

PETITION TO CANCEL
THE REGISTRATIONS FOR ENLIST DUO HERBICIDE

INTRODUCTION

The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals that represents over 1.2 million members and online activists. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), NRDC hereby petitions the U.S. Environmental Protection Agency (EPA) to cancel its October 15, 2014 and March 31, 2015 registrations for the herbicide Enlist Duo. ER 1-6¹; ER 7-36; *see* 7 U.S.C. § 136d(b); 5 USC § 553(e); *Wash. Toxics Coal. v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1031 (9th Cir. 2005), *abrogated on other grounds by Cottonwood Env'tl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1078 (9th Cir. 2015). NRDC does not have any financial interest in the cancellation of Enlist Duo.

In November 2015, EPA moved the Ninth Circuit Court of Appeals for voluntary remand and vacatur of the Enlist Duo registrations, conceding that it had insufficient information to determine whether the pesticide satisfied FIFRA's safety standard. Resp'ts' Mot. for Voluntary Vacatur and Remand, ECF No. 121-1 (Nov. 24, 2015) [hereinafter EPA Mot. for Vacatur and Remand]. The Ninth Circuit granted EPA's motion to remand the registrations and "denied without prejudice to the rights of either party to litigate . . . before the agency" EPA's request for vacatur of the registrations. Order, ECF No. 128, at 2 (Jan. 25, 2016).²

¹ "ER" refers to the Excerpts of Records filed in the case *Natural Resources Defense Council v. U.S. Environmental Protection Agency (NRDC v. EPA)*. *See* Pet'r's Excerpts of Record Volume I to VII, *NRDC v. EPA*, No. 14-73353, ECF Nos. 107-3 to 107-8 (Oct. 23, 2015). Unless otherwise noted, all court documents cited in this petition are from *NRDC v. EPA*, No., 14-73353.

² When citing court documents, this petition uses the page numbers and dates assigned by the Case Management/Electronic Case Files (CM/ECF) system in the document header.

NRDC maintains, as it did in its reply in support of EPA's motion for voluntary remand and vacatur, that EPA need not administer cancellation proceedings before revoking the registration for an unlawfully registered pesticide, because that registration is void ab initio. Pet'r NRDC's Reply in Supp. of EPA's Mot. to Vacate and Remand, ECF No. 125 (Dec. 17, 2015). Nonetheless, because EPA is treating the Enlist Duo registrations as though they are lawful, and because Enlist Duo thus remains on the market while EPA reevaluates the safety of the registrations on remand, NRDC now proceeds in accordance with EPA's presumption and seeks cancellation of the registrations.

EPA's concession that the Enlist Duo registrations do not meet FIFRA's safety standard justifies the initiation of cancellation proceedings. EPA admitted, and argued in court, that the registrations should be vacated, because the agency "did not have all relevant information at the time it made its registration decision." EPA Mot. for Vacatur and Remand, ECF No. 121-1, at 7; *see id.* at 2, 8-11. Specifically, EPA asserted that it had received new information from registrant Dow AgroSciences, Inc. (Dow) regarding potential synergistic effects on non-target plants between Enlist Duo's two active ingredients, the chemicals glyphosate and 2,4-D, only after EPA had already registered the herbicide. *See id.* at 2, 5-6. EPA further conceded it "might not have issued the existing registration had it been aware of the potential synergy information at the time the initial registration was issued." *Id.* at 11.

Cancellation proceedings are further warranted because EPA refused to consider, prior to registering Enlist Duo, additional relevant information regarding the environmental and human-health risks posed by the herbicide's use. As NRDC set forth in comments to EPA and filings in the Ninth Circuit, EPA failed to consider harm to monarch butterflies and refused to

evaluate significant new evidence of glyphosate's health risks, including cancer risk.³ Each of these major omissions independently renders the Enlist Duo registrations invalid and justifies cancellation proceedings.

Please treat this submission not only as a cancellation petition, but also as public comments on EPA's (1) pending remand proceedings for Enlist Duo and (2) deliberations on whether to expand the registration of Enlist Duo to additional states or crops.

