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

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

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

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

BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

Aaron Colangelo
Jared Thompson
Natural Resources Defense Council
1152 15th Street NW, Suite 300
Washington, DC 20005
Telephone: (202) 289-2376
Facsimile: (202) 289-1060

Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-2700
Facsimile: (212) 727-1773

Counsel for Petitioner Natural Resources Defense Council

Dated: October 23, 2015

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

Petitioner Natural Resources Defense Council, Inc. (NRDC) is a non-profit corporation with no parent corporation and no outstanding stock shares or other securities in the hands of the public. NRDC does not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUES AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Petitioner Natural Resources Defense Council (NRDC) challenges respondent U.S. Environmental Protection Agency (EPA)'s unlawful registration orders approving the new pesticide Enlist Duo under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These orders allow Enlist Duo to be sold and used in the United States for the first time. This case presents a textbook example of an administrative agency that erred by entirely failing to consider not one, but two important aspects of the problem before it: human cancer risk and harm to monarch butterflies. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Enlist Duo threatens the vulnerable remnant of North American monarch butterflies. The monarch butterfly, *Danaus plexippus*, is an iconic species famed for its annual migration across the continent. But the migrating population of butterflies has declined precipitously in recent years. This decline has been driven by sharply increasing applications of herbicides to herbicide-resistant crops, which has decimated milkweed, the sole food source for monarch caterpillars. In 1997, approximately one billion monarchs journeyed from summer habitat in the United States and Canada to wintering grounds in Mexico. That number has fallen by over ninety percent; in 2013, only about 33.5 million butterflies—a record low—

reached their winter refuge. Scientists have warned that the monarch migration is at risk of vanishing.

Enlist Duo is an herbicide that is specifically intended to kill milkweed and other target plants. It is designed for use on herbicide-resistant corn and soybeans—the very same uses that have been linked to pervasive milkweed destruction. Both of the active ingredients in Enlist Duo, glyphosate dimethylammonium salt (glyphosate) and 2,4-dichlorophenoxyacetic acid choline salt (2,4-D), are lethal to milkweed. In public comments to EPA, NRDC requested that the agency consider harm to milkweed and monarchs before registering the herbicide. EPA refused to consider the question and proceeded to register Enlist Duo anyway, in two separate orders: first in six states, and then in nine more. By ignoring this environmental harm, EPA violated its duty under FIFRA to ensure that registration of Enlist Duo would not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D).

EPA also erred by ignoring NRDC's request to fully evaluate the effects of glyphosate on human health before registering Enlist Duo. EPA's registration decisions relied on a health risk assessment that the agency conducted over two decades ago, and EPA did not consider significant new studies on glyphosate's cancer risk that have been published since that time. Shortly before EPA expanded Enlist Duo's registration, the World Health Organization's International Agency

for Research on Cancer published a groundbreaking finding that glyphosate is "probably carcinogenic to humans," based in part on research EPA ignored when registering Enlist Duo.

NRDC and other concerned groups promptly notified EPA of this finding, asking the agency to reconsider its initial Enlist Duo registration and not to register Enlist Duo for use in additional states until it considered and addressed the cancer risk. EPA ignored the new cancer finding and registered Enlist Duo for use in the additional states anyway, without explaining why it declined to evaluate the cancer risk. By failing to consider up-to-date science on glyphosate's cancer risk, EPA again violated its statutory duty to ensure that registration of Enlist Duo would not cause "unreasonable adverse effects on the environment," which includes an unreasonable risk to human health. 7 U.S.C. § 136a(c)(5)(C), (D); *id*. § 136(bb).

EPA's registration of Enlist Duo is not supported by substantial evidence, as required under FIFRA, because the agency completely failed to consider important aspects of how the registration would harm human health and the environment. Both registration orders should therefore be vacated as unlawful.

STATEMENT OF JURISDICTION

This Court has jurisdiction under FIFRA, which provides for review in the courts of appeals of "any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). NRDC is challenging EPA's October 2014 order

registering Enlist Duo in six states and March 2015 order registering Enlist Duo in nine additional states. As this Court has interpreted FIFRA, EPA's registration decisions "follow[ed] a public hearing" because EPA solicited and reviewed public comments before making its decisions. *See United Farm Workers of Am., AFL-CIO v. Adm'r, EPA*, 592 F.3d 1080, 1082-84 (9th Cir. 2010); *Pollinator Stewardship Council v. U.S. EPA*, 800 F.3d 1176, 1183 (9th Cir. 2015).

NRDC may bring this action because it was "a party to the proceedings" before the EPA and is "adversely affected" by EPA's orders registering Enlist Duo. 7 U.S.C. § 136n(b). NRDC participated in the agency proceedings by timely submitting comment letters to EPA opposing both proposed registration decisions. ER 451-86, 684-734. The comment letters objected to the registration of Enlist Duo without full assessments of potential adverse effects on monarch butterflies and human health. ER 454, 456-70, 486, 687, 689-702, 717.

In addition, NRDC and its members are "adversely affected" by EPA's registration of Enlist Duo.[1] Some of NRDC's members live in agricultural regions in the fifteen states where EPA approved use of Enlist Duo, and EPA's action increases the risk that these members will suffer health harms from exposure to the herbicide. *See, e.g.*, Gruber Decl. ¶¶ 3-9 (ADD 78-81); Jorgensen Decl. ¶¶ 3, 5-9 (ADD 84-87); Moravec Decl. ¶¶ 13-16 (ADD 94-95); Olmsted Decl. ¶¶ 3-7, 12

[1] As discussed further below, these adverse effects give NRDC standing to challenge the registration orders. *See infra* pages 36-39.

(ADD 98-100, 102); Wetzel Decl. ¶¶ 3-9, 15 (ADD 109-12, 114).[2] Registration of Enlist Duo also injures NRDC's members who derive aesthetic and recreational enjoyment from watching and interacting with monarchs, because Enlist Duo contributes to, and likely exacerbates, milkweed loss and monarch decline. *See, e.g.*, Atkinson Decl. ¶¶ 3-8 (ADD 66-69); Cady Decl. ¶¶ 2-10 (ADD 72-75); Moravec Decl. ¶¶ 3-12, 16 (ADD 90-93, 95); Olmsted Decl. ¶¶ 8-12 (ADD 100-02); Wetzel Decl. ¶¶ 10-15 (ADD 112-14).

Finally, pursuant to FIFRA, NRDC's petitions are timely and venue is proper in this Court because NRDC filed the petitions "in the United States court of appeals for the circuit wherein [NRDC] resides or has a place of business, within 60 days after the entry of [the challenged] order[s]." 7 U.S.C. § 136n(b). EPA's final order registering Enlist Duo for use in the initial six states was dated October 15, 2014, and NRDC filed a petition for review challenging that order on October 30, 2014. ER 7; Case No. 14-73353, ECF No. 1-1. EPA's final order registering Enlist Duo for use in nine additional states was dated March 31, 2015, and NRDC filed a petition for review challenging that order on April 20, 2015. ER 1; Case No. 15-71213, ECF No. 1-2. Venue is proper because NRDC has offices within the Ninth Circuit, in San Francisco and Santa Monica, California, and in Bozeman, Montana. Trujillo Decl. ¶ 4 (ADD 105).

[2] "ADD" indicates the page number in the addendum of standing declarations bound with this brief.

ISSUES PRESENTED

FIFRA prohibits EPA from registering pesticides that will cause "unreasonable adverse effects on the environment," which is defined to include "any unreasonable risk to man or the environment." 7 U.S.C. § 136a(c)(5)(C), (D); *id*. § 136(bb). Under the statute, EPA's registration decisions must be supported by "substantial evidence." 7 U.S.C. § 136n(b).

1. There is extensive evidence that use of herbicides, particularly those containing glyphosate, on herbicide-resistant crops has been a dominant cause of severe monarch butterfly population decline. By refusing to consider harm to the imperiled monarch population, did EPA lack substantial evidence to conclude that registration of Enlist Duo would not cause unreasonable adverse effects on the environment?

2. In the more than two decades since EPA last reviewed glyphosate's cancer risk, significant new studies have been published addressing that risk. Based on a comprehensive evaluation of the relevant peer-reviewed literature, the World Health Organization recently found that glyphosate is "probably carcinogenic to humans." By refusing to consider the new cancer finding and studies underlying it, did EPA lack substantial evidence to determine that registration of Enlist Duo would not cause unreasonable adverse effects on human health?

STATUTORY AND REGULATORY FRAMEWORK

Under FIFRA, any new pesticide must be "registered" with EPA before it can be distributed, sold, or used in the United States. 7 U.S.C. § 136a(a); *Pollinator Stewardship Council*, 800 F.3d at 1177. A pesticide includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," including any "weed," and thus includes chemicals commonly known as herbicides (or weed killers). 7 U.S.C. § 136(t), (u). FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C), (D); *accord* 40 C.F.R. § 152.112(e). The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

Before registering a pesticide, EPA is required to "review . . . all relevant data in the possession of the Agency" and determine "that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) [7 U.S.C. § 136a(c)(5)]." 40 C.F.R. § 152.112(b), (c); *accord Pollinator Stewardship*

Council, 800 F.3d at 1183. EPA's regulations require the agency to consider information "sufficient to evaluate the potential of the [pesticide] product to cause unreasonable adverse effects on man and the environment." 40 C.F.R. § 158.75.

After a new pesticide has been registered, EPA must periodically review that registration to make sure it is still considered safe in light of new science. *See* 7 U.S.C. § 136a(g). EPA must complete its review of each existing pesticide registration by either October 2022 or within 15 years after the date on which a pesticide containing a new active ingredient is first registered, whichever is later. *Id.* § 136a(g)(1)(A)(iii). Thereafter, EPA is required to conduct subsequent reviews of each pesticide registration every fifteen years. *Id.* § 136a(g)(1)(A)(iv).

EPA has explained that "Registration Review is a lengthy process that may take many years to complete" and that "the Agency's policy is to continue to make registration determinations for new actions during this process." ER 579. EPA has further explained that, despite the concurrent progress of any registration reviews, "[p]roposed new registrations are held to the most current data requirements and up-to-date risk assessment practices and must meet the FIFRA no unreasonable adverse effects standard to be registered." *Id.*

In addition to the required registration process (for new pesticides) and registration reviews (for existing pesticides), EPA has the authority to conduct interim administrative reviews of pesticide registrations if there is "significant

evidence raising prudent concerns of unreasonable adverse risk to man or to the environment." 7 U.S.C. § 136a(c)(8). To this end, EPA has promulgated regulations providing for Special Review of registered pesticides "to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment." 40 C.F.R. § 154.1.

The addendum attached to this brief includes a copy of all relevant statutes and regulations.

STATEMENT OF THE CASE

I. Enlist Duo is a new herbicide combining glyphosate and 2,4-D that will perpetuate glyphosate use and increase 2,4-D use

Enlist Duo is an herbicide manufactured by Dow AgroSciences, LLC that contains the active ingredients glyphosate and 2,4-D. ER 8. It is designed and registered for use on Enlist Duo-resistant corn and soybean crops. *Id.* In other words, Enlist Duo is specifically meant for application to corn and soybeans that are genetically engineered to resist the herbicide, so that it can be sprayed later in the growing season and in greater amounts, to kill weeds without killing the crops. ER 847-48, 900. The use of 2,4-D on herbicide-resistant crops is new. ER 8. Glyphosate has been used on herbicide-resistant crops for almost two decades, often under the trade name Roundup (a line of glyphosate-based herbicides developed by Monsanto). *See* ER 685, 689-93, 1162-63, 1169, 1181-83.

Widespread use of glyphosate has spawned a burgeoning problem of weeds that have developed glyphosate resistance. The U.S. Department of Agriculture has recognized that the "nearly exclusive use of glyphosate over the past fifteen years led to the selection of glyphosate-resistant . . . weeds, weeds that could survive an application of the herbicide that once would kill earlier generations."[3] In response to a three-year survey in thirty-one states, forty-nine percent of farmers reported having glyphosate-resistant weeds on their farms in 2012. ER 1028. In its comments to EPA in support of registering Enlist Duo, Dow stated that the problem of "increasing prevalence of glyphosate-resistant" weeds is "rapidly getting worse." ER 1148, 1151; *see also* ER 1169. And according to EPA, "resistance to glyphosate and other herbicides has become a significant economic and pest management issue to growers." ER 30.

