyphosate are used in ornamental plant nurseries and in landscaping. These members are especially susceptible to the health risks associated with

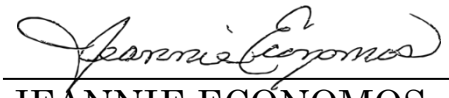
exposure to glyphosate, which is directly tied to EPA's decision in this case. Moreover, the intensive use of glyphosate on crops compromises our members' enjoyment of their local environment.

9. Many farmworkers, including many members of FWAF, are fearful of speaking out about their occupational exposure to pesticides and on how that exposure has affected their health and the health of their family and friends. The majority of farmworkers are immigrants and/or come from immigrant families and are afraid of retaliatory action if they discuss any harms they may have suffered from exposure to glyphosate through their work.

10. In sum, EPA's interim registration review decision for glyphosate injures FWAF's organizational interests in protecting farmworkers, rural farm communities and the environment. FWAF and its members will be redressed if and when this Court vacates the interim registration.

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

Executed on this 25th day of November 2020, in Apopka, FL.



JEANNIE ECONOMOS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF JAY FELDMAN IN SUPPORT OF PETITIONERS' RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I am the Executive Director of Beyond Pesticides. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the interim registration review decision for glyphosate.

2. Beyond Pesticides is a Washington, D.C.-based, nonprofit organization that works to protect public health and the environment with regard to pesticide use. I co-founded Beyond Pesticides in 1981 and have been its Executive Director since then. Beyond Pesticides has members in fifty states and the District of Columbia. Many of the members of Beyond Pesticides are adversely affected by glyphosate, a toxic herbicide that the U.S. Environmental Protection Agency (EPA) recently approved for continued use through an interim registration review decision, the challenged action at issue here.

3. Beyond Pesticides promotes safe air, water, land, and food and works to protect public health and the environment by encouraging

a transition away from the use of toxic pesticides, including herbicides such as glyphosate that is at issue in this lawsuit. With the resources of Beyond Pesticides made available to the public on a national scale, Beyond Pesticides contributes to a significant reduction in unnecessary pesticide use, thus improving protection of public health and the environment. The risks to public health and the environment from glyphosate is enormous.

4. To achieve its goals, Beyond Pesticides provides the public with resources and information on the risks associated with pesticides, including glyphosate.[1] Beyond Pesticides' *Gateway on Pesticide Hazards and Safe Pest Management* provides the public with easy access to current and historical information on pesticide hazards, and safe and organic pest management; drawing on and linking to numerous sources and organizations that include information related to pesticide science, policy, and action. The *Pesticide-Induced Disease Database* (PIDD), with over 1,011 studies, facilitates access to epidemiologic and laboratory

[1] *See Gateway on Pesticide Hazards and Safe Pest Management: Glyphosate*, Beyond Pesticides, https://www.beyondpesticides.org/resources/pesticide-gateway?pesticideid=37 (last visited Sept. 2, 2020).

studies based on real world exposure scenarios that link pesticides to public health effects, including asthma, autism and learning disabilities, birth defects and reproductive dysfunction, diabetes, Parkinson's and Alzheimer's diseases, and several types of cancer. Additionally, Beyond Pesticides' *Genetic Engineering* program publicizes the serious health and pest resistance problems related to genetically engineered (GE) crops as well as provides important links to activists working in the pesticide community.

5. When necessary, and as here, Beyond Pesticides also engages in public interest litigation to address the impacts of pesticides on the environment, its members, and the public interests. Beyond Pesticides submitted organizational comments in 2009, 2018 and 2019 on EPA's registration review of glyphosate.

6. Beyond Pesticides and its members are being, and will be, adversely affected by EPA's interim registration review decision for glyphosate. Many members of Beyond Pesticides live, work, and recreate in and near agricultural areas and other outdoor settings where glyphosate is being, or will be, applied or where crops treated with this harmful pesticide are being, or will be, planted. The rampant

increase in the use of glyphosate in U.S. agriculture and outdoor landscapes, which will continue due to EPA's decision, injures the members of Beyond Pesticides by interfering with their aesthetic enjoyment of outdoor spaces and biodiversity.

7. This is evident from EPA's recent Biological Evaluation, which acknowledged that 93% of the species listed as threatened or endangered under the federal Endangered Species Act are likely to be adversely affected by its decision to continue registering glyphosate. EPA also found that 96% of the critical habitat for these species is likely to be adversely affected by its decision. The scale of these likely adverse impacts on threatened and endangered species underscores severe threat that is posed by continued registration of glyphosate.

8. In sum, EPA's interim registration review decision adversely injures Beyond Pesticides' organizational interests, as well as the aesthetic, recreational, and personal health interests of our members.

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

Executed on this 10th day of December, 2020, in Washington, D.C.

JAY FELDMAN
Executive Director, Beyond Pesticides

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70787 (consolidated)

DECLARATION OF ALICE KEYES IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

2. I have been a member of the Center for Food Safety (CFS) for several years and support their work because they look into how industrial agriculture puts toxins into our ecosystem. These toxins filter into the groundwater, and people with wells—like me—end up ingesting them. I believe there are too many toxins in our food supply. I support CFS's mission to support organic agriculture and ensure that food labeling is clear and understandable for consumers, so we can be informed when foods are produced with pesticides or herbicides.

3. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This

includes being mixed with other chemicals for specific formulations like Roundup.

4. I am a resident of Paradise, Pennsylvania and have lived here since 2012. Paradise is rural, and is a bit of a tourist destination—somewhere for people from New York or New Jersey to get away from the city. I moved here because I've always liked my elbow room and wanted a yard to grow gardens for flowers or vegetables.

5. I am now retired, but I used to work as an insurance underwriter and also founded and ran a nonprofit that used horses for therapy. I am a lifelong gardener; I started at the age of three when my father taught me how to garden. I've planted things everywhere I have lived, from New Jersey to New Mexico to Pennsylvania. Whenever there was an open spot, I wanted to plant something on it. Gardening has been a constant part of my life and continues to be now.

