FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL; PESTICIDE ACTION NETWORK NORTH AMERICA, *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, *Respondent*, NATIONAL ASSOCIATION OF WHEAT GROWERS; NATIONAL COTTON COUNCIL OF AMERICA; AMERICAN FARM BUREAU FEDERATION; NATIONAL CORN GROWERS ASSOCIATION; AMERICAN SOYBEAN ASSOCIATION; NATIONAL SORGHUM PRODUCERS; AGRICULTURAL RETAILERS ASSOCIATION; NATIONAL ASSOCIATION OF LANDSCAPE PROFESSIONALS; MONSANTO COMPANY; GOLF COURSE SUPERINTENDENTS ASSOCIATION OF AMERICA; AMERICAN SUGARBEET GROWERS ASSOCIATION, *Intervenors*.	No. 20-70787 EPA No. EPA-HQ-OPP- 2009-0361

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

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY; MICHAEL REGAN, in his official capacity as Administrator,

Respondents,

NATIONAL ASSOCIATION OF WHEAT GROWERS; NATIONAL CORN GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL; AMERICAN SOYBEAN ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; NATIONAL SORGHUM PRODUCERS; AMERICAN FARM BUREAU FEDERATION; AGRICULTURAL RETAILERS ASSOCIATION; NATIONAL ASSOCIATION OF LANDSCAPE PROFESSIONALS; GOLF COURSE SUPERINTENDENTS ASSOCIATION OF AMERICA; MONSANTO COMPANY,

Intervenors.

No. 20-70801

EPA No. EPA-HQ-OPP-2009-0361

OPINION

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

Argued and Submitted January 10, 2022
Pasadena, California

Filed June 17, 2022

Before: J. Clifford Wallace, Danny J. Boggs,* and
Michelle T. Friedland, Circuit Judges.

Opinion by Judge Friedland

* The Honorable Danny J. Boggs, United States Circuit Judge for the U.S. Court of Appeals for the Sixth Circuit, sitting by designation.

SUMMARY[**]

Pesticides

The panel (1) granted in part and denied in part a petition for review challenging the U.S Environmental Protection Agency's decision determining that glyphosate, the active ingredient in the weedkiller Roundup, does not pose "any unreasonable risk to man or the environment"; and (2) remanded to the agency for further consideration.

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") requires the U.S Environmental Protection Agency ("EPA") to regulate pesticides, which are defined to include herbicides. A pesticide product may not be distributed or sold in the United States until EPA has issued a registration pursuant to FIFRA. A registration functions as a license setting forth the conditions under which the pesticide may be sold, distributed, and used. The EPA may not issue a registration for a pesticide that causes "unreasonable adverse effects on the environment." In 2007, Congress added a new process called "registration review" to the FIFRA scheme governing pesticides, instructing EPA to periodically review pesticide registrations every fifteen years. For pesticides registered before 2007, such as glyphosate, EPA must complete the first registration review by October 1, 2022.

EPA began its registration review of glyphosate in 2009 and completed a preliminary ecological risk assessment of the pesticide in 2015. That assessment concluded that

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

glyphosate may pose certain risks to mammals and birds and may adversely affect terrestrial and aquatic plants, primarily from spray drift. The EPA also released a draft human-health risk assessment and a paper about glyphosate's carcinogenic potential, entitled the Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential ("Cancer Paper"), which concluded that glyphosate posed no serious human-health risks and should be classified as "not likely to be carcinogenic to humans."

In January 2020, EPA issued an Interim Registration Review Decision for glyphosate ("Interim Decision"), which: (1) announced that its earlier draft human-health and ecological risk assessments were final; (2) contained a brief cost-benefit analysis concluding that the benefits outweighed the potential ecological risks when glyphosate is used according to label directions; and (3) laid out various mitigation measures, in the form of label changes for glyphosate products, to reduce the potential ecological risks. According to the Interim Decision, EPA still planned, among other things, to complete an assessment of glyphosate's effect on endangered and threatened species, pursuant to the Endangered Species Act ("ESA").

Two groups of petitioners filed petitions for review of the Interim Decision: one led by Rural Coalition and the other led by Natural Resources Defense Council ("NRDC"). Rural Coalition's petition made two attacks on the Interim Decision. It challenged EPA's conclusions on human health and insisted that EPA should have followed the ESA's procedural requirements before issuing the Interim Decision. NRDC's petition primarily challenges EPA's ecological risk assessment, cost-benefit analysis, and risk-mitigation requirements.

The panel first considered Rural Coalition's challenge to EPA's conclusion that glyphosate poses "no risks to human health." That conclusion rested in important part on EPA's determination, explained in its Cancer Paper, that glyphosate was not likely to be carcinogenic to humans. The panel held that EPA's conclusion was in tension with parts of the agency's own analysis and with the 2005 Guidelines for Carcinogen Risk Assessment ("Cancer Guidelines"), which EPA purported to follow. The panel noted that earlier in the Cancer Paper, EPA had explained that a conclusion regarding the association between glyphosate exposure and risk of non-Hodgkin's lymphoma ("NHL") could not be determined based on the available evidence. The panel stated that EPA could not reasonably treat its inability to reach a conclusion about NHL risk as consistent with a conclusion that glyphosate is not likely to cause cancer within the meaning of the Cancer Guidelines. Because inconsistent reasoning cannot survive substantial-evidence review, the panel concluded that EPA's determination that glyphosate was not likely to be carcinogenic was not supported by substantial evidence. The panel therefore vacated the human-health portion of the EPA's Interim Decision and remanded for further analysis and explanation. Given that vacatur, the panel did not reach Rural Coalition's arguments of other errors pertaining to human health or NRDC's petition challenging the public-comment process that informed the human health portion of the Interim Decision.

The panel next addressed Rural Coalition's claim alleging that EPA impermissibly failed to follow the ESA consultation procedures before issuing the Interim Decision. The ESA protects endangered and threatened species, in part, by requiring federal agencies to consult with the U.S. Fish and Wildlife Service or the National Marine

Fisheries Service. The consultation procedures begin with an agency reviewing its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat, resulting in an effects determination.

The panel determined that Rural Coalition had standing to bring an ESA claim. Rural Coalition's members submitted declarations stating that they regularly engaged in educational and recreational activities involving a variety of endangered species and that glyphosate was threatening their interests by exposing those species to toxic runoff and residues on vegetation. Members therefore had cognizable interests for purposes of standing. Rural Coalition also established causation by showing that EPA might have required more mitigation efforts had the agency completed the ESA's procedures before issuing the Interim Decision and redressability by showing that, at the time the petition was filed, court-ordered relief was possible. The panel rejected intervenor Monsanto's argument that EPA's recent consultation efforts mooted the case.

Turning to the merits of the ESA claim, the panel held that EPA's registration review decision under FIFRA was an "action" that triggered the ESA's consultation requirement; EPA actively exercised its regulatory power, completing an assessment of glyphosate's risks under FIFRA and delineating what constituted acceptable glyphosate use under the statute's safety standard. EPA therefore had to comply with the ESA by making an effects determination before issuing the decision. It was undisputed that EPA did not do so. Accordingly, EPA violated the ESA. Nevertheless, the panel declined to order relief for the ESA violation, noting that, according to the timeline imposed by Congress, EPA must complete its final registration review decision—including formal

consultation—by October 2022. Given that the FIFRA deadline was fast approaching, shortening EPA's time to consult would be only moderately beneficial to Rural Coalition but potentially very disruptive to the agency. The panel declined to vacate the Interim Decision, other than to the extent specified regarding the human-health portion, because it was not clear that vacatur would be beneficial; the Interim Decision included certain mitigation efforts designed to limit the ecological impact of glyphosate use, and vacatur would eliminate those mitigation requirements.

The remaining issue involved petitioners' challenges to the Interim Decision's ecological risk assessment, determination of glyphosate's costs, cost-benefit analysis, and mitigation requirements (collectively, the "ecological portion"), and EPA's responsive motion for remand. The panel granted EPA's motion to remand without vacatur as to the ecological portion of the decision but required EPA to issue a new ecological portion by the October 2022 FIFRA deadline. Because the panel granted EPA's motion, it did not reach the parts of NRDC's and Rural Coalition's petitions that challenged the remanded portion of the Interim Decision.

COUNSEL

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OPINION

FRIEDLAND, Circuit Judge:

Glyphosate, the active ingredient in Roundup, is the nation's most heavily used weedkiller. The Environmental Protection Agency ("EPA") recently assessed whether glyphosate poses "any unreasonable risk to man or the environment" and answered, for the most part, "no." A group of petitioners challenged EPA's decision, arguing, among other things, that EPA did not adequately consider whether glyphosate causes cancer and shirked its duties under the Endangered Species Act ("ESA"). We agree and remand to the agency for further consideration.

I.

A.

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") requires EPA to regulate pesticides, which are defined to include herbicides.[1] *See* 7 U.S.C. §§ 136 *et seq*. FIFRA's primary regulatory mechanism is called "registration." *Id.* § 136a(a). A pesticide product may not be distributed or sold in the United States until EPA has issued a registration, which functions as a license setting forth the conditions under which the pesticide may be sold, distributed, and used. *See id.* § 136a. Those conditions

[1] Under FIFRA, a "pesticide" includes both "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" as well as "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. § 136(u).

include labeling requirements with directions for proper use. *Id.* § 136a(c); *see* 40 C.F.R. § 156.10.