Thus, under current use patterns, glyphosate is rapidly becoming ineffective. EPA has concluded that "[t]he continued viability of the glyphosate . . . technology is widely predicated on the containment of currently resistant weed biotype populations and the delay of any future resistant weed biotype population development." ER 852. And Dow has asserted that without new pesticides like

[3] Animal and Plant Health Inspection Service (APHIS), U.S. Dep't of Agric., Final Environmental Impact Statement for Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties, at iii (2014), *available at* https://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf.

Enlist Duo "to address problems with glyphosate-resistant weeds, U.S. growers will be forced to revert to earlier cultural practices" that did not rely so heavily on glyphosate. ER 1151.

Enlist Duo is intended to be "another tool that could prolong the viability of the glyphosate herbicide technology" by incorporating two herbicides with different mechanisms of action. ER 847, 853. In other words, the combination of chemicals in Enlist Duo is meant to kill weeds that would resist glyphosate alone. ER 846-48, 852.

Thus, at a minimum, Enlist Duo will facilitate the continued use of glyphosate at levels well above what would otherwise be expected, given glyphosate's declining efficacy. ER 847, 853. EPA did not assess how registration of Enlist Duo would affect total herbicide loading in the environment. ER 853. Rather, EPA noted that the analysis was "difficult" and the agency could reach no conclusions. *Id*. Nonetheless, EPA assumed (without citing any evidence) that Enlist Duo will not increase total glyphosate use, because it expects Enlist Duo to substitute for existing uses of other glyphosate-containing pesticides. ER 586.

If Enlist Duo works as designed, however, it has the potential to expand glyphosate use by enticing additional growers to switch from conventional crops to herbicide-resistant Enlist Duo crops. Despite tremendous growth in the proportion of corn and soybean crops that are herbicide-resistant, there is still substantial room

for increases in herbicide-resistant corn acreage. ER 1169 (noting that, as of 2011, only 72 percent of corn acres were herbicide-resistant, compared to 94 percent of soybeans). Enlist Duo is designed to appeal to growers by giving them an herbicide option that can overcome glyphosate-resistant weeds and be used over a longer portion of the growing season. ER 846-48.

As for 2,4-D, EPA recognized that registration of Enlist Duo makes it "likely that 2,4-D use will increase." ER 853. The Department of Agriculture agreed, predicting that approval of Enlist Duo will cause a two- to six-fold increase in the overall use of 2,4-D. APHIS, *supra* note 3, at x. The Department of Agriculture further noted that approval of Enlist Duo will allow 2,4-D "to be used over a wider part of the growing season." *Id*.

II. Enlist Duo poses a significant risk to monarch butterflies

The use of herbicides on herbicide-resistant crops is a leading cause in the sharp decline of the eastern population of North American monarch butterflies.[4]

Each spring, the monarch population embarks on a multi-generational migration that begins in the forests of central Mexico. ER 898, 1236. The butterflies fly north across the United States, reproducing along the way. ER 898,

[4] Monarch butterflies are found both east and west of the Rocky Mountains, although the western population is much smaller than its eastern counterpart. This brief focuses on the eastern population of North American monarchs, because it is this population that traverses the fifteen states where EPA has approved the use of Enlist Duo. References to the monarch population in this brief are specifically to the eastern population of North American monarchs.

1236. By mid-to-late summer, over the span of four to five generations, the population reaches southern Canada. ER 1236. In the fall, the last generation of monarchs flies back to the same forests in Mexico where the population's journey began. *Id.* The butterflies overwinter in Mexico until spring, when the migration cycle begins again. *Id.* The entire migration spans over 2,500 miles. ER 696.

The monarch population cannot complete this extraordinary migration unless it encounters sufficient milkweed along the migratory pathway. ER 693, 695. Because monarch caterpillars depend solely on milkweed plants for their development, migrating female monarch butterflies seek out milkweed on which to lay their eggs. ER 686, 695, 898. When milkweed is scarce, females deplete large amounts of body fat in search of the plant, which can cause them to lay fewer eggs or even die before having the chance to lay eggs. ER 695. With fewer eggs laid, the number of next-generation monarchs available to complete the migration and return to Mexico diminishes. ER 1240. Reduction of milkweed also decreases the number of caterpillars that survive to adulthood, by intensifying competition over a limited food supply. ER 807, 821.

EPA registered the first pesticide containing glyphosate in 1974 and re-registered glyphosate-based pesticides in 1993.[5] ER 685, 690-91. As a non-

[5] Glyphosate was re-registered pursuant to 7 U.S.C. § 136a-1, which required EPA to re-register pesticides that were first registered before November 1, 1984. The re-registration process is separate from both the initial registration

selective herbicidal ingredient, glyphosate does not discriminate between target and non-target plant species; in other words, it can damage and kill both crops and weeds. ER 685, 690. Growers thus initially limited their use of herbicides containing glyphosate. ER 685, 690.

In the mid- to late-1990s, however, glyphosate-resistant corn and soybeans came into wide use. ER 691. This triggered a dramatic increase in the application of glyphosate-based herbicides. ER 690-91. Between 1989 and 1991, before glyphosate-resistant crops were developed, 18.7 million pounds of glyphosate were used on between thirteen and twenty million acres annually; between 2008 and 2009, 182 million pounds of glyphosate were used on over 261 million acres annually—an approximate tenfold increase. ER 690-92.

Glyphosate kills the milkweed on which monarchs rely. ER 693, 899. Milkweed loss, particularly in the agricultural Midwest, has been well documented, and is in large part attributable to increased glyphosate use. ER 890, 1236. A survey of milkweed in Iowa corn and soybean fields in 1999 found milkweed in at least fifty percent of fields. ER 694. By 2009, milkweed was recorded in only eight percent of the fields. *Id.* Additionally, the overall area occupied by milkweed within the fields decreased by ninety percent. *Id.* Relying on these and other data,

---

required by 7 U.S.C. § 136a(a) and the registration review required by 7 U.S.C. § 136a(g). Re-registration was a one-time review of the safety of previously registered pesticides that has now been concluded.

one study extrapolated the loss of milkweed in both agricultural and non-agricultural areas across the entire Midwest and found a fifty-eight percent decline in milkweed from 1999 to 2010. ER 695.

The extensive loss of milkweed has devastated the monarch population. The American Midwest, in particular, constitutes a significant portion of the monarchs' migratory pathway. ER 820-21, 1274. Fifty percent of monarchs that overwinter in Mexico feed on Midwestern milkweed as caterpillars, so reduced milkweed availability in this region has significant effects on the entire population. ER 693, 1274. Furthermore, monarchs tend to lay more eggs in agricultural areas than in non-agricultural areas. ER 694-95. The decline of milkweed in the agricultural Midwest has thus caused a greater-than-proportional reduction in monarch reproduction. *See* ER 695.

Decreased monarch production has, in turn, caused the monarch population to dwindle. During the same period that herbicide-resistant crops became prevalent in the United States, leading to rapidly accelerating herbicide use and milkweed loss, there has been a corresponding and statistically significant decline in the overwintering monarch population in Mexico. ER 695-96. The overwintering population dropped from a high of approximately one billion butterflies in 1997 to a low of approximately 33.5 million butterflies in 2013. ER 689, 695-96.

There is broad scientific consensus among monarch experts that a driving force behind the butterfly's decline is the loss of milkweed in the United States due to the widespread use of herbicides, particularly those containing glyphosate, on herbicide-resistant crops. *See, e.g.*, ER 452-53, 456-65, 684-86, 689-97, 820-21, 890, 898-901, 1203-04, 1236. A 2014 study examining the various threats to the monarch population concluded that "[r]ecent population declines stem from reduction in milkweed host plants in the United States that arise from increasing adoption of genetically modified crops and land-use change, not from climate change or degradation of forest habitats in Mexico." ER 806. The study further concluded that "conserving monarch butterflies by addressing the negative impacts of changing land-use and the adoption of genetically-modified, herbicide resistant crops on host plant abundance is the highest conservation priority." ER 821.

There are several factors underlying this connection between herbicides, herbicide-resistant crops, and milkweed and monarch decline. Herbicides are used more frequently, and at higher rates, when applied to herbicide-resistant crops. ER 899-900. This is particularly destructive to milkweed, because herbicides that cause limited damage to weeds when applied at lower rates are often much more damaging when sprayed at higher rates. ER 900. In addition, milkweed tends to regrow when it is mowed, damaged by tilling, or treated with herbicides that are applied before milkweed shoots emerge in late spring. ER 899. But when

herbicides are paired with herbicide-resistant crops, they can be applied later in the growing season during the milkweed plant's most vulnerable flowering stage. *Id.*

EPA's registration of Enlist Duo poses a significant risk to the beleaguered monarch population. Enlist Duo is specifically intended for suppression of milkweed. ER 57. The final, approved label for Enlist Duo products recommends application "when most [common milkweed] plants have reached the late bud to flower stage of growth." *Id.* Both active ingredients of Enlist Duo, glyphosate and 2,4-D, are toxic to milkweed. ER 899-900. Compounding the risk to monarchs, EPA registered Enlist Duo for use in fifteen states that fall squarely within the monarch's crucial breeding habitat. *Compare* ER 2, *with* ER 1274.

The migrating monarch population is already so diminished that its prospects for recovery are fading. ER 696-97. Continued milkweed loss renders the population susceptible to further decline, compromising its ability to withstand additional stressors such as severe weather, freezing temperatures, disease, predation, and deforestation. *See* ER 696-97, 1244, 1248-49. In 2010, a single storm killed approximately fifty percent of the monarchs overwintering in Mexico—that is, more than the total number of overwintering monarchs measured three years later in 2013. ER 1249; *compare* ER 1247 (noting that overwintering monarch colonies occupied a total of 1.92 hectares during the 2009-2010 winter season), *with* ER 696 (explaining that the area occupied by overwintering

monarchs is a proxy for population size and noting that the butterflies occupied a total of only 0.67 hectares, or 1.65 acres, during the winter of 2013). Given its current size, the monarch population is susceptible to complete eradication by comparable storms. The smaller the population becomes, the more vulnerable it is to these kinds of random events. Additional destruction of milkweed habitat in the butterflies' breeding ground thus puts the monarch at further risk. ER 461-65, 694-97. The population is so precariously small that experts—including those at the Department of Agriculture—have warned that the monarch migration may be coming to an end. ER 456-57, 465 & n.61, 689, 697.

III. Enlist Duo may pose a serious risk to human health

In addition to harming monarchs, Enlist Duo may also threaten human health. In 1985, a committee within EPA's Toxicology Branch concluded that glyphosate was a Category C oncogen, meaning that there was evidence in animal studies that the chemical was possibly carcinogenic to humans.[6] ER 1497; *see also* ER 1525-38. In 1991, based in part on the diagnosis of a single additional tumor in a control group mouse, ER 1515-16, EPA reclassified glyphosate as a Group E oncogen, meaning that there was "evidence of non-carcinogenicity for humans," ER 1316, 1495. A peer review committee "emphasized, however, that designation

[6] EPA, Risk Assessment for Carcinogens, http://www2.epa.gov/fera/risk-assessment-carcinogens (Oct. 2, 2015).

of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances." ER 1495.

In its decision to re-register glyphosate-containing pesticides in 1993, EPA relied on its 1991 designation of glyphosate as a Group E oncogen to conclude that glyphosate has low toxicity to humans. ER 1315-16. There is no evidence in the record that EPA reviewed any more recent studies on glyphosate's cancer risk before registering Enlist Duo.

Since the early 1990s, however, the state of the science on that question has changed. *See* Hsieh Decl. Ex. A, ECF No. 105-3, at 3.[7] In March 2015, the World Health Organization announced that glyphosate is "probably carcinogenic to humans." *Id.* In reaching that conclusion, the World Health Organization undertook a comprehensive evaluation of relevant studies, examining not only EPA's findings from the 1980s and early 1990s, but also evaluating the more recent science published in the decades since. Hsieh Decl. Ex. B, ECF No. 105-4, at 2-3. According to the President's Cancer Panel, these World Health Organization reports are the "gold standard" in evaluating evidence on cancer

[7] For clarity when citing documents filed with this Court, this brief uses the page numbers assigned by the ECF system in the document header.

causation.[8] EPA was aware of this cancer finding before it took final action to expand the Enlist Duo registration, but refused to consider it. Hsieh Decl. Ex. C, ECF No. 105-5, at 2-3.

IV. Procedural history

EPA first proposed to register Enlist Duo for use on herbicide-resistant corn and soybeans on April 30, 2014. ER 855-56. In its proposal, EPA assessed some of the anticipated harms from the expanded use of 2,4-D that would result from the registration, but concluded that "no new assessment is needed for glyphosate" because use on herbicide-resistant crops "is not a new use for glyphosate containing products." ER 856. NRDC timely submitted comments opposing the proposed registration on June 30, 2014. ER 684-734.

