Nos. 20-70787, 20-70801

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, et al.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

RURAL COALITION, et al.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

On Petition for Review of Final Agency Action of the
United States Environmental Protection Agency

BRIEF FOR U.S. ENVIRONMENTAL PROTECTION AGENCY

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GLOSSARY

ATSDR	U.S. Agency for Toxic Substances and Disease Registry
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IARC	World Health Organization's International Agency for Research on Cancer
Interim Decision	EPA's Interim Registration Review Decision for glyphosate
NRDC	Natural Resources Defense Council
ORD	EPA's Office of Research and Development
SAP	Scientific Advisory Panel

INTRODUCTION

In its Interim Registration Review Decision for glyphosate ("Interim Decision"), EPA reasonably concluded that glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern. The record underlying these conclusions is robust, reflecting more than a decade of analysis and thorough review of the scientific literature. Petitioners respond to this record with a studied blindness, attempting to inflate the appearance of risk while disregarding the reams of evidence that rebut their arguments. Petitioners cannot overturn EPA's expert scientific conclusions, which are entitled to the highest deference, merely by arguing that there is some evidence in the record that might support an alternative conclusion or closing their eyes to the record as a whole. That record supports EPA's conclusions with well more than substantial evidence.[1]

Petitioners also contend that EPA violated the Endangered Species Act ("ESA") by not completing a consultation pursuant to

[1] EPA's Interim Decision included other analysis, including in particular of ecological risks, but by separate motion filed simultaneously herewith, EPA is seeking voluntary remand without vacatur of that portion of its decision.

Section 7(a)(2) "prior to registering glyphosate." This claim fails on its face, as the Interim Decision did not register glyphosate. It is evident that the true aim of Petitioners' ESA claim is not to compel consultation on the Interim Decision, but rather to take glyphosate off the market. To justify such relief, Petitioners mischaracterize the Interim Decision as a registration decision and the cause of all alleged effects of glyphosate. But because the Interim Decision is neither a registration decision nor the cause of the effects Petitioners complain of, their "failure to consult" claim fails. Petitioners do not show that the Interim Decision "may affect" ESA-listed species or critical habitats, which is the trigger for consultation. In fact, Petitioners defeat their own argument by contending that the Interim Decision fails to alter the status quo. Furthermore, EPA has already committed to complete a comprehensive, nationwide ESA consultation of the effects of glyphosate before it issues its final registration review decision. Ordering EPA to consult on the Interim Decision—or vacating it—would be counterproductive.

To call Petitioners' proposed remedy an overreach would be an understatement. Their request that the Court abruptly declare each of

the more than five hundred glyphosate product registrations unlawful is contrary to FIFRA, which forbids automatic cancellation of product registrations as a result of the registration review process. It would also cause widespread disruption, as glyphosate is the most widely used herbicide in the United States, such that this remedy would be inappropriate even if it were lawful.

The Court should deny the petitions for review.

STATEMENT OF JURISDICTION

The consolidated petitions for review of the Interim Decision were timely filed on March 20, 2020, "within 60 days after the entry of [the] order." 7 U.S.C. § 136n(b).

STATEMENT OF THE ISSUES

(1) Have Petitioners carried their burden to show that EPA's conclusion that glyphosate does not pose human-health risks of concern is not supported by substantial evidence, where they disregard key components of the record, EPA's analysis, and governing regulations?

(2) Have Petitioners shown that EPA breached a duty to complete ESA consultation on the Interim Decision, when that action did not register glyphosate or cause the effects of glyphosate, and

Petitioners make no showing that the Interim Decision, itself, "may affect" any listed species or critical habitat?

(3) Is Petitioners' claim that EPA failed to complete ESA consultation prudentially moot, where EPA has committed to complete a comprehensive, nationwide consultation on glyphosate prior to issuing its final registration review decision, to begin by November 12, 2021, and consulting on the Interim Decision would likely delay that consultation?

(4) Is vacatur of more than 500 glyphosate product registrations a lawful and appropriate remedy where FIFRA forbids automatic cancellation of such registrations as a result of the registration review process and such cancellation would cause profound disruption?

PERTINENT STATUTES AND REGULATIONS

The pertinent statutes and regulations not provided in Petitioners' briefs are set forth in the Addendum following this brief.

STATEMENT OF THE CASE

I. Statutory and regulatory background.

A. Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

FIFRA generally precludes the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a); 40 C.F.R. pts. 152, 158. Entities that seek such a registration must provide EPA information about the applicant, their specific pesticide product, and the pesticide label. 7 U.S.C. § 136a(c). Once granted, a FIFRA registration is a license conferred to the applicant that establishes the terms and conditions under which the applicant's specific pesticide product may be lawfully sold, distributed, and used in the United States. 7 U.S.C. §§ 136a(c)(1)(A)-(F), 136a(d)(1); *see also Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002); 69 Fed. Reg. 47,732, 47,733 (Aug. 5, 2004).

EPA will register a pesticide if it determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment," among other

requirements. 7 U.S.C. § 136a(c)(5). FIFRA defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). It is unlawful to use a pesticide "in a manner inconsistent with its labeling." *Id.* § 136j(a)(2)(G).

EPA must periodically review pesticide registrations. *Id.* § 136a(g); 40 C.F.R. § 155.40 *et seq*.[2] A registration review reflects EPA's "determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." 40 C.F.R. § 155.57. EPA will create a "registration review case" for one or more active ingredients in a pesticide and all of the products containing such ingredients, establish a docket for public participation, and provide an opportunity for comment. *Id.* §§ 155.42, 155.50. It may "call in" data necessary to conduct its review. *See* 7 U.S.C. §§ 136a(c)(2)(B), (g)(2); 40 C.F.R. § 155.48. EPA will assess changes since the pesticide's last review and

[2] EPA is currently reviewing roughly 1,140 pesticide active ingredients. *See* https://www.epa.gov/pesticide-reevaluation/registration-review-process.

conduct new assessments as needed. 40 C.F.R. § 155.53. In the course of a registration review, EPA may determine that certain label restrictions are appropriate. *See id.* § 155.58(b)(2), (4).

EPA need not tackle the entirety of the registration review at once, but rather may make an "interim registration review decision." *Id.* § 155.56. "Among other things, the 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 submitting the required data, conducting the new risk assessment and completing the registration review." *Id.*

A FIFRA registration remains effective until EPA cancels it, which is a statutorily defined administrative action subject to specific safeguards. *See* 7 U.S.C. § 136d(b); 40 C.F.R. § 155.40; *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1134 (D.C. Cir. 2010). If EPA concludes that a pesticide product does not meet FIFRA's standard, cancellation is not automatic. Rather, EPA has discretion to initiate cancellation proceedings. *See* 7 U.S.C. § 136d(b). To do so, EPA must typically notify the Secretary of Agriculture, provide the Secretary an

analysis of the impact of cancellation on the agricultural economy, and afford the Secretary an opportunity to comment. *Id.* EPA must then send the registrant notice of EPA's intent to cancel the registration or to hold a hearing on cancellation, and publish that notice. *Id.* If EPA issues a notice of intent to cancel the registration (rather than a notice of intent to hold a hearing), EPA may cancel the registration unless the registrant corrects the defect EPA identified or "a person adversely affected by the notice" requests a hearing. *Id.* If a hearing is requested or EPA has issued a notice of intent to hold a hearing, the final decision on cancellation will occur only after completion of an administrative adjudicatory hearing. *See id.* § 136d(b), (d); 40 C.F.R. pt. 164. In making a decision, EPA "shall" consider restricting a pesticide's use or uses as an alternative to cancellation, taking into account the impact of its decision on agriculture. 7 U.S.C. § 136d(b).

This rule—that cancellation of a FIFRA registration cannot be automatic—extends to registration review. Congress provided that pesticide registrations shall not be cancelled "as a result of the registration review process unless [EPA] follows the procedures and

substantive requirements" for cancellation set forth in Section 136d. *Id.* § 136a(g)(1)(A)(v).

B. Endangered Species Act ("ESA").

ESA Section 7(a)(2) directs each federal agency to insure that "any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of" a listed species or destroy or adversely modify designated critical habitat. 16 U.S.C. § 1536(a)(2). To facilitate compliance with those mandates, the ESA's implementing regulations outline a process whereby federal "action agencies" consult with the appropriate expert "consulting agency" (either the National Marine Fisheries Service or the U.S. Fish & Wildlife Service or both, depending on the species involved) to, among other things, analyze the potential impacts of a proposed action on listed species and designated critical habitat. 50 C.F.R. §§ 402.13(a), 402.14(b)(1).

Consultation is required whenever a proposed federal action "may affect" listed species or critical habitat. *Id.* § 402.14(a). Agency "action" and "effects of the action" are defined terms under the ESA. *Id.* § 402.02. If the action will not affect listed species or designated critical habitat, then consultation is not required. *Sw. Ctr. for Biological*

Diversity v. U.S. Forest Serv., 100 F.3d 1443, 1447-48 (9th Cir. 1996); *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 924 (9th Cir. 2020); *Friends of the Santa Clara River v. USACE*, 887 F.3d 906, 927 (9th Cir. 2018).

If, however, the action agency determines that the action "may affect" listed species or critical habitat, it must consult, either formally or informally. 50 C.F.R. §§ 402.13-402.14. Formal consultation is required unless the action agency determines, with the consulting agency's written concurrence, that the proposed action is "not likely to adversely affect" a listed species or critical habitat. *Id.* §§ 402.13(c), 402.14(b)(1). If formal consultation is required, then the consulting agency must prepare a biological opinion stating whether the proposed action is likely to "jeopardize the continued existence of" any listed species or destroy or adversely modify critical habitat. 16 U.S.C. § 1536(b)(3); 50 C.F.R. §§ 402.14, 402.46.

II. The glyphosate registration review.

A. Glyphosate.

Glyphosate is a versatile, broad-spectrum herbicide used in an array of agricultural and other settings. 1-RC_ER-15-16; 2-RC_ER-267.

It functions by inhibiting an enzyme produced by plants. 1-RC_ER-10; 1-RC_ER-15-16; 7-RC_ER-1497.