EPA may not issue a registration for a pesticide that causes "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C); *see also* 40 C.F.R. § 152.112(e). "[U]nreasonable adverse effects on the environment" 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). This is commonly referred to as the FIFRA safety standard.

In 2007, Congress added a new process called "registration review" to the FIFRA scheme governing pesticides, instructing EPA to "periodically review[]" pesticide registrations every fifteen years. *Id.* § 136a(g)(1)(A). For pesticides registered before 2007, such as glyphosate, EPA must complete the first registration review by October 1, 2022. *Id.*

EPA has promulgated regulations delineating an elaborate process for registration review. 40 C.F.R. §§ 155.23–155.58. The regulations require EPA to assess any new information regarding risks to human health and the environment that has emerged since EPA last issued a registration decision for a pesticide to verify that the pesticide continues to satisfy the FIFRA safety standard. *See, e.g.*, *id* §§ 155.40, 155.53(a). The process concludes with a registration review decision, which conveys "the Agency's determination whether a pesticide meets, or does not meet," the FIFRA safety standard. *Id.* § 155.57. The regulations also permit, but do not require, EPA to issue an "interim registration review decision" prior to the registration review decision. *Id.* § 155.56. "[T]he interim registration review decision may require new risk mitigation

measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for . . . completing the registration review." *Id.*

If EPA finds that a pesticide does not satisfy the FIFRA safety standard, EPA may initiate cancellation proceedings to rescind a pesticide's registration, 7 U.S.C. §§ 136a(g)(1)(A)(v), 136d(b); 40 C.F.R. § 155.40(a)(2), or may require mitigation measures to reduce risk to acceptable levels, *see* 40 C.F.R. § 155.58.

B.

Glyphosate is a chemical that kills a broad range of plants by inhibiting an important enzyme. EPA registered the first glyphosate product in 1974, when Monsanto, an agrochemical and agricultural biotechnology company, sought to sell the now-well-known weedkiller Roundup. During its first two decades on the market, Roundup had limited utility to farmers because it killed all vegetation in an application area. But in the mid-1990s, Monsanto developed a "Roundup Ready" crop system, selling Roundup along with seeds genetically modified to tolerate glyphosate. The system allowed farmers to apply glyphosate over genetically modified crops, killing weeds but leaving the crops unharmed. As a result, glyphosate use skyrocketed. The nationwide acreage across which glyphosate is currently used is roughly equivalent to three times the size of California.

Glyphosate is generally applied by being sprayed from planes, ground equipment, or handheld devices. Workers and residential users are exposed to glyphosate when, for example, they handle the chemical during application or enter areas where it was recently sprayed. People are also

exposed to glyphosate when they eat food from crops treated with it.

Whether these exposures create health risks has become a hotly debated and litigated issue. Health concerns proliferated when the International Agency for Research on Cancer ("IARC"), a subdivision of the World Health Organization, classified glyphosate as "probably carcinogenic to humans" in 2015. IARC's conclusion stemmed in part from scientific studies that found an association between glyphosate exposure and non-Hodgkin's lymphoma ("NHL"), a type of cancer that affects white blood cells. The IARC classification spurred a wave of lawsuits against Monsanto. Since 2015, tens of thousands of individuals with NHL have sued Monsanto in state and federal court, alleging that Roundup caused their illnesses. *See, e.g.*, *In re Roundup Prods. Liab. Litig.*, 544 F. Supp. 3d. 950, 953 (N.D. Cal. 2021). Monsanto lost the first three lawsuits to go to trial, and the plaintiffs were awarded tens of millions of dollars. *Id.* at 955–57.

C.

EPA began its registration review of glyphosate in 2009.[2] In September 2015, the agency completed a preliminary ecological risk assessment of the pesticide. The assessment considered glyphosate's effects on all "non-target organisms"—that is, animals and plants not intended to be killed by the pesticide. EPA concluded that glyphosate

[2] For registration review, EPA may evaluate a "pesticide case . . . composed of 1 or more active ingredients and the products associated with the active ingredients" or may evaluate each pesticide product registration individually. 7 U.S.C. § 136a(g)(1)(A)(iii). Here, EPA decided to conduct registration review on glyphosate, an active ingredient.

may pose certain risks to mammals and birds. EPA also determined that glyphosate may adversely affect terrestrial and aquatic plants, primarily from spray drift.

Meanwhile, EPA was working on a human-health risk assessment and, in particular, an analysis of glyphosate's carcinogenic potential. EPA's pesticide unit made a preliminary determination that glyphosate was not likely to be carcinogenic and shared that determination with the agency's Office of Research and Development ("ORD"). In December 2015, ORD offered comments in response, including criticisms of the pesticide unit's approach to reviewing epidemiological studies—specifically, studies of human populations investigating whether glyphosate exposure causes cancer. ORD commented that the pesticide unit seemed to "dichotomize" such studies as "either 'causal' or 'not causal'" rather than recognize "gradations of causality." According to ORD, that approach contravened the "[f]rameworks for data analysis and causal determinations" employed by "the risk assessment community" and "by EPA" in its 2005 Guidelines for Carcinogen Risk Assessment ("Cancer Guidelines" or "Guidelines"). The Cancer Guidelines are intended to guide EPA in classifying chemicals according to their carcinogenic potential. After stating its methodological concerns, ORD expressed disagreement with the pesticide unit's determination that glyphosate was "not likely to be carcinogenic."

ORD's criticisms did not change EPA's overall "not likely" determination, and, in September 2016, EPA defended that determination in a draft paper entitled Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. The agency requested feedback on that draft from an EPA-commissioned Scientific Advisory Panel ("SAP").

The SAP published a report in response. Many of the SAP's comments were similar to ORD's, but the SAP focused on EPA's treatment of laboratory studies that examined whether glyphosate causes tumors in rodents, rather than on the epidemiological studies of human health that ORD had emphasized. The SAP "concluded that the EPA evaluation does not appear to follow the [Cancer Guidelines] in several ways." The SAP also criticized the criteria EPA used to discount tumor results in rodent studies, opining that EPA's approach was not "a conservative approach for public health protection" and was "not advisable" because it was "not consistent with . . . standard ways in which . . . results are typically interpreted."

Ultimately, the SAP was divided as to whether EPA's "not likely" determination was appropriate. According to the report, "[m]any Panel members believe[d] that the EPA did not provide convincing evidence of a lack of carcinogenic effects." These panelists thought that the rodent studies alone provided suggestive evidence of carcinogenic potential. Some panelists, however, argued that results from those studies "are consistent with what would be expected by chance and not reflective of [glyphosate]-induced effects," emphasizing the "wealth of [rodent] studies with insufficiently consistent findings" and an inability to "definitively link[]" the "positive [epidemiological] results . . . to glyphosate-exposure."

One year after receiving the SAP's feedback, EPA released a draft human-health risk assessment for glyphosate and an updated and final paper about glyphosate's carcinogenic potential, now entitled the Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential ("Cancer Paper"). In the draft risk assessment, EPA concluded that glyphosate poses no serious human-health risks, stating, for

instance, that "[g]lyphosate exhibits low toxicity across species, durations, life stages, and routes of exposure." EPA also concluded that "glyphosate should be classified as 'not likely to be carcinogenic to humans'" and explained that conclusion in the Cancer Paper. Separately, EPA responded to the SAP's criticisms, revealing that those criticisms had prompted very few changes between the earlier draft and the finalized Cancer Paper.

In January 2020, EPA issued an Interim Registration Review Decision for glyphosate ("Interim Decision"). The Interim Decision had three main components. First, the Interim Decision announced that the earlier draft human-health and ecological risk assessments were now final—with no changes from those drafts. In summarizing the human-health risk assessment, the Interim Decision explained that the agency "determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." The Interim Decision directed readers to the human-health risk assessment and to the Cancer Paper for additional information. According to EPA, there were "[n]o additional human health data needs" for glyphosate's registration review. The Interim Decision then reaffirmed the ecological risk assessment, confirming that "potential risks of concern were identified for mammals and birds" as well as for "terrestrial and aquatic plants."

Second, the Interim Decision contained a brief cost-benefit analysis. EPA reiterated that glyphosate poses potential risks to mammals, birds, and plants. It also summarized glyphosate's various benefits, such as its ability to provide a broad spectrum of weed control across agricultural and non-agricultural sites and its low cost. EPA concluded that "the benefits outweigh the potential

ecological risks when glyphosate is used according to label directions."

Third, the Interim Decision laid out various mitigation measures, in the form of label changes for glyphosate products, to reduce the potential ecological risks. One label change involves application restrictions to reduce spray drift. Another label change alerts users that glyphosate has the potential to harm non-target organisms. A final label change warns of the risk that glyphosate use can cause herbicide resistance.

