Case Nos. 20-70787, 20-70801

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

NATIONAL ASSOCIATION OF WHEAT GROWERS, *et al.*,

Respondent-Intervenors.

NATURAL RESOURCES DEFENSE COUNCIL, *et al.*,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,
NATIONAL ASSOCIATION OF WHEAT GROWERS, *et al.*,
Respondent-Intervenors.

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

PETITIONERS RURAL COALITION ET AL.'S REPLY BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

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GLOSSARY OF ACRONYMS AND TERMS

APA	Administrative Procedure Act
AHS	Agricultural Health Study
ATSDR	Agency for Toxic Substances and Disease Registry
BE	Biological Evaluation
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
IARC	International Agency for Research on Cancer
NAS	National Academy of Sciences
NHL	non-Hodgkin lymphoma
NMFS	National Marine Fisheries Service
NNG	N-nitrosoglyphosate
ORD	Office of Research and Development
SAP	Scientific Advisory Panel

INTRODUCTION

EPA's duty is to protect the environment and public health. But at every turn, EPA gave the benefit of the doubt to glyphosate and its maker, rather than take a precautionary approach to protecting people and the environment as Congress required in the Endangered Species Act (ESA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

EPA and Intervenors (Monsanto) defend EPA's "no health risks" conclusion in the interim decision as based on a robust review of the science, but from the 1980s to today's breaking news, the evidence of glyphosate's risks mounts. From the 1985 mouse study showing tumors, to the 2015 IARC "probable carcinogen" designation, to the EPA's own 2016 buried report finding suggestive evidence of non-Hodgkin lymphoma (NHL), recently unearthed by a journalist.[1] From the

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[1] Lerner, *The Department of Yes: How Pesticide Companies Corrupted the EPA and Poisoned America*, THE INTERCEPT (June 30, 2021), https://theintercept.com/2021/06/30/epa-pesticides-exposure-opp/.

lawsuits by tens of thousands of people suffering from NHL after glyphosate exposure, to the recent affirmation of the verdict in the first of those cases finding Monsanto's glyphosate products caused NHL, *Hardeman v. Monsanto*, 997 F.3d 941 (9th Cir. 2021), to the third appeal of such a verdict that Monsanto recently lost, *Pilliod v. Monsanto*, 2021 WL 3486893 (Cal. App. 1 Dist. Aug. 9, 2021). Not to mention Bayer/Monsanto's dramatic announcement just weeks ago that by 2023 it will *entirely stop selling* glyphosate products for residential use, to stave off its skyrocketing cancer liability.[2]

Respondents claim that EPA deserves deference to its risk analysis. But this case is not about what EPA did, but what its health assessment left out. EPA had over 12 years to conduct this registration review, and decades of research on the most heavily used pesticide in the country. Yet it chose to finalize its health risk assessment with

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[2] Davies, *Bayer to remove glyphosate from lawn and garden Roundup products*, AGRIPULSE (July 29, 2021), https://www.agri-pulse.com/articles/16246-bayer-to-remove-glyphosate-from-lawn-and-garden-roundup-products.

three major data gaps. First, EPA found there were no cancer risks overall despite coming to "no conclusion" at all as to NHL *specifically*, and in defiance of the Scientific Advisory Panel's (SAP) review. As the recent *thousands* of NHL cancer cases tragically illustrate, this was a grave lapse. Second, EPA baldly concluded there are no occupational risks despite having no evidence of how much glyphosate gets into the bloodstream through skin contact, a major route of exposure. Third, EPA failed to consider the risks from the glyphosate whole formulations used in the real world, which have greater effects than the active ingredient alone. For these voids EPA deserves reversal, not deference.

Finally, it is worth reiterating that when faced with Petitioners' opening brief and reversal, EPA now *admits* that its ecological risk assessment and cost-benefit analysis do not comply with FIFRA. Rather than defend them, EPA asks for a mulligan. These failings on both public health and the environment riddling its decision show a lack of substantial evidence, in violation of FIFRA.

Further, EPA's action had consequences for threatened and endangered species. But in accordance with its longstanding pattern of ignoring the ESA, EPA failed to make *any* effects determination for its decision. Yet EPA had evidence that glyphosate "may affect" imperiled species for years before 2020. In its bid for voluntary remand, EPA now says it will use its draft Biological Evaluation in redoing its ecological risk assessment, all but admitting that ESA consultation should have informed this interim decision. By law EPA needed to initiate consultation at the *earliest possible time* to meaningfully incorporate those findings into its interim action, including mitigation measures that could protect ESA-listed species. Because EPA's interim registration decision violated the hearts of FIFRA and the ESA, the Court should vacate the decision, including all glyphosate product registrations, and send EPA back to the drawing board to conduct the sound, independent analysis it owes to the public.

ARGUMENT

I. EPA LACKED SUBSTANTIAL EVIDENCE FOR ITS CONCLUSION THAT GLYPHOSATE POSES NO HUMAN HEALTH RISKS.

While Respondents may want this Court to require Petitioners to provide substantial evidence *for* glyphosate causing cancer, that is not the standard. The question presented for review is whether EPA supported with substantial evidence its conclusion that glyphosate poses *no* health risks. 7 U.S.C. § 136n(b). It did not, because EPA glossed over three major analysis gaps. First, despite NHL being the most glaring cancer concern, EPA conspicuously admitted it had "no conclusion" as to NHL cancer risk, and yet somehow still concluded there are *no* cancer risks overall. Second, EPA never assessed one of the major routes of occupational exposure: how much glyphosate is absorbed into the bloodstream through skin. Third, EPA completely failed to assess the real-world products that are known to have stronger effects than glyphosate alone. These three major unanswered gaps render the challenged decision without substantial evidence. Petitioners

do not ask the Court to step into EPA's shoes, but merely to recognize the lack of substantial evidence, vacate, and remand.

A. EPA Ignored Evidence of Non-Hodgkin Lymphoma Risk

1. EPA's No Cancer Risk Conclusion Excludes Non-Hodgkin Lymphoma.

NHL is the most well-known form of cancer at issue: tens of thousands of people have contracted this life-threatening cancer from glyphosate exposure. RC Br. 11-12 (citing cases); *Hardeman*, 997 F.3d 950 (describing cases, upholding jury finding exposure to glyphosate caused NHL). EPA (Br. 22-23) claims Petitioners cannot even bring up these cases because they are extra-record. First, that this is undisputedly a record review case does not mean the Court should blind itself to broader context. Namely, while EPA is claiming safety and re-registering this pesticide, tens of thousands of people are suing and proving the opposite: glyphosate causes cancer. And while Monsanto defends EPA's decision to this Court, it otherwise just announced that it will stop selling glyphosate to residential users entirely because of its

current and future NHL liability concerns.[3] Thus Petitioners cite these cases, news articles, and government publications to provide important background for EPA's decision, not to prove that glyphosate causes cancer. RC Br. 6, n.5; *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010) ("Courts may take judicial notice of publications introduced to 'indicate what was in the public realm at the time, not whether the contents of those articles were in fact true.'"). These cases began while EPA was making the challenged decision and EPA was aware of them, *participating* in some. *See* Amicus Brief of U.S. in Support of Monsanto, *Hardeman*, 997 F.3d 941 (9th Cir. 2021) (No. 19-16636), 2019 WL 7494588; RC Br. 11.

Second, despite this context showing that NHL *should* be a primary agency focus, it was not: EPA concluded glyphosate is "not likely" to cause cancer, even when its 2017 Revised Issue Paper *could not conclude that for NHL* specifically. EPA stated:

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[3] *Supra* n.2.

> due to conflicting results and various limitations identified in [epidemiology] studies investigating NHL, a conclusion regarding the association between glyphosate exposure and risk of NHL *cannot be determined* based on the available data.

1-SER-171. (emphasis added). This means that while EPA cannot support a conclusion that glyphosate is "not likely" to cause NHL, it still concluded that overall glyphosate is "not likely" to cause cancer. EPA expressly admits this. *See* EPA Br. 27 n.3. Put differently, EPA admits that it disregarded the *most important cancer* linked to glyphosate in its overall cancer conclusion.

Indeed, in the *Hardeman* case, this Court upheld a verdict that glyphosate was a "substantial cause" of Hardeman's NHL and Monsanto failed to warn of the risks. *Hardeman*, 997 F.3d at 954, 970. There the plaintiff has the burden to prove that glyphosate *was* a substantial cause of his NHL and that the link between glyphosate and NHL was "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available" in 2012. *Id.* This Court affirmed. *Id.* Here, the burden is on *EPA* to show it had

substantial evidence for its 2020 conclusion that *no cancer risk* exists. EPA's decision cannot be squared with *Hardeman*; instead, the agency concluded there was no cancer risk despite not making that conclusion for NHL. This failure to consider an important aspect of the problem renders EPA's "no health risk" conclusion unlawful.