NRDC's comments asserted that EPA could not lawfully register Enlist Duo without first considering all environmental and human health harms. ER 686-87, 717. The comments explained in detail how increasing use of herbicides on herbicide-resistant crops has caused severe declines in milkweed and monarch butterflies, and asserted that approval of Enlist Duo would perpetuate and worsen that harm. ER 690-97. NRDC also noted that, since EPA re-registered glyphosate-

[8] President's Cancer Panel, U.S. Dep't of Health & Human Servs., Reducing Environmental Cancer Risk: What We Can Do Now 13 (2010), *available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

containing pesticides in 1993, over 3,000 new studies have been published on glyphosate's health effects. ER 687, 701. Other commenters similarly requested that EPA evaluate all effects of Enlist Duo on human health and the environment, including effects on monarch butterflies. *E.g.*, ER 743-52, 781-92, 1203.

On October 15, 2014, EPA registered Enlist Duo for use in six states.[9] ER 7-8, 36. EPA assessed only some aspects of how the 2,4-D in Enlist Duo would affect human health and the environment, and "no new assessments were performed for glyphosate." ER 8. EPA did not indicate when it last conducted environmental and human health assessments for glyphosate, but the most recent comprehensive assessments in the administrative record are from 1993, when EPA re-registered glyphosate-containing pesticides. *See* ER 1312-58, 1377. Of particular concern here, EPA refused to consider the question of whether and how Enlist Duo will harm monarch butterflies, and entirely ignored comments regarding new evidence of glyphosate's human health risks from the past two decades. ER 577, 579.

On October 30, 2014, NRDC filed a petition for review in this Court challenging the registration. Case No. 14-73353, ECF No. 1-1. That same day, a group of petitioners led by the Center for Food Safety filed a separate petition for review challenging the registration. Case No. 14-73359, ECF No. 1-2. The Court

[9] Those states are Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. ER 2.

consolidated the two lawsuits in December. Case No. 14-73353, ECF No. 11. Petitioners' requests for administrative and judicial stays of the registration were denied. Case No. 14-73353, ECF No. 15-18, 94.

In the meantime, on October 15, 2014, EPA proposed to expand the registration of Enlist Duo for use in ten additional states. ER 553. NRDC timely submitted comments in opposition to the expanded registration, again asserting that FIFRA requires EPA to consider Enlist Duo's potential effects on human health and the environment (including harm to monarch butterflies) before approving it. ER 451-86.

On March 20, 2015, the World Health Organization published its finding that glyphosate is "probably carcinogenic to humans." Hsieh Decl. Ex. A, ECF No. 105-3, at 3. Days later, NRDC and other concerned parties wrote to EPA and requested that, in light of the World Health Organization's finding, EPA reconsider its initial Enlist Duo registration and not register Enlist Duo for use in additional states. Hsieh Decl. Ex. C, ECF No. 105-5, at 2-3.

Ignoring the World Health Organization's finding, EPA registered Enlist Duo for use in nine additional states in an order dated March 31, 2015.[10] ER 1-2.

[10] Those states are Arkansas, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, and Oklahoma. EPA registered Enlist Duo for use in nine additional states instead of ten, as originally proposed, because it identified potential harm to endangered species in the tenth state, Tennessee. ER 1-2, 4, 6.

To support the expanded registration, EPA relied almost entirely on its analyses from the initial Enlist Duo registration the previous fall, and completed only one additional evaluation that considered effects on endangered species in the additional states. ER 2. There is no evidence in the record that EPA reviewed any of the post-1991 studies on which the World Health Organization relied to conclude that glyphosate is a probable human carcinogen. *Compare* Hsieh Decl. Ex. A, ECF No. 105-3, at 3, *with* Certified Index to the Admin. Record, Case No. 15-71207, ECF No. 21-2.

NRDC filed a second petition for review challenging EPA's second registration order, as did the Center for Food Safety petitioners. Case No. 15-71213, ECF No. 1-2; Case No. 15-71207, ECF No. 1-2. The Court subsequently consolidated all of the petitions for review. Case No. 14-73353, ECF No. 66. Petitioners' requests for administrative and judicial stays of the expanded registration order were denied. Case No. 15-71213, ECF No. 13-4; Case No. 14-73353, ECF No. 94.

V. Other proceedings related to glyphosate and 2,4-D

EPA is currently conducting separate registration reviews for registered pesticides containing glyphosate and those containing 2,4-D. *See* 7 U.S.C. § 136a(g); ER 579. Under FIFRA, these registration reviews need not be completed until October 2022. 7 U.S.C. § 136a(g)(1)(A)(iii)(I).

In addition, in February 2014, NRDC petitioned EPA to conduct an urgent interim administrative review of the registrations for glyphosate-based pesticides, in light of unreasonable adverse effects on monarch butterflies. Case No. 14-73353, ECF No. 26-3; *see* 7 U.S.C. § 136a(c)(8); 40 C.F.R. § 154.10. EPA denied the petition in June 2015, claiming that it would evaluate harm to monarchs at some point in the future. *See* Case No. 14-73353, ECF No. 87-2, at 2.

SUMMARY OF ARGUMENT

FIFRA prohibits EPA from registering any new pesticide unless EPA determines that the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D). This includes an unreasonable risk of harm to human health. *Id*. § 136(bb). That safety finding must be based on information "sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man and the environment." 40 C.F.R. § 158.75. EPA flouted these requirements when it refused to consider evidence of harm to monarchs and cancer risk to people before registering Enlist Duo.

I. In public comments, NRDC and others timely notified EPA of extensive scientific evidence that Enlist Duo poses a serious risk to the imperiled North American monarch butterfly. That evidence shows a strong link between use of herbicides on herbicide-resistant crops, the destruction of milkweed, and the monarch population's stark decline. Despite specifically approving Enlist Duo to

kill milkweed, EPA unlawfully refused to consider adverse effects on monarchs before registering the herbicide.

II. In its comments, NRDC also informed EPA that many new studies on glyphosate's human health effects have been published since the agency re-registered glyphosate-containing pesticides in 1993. NRDC requested that EPA consider those studies before registering Enlist Duo, to ensure safety. Moreover, shortly before EPA expanded Enlist Duo's registration to nine additional states, the World Health Organization published its major new conclusion that glyphosate is "probably carcinogenic to humans." Hsieh Decl. Ex. A, ECF No. 105-3, at 2-3. This cancer finding was based on a comprehensive analysis of peer-reviewed studies assessing the link between glyphosate and cancer, including studies that EPA did not consider when it registered Enlist Duo and that do not appear in the administrative record EPA certified to the Court. Although NRDC and others alerted EPA to this cancer finding (which made headlines around the world), EPA refused to consider the issue and continued to rely on its 1991 determination—which is now almost twenty-five years out of date—that glyphosate is not carcinogenic to humans.

Without considering these central questions—one related to health risk, the other to environmental harm—EPA lacked a sufficient basis to conclude that registration of Enlist Duo would not cause "unreasonable adverse effects on

[humans and] the environment," 7 U.S.C. § 136a(c)(5)(C), (D); *id*. § 136(bb). EPA's orders registering Enlist Duo are thus unsupported by substantial evidence and should be vacated.

STANDARD OF REVIEW

Under FIFRA, a pesticide registration order "shall be sustained if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *NRDC v. U.S. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (quoting *Vasquez v. Astrue*, 572 F.3d 586, 591 (9th Cir. 2009)). "Although the substantial evidence standard of review is relatively deferential to the agency factfinder, [the Court's] review still 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 quotation marks omitted).

Importantly, compared to arbitrary-and-capricious review under the Administrative Procedure Act, "Congress expected greater scrutiny when the enabling statute contains a substantial evidence test." *Union Oil Co. of Cal. v. Fed. Power Comm'n*, 542 F.2d 1036, 1041 (9th Cir. 1976). Therefore, by definition, "if the EPA's pesticide registration is arbitrary and capricious, the EPA cannot show it

was supported by substantial evidence." *Pollinator Stewardship Council*, 800 F.3d at 1188 (Smith, N.R., J., concurring). Agency action is arbitrary and capricious if, among other reasons, "the agency has . . . entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43; *accord Mont. Wilderness Ass'n v. McAllister*, 666 F.3d 549, 555, 558, 561 (9th Cir. 2011). Thus, when an agency fails to consider an important aspect of the problem, there is not substantial evidence on the record for the agency's decision. *See Pub. Citizen Health Research Grp. v. Tyson*, 796 F.2d 1479, 1507 (D.C. Cir. 1986).

ARGUMENT

I. EPA's registration of Enlist Duo is not supported by substantial evidence because EPA refused to consider harm to monarch butterflies

Before registering Enlist Duo as a new pesticide, EPA was required to review "all relevant data in the possession of the Agency," 40 C.F.R. § 152.112(b), determine "that no additional data [were] necessary," *id.* § 152.112(c), and ultimately determine that Enlist Duo will not cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(C), (D); *accord* 40 C.F.R. § 152.112(e). EPA's evaluation of Enlist Duo—and its component ingredients, glyphosate and 2,4-D—ignored all evidence of harm to monarch butterflies. *See* ER 577. Because of this critical omission, EPA's registration orders are not supported by substantial evidence.

A. EPA refused to consider an entire body of scientific literature demonstrating that Enlist Duo poses a serious risk to monarch butterflies

In public comments on EPA's proposed decisions to register Enlist Duo, NRDC and others brought to the agency's attention an extensive body of scientific literature documenting the significant decline of the North American monarch population. NRDC alerted EPA to the considerable risk that Enlist Duo poses to monarchs, as substantiated by studies concluding that use of herbicides, particularly those containing glyphosate, on herbicide-resistant crops has been a driving force behind monarch population decline. ER 451-53, 456-65, 684-86, 689-97, 898-901.

Enlist Duo is specifically intended to suppress milkweed, ER 57, which the monarch population needs to survive. In addition, Enlist Duo's intended pairing with Enlist corn and soybeans, which are resistant to Enlist Duo, enables use of the herbicide frequently, at high volumes, and during the milkweed's most vulnerable flowering stage. ER 899. EPA predicts that Enlist Duo will extend the viability of glyphosate for herbicidal use, and recognizes that Enlist Duo will likely cause 2,4-D use to increase. ER 852-53. According to the Department of Agriculture, EPA's registration of Enlist Duo will increase the use of 2,4-D up to six-fold. APHIS, *supra* note 3, at x. Monarch experts agree that it is precisely the type of activity EPA approved here—the application of herbicides to herbicide-resistant crops—

that has been a leading cause of the monarch's stark decline over the past two decades. *See, e.g.*, ER 806, 820-21, 890, 1236.

Information on Enlist Duo's potential to harm monarch butterflies was thus both "relevant," 40 C.F.R. § 152.112(b), and "necessary," *id.* § 152.112(c), to determining whether registration of Enlist Duo would cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(C), (D). *See* 40 C.F.R. § 158.75. Although the risk that Enlist Duo poses to milkweed and monarchs was properly before the agency, *see, e.g.*, ER 453, 456-65, 686, 689-97, 898-901, EPA refused to consider that information before registering the herbicide, *see* ER 577. Indeed, EPA has never considered, as part of *any* pesticide registration, the impacts that either of Enlist Duo's active ingredients has on monarchs.

Without considering how Enlist Duo would impact milkweed and monarchs, EPA lacked an adequate basis to conclude that registration of Enlist Duo will not cause unreasonable adverse effects on the environment, as required by FIFRA. Because EPA "entirely failed to consider an important aspect of the problem," its registration decisions are arbitrary, capricious, and not in accordance with the law. *State Farm*, 463 U.S. at 43; *accord Mont. Wilderness Ass'n*, 666 F.3d at 555, 558, 561. Those decisions thus necessarily fail the substantial evidence test under FIFRA, which is more rigorous than arbitrary and capricious review. *See Union Oil Co. of Cal.*, 542 F.2d at 1041.

Notably, the Court need not find that Enlist Duo harms monarchs to vacate the unlawful registration: that is the question for EPA. The agency's legal error was in refusing even to consider the matter before registering this pesticide. *See State Farm*, 463 U.S. at 43; *Mont. Wilderness Ass'n*, 666 F.3d at 555, 558, 561.