There are many reasons that glyphosate has become the most commonly used agricultural herbicide in the United States. 1-RC_ER-15. It is a simple-to-use, relatively inexpensive, broad-spectrum herbicide that can be applied with many different types of equipment and used in a variety of agricultural and non-agricultural applications. 1-RC_ER-15-16; 2-RC_ER-267; 2-RC_ER-271; 2-RC_ER-272. This includes its extensive use with glyphosate-resistant crops. 1-RC_ER-15-16; 2-RC_ER-272; 2-RC_ER-284. Glyphosate can be used with such resistant crops to kill weeds, with minimal toxicity to the crop. 1-RC_ER-15-16; 2-RC_ER-267.

Glyphosate is also important in weed-control programs in orchards and high-value specialty crops. 1-RC_ER-15-16; 2-RC_ER-267; 2-RC_ER-276; 2-RC_ER-285-86. It is the "most versatile herbicide in orchard floor management" and can be used to control weeds prior to planting high-value crops. 1-RC_ER-15-16.

Noxious and invasive weed control in aquatic systems, pastures/range lands, public lands, forestry, and rights-of-way also rely

heavily on glyphosate. 1-RC_ER-15-16; 2-RC_ER-267 ("Rights-of-way applications are critical to maintaining vital infrastructure and safety . . . ."); 2-RC_ER-287-88 (discussing harms of invasive plant species); 2-RC_ER-288-89 (invasive aquatic weeds "have cascading ecological effects," and other adverse impacts); 2-RC_ER-290. By providing effective weed control, glyphosate can also help control mosquito borne illness. 1-RC_ER-15-16.

Use of glyphosate carries environmental benefits. 2-RC_ER-271-72 (discussing "glyphosate's role in no-till farming and conservation tillage and reduced carbon emissions," "reduc[ing] soil erosion," and "conserv[ing] soil moisture"). Glyphosate "reduces or eliminates the need for other weed control methods, including other herbicides, many of which pose more risk to humans or the environment." 2-RC_ER-272; 2-RC_ER-271.

Because glyphosate has a broad spectrum of weed control, it "is likely to reduce farm inputs by reducing the number of herbicides and the number of trips over the field for weed control or tillage." 2-RC_ER-272-73. This, in turn, tends to lower labor and fuel costs compared to

other weed-control systems. 2-RC_ER-272-73; *see also* 2-RC_ER-271; 2-RC_ER-284.

B. Overview of the glyphosate registration review process.

The first pesticide product containing glyphosate was registered in 1974. 1-RC_ER-6. The safety of glyphosate was re-assessed in "reregistration" proceedings, *see* 7 U.S.C. § 136a-1, culminating in a 1993 Reregistration Eligibility Decision. 1-RC_ER-6. EPA has also completed risk assessments for glyphosate when new uses were added to glyphosate labels. 1-RC_ER-6. In 2009, EPA began its registration review for glyphosate. *See* 7 U.S.C. 136a(g)(1)(A)(iii); 7-RC_ER-1477; 7-RC_ER-1493-95.

In December 2017, EPA released a "Draft Human Health Risk Assessment in Support of Registration Review" for public comment. 3-RC_ER-514-54; *see also* 3-RC_ER-498 (response to comments). This document explained EPA's conclusion that glyphosate did not pose human health risks of concern. 3-RC_ER-516 (low toxicity across species, with effects observed in most studies "at or above the limit dose"; no effects in route-specific dermal and inhalation studies; no evidence it is neurotoxic or immunotoxic; classified as not likely to be

carcinogenic to humans). As to cancer risks, EPA's analysis was supported by a 216-page revised issue paper. This paper was the result of years of investigation, consideration of a vast array of data and studies, and revised after the input of a scientific advisory panel. *See* 1-SER-43-45; 1-SER50-53 *see also* 1-SER-20. EPA also prepared a "Preliminary Ecological Risk Assessment for Glyphosate and Its Salts" and took comment on this document. *See* 5-RC_ER-945; 3-RC_ER-440.

In April 2019, EPA published its "Glyphosate—Proposed Interim Registration Review Decision," summarizing its proposed conclusions weighing the costs and benefits of glyphosate and set forth certain proposed label requirements. 2-RC_ER-211. EPA responded to comments on this document as well. *See* 2-SER-390; 2-SER-403.

C. The Interim Decision.

The Interim Decision was signed on January 22, 2020. 1-RC_ER-3. EPA issued that decision in order to "(1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation." 1-RC_ER-5. Among other things, the Interim Decision finalized the draft human-health and ecological risk assessments referenced above. 1-RC_ER-6.

The Interim Decision summarized EPA's conclusions (as of the date of signature) on the risks and benefits associated with glyphosate. As to human health, "EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern." 1-RC_ER-11; 1-RC_ER-16. It also summarized EPA's conclusions as to ecological risks. *See* 1-RC_ER-14-17.

EPA concluded that there were certain low-cost measures that would be appropriate to mitigate potential ecological risks posed by glyphosate. These included restrictions on how and when glyphosate can be sprayed, in order to reduce drift of such sprays, a "non-target organism advisory," and herbicide-resistance measures. *See* 1-RC_ER-17-19.

The Interim Decision noted aspects of EPA's registration review that EPA had not yet finalized. 1-RC_ER-5; 1-RC_ER-22. First, EPA was in the process of working with the FWS and NMFS to develop methodologies for conducting national threatened and endangered species assessment for pesticides in accordance with the ESA. 1-RC_ER-5. It therefore "will complete its listed species assessment and

any necessary consultation with the Services for glyphosate prior to completing the glyphosate registration review." 1-RC_ER-5. Second, EPA did not make an Endocrine Disruptor Screening Program determination under the Federal Food, Drug, and Cosmetic Act § 408(p) for glyphosate. *See* 1-RC_ER- 37-38 ("In this ID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate."); 1-RC_ER-5; 1-RC_ER-22. Third, EPA was not addressing certain issues relating to an administrative petition submitted in September 2018. 1-RC_ER-5. Finally, EPA acknowledged that "additional data may be necessary to fully evaluate risks to bees." 1-RC_ER-5; 1-RC_ER-14.

D. Motion for voluntary remand.

Simultaneously herewith EPA has filed a motion for partial voluntary remand without vacatur of the portions of the Interim Decision that do not relate to its conclusions on human health risks or the usage and benefits of glyphosate. Specifically, EPA seeks remand of its finalization of its analysis of the ecological risks and other potential (non-human-health) costs associated with glyphosate. EPA's response

brief thus focuses on Petitioners challenges to EPA's analysis of human-health risks and their arguments under the ESA.

SUMMARY OF ARGUMENT

EPA reasonably concluded that glyphosate is not likely to be a human carcinogen and that it does not pose human-health risks of concern. *See* Argument II. This conclusion is the result of a decade of analysis, review by a scientific advisory panel, revisions in light of that review, and EPA's expert judgment on how the evidence should be weighed. None of the scientific advisory panel believed that glyphosate should be categorized as a likely human carcinogen. EPA's consideration of occupational risks, including the risks associated with dermal exposure and glyphosate formulations, was consistent with its regulations and guidance, and supports the agency's determination that glyphosate does not pose human-health risks of concern. *See* Argument III. This Court's review is to assess whether EPA supported its conclusions "with studies that the agency, in its expertise, deems reliable," and not—as Petitioners would have it—to serve as superintending scientist or re-weigh the evidence and reach its own conclusions. *Lands Council v. McNair*, 537 F.3d 981, 988 (9th Cir.

2008) (en banc), *overruled in part on other grounds by Winter v. NRDC, Inc.*, 555 U.S. 7, 21-22 (2008).

Petitioners fail to show that EPA breached a duty to consult under the ESA on the Interim Decision. *See* Argument IV. The Interim Decision did not register glyphosate, is not the cause of the ongoing effects of glyphosate use, and Petitioners fail to show that the Interim Decision, itself, may affect ESA-listed species or designated critical habitats. Moreover, EPA has a longstanding plan in place to complete a comprehensive, nationwide ESA consultation of the effects of glyphosate use before it completes its final registration review of glyphosate. Petitioners' ESA "failure to consult" claim is prudentially moot. *See* Argument V.

Petitioners seek vacatur of the Interim Decision and incorrectly claim that this will effectively cancel more than 500 individual glyphosate product registrations, which are not subject to judicial review in this action. *See* Argument VI. This claim is contrary to the plain text of FIFRA, which provides that no registration shall be cancelled "as a result of the registration review process" unless EPA follows the requirements for cancellation set forth in FIFRA. 7 U.S.C. §

136a(g)(1)(A)(v). The actual consequence of vacatur of the aspects of the Interim Decision that remain following EPA's request for voluntary remand would be far more limited: further consideration by EPA. Moreover, even if Petitioners' argument were not foreclosed by the statutory text, the Court should refuse to take this drastic approach. Petitioners do not dispute the massive disruptive effect that this remedy would entail, and any purported errors in the Interim Decision are not serious and are likely to be readily correctable on remand.

STANDARD OF REVIEW

Under FIFRA, EPA's order on registration review "shall be sustained if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). This standard is "extremely deferential," *Singh-Kaur v. INS,* 183 F.3d 1147, 1149 (9th Cir. 1999) (citations omitted), more so than the "clearly erroneous" standard for appellate review of trial court findings. *Dickinson v. Zurko*, 527 U.S. 150, 162, 164 (1999).

Courts "must affirm the Administrator's finding where there is 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." *Nat. Res. Def. Council ("NRDC") v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (internal quotation marks and citations omitted); *see Nw. Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1080 (9th Cir. 1989). A reviewing court "should not supplant the agency's findings merely by identifying alternative findings that could be supported by substantial evidence." *Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992); *see Lands Council*, 537 F.3d at 988 (courts should not "act as a panel of scientists" that "instructs [a federal agency] how to validate its hypotheses," "chooses among scientific studies," or "orders the agency to explain every possible scientific uncertainty"). Agency decisions must be sustained so long as the agency's path "may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys, Inc.*, 419 U.S. 281, 286 (1974).

Courts—including the Ninth Circuit—have recognized that the distinction between the "substantial evidence" and "arbitrary and capricious" tests is largely semantic, particularly as applied to review of agency factual conclusions. *See Bonnichsen v. United States*, 357 F.3d 962, 980 n.19 (9th Cir. 2004); *Ass'n of Data Processing Serv. Orgs., Inc. v. Board of Governors of Federal Reserve Sys.*, 745 F.2d 677, 683-84

(D.C. Cir. 1984) (Scalia, J.) (noting that this appeared to be the consensus view). *But see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (N.R. Smith, J., concurring).