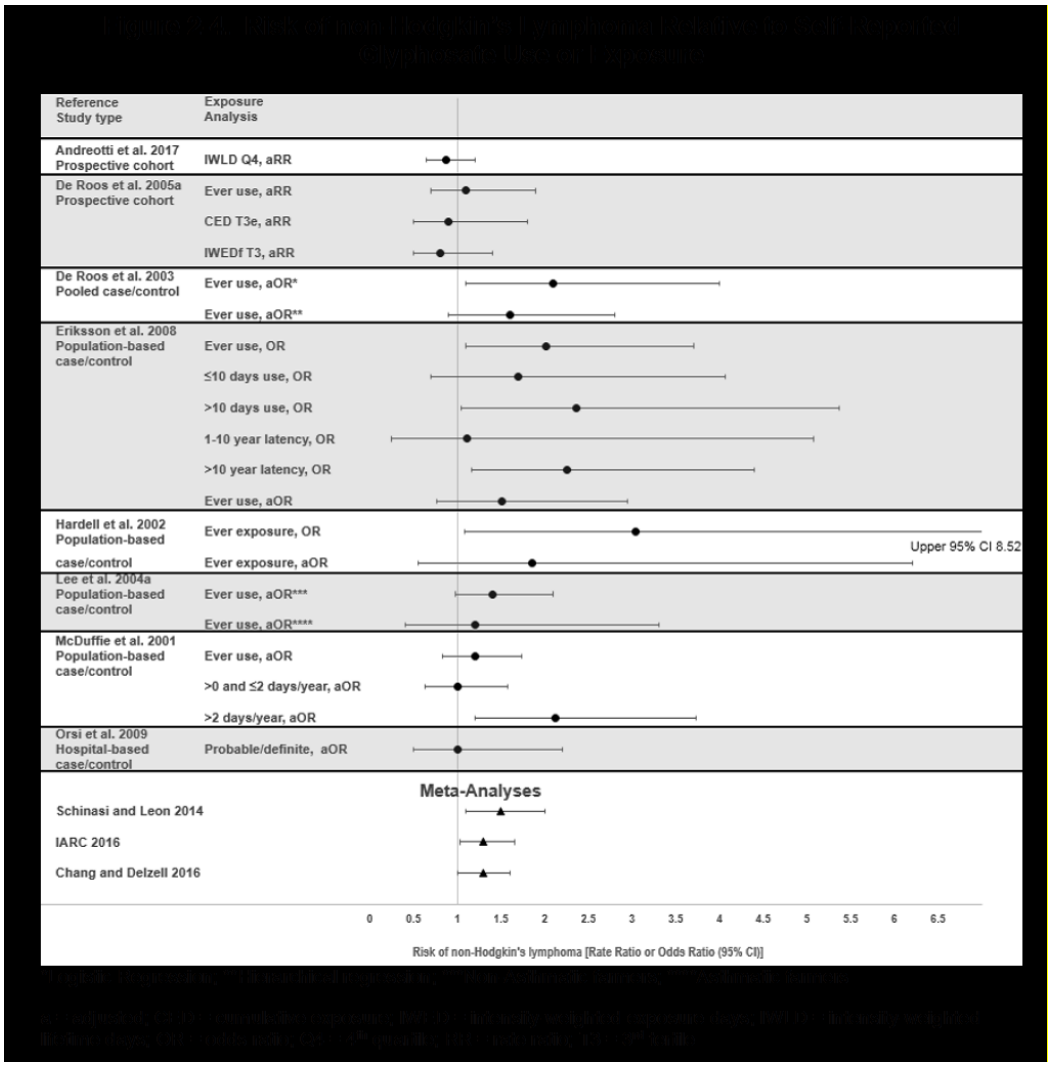
2. EPA Discounted Dozens of Epidemiological Studies and Meta-Analyses in Reliance on Single Study.

EPA's no cancer risk conclusion was possible only by discounting numerous epidemiological studies and meta-analyses finding NHL risk, because they diverged from EPA's single, preferred study (the Agricultural Health Study (AHS)). EPA Br. 29, 39 ("weight of the evidence" supports no cancer conclusion); Monsanto Br. 18-19; *but cf.* *Hardeman*, 997 F.3d at 963-64 (recounting harsh criticisms of the AHS study by experts and even Monsanto staff, including one calling it "junk science").

First, meta-analyses—combining results from multiple studies—are conducted precisely to determine the weight of evidence, taking advantage of the greater number of cases to increase precision and

reach more reliable results than individual studies for examining carcinogenicity. 4-RC_ER-0702. As this ATSDR report graph shows, the majority of studies and all three meta-analyses found increased risk of NHL from glyphosate use/exposure:

Figure 1: Risk of non-Hodgkin's Lymphoma Relative to Self-Reported Glyphosate Use or Exposure



2-RC_ER-0308 (points to right of vertical line represent increased NHL risk).

Second, in contrast to relying on the single AHS and rejecting others, the SAP told EPA meta-analysis is the "best tool" to assess the epidemiology on glyphosate exposure and NHL: relative to individual studies, meta-analysis increases statistical power to detect effects, improves estimates of the effect size, and critically, "resolve[s] uncertainty when reports disagree." 4-RC_ER-0619. Instead, EPA ignored these strengths and defied the expert SAP's recommendation to consider them. 1-SER-091.

The SAP also corrected EPA's mischaracterization of two meta-analyses showing elevated NHL risk as being non-statistically significant, when "in fact, all three meta-analyses show statistically significant" increases. 4-RC_ER-618. Indeed, the SAP found, "all meta-analysis results point to a statistically significant association with the increased risks [of NHL] from 30-50%" for people who have ever been

exposed to glyphosate and noted that the meta-analyses' consistency increased confidence in their results. 4-RC_ER-0619.

The SAP is a congressionally created expert body that EPA appoints and should carry weight. 7 U.S.C. § 136w(d)(1); *League of United Latin Am. Citizens v. Regan,* 996 F.3d 673, 702-03 (9th Cir. 2021) (doubting EPA could set safe chlorpyrifos tolerances as contrary to SAP proceedings).

Third, EPA conspicuously omitted a 2016 evaluation of epidemiological studies by its Office of Research and Development (ORD) in which EPA scientists concluded there is "suggestive evidence" of carcinogenic potential between glyphosate exposure and increased risk of NHL. Just weeks ago, this buried EPA report surfaced for the first time. *See* RC Mot. to Complete or Supp. Record, *filed concurrently*, Exhibit A, 9. The ORD report considered and largely rejected various potential biases, confounding factors, and chance as explanations for increased NHL risk (*id.* at 5-8), factors EPA's pesticide division later used to discount epidemiological studies. 1-SER-090-95.

EPA has not mentioned this study to the Court, nor included it in the record even though it clearly should have. But EPA's 2016 conclusion was that the "weight of evidence is suggestive of carcinogenicity" and a "*concern* for *potential carcinogenic* effects in humans is raised," RC Mot. Supp., Ex. A, 9 (emphases added), a classification joined by many SAP members. 4-RC_ER-0620. At worst this is bad faith by an agency with a long history of colluding with the industry it is supposed to regulate.[4] At best, it shows EPA lacked substantial evidence for its cancer conclusion.

Overall, EPA has no response beyond its myopic focus on its single preferred study. EPA Br. 38-39.[5] Yet, one study cannot render the decision supported by substantial evidence.

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[4] *Supra* n.1.

[5] EPA's bias is further evident in its dismissal of two *additional* meta-analyses finding increased NHL risk, despite both incorporating the updated AHS (Andreotti et al. 2017) that EPA touts. *Id.*; 2-RC-ER-0095; 3-RC_ER-0346; 2-RC_ER-0319; Monsanto Br. 18-20 (EPA's rejection of Zhang and Leon studies).

3. Respondents' Attempts to Ignore SAP and IARC are Unavailing.

Respondents' remaining efforts to brush away cancer risk evidence are ineffective. First, just as EPA ignored the SAP's input on meta-analyses, *supra*, EPA also disregarded its strong objections to EPA's evaluation of the animal carcinogenicity studies. RC Br. 38-39. This is not a technicality: EPA's faulty review of 15 rodent studies was a crucial part of EPA's no cancer risk conclusion. Despite paying lip service to "address[ing] the SAP's concerns," EPA made *no substantive changes* to its Revised Issue Paper. *Compare* EPA Br. 33-34 *with* 4-RC_ER-0651 (SAP citing violations regarding (1) monotonic dose-response, (2) "disregard of exposures > 1000 mg/kg/day," (3) pairwise tests, and (4) historical controls). Despite SAP's criticisms, EPA again concluded not a single study showed evidence glyphosate-caused cancer.

Namely, EPA continued to violate its own Cancer Guidelines by discounting tumors lacking a perfect-world "monotonic" response (1-SER-101, 107) or occurring at doses above 1,000 mg/kg/day, despite the Guidelines permitting high doses much higher than that in rats and

mice. 1-SER-098, 102; 4-RC_ER-0651. And EPA continued to demand both trend and pairwise tests showing statistical significance, rather than either one alone (*e.g.*, 1-SER-109), and to misuse historical control data to discount tumors (*e.g.*, 1-SER-113, 11-RC_ER-2418-21).

Thus, EPA applied overly stringent demands exceeding its own Guidelines, contrary to SAP,[6] to make glyphosate appear safe. *But see* 4-RC_ER-0623 (SAP members noted increased lymphoma risks identified in four mouse studies the supported increased NHL risk in humans).

Second, Respondents claim EPA's evaluation was more thorough than IARC's (EPA Br. 32), yet IARC reviewed an enormous body of work (4-RC-ER-0798-811), rejecting only industry data (per long-standing policy) not publicly available or lacking sufficient detail. 4-RC-

[6] EPA cites *Communities for a Better Environment v. EPA*, 748 F.3d 333, 335-37 (D.C. Cir. 2014), but there, the SAP concluded that EPA could change *or retain* its carbon dioxide standard. Here, the SAP identified serious, unmitigated flaws and made no unanimous conclusion that EPA was correct.