According to the Interim Decision, only three steps remained before EPA would conclude registration review. First, EPA planned to complete an assessment of glyphosate's effect on endangered and threatened species, pursuant to the ESA. As necessary based on that assessment, EPA would then consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service to mitigate any adverse effects on those species.[3] Second, EPA planned

[3] Since the Interim Decision issued, EPA began following the ESA's procedures. The first step is to determine whether an agency action "may affect" an endangered or threatened species or critical habitat. In November 2020, EPA completed a preliminary effects determination, publishing a draft Biological Evaluation that assessed potential effects from all registered uses of glyphosate on ESA-listed species. It found that glyphosate "may affect" all listed species experiencing glyphosate exposure—that is 1,795 endangered or threatened species. In November 2021, EPA issued a final Biological Evaluation with similar conclusions. Under the ESA, a "may affect" determination triggers a requirement that the agency consult with the relevant wildlife agencies to prevent adverse effects. *See Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 922 (9th Cir. 2020). Thus, EPA is now consulting with those agencies. To the extent the draft Biological Evaluation and final Biological Evaluation are not part of the record before us, we take judicial notice of them. *See Dine*

to address a petition that had been filed under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), requesting that EPA restrict glyphosate's use on oats to reduce dietary exposure to the herbicide. And third, EPA planned to conduct an endocrine analysis of glyphosate pursuant to the FFDCA.[4]

D.

In March 2020, two groups of petitioners filed petitions for review of the Interim Decision: one led by Rural Coalition and the other led by Natural Resources Defense Council ("NRDC"). Rural Coalition's petition makes two attacks on the Interim Decision. It challenges EPA's conclusions on human health and insists that EPA should have followed the ESA's procedural requirements before issuing the Interim Decision. NRDC's petition primarily challenges EPA's ecological risk assessment, cost-benefit analysis, and risk-mitigation requirements, though NRDC also asserts that EPA failed to address NRDC's comments on human-health risks made during the public-comment period. We consolidated the petitions and granted a motion to intervene by Monsanto and various agricultural and landscaping groups (collectively, "Monsanto").

In May 2021, EPA filed its answering brief, which addresses only its human-health findings, along with a motion for voluntary partial remand without vacatur. EPA seeks partial remand of the portions of the Interim Decision

Citizens Against Ruining Our Env't v. Bureau of Indian Affs., 932 F.3d 843, 848 n.1 (9th Cir. 2019).

[4] An endocrine analysis strives to determine whether a substance is an endocrine disruptor—for example, whether it has effects in humans or wildlife similar to those of naturally occurring estrogen.

related to glyphosate's ecological risks as well as the agency's cost-benefit analysis. EPA's answering brief and Monsanto's brief do not substantively address those issues but do offer defenses to Petitioners' challenges to EPA's human-health analysis and the alleged failure to comply with the ESA. NRDC agreed that the remand requested by EPA would be appropriate, but Rural Coalition opposed any remand.

We heard oral argument in January 2022.

II.

Under FIFRA, we review EPA's Interim Decision for "substantial evidence when considered on the record as a whole." *NRDC v. EPA*, 857 F.3d 1030, 1035–36 (9th Cir. 2017) (quoting 7 U.S.C. § 136n(b)). This standard requires the administrative record to show "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence." *Id.* at 1036 (quoting *NRDC v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013)). The agency's reasoning must also be coherent and internally consistent. *See NRDC v. EPA*, 31 F.4th 1203, 1210 (9th Cir. 2022) (relying on internal "inconsistencies" in holding that a decision was not supported by substantial evidence); *Lott v. Colvin*, 772 F.3d 546, 551 (8th Cir. 2014) (holding that a decision marked by "internal inconsistencies" was not supported by substantial evidence); *Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1065 (Fed. Cir. 2009) (holding that a decision based on "[i]nconsistent[]" rulings and "contradictory statement[s]" was not supported by substantial evidence).

The Administrative Procedure Act ("APA") governs judicial review of administrative decisions involving the

ESA. *See Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 923 (9th Cir. 2020). Under the APA, courts "shall . . . hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law." 5 U.S.C. § 706; *see NRDC v. Houston*, 146 F.3d 1118, 1125 (9th Cir. 1998).

III.

We first consider Rural Coalition's challenge to EPA's conclusion that glyphosate poses "no risks to human health." That conclusion rests in important part on EPA's determination, explained in its Cancer Paper, "that glyphosate is not likely to be carcinogenic to humans." Rural Coalition contests the Cancer Paper's reasoning, primarily arguing that EPA contravened the Cancer Guidelines it purported to follow. We agree.

EPA's Cancer Guidelines lay out four steps for conducting risk assessments of chemicals' carcinogenic potential. The first step—and the one most relevant here—is hazard identification, which asks whether a chemical can "present a carcinogenic hazard to humans and, if so, under what circumstances." The second step considers the "dose response" to a chemical—in other words, the levels of exposure at which adverse effects might occur. The third step assesses "the conditions of human exposure." The fourth and final step evaluates "the character of the risk," including "[h]ow well . . . data support conclusions about the nature and extent of the risk from various exposures."

For the first step, hazard identification, the Guidelines lay out strategies for reviewing and evaluating data from human and animal studies. For example, the Guidelines

include criteria for identifying reliable epidemiological studies as well as factors to consider when determining whether observed effects in such studies are causal. The Guidelines also provide methods for analyzing tumor data from animal laboratory studies, including tests for determining whether results are statistically significant. In addition, the Guidelines identify potential observations, such as cellular metastases or tumors detected in multiple species, whose presence or absence should add to or detract from the weight of studies' findings.

The culmination of the hazard-identification step is a "weight of evidence narrative." According to the Cancer Guidelines, that narrative should explain the available evidence and summarize how the evidence supports a conclusion about human carcinogenic potential. The Guidelines lay out five standard hazard descriptors for expressing such a conclusion, with criteria for when each applies: "Carcinogenic to Humans," "Likely to Be Carcinogenic to Humans," "Suggestive Evidence of Carcinogenic Potential," "Inadequate Information to Assess Carcinogenic Potential," and "Not Likely to Be Carcinogenic to Humans." Although the choice of a descriptor is holistic and does not automatically compel an ultimate FIFRA conclusion, EPA's choice among those descriptors generally has practical consequences. As the parties explained at oral argument, hazard descriptors indicating higher levels of risk usually prompt more mitigation efforts—for example, labeling requirements intended to protect human health.

EPA ties itself to the Cancer Guidelines in its Interim Decision. The Interim Decision relies on the Cancer Paper to explain its conclusions about human health. And, in that Cancer Paper, EPA explicitly states that it is completing an

"Evaluation of Cancer Classification per the 2005 EPA Guidelines for Carcinogen Risk Assessment [*i.e.*, the Cancer Guidelines]." The Cancer Paper directly quotes the Cancer Guidelines' language about the five hazard descriptors.

In the Cancer Paper, the agency ultimately concludes that "[t]he strongest support is for [the hazard descriptor] 'not likely to be carcinogenic to humans.'" As the Cancer Paper and the Cancer Guidelines explain, the "not likely" descriptor "is appropriate when the available data are considered robust for deciding that there is no basis for human hazard concern." According to EPA's conclusion in the Cancer Paper, glyphosate is "not likely" to be carcinogenic to humans because animal-tumor and genotoxicity studies showed no reason for concern.[5] But this conclusion is in tension with parts of the agency's own analysis and with the guidelines it purports to follow.

A.

EPA's choice of the "not likely" descriptor conflicts with a determination EPA made earlier in the Cancer Paper. Earlier, EPA explained that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available evidence."

In coming to that determination, the Cancer Paper discussed human epidemiological studies showing what could be considered suggestive evidence that glyphosate exposure causes NHL. For example, the Cancer Paper stated that "reported effect estimates across case-control studies and the associated meta-analyses [were] greater than 1,"

[5] The Cancer Paper explains that genotoxicity studies examine whether chemicals damage genetic material on a cellular level.

meaning that most studies EPA examined indicated that human exposure to glyphosate is associated with an at least somewhat increased risk of developing NHL.[6] The Cancer Paper also acknowledged that some epidemiological studies provide evidence of an exposure-response relationship between glyphosate and NHL. One study, for instance, indicated that there was an increased risk of NHL for those with more than ten years of glyphosate exposure. In addition, that same study as well as another indicated that those who are exposed to relatively more glyphosate in a year face a higher risk of NHL.

But EPA discounted epidemiological studies showing increased NHL risk by concluding that "chance and/or bias" could be "an explanation for observed associations in the database." EPA stated that some of the study results showing increased NHL risk were not statistically significant, which raises the concern that those results were due to chance. EPA raised the possibility that confounders, such as exposure to other pesticides, animals, or diesel fumes, were driving the NHL results. EPA also emphasized what it deemed "contradictory results"—that a few studies did not detect a positive association between glyphosate exposure and NHL or an exposure-response relationship. EPA opined that such inconsistencies and limitations

[6] These meta-analyses—which aggregate and analyze the results from individual studies—quantify the increased risk found across the many case-control studies EPA considered. *See Definition: meta-analysis*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/meta-analysis. The effect estimates from the meta-analyses range from 1.3 to 1.5, indicating that those exposed to glyphosate were 30 to 50 percent more likely to develop NHL.

precluded it from coming to any firm determination on glyphosate's potential to cause NHL.

