No. 26-1094

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE ENVIRONMENTAL WORKING GROUP,
PETITIONER

On Petition for a Writ of Mandamus and for Relief from Unreasonably Delayed Agency Action by the Environmental Protection Agency

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PETITION FOR WRIT OF MANDAMUS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to District of Columbia Circuit Rule 28(a)(1), counsel for Petitioner Environmental Working Group certifies as follows:

A. Parties

Petitioner Environmental Working Group is a nonprofit, tax-exempt organization. Respondent is the United States Environmental Protection Agency, which administers and enforces FIFRA, the FFDCA, and related statutes. No intervenors have appeared, and Petitioner is not aware of any amici curiae in this matter.

B. Rulings Under Review

Petitioner Environmental Working Group seeks a writ of mandamus compelling EPA to take action unlawfully withheld or unreasonably delayed in response to its petition requesting that EPA revoke or modify the tolerance for glyphosate on oats and restrict pre-harvest uses that drive dietary exposure, as required by the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act.

C. Related Cases

Petitioner is not aware of any related cases currently pending before this Court or any other court within the meaning of D.C. Circuit Rule 28(a)(1)(C).

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioner Environmental Working Group makes the following disclosure. Environmental Working Group is a nonprofit corporation organized under the laws of the District of Columbia. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock or membership interests.

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GLOSSARY

Term	Definition
APA	Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.
EPA	United States Environmental Protection Agency
EWG	Environmental Working Group
FFDCA	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 et seq.

INTRODUCTION

This case concerns EPA's failure to act on evidence that glyphosate, the most widely used herbicide in the United States and globally, is exposing infants and young children to harmful levels through everyday foods. Congress required EPA to ensure that pesticide residues in food are safe, with particular protection for children. Yet, more than seven years after being presented with substantial scientific evidence that the current tolerance for glyphosate in oats may not meet that standard, EPA has failed to make any final, reviewable determination.

In 2018, Petitioner Environmental Working Group ("EWG"), together with co-petitioners[1], filed a formal administrative petition ("the Petition") under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(d), requesting that EPA revoke or modify the glyphosate tolerance for oats and restrict the use of glyphosate as a pre-harvest desiccant. As amended in 2019, the Petition presents evidence that existing tolerance levels are not protective of infants and young children and that pre-harvest

[1] EWG's co-petitioners included Amy's Kitchen, Inc.; Ben & Jerry's Homemade, Inc.; Clif Bar and Company; Earth's Best Organic; GrandyOats; Happy Family Organics; Independent Natural Food Retailers Association; KIND Healthy Snacks; Lundberg Family Farms; MegaFood; MOM's Organic Market; National Co+op Grocers; Nature's Path Foods Inc.; One Degree Organic Foods USA, Inc.; Organic Valley; Patagonia Provisions; PCC Community Markets; and Stonyfield Farm, Inc.

use of glyphosate predictably increases dietary exposure in foods commonly consumed by children.

Instead of issuing the decision required by law, EPA has declined to resolve the Petition and has tethered any response to a broader registration review process, stating only that it anticipates addressing the Petition in connection with a possible decision in 2026. That is neither a deadline, nor a commitment. It is an open-ended deferral entirely within the agency's control.

In the meantime, EPA leaves in place a food safety standard it has never evaluated in light of the Petition's evidence, including evidence that infants and young children, who face the highest dietary exposure, may be at particular risk. The statute does not permit EPA to postpone that determination indefinitely while exposure continues.It also prevents any judicial review of that evidence from occurring.

EWG therefore seeks a writ of mandamus compelling EPA to perform the discrete act required by law by issuing a final, reviewable response resolving the Petition.

STATEMENT REGARDING ADDENDA

Relevant statutes, regulations, supporting declarations, and exhibits are submitted as separate addenda.

STATEMENT OF JURISDICTION AND APPLICABLE LAW

This Court has jurisdiction pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(h)(1), which vests exclusive jurisdiction in the United States Court of Appeals for the District of Columbia Circuit to review final orders of the EPA establishing, modifying, or revoking pesticide tolerances.

Although EPA has failed to issue a final response to EWG's Petition this Court has authority under the Administrative Procedure Act ("APA") to compel agency action unlawfully withheld or unreasonably delayed. 5 U.S.C. § 706(1). The APA requires agencies to conclude matters presented to them "within a reasonable time." *Id*. § 555(b).

This Court also has authority under the All Writs Act, 28 U.S.C. § 1651(a), to issue a writ of mandamus in aid of its prospective jurisdiction. Mandamus relief is appropriate when an agency's inaction prevents the issuance of a final, reviewable order and thereby frustrates this Court's exercise of its exclusive jurisdiction. *N. States Power Co. v. U.S. Dep't of Energy*, 128 F.3d at 758.

EPA's failure to respond to EWG's Petition has prevented the issuance of a final, reviewable agency action and delayed this Court's exercise of its jurisdiction under the FFDCA. Accordingly, this Court has jurisdiction to

consider this Petition and to grant appropriate relief compelling EPA to perform the discrete, legally required act of issuing a final decision.

ISSUE PRESENTED FOR REVIEW

Whether the EPA's failure, for more than seven years, to issue a final, reviewable decision resolving EWG's Petition seeking revision of the glyphosate tolerance on oats and prohibition of pre-harvest desiccation constitutes agency action unlawfully withheld or unreasonably delayed in violation of the Administrative Procedure Act warranting mandamus relief.

BACKGROUND

I. The Statutory Framework Imposes a Mandatory Duty on EPA to Act.

Mandamus relief is appropriate where an agency has a clear duty to act, the petitioner has a clear right to relief, and no other adequate remedy exists. *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984). Although courts do not use mandamus to direct how an agency exercises its discretion, they may compel an agency to perform a discrete, legally required act that has been unlawfully withheld or unreasonably delayed. 5 U.S.C. § 706(1); *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004).

The Federal Food, Drug, and Cosmetic Act ("FFDCA") authorizes EPA to establish and maintain tolerances for pesticide chemical residues in food. 21 U.S.C. § 346a. EPA may allow a pesticide residue in food only if it determines that the tolerance is "safe," meaning that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide, including dietary exposure. *Id.* § 346a(b)(2)(A)(ii). Congress strengthened and clarified these requirements through the Food Quality Protection Act of 1996 ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489, which amended the FFDCA to establish a uniform, health-based safety standard for pesticide residues in food.

In making safety determinations, Congress directed EPA to afford special protection to infants and children. *Id.* § 346a(b)(2)(C). The statute requires EPA to ensure that tolerances are protective of children and, in most circumstances, to apply an additional tenfold margin of safety to account for pre- and post-natal toxicity and data uncertainties. *Id*. These provisions reflect Congress's judgment that children are uniquely vulnerable to pesticide exposure and that tolerance decisions must be both health-protective and timely.

The FFDCA further establishes a mandatory petition process to ensure agency accountability. Any person may petition EPA to establish, modify, or

revoke a pesticide tolerance. 21 U.S.C. § 346a(d)(1). EPA must issue a final decision either granting or denying the requested relief, supported by a reasoned explanation. *Id*. § 346a(d)(4)(A). That decision constitutes final agency action subject to judicial review in the courts of appeals. *Id*. § 346a(h)(1). EPA thus has a discrete statutory duty to resolve a properly filed petition. *See Norton*, 542 U.S. at 64 (courts may compel agency action where a statute requires a discrete, legally required act).

Independent of the FFDCA, the Administrative Procedure Act ("APA") requires agencies to conclude matters presented to them "within a reasonable time." 5 U.S.C. § 555(b). When an agency fails to take a discrete action it is required to take, courts "shall compel agency action unlawfully withheld or unreasonably delayed." *Id*. § 706(1). This duty is enforceable where an agency has failed to act on a matter it is required to decide. *See SUWA*, 542 U.S. at 64; *In re Ctr. for Biological Diversity*, 53 F.4th 665, 670 (D.C. Cir. 2022).

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which requires periodic registration review of approved pesticides. 7 U.S.C. § 136a(g). Registration review is a multi-year, iterative process through which EPA evaluates whether existing pesticide registrations continue to meet applicable statutory standards. *Id*.

The FIFRA registration process is distinct from, and does not displace, the petition process established under the FFDCA. *See League of United Latin American Citizens v. Regan*, 996 F.3d 673, 715 (9th Cir. 2021) ("The EPA's obligations under the FFDCA are linked to a single issue, safety, but they are mandatory. The whole point of the FQPA would be destroyed if the EPA could exercise unfettered discretion to defer safety considerations until it was prepared to engage in the full multi-factor balancing assessment required for FIFRA registration.").