6. Nearly all of the food I buy is organic, which is a strain on my budget. I am afraid to eat non-organic foods due to the pesticides, chemical fertilizers and herbicides, including glyphosate, which are used on them. It is painful how much more expensive organic foods are when you compare them to conventional foods at the store, and it takes

much more time to investigate and know whether foods are safe. Now that I know about the dangers of pesticides, chemical fertilizers and herbicides, I understand that these are simply the prices we must pay for real food.

7. Beginning in 1975, I lived at two places in Wantage, New Jersey. I did extensive gardening there, growing many flower gardens as well as tomatoes, radishes, beans, cucumbers, zucchini and lettuces. That is when I first began using Monsanto's glyphosate-based Roundup to get rid of weeds and poison ivy. I trusted that the government would not allow Roundup to be sold if it was not safe. I relied on Roundup to use on poison ivy for 36 years.

8. In 1990, I moved to Long Pond, Pennsylvania and did a lot of gardening there, relying on Roundup to keep the poison ivy and other weeds in check. From 2005 until 2011, I lived in Barnesville, Pennsylvania where I had a farm and horses. There, I planted mostly flowers, grasses, strawberries, herbs, shrubs (including blackberry and gooseberry), and trees. I continued using Roundup at this location.

9. At my current home in Paradise, I have mostly flower gardens. I have Rugosa roses, Black-Eyed Susans, mini roses,

Turtleheads, Asters, a native milkweed garden, and butterfly bushes for Monarchs to stop on during their migration. I have not used any pesticides or herbicides, including glyphosate, at this property.

10. I enjoy watching the pollinators that visit my flower gardens. I have tons of Monarch caterpillars, but am not sure how many survived to hatch this year. I grow Joe Pye Weed, a native species that grows tall with huge flower heads that bees love. I also enjoy watching the hummingbirds that visit my property. Pollinators are so necessary in the ecosystem for our food supply; without pollinators, we would have radically changed ecosystems without most of the food we enjoy today.

11. I also enjoy watching the birds and other wildlife that come to my yard. I have several bird feeders and get hours of enjoyment watching the "drama" outside while I wash my dishes. There are so many kinds of wildlife: squirrels, chipmunks, deer, opossum and the occasional bear. If the pollinators and wildlife in my yard decreased, I would lose the enjoyment I get from watching them.

12. I have personally witnessed the loss of honey bees, bumble bees, and pollinators (including Monarchs) in my area, which I believe is caused by neighbors spraying pesticides and herbicides like Roundup.

When I first moved to Paradise, my next-door neighbors had a large vegetable garden that had lots of produce. However, they sprayed Roundup for all kinds of weeds in their yard including clover and dandelions, and pesticides to kill bugs on their vegetable plants; in the last 4-5 years, they complained that they were no longer getting any produce from their vegetable plants. Over that same period, I noticed a distinct lack of butterflies, honey bees, and bumble bees when my neighbors were spraying. My neighbors initially decided to give up on their vegetable garden altogether and I suggested they stop spraying their yard. They did stop spraying the lawn to kill clover, but still use Roundup on other parts of the yard to kill weeds that pop up in mulched or graveled areas. Since they stopped spraying the lawn, the clover has returned and the pollinators have started coming back. The neighbors have made their vegetable garden much smaller than it used to be, but at least it is bearing fruit. However, I am concerned that the continued registration of glyphosate will allow products like Roundup to continue being sold, which is likely to further reduce overall populations of pollinators.

13. Last year, I was diagnosed with lung cancer. I never smoked a day in my life and know in my heart that the years of using glyphosate caused my cancer. I am very conscious of what I eat. I have been a vegetarian since 1977 and vegan since 2011, and do not buy processed foods. I was never in an occupation where I was exposed to hazardous chemicals that could have caused my cancer, either. Because I believed Roundup's advertising—that it was completely safe for humans and animals—I never wore a mask when applying it. I never wore protective gloves and often applied Roundup while wearing shorts and short sleeves. Now, I sign petitions and send letters to state and federal legislators about the dangers of glyphosate whenever I have the opportunity.

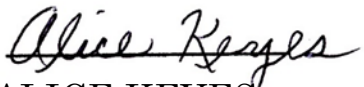
14. My cancer was stage 1 lung cancer adenocarcinoma in situ. I was treated at Sloan Kettering in New York, where they removed a lobe of my lung. I still have effects from this major surgery—shortness of breath and nerve damage. My doctors believe that they removed it all, so I did not have to do chemotherapy. However, my lead doctor, the chief of thoracic surgery at Sloan Kettering, said that there is a 30% chance the cancer will return or show up elsewhere in my body. As a

result, I go for CAT scans every six months to monitor everything. EPA's continued registration of glyphosate threatens my health and recovery from lung cancer.

15. In summary, my personal health and economic interests, as well as my aesthetic and recreational interests in the protection of pollinators and wildlife, have been and will continue to be injured by EPA's registration of glyphosate. Without a court finding that EPA violated its duties in issuing the current registration for glyphosate, my personal health and aesthetic and recreational interests will continue to be adversely impacted. EPA's failure to follow the law makes pollinators more likely to suffer population declines, which would deprive me from the benefits I currently enjoy from their existence.

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

Executed on this 3rd day of December 2020, in Paradise, Pennsylvania.



ALICE KEYES

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF GEORGE KIMBRELL IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I am the Legal Director for Center for Food Safety (CFS) and counsel in this case. I submit this declaration in support of Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Rural Coalition Petitioners) in this matter.

2. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; and Washington, D.C. CFS represents more than 975,000 farmer and consumer members, in every state throughout the country. CFS and its members are being, and will be, adversely affected by the EPA's registration decision for glyphosate.

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. Every day CFS staff works to address the adverse health and environmental impacts of our industrial food system, while at the same time

advocating for a more sustainable future for our food. When we think of "food safety" we mean it in a broad sense: food that is safe for people, but also safe for the planet and workers.

4. Accordingly, CFS's program activities cover the gamut of all aspects of the food and agriculture system including but not limited to: foodborne illness; truth in food labeling; ocean aquaculture and fisheries issue; livestock pollution; soil protection; industrial monocultures; new and emerging food technologies; and many more. A cornerstone of this mission is to advocate for thorough, science-based safety assessments of agricultural products and technologies.

5. As part of its broader mission one of CFS's flagship programs has always been addressing the adverse environmental, health, and socioeconomic impacts of pesticides. CFS has multiple staff—scientific, policy, and legal—that work on this program.