As Rural Coalition correctly argues, EPA's own conclusion from that epidemiological evidence is inconsistent with its ultimate selection of the "not likely" hazard descriptor. According to EPA's Cancer Guidelines, that hazard descriptor is appropriate when the agency determines that "available data are considered robust for deciding that there is no basis for human hazard concern." EPA therefore cannot reasonably treat its inability to reach a conclusion about NHL risk as consistent with a conclusion that glyphosate is "not likely" to cause cancer within the meaning of the Cancer Guidelines.

We made a similar point in *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015), in rejecting an argument by EPA "that since the studies are inconclusive as to the risks of sulfoxaflor for bees, the studies affirmatively prove that sulfoxaflor does *not* cause unreasonable adverse effects on bees." *Id.* at 531. We explained that "[n]either logic nor precedent can sustain this position. We have previously held that an agency cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support." *Id.*; *see also League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 701 (9th Cir. 2021) ("[Because] EPA represents that there are '*uncertainties* concerning the impact of chlorpyrifos on children' . . . EPA has not determined, and on this record reasonably could not determine to a 'reasonable certainty' that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm.").

B.

The analysis underpinning EPA's "not likely" descriptor is also flawed in various other ways. EPA relies on two main propositions to support its chosen hazard descriptor, but neither withstands scrutiny under the agency's own framework.

1.

EPA's first proposition is that "the agency did not consider any of the tumors observed in the animal carcinogenicity studies to be treatment-related" (*i.e.*, caused by glyphosate). According to EPA, "none of the tumors evaluated in individual rat and mouse carcinogenicity studies are treatment-related due to lack of pairwise statistical significance, lack of a monotonic dose response, absence of preneoplastic or related non-neoplastic lesions, no evidence of tumor progression, and/or historical control information (when available)." But EPA's reliance on at least two of these indicia to infer a lack of treatment-related effects—historical-control data and pairwise statistical significance—conflicts with the Guidelines that the agency contends it is following.[7]

EPA's Cancer Paper uses historical-control data selectively and in a manner that is inconsistent with the Cancer Guidelines. Historical-control data show the natural frequency of different types of tumors in an animal strain. As the Cancer Paper acknowledges, the Cancer Guidelines

[7] EPA's flawed use of two of the indicia to infer a lack of treatment-related effects is sufficient to undermine the agency's assessment of the rodent studies it examined. EPA relied upon these indicia so often throughout the Cancer Paper that it is impossible to know what conclusion EPA would have reached without them.

instruct that historical-control data can "add to the analysis, particularly by enabling identification of uncommon tumor types or high spontaneous incidence of a tumor in a given animal strain." For example, according to the Guidelines, historical-control data that show a particular type of tumor is very rare in an animal strain could indicate that, when tumors of that type do occur in a study using that strain, "the result is in fact unlikely to be due to chance." By contrast, the Guidelines explain that historical-control data showing "common tumors" in an animal strain could reduce the importance of "results that are barely statistically significant or in which incidence rates in concurrent controls are unusually low in comparison with historical controls."

Rather than using historical-control data both when the data bolster and when the data undermine studies' results, as would be supported by the Cancer Guidelines, EPA uses this type of data only to discount studies indicating that glyphosate may cause tumors. According to the SAP, there were numerous instances in which historical-control data could *add* weight to tumor findings, but EPA never used the data in that manner. As the SAP observed, "[t]o subjectively choose to use historical control incidence data only in situations where" it ultimately undermines tumor results "is to potentially introduce biases." Replying to the SAP's criticism, EPA states that it "recognize[d] the concerns raised by the panel" and "[a]s a result, historical control data have been presented for those studies where historical control data are available from the performing laboratory for the same species and strain for a study" in the revised Cancer Paper. But although EPA *presents* more historical-control data for various studies in the final Cancer Paper than in the draft reviewed by the SAP, the agency did not change the way in which it factored those data into its analysis: EPA still uses the data only to undermine tumor results, even

ignoring the specific instances in which the SAP explained that historical-control data should increase the import of tumor results.

EPA's reliance on a second indicium, "lack of pairwise statistical significance," is also inconsistent with the Cancer Guidelines. Pairwise comparison and trend tests are two different tests for assessing statistical significance, which is an indication that a particular result is unlikely due to chance. A pairwise comparison test asks whether tumor incidence in a treatment group was higher than in the control group, while a trend test asks whether tumor incidences in all treatment groups increased as the glyphosate dose increased. EPA acknowledges in its Cancer Paper that, according to the Cancer Guidelines, "[s]ignificance in *either* kind of test is sufficient to reject the hypothesis that chance accounts for the result." (emphasis added). But as both ORD[8] and the SAP pointed out, in analyzing various rodent studies, EPA discounts tumor incidences because those incidences were not statistically significant in pairwise comparison tests—when those same tumor incidences were apparently statistically significant using trend tests. Criticizing EPA's approach, "the [SAP] noted that requiring a significant pairwise comparison . . . *in addition to* a significant trend is neither consistent with the [Cancer Guidelines] nor a conservative approach for public health protection." (emphasis in original).[9]

[8] Rural Coalition moves to add another ORD document to the administrative record. Because our resolution of these petitions does not depend on that document, we **DENY** Rural Coalition's motion.

[9] If EPA had determined that these tumor results were not statistically significant in trend tests either, one would expect EPA's summary of the animal studies to have pointed to a lack of statistical

Responding to that criticism, EPA asserts that, although its Cancer Guidelines correctly convey that satisfaction of either a trend test or a pairwise test is sufficient for *statistical significance*, they do "not imply that statistical significance alone in an individual test is sufficient to determine that observed tumors are *treatment-related*." (emphasis added). According to EPA, it "evaluated the animal carcinogenicity data using [the Guideline's] weight of evidence approach, which included both the trend and pairwise analyses." But the Guidelines' reliance on these tests for determining statistical significance is precisely for the purpose of sorting out whether a result is treatment-related rather than caused by chance. The Guidelines clearly explain that "[t]rend tests and pairwise comparison tests are the recommended tests for determining whether chance, rather than a treatment-related effect, is a plausible explanation for an apparent increase in tumor incidence." Thus, EPA's bare assertion that a lack of pairwise statistical significance suggests that tumor results in rodent studies are not treatment-related fails to account coherently for the evidence of statistical significance from trend tests, which the Cancer Guidelines deem similarly probative (though not necessarily conclusive).

2.

EPA's second proposition in support of its selection of the "not likely" descriptor is that concerning results only occurred at high doses. In the Cancer Paper, EPA invokes the Cancer Guidelines' criterion that a chemical can be

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significance *in general* rather than to have focused solely on "a lack of pairwise statistical significance." The agency's response to the SAP's criticism also assumes that various trend tests indicated that tumor results were statistically significant, but it asserts that this did not matter because significance in both types of tests was required to support a conclusion that the tumor results were treatment-related.

considered "not likely to be carcinogenic" when there is "convincing evidence that carcinogenic effects are not likely below a defined dose range." EPA states that, even if the tumors were treatment-related as "some believe," those tumors occurred only at very high glyphosate dosages. According to EPA, increased tumor incidences generally occurred at "the highest doses tested"—"approximately equal to or greater than the limit dose (1000 mg/kg/day)." EPA also mentions that positive results in genotoxicity studies occurred only at "high doses." Importantly, for both the rodent studies and genotoxicity studies, "[t]hese high doses [were] not considered relevant to human health risk assessment based on the currently registered use pattern for glyphosate" because "[m]aximum potential glyphosate exposure [had] been estimated at . . . 7 mg/kg/day . . . which [is] well-below the doses necessary to elicit the effects seen in these animal carcinogenicity and genotoxicity studies."

But EPA's disregard of tumor results occurring at high dosages conflicts with the guidelines EPA purports to follow. The "not likely" descriptor can, in fact, be applied when there is "convincing evidence that carcinogenic effects are not likely below a defined dose range," as EPA states. But the Cancer Guidelines indicate that this use of the "not likely" descriptor is appropriate "when the mode of action is sufficiently understood to conclude that a key event in tumor development would not occur below a certain dose range"—to avoid discounting potentially concerning animal results from laboratory settings unless there is a compelling reason to believe that those results are irrelevant to humans.[10]

[10] A mode of action, according to the Cancer Guidelines, is "a sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation."