II. Dietary Glyphosate Exposure in Food Poses Heightened Risks to Infants and Young Children.

Glyphosate is the most widely used herbicide in the United States and globally. APP-001, 066; Dr. Andrews Decl. ¶5. Its use extends beyond weed control during crop growth and includes pre-harvest applications on certain crops, including oats, often for weed control immediately prior to the harvest. APP-066; Dr. Andrews Decl. ¶5. When applied at this stage of the growing cycle, glyphosate can function to accelerate crop dry-down and facilitate harvest, resulting in residues in harvested grain and in foods made from those grains. APP-066; Dr. Andrews Decl. ¶5. Because these applications occur shortly before harvest, glyphosate can be directly

transported into the edible portion of the plants where it does not readily break down. APP-066; Dr. Andrews Decl. ¶5.

As a result of this late-stage use, dietary exposure to glyphosate through food is pervasive. APP-066; Dr. Andrews Decl. ¶6. Multiple testing efforts, including those conducted by EWG and others, have detected glyphosate residues in a wide range of commonly consumed foods, including oat-based cereals, snacks, and other products frequently marketed to and consumed by children.[2] APP-003, 067; Dr. Andrews Decl. ¶6.

Oats are a particularly significant source of dietary exposure for infants and young children. APP-067; Dr. Andrews Decl. ¶7. Oat-based products are widely used in infant cereals, breakfast foods, and snack products consumed regularly, often daily, by young children. APP-067; Dr. Andrews Decl. ¶7. Because children consume more food per unit of body weight than adults, repeated consumption of oat-based foods containing glyphosate residues can contribute disproportionately to aggregate dietary

[2] EWG's testing detected glyphosate residues in 43 of 45 oat-based food products tested, including products specifically marketed to children. APP-006, 067; Dr. Andrews Decl. ¶6. In 31 of those products, glyphosate levels exceeded 0.16 parts per million, an EWG scientists' calculated benchmark derived from the California's proposed No Significant Risk Level of 1.1 milligrams/day with added Food Quality Protection Act safety factors, and several products contained residues exceeding 1.0 part per million. APP-006, 067; Dr. Andrews Decl. ¶7.

exposure during early developmental periods.APP-67; Dr. Andrews Decl. ¶7.

EPA has acknowledged that young children experience the highest body weight dietary exposure to glyphosate. APP-67; Dr. Andrews Decl. ¶7. In its own risk assessments, EPA has identified children aged one to two years as the population subgroup with the greatest exposure relative to body weight. APP-067; Dr. Andrews Decl. ¶7. EPA has further recognized that this elevated exposure reflects differences in consumption patterns and body weight, which can result in higher exposure on a per-body-weight basis for infants and young children. APP-068; Dr. Andrews Decl. ¶8. Separately, EPA has recognized that infants and young children may be more susceptible to the effects of chemical exposure during critical windows of developmental APP-068; Dr. Andrews Decl. ¶9.

Dietary exposure to glyphosate results in measurable internal exposure. Biomonitoring studies cited in the Petition detected glyphosate or its primary metabolite in a majority of tested urine samples, with detection frequencies increasing over time. APP-002, 007, 0008; Dr. Andrews Decl. ¶10. One longitudinal analysis cited in the Petition found that detection rates for glyphosate in American adults increased from approximately 12 percent of samples in the early 1990s to more than 70 percent by 2016. APP-002,

068; Dr. Andrews Decl. ¶10. These findings confirm that glyphosate exposure is not theoretical or episodic, but widespread, and that dietary intake results in measurable body burden. APP-068; Dr. Andrews Decl. ¶10.

Scientific concern regarding glyphosate exposure leading to health harm has existed for decades. APP-068; Dr. Andrews Decl. ¶10. In 2015, the International Agency for Research on Cancer classified glyphosate as "probably carcinogenic to humans," based on "sufficient" evidence of carcinogenicity in experimental animals and limited evidence of carcinogenicity in humans. APP-069; Dr. Andrews Decl. ¶11. The human evidence included epidemiological studies showing positive associations between glyphosate exposure and non-Hodgkin lymphoma. APP-010, 069; Dr. Andrews Decl. ¶11.

EPA has not maintained a consistent or unequivocal position on glyphosate's carcinogenic potential. Over time, EPA's assessments have reflected internal disagreement, acknowledged data gaps, and shifting analytical approaches. APP-009. EPA scientists and advisory panels have recognized statistically significant findings of health harm in animal studies, dose-response trends, and epidemiological associations that warranted further consideration. APP-012, 069; Dr. Andrews Decl. ¶12. EPA's own Scientific Advisory Panel identified inconsistencies in the evaluation of

conflicting data and dismissal of positive finding trends within EPA's risk-assessment framework. APP-014, 069; Dr. Andrews Decl. ¶12. EPA has acknowledged that some epidemiological evidence shows a positive association between glyphosate exposure and cancer outcomes, while nonetheless characterizing that evidence as insufficient to trigger a carcinogenic risk assessment. APP-009-10, 069; Dr. Andrews Decl. ¶12. During the time EPA has not acted on the petition, glyphosate has continued to be used in food production, including on oats, and consumers have continued to be exposed through commonly consumed foods. APP-073; Dr. Andrews Decl. ¶24. This failure underscores the need for a final, reviewable determination addressing whether the current tolerance satisfies the FFDCA's health-protective standard.

III. EWG's Petition to Modify Glyphosate Tolerances on Oats and Restrict Pre-harvest Uses.

On September 27, 2018, EWG and co-petitioners submitted the Petition to the EPA pursuant to the FFDCA, 21 U.S.C. § 346a(d). APP-001. EWG amended the Petition on March 28, 2019. APP-001.

First, the Petition requested that EPA modify the tolerance for glyphosate residues on oats. APP-001; 071; Dr. Andrews Decl. ¶18. At the time the Petition was filed, the tolerance permitted residues of up to 30 parts per million (ppm). APP-070; Dr. Andrews Decl. ¶15. The Petition explained

that this tolerance had been substantially increased in the 1990s to harmonize U.S. standards with international trade requirements, rather than based on new evidence demonstrating greater safety. APP-070; Dr. Andrews Decl. ¶15. The Petition requested that EPA reduce the tolerance to 0.1 ppm, the level that applied prior to the 1997 and 2008 increase, and evaluate whether any higher tolerance could be shown to meet the FFDCA's safety standard, particularly for infants and children. APP-001-02. Because glyphosate is so widely used, and because oats and oat-derived products are a common part of the American diet, particularly for infants and young children, dietary exposure to glyphosate through food is effectively unavoidable for many consumers. APP-070; Dr. Andrews Decl. ¶16. Individuals cannot reasonably eliminate exposure through personal choice alone, especially where foods perceived as healthy or appropriate for children are among the primary sources of exposure, nor should they be expected to do so. APP-070-71; Dr. Andrews Decl. ¶16.

Second, the Petition requested that EPA prohibit the use of glyphosate as a pre-harvest desiccant on oats. APP-001, 071; Dr. Andrews Decl. ¶19. The Petition explained that this agricultural practice involves application of glyphosate shortly before harvest and results in significantly higher residues in harvested grain and finished food. APP-071; Dr. Andrews Decl. ¶19. The

Petition further explained that pre-harvest desiccation is not necessary for weed control and that its primary effect is to facilitate harvesting, rather than to protect crop yield. APP-071; Dr. Andrews Decl. ¶19.

In support of these requests, the Petition presented scientific evidence concerning dietary exposure to glyphosate, including data showing that oat-based foods frequently consumed by children contain higher glyphosate residues than many other staple grains. APP-072; Dr. Andrews Decl. ¶20. The Petition emphasized that young children experience the highest dietary exposure to glyphosate and that the existing tolerance does not adequately account for the potential health risks associated with that level of exposure, including carcinogenic risks. APP-008-010, 072; Dr. Andrews Decl. ¶10. The Petition requested that EPA respond by granting or denying the requested relief and providing a reasoned explanation supported by the administrative record.

IV. EPA's Actions and Continued Failure to Act following EWG's Petition.

EPA accepted the Petition for review, published it for public comment and received substantial public input. APP-022-23 Yet, EPA did not issue a final, reviewable decision. APP-073; Dr. Andrews Decl. ¶22. In January 2020, EPA expressly recognized the Petition in its Interim Registration

Review Decision ("Interim Decision") but made clear that the decision "does not constitute EPA's response" to EWG's Petition. APP-025. Instead, EPA stated that it *anticipated* issuing a response at a later time in 2020. APP-025. EPA did not do so. APP-073, Dr. Andrews Decl. ¶22.

In 2022, in litigation challenging EPA's Interim Decision, the Ninth Circuit vacated and remanded the human health portion of the decision, holding that EPA's conclusion regarding cancer risk was not supported by substantial evidence and that EPA had violated the Endangered Species Act by failing to make the required effects determinations. *See NRDC v. EPA*, 38 F.4th 34, 43 (9th Cir. 2022).