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 v. U.S. EPA*, 800 F.3d 1176, 1177 (9th Cir. 2015). 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

³ See generally ER 451-86; ER 684-734; Br. of Pet'r Natural Resources Defense Council, ECF No. 106 (Oct. 23, 2015) [hereinafter NRDC Opening Br.]; Decl. of Dr. Sylvia Fallon in Supp. of Pet'r Natural Resources Defense Council's Mot. for Stay Pending Review, ECF No. 15-2 (Dec. 18, 2014); Decl. of Dr. Kristi Pullen in Supp. of Pet'r Natural Resources Defense Council's Mot. for Stay Pending Review, ECF No. 15-3 (Dec. 18, 2014); Reply Decl. of Dr. Sylvia Fallon in Supp. of Pet'r Natural Resources Defense Council's Mot. for Stay Pending Review, ECF No. 36-2 (Feb. 17, 2015); Reply Decl. of Dr. Kristi Pullen in Supp. of Pet'r Natural Resources Defense Council's Mot. for Stay Pending Review, ECF No. 36-3 (Feb. 17, 2015).

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.

The FIFRA regulations further provide that “[t]he registrant shall submit to the Administrator information . . . if the registrant knows, or reasonably should know, that if the information should prove to be correct,” the agency “might regard the information . . . as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.” 40 C.F.R. § 159.195(a). In addition, “[t]he registrant shall submit to the Administrator information . . . if the registrant has been informed by EPA that such additional information has the potential to raise questions about . . . the appropriate terms and conditions of registration of a product.” 40 C.F.R. § 159.195(c).

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 fifteen 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.*

FIFRA also provides procedures for cancelling pesticide registrations. *See* 7 U.S.C. § 136(b). The statute authorizes EPA to initiate cancellation proceedings “[i]f it appears to [EPA] that a pesticide . . . does not comply with the provisions of this subchapter.” *Id.*

BACKGROUND

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 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.” 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; *see also* Charles M. Benbrook, *Trends in Glyphosate Herbicide Use in the United States and Globally*, 28:3 *Envtl. Sci. Europe* 1, 2 (2016). 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. Indeed, “[u]se of glyphosate on some [glyphosate-resistant] crops may have declined, or may soon begin declining in some regions because . . . farmer willingness to pay for repeat applications of glyphosate, or further increase application rates, typically declines as glyphosate-resistant weeds become well established, as they have in much of the U.S.” Benbrook, *supra*, at 10. 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 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*, 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 monarch butterfly, *Danaus plexippus*, is an iconic species famed for its annual migration across the continent. But the eastern population of North American monarchs has declined precipitously in recent years.⁴ 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 eighty percent; this past winter, a mere 150 million monarchs reached their winter refuge—only a slight improvement from the record low of 33.5 million butterflies in 2013.⁵ Scientists have warned that the monarch migration is at risk of vanishing.

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, 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

⁴ Monarch butterflies are found both east and west of the Rocky Mountains, although the western population is smaller than its eastern counterpart. *See* Candace Fallon et al., *The Xerces Soc’y for Invertebrate Conservation, Milkweeds and Monarchs in the Western U.S.* 2 (2015), *available at* <http://monarchjointventure.org/images/uploads/documents/MonarchsandMilkweed-May29.pdf>. This petition 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 petition are specifically to the eastern population of North American monarchs.

⁵ Although the size of the overwintering monarch population fluctuates from year to year, there is a clear overall downward trend starting from the mid-1990s. *See* Monarch Watch, *Monarch Population Status*, MonarchWatch.org (Feb. 26, 2016), <http://monarchwatch.org/blog/>.

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 approximately 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; *see generally* John M. Pleasants, *Monarch Butterflies and Agriculture*, in *Monarchs in a Changing World* 169 (Karen S. Oberhauser, et al., ed., 2015). 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. ER 685, 690-91. As a non-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; *accord* Benbrook, *supra*, at 7 (identifying the commercialization of genetically engineered herbicide-tolerant crops as the “dominant factor” causing the increase in

acreage treated with glyphosate). 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; *see also* Benbrook, *supra*, at 7 (reporting that 12,474,000 kilograms of glyphosate were used for agriculture in 1995, whereas 113,356,000 kilograms of glyphosate were used for agriculture in 2014).