6. 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 issues including the adverse impacts and risks of pesticides.

7. Staff members regularly monitor the Federal Register and submit comments to EPA and other regulatory agencies via the public notice-and-comment process. CFS also regularly sends out action alerts to its members, encouraging them to participate in the notice-and-comment process, or to submit letters to government officials related to the oversight of industrial agriculture, pesticide use, genetically engineered crops, and other issues affecting CFS's mission to build a sustainable food system.

8. Here, CFS submitted organizational comments in 2009, 2018, and 2019 to the EPA docket during its registration review of glyphosate. CFS also submitted more than 100,000 comments on behalf of its members.

9. When necessary, CFS also engages in public interest litigation to address the impacts of industrial food production and pesticides on its members, the environment, and the public interest. As a party to this proceeding, CFS and its members are injured by EPA's glyphosate registration decision. EPA's decision means that glyphosate, the most widely-used pesticide in the country, will continue to be sprayed on hundreds of millions of acres annually. CFS and its members are greatly concerned about the detrimental impacts of this toxic spraying on farmers, the environment, including on endangered species and their habitat, and on their health.

10. CFS and its members are being, and will be, adversely affected by the challenged decision. First, 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 glyphosate will negatively harm creatures they care about, such as Monarch butterfly and other pollinators, injuring CFS members' recreational, vocational, environmental, and aesthetic interests.

11. Second, many of CFS's members are also farmers or gardeners and live in rural areas, where excessive amounts of pesticides

are sprayed over-the-top of commodity crops genetically engineered with resistance, including and especially glyphosate spraying. These members are especially susceptible to the health and environmental risks caused by EPA's continued registration of glyphosate, including cancer risks from exposure. Moreover, the intensive use of glyphosate on crops compromises our farmer members' enjoyment of their local environment and injures the aesthetic and recreational interests of our members in maintaining biodiversity and protecting sensitive species.

12. Third, CFS members' interests are also injured by EPA's failure to consult under the Endangered Species Act with the expert wildlife agencies before making this decision. EPA's recent and belated determination that 93% of listed species and 96% of their critical habitat are likely to be adversely affected by glyphosate confirms the dramatic adverse consequences of the agency's unlawful failure to consult with the expert wildlife agencies before issuing the challenged registration decision.

13. Many of CFS's members have significant personal, environmental, vocational, and recreational interests in regularly observing these imperiled species, including the whooping crane,

Indiana bat, least tern, and rusty-patched bumble bee and preserving their habitats. CFS's members' interests in biodiversity and protection of these sensitive species are injured by EPA's decision to issue the decision without consulting with the expert wildlife agencies.

14. Finally, members of CFS include farmers that have been damaged and will continue to be damaged by an ever-increasing epidemic of weeds that are immune to glyphosate. Glyphosate's registration and the consequential overuse of it has created an infestation of "superweeds" on over 100 million acres of U.S. cropland, creating substantial production costs and burdens for farmers, including CFS farmer members.

15. In sum, EPA's interim registration review decision for glyphosate injures CFS's organizational interests in protecting farmers, the public health, and the environment, as well as the vocational, environmental, aesthetic, recreational, economic, and personal health interests of CFS's hundreds of thousands of farmer and consumer 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 17th day of December, 2020, in Portland, OR.

GEORGE KIMBRELL
LEGAL DIRECTOR, CFS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF LESLIE LIMBERG IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

2. I have been a member of Petitioner Center for Food Safety (CFS) for roughly nine years. As a member of CFS, I rely on CFS to represent my interest in protecting biodiversity, including sensitive species and their habitats, from the adverse impacts of industrial agriculture and pesticide use through litigation, public education, and other means.

3. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This

includes being mixed with other chemicals for specific formulations like Roundup.

4. I live in Wentzville, Missouri. Wentzville is known as "the Crossroads of the Nation" and is within twenty miles of the Mississippi River and the Missouri-Illinois border. Glyphosate is frequently used on genetically engineered (GE) corn and soybean crops in this area.

5. I earned a Bachelor of Science in Nutrition and Dietetics from Dominican University. Although I am retired in my professional life, in my heart I will never retire. In my personal and family life, I always aim to avoid toxins, stay on the lookout for chemicals, and try to find honest food with the least amount of artificial ingredients.

6. I am also always looking for worthwhile causes to which I can lend and raise my voice. One way in which I have done so is being involved in bat habitat improvement, rehabilitation, and public education, particularly for the endangered Indiana bat (*Myotis sodalis*) and the little brown bat.

7. I am a current board member, and past president, of the Missouri Master Naturalists, a volunteer arm of the Missouri

Department of Conservation and the University of Missouri Extension. I have been a member since 2005.

8. I am concerned about the conservation of the Indiana bat's habitat and the species itself, because the bat is a keystone species. Indiana bats are indicators like the proverbial canary in the mine. They are hugely valuable pollinators and control vast swaths of millions of insects every night. They are exceptionally vulnerable to temperature change, microbial diseases, habitat change, and environmental contamination. The bat immune system is already seriously compromised, and it is under threat from chemicals in the environment. Without the Indiana bat, we ourselves are at risk.

9. I know that contributions to the Indiana bat's decline include disturbance from humans during winter hibernation, commercialization of caves, loss of summer habitat, pesticides and other contaminants, and the disease commonly known as white-nose syndrome.

10. In Missouri, the bat habitat consists of hardwood forests with numerous caves interspersed among farmland and watersheds. Caves, sinkholes, and karst formations produce perfect hibernation

temperatures for bats. Bat habitat is primarily porous dolomite-limestone caves carved out by underground water. These water sources are critical when conditions are hot and droughty, as well as in winter, with deep drops well below freezing temperatures. Groundwater with fertilizer, chemical, and pesticide run off can pollute these water sources that are so important for the bats.

11. Southern Illinois, where glyphosate is used on corn, soy, and cotton, is also extremely important for the Indiana bat's survival. Several major rivers converge and drain into the Mississippi River Watershed in this area. This watershed consists of important cropland and swampland for bats. Bats living in the caves of southern Illinois and Missouri can fly fifty to one hundred miles in a night and their primary feeding ground is wherever there are the most insects. The swamps of Illinois are important feeding grounds for bats, as they are breeding grounds for the insects on which bats subsist. In turn, the chemicals that are being used in croplands in Illinois and other Midwestern states threaten the bat's health, since the insects and larvae on which bats subsist feed on corn and soybean crops.