B. EPA has never previously considered impacts to monarchs and thus could not rely exclusively on its previous risk assessments for glyphosate

In its initial registration decision for Enlist Duo, EPA reasoned that it did not need to conduct any new risk assessments for glyphosate, because registration of Enlist Duo ostensibly would not result in any new use of glyphosate. *See* ER 8; *see also* EPA Opp. to Mot. to Stay, Case No. 14-73353, ECF No. 24, at 14 ("[T]he registration does not change the lawful scope of glyphosate use, and EPA properly relied on its prior assessments and existing glyphosate registrations in finding that the glyphosate portion of Enlist Duo will not cause 'unreasonable adverse effects on the environment.'" (quoting 7 U.S.C. § 136a(c)(5))).

This approach violates FIFRA's registration requirement, because it disregards the fact that EPA has *never* considered impacts to monarch butterflies when previously registering any glyphosate-containing pesticide. The strong body of science demonstrating the link between monarch decline and herbicide use on herbicide-resistant crops emerged after 1993, the last time EPA re-registered

glyphosate-based pesticides. And NRDC presented that evidence to EPA in timely comments opposing the proposed registration of Enlist Duo.

Moreover, the agency cannot rely on an unsupported assumption that the total amount of glyphosate used will remain constant to conclude that the glyphosate in Enlist Duo will not harm monarchs. *Compare* ER 853, *with* ER 586. EPA explicitly did not evaluate how Enlist Duo's registration would affect "total loading of herbicides." ER 853. Contrary to the agency's assumption, glyphosate's decreasing efficacy strongly suggests that reliance on glyphosate-containing pesticides will decrease but for EPA's registration of Enlist Duo. *See* ER 852; *supra* pages 10-11. And the record indicates that Enlist Duo may even prompt growers to expand their reliance on glyphosate-containing pesticides. *See supra* page 12. Either way, Enlist Duo's registration harms milkweed and monarchs by perpetuating or expanding heavy glyphosate use.

EPA may certainly consider data submitted to support older pesticide applications when registering a new pesticide (provided certain conditions in the statute are met). *See* 7 U.S.C. § 136a(c)(1)(F). But that does not mean that EPA may consider *only* the data submitted with older pesticide applications, ignoring all other relevant information properly before the agency. EPA itself, in its response to comments on Enlist Duo, acknowledged that "[p]roposed new registrations are held to the most current data requirements and up-to-date risk assessment

practices." ER 579. Defying this principle, EPA unlawfully relied on an incomplete and outdated set of data, turning a blind eye to overwhelming new evidence that Enlist Duo will harm monarchs.

C. EPA's duty to ensure the safety of Enlist Duo at the time of registration is independent from, and additional to, its duty to ensure the continued safety of previously registered pesticides containing glyphosate

In its response to comments on the Enlist Duo registration, EPA attempted to justify its failure to consider Enlist Duo's effects on monarch butterflies by explaining that the agency plans to evaluate glyphosate's effects on monarchs at some point in the future, as part of its registration review for glyphosate-containing pesticides. ER 577, 579. This approach violates FIFRA. The statute provides multiple mechanisms for re-evaluating the safety of pesticides that have already been registered, *see, e.g.*, 7 U.S.C. § 136a(g) (registration review); *id*. § 136a(c)(8) (interim administrative review), but that does not relieve EPA of the responsibility to make an initial safety determination for new pesticides based on all relevant information. Simply put, EPA may not register a new pesticide, acknowledge major unanswered questions about harm, and announce that it will consider those questions later, after the pesticide is already on the market. *See* 7 U.S.C. § 136a(c)(5)(C), (D).

Moreover, whether glyphosate alone harms monarchs (the question EPA promises to consider later) is not the same as whether Enlist Duo does. Enlist Duo

contains two active ingredients, glyphosate and 2,4-D, and registration of Enlist Duo will significantly increase use of 2,4-D, which also kills milkweed. *See* APHIS, *supra* note 3 at x; ER 900-01. EPA did not provide any explanation for its failure to consider 2,4-D's impacts on monarchs. *See* ER 577. Under FIFRA, EPA is required to consider all relevant evidence of environmental harm, including harm to monarchs, before registering a pesticide.

II. EPA's registration of Enlist Duo is not supported by substantial evidence because EPA refused to consider decades of research regarding glyphosate's health effects, specifically new studies on cancer risk

EPA's registration of Enlist Duo was also unlawful because the agency entirely failed to consider current scientific findings about glyphosate's human health effects, specifically its cancer risks. NRDC's comments alerted EPA that its previous health assessments for glyphosate were outdated, pointing out that "over 3000 studies have been published" since EPA re-registered glyphosate-containing pesticides in 1993, providing a basis for setting much more stringent exposure limits for glyphosate. ER 454, 469-70, 687, 701-02. NRDC also objected to registration of Enlist Duo absent "an updated assessment of its glyphosate component," without which the agency "cannot properly find that Enlist Duo will not cause unreasonable adverse effects on human health or the environment." ER 454, 469-70, 486, 687, 701-02, 717. But in registering Enlist Duo, EPA performed

"no new assessments" for glyphosate, and EPA's response to comments entirely ignored these health threats. ER 8, 577-79.

Validating NRDC's concerns, in March 2015 the World Health Organization determined that glyphosate is "probably carcinogenic to humans." Hsieh Decl. Ex. A, ECF No. 105-3, at 3. Although NRDC and others notified EPA of this cancer finding before the agency issued its amended registration of Enlist Duo, the agency by its own admission "expressly declined to revisit any human health risk issues" in its expanded registration decision. EPA's Opp'n to Mot. to Stay, Case No. 15-71213, ECF No. 29-1, at 17; *see* ER 5-6. EPA's conclusion that the glyphosate in Enlist Duo will not harm human health is thus based on outdated science and an agency review of that science conducted over twenty years ago. *See* ER 1287-89, 1312-32, 1377-1394.

EPA's willful ignorance violates FIFRA. EPA may not register a pesticide if it poses an unreasonable health risk to people. 7 U.S.C. §§ 136a(c)(5)(D), 136(bb). FIFRA regulations require EPA to consider data "sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man," 40 C.F.R. § 158.75, including "all relevant data" in the agency's possession, *id*. § 152.112(b). Such data include evidence of cancer risk that has been published in the last twenty-five years.

In light of the current science, the studies on which EPA previously relied to determine that glyphosate was sufficiently safe for humans—primarily, the studies EPA relied on when it re-registered glyphosate-based pesticides in 1993—are no longer adequate, decades later, to assess Enlist Duo's health risks. Those studies predated the World Health Organization's new finding by over two decades and preceded the publication of myriad relevant new studies assessing the links between glyphosate and human health harms, including cancer. Notably, the studies selected for inclusion in the World Health Organization's summary of its glyphosate carcinogenicity finding appear nowhere in the certified administrative record for this case. *Compare* Hsieh Decl. Ex. A, ECF No. 105-3, at 3, *with* EPA's Certified Index to the Admin. Record, Case No. 15-71207, ECF No. 21-2. EPA may not lawfully ignore more than two decades of scientific and medical research on cancer risk when approving a new pesticide.

By refusing to consider significant new evidence of Enlist Duo's health risks in general, and cancer risk in particular, before registering Enlist Duo, EPA lacked an adequate basis to conclude that Enlist Duo would not cause "unreasonable adverse effects" on human health. 7 U.S.C. § 136a(c)(5)(C), (D). Because EPA "entirely failed to consider an important aspect of the problem," its registration of Enlist Duo is arbitrary, capricious, and not in accordance with the law. *State Farm*, 463 U.S. at 43; *accord Mont. Wilderness Ass'n*, 666 F.3d at 555, 558, 561. The

registration thus necessarily fails the more rigorous substantial evidence test too. *See Union Oil Co. of Cal.*, 542 F.2d at 1041.

As with the harm to monarch butterflies, the Court need not conclude that Enlist Duo poses an unreasonable health risk to vacate the unlawful registration. Instead, EPA erred by failing even to consider that health risk based on recent data, including the World Health Organization's finding and the post-1991 studies on glyphosate's cancer risk underlying that finding. *See State Farm*, 463 U.S. at 43; *Mont. Wilderness Ass'n*, 666 F.3d at 555, 558, 561.

III. NRDC has standing to challenge EPA's registration of Enlist Duo

To establish standing, NRDC must show that the interests it seeks to protect are germane to its organizational purposes, that this litigation will not require its members' individual participation, and that its members would have standing to sue in their own right. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977).

NRDC satisfies this test. Protection of wildlife and human health is germane to NRDC's organizational mission, which is "to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends." Trujillo Decl. ¶¶ 6-8 (ADD 105-06). In addition, this lawsuit does not require the participation of individual NRDC members, because NRDC does not seek any individualized relief for its members. *See Hunt*, 432 U.S. at 344.

NRDC's members would have standing to sue on their own because they suffer "injury in fact" that is traceable to the challenged EPA orders and likely to be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). NRDC members suffer two injuries from the Enlist Duo registration: health risks from potential exposure to Enlist Duo and diminished enjoyment of monarch butterflies.

First, NRDC's members include individuals who live in areas where Enlist Duo is registered for use and who could be exposed to it during their daily activities. Gruber Decl. ¶¶ 4-8 (ADD 79-80); Jorgensen Decl. ¶¶ 3-7, 9 (ADD 84-87); Moravec Decl. ¶¶ 13-15 (ADD 94-95); Olmsted Decl. ¶¶ 3-7 (ADD 98-100); Wetzel Decl. ¶¶ 3-9 (ADD 109-12). Because both active ingredients in Enlist Duo are linked to serious health harms, NRDC's members are reasonably concerned that exposure to Enlist Duo may be harmful. *See* ER 686, 701-02 (identifying severe potential health risks from exposure to glyphosate and 2,4-D); Hsieh Decl. Ex. A, ECF No. 105-3, at 3; Gruber Decl. ¶¶ 4-8 (ADD 79-80); Jorgensen Decl. ¶¶ 3-7, 9 (ADD 84-87); Moravec Decl. ¶¶ 13-15 (ADD 94-95); Olmsted Decl. ¶¶ 3-7 (ADD 98-100); Wetzel Decl. ¶¶ 3-9 (ADD 109-12). These members have no control over whether, when, how, and where Enlist Duo will be applied to corn and soybean crops grown in their communities. Gruber Decl. ¶ 8 (ADD 80); Jorgensen

Decl. ¶¶ 3, 5 (ADD 84-85); Moravec Decl. ¶ 15 (ADD 94-95); Olmsted Decl. ¶¶ 3-6 (ADD 98-99); Wetzel Decl. ¶¶ 3-9 (ADD 109-12). This "credible threat of harm" to NRDC members' health interests "is sufficient to constitute actual injury for standing purposes." *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002); *NRDC*, 735 F.3d at 878-79 (holding that NRDC had standing to challenge EPA's registration of a pesticide that "increase[d] the threat of future harm to NRDC's members").

In addition, NRDC's members include individuals who enjoy observing, studying, and interacting with monarch butterflies in the states where EPA has approved use of Enlist Duo. Atkinson Decl. ¶¶ 3-8 (ADD 66-69); Cady Decl. ¶¶ 2, 4-7, 9-10 (ADD 72-75); Moravec Decl. ¶¶ 2-12, 16 (ADD 90-93, 95); Olmsted Decl. ¶¶ 8-12 (ADD 100-02); Wetzel Decl. ¶¶ 10-15 (ADD 112-14). These members' "desire to use or observe an animal species, even for purely esthetic purposes, is undeniably a cognizable interest for purpose of standing." *Lujan*, 504 U.S. at 562-63. EPA's registration of Enlist Duo contributes to, and is likely to exacerbate, milkweed and monarch decline. The registration therefore harms these members' interest in monarch butterflies and impairs their enjoyment of the outdoors. Atkinson Decl. ¶¶ 3-8 (ADD 66-69); Cady Decl. ¶¶ 4-10 (ADD 72-75); Moravec Decl. ¶¶ 2-12, 16 (ADD 90-93, 95); Olmsted Decl. ¶¶ 8-12 (ADD 100-02); Wetzel Decl. ¶¶ 10-15 (ADD 112-14). The injuries to NRDC members' health

and enjoyment of monarch butterflies are traceable to EPA's orders registering Enlist Duo. EPA's registration orders enabled the sale and distribution of Enlist Duo for the first time, thereby allowing Enlist Duo to be used in ways that may expose NRDC members to the herbicide and allowing Enlist Duo to harm milkweed and monarchs.