When, as here, "the agency is making predictions, within its area of special expertise, at the frontiers of science" a reviewing court must "generally be at its most deferential." *NRDC*, 735 F.3d at 877 (quotation marks omitted); *see also Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). An agency "is not required to support its finding with anything approaching scientific certainty." *ASARCO, Inc. v. Occupational Safety & Health Admin.*, 746 F.2d 483, 490 (9th Cir. 1984) (quotation marks omitted).

The Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, provides the standard of review for Petitioners' ESA claim. Under the APA, a reviewing court may only set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see, e.g.*, *Earth Island Inst. v. Carlton,* 626 F.3d 462, 468 (9th Cir. 2010). A decision is arbitrary and capricious only if the agency "relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the

problem, or offered an explanation that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (internal quotation marks and citation omitted).

ARGUMENT

I. The Court should not consider Petitioners' extra-record evidence.

Petitioners ask the Court to consider a variety of extra-record materials. *See, e.g.*, RC Br. at 11-15 nn.5-16, 44 & n.27, 52; NRDC Br. at x-xi, 11 nn.4-5, 13 n.6, 15-16, 19. These materials include testimony in separate judicial proceedings and declarations. *See* RC Br. at 44 & n.27, 52. None of these materials are properly before the Court.

First, the Court's review is confined to the administrative record EPA compiled. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985); *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.,* 450 F.3d 930, 943 (9th Cir. 2006); *Rybachek v. EPA*, 904 F.2d 1276, 1296 n.25 (9th Cir. 1990) (rejecting motion to take judicial notice). If Petitioners believed these materials had a bearing on EPA's decision, the proper course would

have been to bring them to EPA's attention during the public comment period. Petitioners have not moved to supplement the administrative record, and they do not even acknowledge the pertinent standard for seeking consideration of extra-record material. *See Ctr. for Biological Diversity,* 450 F.3d at 943; *Friends of the Earth v. Hintz*, 800 F.2d 822, 829 (9th Cir. 1986). They have thus waived any argument that they meet this standard. *See, e.g.*, *Padgett*, 587 F.3d at 985 n.2.

Second, even if judicial review were not confined to the administrative record, Petitioners' blanket request fails to support taking judicial notice of these materials. These materials do not pertain to matters of indisputable public record, but rather are cited to prove the truth of Petitioners' specific and detailed factual claims regarding glyphosate. *See* Fed. R. Evid. 201 (materials must be "not subject to reasonable dispute" and from a source whose accuracy cannot be reasonably questioned); *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001). It is particularly clear that the testimony Petitioners cite from other cases and the untested declarations they have proffered do not meet the standard for judicial notice.

II. EPA's conclusion that glyphosate does not pose human-health risks of concern is supported by substantial evidence.

EPA assessed both cancer and non-cancer effects of glyphosate and its metabolites. 1-RC_ER-11. EPA did not identify any risks of concern to human health from glyphosate. 1-RC_ER-11; 2-RC_ER-229; *cf.* 7-RC_ER-1494 (summarizing previous analyses).

After glyphosate was initially classified in 1985 as a "possible human carcinogen," a 1986 scientific advisory panel recommended it be reclassified as "not classifiable as to human carcinogenicity" and that EPA should obtain further data. 1-SER-43. EPA's assessment of glyphosate's cancer risk was revised in 1991 to "evidence of non-carcinogenicity for humans." 1-SER-44; *see also* 7-RC_ER-1494.

In 2015, EPA's Cancer Assessment Review Committee classified glyphosate as "not likely to be carcinogenic to humans." 1-SER-44. Considering this analysis, other scientific studies, and analyses by the World Health Organization's International Agency for Research on Cancer ("IARC") and other international agencies, EPA prepared an issue paper discussing cancer risk. 1-SER-44; *see also infra* at 32 (responding to Petitioner's reliance on IARC's conclusions). This paper

was supported by a "systematic review of the open literature and toxicological databases for glyphosate." 1-SER-44; 1-SER-51-52.

EPA convened a Scientific Advisory Panel ("SAP") to consider this issue paper and the "scientific issues associated with EPA's evaluation of the carcinogenic potential of glyphosate." 4-RC_ER-576; 4-RC_ER-578; 4-RC_ER-585-86; *see also* 4-RC_ER-588 (SAP considered public comments). The SAP's conclusions reflect the thoroughness of EPA's consideration of possible glyphosate-related cancer risk. *See, e.g.*, 4-RC_ER-589-90; 4-RC_ER-594-95 (concluding, for example, that EPA's literature review methods were transparent and appropriate and that EPA had evaluated the relevant epidemiological studies and used a "sound, appropriate, and acceptable approach").

There were certain differences of opinion among members of the SAP. Some panelists suggested EPA should revise its discussion of the epidemiological evidence to state that EPA "cannot exclude the possibility" that observed positive associations between glyphosate exposure and risk of non-Hodgkin lymphoma "suggest human carcinogenic potential." 4-RC_ER-591-92. Other panelists "strongly disagreed," concurring with EPA's analysis in the issue paper that the

epidemiological studies did not suggest carcinogenic potential generally or a link with non-Hodgkin lymphoma in particular. 4-RC_ER-592. The SAP was also divided on whether certain animal studies suggested any link to cancer in rodents. Some panelists agreed that these studies "do not indicate carcinogenicity of glyphosate"; others argued that the studies suggested glyphosate may be a "weak rodent carcinogen and/or tumor promoter." 4-RC_ER-592; *see also* 4-RC_ER-593-94. In the context of these animal studies, the SAP identified concerns that EPA's analysis may have departed from its 2005 Cancer Guidelines in some respects. 4-RC_ER-593.

In the main, while a number of panelists agreed with the EPA issue paper's conclusion that glyphosate is "not likely to be carcinogenic to humans," others "felt that the better descriptor for glyphosate is 'suggestive evidence of carcinogenic potential.'" 4-RC_ER-597. None of the panelists, however, believed that glyphosate should be classified as "likely to be carcinogenic to humans" or "carcinogenic to humans". *See* 4-RC_ER-597; 1-SER-30.

Taking into account the SAP's analysis, EPA prepared a 216-page revised issue paper summarizing EPA's "comprehensive analysis of

available data from submitted guideline studies and the open literature." 1-SER-174-75. EPA concluded that the strongest evidence supported a cancer classification of "not likely to be carcinogenic to humans." 1-SER-174-75; *see also* 1-SER-172-74. EPA's expert conclusion on the animal carcinogenicity and genotoxicity studies was that they "did not demonstrate a clear association between glyphosate exposure and outcomes of interest related to carcinogenic potential." 1-SER-175. Epidemiological studies provided "no evidence of an association between glyphosate exposure and numerous cancer outcomes." 1-SER-175; *see also* 1-SER-44.[3] After recognizing there were some "considerations [that] could be looked at in isolation" that might support concluding that there was "suggestive evidence of [glyphosate's] carcinogenic potential," EPA concluded that the "strongest support" was for classifying glyphosate as "not likely to be carcinogenic to humans." 1-SER-175.

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[3] EPA noted that "due to conflicting results and various limitations identified in studies investigating [non-Hodgkin lymphoma], a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." 1-SER-175; *cf. infra* at 37-39 (explaining, in further detail, EPA's consideration of non-Hodgkin lymphoma).

EPA specifically addressed the SAP's concerns, including as to EPA's 2005 Cancer Guidelines. 1-SER-21, 25-28. In light of the panel's division on the overall weight of the evidence of glyphosate's carcinogenic potential, EPA affirmed "that the strongest support is for 'not likely to be carcinogenic to humans'" and explained that alternative proposed classifications by some panelists were not consistent with its cancer guidelines. 1-SER-30. It further noted that "none of the panel members believed glyphosate should be classified as 'likely to be carcinogenic to humans' or 'carcinogenic to humans.'" 1-SER-30.

EPA summarized its analysis in its draft human-health risk assessment. *See* 3-RC_ER-516-17; 3-RC_ER-528.[4] It then took and responded to comments on this document. 3-RC_ER-498-500. It finalized the draft human-health risk assessment in the Interim Decision, 1-RC_ER-6; 1-RC_ER-11-12, but only after again taking comments. *See* 2-SER-403. EPA also considered evidence on carcinogenicity obtained after the SAP's review in response to comment

[4] The April 23, 2018, date in this document appears to be a typographical error, and should read "April 23, 2019." *See* Reaves Decl. ¶ 4; *cf.* RC Br. at 20 (arguing that this document issued prior to the close of the comment period).

and other documents. *See, e.g.*, 2-SER-387 (in study of over 54,000 pesticide applicators, "no evidence of a significant positive association was observed between glyphosate exposure and any type of cancer"); 2-SER-391-92.

EPA's analysis of the non-cancer risks of glyphosate was also detailed and thorough, and revealed no risks of concern. 1-RC_ER-11; 3-RC_ER-502 (discussing review of "entire toxicity database"); *see also* 3-RC_ER-514-18; 3-RC_ER-525-28. This analysis included considering glyphosate incident reports, which revealed that most incidents were minor in severity and resolved rapidly. 1-RC_ER-12; 2-RC_ER-233-34. EPA also reviewed the epidemiological literature, finding there was "insufficient evidence to conclude that glyphosate plays a role in any human diseases." 1-RC_ER-12; 3-RC_ER-507-08; 3-RC_ER-540.[5]

[5] Petitioners claim that EPA has found glyphosate is a "liver and kidney toxin." RC Br. at 11; *see also* NRDC Br. at 14. What EPA actually said was that there are "minor indicators of toxicity to the eyes, liver, and kidney" seen at doses at or above the limit dose in most studies. 3-RC_ER-525.

III. Petitioners' attempts to contradict EPA's expert human-health analysis misconstrue the record.

A. EPA thoroughly considered cancer risk and its decision is supported by substantial evidence.

EPA's evaluation of human-health risks was thorough, and it reasonably concluded that glyphosate was not likely to be carcinogenic to humans, including to occupational users. EPA found no risks of concern relating to occupational routes of exposure (dermal- and inhalation-based exposure) to glyphosate, and therefore properly concluded that a detailed quantitative study of occupational risks was not necessary. 2-RC_ER-229; 2-RC_ER-232-33; 3-RC_ER-517; 3-RC_ER-521; 3-RC_ER-525 (no dermal hazard identified); 3-RC_ER-527; 1-SER-46-47. EPA's review of epidemiological studies, animal studies, and genotoxicity studies supported the conclusion that occupational uses of glyphosate do not pose cancer risks. *See, e.g.*, 2-RC_ER-229; 2-SER-387-89; 1-SER-46, 1-SER-49, 1-SER-167, 1-SER-174 (discussing exposure; maximum potential exposure for occupational handlers is "well-below" the doses at which effects were observed in animal carcinogenicity and genotoxicity studies); *see also* 1-SER-54-99 (summarizing extensive evaluation of epidemiological data).