Following that decision, EPA withdrew the Interim Decision and confirmed that it had not resolved the Petition. APP-056. EPA stated that it intends to respond to the Petition "before issuing a final registration review decision for glyphosate" and indicated that it anticipates issuing that final registration review decision in 2026. APP-056.

EPA has thus taken the position that it will not resolve the Petition independently, but instead will address it in connection with the broader registration review process after completing its ongoing work on remand. That approach effectively defers a discrete duty imposed by the FFDCA to a multi-year process of EPA's own design and leaves the Petition without any

defined timeline for resolution.

SUMMARY OF ARGUMENT

EPA has unlawfully withheld and unreasonably delayed action on EWG's Petition seeking to revise the glyphosate tolerance for oats and restrict the use of glyphosate as a pre-harvest desiccant. For more than seven years, EPA has neither granted nor denied the petition.

That inaction has real consequences for public health, particularly for infants and young children. The petition presents evidence that the current tolerance may not be protective of children, yet EPA has never made a final, reviewable determination addressing that evidence. As a result, EPA continues to permit dietary exposure to glyphosate through foods commonly consumed by children without deciding whether that exposure satisfies the FFDCA's safety standard. Congress required EPA to ensure that pesticide tolerances are safe, with particular protection for children. EPA's failure to act leaves that mandate unfulfilled.

First, EPA's delay fails any plausible "rule of reason." EPA has allowed the Petition to remain unresolved for years and has deferred decisionmaking to a broader registration review process governed by a self-imposed, nonbinding timeline that it merely anticipates completing in 2026. That open-ended, self-imposed timeline provides no assurance of

action and cannot justify prolonged inaction on a discrete statutory duty. Additionally, FIFRA registration review does not displace EPA's independent obligation under the FFDCA to resolve a tolerance petition, nor does it permit EPA to defer that duty indefinitely. EPA's decision to fold the petition into a broader, multi-year process of its own design cannot excuse its failure to act.

Second, the delay is especially intolerable because it concerns human health, and specifically children's health. The petition addresses dietary exposure to a pesticide that EPA acknowledges disproportionately affects infants and young children. Where potential risks to children are at stake, delay is least tolerable and weighs heavily in favor of relief.

Finally, EPA's inaction frustrates the statutory scheme Congress established by preventing judicial review altogether. The FFDCA provides for direct appellate review of final tolerance decisions, but EPA's refusal to issue such a decision effectively insulates its inaction from review. Absent mandamus relief, EPA can continue to avoid resolving the petition indefinitely.

STANDING

EWG has standing to seek mandamus relief because EPA's prolonged failure to respond to EWG's Petition deprives EWG of a procedural right

guaranteed by statute and increases the risk of harm to concrete interests Congress sought to protect, including human health and the safety of infants and young children. That procedural injury alone is sufficient to establish standing in an unreasonable-delay case. EWG also independently satisfies Article III through organizational and associational standing.

To establish injury in fact, a petitioner must ordinarily show an invasion of a legally protected interest that is concrete and particularized. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). When a petitioner asserts the denial of a procedural right conferred by statute, however, courts apply a "substantially relaxed" standing inquiry. *Id*. at 572 n.7; *Mass v. EPA*, 549 U.S. 497, 517–18 (2007).

In procedural-injury cases, a petitioner need not demonstrate that compliance with the required procedure would have changed the ultimate outcome. *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94–95 (D.C. Cir. 2002). It is sufficient that the agency's failure to follow required procedures deprives the petitioner of a legally mandated decisionmaking process and increases the risk of harm to concrete interests protected by the statute. *Public Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32–33 (D.C. Cir. 1984).

The FFDCA authorizes any person to petition EPA to modify or revoke a pesticide tolerance, and the APA entitles petitioners to a reasoned response within a reasonable time. *See* 21 U.S.C. § 346a(d); 5 U.S.C. §§ 555(b), 706(1). EPA's failure to act deprives EWG of that process and prevents the issuance of a final, reviewable decision. That deprivation is itself a concrete injury. This Court has repeatedly recognized that the denial of a required agency decision, and the resulting inability to obtain judicial review, constitutes a cognizable injury in unreasonable-delay cases. *See In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992); *Telecomms. Research & Action Ctr.*, 750 F.2d at 79.

Because this procedural right is designed to protect human health, particularly the health of infants and young children, the showing required to establish standing is especially modest. *See Mass.*, 549 U.S. at 517–18. EPA's continued inaction increases the risk that pesticide residues remain in foods consumed by children without the statutorily required determination that those residues are safe. That increased risk is sufficient to establish injury in fact.

EPA's failure to act has independently injured EWG as an organization. An organization suffers injury in fact when agency action or inaction "perceptibly impairs" its ability to carry out its mission and forces it

to divert resources. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015). EWG is a nonprofit organization dedicated to empowering people to live healthier lives in a healthier environment. APP-073; Walsh Decl. ¶3. It advances that mission through scientific research and widely used consumer-facing tools that inform the public about chemical exposures, particularly those affecting infants and children. APP-073; Walsh Decl. ¶3.

EPA's prolonged failure to respond to the Petition has directly impaired those activities. APP-076; Walsh Decl. ¶9. Without a final agency decision addressing whether glyphosate tolerances for oats are safe for infants and children, EWG cannot accurately inform the public, assess EPA's regulatory position, or provide clear guidance to families seeking to reduce exposure.APP-076; Walsh Decl. ¶9.

That regulatory silence has created confusion among EWG's supporters and undermined its ability to fulfill its mission of providing clear, science-based guidance. APP-076; Walsh Decl. ¶9. EPA's inaction has also forced EWG to devote additional staff time and organizational resources to explaining regulatory uncertainty and responding to supporter concerns that should have been resolved through timely agency action. APP-076; Walsh

Decl. ¶10. This diversion of resources and impairment of core activities constitutes a classic organizational injury.

EWG also has standing to bring this action on behalf of its supporters. An organization has associational standing where (1) its members would have standing in their own right; (2) the interests at stake are germane to the organization's purpose; and (3) the claims and relief do not require individual participation. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Courts have recognized that such organizations may assert associational standing where they possess the functional indicia of membership. *See American Legal Found. v. FCC*, 808 F.2d 84, 90–92 (D.C. Cir. 1987).

EWG maintains a large and identifiable base of supporters who regularly engage with its work, rely on its research and guidance, and support its activities financially.APP-075; Walsh Decl. ¶7. EWG's supporters include parents and caregivers concerned about chemical exposures in foods consumed by infants and young children. APP-075; Walsh Decl. ¶7. One such supporter is a grandparent of multiple young children who regularly consume oat-based foods and who relies on EWG's research to make informed decisions about food safety. APP-078; Hirshberg Decl. ¶¶4, 5, 8. The supporter is concerned that glyphosate residues in

oat-based foods may pose risks to children and that EPA has failed to determine whether existing tolerances adequately protect infants and young children. APP-079; Hirshberg Decl. ¶11.EPA's failure to act leaves the supporter unable to know whether the foods consumed by their family are adequately protected by federal safety standards and prolongs exposure to a pesticide that may be difficult to avoid through individual consumer choices alone. APP-080; Hirshberg Decl. ¶11. Those injuries, including uncertainty regarding safety, inability to rely on regulatory protections, and ongoing exposure to a potentially harmful substance, are concrete and particularized. Because at least one supporter would have standing to sue in his or her own right, EWG may assert associational standing.

Finally, EWG's injuries are directly traceable to EPA's failure to act and would be redressed by the relief sought. An order requiring EPA to issue a final, reviewable decision would restore the decisionmaking process Congress mandated and reduce the risk of ongoing harm, which is sufficient for Article III. *See Massachusetts v. EPA*, 549 U.S. 497, 517–18, 525–26 (2007).

ARGUMENT

EPA's failure to respond to EWG's Petition constitutes agency action unlawfully withheld and unreasonably delayed in violation of the APA. The

governing statutes impose a clear duty on EPA to respond to properly filed petitions seeking modification of a pesticide tolerance, and EPA has offered no lawful justification for allowing that petition to remain undecided for more than seven years.

I. EPA Has Unlawfully Withheld Action It Is Required to Take on EWG's Petition.

Mandamus is an extraordinary remedy, appropriate when a petitioner demonstrates a clear entitlement to relief and a corresponding, nondiscretionary duty on the part of the agency. *See N. States Power Co. v. U.S. Dep't of Energy*, 128 F.3d 754, 758 (D.C. Cir. 1997); *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000) (describing mandamus as reserved for clear violations of a duty to act). To obtain such relief, a petitioner must show that the agency has failed to perform a clear legal duty, that no other adequate means exist to secure the requested relief, and that the circumstances present compelling equitable grounds warranting judicial intervention. *See In re Nat'l Nurses United*, 47 F.4th 746, 752 (D.C. Cir. 2022); *In re Core Commc'ns, Inc.*, 531 F.3d 849, 860 (D.C. Cir. 2008); *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005). EWG satisfies each of these requirements here.