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; *see* Pleasants, *supra*, at 177-78. A survey of milkweed in Iowa corn fields 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, 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, 1273-74. 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.⁶ 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. That 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 dominant cause of 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; see Pleasants, *supra*. 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

⁶ At the same time, conserving milkweed habitat in the Midwest alone is insufficient to ensure long-term survival of the monarch butterfly population. See generally D.T. Flockhart et al., *Tracking Multi-Generational Colonization of the Breeding Grounds by Monarch Butterflies in Eastern North America*, 280: 1768 Proc. Royal Botanical Soc’y 1 (2013).

higher rates, when applied to herbicide-resistant crops. ER 899-900; *see*, Benbrook, *supra*, at 7 (“Not only has glyphosate been sprayed on more hectares planted to [herbicide-tolerant] crops, it has also been applied more intensively—i.e., more applications per hectare in a given crop year, and higher one-time rates of application.”); *id.* at 3 fig. 1, 10. 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 to suppress 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 2002, a single storm killed approximately 500 million monarchs—that is, over three times

the 150 million monarchs overwintering in Mexico during the 2015-16 winter.⁷ 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. Diminishing colony size also decreases the efficiency of locating mates among overwintering monarchs, which can lead to lower fecundity in the spring. Semmens, *supra* note 7, at 5-6.

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. In March 2016, scientists from the U.S. Geological Survey, Scripps Institution of Oceanography, and other institutions

⁷ See also Brice X. Semmens, *Quasi-Extinction Risk and Population Targets for the Eastern, Migratory Population of Monarch Butterflies* (*Danaus Plexippus*), 6 *Sci. Reports* 1, 5-6 (2016) (explaining that “tightly clustered overwintering colonies convey important microclimate advantages that diminish as colony size decreases,” so that “[d]iminishing colony size can therefore result in higher winter mortality rates”); compare Lincoln P. Brower et al., *Catastrophic Winter Storm Mortality of Monarch Butterflies in Mexico During January 2002*, in *The Monarch Butterfly: Biology and Conservation* 151, 162 (Karen S. Oberhauser & Michelle J. Solensky, eds.) (2002), with Monarch Watch, *supra* note 5 (reporting that overwintering monarchs occupied 4.01 hectares during the 2015-2016 winter season), and World Wildlife Fund, *Aumenta la Superficie Ocupada por la Mariposa Monarca en Los Santuarios Mexicanos* (Feb. 26, 2010), <http://www.wwf.org.mx/?262370/Aumenta-superficie-ocupada-por-mariposa-monarca-en-santuarios-mexicanos> (same), and ER 696 (explaining that the area occupied by overwintering monarchs is a proxy for population size), and Pollinator Health Task Force, *National Strategy to Promote the Health of Honey Bees and Other Pollinators* (May 19, 2015) (assuming an estimated density of 37.5 million butterflies per hectare).

Severe storms are not uncommon. In 2010, for example, 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 (reporting that the butterflies occupied a total of only 0.67 hectares, or 1.65 acres, during the winter of 2013). As recently as March 2016, a severe storm hit the monarchs' overwintering habitat. See *Monarch Butterflies Struggle Against Snowstorm in Mexico—Video*, *The Guardian* (Mar. 15, 2016), <http://www.theguardian.com/world/video/2016/mar/15/migrating-monarch-butterflies-snowstorm-mexico-video>. Although monarch experts are still working to quantify the storm's impact, preliminary data point to fifty percent monarch mortality.

concluded that the migratory population of eastern monarchs faces a “substantial probability”—from eleven to fifty-seven percent over twenty years—of extinction. Semmens, *supra* note 7, at 1-6; *accord* Press Release, U.S. Geological Survey, Eastern Monarch Butterflies at Risk of Extinction Unless Numbers Increase (Mar. 21, 2016).

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. ER 1497; EPA, Risk Assessment for Carcinogens, <http://www2.epa.gov/fera/risk-assessment-carcinogens> (Oct. 2, 2015); *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 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 was no evidence in the administrative record for the Enlist Duo registrations 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 (Oct. 23, 2015). 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, the World Health Organization’s reviews are the “gold standard” in evaluating evidence on cancer causation. 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. 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. Subsequently, in June 2016, the World Health Organization announced its finding that 2,4-D is “possibly carcinogenic to humans.” Int’l Agency for Agency for Research on Cancer (IARC), World Health Org., *IARC Monographs Evaluate DDT, Lindane, and 2,4-D*, at 1 (June 23, 2015), *available at* https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr236_E.pdf.