ER-0696, 0753, 0764. In contrast, EPA relied heavily on industry summaries of studies. 1-INT_SER-35 (citing Greim (2015), Williams (2000) and Kier and Kirkland (2013), among six works belatedly identified by EPA as "funded and/or linked to Monsanto Co. or other registrants." 1-SER-049 n.11). To the extent EPA claims its review was more transparent (EPA Br. 32), the record is rife with EPA conflicts of interest.[7]

4. Carcinogenic Contaminant

In response to Petitioners' N-nitrosoglyphosate (NNG) contaminant argument (RC Br. 40), EPA does not deny that (1) it has a 1980 policy requiring that contaminants of this carcinogenic class be tested when present in pesticides at levels greater than or equal to 1 part per million (ppm),[8] or (2) that pre-1993 data show NNG exceeded

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[7] The EPA committee head that first assessed glyphosate's carcinogenicity is under investigation by EPA's Inspector General for possibly colluding with Monsanto in "glyphosate defense." 3-RC_ER-452-453; 1-INT-SER-28; RC Br. at 39.

[8] EPA found fully 80% of N-nitrosamines tested carcinogenic. 45 Fed. Reg. 42,855 (June 25, 1980).

that level in over 7% of glyphosate samples. RC Br. 40, 2-RC_ER-0093. EPA does not state that this policy changed, or that subsequent sampling showed NNG levels have fallen.

EPA instead argues NNG content "is not toxicologically significant" because the "vast majority" of samples contained NNG levels below 1 ppm. EPA Br. 37. But even 93% is not "the vast majority:" assuming the samples represent the universe of glyphosate today, 7% means 2 of every 27 glyphosate batches, or *22 million* of the 300 million lbs. of glyphosate used annually. That EPA came to same erroneous conclusion before (EPA Br. 36) does not negate the need to address it now. EPA lacks substantial evidence for its health determination where it ignores this carcinogenic contaminant issue, contrary to its own guidance to test for this type of contaminant when levels in samples exceed 1 ppm. *Pollinator Stewardship Council v. EPA*, 806 F.3d 529, 531-32 (9th Cir. 2015) (when EPA sets its own levels, it cannot ignore them).

B. EPA Did Not Assess Skin Absorption of Glyphosate.

Turning to the second major data gap, EPA concluded that glyphosate causes no health harms without actually assessing how much glyphosate enters peoples' bloodstream through skin contact. RC Br. 31-35, 42-44. Without this information, EPA cannot have substantial evidence to conclude there are no long-term health harms from glyphosate exposure.

1. EPA had No Dermal Penetration Study.

Despite stating that skin absorption is a significant factor in occupational risk, EPA did not collect even one absorption study. RC Br. at 31-35, citing 3-RC_ER-0525 ("A dermal absorption study is not available in the toxicity database"); 3-RC_ER-0542 ("dermal penetration" study not submitted).

EPA argues it did consider dermal penetration, EPA Br. 44 (citing 2-SER-422-23, IARC's brief description of a 1991 study), but this study appears nowhere in the record. EPA's post-hoc citation to a study that EPA *does not have* cannot provide substantial evidence supporting its

"no health risk" conclusion.[9] Rather, the record is clear: "*no study* examined the rates of absorption in humans." 4-RC_ER-0795 (emphasis added).

2. EPA Ignored Dermal Exposure Route and Set No Limits for Skin Contact.

Because it separately declared there is no skin hazard, EPA declined to investigate how much glyphosate reaches the bloodstream from skin contact. EPA Br. 40. But hazard and absorption are two distinct phenomena and EPA cannot say there is no risk from skin exposure to glyphosate without knowing how much will *actually* enter the bloodstream.

EPA essentially decided workers could *bathe* in glyphosate without injury, either short- or intermediate-term, because it set *no* limit for dermal absorption, despite setting oral exposure limits. 3-RC_ER-529. EPA assumed the maximum amount of glyphosate a

[9] Neither does EPA's second citation (1-SER-042: an unsubstantiated, one-sentence claim that dermal penetration is "relatively low") constitute substantial evidence.

worker might absorb (7 mg/kg/day) based on generic data gathered from a consortium of chemical companies (1-SER-045, n.8) and then concluded this estimated exposure is safe because it is "well-below the doses necessary to elicit the effects [tumors] seen in these animal carcinogenicity and genotoxicity studies." 1-SER-170; EPA Br. 30. But EPA failed to apply the typical 100-fold safety factor necessary to account for potentially increased susceptibility of humans. 3-RC_ER-529 (translating from the animal benchmark of 100 mg/kg/day to a maximum safe human exposure level of just 1.00 mg/kg/day for chronic toxicity).

Substantial evidence does not support EPA's "no risk" conclusion. The regulatory system's purpose is to identify how much is safe, and here we have no idea what amount of absorption is "well below" the glyphosate level that caused tumors in animals. If 7 mg/kg/day is "well-below" a carcinogenic or otherwise harmful exposure, what about 20 or even 200 mg/kg/day. Even 7 mg/kg/day is *7 times* the level EPA deems safe for short-, intermediate-term, and chronic oral exposure. 3-RC_ER-

529. EPA violated FIFRA when it failed to provide any rationale for why it did not accord the same level of protection to workers who are occupationally exposed as to people who are primarily exposed through food residue.

C. EPA Lacked Data on Real-World Formulations.

Finally, EPA failed to assess almost any of the real-world products. RC Br. 41-47; 1-SER-126; 1-SER-046. This massive knowledge gap shows that EPA lacked substantial evidence for its "no health risk" conclusion and failed to look at an important aspect of the problem.

Respondents acknowledge that registration review includes all glyphosate products (EPA Br. 45-46; Monsanto Br. 37) but want to avoid real assessment of those products' impacts. Congress charged EPA with assessing changes since last registration decision, including the many new glyphosate formulations. RC Br. 41-2. EPA's regulations require it to set as its baseline the reregistration date, here 1993. 40 C.F.R. § 155.42(d). Since then, glyphosate products expanded 10-fold from 56 to 555, 10-RC_ER-2091, and use skyrocketed from 18.7 million pounds, *id.*, to over 300 million pounds today. RC Br. 9-10. EPA's

excuses for failing to investigate the new formulations and how they impact human health and the environment fall flat.

First, EPA (Br. 46-47) makes the review process sound like it should wait to be handed evidence of a formulation change, but the whole point is for EPA to call for the new data; FIFRA explicitly gives EPA this power. 40 C.F.R. § 155.56; 7 U.S.C. § 136a(c)(2)(B). EPA said it would "check to see whether there are any issues concerning the inert ingredients in a product that is undergoing registration review." EPA Br. 48. But EPA failed to do that for most glyphosate products during this lengthy registration review period.[10] EPA says (Br. at 49) its decision purportedly "takes into account glyphosate formulations" but it cannot point to any place where it *actually* does so.

As to "inert" ingredients, EPA's assessment of various inerts over the years is insufficient (Br. 49): registration review's purpose is to

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[10] EPA states that the final registration review decision is forthcoming but has made no indication that it intends to call in data on formulations between now and its final decision; regardless, it already finalized its human health risk assessment.

collect the most up-to-date data and compare them to the baseline (1993). 40 C.F.R. § 155.42(d). Moreover, EPA's inert assessment does not address formulations. 2-RC_ER-0078-79.

Second, EPA dismisses (Br. 54) Monsanto scientists' statements that various formulations should be tested to assess skin absorption and associated health risks (RC Br. 44-45) as "pre-dating" evidence upon which EPA relied to make its human health decision. But EPA has no explanation for how it has resolved those comments or how its subsequent evidence—not including formulation testing—negated those statements. Despite its own recognition that "further study of glyphosate formulations could be beneficial" (EPA Br. 55), EPA completely disavows its duty to study these formulations *now*, before concluding there are no health risks as part of *this* registration review.

Finally, Petitioners do not claim—as EPA (Br. 45) argues—that EPA needed to develop extensive information on each of the 555 glyphosate products. Rather, EPA's registration review duty extends to *all* products and EPA could and should have used its data call-in power

to at least require testing for categories of different formulations based on the various surfactants.[11] There is a middle ground between developing extensive data on each individual product and doing nothing. EPA's "no health risk" conclusion cannot be upheld on this record of EPA doing nothing as to real-world glyphosate product use.

* * *

Petitioners need not prove that glyphosate causes cancer or other health harms—only that EPA lacked substantial evidence to claim there are no health risks at all. Given the above major gaps in its assessment, it cannot reasonably be concluded that EPA had substantial evidence that there are "no risks of concern" for health or that there is a rational connection between the record evidence and EPA's conclusion.

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[11] EPA registers identical or substantially similar products as "Me-Too" registrations, so it can identify categories of products that are substantially similar enough that will still assess their safety with the most up-to-date data possible. EPA, https://www.epa.gov/pria-fees/pria-glossary#M (definition of "Me-Too Product").

II. EPA VIOLATED THE ESA.

The ESA is a precautionary statute, congressionally enacted to make endangered species protection the highest priority, requiring agencies to act with "institutionalized caution" when undertaking any action that might impact endangered species or their habitat. RC Br. 64. EPA violated the ESA by refusing to consult with the expert Services at the earliest time, *before* its decisions regarding glyphosate registration review, interim or otherwise, would have effects on endangered species. EPA started the registration review process in 2009, knowing the full extent of glyphosate's widespread usage in massive (and growing) quantities. RC Br. 62-63. EPA had enough information at that time to determine that glyphosate "may affect" listed species and their habitats, which is an extremely low legal threshold. *Karuk Tribe of Calif. v. USFS*, 681 F.3d 1006, 1027 (9th Cir. 2012). Instead, EPA avoided making *any* ESA determination for this action, delaying its ESA consultation duties and circumventing implementation of informed, protective measures in the interim. RC_ER-0035. This failure violates the ESA and puts nearly 1,800

species, across over 285 million acres of farmland, in danger. RC Br. 62-63.