12. Glyphosate is detrimental in terms of the health hazards it poses to Indiana bat populations. Glyphosate is acutely toxic to bats, leading to reduced immune function, reduced brain activity, lowered fat reserves, and scarred wing membranes. Bats have natural mycorrhizal fungi that are native to bat health. Glyphosate alters these natural microorganisms that keep bat diseases in check. As bats penetrate and pollinate flowers and crops sprayed with glyphosate, this kills the native microorganisms that keep bats' immune systems strong, making them more susceptible to diseases.

13. Bats are an important indicator species, as they interact with all parts of the ecosystem from air to water. In addition to acute exposure and exposure from pollinating activities, bats can ingest glyphosate through contaminated water sources. Bats have the lowest of reproductive rates, at one young per year, so their survival and function with crop pollination is critical. Glyphosate-based herbicide formulations act as reproductive toxicants and threaten the survival of the endangered Indiana bat population.

14. As a member of the Missouri Master Naturalists, I have taken part in multiple activities to help protect the Indiana bat,

particularly to help research, reduce, and prevent occurrences of "white nose syndrome," an illness that has killed millions of bats since 2006, causing massive population declines for multiple hibernating bat species, including the Indiana bat.

15. One such activity is netting to help research occurrences of white nose syndrome. When bats come out of hibernation, we put up nets to capture the bats, and observe and record their weight, wingspan, occurrences of white nose syndrome, and their overall health.

16. Caves that serve as bat habitat must now be gated to reduce the vulnerability of fragile bats from park visitors and sports enthusiasts (spelunkers) who contribute to the spread of disease. With the Missouri Master Naturalists, I have also gated off caves to prevent the public from entering and spreading disease or otherwise disturbing the bats.

17. I have participated, and plan to continue to participate, in these activities in various locations throughout Missouri, including the Ozark National Scenic Riverways, Missouri's largest national park, in Shannon County; Washington State Park, in Washington County;

Johnson Shut-Ins State Park, in Reynolds County; and Elephant Rocks State Park, in Iron County.

18. The Missouri Master Naturalists also work to conserve Indiana bat populations in Illinois. As a volunteer with Missouri Master Naturalists, I have provided, and continue to provide, ongoing assistance on bat habitat conservation in southern Illinois. For example, I have helped with research on the impacts of flooding on populations of roosting colonies in Green Ash, Sweet Gum, and Pin Oak trees in the Greater Mississippi River floodplain and adjacent farmland, including the Oakwood Bottoms floodplain, in Jackson County, Illinois, east of the Big Muddy River and Cedar Creek; as well as in the Bluff Lake Swamp area, near Millcreek, in Union County, Illinois.

19. From 2007 to 2010, I did seasonal work from June through August with Bat Conservation International in Texas, approximately five hours a week, taking part in the Friday night public education event for locals and tourists to view and learn about Austin's South Congress Bridge bats. I also volunteered sixteen hours yearly with Bat Conservation International to build and install bat houses in Texas.

20. I will continue to assist with bat conservation efforts in northern Missouri, noting that migration and emergence through the Missouri Department of Conservation (MDC). When the COVID-19 pandemic is over and it is safe to travel, I plan to continue my out-of-state conservation efforts in Illinois and Texas.

21. At least 3 days a week, following advice of Xerces Society, I plant native habitats in Missouri, where I am an ecological restorationist. I establish native plant habitats specifically for pollinating species. I am very interested in conserving the endangered Monarch butterfly. Every year for the last three years, I have helped plant 2-3,000 milkweed plants from the MDC nursery in Central East Missouri for Monarchs. I created a half acre of pollinator habitat at the University of Missouri extension in St. Peters, Missouri. I also created habitat in at least eight county parks in St. Charles County, Missouri, to facilitate insect and bird populations. I am a lifetime member of the Missouri Prairie Foundation and know that reestablishing original habitat on Missouri prairies is very important for bats and other pollinators in Missouri.

22. In addition to these activities, I help with outreach and public education so humans do not disturb the bats and their habitats. I plan to continue these activities and continue to volunteer with conservationists.

23. In light of my ongoing efforts to protect and conserve the habitat of Indiana bats in both Missouri and Illinois, I am injured by EPA's registration of glyphosate, and by its failure to consult with the U.S. Fish and Wildlife Service (FWS) regarding the impacts that this decision will have on the Indiana bat population.

24. I am worried about how the registration of glyphosate may affect Indiana bats because they subsist on insects, moths, and larvae that frequent agricultural fields. Additionally, groundwater that may contain toxic chemicals or runoff from application of glyphosate may enter the caves that serve as habitat for the bats.

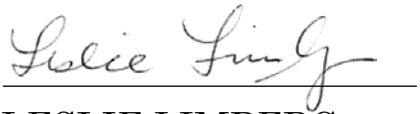
25. It concerns me that EPA failed to consult with FWS regarding the impacts of glyphosate on Indiana bats. Allowing glyphosate to be used on corn, soybeans, and cotton in the agricultural fields surrounding the bat habitat, and that serve as the habitat for the insects on which the bat subsists, will be another stress that will harm

the recovery of the Indiana bat. I am injured by the threat to the continued existence of the Indiana bat from the use of glyphosate.

26. In summary, I have personal, aesthetic, and recreational interests in the preservation of Indiana bats and their habitat. These interests are being harmed by EPA's failure to consult with FWS on impacts of its registration of glyphosate on the Indiana bat. Specifically, I believe EPA's failure to follow the law makes the species more likely to suffer further population declines. The decline of the Indiana bat injures my ongoing efforts to protect and conserve the species, and deprives me of the benefits I currently enjoy from their existence. Consultation with FWS could result in protective measures aimed at reducing impacts of this pesticide on the Indiana bat, which is important to ensure that my interests in the species are preserved and remain free from injury.

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

Executed on this 16th day of December 2020, in Wentzville, Missouri.