IV. Enlist Duo may pose a risk to non-target plants

There are studies that suggest that the combination of glyphosate and 2,4-D might have harmful synergistic effects on non-target plants. *See, e.g.*, ER 774-75. While assessing the safety of 2,4-D for use in Enlist Duo, EPA formally requested from Dow “end-use product data addressing phytotoxicity since some of the formulations are mixed with glyphosate.” Letter from Daniel Kenny, Chief, Herbicide Branch, Registration Division, Office of Pesticide Programs, EPA, to Diego Fonseca, Regulatory Leader, Regulatory Affairs, Dow AgroSciences, LLC 1 (Nov. 5, 2012) [hereinafter Synergy Letter]; *see also* 40 C.F.R. § 159.195(c) (“The registrant shall submit to the

Administrator information . . . if the registrant has been informed by EPA that such additional information has the potential to raise questions about . . . the appropriate terms and conditions of registration of a product.”). Specifically, EPA requested “seedling emergence and vegetative vigor studies on the formulated product,” Synergy Letter, *supra*, at 1, which are typically studies that the agency requests to assess a pesticide’s effects on non-target plants, *see* 40 C.F.R. § 158.660.

It appears that EPA never received these data from Dow prior to registering Enlist Duo. *See* ER 1104 (stating that “no terrestrial plant data for this formulation are available”). In its 2013 ecological risk assessment for use of 2,4-D on Enlist corn and soy, EPA “anticipated that there could be additional toxicological effects (synergistic or additive)” for “the 2,4-D choline salt-glyphosate formulation.” ER 1045. The agency acknowledged that “it is possible that the 2,4-D choline salt/glyphosate formulation will be more toxic to plants than the single active ingredient products,” ER 1104, and that “[t]his could change the outcome of the [risk] assessment by yielding more sensitive toxicity values for terrestrial plants,” ER 1045. Nonetheless, EPA appears not to have followed through on its earlier data request from Dow.

V. 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-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. In addition, EPA received comments that its "assessment also ignored any of the 2,4-D/glyphosate combination's synergistic effects, which it acknowledged may be more toxic to plants than the single active ingredient products." ER 1104 (internal quotation marks omitted).

On October 15, 2014, EPA registered Enlist Duo for use in six states.⁸ 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 its 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. With respect to potential synergistic effects on plants, EPA simply asserted, "Given that there is no indication of synergism between 2,4-D and glyphosate for mammals, freshwater fish, and freshwater invertebrates, EPA believes it is reasonable to assume that there are no synergistic interactions for the taxonomic groups that were not tested, including plants." ER 573.

⁸ Those states are Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. ER 2.

On October 30, 2014, NRDC filed a petition for review in this Court challenging the registration. Petition for Review, ECF No. 1-1 (Oct. 30, 2014). That same day, a group of petitioners led by the Center for Food Safety filed a separate petition for review challenging the registration. Petition for Review, Case No. 14-73359, ECF No. 1-2 (Oct. 30, 2014). The Court consolidated the two lawsuits in December. Order, ECF No. 11 (Dec. 11, 2014).

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, 2015.⁹ ER 1-2. To support the expanded registration, EPA depended 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

⁹ 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 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, ECF No. 53-2 (Apr. 13, 2015).

NRDC filed a second petition for review challenging EPA's second registration order, as did the Center for Food Safety petitioners. Petition for Review, Case No. 15-71213, ECF No. 1-2 (Apr. 20, 2015); Petition for Review, Case No. 15-71207, ECF No. 1-2 (Apr. 20, 2015). The Court subsequently consolidated all of the petitions for review. Order, ECF No. 66 (June 2, 2015).