Nothing in Respondents' answering briefs changes this conclusion. First, Petitioners have standing and the claim is not moot. Second, EPA had discretion to act to the benefit of species in the interim decision, making it an "action" under the ESA. Third, because the decision is agency action, and EPA had enough information to make a "may affect" determination, EPA had a duty to consult at the earliest possible time, before issuing its interim decision. EPA's decision to issue the challenged action without making any effects determination whatsoever violated the ESA.

A. The Court Has Jurisdiction.

1. Petitioners Have Standing.

Contrary to Monsanto's (solo) arguments (Br. 49-54), Petitioners have standing. *E.g., Nat'l Family Farm Coal. v. EPA*, 966 F.3d 893, 910 (9th Cir. 2020). Petitioners' members are injured by EPA's failure to consult at the earliest possible time (or even to make any ESA "no effect/may affect" decision whatsoever before issuing this decision). ESA

compliance ensures EPA conducts registration review in the way most protective of endangered species, including making decisions about how "glyphosate can continue to be sold and used throughout the United States." RC Br. Addendum (A) A109 ¶ 3 (Bishop decl). EPA has the responsibility to adjust the registration through registration review, and consultation with the expert Services informs those adjustments to be protective of endangered species. The plain "causal connection" between Petitioners' injuries and the interim decision is that the decision may have included more protective measures, if undertaken after consultation with the Services, as the ESA requires. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992).

Petitioners' members' injuries are redressable by a favorable decision, specifically by the Court ordering consultation before any registration review decisions are made, independent of the Court's decision on vacatur. Then, any registration review decisions and included mitigation measures could be truly protective of endangered species. And these injuries are additionally redressable by vacatur.

Vacatur will not exacerbate Petitioners' injuries but instead could halt use of glyphosate products.[12] *Infra.*

Contrary to Monsanto's improper attempt to *raise* Petitioners' standing bar, the bar is actually lower, because their injuries are partially procedural (Section 7 consultation set a strict procedure to ensure compliance with ESA's substantive commands), claims which have a more relaxed standard for causation and redressability. *NFFC*, 966 F.3d at 910; *Lujan*, 504 U.S. at 572 n.7. All that is required is a "reasonable probability of the challenged action's threat to [Petitioners'] concrete interest." *Hall v. Norton*, 266 F.3d 969, 977 (9th Cir. 2001). To satisfy redressability Petitioners need only show that that "the relief requested—that the agency follow the correct procedures—*may* influence the agency's ultimate decision." *NFFC*, 966 F.3d at 910

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[12] Even if the Court disagrees that vacating the interim registration decision ends all glyphosate use pending a new registration, if the Court vacated EPA's interim decision to send it back to consult and create more protective mitigation measures, the Court could stay vacatur as to the existing mitigation measures to keep them in place pending new action. *See infra.*

(quoting *Salmon Spawning and Recovery All. v. Gutierrez*, 545 F.3d 1220, 1227 (9th Cir. 2008)) ("This is not a high bar to meet.").

Finally, Monsanto tries to rely on *Salmon Spawning,* but there the court could not withdraw the U.S. from a treaty, the source of plaintiffs' harm. *Salmon Spawning*, 545 F.3d at 1227. Here, consultation will give EPA vital information about how the registration decision will affect species, and in turn how to best mitigate the registrations' harm to species, which will redress Petitioners' injuries. RC Br. 76. [13]

[13] Nor did Petitioners waive their ESA claim. Petitioner Center for Food Safety included ESA consultation in its comments on the proposed decision, including that consultation must occur "at the earliest possible time." 2-RC_ER-0069-70. Petitioner Center for Biological Diversity commented that consultation should occur at the preliminary risk assessment stage, that is, before the interim registration, which *finalized* risk assessments. RC_ER-014. Further, Petitioners could not file a 60-day ESA notice because FIFRA requires petitions for review to be filed within 60 days of the decision, 7 U.S.C. § 136n(b), nor did they have to do so, since this this case is brought pursuant to FIFRA.

2. Petitioners' ESA Claim is Not Prudentially Moot.

EPA incorrectly argues (Br. 65-68) that Petitioners' ESA claim is prudentially moot because EPA has already committed to a future effects determination. Prudential mootness is a discretionary doctrine rarely applied. *Deutsche Bank Nat. Tr. Co. v. F.D.I.C.*, 744 F.3d 1124, 1133 (9th Cir. 2014). In environmental cases, courts have generally refused to dismiss on prudential mootness grounds even when the agency commits to doing the required environmental analysis, *Colorado Environmental Coalition v. Office of Legacy Management*, 819 F. Supp. 2d 1193, 1203 (D. Colo. 2011), or when consultation is already underway, *American Rivers Inc. v. NOAA Fisheries*, 2004 WL 2075032, at *3 (D. Or. Sept. 14, 2004). *See also NRDC v. Norton*, 2007 WL 14283, at *7 (E.D. Cal. Jan. 3, 2007) (courts refuse to dismiss on prudential mootness grounds when agency does not "indicate an intent to change its operations.").

In contrast, a proper doctrinal application is the narrow instance—not the facts here—where consultation is the only relief sought, and the agency has already completed consultation. *S. Utah*

Wilderness All. v. Smith, 110 F.3d 724, 727-30 (10th Cir. 1997); *Voyageurs Nat. Park Ass'n v. Norton*, 381 F.3d 759, 765 (8th Cir. 2004). Here, EPA has *not* completed consultation, nor committed to completing it before issuing any new interim registration decision.

B. The Interim Registration is Cognizable Agency Action Under the ESA That Required ESA Compliance

EPA argues (Br. 57-58) that because its interim registration decision "did not 'register glyphosate'" it somehow did not trigger the agency's Section 7 duties. But whatever EPA calls it, the interim decision was unquestionably an action under the ESA and therefore required a "no effects/may affect" determination and likely consultation if EPA determined it may affect any ESA protected species.

"Agency action" under the ESA is "*any action* authorized, funded, or carried out" by federal agencies 16 U.S.C. § 1536(a)(2) (emphasis added); 50 C.F.R. § 402.02 (examples). This definition "is to be construed broadly." *Karuk Tribe*, 681 F.3d at 1027. In *Karuk Tribe*, this Court explained that the inquiry for cognizable "agency action" triggering ESA duties is two-fold: asking (1) whether there is

affirmative action and (2) if the agency has discretion to influence the activity for the species' benefit. *Id.* at 1021; *Ctr. for Biological Div. v. EPA*, 847 F.3d 1075, 1090 (9th Cir. 2017). *See* RC Br. 68-69. Regarding whether EPA must consult before the interim decision, "[t]he relevant question is whether the agency *could* influence a private activity to benefit a listed species, not whether it must do so." *Karuk Tribe*, 681 F.3d at 1024 (emphasis added). Both of these prongs are unquestionably met here. Crucially*, neither Respondent actually challenges* that this decision meets the ESA definition of "agency action," they only wish to avoid the consequences that follow from that, which is that EPA had to make *some* ESA determination before issuing it, which it failed to do.[14]

[14] Notably, EPA as a mere action agency receives no deference on any ESA decisions or interpretations. *Bennett v. Spear*, 520 U.S. 154, 169 (1997) ("species and habitat investigations [under the ESA]" are not "within the action agency's expertise"); *Conservation Law Found. v. Ross*, 422 F. Supp. 3d 12, 28 (D. D.C. 2019) (rejecting deference argument, explaining "it is not the *action* agency that is the expert as to its duties under the ESA ....").

Through the interim registration, EPA had discretionary control to benefit protected species through mitigation measures or otherwise, like deciding which factors to consider in the ecological risk assessment. Petitioners' critique of the *effectiveness* of EPA's mitigation measures is beside the point here.

Nor can this plainly affirmative, discretionary registration decision be transformed into mere "inaction," as EPA claims (Br. 61).[15] The point is that mitigation measures are designed to affect endangered species, and more generally, that EPA has discretion to implement protections in the interim. And EPA's far-reaching claim (Br. 57) that registration review decisions do not register pesticides and therefore do not trigger ESA duties proves too much: If that were the case, EPA

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[15] Nor is EPA's cite to *Western Watersheds Project v. Matejko*, 468 F.3d 1099, 1108 (9th Cir. 2006), applicable here. In fact, that case explains that EPA *has* a "continuing duty" to register pesticides, alter, and cancel registrations under FIFRA. *Id.* at 1110. Moreover, in *Western Watersheds*, the agency had no ability to "inure to the benefit of protected species." Here, EPA does have that ability. Likewise, *Cal. Sportfishing Prot. All. v. FERC*, is inapplicable. 472 F.3d 593 (9th Cir. 2006) (agency's continuing operation of a project not "agency action").

would not have to consult on *final* registration either. Because EPA has discretion to act to benefit species, the interim registration is "agency action" for purposes of the ESA and EPA violated the ESA by issuing the decision without even addressing, let alone complying with Section 7's mandates.[16]

C. Consultation Must Occur at the "Earliest Possible Time."

EPA was required to consult with the Services at "the earliest possible time" to determine whether the decision "may affect listed species or critical habitat." 50 C.F.R. § 402.14(a). The Ninth Circuit has emphasized that ESA Section 7 imposes the duty to consult "*before* engaging in any discretionary action that may affect a listed species or critical habitat." *Karuk Tribe*, 681 F.3d at 1020 (emphasis added). This

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[16] Another example of EPA retaining discretionary control to benefit species is EPA's recent request for partial remand. EPA now wishes to "reevaluate" the FIFRA ecological risk assessment and mitigation measures in the interim decision to, *inter alia*, consider the issued draft ESA Biological Evaluation (*i.e.*, effects determination), essentially admitting that ESA consultation should guide the interim decision. EPA Remand. Mot. Reply, ECF 99 at 4.

is because the objective of consultation is to "identify reasonable and prudent alternatives that will avoid the action's unfavorable impacts." *Id.* EPA plainly violated this core ESA mandate by issuing the decision without any ESA compliance.