Petitioners barely engage with the record supporting EPA's determination. Indeed, Petitioners entirely omit EPA's revised issue paper, which is the most thorough discussion of the reams of evidence EPA assessed on human carcinogenicity, from their excerpts of record. Instead, Rural Coalition argues that certain agencies or individuals—the IARC, some members of the SAP, or members of EPA's Office of Research and Development ("ORD")—expressed different views from EPA on glyphosate's cancer risk.[6] *See* RC Br. at 37-39. But Rural Coalition cannot carry its burden merely by showing that "it is possible to draw two inconsistent conclusions from the evidence." *NRDC*, 735 F.3d at 877 (holding also that courts must be at their most deferential toward agency scientific conclusions). This alone disposes of much of Rural Coalition's argument, because it is not enough to simply point to contrary views rather than demonstrate that EPA's analysis *lacked* substantial evidence.

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[6] Rural Coalition also points to certain jury verdicts, *see* RC Br. at 11-12, which were decided on de novo records created before a lay jury, assessed on the preponderance-of-the-evidence standard. They are irrelevant to this Court's deferential review of EPA's expert analysis of glyphosate based on the record before EPA at the time it made its decision.

Regardless, Rural Coalition's suggestion of a scientific consensus that glyphosate is likely carcinogenic, *see* RC Br. at 22, 36, flies in the face of the evidence. Although IARC characterized glyphosate as "probably carcinogenic to humans" in a 2015 paper, *every single one* of the numerous other agencies and organizations that has recently conducted a scientific review of glyphosate has concluded that glyphosate does not pose a likely risk of cancer in humans. 2-SER-414-15; 1-SER-43-44; 3-RC_ER-499-500.[7] Moreover, EPA expressly addressed IARC's findings and explained why EPA's conclusion was both more robust and more transparent than IARC's analysis. *See* 2-RC_ER-217-18; 3-RC_ER-499-500; 4-RC_ER-585; 5-RC_ER-939 (IARC conclusion reflects "'limited evidence' of carcinogenicity," but "chance, bias, or confounding could not be ruled out with reasonable confidence").

[7] IARC is an "authoritative body" for purposes of California's listing of carcinogens; California automatically lists chemicals as "known to the state to cause cancer" based on the findings of such "authoritative bodies." *See* Cal. Code Reg. § 25306(a), (m); <https://oehha.ca.gov/proposition-65/how-chemicals-are-added-proposition-65-list>; *Nat'l Ass'n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1251-52 (E.D. Cal. 2020) (discussing this process as to glyphosate).

Rural Coalition also mischaracterizes the SAP's conclusions. *None* of the panelists concluded that glyphosate should be classified as carcinogenic to humans or likely to be carcinogenic to humans. Many agreed with EPA's classification of glyphosate as not likely to be carcinogenic to humans, while others merely thought there was "suggestive evidence of carcinogenic potential." *See supra* at 26. EPA considered the views of the SAP and, in its expert judgment, reasonably concluded that the strongest support was for classifying glyphosate as not likely to be carcinogenic to humans. *See id.*; *NRDC*, 735 F.3d at 877; *Cmtys. for a Better Env't v. EPA*, 748 F.3d 333, 337 (D.C. Cir. 2014) (EPA acted reasonably in reaching its conclusion notwithstanding that scientific advisory committee indicated that record evidence could support a different result; EPA is entitled to weigh evidence).

Nor is Rural Coalition's rhetoric that the SAP "found EPA flouted its Cancer Guidelines" accurate. RC Br. at 38. Rather, the SAP identified specific possible points of departure from those guidelines related to EPA's assessment of certain animal studies. The SAP's concerns included:

- whether EPA relied on the absence of a monotonic dose relationship, in which increased doses correlate to increased risks, in assessing certain animal studies;

- urging a better explanation of EPA's use of historical control data;

- EPA's statistical testing, including its use of pairwise testing versus trend testing in rodent tumor studies; [8] and

- how EPA treated results generated by doses exceeding the "limit dose" or 1000 mg/kg/day.

See 4-RC_ER-593-94; 4-RC_ER-596; 4-RC_ER-624-28; 4-RC_ER-651; 4-RC_ER-657.[9] Often, only some members of the panel held these concerns, with others disagreeing. *See* 4-RC_ER-593-94; 4-RC_ER-621; 4-RC_ER-624-27; 4-RC_ER-657; *see also* 1-SER-27.

EPA carefully addressed the SAP's concerns. *See, e.g.*, 1-SER-25-27 (EPA considered both trend and pairwise tests; providing context from EPA's guidance; discussing revisions to the issue paper in

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[8] A "trend test" compares data across all groups studied to determine whether an effect is seen, such as increased effects at increased doses. A "pairwise" test compares results from two particular groups to determine if any observed difference is statistically significant.

[9] At least one of the sound bites from Rural Coalition's string-citation, *see* RC Br. at 38, does not relate to the application of EPA's cancer guidelines. *See, e.g.*, 4-RC_ER-621 (discussion of EPA's non-Hodgkin lymphoma analysis).

response to the SAP analysis); 1-SER-27-28 (EPA updated discussion of historical control data where studies had such data); 1-SER-28 (EPA did not exclude high-dose data that exceeded 1000 mg/kg/day; EPA's approach was consistent with its guidelines); *id.* (lack of monotonic dose response was only one line of evidence EPA considered, in only certain studies); *cf.* 1-SER-22-24 (response to SAP relating to certain concerns about epidemiological studies, including as to non-Hodgkin lymphoma). This is exactly how the SAP process is supposed to work, with the panel identifying potential issues and EPA considering their views.

EPA ORD's comments, *see* 5-RC_ER-939-41, are hardly the definitive conclusions that Rural Coalition makes them out to be, *see* RC Br. at 37-38. This review reflected a preliminary discussion by a handful of scientists nine months before EPA finished its initial issue paper on glyphosate carcinogenicity, let alone the SAP review and subsequent revisions. 5-RC_ER-939 ("an in-depth review of the original literature was not undertaken" by many of the commenters); 5-RC_ER-941 ("ORD reviewers have not extensively discussed which descriptor might be most appropriate for glyphosate."). ORD recommended ways that EPA could strengthen its assessment, including by providing "a

detailed and thorough discussion of the rationale that caused [EPA's Office of Pesticide Programs] to come to a different conclusion than IARC" and that EPA develop charge questions for the SAP. 5-RC_ER-0941. EPA did just that. *See* 2-RC_ER-217-18; 3-RC_ER-499-500; 4-RC_ER-585; 5-RC_ER-939.[10] These preliminary comments cannot (and do not attempt to) negate the hundreds of pages of evidence and analysis supporting EPA's conclusions.

EPA considered—and rejected—Rural Coalition's recycled argument regarding N-nitrosoglyphosate (NNG) contamination first raised nearly 30 years ago, finding that NNG content was not toxicologically significant. *See* RC Br. at 40; 2-RC_ER-93*;* 3-RC_ER-505; 2-SER-421.[11] EPA reasonably relied on this conclusion given that "[n]o new data have been presented to warrant a reevaluation of the Agency's conclusion." 3-RC_ER-505; *see* 40 C.F.R. § 155.53(a) (registration review "assess[es] changes since a pesticide's last review" and looks at "new data or information"); *see also Alon Ref. Krotz*

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[10] EPA also addressed ORD's comments on assessment of rodent tumor studies. *See* RC Br. at 37; 5-RC_ER-940.

[11]https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf

Springs, Inc. v. EPA, 936 F.3d 628 (D.C. Cir. 2019) (per curiam) (once EPA resolves an issue, it may defend against related criticism by referring to the prior proceeding).

Regardless, this conclusion is also reasonable on its substance. The vast majority of the samples assessed (more than 92%) contained levels of NNG *below* the 1.0 part-per-million threshold. 3-RC_ER-505; 2-SER-421. Thus, for purposes of EPA's overarching consideration of glyphosate in registration review, the conclusion that NNG content generally "is not toxicologically significant" is supported by substantial evidence.[12] If individual products contain contaminants that exceed EPA's level of concern, these must be reported to EPA and are assessed on a case-by-case basis. *See* 3-RC_ER-505.

Rural Coalition cites epidemiological studies summarized in a draft report from the U.S. Agency for Toxic Substances and Disease Registry ("ATSDR") as evidence that EPA "failed to consider" risks of non-Hodgkin lymphoma. RC Br. at 39. Rural Coalition omits that this

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[12] Rural Coalition's argument is also contradicted by the epidemiological studies that do not establish a connection between actual glyphosate use (which would incorporate the effects of exposure to commonly occurring contaminants) and cancer risk. *See supra* at 27.

was a draft report which "does not represent and should not be construed to represent any agency determination or policy." 2-RC_ER-298. Rural Coalition's argument also has no basis in fact. EPA considered each of the epidemiological studies concerning non-Hodgkin lymphoma in reaching its conclusions, including its own assessment of their quality and weight. *See* 1-SER-61-74, 1-SER-89-90; 2-SER-391-92; 1-RC_ER-12.

Relatedly, Rural Coalition is wrong that EPA otherwise did not adequately consider non-Hodgkin lymphoma risk, including glyphosate's effects on bone-marrow. *See* RC Br. at 40-41; 1-SER-129, 145-47; 1-SER-148-52 (summary table); 1-SER-161. EPA considered at length whether glyphosate might be connected to non-Hodgkin lymphoma. 1-SER-60; 1-SER-62-63; 1-SER-87-99; 1-SER-22-24. As many members of the SAP agreed, the available studies did not demonstrate that glyphosate had *any* effect on non-Hodgkin lymphoma risk that could not be explained as the result of chance or bias. *See* 1-SER-98; 3-RC_ER-592; 2-SER-387 (in 54,000 applicator study "no evidence of a significant positive association was observed between glyphosate exposure and any type of cancer"); 2-SER-391-92 (when EPA

corrected for errors it identified in Zhang meta-analysis, risk of non-Hodgkin lymphoma was not statistically significant). Even to the extent that some panelists thought there might be some effect on non-Hodgkin lymphoma risk, they concluded that any effect would be "relatively small in magnitude." 1-SER-98.

