

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council,)	
Inc.)	
)	
Petitioner,)	
)	
v.)	Case No. 15-71213
)	
United States Environmental Protection)	
Agency,)	
)	
Respondent.)	
)	

**PETITIONER NATURAL RESOURCES DEFENSE COUNCIL’S
MOTION TO STAY AMENDED REGISTRATION PENDING REVIEW**

Pursuant to Federal Rule of Appellate Procedure 18 and 5 U.S.C. § 705, Petitioner Natural Resources Defense Council (NRDC) moves to stay the United States Environmental Protection Agency (EPA)’s unlawful amended registration of the herbicide Enlist Duo, which contains as active ingredients the chemicals glyphosate and 2,4-D. Absent a stay, Enlist Duo will be authorized for widespread use pending judicial review, causing irreparable harm to both the imperiled North American monarch butterfly and to people.

NRDC previously challenged and moved to stay EPA’s initial registration of Enlist Duo, which was limited to six states. *See* Case No. 14-73353, ECF Nos. 1-1,

15-1. That stay motion is still pending before this Court. EPA has now amended its registration decision to allow use of Enlist Duo in fifteen states instead of six, more than doubling the approved geographic area where this pesticide can be applied. ECF No. 1-3 at 2-3.¹ The new states where Enlist Duo can now be used comprise crucial portions of migration corridors for the monarch butterfly. NRDC's arguments for a stay apply with even more force to the amended registration, which authorizes more pervasive and thus more harmful use of the herbicide than was originally approved and ignores significant new information about the human health risks posed by glyphosate.

PROCEDURAL BACKGROUND

EPA registered Enlist Duo for use in six states in October 2014. *See* Case No. 14-73353, ECF No. 15-11 at 20, ECF No. 15-13. NRDC and Center for Food Safety et al. separately petitioned for review of that registration decision and also moved to stay the registration. *See* Case No. 14-73353, ECF Nos. 1-1, 15-1; Case No. 14-73359, ECF Nos. 1-2, 32-1. Those stay motions are still pending. EPA issued an amended registration for Enlist Duo in March 2015, expanding the approved use of the pesticide to nine additional states. *See* ECF No. 1-3 at 2-3. In doing so, EPA relied on the same record as it did for its initial registration of Enlist Duo, plus one additional study relating to endangered species. *See id.* at 3.

¹ The ECF pagination is used for all citations to ECF documents.

Both NRDC and Center for Food Safety challenged EPA's amended registration decision by filing new petitions for review and by moving to amend their original petitions for review. *See* ECF No. 1-2; Case No. 15-71207, ECF No. 1-2; Case No. 14-73353, ECF No. 60-1; Case No. 14-73359, ECF No. 60-1. Both petitioners also moved to consolidate all four petitions for review. *See* ECF No. 3-1; Case No. 15-71207, ECF No. 2-1. Petitioners' motions to amend, as well as the motions to consolidate, remain pending.

Thereafter, NRDC moved EPA to stay its amended registration of Enlist Duo, pending review by this Court. Decl. of Margaret Hsieh Ex. A; *see* Fed. R. App. P. 18(a)(1) ("A petitioner must ordinarily move first before the agency for a stay pending review of its decision or order."). EPA denied NRDC's motion, *see* Hsieh Decl. Ex. B, and NRDC now moves this Court for a stay pending judicial review. Respondent EPA opposes NRDC's motion. Center for Food Safety concurs in NRDC's request for a stay pending review and will move separately for its own stay pending review.

ARGUMENT

The circumstances here warrant a stay because: (1) NRDC is likely to succeed on the merits of its challenge to the amended registration decision, (2) NRDC will suffer irreparable harm without a stay, and (3) the balance of equities strongly favors granting a stay. The same arguments that support NRDC's

pending motion to stay the original Enlist Duo registration, *see* Case No. 14-73353, ECF Nos. 15-1, 36-1, apply to EPA's expanded approval decision.²

I. Standard governing issuance of a stay

“A party seeking a stay must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of relief, that the balance of equities tip[s] in his favor, and that a stay is in the public interest.”

Humane Soc’y of the U.S. v. Gutierrez, 558 F.3d 896, 896 (9th Cir. 2009). When a stay is sought against the government, the last two factors merge. *Leiva-Perez v. Holder*, 640 F.3d 962, 970 (9th Cir. 2011).

II. NRDC is likely to succeed on the merits of its challenge to EPA's amended registration decision for Enlist Duo

NRDC has “a substantial case for relief on the merits,” *Leiva-Perez*, 640 F.3d at 968, because NRDC can show that EPA violated the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(c)(5)(C), (D); *see* Case No. 14-73353, ECF No. 15-1 at 10-18, ECF No. 36-1 at 7-15.

A. Statutory and regulatory scheme

FIFRA authorizes EPA to register a pesticide for sale only upon determining that the pesticide “will perform its intended function without unreasonable adverse effects on the environment,” 7 U.S.C. § 136a(c)(5)(C), and that “when used in

² This motion does not advance the full set of arguments that NRDC plans to raise on the merits. It asserts only those contentions that are most amenable to adjudication prior to EPA's production of the administrative record.

accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment,” *id.*

§ 136a(c)(5)(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).

FIFRA’s definition of “unreasonable adverse effects on the environment” also includes “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 [i.e., the Food Quality Protection Act (FQPA)].” *Id.* Under the § 346a standard, EPA may allow a pesticide chemical residue on food only if it will be “safe,” which is defined to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.” 21 U.S.C. § 346a(b)(2)(A)(i), (ii). Section 346a further requires that “an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” *Id.* § 346a(b)(2)(C). EPA “may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.” *Id.*

B. NRDC has “a substantial case for relief on the merits” because EPA entirely failed to evaluate Enlist Duo’s impacts on monarch butterflies

To ascertain that Enlist Duo will not cause unreasonable adverse effects on the environment, EPA was required to evaluate impacts on monarch butterflies before making its amended registration decision. Herbicides containing glyphosate—one of the active ingredients in Enlist Duo—have devastated the North American monarch population by decimating milkweed, the sole food source for monarch caterpillars. Decl. of Sylvia Fallon ¶¶ 9, 11-14, Case No. 14-73353, ECF No. 15-2. That population has declined by approximately ninety percent since the late 1990s, driven in large part by a dramatic increase in the use of glyphosate-containing herbicides. *Id.* ¶¶ 8-9, 13-14. EPA cannot ensure that its amended registration of Enlist Duo will not cause “unreasonable adverse effects on the environment,” 7 U.S.C. § 136a(c)(5)(C), (D), without at least considering whether and how Enlist Duo will affect monarchs.

EPA has never considered glyphosate’s impacts on monarchs in connection with any pesticide registration decision. After Petitioners challenged EPA’s initial registration of Enlist Duo in this Court, the agency expanded the pesticide’s approval from six states to fifteen, yet still refused even to consider the extent to which Enlist Duo will harm monarchs. EPA’s amended decision is arbitrary and capricious because the agency “entirely failed to consider an important aspect of

the problem.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The agency’s omission is all the more egregious, given that the nine new states added by the amended registration, like the six states included in the original registration, make up critical portions of the migration pathways for monarchs. *See* Hsieh Decl. Ex. C at 15438, fig. 3.

C. “Serious questions” also exist as to whether EPA critically underestimated the human health risks posed by Enlist Duo

Although EPA’s failure to consider Enlist Duo’s adverse effects on monarchs is, by itself, sufficient to render the registration invalid, EPA’s failure to evaluate the herbicide’s health risks in accordance with FIFRA also supports a stay. *See* Case No. 14-73353, ECF No. 15-1 at 16-18, ECF No. 36-1 at 13-15. Pending production of the full administrative record, NRDC can show at least “serious questions,” *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011), going to the merits of that claim.

First, EPA ignored risks of cancer posed by exposure to glyphosate. Shortly before EPA issued its amended registration for Enlist Duo, the World Health Organization’s International Agency for Cancer Research (IARC) announced its finding that glyphosate was “probably carcinogenic to humans.” *See* Hsieh Decl. Ex. D at 491. EPA’s amended registration makes no mention of this cancer finding by an authoritative agency.

The second active ingredient in Enlist Duo, 2,4-D, is also associated with a number of adverse health outcomes, including higher rates of birth defects, potential for reduced sperm quality, and other signs of endocrine system disruption—particularly through heightened impacts on the thyroid system. Decl. of Kristi Pullen ¶¶ 6-8, Case No. 14-73353, ECF No. 15-3. Suppression of thyroid hormones during early life stages can cause permanent and irreversible damage to the brain, resulting in developmental delays, lower IQ level, and behavioral problems. *Id.* ¶ 7.

EPA underestimated 2,4-D's toxicity to fetuses, infants, and children by dismissing evidence of thyroid toxicity at low exposures. *Id.* ¶¶ 8-10. In addition, the agency documents currently available give no indication that EPA adequately accounted for exposure of fetuses, infants, and children to 2,4-D through various pathways, including breast milk and spray drift. *Id.* ¶¶ 12-13. EPA further erred in failing to apply the additional tenfold safety factor (margin of error) required by the FQPA to account for uncertainty as to both increased toxicity and greater exposure in infants and children. *Id.* ¶ 11; *see* 21 U.S.C. § 346a(b)(2)(C).

* * *

Because EPA took no further steps to evaluate the risks to either monarchs or human health before significantly expanding the terms of its Enlist Duo registration, NRDC's strong likelihood of success on the merits remains

undiminished, especially in light of substantial new information bearing directly on the health harms.

III. If Enlist Duo is allowed on the market despite EPA’s unlawful amended registration decision, NRDC and its members will suffer irreparable harm through loss of monarch butterflies and exposure to potentially dangerous levels of 2,4-D and glyphosate

The irreparable harm threatened by EPA’s initial decision to register Enlist Duo in six states, *see* Case No. 14-73353, ECF No. 15-1 at 18-21, ECF No. 36-1 at 16-19, is amplified by the agency’s decision to expand that registration to nine additional states. In December 2014, Dow AgroSciences, the developer, manufacturer, and sole registrant of Enlist Duo, represented that it intended to launch Enlist Duo in 2015. Decl. of Damon Palmer ¶ 8, Case No. 14-73353, ECF No. 8-2. The distribution, marketing, and use of Enlist Duo, including in the nine states at issue here, are therefore imminent if not already underway.

As explained above, EPA’s amended registration will lead to elevated use of Enlist Duo, thereby increasing the decimation of milkweed—the only food source for monarch caterpillars—and the resulting decline in the monarch population attributable to that herbicide. *See* Fallon Decl. ¶¶ 11-16. The Supreme Court has instructed that “[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable.” *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987). And this Court has recognized that the destruction of wildlife “is, by definition,

irreparable” harm. *Humane Soc’y of the U.S. v. Gutierrez*, 523 F.3d 990, 991 (9th Cir. 2008). The approved use of Enlist Duo in the nine additional states will cause irreparable harm by contributing to the ongoing loss of monarchs, particularly when the monarch population is already so imperiled that continued suppression of milkweed, even over a single migration cycle, threatens to foreclose meaningful recovery. *See* Fallon Decl. ¶¶ 16-17.

In addition, EPA’s amended order will increase human exposure to the health risks posed by Enlist Duo, causing further irreparable harm. *See* Case No. 14-73353, ECF No. 15-1 at 21. As noted, 2,4-D can decrease thyroid hormone levels, Pullen Decl. ¶ 8, and even slight suppression of thyroid hormones during development can cause permanent health harm, *id.* ¶¶ 7, 14. As reflected in the recent IARC announcement, moreover, exposure to glyphosate creates risks of cancer. *See* Hsieh Decl. Ex. D. Exposure to a probable carcinogen constitutes further irreparable harm that NRDC’s members will suffer absent a stay.

IV. The irreparable harms to monarchs and human health outweigh any countervailing interests

As discussed in NRDC’s pending motion to stay EPA’s initial registration of Enlist Duo, the balance of harms tips sharply in favor of a stay. Case No. 14-73353, ECF No. 15-1 at 21-24, ECF No. 36-1 at 19-21. EPA correctly conceded that the balance of harms “will usually favor an injunction to protect the environment.” Case No. 14-73353, ECF No. 24 at 24; *see Amoco Prod. Co.*, 480

U.S. at 545. The same is true of an injunction to protect human health. *See Golden Gate Rest. Ass'n v. City and Cnty. of San Francisco*, 512 F.3d 1112, 1126 (9th Cir. 2008), *abrogated on other grounds in Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). IARC's recent finding that glyphosate is "probably carcinogenic to humans" tips that balance even further in NRDC's favor. Hsieh Decl. Ex. D at 491.

EPA has not identified countervailing factors sufficient to disturb this balance. The agency insists that Enlist Duo is "new" and "improved" compared to other weed control methods. Case No. 14-73353, ECF No. 24 at 24. However, non-pesticide weed control methods exist to help growers combat glyphosate-resistant weeds, and they will do so better than Enlist Duo. *See* Decl. of Charles Benbrook ¶ 14, Case No. 14-73353, ECF No. 15-4. And NRDC has presented evidence that Enlist Duo will actually *harm* growers, by promoting the development of glyphosate-resistant weeds. *See id.* ¶ 15.

V. Standing

NRDC and its members are adversely affected by EPA's amended registration decision and have standing to challenge it. To establish standing, NRDC must show that its members would have standing to sue in their own right, that the interests NRDC seeks to protect are germane to its organizational purposes, and that this litigation will not require its members' individual

participation. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977).

NRDC satisfies this test. NRDC's members would have standing to sue on their own because they suffer "injury in fact" traceable to the challenged EPA decision and that is likely to be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)); Decl. of Kathryn Atkinson ¶¶ 6, 7; Decl. of Janet Cady ¶¶ 8, 9; Decl. of Carl Jorgensen ¶¶ 3, 6-8. In addition, protection of wildlife and human health are germane to NRDC's organizational mission, and this litigation will not require the participation of individual NRDC members. *See Hunt*, 432 U.S. at 343; Decl. of Gina Trujillo ¶¶ 5-7.

* * *

For the reasons set forth above, NRDC respectfully requests the Court to stay EPA's amended registration of Enlist Duo pending review.

Dated: May 26, 2015

Respectfully submitted,

/s/ Margaret T. Hsieh

Margaret T. Hsieh

Nancy S. Marks

Natural Resources Defense Council

40 W. 20th Street

New York, NY 10011

Telephone: (212) 727-2700

Facsimile: (212) 727-1773

mhsieh@nrdc.org

Aaron Colangelo

Natural Resources Defense Council

1152 15th Street NW, Suite 300

Washington, DC 20005

Telephone: (202) 289-2376

Facsimile: (202) 289-1060

acolangelo@nrdc.org

Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of Petitioner NRDC's Motion for Stay

Pending Review by ECF on May 26, 2015, on the following counsel:

T. Monique Peoples
U.S. Department of Justice, ENRD
Environmental Defense Section
P.O. Box 7611
Washington, DC 20044

John Brett Grosko
United States Department of Justice
Wildlife and Marine Resources Section
P.O. Box 7611
Washington, D.C. 20044-7611
Tel.: 202.305-0342
Fax: 202.305-0275

Christopher Landau
Kirkland & Ellis LLP
Suite 1200
655 Fifteenth St., NW
Washington, DC 20005

/s/ Margaret T. Hsieh
Margaret T. Hsieh