First, EPA has a clear statutory duty to respond to EWG's administrative petition seeking modification of a pesticide tolerance under the FFDCA. *See* 21 U.S.C. § 346a(d)(4)(A). The action EWG seeks to compel is discrete and legally required: a final, reviewable response resolving the Petition. EWG does not ask this Court to dictate the substance of EPA's decision or to resolve the merits of the underlying petition. Instead, it asks this Court to require that EPA make one.

EPA's duty to act was triggered years ago. EWG filed its original petition in September 2018 and amended it in March 2019. Instead, EPA has deferred resolution of the petition to the broader registration review process, stating only that it *anticipates* addressing the petition in connection with a potential decision in 2026. APP-061. But an agency's anticipation is not a commitment, and it provides no assurance that action will occur at all.

Further, EPA's failure to act is not merely delay; it is the failure to take a discrete agency action that the statute requires. *See* 5 U.S.C. § 706(1); *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004). EPA has already accepted the petition, developed an extensive administrative record, and conducted multiple risk assessments addressing the issues presented. By neither granting nor denying the Petition, EPA has unlawfully withheld agency action required by statute.

Second, EWG has a clear right to relief. The FFDCA establishes a petition process through which interested parties may seek modification of pesticide tolerances and obtain judicial review of EPA's response. 21 U.S.C. § 346a(d), (h)(1). That statutory scheme guarantees a decision, and EPA's failure to respond deprives EWG of the very process Congress provided.

Third, EWG has no other adequate remedy at law. The FFDCA permits judicial review only of final agency action. 21 U.S.C. § 346a(h)(1). Because EPA has issued no response to the Petition, there is no final, reviewable decision and no administrative recourse available to EWG. Absent mandamus, EPA's inaction would continue to evade judicial review altogether. A writ of mandamus compelling EPA to issue a final response is therefore the only adequate means of relief.

II. The TRAC Factors Compel Mandamus Relief.

To determine whether an agency has unreasonably delayed action, this Court applies the "*TRAC* factors" established by this Court in *Telecommunications Research & Action Center v. FCC* , 750 F.2d 70, 79–80 (D.C. Cir. 1984). The *TRAC* factors include: (1) whether the time an agency takes to act is governed by a rule of reason; (2) whether Congress has provided a timetable or other indication of the expected pace of agency action; (3) whether delays that might be tolerable in the sphere of economic

regulation are less acceptable where human health and welfare are at stake; (4) the effect of expediting delayed action on competing agency priorities; (5) the nature and extent of the interests prejudiced by the delay; and (6) whether the court need find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed. *TRAC*, 750 F.2d at 80. These factors guide a holistic, equitable inquiry into whether delay is "so egregious as to warrant mandamus." *Id.* at 79.

Applied here, EPA's prolonged failure to issue a final, reviewable response to EWG's petition constitutes unreasonable delay warranting mandamus relief.

A. EPA's Seven-Year Delay, Driven by Its Deferral to Registration Review, Violates Any Plausible Rule of Reason.

The first TRAC factor, the "rule of reason," strongly favors relief because EPA's delay cannot be reconciled with any reasonable timeline. *See Public Citizen*, 740 F.2d at 32 (D.C. Cir. 1984) (explaining that excessive delay undermines agency accountability and creates uncertainty for affected parties); *In re American Rivers*, 372 F.3d 413, 419 (D.C. Cir. 2004) ("[A] reasonable time for agency action is typically counted in weeks or months, not years."); *In re National Nurses United*, 47 F.4th 746, 753–54 (D.C. Cir.

2022) (agencies may not "indefinitely postpone decisions that Congress has required them to make").

EWG filed its petition in 2018 and amended it in 2019. Rather than issuing the decision required by statute, EPA has declined to resolve the Petition and instead deferred action to the broader registration review process, stating that it would be "appropriate" to respond only after completing its ongoing review on remand and in connection with a future final registration review decision, which it merely anticipates issuing in 2026. APP-060. But an agency's anticipation is not a commitment, and it provides no assurance that action will occur at all. An agency cannot satisfy *TRAC* by postponing action to an open-ended timeline of its own making, particularly after its duty to act has long since been triggered. Courts evaluate delay based on elapsed time and statutory obligations, not on an agency's projection of future action. *See In re Center for Biological Diversity,* 53 F.4th 665 (D.C. Cir. 2022).

Seven years of inaction on a discrete statutory duty is far beyond what this Court has deemed reasonable and independently warrants mandamus relief. This Court has repeatedly granted mandamus in analogous circumstances where agencies allowed required actions to languish for years without resolution. *See In re Bluewater Network*, 234 F.3d at 1315–16

(finding a "blatant violation" where the agency failed to complete a required rulemaking despite taking preliminary steps); *In re Am. Rivers*, 372 F.3d 413, 419–20 (D.C. Cir. 2004) (granting relief after approximately six years of delay); *In re Core Commc'ns, Inc.*, 531 F.3d at 855–57 (holding delay unreasonable where agency failed to act within a reasonable timeframe despite ongoing proceedings); *In re Ctr. for Biological Diversity*, 53 F.4th 665, 671–73 (D.C. Cir. 2022) (compelling agency action after years of inaction in the face of a clear statutory obligation).

Furthermore, by deferring its response to a future registration review decision, EPA places resolution of the Petition on a timeline that is both uncertain and entirely within the agency's control. That approach ignores the critical distinction between EPA's obligations under the FFDCA, as amended by FQPA, and its responsibilities under FIFRA.

The FFDCA imposes a health-protective, petition-driven mandate requiring EPA to ensure, based on current evidence, that pesticide tolerances meet a "reasonable certainty of no harm," with explicit protections for infants and children. 21 U.S.C. § 346a(b)(2)(A), (C). When presented with new evidence, EPA must make a discrete determination and issue a final, reviewable decision granting or denying the petition. *Id.* § 346a(d), (h)(1).

FIFRA registration review serves a different function. It is a periodic,

programmatic reassessment conducted on a rolling, multi-year schedule of EPA's own design. 7 U.S.C. § 136a(g). Although it may involve consideration of similar scientific issues, it does not require EPA to resolve a specific tolerance petition or to issue a final, reviewable order addressing that petition. *See NRDC*, 38 F.4th at 43.

That distinction is dispositive. A tolerance petition triggers a discrete, nondiscretionary duty to decide, and EPA may not satisfy that obligation by deferring action to a broader regulatory process that may unfold over many years. Nor may EPA subordinate a statutory duty to a timeline of its own creation. *See Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984).

Courts have rejected this exact approach. In *League of United Latin American Citizens v. Regan*, EPA declined to resolve a tolerance petition on the ground that it would address the relevant safety issues in a future registration review. 996 F.3d at 701–03. The Ninth Circuit held that this was "one more attempt at delay" and "a total abdication of the EPA's statutory duty," emphasizing that the FFDCA's safety mandate "permits no further delay." *Id*. at 703. The court further explained that EPA's FFDCA obligations are mandatory and focused on safety, and cannot be deferred to the multi-factor balancing inherent in FIFRA registration review. *Id.* at 715. The

same is true here.

EPA has declined to resolve the Petition and instead tied its response to the broader registration review process, which it merely anticipates concluding in 2026. But that self-imposed, nonbinding timeline does not excuse years of inaction on a clear statutory duty.

Nothing in the FFDCA permits EPA to leave a properly filed petition unresolved while it pursues a separate, multi-year regulatory process. Where, as here, EPA declines to determine whether an existing tolerance remains safe in light of new evidence, it fails to carry out the core obligation Congress imposed.

B. Congress's Statutory Scheme Requires Timely Agency Action.

The second TRAC factor considers whether Congress has provided a timetable or other indication of the speed with which the agency is expected to act. *TRAC*, 750 F.2d at 80. Here, Congress's directives under the FFDCA require EPA to ensure that pesticide tolerances remain protective of public health. The statute mandates that EPA determine, based on current evidence, that a tolerance meets the standard of a "reasonable certainty of no harm," including consideration of aggregate exposure and heightened risks to infants and children. 21 U.S.C. § 346a(b)(2)(A), (C).

Although the FFDCA does not impose a date-certain deadline, it

requires EPA to issue a final, reviewable order granting or denying a petition. *Id*. § 346a(d), (h)(1). That obligation must be carried out within a reasonable time under the APA. *See* 5 U.S.C. § 555(b). EPA's prolonged inaction is incompatible with this framework. A tolerance cannot satisfy the FFDCA's safety standard if EPA declines to assess whether new evidence renders it unsafe. By failing to act, EPA is not preserving the status quo and is allowing an existing tolerance to persist without the determination Congress requires.