The record thus confirms that EPA thoroughly examined cancer risk, and properly acknowledged residual uncertainty as to non-Hodgkin lymphoma. *See* 1-SER-175. Notwithstanding this limited area of uncertainty, substantial evidence supports EPA's expert judgment that the weight of the evidence most strongly supports the overall conclusion that glyphosate is not likely to be carcinogenic to humans. *See* 1-SER-174-75; *see also* 1-SER-172-74; *supra* Argument II; *see NRDC*, 735 F.3d at 877; *Nat'l Family Farm Coal. v. EPA*, 966 F.3d 893, 919 (9th Cir. 2020); *ASARCO, Inc.*, 746 F.2d at 490 (agencies need not achieve anything approaching scientific certainty).

In short, consistent with nearly every other agency that has considered glyphosate's carcinogenicity in recent years, EPA reasonably concluded that glyphosate is not likely to be carcinogenic to humans. This Court's role is not to re-weigh the evidence before EPA and reach

its own conclusion. *See Lands Council*, 537 F.3d at 988; *Cal., Dep't of Educ. v. Bennett*, 843 F.2d 333, 338 (9th Cir. 1988).

B. Substantial evidence supports EPA's analysis of workers' skin exposure to glyphosate.

Rural Coalition also claims that EPA failed to conduct a necessary analysis of risks associated with workers' skin exposure to glyphosate. *See* RC Br. at 31-35. Rural Coalition is wrong for several reasons.

EPA relied on the dermal toxicity study that Rural Coalition cites in assessing "short- and intermediate-term dermal" effects. 3-RC_ER-527. This study reflected that even at very high exposure levels (the "limit dose") there was "no dermal or systemic toxicity." 3-RC_ER-527. As a result, EPA reasonably determined that a precise quantification of dermal risk was not necessary. 3-RC_ER-527. Similarly, and consistent with EPA's guidelines, because glyphosate did not pose a dermal hazard even at high exposure levels, EPA reasonably determined that it did not need to conduct further in-depth studies of how much glyphosate may be absorbed through the skin. 3-RC_ER-525; 3-RC_ER-542 (table noting such a study was not required under EPA's 40 C.F.R. Part 158 data requirements); 9-RC_ER-2057 (EPA guidelines reflecting that absorption studies may be required on an

individual basis where compounds show serious toxic effect); *see also* 40 C.F.R. §§ 158.500(d), Table 1, and (e), test note 35 & 158.110(b) (dermal penetration study is only "conditionally required," if specified conditions are met and based on, among other things, results of previous testing).

Nor was this the only evidence before EPA that skin exposure does not pose a significant health risk. Incident reports reflect that the dermal hazards associated with glyphosate use are not significant. 1-RC_ER-12; 2-RC_ER-233-34. Likewise, epidemiological studies provided "insufficient evidence to conclude that glyphosate plays a role in any human diseases," including those that pose longer-latency risks, such as cancer. 1-RC_ER-12; *see also* 1-SER-94, 1-SER-175; 1-SER-54-99 (summarizing studies); 2-SER-281-82, 2-SER-287-92 (epidemiological studies reflect real-world exposure; epidemiological studies did not provide sufficient evidence to conclude glyphosate plays a role in any of the health outcomes studied, including cancer). Such studies included assessments of occupational exposure to glyphosate. *See, e.g.*, 2-SER-387 (no evidence of a significant positive association between glyphosate exposure and any type of cancer). The SAP also agreed that the epidemiological studies EPA identified provided no

reliable evidence of an association between glyphosate exposure and most types of cancer. *See* 4-RC_ER-589-90; 1-SER-94.

Rural Coalition declares the dermal toxicity study "outdated" and "stale" solely because it was conducted in 1982. RC Br. at 31-32. The cases Rural Coalition relies on do not support this fallacy. In *Sierra Club v. EPA*, not only was the data at issue (emissions) mutable over time, but the record also contained updated data generated from an improved methodology. 671 F.3d 955, 963-68 (9th Cir. 2012). Rural Coalition's other cases are similar. *See Lands Council v. Powell*, 379 F.3d 738, 748-49 (9th Cir. 2004) (reliance on thirteen-year old study was improper because such data could not address "current habitat conditions, and any degradation or improvement in the last thirteen years"); *N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1086 (9th Cir. 2011) (reliance on old aerial surveys did not account for the possible changes in landscape and habitat that may occur over time).

Rural Coalition focuses only on this study's age. It offers no reason as to why this sound study is no longer reliable or why the age of the study calls its conclusions into question. It has therefore not carried

its burden. *See, e.g.*, *League of Wilderness Def./Blue Mountains Biodiversity Project v. Connaughton*, 752 F.3d 755, 763 (9th Cir. 2014) (plaintiffs unlikely to prevail in arguing that data were stale when plaintiffs failed to provide reliable evidence that the results were incorrect); *Alaska Survival v. Surface Transp. Bd.*, 705 F.3d 1073, 1088 (9th Cir. 2013) (similar).[13]

Regardless, Rural Coalition's demand for a further dermal penetration study on the theory that this dermal toxicity study was the sole evidence before EPA on risks to workers due to skin exposure is also unavailing, for at least two reasons. First, Rural Coalition fails to establish that analysis of dermal penetration was required at all. *See* 3-RC_ER-542; 9-RC_ER-2057 (EPA guidelines did not call for such a study); *see supra* at 40-41. Even assuming that glyphosate may penetrate skin and be absorbed into the body, this does not show that

[13] Because Rural Coalition has failed to show that additional data is necessary, its citations to EPA's regulations authorizing EPA to obtain such additional data, RC Br. at 33-34, are irrelevant. Rural Coalition also baldly asserts that "there are many additional human health data needs." *Id.* at 34. This argument is waived because Rural Coalition fails to adequately develop it in its brief. *See, e.g.*, *United States v. Kimble*, 107 F.3d 712, 715 n.2 (9th Cir. 1997).

such absorption causes any harmful effect. *See* 9-RC_ER-2057 ("Dermal absorption studies are complex kinetic studies which, in and of themselves, provide no information on the biological activity (toxicity) of a compound").

Second, Rural Coalition is simply wrong that EPA did not consider dermal penetration of glyphosate. It found that dermal penetration of glyphosate is "relatively low for human skin (<1%) indicating dermal exposure will only contribute slightly to a systemic biological dose." *See* 1-SER-46; *cf. also* 2-SER-426-27 ("Small amounts of glyphosate can be absorbed after dermal exposures"; "no more than 2%" absorption of a particular formulation).

The record reflects EPA has reasonably considered dermal exposure to glyphosate. Rural Coalition fails to establish that EPA's conclusions are not supported by substantial evidence. *See NRDC*, 735 F.3d at 877; *ASARCO, Inc.*, 746 F.2d at 490.

C. EPA's consideration of glyphosate formulations was consistent with its regulations and supported by substantial evidence.

The record also does not support Rural Coalition's argument that EPA ignored the effects of glyphosate in "the real world" (i.e., as

formulated). RC Br. at 41; *see id.* at 30. Rural Coalition demands that EPA must conduct an individual and in-depth assessment of each and every glyphosate formulation. *See id.* at 42 ("*all* of the registered products containing glyphosate"); *id.* at 44-45 ("formulation-specific testing"; "much less all of them"). This request that the Court vastly multiply the extensive analysis that EPA performed over the last decade misunderstands the registration review process and ignores the record EPA compiled.

EPA's regulations governing registration review are found in 40 C.F.R. Part 155, Subpart C, § 155.40 *et seq*., and were first promulgated in 2006. *See* 71 Fed. Reg. 45720 (Aug. 9, 2006). Rural Coalition does not challenge these regulations and therefore has waived any argument attempting to do so. *See, e.g.*, *Padgett v. Wright*, 587 F.3d 983, 985 n.2 (9th Cir. 2009). Regardless, the statute of limitations for such a challenge has long passed. *See* 28 U.S.C. § 2401(a).

Under these regulations, EPA creates a "registration review case" composed of "one or more active ingredients" and all of the products containing such ingredients. 40 C.F.R. § 155.42(a); *see also* 7 U.S.C. § 136a(g)(1)(A)(iii); *cf.* 70 Fed. Reg. 40,251, 40,258-59 (July 13, 2005)

("Decisions made on the active ingredients would apply to products in the case."). As to the "pesticide," EPA will "assess changes since a pesticide's last review." 40 C.F.R. § 155.53(a) (EPA "will assess any changes that may have occurred since the Agency's last registration decision"). It will "consider" whether a new risk assessment for a pesticide is warranted based on "any new data or information on the pesticide," *id.*, and whether a "new assessment of the pesticide is needed." *Id.* at § 155.53(b).

EPA will also "consider" whether "new data or information regarding an individual pesticide product," including as to inert ingredients, warrant additional review of the pesticide product's registration. *Id.* at § 155.53(a); *id.* at 152.3 ("pesticide product" means the "particular form . . . in which the pesticide is, or is intended to be, distributed or sold"). If EPA finds that "additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate." *Id.* at 155.53(b)(2).

Thus, EPA's regulations do not require individualized review of every single pesticide product in a registration review case, but are rather directed toward considering specific concerns raised by changes since a pesticide's last review and newly available data or information. EPA made this explicit when it proposed these regulations, explaining that it was proposing a "tailored approach" under which the "scope and depth of the review would be commensurate with the complexity of the issues presented by the pesticide." 70 Fed. Reg. at 40,261 (citing 40 C.F.R. § 155.53 as reflecting this tailored approach); 65 Fed. Reg. 24,586, 24,589 (Apr. 26, 2000). For instance, EPA considered what the "unit of review" should be in assessing pesticide registrations. 70 Fed. Reg. at 40,258-59, 40,261. Rather than separately review each individual pesticide product (or each different formulation), EPA proposed that its unit of review should be on the level of the pesticide's active ingredient. 70 Fed. Reg. 40,251; *see also id.* at 40,258-59 (because advances in science are developed generically, product-specific unit of review might not be "scientifically sound").