Lastly, the injuries to NRDC members are likely to be redressed, at least in part, by an order vacating Enlist Duo's registration. As to health harms, vacatur would prevent NRDC members from being exposed to Enlist Duo, thereby ameliorating their concerns and eliminating any harms. Vacatur would also help to safeguard NRDC members' interests in observing and interacting with monarch butterflies. Enlist Duo's registration is expected to increase 2,4-D use and to perpetuate or increase heavy glyphosate use, both of which will harm milkweed. *See supra* pages 11-12. Vacating the registration would prevent these effects, thereby benefiting monarch butterflies and NRDC's members. *See WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1157 (9th Cir. 2015) ("[A] litigant challenging an agency action need not eliminate any other contributing causes to establish its standing. The relevant inquiry is instead whether a favorable ruling could redress the challenged cause of the injury." (internal citation and quotation marks omitted)). Therefore, NRDC has standing to challenge EPA's registration of Enlist Duo.

CONCLUSION

For the foregoing reasons, the Court should grant the petitions for review and vacate EPA's registration of Enlist Duo.

Dated: October 23, 2015

Respectfully submitted,

/s/ Aaron Colangelo
Aaron Colangelo
Jared Thompson
Natural Resources Defense Council
1152 15th Street NW, Suite 300
Washington, DC 20005
Telephone: (202) 289-2376
Facsimile: (202) 289-1060
acolangelo@nrdc.org
jared.thompson@nrdc.org

Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-2700
Facsimile: (212) 727-1773
mhsieh@nrdc.org

Counsel for Petitioner NRDC

STATEMENT OF RELATED CASES

There are no other related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 8,986 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Times New Roman font.

Dated: October 23, 2015

/s/ Aaron Colangelo
Counsel for Petitioner NRDC

CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2015, I electronically filed the foregoing brief and the accompanying declarations of Kathryn Atkinson, Janet Cady, LeRoy Gruber, Carl Jorgensen, Shelby Moravec, William Olmsted, Gina Trujillo, and Diane Wetzel with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: October 23, 2015

/s/ Aaron Colangelo
Counsel for Petitioner NRDC

STATUTORY AND REGULATORY ADDENDUM

Table of Contents

7 U.S.C.A. § 136

§ 136. Definitions

Effective: August 3, 1996
Currentness

For purposes of this subchapter--

(a) Active ingredient

The term “active ingredient” means--

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

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

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

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

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

(b) Administrator

The term “Administrator” means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term “adulterated” applies to any pesticide if--

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

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

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

(d) Animal

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

(e) Certified applicator, etc.

(1) Certified applicator

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

(2) Private applicator

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

(3) Commercial applicator

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

(4) Under the direct supervision of a certified applicator

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

(f) Defoliant

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

(g) Desiccant

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

(h) Device

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

(i) District court

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

(j) Environment

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

(k) Fungus

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

(l) Imminent hazard

The term “imminent hazard” means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C.A. § 1531 et seq.].

(m) Inert ingredient

The term “inert ingredient” means an ingredient which is not active.

(n) Ingredient statement

The term “ingredient statement” means a statement which contains--

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

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

(o) Insect

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

(p) Label and labeling

(1) Label

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

(2) Labeling

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

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

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

(q) Misbranded

(1) A pesticide is misbranded if--

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

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

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

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

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

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

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

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

(2) A pesticide is misbranded if--

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

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

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

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

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

ADD 6

(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.

ADD 10

(jj)[3] Maintenance applicator

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

(kk) Service technician

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

(ll) Minor use

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

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

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

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

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

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

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

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

(mm) Antimicrobial pesticide

(1) In general

The term “antimicrobial pesticide” means a pesticide that--

(A) is intended to--

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

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

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

(2) Excluded products

The term “antimicrobial pesticide” does not include--

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

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

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

(nn) Public health pesticide

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

(oo) Vector

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

CREDIT(S)

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

Notes of Decisions (9)

Footnotes

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

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

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

7 U.S.C.A. § 136, 7 USCA § 136

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

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

Currentness

(a) Requirement of registration

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

(b) Exemptions

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

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

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

(c) Procedure for registration

(1) Statement required

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

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

(B) the name of the pesticide;

ADD 14

(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;

ADD 18

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

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

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

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

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

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

(C) Simplified procedures

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

(D) Exemption

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

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

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

(E) Minor use waiver

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

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

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

(3) Application

(A) In general

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

(B) Identical or substantially similar

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

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

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

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

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

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

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

(C) Minor use registration

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

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

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

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

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

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

(D) Adequate time for submission of minor use data

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

(4) Notice of application

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

(5) Approval of registration

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

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

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

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

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

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

(6) Denial of registration

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

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

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)--

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

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

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

ADD 23

(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.

ADD 25

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

(d) Classification of pesticides

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

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

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

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

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

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

(2) Change in classification

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

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

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

(e) Products with same formulation and claims

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

(f) Miscellaneous

(1) Effect of change of labeling or formulation

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

(2) Registration not a defense

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

(3) Authority to consult other Federal agencies

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

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of--

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

(B) 1 or more fertilizer products,

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

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

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

(iii) Initial registration review

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

(I) October 1, 2022; or

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

(iv) Subsequent registration review

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

(v) Cancellation

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

(B) Docketing

(i) In general

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

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

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

(ii) Protected information

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

(C) Limitation

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

(2) Data

(A) Submission required

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

(B) Data submission, compensation, and exemption

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

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

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

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

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

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

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

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

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

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

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

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

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

(ii) Requirements

Proposed regulations issued under clause (i) shall--

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

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

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

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

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

(iii) Comments

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

(B) Final regulations

(i) Issuance

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

(ii) Failure to meet goal

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

(iii) Requirements

In issuing final regulations, the Administrator shall--

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

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

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

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

(bb) revised procedures for application review; and

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

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

(C) Expedited review

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

(D) Alternative review periods

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

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

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

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

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

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

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

(E) Wood preservatives

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

(F) Notification

(i) In general

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

(ii) Final decision

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

(iii) Exemption

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

(iv) Limitation

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

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

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

(4) Annual report

(A) Submission

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

(B) Requirements

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

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

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

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

CREDIT(S)

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

Notes of Decisions (92)

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

End of Document

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

7 U.S.C.A. § 136a-1

§ 136a-1. Reregistration of registered pesticides

Effective: October 1, 2012
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 this section 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 this section 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) of this section.

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of this section 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 this section 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) of this section, 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) of this section 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) of this section 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) of this section 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) of this section 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) of this section 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) of this section, 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) of this section, 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) of this section, 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) of this section 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) of this section 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 of 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) of this section who has submitted a notice under subsection (d)(2) of this section 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) of this section, 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) of this section, 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) of this section, 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) of this section 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) of this section.

(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) of this section 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) of this section, 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) of this section, 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) of this section, 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) of this section and of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions

(A) In general

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

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

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

(B) Product-specific data

(i) In general

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

(ii) Timing

(I) In general

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

(II) Extraordinary circumstances

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

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

(D) Determination to not reregister

(i) In general

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

(ii) Timing for regulatory action

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

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

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

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

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

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

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

(h) Compensation of data submitter

If data that are submitted by a registrant under subsection (d), (e), (f), or (g) of this section 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 aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017.

(D) Maximum amount of fees for registrants

The maximum annual fee payable under this paragraph by--

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

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

(E) Maximum amount of fees for small businesses

(i) In general

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

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

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

(ii) Definition of small business

(I) In general--

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

(aa) has 500 or fewer employees; and

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

(II) Affiliates

(aa) In general

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

(bb) Affiliated persons

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

(cc) Indicia of control

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

(F) Fee reduction for certain small businesses

(i) Definition

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

(I) has 500 or fewer employees;

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

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

(ii) Waiver

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

(iii) Limitation

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

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

ADD 50

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

(I) The authority provided under this paragraph shall terminate on September 30, 2017.. [1]

(2) Other fees

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

(j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) of this section (other than subsection (i)(1) of this section) 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) of this section shall be deposited in the fund and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title. Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications. The Administrator shall, prior to expending any such moneys derived from fees--

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

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

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

(B) The Administrator shall also--

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

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

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

(A) The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2013 through 2017, between $^{1}/_{9}$ and #, 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.

ADD 52

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

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

(A) In general

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

(B) Activities

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

(i) the electronic tracking of--

(I) registration submissions; and

(II) the status of conditional registrations;

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

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

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

(5) Unused funds

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

(A) maintained on hand or on deposit;

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

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

(6) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) of this section are used only for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (l) of this section. 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) of this section 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) of this section. 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) of this section.

(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) of this section 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) of this section 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.

ADD 54

(n) Authorization of funds to develop public health data

(1) “Secretary” defined

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

(2) Consultation

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

(3) Benefits to support family

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

(4) Additional time

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

(5) Arrangements

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

(6) Support

The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act [42 U.S.C.A. § 201 et seq.], or other appropriate authorities. After a determination is made under subsection (d) of this section, 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, Oct. 25, 1988, Pub.L. 100-532, Title I, § 102(a), Title VIII, § 801(q)(2)(A), 102 Stat. 2655, 2683; amended Nov. 28, 1990, Pub.L. 101-624, Title XIV, § 1493, 104 Stat. 3628; Dec. 13, 1991, Pub.L. 102-237, Title X, § 1006(a)(4), (e), (f), 105 Stat. 1895 to 1897; Aug. 3, 1996, Pub.L. 104-170, Title I, § 103, Title II, §§ 210(c)(2), (f)(1), 232, 237, Title V, § 501, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Nov. 26, 2001, Pub.L. 107-73, Title III, 115 Stat. 686; Feb. 20, 2003, Pub. L. 108-7, Div. K, Title III, 117 Stat. 513; Jan. 23, 2004, Pub.L. 108-199, Div. G, Title V, § 501(c), (d)(1), (e), 118 Stat. 419, 422; July 7, 2004, Pub.L. 108-271, § 8(b), 118 Stat. 814; Oct. 9, 2007, Pub.L. 110-94, § 4(a) to (c), (d)(1), (e), 121 Stat. 1001, 1002; Pub.L. 112-177, § 2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329.)

Notes of Decisions (5)

Footnotes

1 So in original. Probably should be followed by a period.

7 U.S.C.A. § 136a-1, 7 USCA § 136a-1

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

End of Document

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

7 U.S.C.A. § 136n

§ 136n. Administrative procedure; judicial review

Currentness

(a) District court review

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

(b) Review by court of appeals

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

(c) Jurisdiction of district courts

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

(d) Notice of judgments

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

CREDIT(S)

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

Notes of Decisions (65)

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

End of Document

40 C.F.R. § 152.112

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

Effective: February 10, 2009
Currentness

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

Credits

[72 FR 61028, Oct. 26, 2007; 73 FR 75595, Dec. 12, 2008]

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

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

Notes of Decisions (32)

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

End of Document

40 C.F.R. § 154.1

§ 154.1 Purpose and scope.

Currentness

(a) Purpose. The purpose of the Special Review process is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process is intended to ensure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that, following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, reclassify, or require modifications to the registration of the product(s) in question unless it has been shown during the Special Review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks. Following completion of the Special Review process, a pesticide in question may be returned to the registration process.

(b) Scope. This part sets forth the substantive standards for initiating a Special Review of a pesticide product and the procedures for initiating and conducting the Special Review.

SOURCE: 50 FR 49015, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

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

Notes of Decisions (30)

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

40 C.F.R. § 154.10

§ 154.10 Petitions to begin the Special Review process.

Currentness

The Administrator may evaluate a pesticide use under the criteria of § 154.7 either on his own initiative, or at the suggestion of any interested person.

SOURCE: 50 FR 49015, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

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

Notes of Decisions (5)

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

40 C.F.R. § 158.75

§ 158.75 Requirements for additional data.

Effective: December 26, 2007
Currentness

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

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

ADDENDUM OF DECLARATIONS IN SUPPORT OF STANDING

Table of Contents

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF KATHRYN ATKINSON

I, KATHRYN ATKINSON, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for about fifteen years.

2. I support NRDC because I believe that we as humankind were given the Earth to be stewards, and that we have done a very poor job. I remember growing up in Northern California when it was gloriously beautiful—filled with vineyards and orange trees—before that beauty was gradually destroyed by development. There I was taught not to destroy things, not to trash the environment. I have done my best to live by this value, and to teach my own children to do the same. My concern has extended beyond my own practices to those of society more generally: I remember learning about the horrible consequences of freely spraying insecticides from Rachel Carson's *Silent Spring*. I believe we are incredibly foolish to destroy species, including by the overuse of chemicals. I have long supported NRDC's efforts to prevent this foolishness.