The statute's structure confirms this conclusion. By conditioning judicial review on a final agency decision, Congress ensured that tolerance determinations remain subject to oversight and cannot be left indefinitely unresolved. Allowing EPA to delay for years, while deferring to a separate process with no binding deadline, would effectively insulate its inaction from review and nullify the petition process Congress established.

Accordingly, the second TRAC factor strongly favors relief.

C. EPA's Delay Is Especially Intolerable When Children's Health Is at Stake.

The third TRAC factor, which recognizes that delays are "less tolerable when human health and welfare are at stake," strongly favors relief because EPA's delay directly implicates human health, particularly the health of infants and young children.

Courts have consistently held that delay is least tolerable where human health is at stake. In *Public Citizen Health Research Group v. Commissioner, FDA*, the D.C. Circuit recognized that prolonged inaction on matters affecting health may warrant judicial intervention, particularly where delay denies petitioners the process Congress guaranteed. 740 F.2d at 32.

Most directly, in *In re Center for Biological Diversity*, the court granted mandamus where EPA failed for years to complete a legally required determination concerning a pesticide, holding that such inaction unlawfully frustrated judicial review and violated statutory mandates designed to protect health and the environment. 53 F.4th 665, 671–74 (D.C. Cir. 2022). The court emphasized that mandamus is appropriate where delay becomes "so egregious as to warrant judicial intervention," particularly where Congress has prioritized protection of health and safety. *Id*. at 672–73.

EWG's petition concerns widespread dietary exposure to glyphosate, a pesticide to which EPA has acknowledged infants and young children experience higher dietary exposure. APP-067; Dr. Andrews Decl. ¶8. EPA's own dietary risk assessments identify children aged one to two years as the population subgroup with the highest exposure to glyphosate relative to body weight. APP-067; Dr. Andrews Decl. ¶8. That elevated exposure reflects differences in consumption patterns and body weight, resulting in

higher exposure on a per-body-weight basis for young children. Separately, young children may be more susceptible to the effects of chemical exposure during critical developmental periods. APP-054, 067-68; Dr. Andrews Decl. 7, 9. Congress, through the FQPA, expressly recognized that infants and children face heightened susceptibility to pesticide exposure and required EPA to apply an additional margin of safety to protect against those risks. 21 U.S.C. § 346a(b)(2)(C); *see also id*. § 346a(b)(2)(A)(ii). That statutory mandate underscores that delays in evaluating potentially unsafe tolerances are particularly unacceptable where children's health is at stake.

The administrative record demonstrates that this glyphosate exposure is routine and ongoing. Oat-based foods, widely consumed by infants and young children, are a significant source of dietary glyphosate exposure, and residue levels in those foods are directly governed by the tolerance and agricultural practices challenged in the petition. APP-001, 014, 067; Dr. Andrews Decl. ¶7. Testing and biomonitoring evidence cited in the petition confirms that dietary exposure results in measurable internal exposure at the population level, meaning that EPA's continued inaction permits ongoing exposure under a regulatory threshold that has never been affirmatively reassessed in response to the petition. APP-068; Dr. Andrews Decl. ¶10.

Scientific concern regarding glyphosate exposure further heightens the

urgency of agency action. As documented in the petition, authoritative scientific bodies have identified potential carcinogenic risks, and EPA itself has acknowledged unresolved scientific questions and data gaps regarding long-term and childhood exposure. APP 009-10. These uncertainties do not justify delay.

EPA's delay perpetuates potential exposure under a regulatory standard that EPA has never revised in response to the petition's evidence. This Court's precedent makes clear that where an agency fails for years to resolve a petition implicating public health, despite developing a record and acknowledging its obligation to act, the delay is unreasonable as a matter of law. *See In re Ctr. for Biological Diversity*, 53 F.4th 665, 671–73 (D.C. Cir. 2022) (compelling action after years of delay); *Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984) (recognizing that delay is least tolerable where health is at stake). Because EPA's inaction here prolongs ongoing exposure affecting a population Congress identified as uniquely vulnerable, this factor weighs heavily in favor of mandamus relief.

D. EPA's Delay Prejudices Statutory Interests and Frustrates Judicial Review.

The fifth TRAC factor, which considers the nature and extent of the interests prejudiced by delay, strongly favors mandamus relief. Under this factor, courts assess not only concrete harms, but also whether agency delay

deprives parties of statutory procedures designed to protect their interests and ensure accountability. *See Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984); *TRAC*, 750 F.2d at 80.

Congress provided for direct court of appeals review of EPA's final tolerance determinations under the FFDCA. 21 U.S.C. § 346a(h)(1). But EPA's failure to issue any final, reviewable decision prevents that jurisdiction from ever attaching. In practical effect, EPA's inaction prevents judicial review from occurring at all and deprives EWG of the review mechanism Congress expressly provided.

That is precisely the circumstances in which mandamus relief is warranted. As this Court recognized in *TRAC*, agency delay constitutes a cognizable injury where it precludes judicial review and frustrates the statutory scheme Congress enacted. *TRAC*, 750 F.2d at 80. Here, EPA's prolonged failure to act does not merely delay review, it prevents it altogether. By withholding a final decision, EPA effectively insulates its inaction from review and deprives both EWG and this Court of the opportunity to assess whether the agency is complying with its statutory obligations.

Absent judicial intervention, EPA may continue to defer action indefinitely, frustrating both the statutory scheme and this Court's ability to

exercise its assigned role.

III. The Court should issue a writ of mandamus and retain jurisdiction to ensure EPA promptly resolves the petition.

EPA has unlawfully withheld or unreasonably delayed action on a matter it is legally required to decide. A writ of mandamus, or an order compelling agency action under the APA, is therefore appropriate. *See* 5 U.S.C. § 706(1); 28 U.S.C. § 1651(a). EPA has a clear duty to respond to EWG's petition, has failed to do so for years, and has offered no concrete timeline for decision.

Requiring EPA to act imposes no undue burden. EWG does not seek to dictate the substance of EPA's decision, but only to require that EPA make one. Continued delay, by contrast, perpetuates regulatory uncertainty, frustrates Congress's protections for children's health, and deprives EWG of the process the statute guarantees.

The need for relief is particularly acute because Congress vested this Court with exclusive jurisdiction to review EPA's tolerance decisions under the FFDCA. EPA's failure to issue a final, reviewable response prevents that jurisdiction from ever attaching. Mandamus relief is necessary to preserve the Court's ability to exercise its statutory role.

EWG seeks a date-certain order requiring EPA to issue a final,

reviewable response resolving the petition. A firm deadline of sixty (60) days is warranted given EPA's prior commitment to act and its failure to do so. Courts have recognized that open-ended directives are inadequate where an agency has demonstrated prolonged delay and must instead impose concrete deadlines to ensure compliance with statutory obligations. *See In re Core Commc'ns, Inc.*, 531 F.3d at 862; *In re Am. Rivers*, 372 F.3d at 419–20; *In re Bluewater Network*, 234 F.3d at 1315–16.Where, as here, an agency has failed to act despite a clear statutory duty and ample time to do so, only a firm deadline can ensure meaningful relief.

The Court should also retain jurisdiction to ensure compliance. *See In re Ctr. for Biological Diversity & Ctr. for Food Safety*, 53 F.4th at 673. Retaining jurisdiction would not intrude on EPA's discretion but would ensure that the agency performs the discrete, legally required act of issuing a final decision.

CONCLUSION

EPA has allowed EWG's glyphosate petition to languish for years. That prolonged inaction is unreasonable, especially in light of the risks to infants and young children, and violates the APA, undermines the FFDCA's protections for infants and children, and frustrates this Court's exclusive jurisdiction to review EPA's tolerance decisions. Mandamus relief is

therefore warranted to compel EPA to perform the discrete, legally required act of issuing a final, reviewable response resolving the petition within sixty (60) days of the Court's order.

Respectfully submitted this 21st day of April, 2026.

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CERTIFICATE OF COMPLIANCE

This document complies with the page limit of Federal Rule of Appellate Procedure 21(d) because it contains 7,644 words. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: April 21, 2026

/s/ Caroline Leary
Caroline Leary

CERTIFICATE OF SERVICE

I hereby certify that I have this date served a copy of the foregoing Petition for a Writ of Mandamus and the accompanying statutory addendum and appendix upon all parties by U.S. mail or hand delivery at the following addresses:

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Dated: April 21, 2026

/s/ Caroline Leary
Caroline Leary

No. 26-1094

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE ENVIRONMENTAL WORKING GROUP,
PETITIONER

On Petition for a Writ of Mandamus and for Relief from Unreasonably Delayed Agency Action by the Environmental Protection Agency

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PETITIONER'S STATUTORY ADDENDUM

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Statutory Appendix

5 USCS § 555

Current through Public Law 119-73, approved January 23, 2026, with a gap of Public Law 119-70.