EPA further explained that it would assess inert ingredients "in a process that is separate from registration review," without separately

"[e]stablish[ing] registration review cases for inert ingredients." *See* 70 Fed. Reg. 40,251, 40,258-59. EPA stated that it would "check to see whether there are any issues concerning the inert ingredients in a product that is undergoing registration review." *Id.*; *see also id.* at 40,267-68 (EPA will consider whether "new data or information . . . warrant additional review of the pesticide product's registration," such as where the evidence before EPA gives it "concerns about an inert ingredient"). And it explained that given that there were 15,000 registered pesticide products, it was not "practical to conduct a comprehensive review of the composition, labeling, and product-specific data for each product." *Id.* at 40,261-62; *see also* 3-RC_ER-505.

EPA reiterated that it was adopting this tailored approach in the final rule promulgating these regulations. It rejected proposals that it conduct a comprehensive, product-specific review of every individual product registration, explaining that the need for a review of particular individual product registrations could be addressed through the comment process. *See* 71 Fed. Reg. at 45,724, 45,726; *see also id.* at 45,729 (product-specific data requirements are generally met through

registration and reregistration process; such data would generally not be needed to support registration review).

Thus, while EPA agrees that its registration review takes into account glyphosate formulations, Rural Coalition is wrong to argue that EPA must conduct a product-by-product review of every single glyphosate formulation. EPA assesses specific formulations or inert ingredients where EPA determines that newly available data or information demonstrates a need to do so. Here, EPA's consideration of the overarching evidence did not reflect the need for a more granular review of a particular formulation.

First, because "there are over 500 glyphosate products registered at different times in the US, the agency has assessed new inert ingredients at multiple points over the years for different formulations of glyphosate." 2-RC_ER-220 (EPA considers hazard potential using a "battery of toxicity data"); *see also* 3-RC_ER-441 (inert ingredients are assessed when proposed for use as part of a pesticide product); 3-RC_ER-504-05. Furthermore, EPA assesses inert ingredients when establishing tolerances or tolerance exemptions for residues of inert ingredients in pesticide formulations that may be present in or on food.

See 21 U.S.C. § 346a; 40 C.F.R. Part 180. Any further agency consideration of inert ingredients in glyphosate formulations occurs against the backdrop of this already extensive testing.

Second, EPA considered incident reports and epidemiological studies, which reflect the real-world effects of glyphosate use, as formulated. *See* 7-RC_ER-1504-06; 7-RC_ER-1527-73. The incident reports reflected that health effects, including dermal effects, "were generally mild and resolved rapidly." 1-RC_ER-12; 2-RC_ER-233-34; 3-RC_ER-540; 6-RC_ER-1264; *cf.* 2-SER-257-59, 2-SER-292 (noting four cases that presented more significant dermal effects, most of which resolved over time; incidents are "generally mild/minor to moderate and resolve rapidly"). As just discussed, epidemiological studies also did not demonstrate that there was a connection between glyphosate use in the real world and cancer or any other diseases. *See supra* at 27, 29-30, 41. Such studies "better reflect toxicity *of the end-use product*, as opposed to the active ingredient as well as *exposure to a mixture of compounds*" than animal studies. *See* 2-SER-281-82 (emphasis added).

Third, EPA considered "[a]ll studies [addressing glyphosate formulations] of adequate scientific caliber" in considering the toxicity

of glyphosate formulations. 2-RC_ER-220-21 (explaining that while *in vivo* studies are more probative than *in vitro* studies, the *in vivo* studies were not of adequate scientific caliber); 3-RC_ER-504-05 (similar); 2-SER-379-86 (similar, including summary table). In the revised issue paper, EPA also identified and summarized the available studies on genotoxic potential of glyphosate formulations. *See* 1-SER-234-46.

Pursuant to EPA's regulations, the record before EPA was, therefore, sufficient to sustain its conclusions on the absence of human-health risks of concern. Rural Coalition fails to meaningfully engage with this record and attempts to sidestep the limited nature of this Court's review.

This Court's task is only to ensure that EPA's decision was supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *NRDC*, 735 F.3d at 877 ("more than a mere scintilla, but less than a preponderance"); *see also Bowman Transp.*, 419 U.S. at 284 (agency decisions must be sustained so long as the agency's path "may reasonably be discerned"). EPA's inquiry is shaped by the nature of the problem in front of it, and EPA need not resolve every scientific uncertainty in order to make a decision.

See, e.g., *Lands Council*, 537 F.3d at 988; *Chamber of Commerce of the United States v. SEC*, 412 F.3d 133, 142 (D.C. Cir. 2005); *Nat'l Family Farm Coal.*, 966 F.3d at 919 (EPA may rely on limited evidence; citing supporting cases); *cf. FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1160 (2021) ("The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies."). EPA's assessment of glyphosate, including its formulations, easily exceeds this standard.

In fact, the record speaks directly to the concerns Rural Coalition now raises. EPA considered exactly the dermal effects from glyphosate formulations described in incident reports that Rural Coalition cites. *See* RC Br. at 43-44. Rural Coalition simply omits that such dermal effects typically are mild and resolve rapidly.[14] Similarly, EPA's consideration of epidemiological studies speak to whether glyphosate formulations pose risks of systemic toxicity or longer-term risks, such as

[14] Rural Coalition also attacks EPA's analysis with an extra-record declaration, RC Br. at 44, which is not properly before the Court. Regardless, this declaration is simply the anecdotal assertions of a single individual who perfunctorily attributes certain harms to glyphosate.

cancer. *See id.* at 44-46. Again, EPA found no links between glyphosate as-used and any human diseases. *See supra* at 41.

As discussed, EPA considers inert ingredients in registration review where specific new information is brought to its attention about particular ingredients. Rural Coalition's brief addresses only one specific type of surfactant: POEA. RC Br. at 45-46. But the evidence Rural Coalition is relying on reflects that EPA has examined the health risks of the class of surfactants to which POEA belongs (alkyl amine polyalkoxylates or "AAPs"). EPA found that AAPs were sufficiently safe that it could exempt them from the requirement that a food-residue tolerance be established. *See* 74 Fed. Reg. 28,616, 28,618 (June 17, 2009); 7-RC_ER-1578-80 (AAPs are "not acutely toxic," "[t]here is no evidence that the AAPs are neurotoxic, mutagenic, or clastogenic," and there is "no clear target organ" affected by AAPs); 7-RC_ER-1589 ("There is no evidence that the AAPs are carcinogenic."); 7-RC_ER-1579-80; 7-RC_ER-1607-08 (no occupational handler risks of concern except for workers applying AAPs to ornamental plants in greenhouses using specific equipment, at the maximum allowed percentages of

AAPs).[15] Tellingly, even Petitioner Center for Food Safety acknowledged in its comments to EPA that "[t]here is insufficient evidence to conclude that glyphosate preparations containing POEA are more toxic than those containing alternative surfactants." 2-RC_ER-87 (quotation marks and citation omitted).

Rural Coalition further rehashes its argument that EPA should have conducted dermal absorption studies, now demanding such studies for every single glyphosate formulation. *See* RC Br. at 44-47. This argument fails for similar reasons as discussed above. *See supra* Argument III.B. Rural Coalition also reiterates its discredited claims that glyphosate itself is genotoxic, a carcinogen, or poses other health hazards. RC Br. at 45-46. Again, EPA reasonably concluded to the contrary. *See supra* Argument III.A. Finally, the views of certain Monsanto scientists which pre-date the extensive array of more recent

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[15] The barely seven-page European Food Safety Authority ("EFSA") report that Rural Coalition also cites reflects that, while summary data suggested that POEA was more toxic than glyphosate alone, EFSA lacked adequate information to perform the relevant health risk assessments. *See* 6-RC_ER-1224; 6-RC_ER-1229. But even if it had reached a conclusion that POEA posed human-health risks, *see* RC Br. at 46, this is insufficient as a matter of law to show that EPA's analysis lacks substantial evidence. *See supra* at 19-20.

evidence on which the Interim Decision relies also do not undermine EPA's decision. *See* RC Br. at 44, 46; 1-SER-178-220 (listing references); 1-RC_ER-12; 3-RC_ER-540; 2-SER-387-89. Nor do these materials attempt to speak to the validity of the evidence before EPA in the form of, for example, incident reports.

EPA recognized that further study of glyphosate formulations could be beneficial, and described a four-objective research plan. *See* 1-SER-176-77; 2-RC_ER-220-21. Moreover, as EPA has acknowledged, it has a continuing obligation to respond to emerging risk concerns, and not to defer action until its next registration review. *See Nat'l Family Farm Coal*, 966 F.3d at 922-23. Thus, should particular information be developed that one or more of the over 500 glyphosate formulations may pose a health risk, these concerns can—and will—be proactively considered on an ongoing basis. *Cf.* 40 C.F.R Part 158 (data requirements for registration of pesticides, including Subpart F requirements for certain product-specific toxicology data). EPA did not, however, need to wait for additional studies of every single glyphosate formulation before reaching a conclusion on health risks.

D. EPA thoroughly assessed human-health risks raised in comments.

EPA considered and addressed comments on the draft human-health risk assessment and exhaustively assessed the potential risks to human-health related to glyphosate, including the laundry list of risks NRDC perfunctorily alleges. *See* NRDC Br. at 58; 2-SER-390 (comments were duplicative of issues EPA had already considered and did not result in changes to the risk assessment); 1-RC_ER-8-9; 2-RC_ER-231-33; 3-RC_ER-498-508; 3-RC_ER-514-18; 3-RC_ER-524-25; 3-RC_ER-527-28; 3-RC_ER-530-34; 3-RC_ER-538; 7-RC_ER-1503-05; *cf.* 1-RC_ER-22 (EPA has not finalized its analysis of potential endocrine risks). The analysis EPA prepared on human-health risks constitutes well more than substantial evidence for its decision. It is not this Court's role to act as a superintending scientist. *See Lands Council*, 537 F.3d at 988; *cf.* NRDC Br. at 59 (conceding that EPA may determine which studies are "integral" to assessing health risks of

glyphosate). NRDC also claims that EPA did not include the ATSDR draft report in the record. NRDC Br. at 59. This claim is not true.[16]

IV. Petitioners fail to show that EPA is violating the ESA.

Petitioners contend that EPA is violating the ESA because it has not completed a consultation "prior to registering glyphosate." RC Br. at 68; *accord id*. at 6, 8, 62, 79. The plain, and fatal, defect with this claim is that the Interim Decision did not "register glyphosate." By law, a registration review decision neither registers a pesticide nor cancels an existing registration. 7 U.S.C. §§ 136a(g)(1)(A)(v), 136d(b). Petitioners' erroneous premise that the Interim Decision "registered glyphosate" is puzzling given their acknowledgement that the first of the hundreds of glyphosate product registrations dates to 1974, and that EPA reregistered glyphosate in 1993. RC Br. at 8, 72.