3. My current home is in Gainesville, Missouri, in the Ozarks. I moved there almost fifteen years ago, after I retired. There is quite a lot of undeveloped land in the Ozarks, and wildlife is generally plentiful. One exception is the monarch butterfly, which I do not see as often as I used to, though it is among my favorite animals to watch in the Ozarks. In an effort to support the monarchs, I have abstained from using pesticides on my property. I have also planted milkweed,

which I understand to be the only food that monarch caterpillars eat, on my deck. I intend to plant more in my garden, and in my children's gardens nearby as well. There, I hope the milkweed can grow undisturbed and nourish the monarchs.

4. Over time, I have learned about the decline of the monarchs in North America. I have read a number of news articles since I moved to Missouri about the subject, including several published by NRDC. I spend much of my time now volunteering at the local library. Through my work there, I have come across many books and magazines discussing the destruction of milkweed, and the harm it has caused to monarchs. I was horrified to learn that the misguided use of pesticides to increase profit for agricultural producers and to keep roadsides pristine was destroying these creatures.

5. I have personally witnessed this decline: I remember that, when I moved to the Ozarks, my mother's garden was full of monarchs. Now, though I still see them, I do so much less frequently—even though I live in the same area, and even though I do my best to attract monarchs to my property with milkweed. This past summer, I saw absolutely no monarchs. In talking to other residents of my area, I found that no one else had seen any monarchs either.

6. I am aware that the United States Environmental Protection Agency (EPA) has recently approved a new herbicide, called Enlist Duo, for use on soybeans and corn in Missouri. I am aware that Enlist Duo contains glyphosate, a chemical that

kills milkweed, and which has become increasingly prevalent over the last two decades. I understand that Enlist Duo also contains 2,4-D, which kills milkweed as well.

7. I am worried that Enlist Duo harms the monarch population, which is already vulnerable. I fear that, if Enlist Duo were to be widely used, monarchs would disappear entirely from my garden and my children's gardens. I would no longer have the pleasure of seeing the butterflies, of nourishing them with the plants I grow, and of sharing my enjoyment in watching the monarchs with my children, who care for the Earth as I do. I feel that humankind has failed, as far as monarchs were concerned, to be good stewards of nature. I feel that the use of Enlist Duo is another instance of people focusing totally on profit, at the expense of the good of the globe. These thoughts trouble me even though monarchs have not yet entirely disappeared from my garden, because even seeing fewer monarchs makes me recall with sadness how many more there used to be. My concerns regarding Enlist Duo diminish my enjoyment in seeing those few remaining monarchs.

8. The EPA is meant to protect the environment, but I do not think that, in this instance, it has done a good job. I am aware that NRDC is challenging the EPA's registration of Enlist Duo in part because the EPA has never considered the effects of either glyphosate or 2,4-D on monarch butterflies. I think EPA's actions have

been short-sighted: we should not wait until we've destroyed the planet beyond repair before we act to save it. I therefore fully support NRDC's lawsuit to revoke EPA's approval of Enlist Duo. If NRDC were to prevail, I would look forward to the recovery of the monarch population in the Ozarks. Seeing more monarchs would increase my enjoyment in watching the butterflies in my and my children's gardens. I would take comfort knowing that they had been protected from a serious threat.

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

Kathryn Atkinson — 10/19/15

Kathryn Atkinson — Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF JANET CADY

I, JANET CADY, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for about twelve years.

2. I have lived in Maple Grove, Minnesota for around 40 years, and plan to live at my current address for as long as my health allows.

3. I support NRDC because I feel strongly that we as humankind only have one planet, and we are abusing it. I try, through supporting NRDC, to do my part in stopping this abuse. Of significant interest to me is that we take a closer look at the effects of pesticides on the environment. I appreciate that organizations including NRDC are speaking out on this issue, and supporting the adoption of alternative, more responsible practices.

4. I have developed a strong affinity for monarch butterflies over the last two years. I have a friend who is also extremely interested in monarchs. She showed me how to identify monarch caterpillars, and taught me about the monarch's life cycle: its transformation from egg to caterpillar to chrysalis to adult. She taught me as well about the importance to monarchs of milkweed, which is the only food that monarch caterpillars eat. Because of my friend's influence, I now enjoy observing monarchs in all stages of their development whenever I encounter them on my own property and in the surrounding area. When I find a monarch caterpillar, I will sometimes take it into my home, and tend to it, by feeding it milkweed. One of my

neighbors, a young girl, has developed an interest in monarchs as well. I enjoy showing her the caterpillars I find, and seeing those that she finds.

5. As I have grown more interested in monarchs, I have also learned more about their role in the environment. I have watched television programs about monarchs, and I have read materials about them produced by NRDC and other organizations that work to protect monarchs. Through these media, and through conversations with the aforementioned friend who taught me about monarchs, I have learned of the grave threat posed to monarchs by the destruction of milkweed. It is my understanding that herbicides used in large-scale agricultural production have killed vast quantities of milkweed across the United States, and that this has contributed to a sharp decline in the number of North American monarchs.

6. I have personally seen evidence of this decline. I had always taken for granted that there would be a lot of monarchs near where I live. Now, there are fewer around, relative even to just a few years ago. As a result, I now have fewer opportunities to enjoy observing them than in the past. I have been particularly aware of and particularly saddened by this change because I am now better educated about monarchs than I was before.

7. Out of concern for the future of the monarchs, I have allowed milkweed to grow freely on my property. Though others in my area consider milkweed a nuisance, I consider it a vital part of the local ecosystem. I have also tried to

educate those close to me about the crisis that monarchs are facing, in hopes that they will act on their own to preserve milkweed and protect the monarchs.

8. I am aware that the United States Environmental Protection Agency (EPA) has recently approved a new herbicide, called Enlist Duo, for use on soybeans and corn in Minnesota. I know that Enlist Duo contains glyphosate, a chemical widely believed to be a leading contributor to the decline in milkweed. I am aware that, in addition to glyphosate, Enlist Duo contains the herbicide 2,4-D, which also destroys milkweed.

9. I am worried that farmers' use of Enlist Duo is causing the monarch population decline to continue and perhaps accelerate. I used to take for granted that monarchs would be abundant in my area; now, I have already seen their numbers decrease significantly. I fear that monarchs may even disappear from my area entirely. If that were to happen, I would no longer have the pleasure of finding monarch eggs on the underside of leaves. I would no longer be able to enjoy tracking the development of a monarch caterpillar into a chrysalis, and then into a butterfly. I would not be able to share these experiences with my friend who taught me about monarchs, or with my young neighbor. I would be sad to know that my young neighbor would be deprived of the joy she has so recently discovered in learning about a beautiful species. Already, because of the monarchs' decline, these pleasures have become rarer for me. I would feel that the use of dangerous

chemicals, already a significant problem, had become further entrenched in American agricultural practices, and I would feel that my health and the health of the environment were in danger.

10. The EPA is set up to protect the environment, but I do not feel that it shares my way of thinking about important issues, such as the use of glyphosate and 2,4-D. I do not trust that EPA has adequately studied the pros and cons of approving Enlist Duo. For these reasons, I support NRDC's lawsuit to revoke EPA's approval of Enlist Duo. NRDC's success in this lawsuit would give me hope that alternatives to the current destructive agricultural practices are possible. It would allow me to observe the monarchs in my area without fear for the future of the species and would safeguard the enjoyment I derive from seeing and interacting with the species. I would also be very glad to know that younger generations, such as that to which my neighbor belongs, could experience the same pleasure that I have.

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

Janet Cady

Janet Cady

10-16-15

Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF LEROY GRUBER

I, LEROY GRUBER, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for about eleven years.

2. Among other reasons, I support the NRDC because I am concerned about the impacts of chemicals, including pesticides, on human health and the environment. Reading Rachel Carson's *Silent Spring* was a major turning point in my life, opening my eyes to the detrimental effects of indiscriminate pesticide use on the natural world. Another critical moment in my life occurred when I read *The Limits to Growth*, a report commissioned by the Club of Rome. Through this report, I became convinced that mankind is releasing chemicals into the environment much more quickly than we can neutralize the resulting harmful effects; I firmly believe that we must take action to reverse this trend. I understand that one of NRDC's central purposes is to safeguard human health and the environment from the toxic effects of pesticides and other chemicals, and I strongly support this objective.

3. I worked in the environmental field for thirty-five years. As a Supervising Engineer at the Hamilton County Department of Environmental Services (DES) in Ohio, I became acutely aware of the human health risks, such as cancers and neurodevelopmental harms, posed by exposure to chemicals in the environment. I realized that exposures to even low concentrations of chemicals can pose serious

health risks over time. I also realized that exposures to high concentrations of chemicals, even if briefly, can result in significant health harms. This awareness has heightened my concerns regarding exposure to pesticides, including the herbicide Enlist Duo.

4. For the past eleven years, I have lived in rural Goshen, Ohio. My property is situated near large agricultural fields planted with soybeans and corn. I am aware that chemicals are sprayed on these fields, even though I do not know the exact identity of those substances. I have seen machines spraying chemicals in the morning, even when winds are blowing at higher speeds.

5. I am aware that EPA recently approved the herbicide Enlist Duo for use on soybeans and corn in Ohio. In addition, I am aware that Enlist Duo contains 2,4-D and glyphosate, and that both chemicals are associated with various human health risks. In particular, I understand that glyphosate is a probable human carcinogen. I am concerned that Enlist Duo will be used on the fields next to my property, and that I will be exposed to this herbicide and the health risks it poses, including increased risk of developing cancer.

6. I am particularly concerned about exposure to Enlist Duo through aerial pathways between my property and the adjacent fields. I am aware that pesticides do not end up only on target crops. Rather, they invariably travel off site, including through spray drift and volatilization. Among my other responsibilities at the

Hamilton County DES, I used to model air pollutant emissions. Through this experience, I became aware of the ease with which chemicals can be borne through the air. I am thus especially worried about breathing in Enlist Duo through spray drift and volatilization from the fields next to my home.

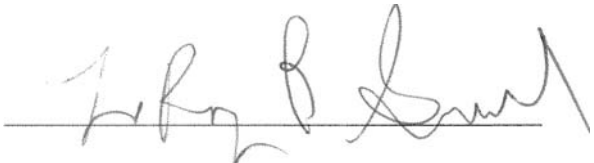
7. When I first moved to Goshen, I obtained drinking water from a cistern on my property. Because I was concerned about pesticide spray drift contaminating my cistern water, however, I spent about $5,000 installing a water line that would allow me to obtain public drinking water from Clermont County. Although I am now less concerned about herbicide exposure through my drinking water, I remain very concerned that I may be exposed to harmful chemicals such as glyphosate and 2,4-D through inhalation of airborne Enlist Duo from the neighboring fields.

8. I avoid using herbicides on my own property, in part because I am concerned about the health risks associated with exposure to these chemicals. However, there is nothing I can do to prevent Enlist Duo from being used on the fields next to my property, where I intend to stay.

9. EPA has a duty to protect the public from the health risks posed by exposure to herbicides. I am aware that NRDC has challenged EPA's decision to approve Enlist Duo in part because the agency failed to take into account adequately the health risks the pesticide poses. I support NRDC's lawsuit to revoke EPA's approval of Enlist Duo. If the court were to invalidate EPA's approval of Enlist

Duo, and thereby prevent the herbicide from being used near my home, this would protect me from the health risks posed by exposure to it.

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



LeRoy Gruber

Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF CARL JORGENSEN

I, CARL JORGENSEN, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC), and have been for about twenty-eight years.

2. I have been an environmentalist since even before the word was coined. I have been very fortunate to have visited many of the beautiful places in our country. This has given me a front-row seat to some of the damage that man's heavy-handed interference in nature has brought about. Even on my own property, it has been alarming to see, over the years, a decline in air quality, water quality, and the abundance of creatures that I used to see in my backyard. I believe we need to pay attention to these phenomena: they are the canaries in the coal mine, before we become endangered ourselves. I feel that NRDC effectively fights against these dangerous trends.

3. My home sits on a three-acre plot adjacent to a stream. The stream empties into a small creek that flows into the Kansas River, which itself is a tributary to the Missouri River. My geographic situation has made me keenly aware of the ways in which waterways are connected, and therefore, of the ways in which pollutants, including pesticides, can be carried downstream, from one to the next. Wyandotte County, Kansas, where I live, gets its drinking water from the Missouri River. My county is downstream from areas with heavy agribusiness in Kansas, Missouri, and Nebraska. I worry that chemicals used on crops in those areas might wash into

small streams that, like the one near my house, carry water into the Missouri River, contaminating Wyandotte County's drinking water. I am particularly worried in light of the heavy rain storms that occur in my region, which I fear might disperse agricultural pollutants far beyond the area immediately surrounding the farms. I fear that I, along with all my neighbors, might drink these pollutants every day, without our knowledge, and with little ability to avoid doing so.