LESLIE LIMBERG

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF SUGUET LOPEZ IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I am the Executive Director of Organización en California de Líderes Campesinas. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition for Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. Organización en California de Líderes Campesinas (Líderes Campesinas) is a tax-exempt, nonprofit membership organization of 285 farmworker women and girls located in Oxnard, California and has organized its Chapters around rural regions in California, including: Salinas, Greenfield, Soledad, Madera, Huron, Merced, Fresno, Ventura County, Coachella Valley, Northern Santa Barbara, Sonoma, Napa, and Kern. Líderes Campesinas represents a culmination of decades of work by farm working women (*campesinas*). Farmworker women have been

the leaders of many grassroots and mobilizing efforts to improve the lives of farmworker communities. Líderes Campesinas provides these long-time leaders and activists with the opportunity to coordinate their work statewide and has built collectives so that *campesinas* may become agents of change and be a more effective unified voice. Líderes Campesinas and its members are being, and will be, adversely affected by the EPA's interim registration review decision for glyphosate.

3. The principal goal of Líderes Campesinas is to form a network of communication through California to promote the development of a united effort between *campesinas* and other groups who advocate the rights of the *campesina* community. Líderes Campesinas attempts to secure the progression of programs that help other *campesinas* discover their own capacity to be a leader and serve as a vehicle to guide them in the process of discovering their rights as a member of a family, local community, nation, and global community.

4. Líderes Campesinas operates in thirteen regional chapters in California and addresses a wide range of topics affecting *campesinos*, including the effects of pesticides on farmworkers and rural agricultural communities. Líderes Campesinas has educated farmworkers and

created brochures in Spanish to provide written information for *campesinas*, including brochures on how to prevent pesticide poisoning.

5. Líderes Campesinas has also worked with federal and state agencies and other organizations and public service providers to achieve better results on rural health issues.

6. When necessary, and as here, Líderes Campesinas also engages in public interest litigation to protect the interests of rural farmworkers and communities. Líderes Campesinas submitted organizational comments in 2019 to the EPA docket during its registration review of glyphosate, the pesticide product at issue in this petition for review.

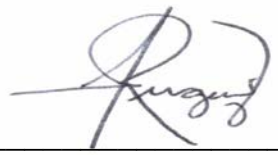
7. As a party to this proceeding, Líderes Campesinas and its members are injured by the interim registration review decision for glyphosate. Líderes Campesinas and its members are concerned by the detrimental impacts on farmworkers and on the public health of rural farm communities that will result from the continued registration and use of glyphosate.

8. Many of Líderes Campesinas' members are farmworkers and live in rural areas where large amounts of pesticides are sprayed on

genetically engineered crops that are resistant to glyphosate. These members are especially susceptible to the environmental and health risks associated with EPA's interim registration review decision from exposure to glyphosate through skin contact. Moreover, the intensive use of glyphosate on crops compromises our members' enjoyment of their local environment.

9. In sum, EPA's interim registration review decision for glyphosate injures Líderes Campesinas' organizational interests in protecting farmworkers, rural farm communities and the environment. Líderes Campesinas and its members will be redressed if and when this Court vacates the interim registration.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 16th day of December 2020, in Oxnard, CA.



SUGUET LOPEZ
EXECUTIVE DIRECTOR

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70787 (consolidated)

DECLARATION OF EDILIA MALDONADO IN SUPPORT OF PETITIONERS RURAL COALITION, ET AL.'S OPENING BRIEF

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

1. I am a member of Rural Coalition/Coalición Rural. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. I speak Spanish and worked with a translator in the drafting of this declaration in English.

3. I am a nursery worker in southern Florida who worked in ornamental plant nurseries from 2007 to 2017.

4. I am a member of Rural Coalition and joined the organization because I support its mission to create a just and sustainable food system. For me, the protection of farmworker families is an essential component of a more just and sustainable food system.

5. Through my work in ornamental plant nurseries, I was

exposed to pesticides containing glyphosate for ten years. When glyphosate was sprayed on the ornamental plants where I work, the spraying sometimes occurred all day, even when there were strong winds. In such instances, even with proper protection, including gloves and a facemask, I would still get glyphosate on my skin and into my lungs through spray drift.

6. I and other workers at the nursery often experienced nausea and headaches after glyphosate was sprayed.

7. One day, after my husband noticed visible changes in my appearance and I started to walk differently, I went to a neurologist. I took the labels of the pesticides that I have been exposed to, including glyphosate-formulated products.

8. Upon viewing the pesticide labels, my neurologist told me that it was likely my exposure to the chemicals sprayed in the fields where I worked that was affecting my nervous system. In particular, the neurologist said that it was two of the chemicals, one of which was glyphosate, that were affecting my nervous system.

9. I was subsequently diagnosed with Parkinson's disease and can no longer work because of the disease. In fact, I even struggle to

move around my home anymore because the disease is too severe. I can do some simple things around the house but I mostly require assistance from my son and friends.

10. I am aware that EPA recently registered glyphosate again, allowing its continued use around the country, including ornamental nurseries I long worked in and continue to live near.

11. I am concerned that the continued registration of glyphosate will result in additional exposure through spray drift due to the prevalence of spraying near where I live and that it could worsen my Parkinson's disease. For the rest of my life, I will have to deal with the health outcomes of exposure to glyphosate drift. I am also concerned about the health of other nursery workers who are routinely exposed to glyphosate on the job.

12. In sum, exposure to glyphosate has already significantly affected my health and quality of life. EPA's recent registration decision that allows glyphosate to continue to be used further injures me from continued exposure in my community, where glyphosate spraying is widespread. Without a court finding that EPA violated its duties in

issuing the current registration for glyphosate, my health interests will continue to be adversely impacted.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 16th day of December 2020, in Florida City, FL.

Edilia Maldonado

EDILIA MALDONADO

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF LORETTE PICCIANO IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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

1. I am the Executive Director of Rural Coalition. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. Rural Coalition is a tax-exempt, nonprofit membership organization located in Washington, D.C. Rural Coalition represents 50 grassroots and community based organizational members. Rural Coalition and its members are being, and will be, adversely affected by the EPA's interim registration review decision for glyphosate.