It is evident that Petitioners are attempting to use the Interim Decision as a surrogate to challenge EPA's prior registration orders. This, they may not do. Any challenge to these earlier separate and distinct actions is time-barred. The only agency "action" before the

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[16] *See* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-14431 (attachment six); Certified Index, *NRDC v. EPA*, No. 20-70787, Doc. 11737189 at 59; Index-RC_ER-ii; 2-RC_ER-297.

Court here is the Interim Decision, and the only question is whether Petitioners have shown that *that* action "may affect" listed species or designated critical habitat that Petitioners assert an interest in. 50 C.F.R. § 402.14(a). That showing is absent. Petitioners' entire effort is to mischaracterize the Interim Decision as a "registration decision" and misattribute alleged effects of EPA's prior registration decisions to it. There is no showing that the Interim Decision itself causes effects.

The ESA defines "effects of the action" as "all consequences to listed species or critical habitat *that are caused by the proposed action*, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur." 50 C.F.R. § 402.02 (emphasis added). The Interim Decision is plainly not the cause of registration decisions that preceded it or their effects. The Interim Decision did two things. First, it finalized two assessments: (1) Glyphosate Draft Human Health Risk Assessment for Registration Review; and (2) Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts. 1-RC_ER-6. Second, it determined that certain interim risk mitigation measures

were necessary, including labeling changes to add a "non-target organism advisory" to "alert users" that glyphosate is toxic to plants and steps to "manage off-target spray drift," including maximum wind speeds for spraying and minimum droplet sizes. 1-RC_ER-17-22. Petitioners do not identify evidence showing that the act of finalizing the assessments or issuing the non-target organism advisory, and/or measures to manage off-target spray drift "may affect" ESA-listed species or critical habitats.[17]

Rather, Petitioners assert that the "advisory changes nothing about how glyphosate will continue to be used" and that EPA "offers no information as to how any of the[] three 'mitigation' measures will reduce the known risks to plants, birds, fish, amphibians, or aquatic invertebrates." RC Br. at 77; *id*. at 24; *accord id*. at 57 (asserting that "EPA's label mitigation measures in its decision—which address pesticide resistance, non-target organisms, and spray drift—differ little from those on current glyphosate product labels"). Petitioners refute

[17] Petitioners assert that EPA included the non-target organism advisory "instead of consulting." RC Br. at 77. EPA has not stated, however, that the advisory was intended as a substitute for consultation.

their own "failure to consult" claim by claiming that the Interim Decision does not alter the status quo. To "affect" under ESA Section 7 "is to bring about a change." Endangered Species Consultation Handbook (March 1998) at x, available at www.fws.gov/endangered/esa-library/pdf/esa_Section7_handbook.pdf. An action that does not alter the status quo does not "affect" and, hence, does not trigger a duty to consult.

While arguing on the one hand that the Interim Decision changes nothing, Petitioners argue inconsistently on the other hand that the Interim Decision causes any and all effects of glyphosate. For the latter assertion, Petitioners recite EPA's findings of effects from its draft Biological Evaluation ("BE"). The problem with Petitioners' reliance on the BE is that EPA prepared the BE to assess the duty to consult on the effects of glyphosate, which is not in dispute. As explained below, EPA has committed to consult on glyphosate. And as explained above, glyphosate was authorized for sale and use pursuant to EPA actions long before the Interim Decision. The Interim Decision does not cause listed species or critical habitats to be "exposed to glyphosate" as Petitioners contend. RC Br. at 71. Thus, Petitioners do not show that

the Interim Decision itself triggered ESA consultation by pointing to the draft BE's analysis of EPA's prior registration orders.

Petitioners' true complaint here is not that the Interim Decision will cause new effects, but rather that it does not eliminate pre-existing effects. Petitioners relatedly contend that ESA consultation could lead to additional mitigation. RC Br. at 76. But the consultation duty is triggered by what an agency action *does*, not what it *does not do*. "Ninth Circuit cases have emphasized that section 7(a)(2) consultation stems only from 'affirmative actions'" and that "'inaction' is not 'action' for section 7(a)(2) purposes." *Western Watersheds Project v. Matejko*, 468 F.3d 1099, 1108 (9th Cir. 2006); *see also Cal. Sportfishing Prot. All. v. FERC*, 472 F.3d 593 (9th Cir. 2006). Thus, any claim that EPA failed to mitigate alleged effects of previous product registrations through the Interim Decision is alleged inaction, which does not trigger a consultation duty. Petitioners' disapproval of the Interim Decision's labeling changes is a substantive disagreement with the merits of the Interim Decision, not a basis to claim that ESA consultation was triggered.

The fallacy of Petitioners' "failure to consult" claim is further illustrated by the fundamental disconnect between the legal violation they allege and the relief they request. Petitioners do not request that EPA be ordered to reconsider whether the Interim Decision requires consultation by making an effects determination. Instead, Petitioners ask this Court to reach beyond the Interim Decision and cancel all existing registrations for products containing glyphosate. RC Br. at 79. This request underscores that Petitioners' true quarrel is not with effects allegedly caused by the Interim Decision itself, but rather with those resulting from EPA's prior product registrations, and with the length of time required to complete a final registration review decision accompanied by ESA consultation. Vacating the Interim Decision would not produce the result that Petitioners seek of canceling glyphosate registrations or hastening completion of the final registration decision and consultation on that action. Rather, vacating the Interim Decision would likely delay adoption of the measures that EPA determined would reduce risk to listed species whose range and/or critical habitat co-occur with glyphosate use.

Practically speaking, EPA has not produced ESA effects determinations or completed consultation on interim registration review decisions, as those decisions are used to implement mitigation measures more quickly than waiting for a final registration review decision. 40 C.F.R. § 155.53(a). The practical effect of requiring ESA analysis at the interim review stage would be to further complicate and delay, and thereby discourage the issuance of such discretionary actions.

Petitioners' reliance on cases in which this Court took issue with the scope of ESA consultation is misplaced. *See* RC Br. at 66, 78 (citing *Conner v. Burford*, 848 F.2d 1441 (9th Cir. 1988) and *Lane County Audubon Soc'y v. Jamison*, 958 F.2d 290 (9th Cir. 1992)). In each of those cases, the Court held that consultation could not be deferred until later stages of agency decision making if doing so could lead to a narrower scope of analysis and consideration of effects than an earlier, more comprehensive consultation. *See Conner*, 848 F.2d at 1453-55; *Lane County*, 958 F.2d at 294. That concern over the scope of consultation is not present here. As is apparent from the draft BE, EPA is proceeding with a comprehensive nationwide consultation on the

effects of glyphosate. The dispute here is not over the scope of consultation, but rather its timing. Petitioners complain that consultation has not been completed on glyphosate sooner than EPA has committed to do. But Petitioners have not shown that the Interim Decision triggered this consultation or that consultation on the Interim Decision would be superior to, or could be completed any sooner than, the consultation EPA already plans to complete on the final registration review decision. Petitioners' claim that EPA "failed to consult" on the Interim Decision will not hasten completion of the final registration review decision or consultation on that decision.

In sum, Petitioners do not show that EPA failed to consult on the Interim Decision itself. It is not the action that Petitioners claim it is, and it does not cause the effects that Petitioners claim it does. Vacating the Interim Decision would not produce the relief that Petitioners seek. In fact, ordering EPA to complete an effects determination on the Interim Decision would be redundant to, and likely delay, the comprehensive consultation EPA has already committed to complete before it issues its final registration review decision.

V. Petitioners' ESA claim is prudentially moot.

Not only have Petitioners failed to show that EPA breached a duty to consult on the Interim Decision, their "failure to consult" claim is prudentially moot because EPA has already committed to "complete nationwide ESA section 7(a)(2) effects determination for glyphosate and, as appropriate, request initiation of any ESA section 7(a)(2) consultations with the Services that EPA may determine to be necessary as a result of those effects determinations."[18] 1-RC_ER-36. EPA reached a significant milestone towards this commitment on November 27, 2020 when it issued a draft BE. The draft 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.

Preparation of the draft BE was a significant undertaking given the hundreds of different pesticide products containing glyphosate that have been registered for wide-ranging uses across wide-ranging

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[18] EPA announced its intention to prepare the effects determination in July 2015 as part a settlement reached in prior litigation. *Ctr. for Biol. Diversity, et al. v. EPA, et al.*, No. 3:07-cv-02794-JCS (N.D. Cal.), Stip. Amending Original Stip. Settlement (ECF 154 at 4, ¶¶ 1, 3).

environments, requiring EPA to assess potential effects to all 1,795 ESA-listed species and 792 designated critical habitats. Though ESA consultation is not a public process, EPA took public comment on the draft BE for 60 days, which it extended by 45 days. EPA concluded in the draft BE that formal consultation is required for 1,676 listed species and 759 designated critical habitats. EPA will issue its final BE and begin consultation with the Services by November 12, 2021.[19]

The doctrine of prudential mootness allows a court to "stay its hand" and "withhold relief it has the power to grant." *Chamber of Commerce v. U.S. Dep't of Energy*, 627 F.2d 289, 291 (D.C. Cir. 1980) (citation omitted). Prudential mootness is particularly apt where, as here, "it appears that a challenged 'continuing practice' is, at the moment adjudication is sought, undergoing significant modification so that its ultimate form cannot be confidently predicted." *A.L. Mechling Barge Lines v. United States*, 368 U.S. 324, 331 (1961); *see also Deutsche Bank Nat'l Tr. Co. v. FDIC*, 744 F.3d 1124, 1135-38 (9th Cir. 2014)

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[19] *See Ctr. for Biol. Diversity, et al. v. EPA*, No. 3:11-cv-00293-JCS (N.D. Cal.), Stip. Partial Settlement Agreement (ECF 364 at 3, 6 ¶ 2); *see also id.* at ECF 383 at 2, ¶ 1.

(applying the doctrine of prudential mootness); *Hunt v. Imperial Merch. Servs.*, 560 F.3d 1137, 1142 (9th Cir. 2009) (Court "assum[ing] that we have discretion to dismiss this case as 'anticipatorily moot'") (citing *Chamber of Commerce*, 627 F.2d at 291); *Reeve Aleutian Airways v. United States*, 889 F.2d 1139, 1144 (D.C. Cir. 1989).