United States Code Service > TITLE 5. GOVERNMENT ORGANIZATION AND EMPLOYEES (§§ 101 — 13146) > Part I. The Agencies Generally (Chs. 1 — 10) > CHAPTER 5. Administrative Procedure (Subchs. I — V) > Subchapter II. Administrative Procedure (§§ 551 — 559)

§ 555. Ancillary matters

(a) This section applies, according to the provisions thereof, except as otherwise provided by this subchapter [*5 USCS §§ 551* et seq.].

(b) A person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding. So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function. With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. This subsection does not grant or deny a person who is not a lawyer the right to appear for or represent others before an agency or in an agency proceeding.

(c) Process, requirement of a report, inspection, or other investigative act or demand may not be issued, made, or enforced except as authorized by law. A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

(d) Agency subpenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought. On contest, the court shall sustain the subpena or similar process or demand to the extent that it is found to be in accordance with law. In a proceeding for enforcement, the court shall issue an order requiring the appearance of the witness or the production of the evidence or data within a reasonable time under penalty of punishment for contempt in case of contumacious failure to comply.

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

History

HISTORY:

Sept. 6, 1966, *P. L. 89-554*, § 1, *80 Stat. 385*.

End of Document

5 USCS § 706, Part 1 of 7

Current through Public Law 119-73, approved January 23, 2026, with a gap of Public Law 119-70.

United States Code Service > TITLE 5. GOVERNMENT ORGANIZATION AND EMPLOYEES (§§ 101 — 13146) > Part I. The Agencies Generally (Chs. 1 — 10) > CHAPTER 7. Judicial Review (§§ 701 — 706)

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title [*5 USCS §§ 556* and *557*] or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

History

HISTORY:

Sept. 6, 1966, *P. L. 89-554*, § 1, *80 Stat. 393*.

End of Document

7 USCS § 136a

Current through Public Law 119-73, approved January 23, 2026, with a gap of Public Law 119-70.

United States Code Service > TITLE 7. AGRICULTURE (Chs. 1 — 116) > CHAPTER 6. INSECTICIDES AND ENVIRONMENTAL PESTICIDE CONTROL (§§ 121 — 136y) > ENVIRONMENTAL PESTICIDE CONTROL (§§ 135 — 136y)

§ 136a. Registration of pesticides

(a) Requirement of registration. Except as provided by this Act [7 USCS §§ 136 et seq.], no person in any State may distribute or sell to any person any pesticide that is not registered under this Act [7 USCS §§ 136 et seq.]. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act [7 USCS §§ 136 et seq.] and that is not the subject of an experimental use permit under section 5 [7 USCS § 136c] or an emergency exemption under section 18 [7 USCS § 136p].

(b) Exemptions. A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration.

(1) Statement required. Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this Act [7 USCS §§ 136 et seq.] after the date of enactment of the Federal Pesticide Act of 1978 [enacted Sept. 30, 1978], data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause [enacted Aug. 3, 1996] and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act [*7 USCS §§ 136* et seq.], if the Administrator determines that an

applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after enactment of this clause [enacted Aug. 3, 1996], except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after the date of enactment of this clause [enacted Aug. 3, 1996] by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration.

(A) In general. The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this Act [7 USCS §§ 136 et seq.], any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the

economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10 [*7 USCS § 136h*], within 30 days after the Administrator registers a pesticide under this Act [*7 USCS §§ 136* et seq.] the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision.

(B) Additional data.

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this Act [*7 USCS §§ 136* et seq.], if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act [*7 USCS §*

136d(d)]. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act [7 USCS §§ 136 et seq.]. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act [7 USCS §§ 136 et seq.], a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 4 [7 USCS § 136a-1] for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996], if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 4 [7 USCS § 136a-1]; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996], for the submission of data under section 4 [7 USCS § 136a-1] for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause

human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1) [*7 USCS § 136d(f)(1)*]. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2) [*7 USCS § 136d(f)(2)*]. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)

(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after the date of enactment of this clause [enacted Aug. 3, 1996], the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures. Within nine months after the date of enactment of this subparagraph, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption. No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver. In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Time for acting with respect to application.

(A) In general. The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify

the applicant of the Administrator's determination that it does not comply with the provisions of the Act [*7 USCS §§ 136* et seq.] in accordance with paragraph (6).

(B) Identical or substantially similar.

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 33(f)(4)(B) [*7 USCS § 136w-8(f)(4)(B)*] and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 33(f)(4)(B) [*7 USCS § 136w-8(f)(4)(B)*], or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration.

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 18 for that minor use.

(D) Adequate time for submission of minor use data. If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application. The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration. The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act [*7 USCS §§ 136* et seq.];

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 24(c) of this Act [*7 USCS § 136v(c)*], a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration. If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6 [*7 USCS § 136d*].

(7) Registration under special circumstances. Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act [*7 USCS §§ 136* et seq.].

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this Act [*7 USCS §§ 136* et seq.], and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act [*7 USCS §§ 136* et seq.].

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act [*7 USCS §§ 136* et seq.], and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review. Notwithstanding any other provision of this Act [*7 USCS §§ 136* et seq.], the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act [*7 USCS §§ 136* et seq.], unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms “validated test” and “other significant evidence” as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling.

(A) Additional statements. Subject to subparagraphs (B) and (C), it shall not be a violation of this Act [*7 USCS §§ 136* et seq.] for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements. Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval.

(i) Notification. A registration may be modified under subparagraph (A) if —

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval. Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale. A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection. A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action. A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution. The label or labeling required under this Act for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that —

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides.

(A) Not later than 1 year after the date of enactment of this paragraph [enacted Aug. 3, 1996], the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) Interagency working group.

(A) Definition of covered agency. In this paragraph, the term “covered agency” means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment. The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (*16 U.S.C. 1536*) for pesticide registration and registration review.

(C) Duties. The interagency working group established under subparagraph (B) shall—

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including—

(I) requirements under this Act and the Endangered Species Act of 1973 (*16 U.S.C. 1531* et seq.);

(II) Federal case law regarding the intersection of this Act and the Endangered Species Act of 1973 (*16 U.S.C. 1531* et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of—

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this Act [*7 USCS §§ 136* et seq.] and the Endangered Species Act of 1973 (*16 U.S.C. 1531* et seq.), including—

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (*16 U.S.C. 1536(a)(2)*); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (*16 U.S.C. 1531* et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports.

(i) Progress reports.

(I) In general. Not later than 18 months after the date of enactment of this paragraph [enacted Dec. 20, 2018], the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

(II) Requirements. The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results.

(I) In general. Not later than 1 year after the date of enactment of this paragraph [enacted Dec. 20, 2018], the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements. The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation. Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports. Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector. In carrying out the duties under this paragraph, the working group shall, as appropriate—

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Chapter 10 of title 5, United States Code. Chapter 10 of title 5, United States Code [*5 USCS §§ 1001* et seq.], shall not apply to the working group established under this paragraph.

(G) Savings clause. Nothing in this paragraph supersedes any provision of—

(i) this Act [*7 USCS §§ 136* et seq.]; or

(ii) the Endangered Species Act of 1973 (*16 U.S.C. 1531* et seq.), including the requirements under section 7 of that Act (*16 U.S.C. 1536*).

(d) Classification of pesticides.

(1) Classification for general use, restricted use, or both.

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification. If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 6(b) [*7 USCS § 136d(b)*].

(3) Change in classification from restricted use to general use. The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 16 of this Act [*7 USCS § 136n*].

(e) Products with same formulation and claims. Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous.

(1) Effect of change of labeling or formulation. If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act [*7 USCS §§ 136* et seq.].

(2) Registration not a defense. In no event shall registration of an article be construed as a defense for the commission of any offense under this Act [*7 USCS §§ 136* et seq.]. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act [*7 USCS §§ 136* et seq.].

(3) Authority to consult other federal agencies. In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products. Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this Act [*7 USCS §§ 136* et seq.]; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 4, 5, 7, 15, and 17(a)(2) [*7 USCS §§ 136a-1*, *136c*, *136e*, *136m*, *136o(a)(2)*] if the mixture or other combination is accompanied by the labeling required under this Act [*7 USCS §§ 136* et seq.] for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(5) Bilingual labeling.

(A) Requirement.