3. Born of the civil rights and anti-poverty rural movements, Rural Coalition has worked for 40 years to assure that diverse organizations from all regions, ethnic and racial groups and genders

have the opportunity to work in solidarity on the issues that affect us all. Rural Coalition amplifies the voices of our 50 grassroots member organizations, representing African American, American Indian, Asian American, Euro-American, Latino, and women farmers, ranchers, farm workers, and rural communities. Rural Coalition seeks: just and sustainable food systems that bring fair returns to our diverse small farmers and ranchers, tribal and other small communities; fair and safe working conditions and dignity for farmworkers and food chain workers; protection of mother earth now and for our children's children; and safe, adequate and healthy food for all, especially for the elders, youth, and most vulnerable among us.

4. With our members, Rural Coalition engages in an integrated program of public policy monitoring, technical assistance, capacity-building, participatory collaborative research, and education so that together we may secure the best possible federal policy outcomes and forge innovative, community-driven solutions with the grassroots communities we serve. Rural Coalition issues briefs and reports on various public policy matters including the Farm Bill. In our reports we have consistently addressed the needs and concerns of historically

underserved minority family farming communities. Another of Rural Coalition's core program areas is worker protection, including protection of farmworkers.

5. Rural Coalition staff submits comments to EPA, U.S. Department of Agriculture agencies, and other regulatory agencies via the public notice-and-comment process. Rural Coalition also regularly provides action alerts to its members to encourage effective participation in the notice-and-comment and other components of the administrative rule making process. State and federal lawmakers who legislate in the area of worker protections are accustomed to requesting and receiving frequent, informative written and verbal policy guidance from Rural Coalition that is useful in building and maintaining just and sustainable food systems of which farm worker protections is an essential component.

6. When necessary, and as here, Rural Coalition also engages in public interest litigation to address the impacts of the current industrial food production model and its impacts on farmworkers and rural communities. Rural Coalition submitted organizational comments

in 2019 to the EPA docket during its registration review of glyphosate, the pesticide product at issue in this petition for review.

7. Rural Coalition and its members are injured by EPA's interim registration review decision for glyphosate. Rural Coalition and its members are concerned by the detrimental impacts on farmers, farmworkers, and on the public health of rural farm communities that will result from the continued registration and use of glyphosate.

8. Many of Rural Coalition's members are farmers, farmworkers and/or live in rural areas where excessive amounts of glyphosate are applied to crops, including crops genetically engineered with resistance to glyphosate. These members are especially susceptible to the health risks associated with EPA's decision to continue registering glyphosate. Moreover, the intensive use of glyphosate on crops compromises our members' enjoyment of their local environment and the ecological balance in their communities.

9. Rural Coalition's farmworker member groups represent workers whose work is largely concentrated in the harvest of fresh fruits and vegetables. Many workers also work in the nursery industry, and also to maintain golf courses and other landscapes.

10. We work closely with our farmworker organizational members as they try to assist workers who suffer negative consequences from glyphosate exposure. Many farmworkers are afraid to report exposures for fear of losing their job. In addition, they are often reticent to seek medical care due to fear and loss of pay due to a lack of sick leave, as well as fear of unexpected medical costs and consequences for their immigration status. These workers are likely to have some of the most numerous and harmful consequences of glyphosate exposure.

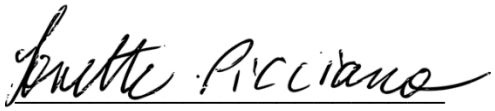
11. Members of Rural Coalition also include farmers that have already been damaged or are likely to be damaged by glyphosate. For example, many African American farmers in Alabama, who grow mostly southern vegetables like okra, crowder peas, collards, turnip and mustard greens, do not use glyphosate. However, many of these same farmers in Alabama and elsewhere grow these crops in proximity to soybeans, corn and peanut which are sprayed with glyphosate. This adds to the costs of production on their individual farm operations because they must often adapt their farm budgets, marketing, and general farm operations to protect against glyphosate spray drift from.

12. Many of our farmer members have reported that the emergence of weeds resistant to glyphosate has caused a treadmill effect where greater and greater amounts of other herbicides are sprayed on neighboring farms, causing additional harms from spray drift. Integrated pest management and other sustainable methods including the restoration of soil health, not more toxic chemicals, will be a much better investment to addressing the mitigation of invasive species, while protecting farm families, workers, pollinators and soil and water resources.

13. In sum, EPA's interim registration review decision for glyphosate injures Rural Coalition's organizational interests in protecting farmworkers, rural farm communities, and the environment, as wells as the health, economic, and personal interests of our members. Rural Coalition and its members will be redressed if and when this Court vacates the interim registration.

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

Executed on this 14th day of December 2020, in Washington, DC.



LORETTE PICCIANO
Executive Director

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70787 (consolidated)

DECLARATION OF BARBARA SHIPMAN IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety (collectively Petitioners) in their Petition of Review of the Environmental Protection Agency's (EPA) interim registration review decision for glyphosate.

2. I am a member of Rural Coalition and was elected to and serve on the Rural Coalition Board of Directors. I joined Rural Coalition because I support the organization's goal to ensure that socially disadvantaged farmers, youth with limited resources, and veteran women are included in the opportunities, economies, and future for small scale operators of agriculture business.

3. I am also the founder and Executive Director of Cottage House Incorporation, a nonprofit organization that works to inspire youth and help promote sustainable agricultural solutions and economic

development in rural Southeastern Alabama through community programs, entrepreneurship, leadership, life skills and more.

4. I live in Ariton, Alabama.

5. I am a US Army Veteran and have served in the Georgia and Alabama National Guard.

6. I am fifth-generation farmer and community leader in rural Southeastern Alabama. My farm is certified organic by the U.S. Department of Agriculture (USDA). USDA has also certified my farm for Good Agricultural Practices (GAP) growing fresh vegetables. These certifications are rare enough in my region—especially among African Americans and veterans—that teaching others about how to succeed as a farmer has become my second calling. In 2007, I received the Alabama A&M University's Distinguished Community Service Award for Youth Development and Agriculture. I received the USDA Alabama Natural Resources and Conservation Service Small Farmer of the Year Award in 2008, and was inducted into the Alabama 4-H Wall of Fame in December 2010.