Indeed, when that mode of action is sufficiently understood, the Cancer Guidelines contemplate that the chemical would merit "multiple descriptors": it "could be described as likely to be carcinogenic above a certain dose range but not likely to be carcinogenic below that range." Despite these instructions, the Cancer Paper provides no explanation of any "mode of action" indicating that tumors are not likely to occur below a certain glyphosate dosage range, nor does it offer two different hazard descriptors for dosages above and below that range. Instead, EPA asserts that the potentially concerning results observed at high doses in the studies it reviewed are undeserving of significant consideration for two related reasons: because the Cancer Guidelines encourage considering human-exposure levels, which EPA asserts are far below the high doses associated with those results; and because those high doses exceeded a so-called "limit dose" that EPA says is established by the agency's Health Effects Test Guidelines.[11]

But the Cancer Guidelines do not support disregarding results simply because they are based on exposures that exceed typical human-exposure levels. More specifically, no part of the hazard assessment Guidelines encourages disregarding results occurring at high dosage ranges for any reason other than when there is evidence of excessive toxicity. Excessive toxicity occurs when a dose is so high that the sheer amount of the chemical induces abnormal responses in laboratory animals. Excessive toxicity is rare,

[11] The Health Effects Test Guidelines provide directions to researchers who are designing studies. They are published by EPA to "minimize variations among the testing procedures that must be performed to meet the data requirements" of EPA under FIFRA and other laws. As explained below, those guidelines do not establish any such limit dose.

so, according to the Cancer Guidelines, "[i]n general . . . effects seen at the highest dose tested are assumed to be appropriate for assessment." That highest dose "is generally selected to provide the maximum ability to detect treatment-related carcinogenic effects while *not* compromising the outcome of the study through excessive toxicity." (emphasis added). The Cancer Guidelines further provide that results "may be regarded as not appropriate to include in assessment of the potential for human carcinogenicity of the agent" only "[i]f adequate data demonstrate that the effects are solely the result of excessive toxicity rather than carcinogenicity of the tested agent *per se*." Despite EPA's various invocations of its Guidelines, the agency provides no evidence of excessive toxicity yet nonetheless disregards high-dosage results.

Indeed, disregarding results occurring at high dosage ranges seems contrary to the "purpose" of a hazard assessment. According to the Cancer Guidelines, the "purpose" of a hazard assessment "is to construct a total analysis examining what the biological data reveal as a whole about carcinogenic effects and mode of action of the agent, and their implications for human hazard and dose-response evaluation." Consistent with this understanding, subsequent steps in the Cancer Guidelines' risk assessment—ones that follow only once EPA has determined that there is, in fact, a hazard—integrate human-exposure patterns into the risk assessment through a variety of complex methods. In fact, as explained above, choosing a hazard descriptor is presented in the Guidelines as part of the hazard-identification step, and a subsequent step focuses

entirely on characterizing "the conditions of human exposure."[12]

EPA suggests that other agency guidelines support disregarding results above a so-called "limit dose" of 1,000 mg/kg/day, but that suggestion is also unsupported. According to EPA, its Health Effects Test Guidelines establish that there is a generally applicable "limit dose" of 1,000 mg/kg/day. Those guidelines, however, do not establish any such limit dose. Instead, the guidelines simply explain that, when researchers design an experiment, the important consideration for choosing the highest dose is—once again—excessive toxicity. According to the guidelines, researchers should carefully choose the highest dose to be administered with the goal that "[t]he highest-dose level should elicit signs of toxicity without substantially altering the normal life span due to effects other than tumors." The guidelines state that "[t]he highest dose tested

[12] Quoting a fragment from the Cancer Guidelines in the Cancer Paper's "not likely" explanation, EPA seems to suggest that part of the Guidelines supports using human-exposure patterns to exclude results. The full passage from the Cancer Guidelines states the following, with the underlined part reflecting the fragment EPA quotes in its Cancer Paper: "*Weighing of the evidence includes addressing not only the likelihood of human carcinogenic effects of the agent but also the conditions under which such effects may be expressed*, to the extent that these are revealed in the toxicological and other biologically important features of the agent." Read in context, this sentence in the Cancer Guidelines is not encouraging the agency to integrate human-exposure patterns into its hazard assessment. The sentence appears in an introductory section with instructions for completing a "Weight of Evidence Narrative" that will explain the hazard-assessment reasoning. Rather than conveying a method for evaluating study results in a hazard assessment, the sentence simply encourages the agency to describe the biological pathways through which tumors develop—insofar as the agency has such information available—as part of producing a comprehensive narrative for the public.

need not exceed 1,000 mg/kg/day." (emphasis added). "Need not" indicates that the highest dose ultimately selected does not *have* to exceed 1,000 mg/kg/day, but it can. Also, because the highest dose tested in a completed study was presumably selected to *avoid* excessive toxicity, these guidelines do not support EPA's disregard of tumor results occurring at and above that 1,000 mg/kg/day dosage.

The SAP expressly stated the concern that EPA improperly discounted study results involving dosages at or above 1,000 mg/kg/day: "Disregarding responses at any dose above a pre-selected 'limit dose,' even though the dose did not exceed the maximum tolerated dose"—that is, the maximum dose before excessive toxicity kicks in—"is not in keeping with the way rodent bioassays are normally interpreted . . . . Thus selecting 1,000 mg/kg/day *a priori* as the limit dose appears to be an *ad hoc* decision that is not well-justified, and is not justified on the basis of the [Cancer Guidelines]." Despite the SAP's criticism, EPA declined to change its approach or to meaningfully respond.

C.

For these reasons, EPA's choice of a hazard descriptor is not supported by substantial evidence. Despite EPA's repeated invocation of its Cancer Guidelines, the Interim Decision fails to abide by those Guidelines. Inconsistent reasoning "is, absent explanation, 'the hallmark of arbitrary action.'" *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1145 (9th Cir. 2015) (quoting *Sierra Club v. EPA*, 719 F.2d 436, 459 (D.C. Cir. 1983)). It cannot survive substantial-evidence review. *NRDC v. EPA*, 31 F.4th 1203, 1210 (9th Cir. 2022) (considering internal "inconsistencies" and "EPA's decision to abandon its own guidance . . . without a discernable rationale" in holding that a decision was not supported by substantial evidence).

Vacatur is the traditional remedy for erroneous administrative decisions. *See Pollinator Stewardship Council*, 806 F.3d at 532. To determine whether vacatur is appropriate, we consider at least three factors. First, "we weigh the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1144 (9th Cir. 2020) (quoting *Pollinator Stewardship Council*, 806 F.3d at 532). Second, we consider "the extent to which either vacating or leaving the decision in place would risk environmental harm." *Id.* at 1144–45. Third, we examine "whether the agency would likely be able to offer better reasoning [and] . . . adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Id.* at 1145 (quoting *Pollinator Stewardship Council*, 806 F.3d at 532).

Based on these considerations, we vacate the human-health portion of EPA's Interim Decision and remand for further analysis and explanation. The first factor clearly weighs in favor of vacatur. EPA's errors in assessing human-health risk are serious. Moreover, no disruptive consequences will result from vacating the human-health portion of the Interim Decision because that portion simply maintained the status quo—the Interim Decision imposed no new mitigation measures associated with human health. For similar reasons, vacating the human-health portion is unlikely to risk environmental harm, and thus the second factor also weighs in favor of vacatur. The last factor is more uncertain. It is possible that EPA could come to the same human-health conclusion on remand, but the agency's explanation would need to be so different that we cannot make a confident prediction on this factor. With two factors

weighing in favor of vacatur, uncertainty with respect to this last one does not tip the scale in the other direction.[13]

In light of this holding, we need not reach Rural Coalition's arguments about other alleged errors pertaining to human health. *See Pollinator Stewardship Council*, 806 F.3d at 532 ("The matter must be remanded to the agency. We need not reach the other claims of error raised by petitioners."). Similarly, our vacatur makes it unnecessary to address NRDC's objection that EPA did not comply with its procedural obligation to respond to NRDC's comments about human health—because further proceedings, including a new public-comment process, will be needed on remand.[14]

IV.

We next address Rural Coalition's Endangered Species Act claim. Congress enacted the ESA "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved" and "to provide a program for the conservation of such endangered species and threatened species" (collectively, "listed species"). 16 U.S.C. § 1531(b). The ESA reflects "a conscious decision by Congress to give endangered species

[13] We decline to rule on any effect this vacatur might have on glyphosate's registration. Even assuming that we could order deregistration outright, we would not do so here. Given the errors we have pointed out—and our uncertainty regarding how correcting those errors will alter EPA's final conclusion—deregistration would be a disproportionate and highly disruptive remedy.

[14] As NRDC pointed out and EPA did not dispute at oral argument, vacatur of the human-health portion will require the agency to conduct a new public-comment process. 40 C.F.R. §§ 155.56, 155.58(a).

priority over the 'primary missions' of federal agencies." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).

The ESA protects those species, in part, by requiring federal agencies to consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service (the "Services"). Section 7(a)(2) of the ESA mandates that every federal agency "shall, in consultation with and with the assistance of [the Services], insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat. 16 U.S.C. § 1536(a)(2). The consultation process unfolds as follows: "[A]t the earliest possible time," the agency proposing the action assesses whether a proposed action "may affect" an endangered or threatened species or its critical habitat, 50 C.F.R. § 402.14(a), making a so-called "effects determination." "May affect" is broadly understood. It includes "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (quoting *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009)). If the agency determines that its action "may affect" a listed species or critical habitat, "formal consultation" is generally necessary. 50 C.F.R. § 402.14(a)–(b). Formal consultation requires the Services to prepare a "biological opinion" on whether the proposed action "is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat." *Id.* § 402.14(g)(4), (h). If the Services conclude that "the agency action would place the listed species in jeopardy or adversely modify its critical habitat," *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 652 (2007), they

must recommend "reasonable and prudent alternatives" to the proposed action, *id.* (quoting 16 U.S.C. § 1536(b)(3)(A) and 50 C.F.R. § 402.14(h)(2)).