NRDC filed its opening brief in October 2016. NRDC Opening Br., ECF No. 106. Shortly thereafter, in November 2016, EPA represented to the Ninth Circuit that it was "in receipt of new information regarding potential synergistic effects between the two ingredients [in Enlist Duo] on non-target plants." EPA Mot. for Vacatur and Remand, ECF No. 121-1, at 2; *see also* Letter from Susan Lewis, Division Director, Registration Division, Office of Pesticide Programs, EPA, to Diego Fonseca, Dow AgroSciences LLC, ECF No. 121-2 (Nov. 24, 2015); Decl. of Donald Brady, Ph.D, ECF No. 121-3 (Nov. 24, 2015). EPA explained that Dow had "made claims of 'synergistic herbicidal weed control' in its . . . patent applications for Enlist Duo," claims that Dow had not shared with EPA prior to the agency's decisions to register Enlist Duo—despite Dow's obligation to do so. EPA Mot. for Vacatur and Remand, ECF No. 121-1, at 5; *see* 40 C.F.R. § 159.195(a) ("The registrant shall submit to the Administrator information . . . if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information . . . as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.").

In light of Dow's synergy claim, EPA expressed concerns that current mitigation measures on the approved pesticide label "may not be adequate to protect non-target plant species located outside the treated fields," including species listed as threatened or endangered

under the Endangered Species Act. *Id.* at 7, 8 & n.1. EPA sought both “a voluntary remand in order to reconsider the Enlist Duo registration in light of the new information” and “vacatur of the registration because EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment.” *Id.* at 2. EPA further asserted that “it can no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in FIFRA,” *id.* at 7-8; that EPA cannot now determine “whether a new registration could be issued,” *id.* at 8; and that “EPA can no longer be confident that Enlist Duo will not cause risks of concern,” *id.* at 9.

VI. 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. Tab B: Petition to Conduct Interim Administrative Review for the Pesticide Glyphosate, in Light of Serious Harm to Monarch Butterflies, ECF No. 26-3 (Jan. 23, 2015); *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* Letter from Jack E. Housenger, Office of Pesticide Programs, EPA, to Margaret Hsieh and Sylvia Fallon, NRDC, ECF No. 87-2, at 2 (July 17, 2015).

ARGUMENT

Cancellation is warranted, because EPA’s registration decisions for Enlist Duo do not comport with FIFRA’s registration requirements.

I. Continued registration of a pesticide is unjustified absent a valid safety determination by EPA based on sufficient data

EPA may register a pesticide only after the agency has found, based on sufficient data, that use of the pesticide will not cause “unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 158.75. In other words, a pesticide registration can be lawful only if EPA first makes a valid, affirmative finding that the pesticide meets FIFRA’s safety standard. *See id.* To make such a finding, EPA must 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. EPA must also determine that “no additional data are necessary” to make a determination of no unreasonable adverse effects. 40 C.F.R. § 158.112; *accord Pollinator Stewardship Council*, 806 F.3d 520, 528 (9th Cir. 2015).

FIFRA authorizes EPA to undertake cancellation proceedings “[i]f it appears to [EPA] that a pesticide . . . does not comply with the provisions of this subchapter,” 7 U.S.C. § 136d(b). Noncompliance with FIFRA’s registration requirements—including its requirement for an initial safety determination by EPA based on sufficient data—thus justifies the initiation of cancellation proceedings.

II. EPA has never made a valid safety determination for Enlist Duo based on sufficient data

In registering Enlist Duo, EPA determined that the herbicide would not cause unreasonable adverse effects on the environment or human health. *See* U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 158.75. However, that safety determination is rendered invalid by EPA’s failure

to consider (A) adequate information regarding Enlist Duo's synergistic effects on non-target plants, (B) any information regarding Enlist Duo's adverse impacts on monarchs, and (C) up-to-date information regarding Enlist Duo's human-health risks, including cancer risk.

A. EPA expressly rescinded its safety determination for Enlist Duo, because that finding rested on inadequate information about harm to non-target plants

As discussed, EPA conceded in court that it “cannot be sure, without a full analysis of the new information [regarding Enlist Duo's synergistic effects on non-target plants], that the current registration does not cause unreasonable effects to the environment.” EPA Mot. for Vacatur and Remand, ECF No. 121-1, at 2; *see generally supra* Background Section V. In effect, EPA acknowledged that its registrations of Enlist Duo were not based on “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.