7. In addition to farming full time, I have spent the last 15 years creating a beginning farmer curriculum, hosting over 1,000

children per year at Farmer Bootcamp, introducing them to farming, animal husbandry, planting and markets. Farmer Bootcamp also teaches an average of 20 new farmers per year to plan, plant, and operate farm business operations.

8. I have worked for many years to develop an organically certified farm. However, my local government routinely sprays glyphosate on weeds on land they own along the road where my farm is located. I have urged them to halt this practice because these applications can cause my crop to fail required testing at the state lab needed to maintain my organic certification. They have honored my request, because I have agreed to handle the mowing along the road adjacent to my land, at my own cost—an additional expense of my time.

9. I have also had to negotiate with a local power company, which has a right-of-way (ROW) for power lines and equipment on my land, to stop spraying glyphosate. This means I also need to bush hog (mechanically remove with my bush hog mower) the undergrowth on the ROW. The power company has supplied me access to do so—but it is also at my own cost and time.

10. In both cases, the mechanical weed removal works and protects my crops and my certifications from the threat posed by glyphosate.

11. I have also observed that fresh products including grapes and citrus that are grown in operations using glyphosate for weed control and purchased in grocery stores have a much shorter shelf life and are prone to mold. I find that organically produced products have a longer shelf life with less waste.

12. I am aware that the EPA recently registered glyphosate again, allowing its continued use around the country, including the roads that neighbor my farm.

13. I and other farmers are deeply concerned about the effects that glyphosate can have on the ecosystem services that provide for our farms and the potential harm to our organic certification. It takes a lot of work to acquire and maintain organic and GAP Certification and losing those certifications because of glyphosate drifting onto my farm would be devastating to my business. Many other farmers—and especially African American farmers in this area which has a deep history of plantation agriculture (cotton) and racial injustice—do not

have the same ability to negotiate with local entities to protect their farms without fear of affecting their relationships with local authorities and other farmers, or other forms of retaliation.

14. In sum, EPA's interim registration review decision for glyphosate injures my business and quality of life. EPA's decision to allow glyphosate to continue to be registered threatens me and my business with continued exposure to glyphosate along the road and on the ROW where my farm is located. In order to prevent glyphosate from being sprayed on the road and ROW, I must mechanically remove the weeds, which is an additional cost to me and my farm. Without a court finding that EPA violated its duties in issuing the current registration for glyphosate, my personal interests will continue to be adversely impacted.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 7th day of December, 2020, in Ariton, Alabama.

Barbara Shipman

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70787 (consolidated)
RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	Case No. 20-70801 (consolidated)

DECLARATION OF TERRY SHISTAR, PH.D. IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

I, TERRY SHISTAR, declare that if called to witness in this action I would competently testify of my own personal knowledge, as follows:

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

2. I am a member of Beyond Pesticides and have served on its board of directors since 1984. I joined Beyond Pesticides because I support the organization's mission to transition to a world that is free of toxic pesticides and I volunteer as the organization's science consultant. I am a regular contributor to *Pesticides and You*, which is Beyond Pesticides' journal that is published quarterly. I have also contributed to other publications, such as *Ending Toxic Dependency* (2007), and often comment on regulatory issues.

3. I live in Lawrence, Kansas, and am retired. I have a Ph.D. in Systematics and Ecology from the University of Kansas, where I also

taught seminars in hazardous materials policy, risk assessment, and environmental ethics.

4. In addition to my home in Kansas, I also own a cabin situated on approximately 100 acres in Andrew County, Missouri. This property is located along the Nodaway River and is partly in a conservation easement. I want to protect biodiversity and my land is an important island surrounded by large, conventional farms. There is a rare woodland wetland located on my property in a riparian woodland, which provides much needed habitat in a landscape that is otherwise dominated by agriculture.

5. I am concerned about the loss of pollinators and the role that pesticides, especially glyphosate, has had in their population decline. I specifically plant species like echinacea and rose mallow for the benefit of pollinators. I also let morning glory run wild, because bumble bees and hummingbirds love it. I have even let the morning glory overrun my vegetables because every morning I get to see the bumble bees and hummingbirds enjoying it. I also plant milkweed for Monarch butterflies and have multiple birdfeeders.

6. I am also concerned about the impact of glyphosate on threatened and endangered species like the least tern (*Sterna antillarum*). The least tern is the smallest of the terns in North America and nests on sand bars in river beds. In addition to being listed on the federal Endangered Species List, the least tern is also listed as endangered in both Kansas and Missouri.

7. The Kansas Department of Wildlife has designated portions of Douglas County, where my primary residence is, as critical habitat for least tern. In Missouri, where my cabin is located, the nearby Missouri River provides habitat important for least tern. In addition, the Nodaway River, which forms the boundary of my property, provides habitat for least tern, including numerous sandbars that are important for nesting. The nearby Nodaway Valley Conservation Area also provides nearly 4,000 acres of habitat for least tern and other wildlife and is designated as an Important Bird Area by Audubon Missouri.

8. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This includes being mixed with other chemicals for specific formulations like

Roundup. I am also aware that EPA recently determined that the least tern is likely to be adversely affected by its decision to continue the glyphosate registration.

9. EPA's registration of glyphosate affects me personally. Where my cabin is located, my property is surrounded by corn and soybean farms. The area to the west of my property is sprayed with glyphosate and it has drifted onto my property before. This directly affects my health and the health of species that I am concerned about and try to provide habitat for on my property. Even if glyphosate does not drift onto my property directly, the pollinators and endangered species like the least tern that I care about can still be affected if they forage on nearby land or water that has been sprayed with glyphosate or are impacted by contaminated runoff.

10. I have personal, aesthetic, and recreational interests in protecting pollinators and wildlife from population decline due to glyphosate and these interests are harmed by EPA's registration of glyphosate. Should the court overturn EPA's registration of glyphosate, it would create a lot of opportunities, because when you have an agricultural system that is so dependent on one chemical and you

remove that chemical from the mix, farmers could do something different, like growing organic produce. In 2019, organic sales in the U.S. topped $55 billion. Organic is a management system that works without chemicals like glyphosate and could be readily expanded if the court vacated EPA's registration. Vacating EPA's decision would also protect the pollinators and endangered species that I enjoy viewing on or near my property and for which I use my land to benefit.

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

Executed on this 10th day of December 2020, in Fillmore, Missouri.