EPA had the ability to implement meaningful mitigation measures at the interim decision stage, thus consultation was required before the decision was finalized, to ensure the agency action is as protective as possible.[17] EPA's argument (Br. 63) that interim registration decisions "are used to implement mitigation measures more quickly than waiting for a final registration review decision" misses the point. First, creating mitigation measures two years before the 2022 deadline, when the review process started in *2009*, is not implementing mitigation measures "quickly." Second, the point is not to issue them

[17] Petitioners need not show that consultation on the interim decision could be completed any sooner than consultation on the final registration. EPA Br. 63.

quickly, but to make sure they are meaningful. Hence the ESA requirement of consultation "at the earliest possible time."

Nor will requiring ESA analysis before the interim decision "complicate and delay" the process. EPA Br. 63. Rather, initiating consultation at the required time allows EPA to make more informed decisions throughout the entire process, and crucially *with* the expertise of the Services. Petitioners do not argue that EPA would have to undertake a new consultation process for the final registration decision. The ESA framework allows agencies to build upon initial consultation through reinitiation, should any new developments reveal effects of the action "not previously considered." 50 C.F.R. § 402.16(a).

The core issue is how to comport the ESA's mandates with EPA's bifurcated registration process. EPA's FIFRA regulations create this "interim" final registration, but do not grapple with how this process impacts EPA's duties under the ESA. EPA cannot dispute that the interim registration is a discretionary, final agency action. In such cases, it cannot pass the buck on its ESA duties to *another* final agency

action (the final registration). Further, if EPA is going to bifurcate its registration process into two parts as here, consultations on the interim decision is the logical chronology of events, given the requirement to consult at the earliest possible time. The ESA required EPA, when it *chose* to separate a registration into distinct agency actions, to consult before the first action, thus informing the second.

Alternatively, EPA should have done at least part of its registration consultation before this interim decision, finishing it during the final registration. EPA had options here, but it could not do what it did: entirely ignore its ESA duties in the interim and put them off until a later agency action at the end of the process.

D. EPA Had the Information to Make A "May Affect" Determination Prior To The Interim Decision but Refused.

Finally, contrary to EPA's erroneous claim (Br. 58), it is not Petitioners' burden to prove that the glyphosate registration decisions "may affect" endangered species or that EPA's "no effect" decision was arbitrary and capricious. That would be impossible *because EPA made no effects determination to attack*. EPA was required to make its own

"may affect/no effect" determination prior to the interim decision, but it simply refused to do so. 50 C.F.R. § 402.14(a).

However, EPA had the necessary information to make a "may affect" determination at that time. EPA knew that glyphosate use would overlap with the presence of listed species and critical habitats. This is not surprising given the increasingly vast application of glyphosate, the most widely used pesticide in the U.S.

In 2011, EPA requested that the National Academy of Sciences (NAS) recommend ways to assess the effects of proposed FIFRA actions on ESA species.[18] In the resulting report, NAS concluded that EPA should determine "may affect" by "asking whether areas proposed for pesticide application and known (or suspected) species ranges or habitats coexist." *Id.* at 32. That is, whenever pesticide application

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[18] NATIONAL RESEARCH COUNCIL, ASSESSING RISKS TO ENDANGERED SPECIES FROM PESTICIDES, National Academies Press (2013), https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides.

overlaps with the presence of listed species, EPA should make a "may affect" determination.

In the interim decision, EPA anticipated that listed species and critical habitat would be present in glyphosate spraying areas:

> the ecological risk assessment supporting this ID for glyphosate *does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat*. Although the EPA has not yet completed [effects determinations], for this ID, the EPA's evaluation *assumed*, for all taxa of non-target wildlife and plants, *that listed species and designated critical habitats may be present in the vicinity of the application of glyphosate*.

RC_ER-0035 (emphasis added). In other words, instead of doing what it was required to do—make an effects determination before taking action that would affect endangered species—EPA flatly refused to do so, in the same breath admitting that glyphosate will be sprayed in areas with endangered species and critical habitat. This knowledge is enough to make a "may affect" determination, triggering the ESA's consultation requirement. EPA avoided making an effects determination knowing

that it would trigger consultation duties that would need to be performed before the interim decision was finalized.

* * *

Based on the above, the Court should grant the petition for review on ESA grounds and vacate and remand. EPA violated the ESA for this decision.[19]

III. THE COURT CAN AND SHOULD VACATE THE GLYPHOSATE REGISTRATION DECISION.

Vacatur is the presumptive remedy. RC Br. 79-81. Respondents try to avoid this result the same way they argue against violations of FIFRA and the ESA: they want to have it both ways. EPA can make interim decisions, but they are immune from judicial review, and products are included in registration review and accounted for, but

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[19] Alternatively, if the Court concludes the current record is not sufficient to grant the petition for review on ESA grounds alone, but also decides to grant voluntary partial remand as to EPA's ecological risk assessment, Petitioners request that judgment on this claim be deferred until completion of that further assessment, since EPA acknowledges its ecotoxicity redo and potential further mitigation will logically overlap and have ESA ramifications on the further interim final decision. RC_ER-0035.

vacatur cannot impact those same products' registrations. EPA Br. 6, 49, 74; Monsanto Br. 61-65.

First, Respondents are wrong that vacatur cannot stop pesticide use when that use was approved in a registration review decision. No later cancellation is required. Second, all products containing the active ingredient are part of that registration review decision and subject to the same vacatur. Third, that EPA's decision is labeled "interim" makes no difference. Finally, while vacatur is warranted here, the remedy can be narrowed to avoid interim disruptive consequences if needed.

A. Vacatur Does Not Require Later Pesticide Cancellation.

Vacatur is the statutory remedy that *courts* apply; that EPA goes through a different process to cancel pesticides is irrelevant. While EPA is required to follow certain procedures to cancel a pesticide, 7 U.S.C. § 136d, a court reviewing an EPA action does not. 7 U.S.C. § 136n (reviewing court to "affirm[] or set aside[]" a challenged EPA order). EPA elsewhere agrees that courts can vacate registrations. EPA Mt. to Remand Reply, ECF 99 at 16.

This difference makes sense, because vacatur simply reverts to the *status quo ante*, making it as if the permit or license was never granted; there is nothing to cancel by additional procedures. In other situations where agency revocation of a license or permit would require that agency to give some additional process to the license holder, courts can and do vacate those licenses, making activity under them unlawful. *See e.g., Coal. to Protect Puget Sound Habitat v. U.S. Army Corps of Eng'rs*, 466 F. Supp. 3d 1217 (W.D. Wash. 2020) (partially vacating general Clean Water Act permit for commercial shellfish aquaculture in Washington, making activities under permit unlawful) *aff'd* 843 F. App'x 77, 80 (9th Cir. 2021); 33 U.S.C. § 1344 (general permit may be revoked or modified by the Secretary only "after opportunity for public hearing"...). To the extent the process set up in §136d gives pesticide registrants due process prior to their registrations being cancelled, those same registrants intervene in court. ECF 35. Cancellation is not requested here (EPA Br. 73), so EPA's statutory duties to cancel

pesticides are wholly irrelevant to the Court's authority under FIFRA to vacate EPA decisions.

B. Vacatur Applies to All Products in Interim Registration.

Respondents also claim that even if the interim registration decision was vacated, the Court cannot vacate the registrations of all products containing glyphosate. EPA Br. 69-74; Monsanto Br. 61-65. Not so.

EPA and Monsanto acknowledge that the registration review encompasses all products containing the same active ingredient. EPA Br. 6; Monsanto Br. 37; 40 C.F.R. § 155.42. It follows that vacatur of that decision includes all pesticides included in the decision. *See e.g., Idaho Sporting Cong., Inc. v. Rittenhouse,* 305 F.3d 957, 966 (9th Cir. 2002) ("If the Forest Plan's standard is invalid, or is not being met, then the timber sales that depend upon it to comply with the Forest Act are not in accordance with law and must be set aside."); *Coal. to Protect Puget Sound*, 466 F. Supp. 3d at 1224 n.7 (rejecting industry argument that invalidation of the general permit "leaves untouched the [agency's]

verifications of projects under that permit," because those verifications did not stand alone and "in no way corrected the serious deficiencies in the [agency's] initial analysis.") *aff'd* 843 F. App'x 77, 80 (9th Cir. 2021) (upholding district court remedy, including that 900-plus individual authorizations under general permit also vacated).

Those 555 products are only registered because the active ingredient glyphosate was registered and rely on that active ingredient registration to exist. 7 U.S.C. § 136a(c)(1)(F)(i); (c)(3)(B); (c)(7). Even if this Court only vacated the registration as to glyphosate the active ingredient, that would remove the underlying basis for registering all 555 products.

C. Calling Decision "Interim" Does Not Change Remedy.

That EPA labeled its decision "interim" makes no difference to the remedy available. In this "interim" decision, EPA finalized its human health risk assessment. RC_ER-0006. While it has now walked back its ecological risk assessment and cost/benefit analysis, ECF 82-1, it maintains that there are no human health risks from glyphosate and this conclusion will not change in any final registration review decision.