Notably, although EPA refers to the synergy data as “new information,” the data existed *before* EPA registered Enlist Duo. *See* EPA Mot. for Vacatur and Remand, ECF No. 121-1, at 5. Although Dow was obligated to provide EPA with that information to inform EPA's deliberations *before* the agency registered Enlist Duo, *see* 40 C.F.R. § 159.195(a)(3), Dow did not do so. Without considering the information underlying Dow's synergy claim, EPA could not have made an adequately informed determination that Enlist Duo meets FIFRA's safety standard, and this omission renders the registrations invalid.

B. EPA refused to consider harm to monarch butterflies

In registering Enlist Duo, EPA also ignored evidence that registration of Enlist Duo would harm the already imperiled population of North American monarchs.

I. EPA ignored 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, a risk 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*, 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.

2. 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 (Jan. 23, 2015) (“[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* Background Section I. And the record indicates that Enlist Duo may even prompt growers to expand their reliance on glyphosate-containing pesticides. *See id.* 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.

3. 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*, 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.

C. EPA refused to consider decades of research regarding glyphosate's health effects, specifically new studies on cancer risk

EPA's registration of Enlist Duo also violated FIFRA 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; *see also* John Peterson Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, 15:19 *Envtl. Health* 1, 1-13 (2016) (concluding that animal and epidemiology studies published over the past decade identify the need for a new look at glyphosate toxicity). 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.”¹⁰ 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, *NRDC v. EPA*, Case No. 15-71213, ECF No. 29-1, at 17 (June 22, 2015); *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.

¹⁰ In June 2016, the World Health Organization announced its subsequent finding that 2,4-D is possibly carcinogenic to humans. *See* Int’l Agency for Agency for Research on Cancer (IARC), World Health Org., IARC Monographs Evaluate DDT, Lindane, and 2,4-D, at 1 (June 23, 2015), *available at* https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr236_E.pdf. EPA should consider this finding, as well as the underlying studies, as it reconsiders the Enlist Duo registrations on remand.

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 EPA’s certified administrative record for the Enlist Duo registration decisions. *Compare* Hsieh Decl. Ex. A, ECF No. 105-3, at 3, *with* Certified Index to the Admin. Record, ECF No. 53-2. 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). EPA’s decisions to register Enlist Duo thus do not comport with FIFRA.

III. Because EPA failed to make a valid initial safety determination for Enlist Duo, continued registration of the herbicide is inconsistent with FIFRA

When EPA “has no real idea whether [a pesticide] will cause unreasonable adverse effects,” the agency’s registration decision violates FIFRA. *Pollinator Stewardship Council*, 806 F.3d at 531. Without having considered—either adequately or at all—Enlist Duo’s synergistic effects on non-target plants, impacts on monarch butterflies, and risks to human health, the agency cannot have a real idea whether Enlist Duo will pose unreasonable adverse effects to humans or the environment. Continued registration of Enlist Duo thus “does not comply with the

provisions of this subchapter,” 7 U.S.C. § 136d(b)—in particular, the registration provision requiring an affirmative safety determination based on sufficient data, *see id.* § 136a(c)(5)(C), (D); 40 C.F.R. § 158.75—thereby warranting the initiation of cancellation proceedings.

CONCLUSION

EPA’s concession that Enlist Duo does not meet FIFRA’s safety standard is, on its own, sufficient to warrant cancellation proceedings. EPA’s disregard of harm to monarchs, and the agency’s refusal to consider up-to-date information on glyphosate’s health risks, also both independently justify initiation of the cancellation process.

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Respectfully submitted,



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APPENDIX: LIST OF CITED DOCUMENTS¹¹

I. Excerpts of record (ER) from *NRDC v. EPA*

- ER Volume I, ECF No. 107-3
- ER Volume II, ECF No. 107-4
- ER Volume III, ECF No. 107-5
- ER Volume IV, ECF No. 107-6
- ER Volume V, ECF No. 107-7
- ER Volume VI, ECF No. 107-8
- ER Volume VII, ECF No. 107-9

II. Other court documents from *NRDC v. EPA*

Case No. 14-71213

- EPA's Opp'n to Mot. to Stay, ECF No. 29-1 (June 22, 2015)