Rural Coalition argues that EPA failed to comply with these obligations before issuing the Interim Decision. At the threshold, Intervenor Monsanto argues that we should not decide the merits of this claim because Rural Coalition lacks standing, the claim is moot, and/or the claim was not adequately preserved. To help explain our analysis of these arguments, we first describe the aspects of the Interim Decision relevant to the ESA claim. We then answer all of the threshold questions in Rural Coalition's favor and, on the merits, agree with Rural Coalition that EPA violated the ESA.

A.

The Interim Decision contains the critical pieces of EPA's registration review of glyphosate. It "finalizes" the human and ecological risk assessments and announces that "[n]o additional data are required." As to human health, it "determine[s] that there are no risks to human health from the current registered uses of glyphosate" and imposes no health-related mitigation requirements. As to ecological risk, it finds potential risks to animals and plants and "require[s]" mitigation in light of those risks, laying out specific language for glyphosate product labels. Crucially, the Interim Decision "concludes that the benefits outweigh the potential ecological risks" when glyphosate is used according to the restrictions imposed by the Interim Decision. That conclusion is the critical determination that the pesticide complies with FIFRA's safety standard. *See Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1133 (9th Cir. 2020) ("FIFRA uses a cost-benefit analysis to ensure that there is no unreasonable risk created for people or the

environment from a pesticide." (quoting *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 522–23 (9th Cir. 2015))).[15]

B.

1.

We turn to the first threshold question: whether Rural Coalition lacks standing to bring an ESA claim. Article III standing requires "(1) a concrete and particularized injury that is 'actual or imminent, not conjectural or hypothetical'; (2) a causal connection between the injury and the defendant's challenged conduct; and (3) a likelihood that a favorable decision will redress that injury." *Pyramid Lake Paiute Tribe of Indians v. Nev. Dep't of Wildlife*, 724 F.3d 1181, 1187 (9th Cir. 2013) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).[16]

[15] The Interim Decision outlines only two more tasks, in addition to ESA consultation, that EPA intends to complete before issuing a final registration review decision: an endocrine analysis required by the FFDCA and resolution of a petition filed under the FFDCA. But EPA made clear that there is nothing left for the agency to do under FIFRA's mandate itself. The ESA analysis, FFDCA analysis, and response to the FFDCA petition are discrete processes guided by other statutes. At oral argument, EPA confirmed, "[T]he Interim Decision . . . basically finalized everything except for the Endangered Species Act consultation, which the agency committed to do before making a final decision. It looked at human health and ecological risk, which are the factors under the statute—under FIFRA."

[16] Rural Coalition asserts an injury on behalf of its members and thus must also meet the requirements for associational standing. "[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's

"To satisfy the injury-in-fact requirement of the Article III inquiry, 'a plaintiff asserting a procedural injury must show that the procedures in question are designed to protect some threatened concrete interest of his that is the ultimate basis of his standing.'" *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008) (quoting *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003)). Rural Coalition's members have submitted declarations stating that they regularly engage in educational and recreational activities involving a variety of endangered species, including the Indiana bat, whooping crane, and least tern. These members also allege that glyphosate is threatening their interests by exposing those species to toxic runoff and residues on vegetation. The interests identified in the Rural Coalition declarations are "undeniably . . . cognizable interest[s] for [the] purpose of standing." *See Lujan*, 504 U.S. at 562–63. In addition, the consultation procedures that Rural Coalition claims were required but not completed are intended to protect these types of interests. *See Salmon Spawning*, 545 F.3d at 1226 ("These procedures are designed to advance the ESA's overall goal of species preservation, and thus the [members'] specific goals as to . . . preservation, by ensuring agency compliance with the ESA's substantive provisions."). Accordingly, the injury-in-fact requirement is met.

Rural Coalition has also established causation. We have held that an alleged violation of the consultation requirement constitutes a "procedural injury" for standing purposes.

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purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Criteria (b) and (c) are not contested, and we are satisfied that they are met here. We therefore focus our analysis on (a).

Citizens for Better Forestry, 341 F.3d at 971. When a procedural injury is asserted, "[t]he causation requirement is satisfied by showing a 'reasonable probability of the challenged action's threat to [the petitioner's] concrete interest.'" *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 910 (9th Cir. 2020) (quoting *Hall v. Norton*, 266 F.3d 969, 977 (9th Cir. 2001)). Here, EPA reconsidered the conditions under which the most heavily used herbicide in the nation may be used, acknowledging in the Interim Decision that glyphosate poses "potential risks of concern" for mammals, birds, and plants. Yet the agency imposed few limitations on glyphosate use. Thus, there is a reasonable probability that the requested ESA procedures—that is, an effects determination and consultation—would lead to greater restrictions on glyphosate, thereby reducing the threat posed to the species that are the focus of Rural Coalition members' interests.

EPA's recent analysis of glyphosate's impact on listed species—that is, its ESA effects determination—in preparation for its final registration review decision adds support for our conclusion. After issuing the Interim Decision, EPA published a draft Biological Evaluation ("BE") followed by a final BE. According to EPA, the BE is a "comprehensive, nationwide assessment of the effects of glyphosate on ESA-listed species and critical habitats that determines the need for consultation, and its scope." Put differently, the BE broadly assesses the effect of current glyphosate use—the very use that is the subject of the Interim Decision.[17] The BE found that glyphosate "may

[17] Although EPA and Monsanto urge otherwise, we assume that whatever consultation would have occurred if EPA had consulted with the Services on the Interim Decision would have been equivalent to EPA's current consultation. From a practical standpoint, the only

affect" all ESA-listed species that experience glyphosate exposure—that is, 1,795 species—and is likely to adversely affect 93% of those species. EPA has begun formal consultation about how to mitigate these adverse effects.

Monsanto argues unconvincingly that the causation requirement is not satisfied. According to Monsanto, the Interim Decision did not grant or extend glyphosate's *registration*, and EPA could not cancel that registration through such a decision. Instead, if the agency intends to cancel a pesticide's registration, it must initiate cancellation through an elaborate statutory process. *See* 7 U.S.C. § 136d(b). Accordingly, on Monsanto's view, the Interim Decision is not the reason glyphosate can continue to be sold, and thus there is no causal link between Rural Coalition's injury and EPA's action. But causation does not require that the defendant's unlawful conduct be the only cause of the alleged injury. Had EPA observed the consultation requirement prior to issuing the Interim Decision, even if glyphosate's registration had not been cancelled outright, the Interim Decision might have imposed more restrictions on glyphosate's use than the Interim

differences between the Interim Decision and the anticipated final registration review decision in terms of subject matter for potential consultation are the outstanding analyses under the FFDCA. It is difficult to believe that those analyses would make a difference in the ESA consultation process, and no party has even suggested that they would. Accordingly, we treat the hypothetical consultation process that could have been done prior to issuance of the Interim Decision and the current consultation process EPA has undertaken prior to its final decision as essentially the same endeavor. Monsanto's brief is in accord. In arguing that Rural Coalition's ESA claim is not redressable, Monsanto contends that "[t]he very process that Petitioners want EPA to undertake is already being undertaken," effectively acknowledging that the scope of EPA's current consultation endeavor is equivalent to whatever might have been required for the Interim Decision.

Decision's new label requirements actually did. That is sufficient to satisfy the causation requirement given that the alleged violation is procedural in nature. *See Salmon Spawning*, 545 F.3d at 1229 (holding that causation is satisfied for a procedural injury when "[t]he asserted injury is not too tenuously connected to the agencies' failure" to take action).

When petitioners allege a procedural violation, the redressability prong is satisfied by showing that the agency decision "could be influenced" by the procedures at issue. *Hall*, 266 F.3d at 977; *see also Nat'l Fam. Farm Coal.*, 966 F.3d at 911 (explaining that the redressability requirement is satisfied when relief "*may* influence the agency's ultimate decision of whether to take or refrain from taking a certain action" (quoting *Salmon Spawning*, 545 F.3d at 1226–27)). Broadly speaking, Rural Coalition requests that the agency complete the consultation procedures found in the ESA. As explained above, it is apparent that EPA might have required more mitigation efforts had the agency completed an effects determination and consulted before issuing the Interim Decision.

Monsanto also argues that any alleged injury is not redressable because EPA began following the ESA consultation procedures before Rural Coalition filed its petition for review of the Interim Decision. By the time Rural Coalition filed its opening brief, the agency had released a draft BE in preparation for its final registration review decision. Since then, EPA has released a final BE and has begun formally consulting. Monsanto argues that an order to complete consultation procedures would not prompt EPA to do anything more than it is already doing, and that any injury is therefore not redressable. *See Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) (requiring "some possibility

that the requested relief will *prompt* the injury-causing party to reconsider the decision that allegedly harmed the litigant" (emphasis added)).