This means EPA has made a *final* decision that glyphosate and all products meet the FIFRA safety standard as to human health. If EPA lacked substantial evidence for that decision, the violation has already occurred, no matter the outcome of EPA's ecological risk assessment redo or its "final" registration review decision. *See e.g.*, *Mobil Oil Corp. v. EPA*, 35 F.3d 579 (D.C. Cir. 1994) (vacating interim EPA waste rule).

D. Vacatur Is Warranted.

1. Serious Error

EPA's violations of FIFRA and the ESA are serious errors weighing heavily in favor of vacatur. RC Br. 80. Glyphosate is an intended toxin linked to cancer placing at risk those frontline workers who labor daily to bring food to our tables. Failure to ensure the safety of the most widely used pesticide based on the most up-to-date evidence is a serious error going to the heart of FIFRA's safety standard and the registration review purpose. So too is EPA's failure to make any effects determination or to consult under the ESA before issuing the decision, as this procedure goes to the very core of the ESA and must be strictly enforced to protect imperiled species. *Nat'l Parks Conservation Ass'n v.*

Jewell, 62 F. Supp. 3d 7, 20-22 (D.D.C. 2014) (agency's failure to consult was a serious error justifying vacatur of underlying agency action).

Further, if this Court denies EPA's motion for remand, EPA's FIFRA errors as to the ecological risk assessment and its cost-benefit analysis are serious. And even if the Court grants the motion, that EPA is admitting more analysis is needed supports Petitioners. While not technically admitting fault, EPA implicitly acknowledges that these assessments are not be lawful or defensible. ECF 82-1. Petitioners agree. RC at 80.

2. Disruptive Consequences

Disruptive consequences should only be given weight when the agency can make the *exact same* decision on remand. *Pollinator Stewardship*, 806 F.3d at 532 (inquiry is whether the "same rule would be adopted on remand"). If "a different result *may* be reached," that undermines any "disruptive consequences of an interim change that may itself be changed" and supports vacatur. *Id*. (emphasis added); *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151.

EPA absolutely will not make the same decision on remand. Indeed, if the Court grants voluntary remand, EPA has *already indicated* that it will change its ecological assessment and cost-benefit analysis. ECF 82-1. EPA says it will now consider its draft Biological Evaluation, finding thousands of species will likely be adversely affected by glyphosate use. *Id.* And if this Court holds EPA's human health risk assessment violated FIFRA and/or its failure to make an effects determination violated the ESA, any subsequent new "interim" registration decision will be fundamentally different than what EPA issued in January 2020.

Further, the relevant disruptive consequences should only be those that relate to protecting the purposes of the statute, *i.e.*, the environment and human health under FIFRA and endangered species under the ESA. *NFFC*, 960 F.3d at 1144-45; *Pollinator Stewardship*, 806 F.3d at 532; *see also All. for the Wild Rockies*, 907 F.3d *v. U.S. Forest Serv.*, 907 F.3d 1105, 1122 (9th Cir. 2018) (vacatur "appropriate when leaving in place an agency action risks more environmental harm

than vacating it"). EPA cites *California Communities Against Toxics v. EPA* for the proposition that the Court may consider economic consequences from vacatur, EPA Br. 75 n.21, but EPA glosses over that there disrupting the power supply would result in the use of diesel generators, causing the very air pollution that the Clean Air Act was to prevent. 688 F.3d 989, 994 (9th Cir. 2012). Regardless, economic harm like that alleged has not stopped this Court from vacating pesticides. *NFFC*, 960 F.3d at 1145.

Further, Respondents' environmental harm allegations are faulty. First, EPA assumes (Br. 75) glyphosate products can still be used; this is wrong because, as explained above, vacatur voids the registration and sets the clock back to before it was ever registered, meaning that the products cannot still be lawfully used. *Supra.*

Second, EPA (Br. 76) assumes without evidence that users will switch to more harmful pesticides and that widespread use of glyphosate is *good* for the environment. EPA's only citation (Br. 12) is to its own *Response to Comments, Usage and Benefits* document. 2-

RC_ER-00271-72 (summarizing public comments but not providing any data or scientific analysis). These are highly debatable conclusions without any evidentiary basis in the record, and cannot meet Respondents' heavy burden to show that something other than the presumptive remedy of vacatur is warranted. *All. for the Wild Rockies*, 907 F.3d at 1121-22 ("Presumption of vacatur" unless Defendants meet their burden to show otherwise).

Third, as a practical matter, if this Court vacates the interim registration and all products, EPA is poised to make a final interim registration decision by October 2022 (assuming it meets the statutory deadline). While Respondents claim the sky will fall if glyphosate is unavailable, EPA can re-register the active ingredient and products if it finds, based on substantial evidence, that they meet the FIFRA safety standard as part of that coming decision.

Finally, vacatur is a scalpel, not a machete. If the Court deems it equitable, it may narrow vacatur to limit disruptive consequences. 7 U.S.C. § 136n(b) (court may "set aside the order complained of in whole

or in part."). For example, the Court could vacate the registration decision as to use in counties with threatened or endangered species as listed in EPA's draft Biological Evaluation and stay the vacatur as to remaining use. However, Respondents have provided no suggestions as to how to craft such an equitable remedy nor met their burden to show it is warranted. *All. for the Wild Rockies*, 907 F.3d at 1121-22.

CONCLUSION

For the above reasons, the Court should grant the petition for review, hold that EPA has violated FIFRA and the ESA, and vacate the decision.

Respectfully submitted this 13th day of August, 2021.

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§ 136d. Administrative review; suspension

Effective: August 3, 1996
Currentness

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a-1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either--

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide

the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of “imminent hazard”. The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of Title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator

shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator--

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the

registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a-1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines

that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of--

(A) such possession,

(B) the quantity of such pesticide such person possesses, and

(C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

CREDIT(S)

(June 25, 1947, c. 125, § 6, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 984; amended Pub.L. 94-140, § 1, Nov. 28, 1975, 89 Stat. 751; Pub.L. 95-251, § 2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub.L. 95-396, §§ 11, 12, Sept. 30, 1978, 92 Stat. 828; Pub.L. 98-620, Title IV, § 402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub.L. 100-532, Title II, § 201, Title IV, § 404, Title VIII, § 801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub.L. 101-624, Title XIV, § 1494, Nov. 28, 1990, 104 Stat. 3628; Pub.L. 102-237, Title X, § 1006(a)(5), (b)(1), (2), (3)(C) to (E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub.L. 104-170, Title I, §§ 102, 106(a), Title II, §§ 210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

Notes of Decisions (70)

7 U.S.C.A. § 136d, 7 USCA § 136d
Current through PL 117-36 with the exception of PL 116-283, Div. A, Title XVIII, which takes effect January 1, 2022.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136w

§ 136w. Authority of Administrator

Effective: August 3, 1996
Currentness

(a) In general

(1) Regulations

The Administrator is authorized, in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides.

(2) Procedure

(A) Proposed regulations

At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

(B) Final regulations

At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect

of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) Time requirements

The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) Publication in the Federal Register

The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

(3) Congressional committees

At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) Congressional review of regulations

Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

(b) Exemption of pesticides

The Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter.

(c) Other authority

The Administrator, after notice and opportunity for hearing, is authorized--

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is

enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this subchapter as well as to accomplish the other purposes of this subchapter;

(4) to specify those classes of devices which shall be subject to any provision of section 136(q)(1) or section 136e of this title upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this subchapter;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in the ingredient statement.

(d) Scientific advisory panel

(1) In general

The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 136d(b) of this title and of the proposed and final form of regulations issued under subsection (a) within the same time periods as provided for the comments of the Secretary of Agriculture under such section 136d(b) and subsection (a) of this section. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 136d(b) of this title or subsection (a) of this section, as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this subchapter. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator shall publish in the Federal Register the name, address,

and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this subchapter, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(2) Science Review Board

There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be compensated in the same manner as members of the Panel.

(e) Peer review

The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this subchapter by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term “peer review” shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.

CREDIT(S)

(June 25, 1947, c. 125, § 25, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 997; amended Pub.L. 94-140, §§ 2(a), 6, 7, Nov. 28, 1975, 89 Stat. 751, 753; Pub.L. 95-396, § 23, Sept. 30, 1978, 92 Stat. 836; Pub.L. 96-539, §§ 1, 2(a), 4, Dec. 17, 1980, 94 Stat. 3194, 3195; Pub.L. 98-201, § 1, Dec. 2, 1983, 97 Stat. 1379; Pub.L. 98-620, Title IV, § 402(4)(D), Nov. 8, 1984, 98 Stat. 3357; Pub.L. 100-352, § 6(i), June 27, 1988, 102 Stat. 664; Pub.L. 100-532, Title VI, §§ 602, 605, Title VIII, § 801(n), Oct. 25, 1988, 102 Stat. 2678, 2679, 2683; Pub.L. 102-237, Title X, § 1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895; Pub.L. 104-170, Title I, § 104, Title II, § 235, Aug. 3, 1996, 110 Stat. 1490, 1509.)

Notes of Decisions (2)

7 U.S.C.A. § 136w, 7 USCA § 136w
Current through PL 117-36 with the exception of PL 116-283, Div. A, Title XVIII, which takes effect January 1, 2022.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 33. Navigation and Navigable Waters (Refs & Annos)
Chapter 26. Water Pollution Prevention and Control (Refs & Annos)
Subchapter IV. Permits and Licenses (Refs & Annos)

33 U.S.C.A. § 1344

§ 1344. Permits for dredged or fill material

Currentness

(a) Discharge into navigable waters at specified disposal sites

The Secretary may issue permits, after notice and opportunity for public hearings for the discharge of dredged or fill material into the navigable waters at specified disposal sites. Not later than the fifteenth day after the date an applicant submits all the information required to complete an application for a permit under this subsection, the Secretary shall publish the notice required by this subsection.