4. I am concerned as well about my exposure to pesticides through local application on roadsides and lawns. I have consistently seen trucks spraying the roads with herbicides on behalf of the government agency that manages the local roads. Whenever these trucks pass by my house, I shut the windows in my house, because I worry about exposure to harmful chemicals. You can smell these chemicals in the air, and it seems clear to me that they are dangerous.

5. I fear that wind or rain might carry herbicides onto my own property. Many people in my neighborhood keep small garden plots, on which they spray herbicides. I avoid applying herbicides, but I worry that when I mow my own lawn, I am kicking herbicides into the air I breathe. Moreover, though Chicago may be known as the "Windy City," I understand that Kansas City, Kansas, where I live, is actually windier. I worry that the high winds in my area disperse dangerous chemicals to my neighborhood from distant areas. These threats leave me concerned about the health risks from breathing in toxins.

6. I worry particularly about the health of the children in my neighborhood. My cousin's young daughter died tragically of brain cancer that, I strongly suspect, was caused by her exposure to toxic pesticides used on the grassy lawns on which she played. I am troubled deeply by the thought that the schoolchildren near me might be similarly exposed when they walk to school on sidewalks along which herbicides have been sprayed just minutes or hours earlier. It is my understanding that childhood cancers have become increasingly prevalent in recent years, in part because of an increase in the use of poisonous chemicals, including those employed by American agribusiness.

7. I am aware that the United States Environmental Protection Agency (EPA) recently approved a new herbicide, called Enlist Duo, for use on soybeans and corn in Kansas and several other states, including some of those upstream of where I live along the Missouri River. I understand that Enlist Duo contains 2,4-D and glyphosate, both of which are widely believed to contribute to grave human health harms. 2,4-D has been linked to non-Hodgkin's lymphoma, decreased fertility, higher rates of birth defects, and hormonal disruption, while glyphosate is considered probably carcinogenic to humans.

8. The EPA ought to resist the political pressure of the big chemical companies and look after the interests of citizens like me. This means that it should thoroughly study any new pesticides before it allows the pesticides to be sold in the United

States, and prevent people from being exposed to even more poisons than are already polluting our environment. I feel that the EPA has failed to do its job with respect to Enlist Duo. I believe that by allowing chemicals that are probably carcinogenic to be used in herbicides—as EPA has done with Enlist Duo, which contains the probable carcinogen glyphosate—the EPA is playing Russian roulette with people's health.

9. Because the EPA has approved Enlist Duo for use by farmers in my region, the fears that I have described are magnified. The farmers near me could be using Enlist Duo, and I would be completely unaware. I therefore feel less safe drinking the local tap water. I am even more uncertain that the air I breathe is safe. I am more certain that our society has continued in its dangerously cavalier usage of toxic chemicals. I am concerned for my own health, and I feel the risk posed by the use of Enlist Duo outweighs any potential rewards. The EPA has further lost my trust because of its decision to register Enlist Duo. If NRDC were to prevail in this lawsuit, these concerns would be diminished, and I would feel secure knowing that the EPA had been forced to act in accordance with its mandate to protect the environment and the health of citizens like me. I therefore fully support NRDC in this matter.

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

Carl Jorgensen

19 OCT. 15

Carl Jorgensen | Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF SHELBY MORAVEC

I, SHELBY MORAVEC, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for over ten years.

2. I support NRDC because I am concerned about the profound impacts of human activities on the environment; I worry about how these impacts affect the well-being of both humans and wildlife, including monarch butterflies. I understand that preservation of wildlife is one of NRDC's core missions, and it is one that I stand firmly behind.

3. For many years, I lived in Beverly Shores, Indiana, along the Indiana Dunes National Lakeshore. Beverly Shores is an idyllic spot that is only one hour away from Chicago. Despite the proximity, Beverly Shores is worlds apart from the city; the difference between the two areas is like the difference between night and day. I used to live in Chicago, but purchased my property in Beverly Shores back in October 1999. My husband and I moved to this area in part because of our love for the outdoors, including our desire to be close to nature and wildlife. The Indiana Dunes National Lakeshore and surroundings support some of the most diverse flora and fauna in the Midwest. Hosts of migrating birds and insects, including monarch butterflies, used to travel through this magical area.

4. In Beverly Shores, I enjoyed taking regular walks along the lakeshore, into town, and in the National Park. I have a Border Collie and would frequently take

her on walks within a one- to two-mile radius of my home. It was a joy to observe wildlife and experience nature during these walks.

5. Monarch butterflies used to be abundant in the Beverly Shores/Indiana Dunes area. When I first moved to this area, there were too many butterflies to count. I remember walking along the sun-drenched dunes during my first spring there, and seeing countless monarchs flitting amongst the native milkweed, wildflowers, and grasses. Monarch chrysalises hung from the milkweed on the dunes, and it gave me great pleasure to see the butterflies emerging from their chrysalises. The butterflies, chrysalises, and caterpillars were a part of the natural landscape and could be seen all along the lakeshore. At certain times of year, I could walk down the street and see monarchs everywhere.

6. Over the years, however, there has been a dramatic decline in the number of monarchs that migrate through the Beverly Shores/Indiana Dunes area. While the decline has taken place gradually, I have become acutely aware of it over the past six years. Last year, I was dismayed to see only one monarch butterfly, which alighted on a sunflower in my yard. I was also disheartened not to see a single monarch caterpillar. When I first moved to the Indiana Dunes area, there were so many monarchs that, when I walked along the lakefront after a storm, the ground would be covered with butterflies that had been battered by the rain. I have not seen a sight like this for years. Nowadays, there are so few monarchs that I hardly

notice any downed butterflies even after heavy storms. And even on clear days, it is now unusual to see a monarch butterfly.

7. In May 2015, I moved to La Porte, Indiana, which is in the same general area as Beverly Shores, approximately half an hour away. La Porte is a rural community, and my house is on an idyllic five-acre site surrounded by farmland. I enjoy experiencing the natural beauty of the area, including on walks with my dog, much as I did in Beverly Shores. Since I moved, I have continued counting monarch butterflies and have seen shockingly few around my home: only about a dozen all summer long. I have also driven around the surrounding countryside looking for milkweed. While I have seen some on my own property, I rarely see it among the numerous corn and soybean fields near my home. There has been no indication that the decline in monarchs that I have witnessed in this area has abated.

8. Through conversations with other naturalists in the area, I have learned to help monarchs by not removing milkweed. To support the butterflies, I have also consulted the owner of a local nursery many times to seek advice on what butterfly-attractive plants to grow on my property. In addition to following his advice, I refrain from using pesticides, so as to avoid harming monarchs.

9. Throughout the years, I have read field guides and followed news on monarchs with great interest. I have browsed the internet to learn more about these

wonderful creatures. And about two years ago, I read Barbara Kingsolver's *Flight Behavior*, a novel about the plight of monarch butterflies that struck a deep chord with me.

10. Watching monarchs means a great deal to me. Seeing them makes me feel connected to the natural world, and each sighting is a poignant reminder that humans and wildlife are co-inhabitants of this earth. It is a great pleasure to see the butterflies, and I enjoy sharing these increasingly rare sightings with others. I am acutely aware of the dwindling number of monarchs, and the decline of this beautiful species is of great concern to me. I fear that monarchs will disappear entirely, a loss that would fill me with sadness.

11. As minimal as the monarch migration has now become, I absolutely plan to continue watching the butterflies every year. I will continue growing butterfly-attractive plants on my property and refraining from herbicide use. I also plan to let any milkweed that I find grow wild.

12. I am aware that use of herbicides containing glyphosate and 2,4-D has contributed to the monarch's decline. In addition, I understand that these herbicides destroy milkweed, which monarch caterpillars need to survive. I am concerned that further increases in the use of glyphosate and 2,4-D would be devastating to monarchs, bringing an end to their annual migration through my area and my ability to watch them.

13. I am aware that in spring 2015, the World Health Organization determined that glyphosate is probably carcinogenic to humans. I also understand that 2,4-D has been linked to a variety of human-health harms, including non-Hodgkin's lymphoma and hormonal disruption.

14. I am sensitive to the dangers of pesticides because of my family's own tragic experiences. My husband is from a family of farmers in Illinois. Both his maternal grandparents died of awful cancers. I painfully recall that both of them attributed their illnesses to their having breathed pesticides on their farms. I am also troubled because of my experience with my previous dog, who died of leukemia. Before my dog passed away, my husband and I took him to a veterinary oncologist. The first question the oncologist asked us was whether our dog had been exposed to lawn chemicals, which he said were the leading cause of cancer in dogs.

15. Since I moved to La Porte, I have become particularly concerned about the health effects of exposure to pesticides. My property is adjacent to farms on two sides, and my house is separated from those farms only by small wooded areas. About two months ago, I saw a farmer using a tractor to spray something on his crops near my house. I am now certain that he was spraying pesticides, because everything where he sprayed is now dead, except for his crops. I am confident that the other farmers near my house use similar chemicals. My drinking water comes from a well on my property, and I fear that pesticides will run off into it through

the soil. I also worry that pesticides could enter the aquifer, threatening the health of my entire community. I take care to avoid such exposure to pesticides, for example, by purchasing organic produce. But I am troubled to know that my husband and I might nonetheless suffer because we live near farms on which glyphosate or 2,4-D might be applied. I also continue to worry about the health of my dog. Because I fear she might be exposed to toxic pesticides, including Enlist Duo, I avoid taking her on walks next to farms, though it is not so easy to do so in such an agricultural area.

16. I am aware that the U.S. Environmental Protection Agency (EPA) recently approved the use of Enlist Duo, an herbicide that contains both glyphosate and 2,4-D. I am also aware that NRDC has challenged EPA's decision to approve Enlist Duo in part because the agency failed to evaluate the pesticide's impacts on monarchs. I support NRDC's lawsuit to invalidate EPA's approval of Enlist Duo. If the court were to revoke EPA's approval of Enlist Duo, and thereby prevent further increases in the use of glyphosate and 2,4-D, this would help safeguard the annual migration of monarchs through my area and the fulfillment that I derive from watching these beautiful creatures. It would also alleviate my concerns about the health risks that I, my husband, and my dog face through exposure to Enlist Duo.

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

Shelby Moravec — 10/19/15

Shelby Moravec — Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF WILLIAM OLMSTED

I, WILLIAM OLMSTED, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for approximately twenty years.

2. My support for NRDC is grounded in my concerns about mankind's impacts on the environment, and the resulting harms to both human health and wildlife. I spent a lot of time outdoors while growing up, and this experience instilled in me a lasting interest in the natural world. I have cared about conservation since childhood. This concern deepened during my time in college, when I read Rachel Carson's *Silent Spring* and learned about the devastating effects that pesticides can have on the environment. I worry about the widespread use of pesticides in American agriculture and the detrimental impacts on both human health and wildlife, including monarch butterflies. I understand that one of NRDC's core goals is to protect human health and wildlife from the harms posed by toxics in our environment, and I strongly support this goal.

3. My concern about the adverse effects of pesticides on human health was intensified in 1971, when I acquired an old farmhouse in Washburn County, Wisconsin, to serve as a summer home. All the water on my property came from—and still comes from—local wells. As a member of an active local homeowners association, I became very concerned about changes in water quality due to the

runoff of fertilizers and pesticides from the surrounding farmland. I became particularly worried about contamination of my drinking water.

4. My home in Wisconsin is located half a mile down the road from a working farm of about 140 acres. Soybeans are the dominant crop grown on this farm, although corn is planted there as well. In addition, there is another active farm of about two to three hundred acres three miles south of where I live. Both corn and soybeans are grown on that farm too.

5. Both my home and the nearby farms are part of the Long Lake watershed. Long Lake is an artificial lake that is about twenty miles long. There are working farms on three sides of the lake, all within approximately half a mile of the shore. Runoff from the farmland flows into the lake.

6. I am aware that EPA recently approved the use of the herbicide Enlist Duo for use on soybeans and corn in Wisconsin. I am also aware that Enlist Duo contains 2,4-D and glyphosate, chemicals that both pose various human health risks. I am worried that Enlist Duo will be applied to the soybean and corn fields near my property, and to the other farmland surrounding Long Lake. I am very concerned that Enlist Duo will contaminate my drinking water—since my property shares a water table with Long Lake and the surrounding agricultural fields—and that my personal health and well-being will suffer from my consumption of that water.