We disagree. "When evaluating whether [the standing] elements are present, we must look at the facts as they exist[ed] at the time the complaint was filed." *Slayman v. FedEx Ground Package Sys., Inc.*, 765 F.3d 1033, 1047 (9th Cir. 2014) (alteration in original) (quoting *ACLU of Nev. v. Lomax*, 471 F.3d 1010, 1015 (9th Cir. 2006)). At the time Rural Coalition filed its petition, court-ordered relief was possible. EPA had not even completed a *draft* BE, and it was unclear when the agency would do so. Thus, we could have, for example, remanded the Interim Decision, directed the agency to comply with the ESA, and even imposed a deadline for completing the effects determination required by the statute—that is, ordered EPA to finalize a BE and to initiate any required consultation by a certain date. *See, e.g.*, *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 703 (9th Cir. 2021); *see also Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 936–38 (9th Cir. 2008); *Alaska Ctr. For Env't v. Browner*, 20 F.3d 981, 986–87 (9th Cir. 1994). An aggressive deadline—and any court oversight that might accompany such a deadline—presumably would have spurred EPA to act at least somewhat faster than it otherwise would have, redressing Rural Coalition's injury. That is enough for Rural Coalition to have standing.

2.

Monsanto alternatively argues that EPA's recent consultation efforts moot this case. "If an event occurs that prevents the court from granting effective relief, the claim is moot and must be dismissed." *Am. Rivers v. Nat'l Marine Fisheries Serv.*, 126 F.3d 1118, 1123 (9th Cir. 1997); *see*

Church of Scientology of Cal. v. United States, 506 U.S. 9, 12 (1992). On Monsanto's view, even assuming there is standing, we can no longer grant effective relief on the ESA claim now that EPA has begun formally consulting with the Services.

But Monsanto's understanding of the relief available here is too narrow. Broadly speaking, the allegedly unlawful behavior targeted by the petition is a failure to complete procedures required by the ESA before formally concluding whether and how glyphosate may be used consistent with FIFRA's safety standard, and that behavior still has not been rectified. The allegedly unlawful behavior could be remedied by our imposition of an aggressive deadline for the completion of consultation, an order for EPA to complete the parts of consultation within its control with the utmost speed, or an order for EPA to file status reports with our court on consultation's progress.[18] Such relief could meaningfully

[18] A consultation deadline would implicate the obligations of the Services in addition to obligations of EPA. That would seem permissible under the principle that injunctive court orders may "bind[] the parties defendant but also those identified with them in interest, in 'privity' with them, represented by them or subject to their control." *Regal Knitwear Co. v. NLRB*, 324 U.S. 9, 14 (1945); *accord Golden State Bottling Co. v. NLRB*, 414 U.S. 168, 179 (1973); *see also Class Plaintiffs v. City of Seattle*, 955 F.2d 1268, 1277 (9th Cir. 1992) ("[A] judgment can bind persons not parties to the litigation in question and not subject *in personam* to the jurisdiction of the court if the persons are in privity with parties to the litigation."). In general, "[t]here is privity between officers of the same government." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 402–03 (1940); *accord Fund for Animals, Inc. v. Lujan*, 962 F.2d 1391, 1398 (9th Cir. 1992); *see Ma Chuck Moon v. Dulles*, 237 F.2d 241, 243 (9th Cir. 1956) (finding privity between the U.S. Secretary of State and the Attorney General for res judicata purposes because the actions at issue were "in effect suits against the United States"). Even if we could not bind the Services, however, our ability to compel EPA to act quickly is sufficient to avoid mootness.

hasten ESA compliance, especially because EPA appears inclined to delay consultation given that it has already pushed the entire consultation process until the final year of registration review. Thus, Rural Coalition's claim is not moot.[19]

3.

Monsanto additionally argues that Rural Coalition's ESA claim was not preserved during the public-comment period. This argument is unconvincing. A Rural Coalition petitioner, Center for Biological Diversity, discussed ESA consultation in its comments on the proposed Interim Decision. The Center argued that "EPA must consult with the Services on its continuing and ongoing authority over this pesticide to satisfy its duty to [en]sure that its use will not jeopardize or adversely modify protected species or their critical habitat well *before* it proposes a registration review decision." The Center also implored EPA to "[i]ncorporate necessary factors into evaluation and any proposed decision"

[19] Cases in which we have deemed consultation claims moot when the agency had already begun consulting are not to the contrary. *See All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121 (9th Cir. 2018); *All. for the Wild Rockies v. U.S. Dep't of Agric.*, 772 F.3d 592, 601 (9th Cir. 2014). The plaintiffs in those cases sought reinitiation of consultation, which could not be ordered once it had already occurred. Here, Rural Coalition seeks compliance with and *completion of* the ESA's consultation requirement, not just the initiation or reinitiation of consultation. *See Env't Def. Ctr. v. Bureau of Ocean Energy Mgmt.*, — F.4th —, 2022 WL 1816515, at *21 (9th Cir. 2022) (holding that, because consultation with the Fish and Wildlife Service was still ongoing, the court had jurisdiction over a claim that an agency failed to consult before acting); *see also All. for the Wild Rockies v. Savage*, 897 F.3d 1025, 1031 (9th Cir. 2018) (holding that a reconsultation claim was moot because the federal defendants *completed* reconsultation and the plaintiff, therefore, "ha[d] obtained all that it sought with this claim").

including "effects on species listed as protected under the ESA and their critical habitat." Those comments sufficiently raised the issue that EPA failed to comply with the ESA consultation requirement before issuing its Interim Decision. *See Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) ("[A] claimant need not raise an issue using precise legal formulations, as long as enough clarity is provided that the decision maker understands the issue raised.").

C.

We now turn to the merits of Rural Coalition's ESA argument. As explained above, the consultation procedures begin with an agency "review[ing] its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat," 50 C.F.R. § 402.14, resulting in an effects determination. It is undisputed that EPA made no such effects determination before issuing the Interim Decision. Thus, the key question is whether the Interim Decision is an "action" that triggers the consultation procedures found in the ESA. Rural Coalition argues that the answer is "yes" because the Interim Decision was a consequential milestone that essentially approved continued glyphosate use across the United States. EPA and Monsanto disagree. They argue that Rural Coalition's grievance is with EPA's failure to require more mitigation measures, not any affirmative action taken by the agency.

We have held that "agency action" under the ESA has only two requirements. There is "agency action" whenever an agency makes a decision that is (1) affirmative and (2) discretionary about whether, or under what conditions, to allow private activity to proceed. *Karuk Tribe*, 681 F.3d at 1011. That the second requirement is satisfied is not disputed here—EPA clearly has the power to restrict pesticide use by private parties through mitigation measures

to protect listed species. 40 C.F.R. §§ 155.40(a)(2), 155.56, 155.58(b)(2).

We agree with Rural Coalition that the first requirement is also satisfied, because the Interim Decision is an affirmative act. An agency must adhere to the consultation requirement when it makes an "affirmative" act or authorization. *Cal. Sportfishing Prot. All. v. FERC*, 472 F.3d 593, 595 (9th Cir. 2006). But "[w]here private activity is proceeding pursuant to a vested right or to a previously issued license, an agency has no duty . . . under Section 7 if it takes no further affirmative action regarding the activity." *Karuk Tribe*, 681 F.3d at 1021; *W. Watersheds Project v. Matejko*, 468 F.3d 1099, 1108 (9th Cir. 2006) ("'[I]naction' is not 'action' for section 7(a)(2) purposes."). Here, EPA actively exercised its regulatory power, completing an assessment of glyphosate's risks under FIFRA and delineating what constituted acceptable glyphosate use under the statute's safety standard. *See Karuk Tribe*, 681 F.3d at 1024 (finding affirmative action when "the Forest Service formulated precise criteria for the protection of coho salmon, communicated those criteria to prospective miners, and approved the miners' activities under a [Notice of Intent] only if they strictly conformed their mining to the specified criteria").

EPA and Monsanto's primary argument is that Rural Coalition is objecting to inaction, not action, when it complains that EPA would have instituted more mitigation efforts if EPA had engaged in ESA consultation. That argument fails. EPA and Monsanto mainly rely upon *Western Watersheds*, 468 F.3d 1099. That case involved a Bureau of Land Management ("BLM") decision *not* to regulate private parties' diversions of water—diversions that were completed pursuant to those parties' pre-existing

rights-of-way. We assumed that BLM had the power to regulate the diversions but held that BLM's decision not to exercise that power was not an affirmative action. *Id.* at 1107–09. We explained, "BLM did not *fund* the diversions, it did not *issue* permits, it did not *grant* contracts, it did not *build* dams, nor did it *divert* streams." *Id.* at 1109; *see also Cal. Sportfishing*, 472 F.3d at 598, 595 (holding that "the agency[] ha[d] proposed no affirmative act that would trigger the consultation requirement" for operations of a hydroelectric plant that were authorized by an earlier permit, even though the agency was empowered to "unilaterally institute proceedings to amend the license if it so chose"). The Interim Decision is unlike the agency inaction in *Western Watersheds*. Here, EPA did not simply stand aside as regulated parties continued to use glyphosate. Instead, EPA exercised its regulatory power under FIFRA—engaging in a re-assessment that was *required by statute*—and delineated the manner in which glyphosate could be used consistent with the FIFRA safety standard.