(b) Specification for disposal sites

Subject to subsection (c) of this section, each such disposal site shall be specified for each such permit by the Secretary (1) through the application of guidelines developed by the Administrator, in conjunction with the Secretary, which guidelines shall be based upon criteria comparable to the criteria applicable to the territorial seas, the contiguous zone, and the ocean under section 1343(c) of this title, and (2) in any case where such guidelines under clause (1) alone would prohibit the specification of a site, through the application additionally of the economic impact of the site on navigation and anchorage.

(c) Denial or restriction of use of defined areas as disposal sites

The Administrator is authorized to prohibit the specification (including the withdrawal of specification) of any defined area as a disposal site, and he is authorized to deny or restrict the use of any defined area for specification (including the withdrawal of specification) as a disposal site, whenever he determines, after notice and opportunity for public hearings, that the discharge of such materials into such area will have an unacceptable adverse effect on municipal water supplies, shellfish beds and fishery areas (including spawning and breeding areas), wildlife, or recreational areas. Before making such determination, the Administrator shall consult with the Secretary. The Administrator shall set forth in writing and make public his findings and his reasons for making any determination under this subsection.

(d) "Secretary" defined

The term "Secretary" as used in this section means the Secretary of the Army, acting through the Chief of Engineers.

(e) General permits on State, regional, or nationwide basis

(1) In carrying out his functions relating to the discharge of dredged or fill material under this section, the Secretary may, after notice and opportunity for public hearing, issue general permits on a State, regional, or nationwide basis for any category of activities involving discharges of dredged or fill material if the Secretary determines that the activities in such category are similar in nature, will cause only minimal adverse environmental effects when performed separately, and will have only minimal cumulative adverse effect on the environment. Any general permit issued under this subsection shall (A) be based on the guidelines described in subsection (b)(1) of this section, and (B) set forth the requirements and standards which shall apply to any activity authorized by such general permit.

(2) No general permit issued under this subsection shall be for a period of more than five years after the date of its issuance and such general permit may be revoked or modified by the Secretary if, after opportunity for public hearing, the Secretary determines that the activities authorized by such general permit have an adverse impact on the environment or such activities are more appropriately authorized by individual permits.

(f) Non-prohibited discharge of dredged or fill material

(1) Except as provided in paragraph (2) of this subsection, the discharge of dredged or fill material--

(A) from normal farming, silviculture, and ranching activities such as plowing, seeding, cultivating, minor drainage, harvesting for the production of food, fiber, and forest products, or upland soil and water conservation practices;

(B) for the purpose of maintenance, including emergency reconstruction of recently damaged parts, of currently serviceable structures such as dikes, dams, levees, groins, riprap, breakwaters, causeways, and bridge abutments or approaches, and transportation structures;

(C) for the purpose of construction or maintenance of farm or stock ponds or irrigation ditches, or the maintenance of drainage ditches;

(D) for the purpose of construction of temporary sedimentation basins on a construction site which does not include placement of fill material into the navigable waters;

(E) for the purpose of construction or maintenance of farm roads or forest roads, or temporary roads for moving mining equipment, where such roads are constructed and maintained, in accordance with best management practices, to assure that flow and circulation patterns and chemical and biological characteristics of the navigable waters are not impaired, that the reach of the navigable waters is not reduced, and that any adverse effect on the aquatic environment will be otherwise minimized;

(F) resulting from any activity with respect to which a State has an approved program under section 1288(b)(4) of this title which meets the requirements of subparagraphs (B) and (C) of such section,

is not prohibited by or otherwise subject to regulation under this section or section 1311(a) or 1342 of this title (except for effluent standards or prohibitions under section 1317 of this title).

(2) Any discharge of dredged or fill material into the navigable waters incidental to any activity having as its purpose bringing an area of the navigable waters into a use to which it was not previously subject, where the flow or circulation of navigable waters may be impaired or the reach of such waters be reduced, shall be required to have a permit under this section.

(g) State administration

(1) The Governor of any State desiring to administer its own individual and general permit program for the discharge of dredged or fill material into the navigable waters (other than those waters which are presently used, or are susceptible to use in their natural condition or by reasonable improvement as a means to transport interstate or foreign commerce shoreward to their ordinary high water mark, including all waters which are subject to the ebb and flow of the tide shoreward to their mean high water mark, or mean higher high water mark on the west coast, including wetlands adjacent thereto) within its jurisdiction may submit to the Administrator a full and complete description of the program it proposes to establish and administer under State law or under an interstate compact. In addition, such State shall submit a statement from the attorney general (or the attorney for those State agencies which have independent legal counsel), or from the chief legal officer in the case of an interstate agency, that the laws of such State, or the interstate compact, as the case may be, provide adequate authority to carry out the described program.

(2) Not later than the tenth day after the date of the receipt of the program and statement submitted by any State under paragraph (1) of this subsection, the Administrator shall provide copies of such program and statement to the Secretary and the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service.

(3) Not later than the ninetieth day after the date of the receipt by the Administrator of the program and statement submitted by any State, under paragraph (1) of this subsection, the Secretary and the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service, shall submit any comments with respect to such program and statement to the Administrator in writing.

(h) Determination of State's authority to issue permits under State program; approval; notification; transfers to State program

(1) Not later than the one-hundred-twentieth day after the date of the receipt by the Administrator of a program and statement submitted by any State under paragraph (1) of this subsection, the Administrator shall determine, taking into account any comments submitted by the Secretary and the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service, pursuant to subsection (g) of this section, whether such State has the following authority with respect to the issuance of permits pursuant to such program:

(A) To issue permits which--

(i) apply, and assure compliance with, any applicable requirements of this section, including, but not limited to, the guidelines established under subsection (b)(1) of this section, and sections 1317 and 1343 of this title;

(ii) are for fixed terms not exceeding five years; and

(iii) can be terminated or modified for cause including, but not limited to, the following:

(I) violation of any condition of the permit;

(II) obtaining a permit by misrepresentation, or failure to disclose fully all relevant facts;

(III) change in any condition that requires either a temporary or permanent reduction or elimination of the permitted discharge.

(B) To issue permits which apply, and assure compliance with, all applicable requirements of section 1318 of this title, or to inspect, monitor, enter, and require reports to at least the same extent as required in section 1318 of this title.

(C) To assure that the public, and any other State the waters of which may be affected, receive notice of each application for a permit and to provide an opportunity for public hearing before a ruling on each such application.

(D) To assure that the Administrator receives notice of each application (including a copy thereof) for a permit.

(E) To assure that any State (other than the permitting State), whose waters may be affected by the issuance of a permit may submit written recommendations to the permitting State (and the Administrator) with respect to any permit application and, if any part of such written recommendations are not accepted by the permitting State, that the permitting State will notify such affected State (and the Administrator) in writing of its failure to so accept such recommendations together with its reasons for so doing.

(F) To assure that no permit will be issued if, in the judgment of the Secretary, after consultation with the Secretary of the department in which the Coast Guard is operating, anchorage and navigation of any of the navigable waters would be substantially impaired thereby.

(G) To abate violations of the permit or the permit program, including civil and criminal penalties and other ways and means of enforcement.

(H) To assure continued coordination with Federal and Federal-State water-related planning and review processes.

(2) If, with respect to a State program submitted under subsection (g)(1) of this section, the Administrator determines that such State--

(A) has the authority set forth in paragraph (1) of this subsection, the Administrator shall approve the program and so notify (i) such State and (ii) the Secretary, who upon subsequent notification from such State that it is administering such program, shall suspend the issuance of permits under subsections (a) and (e) of this section for activities with respect to which a permit may be issued pursuant to such State program; or

(B) does not have the authority set forth in paragraph (1) of this subsection, the Administrator shall so notify such State, which notification shall also describe the revisions or modifications necessary so that such State may resubmit such program for a determination by the Administrator under this subsection.

(3) If the Administrator fails to make a determination with respect to any program submitted by a State under subsection (g)(1) of this section within one-hundred-twenty days after the date of the receipt of such program, such program shall be deemed approved pursuant to paragraph (2)(A) of this subsection and the Administrator shall so notify such State and the Secretary who, upon subsequent notification from such State that it is administering such program, shall suspend the issuance of permits under subsection (a) and (e) of this section for activities with respect to which a permit may be issued by such State.

(4) After the Secretary receives notification from the Administrator under paragraph (2) or (3) of this subsection that a State permit program has been approved, the Secretary shall transfer any applications for permits pending before the Secretary for activities with respect to which a permit may be issued pursuant to such State program to such State for appropriate action.

(5) Upon notification from a State with a permit program approved under this subsection that such State intends to administer and enforce the terms and conditions of a general permit issued by the Secretary under subsection (e) of this section with respect to activities in such State to which such general permit applies, the Secretary shall suspend the administration and enforcement of such general permit with respect to such activities.

(i) Withdrawal of approval

Whenever the Administrator determines after public hearing that a State is not administering a program approved under subsection (h)(2)(A) of this section, in accordance with this section, including, but not limited to, the guidelines established under subsection (b)(1) of this section, the Administrator shall so notify the State, and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days after the date of the receipt of such notification, the Administrator shall (1) withdraw approval of such program until the Administrator determines such corrective action has been taken, and (2) notify the Secretary that the Secretary shall resume the program for the issuance of permits under subsections (a) and (e) of this section for activities with respect to which the State was issuing permits and that such authority of the Secretary shall continue in effect until such time as the Administrator makes the determination described in clause (1) of this subsection and such State again has an approved program.