TERRY SHISTAR, PH.D.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70801 (consolidated)
NATURAL RESOURCES DEFENSE COUNCIL, INC., et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, and NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., *Respondent-Intervenors.*	)	Case No. 20-70787 (consolidated)

DECLARATION OF MARIA WALKER IN SUPPORT OF PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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

1. I submit this declaration in support of the opening brief of Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety in their Petition for Review of the U.S. Environmental Protection Agency's (EPA) order approving the interim registration review decision for the herbicide glyphosate.

2. I have been a member of the Center for Food Safety (CFS) for at least ten years. I appreciate CFS's work in Hawai'i, and on Kauai in particular because of the many issues we face with genetically modified organisms (GMOs) and pesticides here. Organizations like CFS are really helpful for mitigating the harms of toxic pesticide use.

3. I am aware that in 2020, EPA issued an interim registration review decision for glyphosate. As a result of this decision, glyphosate can continue to be sold and used throughout the United States. This includes being mixed with other chemicals for specific formulations like Roundup.

4. I am a resident of Kapa'a, Hawai'i, located on Kauai. The island's population is 70,000. My town is a mixed rural area with lots of agricultural and homestead land. This island has the most available usable agricultural land, and has been used for sugar cane, pineapple, and other crops in the past.

5. In the 1990s, larger corporations like Syngenta and Bayer moved in to do research on corn due to our year round growing system. They became large employers in the area, and our state and county charge very low taxes for the use of the land. This agricultural research led to a lot of heavy pesticide applications near homes, schools, and a medical center. Because of the increased pesticide use, there is a high rate of negative health effects in the area, including birth defects, cancer, asthma, and children and teachers being hospitalized after spraying occurred nearby.

6. I am self-employed and do a mix of work including house cleaning, bookkeeping, and managing a costume shop for a theatre. My husband is a teacher at the local high school and the sustainability coordinator at Kaua'i Community College. We also keep bees.

7. We live on a half-acre with many native plants, a large garden, and many fruit trees both for the bees and our own enjoyment. I grow taro, green beans, avocados, bananas, mangos, passionfruit, citrus fruits, sugar cane, various kinds of greens and many other vegetables. I also have many flowering plants. I grow mamaki, ohia lehua, aweoweo, and pua kala specifically to attract native bees and butterflies.

8. When we first moved to this property sixteen years ago, we had many carpenter bees, which have since disappeared. I am extremely concerned about the loss of our native bee populations. There are seven species of yellow-faced native bee species that are endangered in Hawai'i, which we never see even though we plant things to attract them. There are two native butterfly species which are no longer present, and I never hear or see the native bat species which I used to enjoy watching here. I believe the loss of these species is due to the prevalence of glyphosate use on the island, which directly affects the health of pollinators and results in the loss of many host and foraging plants needed by our native species.

9. It is very rainy where I live: we are at an elevation of 500 feet and get at least 90 inches of rain per year. Things grow very fast

here because of this, and keeping on top of weeds can be difficult. People find it easy to spray pesticides to control weeds, and you see obvious places where big swaths have been sprayed and everything is brown and dead. Our state agriculture body is very supportive of pesticide use, and makes it very difficult to change the status quo.

10. I've had a lifelong interest in plants, and losing Hawai'i's native plants at such a rapid rate is extremely concerning to me. Many of these native plants are only surviving in botanical gardens where people actively propagate and protect them. I feel connected to this island and work hard to preserve and protect what is still here. Feeling the loss of these species causes powerful spiritual and emotional impacts for me.

11. I love seeing native animals and plants growing the way they are supposed to and fulfilling their role in the ecosystem. The growing lack of native plants is disturbing, and it is critical to protect the ones we have.

12. In Hawai'i, we import about 90 percent of our food products, even though in the past the islands produced much more of their own food. It is so important for us to have bees and other pollinators for food

production so we can start producing our own food again instead of shipping it here.

13. Before the COVID-19 pandemic, we used to sell our surplus fruits and vegetables at the local market. We also sold our honey and beeswax candles before the market was closed for the pandemic. We plan to continue selling these items when the market opens up and it is safe to attend again.

14. Every season, we have bee colonies that die off. I know that glyphosate affects bees' ability to locate themselves and find their way back to the hive. Glyphosate also affects bees' immune systems, and make them more susceptible to viruses and pests. We lose close to half of our hives every year, and all the beekeepers on the island have similar experiences. This is damaging both economically and emotionally, because this is part of our livelihood.

15. Because of glyphosate use on the island, almost all of the state tests done on honey revealed some amount of glyphosate. We do not spray on our property, but others do spray on their property, and the bees can carry it back to the hives. Consumers looking for honey

with absolutely no pesticide residues will have difficulty finding it, and this makes it harder for the beekeepers here.

16. Even though we are careful not to use pesticides on our property, I am concerned that we could experience health effects if use continues on the island. The West side of the island has higher rates of cancer, asthma, and birth defects due to the proximity and concentrations of agricultural land where pesticides are applied. I am concerned that as use continues, these risks will extend to where I live. I am disturbed by the fact that if my daughter were to come home and raise a family here, they might be exposed to glyphosate and experience detrimental health effects.

17. In summary, my economic, aesthetic, emotional, and spiritual interests in the protection of native plants and pollinators have been, and will continue to be, injured by EPA's registration of glyphosate. Without a court finding that EPA violated its duties in issuing the current registration for glyphosate, my interests will continue to be adversely impacted. EPA's failure to follow the law makes pollinators more likely to suffer population declines, which

would deprive me from the benefits I currently enjoy from their existence.

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

Executed on this 23rd day of November 2020, in Kapa'a, Hawai'i.

MARIA WALKER

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 15. Certificate of Service for Electronic Filing

Instructions for this form: http://www.ca9.uscourts.gov/forms/form15instructions.pdf

9th Cir. Case Number(s) 20-70801, 20-70787

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.

Service on Case Participants Who Are NOT Registered for Electronic Filing:

☐ 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' Rural Coalition et al.'s Opening Brief

Signature s/Amy van Saun **Date** Dec 18, 2020

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

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) 20-70801, 20-70787

I am the attorney or self-represented party.

This brief contains 14,000 **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/Amy van Saun **Date** Dec 18, 2020

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov