UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioner*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Respondent*, and DOW AGROSCIENCES LLC, *Intervenor-Respondent*.	Nos. 14-73353, 15-71213
CENTER FOR FOOD SAFETY, *et al.*, *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*, *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor-Respondent*.	Nos. 14-73359, 15-71207

PETITIONERS CENTER FOR FOOD SAFETY *ET AL.*'S JOINDER IN, AND RESPONSE TO, RESPONDENT EPA'S MOTION FOR VOLUNTARY VACATUR AND REMAND

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On November 24, 2015, Respondent Environmental Protection Agency (EPA) filed Respondents' Motion for Voluntary Vacatur and Remand, Dkt. 121-1. EPA asks the Court to vacate and remand EPA's registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of the herbicide Enlist Duo. Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity hereby join in EPA's motion, which seeks precisely the relief Petitioners sought in challenging EPA's registration. Petitioners also respond to comments Intervenor Dow AgroSciences (Dow) made publicly following EPA's motion, and offer this brief to provide additional perspective on why vacatur is mandated in this circumstance.

I. BACKGROUND

Following EPA's registration on October 15, 2014 of the herbicide Enlist Duo, Petitioners challenged the registration on the grounds that it violated FIFRA and the Endangered Species Act (ESA) by failing to adequately assess effects on the environment, including non-target species, and by failing to consult the U.S. Fish and Wildlife Service concerning effects on species listed as threatened and endangered, as the ESA requires. In March 2015, EPA amended its registration to allow use in nine additional states; Petitioners challenged this as well. Petitioners filed their opening merits brief on October 23, 2015; EPA's answering brief is due

on December 18, 2015. EPA now asks the Court to vacate the registration, conceding it overlooked important evidence that Enlist Duo's principal ingredients, 2,4-D and glyphosate, interact in a manner that makes the mixture more toxic than EPA had supposed.

According to EPA, "while searching the free patents online database" in August 2015, it discovered that Dow had applied for a patent claiming Enlist Duo's ingredients have synergistic effects, making the mixture more toxic than the sum of the ingredients alone. Decl. of Donald Brady, Dkt. 121-3 at 3. *See* EPA Motion, Dkt. 121-1 at 5 (with hyperlink to U.S. Patent Office folder containing Dow's patent application, first filed in December 2013). EPA, on October 13, 2015, asked Dow for information regarding this synergy, Dkt. 121-2, and received Dow's response on November 9, Dkt. 121-1 at 6. EPA moved to vacate the registration on November 24, 2015, after its preliminary review revealed the small buffers EPA's registration requires will not protect non-target plants, including endangered plants, thus violating FIFRA and the ESA. Dkt. 121-3, paras. 11-12.

Dow then released a public statement (a "Fact Sheet") asserting it "has now provided EPA with ample data to show that synergy of concern for non-target threatened or endangered plant species does not exist with the final Enlist Duo formulation when used at EPA-prescribed labeled rates of use." Decl. of Paul Achitoff, Exh. 1. Dow "calls upon" EPA to either reverse course, assume no

synergistic effects exist, and leave the registration in place without alteration, or at least hurry up and reapprove Enlist Duo so Dow and its customers will not be inconvenienced. *Id*.

II. VACATUR IS THE APPROPRIATE REMEDY HERE

When a court finds an agency's decision unlawful, vacatur is the standard remedy. *See, e.g.*, 5 U.S.C. § 706(2)(A) ("The reviewing court shall ... set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]"; *Se. Alaska Conserv. Council v. U.S. Army Corps of Eng'rs*, 486 F.3d 638, 654 (9th Cir. 2007) (vacatur is "the normal remedy for an unlawful agency action," and "a court should vacate the agency's action and remand to the agency to act in compliance with its statutory obligations.") (internal quotation marks and citation omitted), *rev'd on other grounds sub nom. Coeur Alaska v. Se. Alaska Conserv. Council*, 557 U.S. 261 (2009).

To determine whether it should vacate an agency decision, this Court must look at: (1) the seriousness of an agency's errors, and (2) the disruptive consequences that would result from vacatur. *Cal. Communities Against Toxics v. U.S. Envtl. Prot. Agency*, 688 F.3d 989, 992 (9th Cir. 2012) (*per curiam*) ("Whether agency action should be vacated depends on how serious the agency's errors are and the disruptive consequences of an interim change that may itself be

changed.") (internal quotation marks omitted) (quoting *Allied–Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993)). In balancing these factors in cases where, as here, an agency violates the ESA, courts must tip the scales in favor of the endangered species under the ESA's "institutionalized caution" mandate. *Sierra Club v. Marsh*, 816 F.2d 1376, 1383 (9th Cir.1987) (citation and quotation omitted); *see also Native Fish Soc'y & McKenzie Flyfishers v. Nat'l Marine Fisheries Serv.*, No. 3:12-CV-00431-HA , 2014 WL 1030479, at *3–4 (D. Or. Mar. 14, 2014) (noting "institutionalized caution" mandate in weighing *Allied–Signal* factors).

Courts in the Ninth Circuit decline vacatur pending remand only in rare circumstances, principally where vacatur will result in serious irreparable environmental harm. *See Humane Soc'y v. Locke*, 626 F.3d 1040, 1053 n. 7 (9th Cir. 2010) ("In rare circumstances, when we deem it advisable that the agency action remain in force until the action can be reconsidered or replaced, we will remand without vacating the agency's action."); *see Pollinator Stewardship Council, v. EPA*, __ F.3d __, 2015 WL 7003600 at *12 (9th Cir. Nov. 12, 2015); *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 951 (N.D. Cal. 2010) ("[T]he

Ninth Circuit has only found remand without vacatur warranted by equity concerns in limited circumstances, namely serious irreparable environmental injury.").[1]

EPA points out that vacatur is required in this case, to prevent irreparable environmental harm. EPA Motion, Dkt. 121-1 at 9-10; Decl. of Donald Brady, Dkt. 121-3 at 4-5. Petitioners not only agree, but believe EPA greatly downplays the potential for harm by focusing only on the buffers and terrestrial plants. If, as EPA now believes, Enlist Duo is more toxic than EPA had assumed, the herbicide may present a greater threat to all wildlife, and to human health. As Petitioners' opening brief describes in detail, even without this particular evidence, EPA's registration is riddled with errors and violates FIFRA and the ESA.

Petitioners (and petitioner in the consolidated challenge) are not alone in questioning EPA's assessment of Enlist Duo's risks. For example, a recent investigation details the questionable assumptions EPA employed in disregarding substantial evidence that one of Enlist Duo's main ingredients, 2,4-D (also one of the two main ingredients in Agent Orange, the notorious Vietnam-era defoliant)

[1] For example, in *Idaho Farm Bureau Federation v. Babbitt*, 58 F.3d 1392 (9th Cir. 1995), the U.S. Fish and Wildlife Service proposed to list a rare snail as an endangered species under the ESA, 58 F.3d at 1395, but failed to provide the public with an opportunity to review a report concerning the snails during the comment period. *Id.* at 1402–04. This Court recognized FWS's procedural error, but held the district court erred in vacating the rule listing the snail as endangered because vacatur risked contributing to "the potential extinction of an animal species." *Id.* at 1405. Moreover, the agency's error was unlikely to alter the agency's final decision. *Id*. at 1405–06.

does not cause kidney damage in humans at exposure levels EPA's registration allows:

> Industry-funded researchers have found kidney trouble before in animals consuming low doses of 2,4-D, the Tribune found. An industry group representing Dow and other 2,4-D manufacturers submitted five studies to the EPA in the 1980s that documented kidney abnormalities in rats and mice at doses far lower than the one the agency now is using to set safety levels for people.

http://www.chicagotribune.com/news/watchdog/ct-gmo-crops-pesticide-resistance-met-20151203-story.html (last viewed December 4, 2015).

Further:

> [T]he government's maximum-exposure projections show that U.S. children ages 1 to 12 could consume levels of 2,4-D that the World Health Organization, Russia, Australia, South Korea, Canada, Brazil and China consider unsafe.

Id. Thus, this matter cannot responsibly be resolved merely by tacking on a few feet to the buffers and hustling out a new registration, let alone swept under the rug because Dow is impatient. Absent vacatur, Enlist Duo will be approved for use on vast acreage in fifteen states—and EPA had already announced plans to extend the registration to more states soon.

Petitioners also agree with EPA that potential for harm far outweighs any likely economic disruption to Intervenor Dow. EPA Motion, Dkt. 121-1 at 10. Dow has declared publicly its confidence that "any potential synergy between 2,4-D choline and glyphosate can be promptly resolved in the next few months, in

time for the 2016 crop use season."[2] If EPA does rush out a new registration, vacatur will have cost Dow little to nothing. But even if EPA does not, the Court should vacate. The types of harms EPA admits are threatened at this juncture are irreparable, even if human health were not also at risk:

> [T]he plain language of the [Endangered Species] Act, buttressed by its legislative history, shows clearly that Congress viewed the value of endangered species as "incalculable." Quite obviously, it would be difficult for a court to balance the loss of a sum certain—even $100 million—against a congressionally declared "incalculable" value, even assuming we had the power to engage in such a weighing process, which we emphatically do not.

Tenn. Valley Auth. v. Hill, 437 U.S. 153, 187-88 (1978).

Regarding the other factor relevant to whether to vacate the registration, the seriousness of EPA's errors, EPA acknowledges that because its registration failed to incorporate the synergistic effects of combining Enlist Duo's two main ingredients, "EPA can no longer be confident that Enlist Duo will not cause risks of concern to non-target organisms, including those listed as endangered, when used according to the approved label." EPA Motion, Dkt. 121-1 at 10. Specifically, EPA admits "the 30-foot buffer [around sprayed fields] included in the registration may not be adequate." *Id*. at 6. EPA also admits it is not sure whether it can again register Enlist Duo, let alone with the same restrictions as before. *Id*. at 8 (EPA cannot now determine "whether a new registration could be

[2] https://www.dowagro.com/en-us/newsroom/pressreleases/2015/11/enlist-duo-statement#.Vl-NWpfG8Xg

issued and, if so, whether additional terms and conditions would be necessary for the new registration.") These facts demonstrate EPA's errors are sufficiently serious to warrant vacatur. *See Pollinator Stewardship,* 2015 WL 7003600 at *13 (vacatur required where "on remand, a different result may be reached")*; North Carolina v. U.S. Envtl. Prot. Agency*, 531 F.3d 896, 900 (9th Cir. 2008) (concluding that the EPA's rule "must" be vacated because "fundamental flaws" prevented the EPA from promulgating the same rule on remand).

III. DOW'S OBJECTIONS ARE WITHOUT MERIT

In its "Fact Sheet," Dow notes it has delivered to EPA information Dow deems sufficient to dispel any concern. Of course, FIFRA prohibits *EPA*—not *Dow*—from registering a pesticide that has "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). EPA had already reviewed Dow's data before EPA filed its motion to vacate; Dow's assessment of it is irrelevant.

Dow also notes that its synergy patent claim that precipitated EPA's motion "was ultimately expressly abandoned by the company when a thorough review of all the data generated found the synergies were not present in the final formulation selected for Enlist Duo." Achitoff Decl., Exh. 1. Dow fails to point out (at least in that document) that *Dow failed to abandon its claim until only a few weeks ago, on November 12, 2015*—a year after EPA registered Enlist Duo—and *only after EPA*

had demanded Dow's synergy data.[3] Dow obviously knew, by the time EPA registered Enlist Duo in October 2014, the formulation EPA had selected, but Dow did nothing to withdraw its patent claim until loss of the Enlist Duo registration was at stake. Dow's "nothing to see here" suggestion—that it should be obvious that this is all a false alarm, Dow's patent application was wrong, EPA's concern is unfounded, and the restrictions EPA imposed insure endangered species, human health, and the environment are fully protected—lacks any credibility. Under these circumstances, it would be grossly irresponsible to leave Enlist Duo on the market.

EPA violated its duties under FIFRA and the ESA once already, and must not compound its errors by failing to thoroughly re-examine its assumptions about Enlist Duo's toxicity during remand, after vacatur. It also is now even more obvious than ever that, as Petitioners demonstrated in their opening brief, Dkt. 107-1, EPA cannot meet its duties under the ESA to "insure" its registration is not likely to jeopardize any endangered species or any of their designated critical habitats, without first consulting the U.S. Fish and Wildlife Service, which EPA has thus far refused to do. 16 U.S.C. § 1536(a)(2).

Whether Enlist Duo's ingredients have synergistic effects has not suddenly become an issue just now; EPA has merely just now decided to grapple with it.

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[3] *See* Dow's express abandonment, filed Nov. 12, 2105; http://portal.uspto.gov/pair/view/BrowsePdfServlet?objectId=IGWNSLA5PXXIFW3&lang=DINO

EPA as well as Petitioners expressed concerns about synergistic effects long before EPA registered the herbicide. In its risk assessment dated January 15, 2013, EPA "anticipated" the precise problem now presented:

> Given that a dual herbicide product is being registered – 2,4-D choline salt/glyphosate – data for this herbicide combination are *necessary for a thorough toxicological assessment*. The stress of simultaneous exposure to two herbicides *may cause additive or synergistic effects in terrestrial plants and lead to increased toxicity*.

Petitioners' Excerpts of Record Vol. VI, ER1089; EPA's January 15, 2013 risk assessment at 47 (emphases added). Again:

> [I]t is *anticipated* that there could be additional toxicological effects (synergistic or additive) because of the presence of two herbicides. This could change the outcome of the assessment by *yielding more sensitive toxicity values for terrestrial plants, thus modifying minimum buffer distances*.

Petitioners' Excerpts of Record Vol. VI, ER1045; EPA's January 15, 2013 risk assessment at 3 (emphases added). Petitioner CFS submitted comments discussing the likelihood of synergistic effects between 2,4-D and glyphosate, citing published scientific studies. Petitioners' Excerpts of Record Vol. V, ER748-749; Center for Food Safety's June 30, 2014 Comments to EPA on EPA's Proposed Registration of Enlist Duo™ Herbicide Containing 2,4-D and Glyphosate for New Uses on Herbicide-Tolerant Corn and Soybean, at 14-16.

EPA now has an opportunity—a mandate—to meet its duties under FIFRA and the ESA, and ensure Enlist Duo's safety. The registration therefore should be vacated and remanded so that EPA may correct its errors.

Respectfully submitted this 7th day of December, 2015.

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