7. I have a deep attachment to my summer home and the surrounding area, where I feel a strong connection with the natural world. It would be devastating to me if my water were to become contaminated by Enlist Duo, diminishing the fulfillment that I derive from using the natural resources on my land. The value of my property would also plummet if my water were to become contaminated with 2,4-D or glyphosate, as nobody wants to live in a home where you cannot safely drink the water.

8. My concerns about Enlist Duo are not limited to my worries about contamination of my drinking water. I understand that the herbicide has contributed to the decline of the monarch butterfly—a decline that I have personally observed from my Wisconsin home.

9. When I first moved to Wisconsin in 1971, monarchs were abundant in my area. Along with my wife and children, I took daily walks to the nearby Audubon sanctuary, which included a large, forty-acre meadow filled with wildflowers. I would see hundreds of monarchs there throughout the summer. There were two waves of butterflies each year—one heading north in early summer and one returning south in late summer, approximately ten weeks later. When the monarchs were migrating through my area, I would spot about half a dozen or more butterflies each day. Although monarch caterpillars were much harder to spot, I would nonetheless see about half a dozen caterpillars every summer.

10. Beginning around 1998, however, I began to notice a decline in the number of monarchs migrating through my area. The decline has progressed over the years, and the last few years have been disastrous. I continue to take daily walks through Hunt Hill, the site of the Audubon nature reserve hear my home. The Friends of Hunt Hill Audubon Society currently manages this site, and the members of this group have been very assiduous in planting milkweed in the hopes of attracting more monarchs. Despite these efforts, I saw only seven monarch butterflies, and no monarch caterpillars, in the summer of 2014. Although I saw slightly more monarchs this past summer, there were not nearly as many as there used to be. It has been distressing to witness this decline, one that diminishes the fulfillment I derive from watching these beautiful insects.

11. Prior to 1971, I had been living full-time in Chicago. However, I decided to establish a summer home in Wisconsin in part so that my wife, children, and I could be closer to nature. Monarchs have been an integral part of the natural world that drew me to Wisconsin. I intend to continue watching monarchs there every year, for as long as they are around. However, I have been dismayed to observe their faltering migration, a loss that lessens my enjoyment of the natural environs that attracted me to rural Wisconsin. Over the years, I have read articles and followed news on monarchs and the dwindling monarch migration. I understand that glyphosate and 2,4-D both destroy milkweed, which is the sole food source for

monarch caterpillars. I am concerned that further increases in the use of these chemicals—made possible by EPA's approval of Enlist Duo in states including Wisconsin—would spell disaster for monarchs. The precipitous drop in butterfly numbers has already diminished my delight in witnessing the annual monarch migration, and I worry that the butterflies will cease their journey through the Long Lake area altogether.

12. I am aware that NRDC has challenged EPA's recent decision to approve Enlist Duo, both because the agency failed to evaluate the pesticide's impacts on monarchs and because it did not adequately acknowledge the human health risks it poses. I support NRDC's lawsuit to invalidate EPA's approval of Enlist Duo. If the court were to reverse EPA's approval of Enlist Duo, and thereby restrict further increases in the use of glyphosate and 2,4-D, this would help protect the annual migration of monarchs through the Long Lake area in Wisconsin and the fulfillment that I derive from watching these wondrous creatures. A court decision revoking EPA's approval of Enlist Duo would also safeguard my drinking water from contamination by glyphosate and 2,4-D, shielding me from the health risks posed by exposure to these toxic chemicals.

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

William Olmsted

10/16/2015

Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF GINA TRUJILLO

I, GINA TRUJILLO, do hereby affirm and state:

1. I am the Director of Membership for the Natural Resources Defense Council (NRDC). I have served in this position since January 2015.

2. My duties include supervising the preparation of materials that NRDC distributes to members and prospective members. Those materials describe NRDC and identify its mission.

3. NRDC is a membership organization incorporated under the laws of the State of New York. It is recognized as a not-for-profit corporation under section 501(c)(3) of the United States Internal Revenue Code.

4. NRDC's U.S. offices are located in New York, New York; Washington, D.C.; Chicago, Illinois; Bozeman, Montana; San Francisco, California; and Santa Monica, California.

5. NRDC currently has approximately 294,800 members in the United States. There are NRDC members residing in each of the fifty United States and in the District of Columbia.

6. NRDC's mission statement declares that the organization's purpose is "to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends." The mission statement goes on to declare that NRDC strives "to protect nature in ways that advance the long-term welfare of present and future generations," and "to help create a new way of life for humankind, one that

can be sustained indefinitely without fouling or depleting the resources that support all life on Earth." Accordingly, protecting human health by preventing pollution ranks among NRDC's top institutional priorities. As set forth in NRDC's statement of priorities: "Toxic chemicals in our environment . . . have been linked to cancer, birth defects and brain impairments. Reducing or eliminating the load of these dangerous chemicals in . . . the air we breathe, the food we eat and the water we drink can help reduce the toll of human disease and suffering."

7. Protecting monarch butterflies from the adverse effects of Enlist Duo is paradigmatic of NRDC's efforts to safeguard wildlife. NRDC has dedicated significant resources to defending animal species against toxic chemicals, including pesticides.

8. Protecting human health from the adverse effects of Enlist Duo likewise exemplifies NRDC's work. NRDC has sought for years to limit human exposure to toxics.

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

Gina Trujillo

Gina Trujillo

10/19/15

Date

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc. Petitioner, v. United States Environmental Protection Agency et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73353, 15-71213
Center for Food Safety, et al., Petitioners, v. United States Environmental Protection Agency, et al., Respondents, Dow AgroSciences LLC, Respondent-Intervenor.	)	Case Nos. 14-73359, 15-71207

DECLARATION OF DIANE WETZEL

I, DIANE WETZEL, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for approximately eleven years.

2. My support for NRDC stems from my love of the outdoors and my profound concerns about environmental degradation and its impacts on both human beings and other creatures. Being a member of NRDC helps me give voice to my environmental concerns. I support NRDC's efforts to safeguard human health and wildlife, including monarch butterflies, from the harms arising from rampant pesticide use in America.

3. I have lived in West Lafayette, Indiana, for the past eighteen years, and plan to continue to live there for the foreseeable future. My home is located in a heavily agricultural area, where corn and soybeans are the dominant crops. There is a field directly behind my home, where corn and soybeans are planted in alternating years. Half a mile down the road in the opposite direction, there is another field planted with corn and soybeans. In addition, the entire area starting from about two miles north of my home is devoted to agriculture, with corn and soybean fields stretching as far as the eye can see.

4. I have seen pesticides being sprayed on the corn and soybean fields near my home. Sometimes, vehicles with large, liquid-filled tanks, bearing "flammable" warning labels, use mechanical arms to spray chemicals on the fields. I have also

seen crop-dusting planes spraying pesticides on the fields two miles from my home.

5. I am aware that EPA has approved the use of the herbicide Enlist Duo for use on corn and soybeans in Indiana. I understand that Enlist Duo contains the chemicals 2,4-D and glyphosate. I am aware that 2,4-D has been linked to thyroid disorders and other human health harms, and that glyphosate is probably carcinogenic to humans, according to recent findings. I am concerned that Enlist Duo will be applied to the corn and soybean fields near my property, and that my health will be detrimentally affected by both inhalation of 2,4-D or glyphosate and consumption of drinking water contaminated with 2,4-D or glyphosate.

6. I am worried about direct exposure to Enlist Duo through volatilization and spray drift. When the weather permits, I go running or biking through the countryside three or four times a week. Doing so takes me past the corn and soybean fields near my home. I have breathed in pesticides on some of these excursions. While biking, for example, I have smelled heavy chemical odors emanating from the fields. I am therefore concerned that I will inhale Enlist Duo used in the fields around my property during my regular runs and bike rides.

7. I am also concerned about being exposed to Enlist Duo through my drinking water. Although my drinking water comes from the West Lafayette municipal water system rather than local wells, testing has revealed high levels of the

pesticide atrazine in that system. This indicates to me that pesticides enter, and are not fully removed from, the municipal water supply from which I obtain my drinking water. Accordingly, I fear that Enlist Duo, like atrazine, will contaminate the water that I drink.

8. I plan to continue living in my current home for at least the next five years, and perhaps indefinitely. My husband is Director of Convocations at Purdue University, and given the job market, it is unlikely that he will take a post elsewhere in the near future. In addition, maintaining an active lifestyle is important to me, so I plan to continue running and biking in the area around my home three to four times a week. EPA's approval of Enlist Duo for use in my area thus threatens to expose me to 2,4-D and glyphosate, thereby putting my health at risk.

9. In addition, I am concerned that my fourteen year-old son—who breathes the same air and drinks the same water as I do—will suffer health harms through exposure to Enlist Duo. I understand that there has been an increase in thyroid disorders among children in my area in recent years. One of my friend's doctors informed her, for example, that he has observed more and more cases of thyroid conditions among local children. I am aware that 2,4-D has been implicated in thyroid and developmental disorders. I am also aware that children are particularly vulnerable to the health risks posed by 2,4-D. I am therefore especially concerned

that my son will be harmed by inhalation of Enlist Duo applied to the corn and soybean fields in my area, and by drinking municipal water contaminated with 2,4-D.

10. My misgivings about EPA's approval of Enlist Duo are grounded not only in my concerns about my health and the health of my family, but also in my concerns about the fate of the monarch butterfly migration. I am aware that glyphosate and 2,4-D have contributed significantly to the decline of the monarch butterfly. I have personally observed this decline in the area where I live.

11. I first became interested in monarch butterflies about seven or eight years ago, when my son was in kindergarten. As part of a school project, my son was given a monarch cocoon. I bought my son books on monarchs and, upon reading about the butterflies myself, became fascinated by these complex and lovely creatures. I have since followed news on monarchs in newspapers and magazines, and on the websites of organizations including NRDC.

12. I moved to West Lafayette in the summer of 1997. During my initial years here, I saw approximately twenty monarchs every spring and summer. I saw the butterflies while running or biking near my home and sometimes on my own property. Seeing these marvelous insects filled me with delight. About twelve years ago, however, I began noticing a decline in the monarchs migrating through

my area. Although the decline took place gradually, it has reached a point where I see only one monarch—or no monarchs at all—each year.

13. When I first moved to West Lafayette, there was nothing growing on my lot. I have since tried to attract monarchs to my property by planting a variety of flowering, butterfly-attractive plants. For example, I have planted butterfly bushes, purple asters, sedum, black-eyed susans, lavender, basil, and thyme. Despite these efforts, I see almost no monarchs now. On the rare occasion that I do spot a monarch, I am filled with excitement. However, the sighting also fills me with anxiety, as I fear that it will be my last. Witnessing the monarch's decline has filled me with great sadness, diminishing the fulfillment I derive from observing these marvelous creatures. It has also lessened my pleasure in gardening, insofar as the plants that I cultivate fail to attract and benefit the butterflies.

14. I understand that glyphosate and 2,4-D both destroy milkweed, which is the only food source for monarch caterpillars. I am also aware that glyphosate is an ingredient in "Roundup Ready" pesticides. When I drive through the area around my home, I see signs bearing the "Roundup Ready" logo along the corn and soybean fields. I am concerned that EPA's approval of Enlist Duo for use in Indiana will increase the amount of glyphosate used in West Lafayette, further decimating the milkweed upon which monarchs depend. That Enlist Duo might also increase the amount of 2,4-D used in my area troubles me further. I have been

dismayed by the significant decline in the number of monarchs migrating through my area, a loss that has taken away from my enjoyment of living in the countryside.

15. EPA should do more to protect both humans and monarchs from the adverse effects of Enlist Duo. I am aware that NRDC has challenged EPA's decision to register Enlist Duo, based on harms to both human health and monarch butterflies. I support NRDC's lawsuit to nullify EPA's approval of Enlist Duo. If the court were to invalidate EPA's approval of Enlist Duo, this would safeguard the air I breathe and the water I drink from contamination by 2,4-D and glyphosate, thereby protecting me from the health risks linked to exposure to these chemicals; it would likewise protect my son from these same health risks. Revocation of Enlist Duo's registration would also limit further expansion in the use of 2,4-D and glyphosate in West Lafayette, protecting the fragile migration of monarchs through my area and the satisfaction I derive from observing the butterflies.

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

Diane Wetzel — 10.19.15

Diane Wetzel — Date