Case No. 14-73353

- Declaration of Dr. Sylvia Fallon in Support of Petitioner Natural Resources Defense Council's Motion for Stay Pending Review, ECF No. 15-2 (Dec. 18, 2014)
- Declaration of Dr. Kristi Pullen in Supp. of Petitioner Natural Resources Defense Council's Motion for Stay Pending Review, ECF No. 15-3 (Dec. 18, 2014)
- EPA Opp'n to Mot. to Stay, ECF No. 24 (Jan. 23, 2015)
- Tab B: Petition to Conduct Interim Administrative Review for the Pesticide Glyphosate, in Light of Serious Harm to Monarch Butterflies, ECF No. 26-3 (Jan. 23, 2015)
- Reply Declaration of Dr. Sylvia Fallon in Support of Petitioner Natural Resources Defense Council's Motion for Stay Pending Review, ECF No. 36-2 (Feb. 17, 2015)
- Reply Declaration of Dr. Kristi Pullen in Supp. of Petitioner Natural Resources Defense Council's Motion for Stay Pending Review, ECF No. 36-3 (Feb. 17, 2015).
- Certified Index to the Admin. Record, ECF No. 53-2 (Apr. 13, 2015)
- Letter from Jack E. Housenger, Office of Pesticide Programs, EPA, to Margaret Hsieh and Sylvia Fallon, NRDC, ECF No. 87-2 (July 17, 2015)
- Hsieh Decl. Ex. A, ECF No. 105-3 (Oct. 23, 2015)
- Hsieh Decl. Ex. B, ECF No. 105-4 (Oct. 23, 2015)
- Hsieh Decl. Ex. C, ECF No. 105-5 (Oct. 23, 2015)
- Brief of Petitioner Natural Resources Defense Council, ECF No. 106 (Oct. 23, 2015)
- Respondents' Motion for Voluntary Vacatur and Remand, *NRDC v. EPA*, No. 14-73353, ECF No. 121-1 (Nov. 24, 2015)

¹¹ The documents listed in this Appendix are cited in the Cancellation Petition. NRDC downloaded these documents onto DVDs, and sent the DVDs to EPA's Document Processing Center located at the following address: Mail Code: 7504P, One Potomac Yard, 2777 S. Crystal Dr., Arlington, VA 22202.

- Letter from Susan Lewis, Division Director, Registration Division, Office of Pesticide Programs, EPA, to Diego Fonseca, Dow AgroSciences LLC, ECF No. 121-2 (Nov. 24, 2015)
- Decl. of Donald Brady, Ph.D, ECF No. 121-3 (Nov. 24, 2015)
- Petitioner NRDC's Reply in Support of EPA's Motion to Vacate and Remand, ECF No. 125 (Dec. 17, 2015)
- Order, ECF No. 128 (Jan. 25, 2016)

III. Other documents

- 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 (2014)
- Charles M. Benbrook, *Trends in Glyphosate Herbicide Use in the United States and Globally*, 28:3 *Envtl. Sci. Europe* 1 (2016)
- Lincoln P. Brower et al., *Catastrophic Winter Storm Mortality of Monarch Butterflies in Mexico During January 2002*, in *The Monarch Butterfly: Biology and Conservation* 151 (Karen S. Oberhauser & Michelle J. Solensky, eds.) (2002)
- EPA, Risk Assessment for Carcinogens (Oct. 2, 2015)
- Candace Fallon et al., *The Xerces Soc'y for Invertebrate Conservation, Milkweeds and Monarchs in the Western U.S.* (2015)
- D.T. Flockhart et al., *Tracking Multi-Generational Colonization of the Breeding Grounds by Monarch Butterflies in Eastern North America*, 280: 1768 *Proc. Royal Botanical Soc'y* 1 (2013)
- Int'l Agency for Agency for Research on Cancer (IARC), World Health Org., IARC Monographs Evaluate DDT, Lindane, and 2,4-D (June 23, 2015)
- Letter from Daniel Kenny, Chief, Herbicide Branch, Registration Division, Office of Pesticide Programs, EPA, to Diego Fonseca, Regulatory Leader, Regulatory Affairs, Dow AgroSciences, LLC (Nov. 5, 2012)
- *Monarch Butterflies Struggle Against Snowstorm in Mexico—Video*, *The Guardian* (Mar. 15, 2016)
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