(i) In general. Subject to clause (ii), not later than the applicable deadline described in subparagraph (B), each registered pesticide product released for shipment shall include—

(I) the translation of the parts of the labeling contained in the Spanish Translation Guide described in subparagraph (G) on the product container; or

(II) a link to such translation via scannable technology or other electronic methods readily accessible on the product label.

(ii) Exceptions. Notwithstanding clause (i)—

(I) an antimicrobial pesticide product may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label; or

(II) a non-agricultural pesticide product that is not classified by the Administrator as restricted use under subsection (d)(1)(A) may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label.

(B) Deadlines for bilingual labeling.

(i) Pesticide products classified as restricted use. In the case of pesticide products classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph is the date that is 3 years following the date of enactment of this paragraph [enacted Dec. 29, 2022].

(ii) Pesticide products not classified as restricted use. In the case of pesticide products not classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph shall be as follows:

(I) Agricultural.

(aa) Acute Toxicity Category I. For agricultural pesticides classified as Acute Toxicity Category I, the date that is 3 years after the date of enactment of this paragraph [enacted Dec. 29, 2022].

(bb) Acute Toxicity Category II. For agricultural pesticides classified as Acute Toxicity Category II, the date that is 5 years after the date of enactment of this paragraph [enacted Dec. 29, 2022].

(II) Antimicrobial and non-agricultural.

(aa) Acute Toxicity Category I. For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category I, the date that is 4 years after the date of enactment of this paragraph [enacted Dec. 29, 2022].

(bb) Acute Toxicity Category II. For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category II, the date that is 6 years after the date of enactment of this paragraph [enacted Dec. 29, 2022].

(III) Other pesticide products. With respect to pesticide products not described in subclause (I) or (II), the date that is 8 years after the date of enactment of this paragraph [enacted Dec. 29, 2022].

(C) Implementation.

(i) Non-notification.

(I) In general. In carrying out this paragraph, the Administrator shall allow translations of the parts of the label of a pesticide contained in the Spanish Translation Guide described in subparagraph (G) and scannable technology or other electronic methods to be added using non-notification procedures.

(II) Non-notification procedure defined. In this clause, the term "non-notification procedure" refers to a procedure under which a change may be made to a pesticide label without notifying the Administrator.

(ii) Cooperation and consultation. In carrying out this paragraph, the Administrator shall cooperate and consult with State lead agencies for pesticide regulation for the purpose of implementing bilingual labeling as provided in this paragraph as expeditiously as possible.

(iii) End use labeling. The labeling requirements of this paragraph shall apply to end use product labels.

(iv) Incorporation timeframe. After initial translation deadlines provided in subparagraph (B), updates to the Spanish Translation Guide described in subparagraph (G) shall be incorporated into labeling on the earlier of—

(I) in the case of agricultural use pesticide labels, as determined by the Administrator—

(aa) 1 year after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); and

(II) in the case of antimicrobial and non-agricultural use pesticide labels, as determined by the Administrator—

(aa) 2 years after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G).

(v) Notification of updates to the Spanish Translation Guide for Pesticide Labeling. Not later than 10 days after updating the Spanish Translation Guide described in subparagraph (G), the Administrator shall notify registrants of the update to such guide.

(D) Accessibility of bilingual labeling for farm workers. Not later than 180 days after the date of enactment of this paragraph [enacted Dec. 29, 2022], to the maximum extent practicable, the Administrator shall seek stakeholder input on ways to make bilingual labeling required under this paragraph accessible to farm workers.

(E) Plan. Not later than 3 years after the date of enactment of this paragraph [enacted Dec. 29, 2022], the Administrator shall implement a plan to ensure that farm workers have access to the bilingual labeling required under this paragraph.

(F) Reporting. Not later than 2 years after the date of enactment of this paragraph [enacted Dec. 29, 2022], the Administrator shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling required under this paragraph.

(G) Spanish Translation Guide described. The Spanish Translation Guide described in this subparagraph is the Spanish Translation Guide for Pesticide Labeling issued in October 2019, as in effect on the date of enactment of the Pesticide Registration Improvement Act of 2022 [enacted Dec. 29, 2022], and any successor guides or amendments to such guide.

(g) Registration review.

(1)

(A) General rule.

(i) In general. The registrations of pesticides are to be periodically reviewed.

(ii) Regulations. In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review. The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review. Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6 [*7 USCS § 136d*].

(B) Docketing.

(i) In general. Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information. The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 10 [*7 USCS § 136h*].

(C) Limitation. Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this Act [*7 USCS §§ 136* et seq.].

(2) Data.

(A) Submission required. The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption. For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides.

(1) Evaluation of process. To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection [enacted Aug. 3, 1995] for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal. Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation.

(A) Proposed rulemaking.

(i) Issuance. Not later than 270 days after the date of enactment of this subsection [enacted Aug. 3 1995], the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements. Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act [*7 USCS §§ 136* et seq.], considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments. In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations.

(i) Issuance. The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal. If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements. In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review. This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) Alternative review periods. If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection [enacted Aug. 3, 1996], until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives. An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(mm) [*7 USCS § 136(mm)*] is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification.

(i) In general. Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision. If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5, United States Code [*5 USCS §§ 701* et seq.].

(iii) Exemption. This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection [enacted Aug. 3, 1996].

(iv) Limitation. Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report.

(A) Submission. Beginning on the date of enactment of this subsection [enacted Aug. 3, 1996] and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements. A report submitted under subparagraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

History

HISTORY:

June 25, 1947, ch 125, § 3, as added Oct. 21, 1972, P. L. 92-516, § 2, 86 Stat. 979; Nov. 28, 1975, P. L. 94-140, § 12, 89 Stat. 755; Sept. 30, 1978, P. L. 95-396, §§ 2(a), 3–8, 92 Stat. 820–827; Oct. 25, 1988, *P. L. 100-532*, Title I, §§ 102(b), 103, Title VI, § 601(b)(1), Title VIII, § 801(b), *102 Stat. 2667*, 2677, 2680; Nov. 28, 1990, *P. L. 101-624*, Title XIV, Subtitle H, § 1492, *104 Stat. 3628* Dec. 13, 1991, *P. L. 102-237*, Title X, § 1006(a)(3), (b), (c), *105 Stat. 1894*–1896; Aug. 3, 1996, *P. L. 104-170*, Title I, Subtitle A, §§ 105(b), 106(b), Title II, Subtitle A, § 210(b), (c)(1), (d), (e), (f)(2), Subtitle B, §§ 222–224, Subtitle C, § 231, Subtitle D, § 250, *110 Stat. 1491*, 1494–1499, 1503, 1508, 1510; Jan. 23, 2004, *P. L. 108-199*, Div G, Title V, § 501(b), *118 Stat. 419*; Oct. 9, 2007, *P. L. 110-94*, §§ 2, 3, *121 Stat. 1000*; Dec. 20, 2018, *P.L. 115-334*, Title X, § 10115, *132 Stat. 4914*; Dec. 27, 2022, *P.L. 117-286*, § 4(a)(21), *136 Stat. 4307*; Dec. 29, 2022, *P.L. 117-328*, Div HH, Title VI, Subtitle A, § 702, *136 Stat. 5996*.

End of Document

21 USCS § 346a

Current through Public Law 119-73, approved January 23, 2026, with a gap of Public Law 119-70.

United States Code Service > TITLE 21. FOOD AND DRUGS (§§ 1 — 2404) > CHAPTER 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT (§§ 301 — 399i) > FOOD (§§ 341 — 350m)

§ 346a. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption.

(1) General rule. Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) Processed food. Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)].

(3) Residues of degradation products. If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor

substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) Effect of tolerance or exemption. While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1) [*21 USCS § 342(a)(1)*].

(b) Authority and standard for tolerance.

(1) Authority. The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) Standard.

(A) General rule.

(i) Standard. The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety. As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) Rule of construction. With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) Tolerances for eligible pesticide chemical residues.

(i) Definition. As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) Determination of tolerance. Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) Conditions regarding use. For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk. For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) Review. Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) Infants and children. Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children. In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) Factors. In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) Data and information regarding anticipated and actual residue levels.

(i) Authority. In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) Requirement. If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance

is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) Percent of food actually treated. In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) Detection methods.

(A) General rule. A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) Detection limit. A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) International standards. In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) Authority and standard for exemptions.

(1) Authority. The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) Standard.

(A) General rule.

(i) Standard. The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) Determination of safety. The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) Factors. In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) Limitation. An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) Petition for tolerance or exemption.

(1) Petitions and petitioners. Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) Petition contents.

(A) Establishment. A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)

(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) Modification or revocation. The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) Notice. A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) Actions by the Administrator.

(A) In general. The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) Priorities. The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) Expedited review of certain petitions.

(i) Date certain for review. If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which

a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) Required determinations. If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) Action on Administrator's own initiative.

(1) General rule. The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) Notice. Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) Special data requirements.