As noted above, Petitioners do not appear to actually seek consultation on the Interim Decision, only vacatur of product registrations, which not result from vacating the Interim Decision. But even if Petitioners pivot on reply to request that EPA be ordered to make an effects determination for the Interim Decision, it would be appropriate for this Court to stay its hand and withhold such relief given that EPA has a longstanding schedule in place to complete a comprehensive consultation on the final registration decision for glyphosate, and is taking a voluntary remand of the Interim Decision's ecological risk assessment to determine how that assessment may be impacted by the findings of the draft BE. While EPA cannot prejudge the outcome of its analysis on remand, it may be that the results of the BE lead EPA to adopt additional or different mitigation measures than those currently specified in the Interim Decision. Thus, it is uncertain

at this stage what mitigation measures, in the form of labeling amendments, EPA ultimately may determine are necessary. Moreover, vacating the Interim Decision would likely be counterproductive by delaying EPA's currently-planned mitigation measures and consultation on the final registration decision.

Petitioners make little attempt to show that their "failure to consult" claim on the Interim Decision is not moot in light of EPA's existing consultation plan, despite basing their claim almost entirely on the very draft BE that EPA prepared to guide its planned consultation. RC Br. at 70-72. Petitioners make no showing that EPA could complete such a consultation any sooner than the one it already plans to complete, or that a consultation on the Interim Decision would be superior to one performed on the final registration review decision. Rather, Petitioners request vacatur of product registrations, which is not an available remedy on the claim they allege.

VI. Remedy.

A. Petitioners' are wrong in claiming that vacatur of the Interim Decision means vacating hundreds of glyphosate registrations.

Petitioners, citing the standard for registration under FIFRA, claim that vacating the Interim Decision would mean that every glyphosate registration immediately becomes unlawful. *See* NRDC Br at 69, 72-73; RC Br. at 80. This argument assumes that the status of each FIFRA product registration is automatically contingent on the outcome of registration review. *Cf.* NRDC Br at 72-73 (citing 7 U.S.C. § 136a(a)). Their argument is expressly foreclosed by FIFRA.

Nothing in FIFRA makes the status of individual registrations contingent on the outcome of registration review. In substance, the registration review provision requires only that "[t]he registrations of pesticides are to be periodically reviewed." 7 U.S.C. § 136a(g)(1)(A)(i). It does not provide that EPA's past registration decisions are overturned even if EPA affirmatively finds during this review that the pesticide does not meet the FIFRA standard—let alone if EPA makes an *interim* registration review decision assessing *some* risks, but a court then requires EPA to reassess aspects of its analysis.

In fact, FIFRA says the opposite: "[n]o registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title," which govern cancellation of registrations. 7 U.S.C. § 136a(g)(1)(A)(v). Congressional intent is plain. The registration review process is not a basis to automatically overturn any individual product registration, and certainly does not allow immediate cancellation en masse. This provision is written broadly and in the passive voice, forbidding *any* cancellation of any FIFRA registration "as a result of the registration review process," absent further agency action according to the parameters specified by Congress. *Id.*

The only action currently subject to judicial review by this Court is the Interim Decision—not the review of any (let alone all) individual glyphosate product registrations. And a "pesticide product remains registered until EPA or the registrant cancels it." *Reckitt Benckiser*, 613 F.3d at 1134. Even if EPA determines that a pesticide product does not meet the FIFRA standard, cancelling a FIFRA registration requires separate agency action, following a specific, congressionally mandated procedure. *See supra* at 7-9; 7 U.S.C. § 136d(b); 40 C.F.R. §

155.40(a)(2); *see also Reckitt Benckiser*, 613 F.3d at 1134 (cancellation decisions are subject to judicial review). Initiating cancellation proceedings is discretionary with EPA, and occurs on no particular timetable. *See* 7 U.S.C. § 136d(b) (EPA "may" initiate cancellation proceedings). For example, rather than immediately instituting cancellation proceedings EPA might negotiate with the registrant to remove uses that EPA has found pose unreasonable risks, otherwise bring its product into compliance with FIFRA, or voluntarily cancel its registration.

Registration review is just that: an initial review that may lead to cancellation in subsequent administrative proceedings. Adopting Petitioners' requested remedy and vacating each of the more than 500 product-specific glyphosate registrations, *see* 2-RC_ER-221, would leapfrog the agency process, substitute the Court's judgment for EPA's, and vitiate required statutory safeguards.

Petitioners attempt to bypass EPA's determination on whether glyphosate does or does not meet the FIFRA standard. *See* 7 U.S.C. § 136d(b). Even at the time it was issued, the Interim Decision found, based on EPA's analysis so far, that glyphosate *does not* pose human

health risks of concern and, when used according to its label, *does not* pose potential ecological risks outweighing its benefits. Assuming the Court grants EPA's request for voluntary remand, the remaining aspect of the Interim Decision subject to this Court's review will be EPA's conclusion that glyphosate *does not* pose human health risks of concern. Petitioners are asking that the Court treat vacatur of this decision for further consideration by EPA as equivalent to a final decision concluding glyphosate *does* have such unreasonable adverse effects. EPA has never made any finding that glyphosate poses unreasonable adverse effects, and the Court should reject Petitioners' request that it barge ahead of EPA. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 65 (2004) (where the content of agency action is left to the agency's discretion, a court "has no power to specify what the action must be"); *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513 (2009) (courts may not substitute their judgment for that of the agency).

In addition, Petitioners would supplant EPA's discretion over when to initiate cancellation proceedings. Section 136d(b) provides only that EPA "may" initiate cancellation proceedings in certain circumstances, and provides no particular timetable. 7 U.S.C. §

136d(b); *see also* 40 C.F.R. § 155.58(d). Petitioners treat the text as if it used the mandatory "shall" and required cancellation immediately, which would rob EPA of its ability to attempt to resolve issues through negotiation with product registrants. And, in bypassing the required administrative cancellation proceedings, Petitioners would also effectively write out of the statute all of the numerous safeguards Congress required before even one registration can be cancelled, much less all of them. *See supra* at 7-8.

On Petitioners' view EPA gets only one shot at registration review before the Court may abruptly declare hundreds of registrations for the most common herbicide in the United States unlawful. Under this perverse approach, the Court would declare glyphosate unlawful based on an *inchoate* registration review even though Congress forbade the automatic cancellation of registrations where EPA has made a *complete* (and even judicially upheld) registration review decision. 7 U.S.C. § 136a(g)(1)(A)(v).[20]

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[20] Moreover, EPA's registration review here is an interim decision, and the deadline to conduct registration review has not yet elapsed. *See* 7 U.S.C. § 136a(g)(1)(A)(iii). It would be strange to declare glyphosate

If the Court finds fault with the remaining aspects of the Interim Decision, the consequence of vacatur is—by law—far less draconian than Petitioners maintain. Vacatur would have no effect on individual glyphosate registrations, but rather simply vacate the Interim Decision itself.

B. Vacatur of over five hundred glyphosate registrations is not an appropriate remedy.

Vacating the Interim Decision does not mean immediately cancelling every single glyphosate registration. But if it did, the Court should refuse to vacate that decision on equitable grounds. Whether agency action should be vacated depends on the seriousness of any errors and the disruptive consequences of an interim change that may itself be changed. *Nat'l Family Farm Coal.*, 966 F.3d at 929-30. The Court also looks to whether the agency would likely be able to offer better reasoning or adopt the same rule on remand. *See id.*

NRDC entirely fails to address the disruptive consequences of its request, despite recognizing that this factor must be weighed. NRDC Br. at 70. While Rural Coalition gestures at addressing this factor, in

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registrations invalid when EPA has not yet finalized, and has further time to complete, its registration review.

doing so it gives a masterclass on understatement, acknowledging only that "there may be disruptive economic consequences alleged." RC Br. at 80.[21]

There is extensive and undisputed record evidence—not mere allegations—reflecting the disruption Petitioners' remedy would cause. In the short term, the entire array of benefits attendant to glyphosate would rapidly diminish as vacation of the product registrations would render sale or distribution unlawful. And, at the same time, the usage limitations provided on the labels would no longer be enforceable for existing stocks of the products already distributed to end users. *See* 7 U.S.C. §§ 136a, 136j(a)(2)(G), 136l (FIFRA regulates sale and distribution of pesticides; use of unregistered pesticides does not violate FIFRA). After existing stocks were depleted, glyphosate would be unavailable, rendering investments in glyphosate resistant crops moot,

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[21] Rural Coalition also suggests that the only cognizable disruptive consequence the Court can consider is environmental harm. *See* RC Br. at 79-80. There is no such rule. *See, e.g.*, *Nat'l Family Farm Coal.*, 966 F.3d at 929-30; *Cal. Cmtys. Against Toxics*, 688 F.3d at 994 ("If saving a snail warrants judicial restraint, so does saving the power supply" (citation omitted)).

harming manufacturers and sellers of glyphosate, and requiring users to adopt an alternative approach to weed control. *See supra* at 10-13.[22] Vast sectors of the agricultural economy, including the most commonly grown crops in America, would be affected. *See id.* So would the control of invasive species and the other circumstances in which glyphosate is used. *See id.* There would likely be negative environmental consequences, including as users switched to other pesticides that pose greater risk to the environment, and increased costs of labor. *See id.*

For the reasons explained above, should this Court find some error in the Interim Decision, that error is unlikely to be serious. *See, e.g.*, *Nat'l Family Farm Coal.*, 966 F.3d at 929-30; *Cal. Cmtys. Against Toxics*, 688 F.3d at 993. Petitioners' claims that glyphosate poses a human-health risk are contradicted by extensive record evidence. Even if credited, Petitioners' flawed assertions of residual uncertainty do little to show that EPA could not adopt the same decision on remand.

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[22] Under certain circumstances, EPA has authority to permit continued sale and use of existing stocks where a registration has been cancelled. *See* 7 U.S.C. § 136d(a)(1).

The Court should reject Petitioners havoc-causing request to overturn every single individual glyphosate product registration.

CONCLUSION

For the foregoing reasons the petitions for review should be denied.

Respectfully submitted,

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DATED: May 18, 2021

STATEMENT OF RELATED CASES

There are no known related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit established in Ninth Circuit Rule 32-1 because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 13,987 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

/s/ *Benjamin Carlisle*
Benjamin Carlisle

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2021, I electronically filed the foregoing Respondents' Brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ *Benjamin Carlisle*
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ADDENDUM