(j) Copies of applications for State permits and proposed general permits to be transmitted to Administrator

Each State which is administering a permit program pursuant to this section shall transmit to the Administrator (1) a copy of each permit application received by such State and provide notice to the Administrator of every action related to the consideration of such permit application, including each permit proposed to be issued by such State, and (2) a copy of each proposed general permit which such State intends to issue. Not later than the tenth day after the date of the receipt of such permit application or such proposed general permit, the Administrator shall provide copies of such permit application or such proposed general permit to the Secretary and the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service. If the Administrator intends to provide written comments to such State with respect to such permit application or such proposed general permit, he shall so notify such State not later than the thirtieth day after the date of the receipt of such application or such proposed general permit and provide such written comments to such State, after consideration of any comments made in writing with respect to such application or such proposed general permit by the Secretary and the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service, not later than the ninetieth day after the date of such receipt. If such State is so notified by the Administrator, it shall not issue the proposed permit until after the receipt of such comments

from the Administrator, or after such ninetieth day, whichever first occurs. Such State shall not issue such proposed permit after such ninetieth day if it has received such written comments in which the Administrator objects (A) to the issuance of such proposed permit and such proposed permit is one that has been submitted to the Administrator pursuant to subsection (h)(1)(E), or (B) to the issuance of such proposed permit as being outside the requirements of this section, including, but not limited to, the guidelines developed under subsection (b)(1) of this section unless it modifies such proposed permit in accordance with such comments. Whenever the Administrator objects to the issuance of a permit under the preceding sentence such written objection shall contain a statement of the reasons for such objection and the conditions which such permit would include if it were issued by the Administrator. In any case where the Administrator objects to the issuance of a permit, on request of the State, a public hearing shall be held by the Administrator on such objection. If the State does not resubmit such permit revised to meet such objection within 30 days after completion of the hearing or, if no hearing is requested within 90 days after the date of such objection, the Secretary may issue the permit pursuant to subsection (a) or (e) of this section, as the case may be, for such source in accordance with the guidelines and requirements of this chapter.

(k) Waiver

In accordance with guidelines promulgated pursuant to subsection (i)(2) of section 1314 of this title, the Administrator is authorized to waive the requirements of subsection (j) of this section at the time of the approval of a program pursuant to subsection (h)(2)(A) of this section for any category (including any class, type, or size within such category) of discharge within the State submitting such program.

(l) Categories of discharges not subject to requirements

The Administrator shall promulgate regulations establishing categories of discharges which he determines shall not be subject to the requirements of subsection (j) of this section in any State with a program approved pursuant to subsection (h)(2)(A) of this section. The Administrator may distinguish among classes, types, and sizes within any category of discharges.

(m) Comments on permit applications or proposed general permits by Secretary of the Interior acting through Director of United States Fish and Wildlife Service

Not later than the ninetieth day after the date on which the Secretary notifies the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service that (1) an application for a permit under subsection (a) of this section has been received by the Secretary, or (2) the Secretary proposes to issue a general permit under subsection (e) of this section, the Secretary of the Interior, acting through the Director of the United States Fish and Wildlife Service, shall submit any comments with respect to such application or such proposed general permit in writing to the Secretary.

(n) Enforcement authority not limited

Nothing in this section shall be construed to limit the authority of the Administrator to take action pursuant to section 1319 of this title.

(o) Public availability of permits and permit applications

A copy of each permit application and each permit issued under this section shall be available to the public. Such permit application or portion thereof, shall further be available on request for the purpose of reproduction.

(p) Compliance

Compliance with a permit issued pursuant to this section, including any activity carried out pursuant to a general permit issued under this section, shall be deemed compliance, for purposes of sections 1319 and 1365 of this title, with sections 1311, 1317, and 1343 of this title.

(q) Minimization of duplication, needless paperwork, and delays in issuance; agreements

Not later than the one-hundred-eightieth day after December 27, 1977, the Secretary shall enter into agreements with the Administrator, the Secretaries of the Departments of Agriculture, Commerce, Interior, and Transportation, and the heads of other appropriate Federal agencies to minimize, to the maximum extent practicable, duplication, needless paperwork, and delays in the issuance of permits under this section. Such agreements shall be developed to assure that, to the maximum extent practicable, a decision with respect to an application for a permit under subsection (a) of this section will be made not later than the ninetieth day after the date the notice for such application is published under subsection (a) of this section.

(r) Federal projects specifically authorized by Congress

The discharge of dredged or fill material as part of the construction of a Federal project specifically authorized by Congress, whether prior to or on or after December 27, 1977, is not prohibited by or otherwise subject to regulation under this section, or a State program approved under this section, or section 1311(a) or 1342 of this title (except for effluent standards or prohibitions under section 1317 of this title), if information on the effects of such discharge, including consideration of the guidelines developed under subsection (b)(1) of this section, is included in an environmental impact statement for such project pursuant to the National Environmental Policy Act of 1969 and such environmental impact statement has been submitted to Congress before the actual discharge of dredged or fill material in connection with the construction of such project and prior to either authorization of such project or an appropriation of funds for such construction.

(s) Violation of permits

(1) Whenever on the basis of any information available to him the Secretary finds that any person is in violation of any condition or limitation set forth in a permit issued by the Secretary under this section, the Secretary shall issue an order requiring such person to comply with such condition or limitation, or the Secretary shall bring a civil action in accordance with paragraph (3) of this subsection.

(2) A copy of any order issued under this subsection shall be sent immediately by the Secretary to the State in which the violation occurs and other affected States. Any order issued under this subsection shall be by personal service and shall state with reasonable specificity the nature of the violation, specify a time for compliance, not to exceed thirty days, which the Secretary determines is reasonable, taking into account the seriousness of the violation and any good faith efforts to comply with applicable requirements. In any case in which an order under this subsection is issued to a corporation, a copy of such order shall be served on any appropriate corporate officers.

(3) The Secretary is authorized to commence a civil action for appropriate relief, including a permanent or temporary injunction for any violation for which he is authorized to issue a compliance order under paragraph (1) of this subsection. Any action under this paragraph may be brought in the district court of the United States for the district in which the defendant is located or

resides or is doing business, and such court shall have jurisdiction to restrain such violation and to require compliance. Notice of the commencement of such acton[1] shall be given immediately to the appropriate State.

(4) Any person who violates any condition or limitation in a permit issued by the Secretary under this section, and any person who violates any order issued by the Secretary under paragraph (1) of this subsection, shall be subject to a civil penalty not to exceed $25,000 per day for each violation. In determining the amount of a civil penalty the court shall consider the seriousness of the violation or violations, the economic benefit (if any) resulting from the violation, any history of such violations, any good-faith efforts to comply with the applicable requirements, the economic impact of the penalty on the violator, and such other matters as justice may require.

(t) Navigable waters within State jurisdiction

Nothing in this section shall preclude or deny the right of any State or interstate agency to control the discharge of dredged or fill material in any portion of the navigable waters within the jurisdiction of such State, including any activity of any Federal agency, and each such agency shall comply with such State or interstate requirements both substantive and procedural to control the discharge of dredged or fill material to the same extent that any person is subject to such requirements. This section shall not be construed as affecting or impairing the authority of the Secretary to maintain navigation.

CREDIT(S)

(June 30, 1948, c. 758, Title IV, § 404, as added Pub.L. 92-500, § 2, Oct. 18, 1972, 86 Stat. 884; amended Pub.L. 95-217, § 67(a), (b), Dec. 27, 1977, 91 Stat. 1600; Pub.L. 100-4, Title III, § 313(d), Feb. 4, 1987, 101 Stat. 45.)

Notes of Decisions (537)

Footnotes

1 So in original. Probably should be “action”.

33 U.S.C.A. § 1344, 33 USCA § 1344

Current through PL 117-36 with the exception of PL 116-283, Div. A, Title XVIII, which takes effect January 1, 2022.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Regulation

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.16

§ 402.16 Reinitiation of consultation.

Effective: October 28, 2019
Currentness

(a) Reinitiation of consultation is required and shall be requested by the Federal agency or by the Service, where discretionary Federal involvement or control over the action has been retained or is authorized by law and:

(1) If the amount or extent of taking specified in the incidental take statement is exceeded;

(2) If new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered;

(3) If the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or

(4) If a new species is listed or critical habitat designated that may be affected by the identified action.

(b) An agency shall not be required to reinitiate consultation after the approval of a land management plan prepared pursuant to 43 U.S.C. 1712 or 16 U.S.C. 1604 upon listing of a new species or designation of new critical habitat if the land management plan has been adopted by the agency as of the date of listing or designation, provided that any authorized actions that may affect the newly listed species or designated critical habitat will be addressed through a separate action-specific consultation. This exception to reinitiation of consultation shall not apply to those land management plans prepared pursuant to 16 U.S.C. 1604 if:

(1) Fifteen years have passed since the date the agency adopted the land management plan prepared pursuant to 16 U.S.C. 1604; and

(2) Five years have passed since the enactment of Public Law 115–141 [March 23, 2018] or the date of the listing of a species or the designation of critical habitat, whichever is later.

Credits

[84 FR 45017, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (81)

Current through August 5, 2021; 86 FR 43074.

End of Document

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 20-70801, 20-70787

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FOR THE NINTH CIRCUIT

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