Because EPA's registration review decision under FIFRA is the "action" that triggers the consultation requirement, it is irrelevant—despite EPA and Monsanto's suggestion to the contrary—that Rural Coalition takes the view that the Interim Decision does very little to protect listed species and should have contained more mitigation measures. Indeed, the notion that challenging an absence of mitigation efforts is merely an objection to inaction is inconsistent with the purpose of the ESA. Arguing that protection for endangered and threatened species is insufficient is precisely the point of an ESA claim. When aggrieved parties file a lawsuit asserting that the government should not have authorized a certain activity, such as the diversion of water from a river, the core grievance is often that the activity threatens—or, put differently, does not

sufficiently protect—listed species. *See, e.g.*, *NRDC v. Houston*, 146 F.3d 1118 (9th Cir. 1998). Many clearly cognizable ESA claims, then, could easily be framed as a complaint about the failure to institute more mitigation efforts. That framing does not mean that the claim merely challenges inaction.

D.

Because the Interim Decision was an affirmative, discretionary action, EPA had to comply with the ESA by making an effects determination before issuing the decision. It is undisputed that EPA did not do so. Accordingly, EPA violated the ESA.

Nevertheless, because of the odd confluence of circumstances here, we decline to order relief for the ESA violation. Although relief such as a consultation deadline could hasten EPA's compliance with the ESA (and thus we have held that the ESA claim is not moot), we believe that the FIFRA deadline to complete glyphosate's registration review by October 2022 is a sufficient backstop. According to the timeline imposed by Congress, EPA already must complete its final registration review decision—including formal consultation—by that October 2022 deadline. Given that the FIFRA deadline is fast approaching, shortening EPA's time to consult would be only moderately beneficial to Rural Coalition but potentially very disruptive to the agency.

Rural Coalition urges vacatur of the Interim Decision for failure to comply with the ESA. But it is not clear that vacatur would be beneficial here. The Interim Decision includes certain mitigation efforts that EPA designed to limit the ecological impacts of glyphosate use. Although Rural Coalition argues that those requirements are insufficient, if

the requirements affect glyphosate use at all, they likely *reduce* ecological risk. Because vacatur would eliminate those mitigation requirements, we decline to vacate the Interim Decision—other than to the extent specified in Part III above regarding the human-health portion.

V.

The remaining issue involves Petitioners' challenges to the Interim Decision's ecological risk assessment, determination of glyphosate's costs, cost-benefit analysis, and mitigation requirements (collectively, the "ecological portion"), and EPA's responsive motion for remand. We grant EPA's motion to remand without vacatur as to the ecological portion of the decision, but we impose a time limit on the remand.

NRDC argues that EPA failed to consider major environmental and economic costs of glyphosate use, including the costs of creating glyphosate-resistant weeds, harm to soil health caused by glyphosate, and the decimation of milkweed in agricultural fields. In addition, NRDC argues that EPA failed to provide any explanation as to how it weighed the purported benefits and risks of glyphosate use, pointing out that EPA simply concluded in a single sentence that the purported benefits outweigh the risks without any sort of reasoned analysis. Finally, NRDC argues that EPA's decision rests on unsubstantiated assumptions that the mitigation measures will, in fact, reduce the acknowledged ecological risks posed by glyphosate use—without any evidence that the mitigation measures imposed will ensure that glyphosate use satisfies FIFRA's safety standard. Rural Coalition echoes many of these concerns, adding that EPA failed to consider the cost of glyphosate drift as well as the costs to pollinators and to monarch butterflies.

EPA does not respond to the attack on the ecological portion of the Interim Decision. Instead of answering these parts of the petitions, EPA asks us to remand the ecological portion for further consideration without vacatur and thereby asks us not to reach the corresponding claims in NRDC's and Rural Coalition's petitions.

Courts generally grant an agency's request for voluntary remand unless the request is frivolous or made in bad faith. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012); *see also Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993) ("We commonly grant [agency remand] motions, preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete."). Normally, when remand is requested and granted, "the agency intends to take further action with respect to the original agency decision on review." *Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 436 (D.C. Cir. 2018) (quoting *Limnia, Inc. v. U.S. Dep't of Energy*, 857 F.3d 379, 386 (D.C. Cir. 2017)). "[I]ntervening events outside of the agency's control, for example, a new legal decision or the passage of new legislation," counsel in favor of granting such a remand request. *SKF USA Inc. v. United States*, 254 F.3d 1022, 1028 (Fed. Cir. 2001). That said, we have "broad discretion" in deciding whether to do so. *Util. Solid Waste*, 901 F.3d at 436.

Here, EPA has neither conceded error nor given any clear indication of how it will proceed on remand. Instead, EPA has vaguely asserted that "intervening decisions from this Court," "EPA's publication of its draft biological evaluation for glyphosate," and the "change in Administration" warrant a partial remand. EPA specifically

requests that the partial remand be without vacatur to "allow EPA flexibility" to implement the mitigation requirements set forth in the Interim Decision. EPA suggests that, if it decides to reassess aspects of the Interim Decision, it will likely do so in its final registration decision rather than in a new interim decision.

Rural Coalition opposes the remand motion, arguing that EPA's actions are a bad-faith attempt to avoid judicial review. According to Rural Coalition, "EPA seeks remand of part of its action at the eleventh hour to avoid an adverse court ruling with little or no binding commitment to . . . actually change its decision." Rural Coalition further argues that EPA does not have a properly cognizable rationale for its request. Rural Coalition dismisses the BE because it was within EPA's control and dismisses the intervening court decisions that EPA raises because they established no new law and simply required compliance with FIFRA's core mandate.

NRDC, on the other hand, does not oppose EPA's motion but responds to it by urging a 90-day deadline for completing the reconsideration of the ecological portion of the Interim Decision on remand. According to NRDC, EPA is unlikely to issue a final registration review decision by the October 2022 statutory deadline because the agency only recently initiated formal consultation under the ESA, which NRDC predicts will take years. NRDC additionally details how "EPA's pesticide approval process has been beset by consistent delays," arguing that "[t]his history of delay means that a deadline for remand is appropriate." NRDC thus asks that the Interim Decision be re-issued within 90 days.

Although Rural Coalition's arguments have force, we decide to grant EPA's motion to remand largely for practical

reasons. As stated above, the challenges to the ecological portion are properly raised in Petitioners' briefs, but EPA chose not to respond to those challenges in this action, instead filing a motion to remand on the deadline for filing its answering brief. Monsanto also did not substantively respond to those challenges. If we were to evaluate the merits of NRDC's challenges, we first would want to request responsive briefs and to have oral argument on the ecological issues, raising the possibility that the FIFRA October 2022 deadline would arrive before we could complete our review. Thus, while we hesitate to reward what some might consider sloth or indolence, we also recognize that fully litigating the issues could result in an outcome nobody wants: more, and probably unnecessary, delay. Because of these unusual circumstances, we **GRANT** EPA's motion to remand.

We are sympathetic, however, to Petitioners' concerns about delay and gamesmanship. That said, we do not believe that NRDC's proposed 90-day deadline is warranted or that EPA must issue another interim decision before its final decision. Instead, we require EPA to issue a new ecological portion by the October 2022 FIFRA deadline.[20] *See Clean*

[20] EPA points out that the Supreme Court has cautioned that, "[a]t least in the absence of substantial justification for doing otherwise, a reviewing court may not, after determining that additional evidence is requisite for adequate review, proceed by dictating to the agency the . . . time dimension of the needed inquiry." *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 544–45 (1978) (quoting *Fed. Power Comm'n v. Transcont'l Gas Pipe Line Corp.*, 423 U.S. 326, 333 (1976) (per curiam)). This concern is not triggered by the deadline we set because Congress has already "dictat[ed] . . . [the] time dimension" for EPA action here. *Id.* at 545. We avoid any potential issue with "propelling the court into the domain which Congress has set aside exclusively for the administrative agency," *id.* at 545 (quoting *Transcont'l Gas*, 423 U.S. at 333)—which was the Court's concern in *Vermont Yankee*—by

Wis. v. EPA, 964 F.3d 1145, 1176 (D.C. Cir. 2020) ("EPA offers no reason, nor can we think of one, why it should be permitted to evade the Clean Air Act's statutory deadline through a voluntary remand.").

VI.

EPA's motion to remand the ecological portion of the Interim Decision without vacatur of that portion is **GRANTED** subject to the deadline described above. Because we grant EPA's motion, we do not reach the parts of NRDC's and Rural Coalition's petitions that challenge the remanded portion of the Interim Decision.

The remainder of Rural Coalition's petition for review is **GRANTED** in part and **DENIED** in part. We **VACATE** the human health portion of the Interim Decision and **REMAND** for further consideration. Given that vacatur, we do not reach the remainder of NRDC's petition challenging the public-comment process that informed the human health portion of the Interim Decision. And although we agree with Rural Coalition that an ESA violation has occurred, we decline Rural Coalition's request for relief for the reasons stated above.

REMANDED.

imposing a deadline that is the same as Congress's deadline for review of pesticide registrations. *See Clean Wis. v. EPA*, 964 F.3d 1145, 1176 (D.C. Cir. 2020).

meta-analysis

(meh-tuh-uh-NA-lih-sis)

A process that analyzes data from different studies done about the same subject. The results of a meta-analysis are usually stronger than the results of any study by itself.

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Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

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- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - ► A material point of fact or law was overlooked in the decision;
  - ► A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - ► An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ► Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ► The proceeding involves a question of exceptional importance; or
- ► The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- A response, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or response must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms.*
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

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