(1) Requiring submission of additional data. If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS § 136a(c)(2)(B)*];

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act [*15 USCS § 2603*]; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act [*7 USCS § 136a(c)(2)(B)* or *15 USCS § 2603*];

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) Noncompliance. If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) Effective date, objections, hearings, and administrative review.

(1) Effective date. A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) Further proceedings.

(A) Objections. Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) Hearing. An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by 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, such a subpoena may be enforced by a Federal district court.

(C) Final decision. As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) Judicial review.

(1) Petition. In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) Record and jurisdiction. A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in *section 2112 of title 28, United States Code*. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) Additional evidence. If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) Final judgment; Supreme Court review. The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in *section 1254 of title 28 of the United States Code*. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) Application. Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) Confidentiality and use of data.

(1) General rule. Data and information that are or have been submitted to the Administrator under this section or section 409 [*21 USCS § 349*] in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136a*, *136h*].

(2) Exceptions.

(A) In general. Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act [*21 USCS §§ 301* et seq.] or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act [*21 USCS §§ 301* et seq.] or such statutes.

(B) Congress. This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) Summaries. Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) Status of previously issued regulations.

(1) Regulations under section 406 [*21 USCS § 346*]. Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e) [*21 USCS § 371(e)*], under the authority of section 406(a) [*21 USCS § 346(a)*] upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) Regulations under section 409 [*21 USCS § 349*]. Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 [*21 USCS § 349*] on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) Regulations under section 408 [*21 USCS § 348*]. Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph [enacted Aug. 3, 1996] shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(4) Certain substances. With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 201(q)(1) [*21 USCS § 321(q)(1)*] but was so included on the day before the date of the enactment of the Antimicrobial Regulation Technical Corrections Act of 1998 [enacted Oct. 30, 1998], the following applies as of such date of enactment:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409 [*21 USCS § 348*].

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996]) is deemed to have been issued under section 409 [*21 USCS § 348*].

(k) Transitional provision. If, on the day before the date of the enactment of this subsection [enacted Aug. 3, 1996], a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) [*21 USCS § 321(s)*] as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4) [*21 USCS § 321(s)(4)*];

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection [enacted Aug. 3, 1996]. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) Harmonization with action under other laws.

(1) Coordination with FIFRA. To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.].

(2) Revocation of tolerance or exemption following cancellation of associated registrations. If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.], cancels the registration of each pesticide that contains a particular pesticide chemical and that is

labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) Suspension of tolerance or exemption following suspension of associated registrations.

(A) Suspension. If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.], suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) Effect of suspension. The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.]. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) Tolerances for unavoidable residues. In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph [enacted Aug. 3, 1996] under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.], if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) Pesticide residues resulting from lawful application of pesticide. Notwithstanding any other provision of this Act [*21 USCS §§ 301* et seq.], if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.]; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act [*21 USCS §§ 301* et seq.];

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) Tolerance for use of pesticides under an emergency exemption. If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (*7 U.S.C. 136p*) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph [enacted Aug. 3, 1996] governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS § 136p*].

(m) Fees.

(1) Amount. The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d);

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g); or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) Deposit. All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS § 136a-1(k)*]. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) Prohibition. During the period beginning on the effective date of the Pesticide Registration Improvement Renewal Act of 2022 [effective Dec. 29, 2022] and ending on September 30, 2027, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) National uniformity of tolerances.

(1) Qualifying pesticide chemical residue. For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS § 136a(c)(5)*] on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act [*7 USCS §§ 136* et seq.] on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act [*7 USCS § 136a-1(g)*] on or after the date of enactment of this subsection [enacted Aug. 3, 1996].

(2) Qualifying Federal determination. For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

(B)

(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

(3) Limitation. The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

(4) State authority. Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) Petition procedure.

(A) In general. Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) Petition requirements. Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) Authorization. The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) Treatment. In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

(E) Review. Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

(6) Urgent petition procedure. Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) Residues from lawful application. No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) Savings. Nothing in this Act [*21 USCS §§ 301* et seq.] preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) Consumer right to know. Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996], and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) Estrogenic substances screening program.

(1) Development. Not later than 2 years after the date of enactment of this section [enacted Aug. 3, 1996], the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) Implementation. Not later than 3 years after the date of enactment of this section [enacted Aug. 3, 1996], after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS § 136w(d)*] or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration [Authorization] Act of 1978 (*42 U.S.C. 4365*), the Administrator shall implement the program.

(3) Substances. In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) Exemption. Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) Collection of information.

(A) In general. The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B) Procedures. To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) Failure of registrants to submit information.

(i) Suspension. If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) Hearing. If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with *section 554 of title 5, United States Code*. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) Termination of suspensions. The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) Noncompliance by other persons. Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (*15 U.S.C. 2601* and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) Agency action. In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act [*21 USCS §§ 301* et seq.], as is necessary to ensure the protection of public health.

(7) Report to Congress. Not later than 4 years after the date of enactment of this section [enacted Aug. 3, 1996], the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) Schedule for review.

(1) In general. The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996], as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act [enacted Aug. 3, 1996];

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act [enacted Aug. 3, 1996]; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act [enacted Aug. 3, 1996].

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections [subsection] (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) Priorities. In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) Publication of schedule. Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996], the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996]. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) Temporary tolerance or exemption. The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.] or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

(s) Savings clause. Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act [*15 USCS §§ 2601* et seq.] or the Federal Insecticide, Fungicide, and Rodenticide Act [*7 USCS §§ 136* et seq.].

History

HISTORY:

June 25, 1938, ch 675, Ch. IV, § 408, as added July 22, 1954, ch 559, § 3, *68 Stat. 511*; Aug. 28, 1958, *P. L. 85-791*, § 20, *72 Stat. 947*; Oct. 30, 1970, *P.L. 91-515*, Title VI, § 601(d)(1), *84 Stat. 1311*; Nov. 18, 1971, *P. L. 92-157*, Title III, § 303(a), *85 Stat. 464*; Oct. 21, 1972, *P. L. 92-516*, § 3(3), *86 Stat. 998*; Nov. 8, 1984, *P. L. 98-620*, Title IV, Subtitle A, § 402(25)(A), *98 Stat. 3359*; June 16, 1992, *P. L. 102-300*, § 6(b)(1), *106 Stat. 240*; Oct. 29, 1992, *P. L. 102-571*, Title I, § 107(7), *106 Stat. 4499*; Aug. 13, 1993, *P. L. 103-80*, § 3(k), *107 Stat. 776*; Aug. 3, 1996, *P. L. 104-170*, Title IV, § 405, *110 Stat. 1514*; Oct. 30, 1998, *P. L. 105-324*, § 2(b), *112 Stat. 3036*; Oct. 9, 2007, *P. L. 110-94*, § 4(d)(2), *121 Stat. 1002*; Sept. 28, 2012, *P. L. 112-177*, § 2(a)(3), *126 Stat. 1329*; Mar. 8, 2019, *P.L. 116-8*, § 2(c), *133 Stat. 485*; Dec. 29, 2022, *P.L. 117-328*, Div HH, Title VI, Subtitle A, § 703(b), *136 Stat. 6002*.

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28 USCS § 1651, Part 1 of 3

Current through Public Law 119-73, approved January 23, 2026, with a gap of Public Law 119-70.

United States Code Service > TITLE 28. JUDICIARY AND JUDICIAL PROCEDURE (§§ 1 — 5001) > Part V. Procedure (Chs. 111 — 133) > CHAPTER 111. General Provisions (§§ 1651 — 1659)

§ 1651. Writs

(a) The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.

(b) An alternative writ or rule nisi may be issued by a justice or judge of a court which has jurisdiction.

History

HISTORY:

June 25, 1948, ch 646, *62 Stat. 944*; May 24, 1949, ch 139, § 90, *63 Stat. 102*.

End of Document

No. 26-1094

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE ENVIRONMENTAL WORKING GROUP,
PETITIONER

On Petition for a Writ of Mandamus and for Relief from Unreasonably Delayed Agency Action by the Environmental Protection Agency

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PETITIONER'S APPENDIX

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Petitioner's Appendix

PETITION TO MODIFY THE TOLERANCE OF GLYPHOSATE IN OATS TO 0.1ppm AND REQUIRE GLYPHOSATE-CONTAINING PRODUCT LABELS TO EXPLICITLY PROHIBIT THE USE OF GLYPHOSATE AS A PREHARVEST DESICCANT

Amended 28 March 2019

The Environmental Working Group (EWG), joined by Amy's Kitchen, Ben & Jerry's Homemade, Inc., Clif Bar and Company, Earth's Best Organic, GrandyOats, Happy Family Organics, Independent Natural Food Retailers Association, KIND Healthy Snacks, Lundberg Family Farms, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., Organic Valley, Patagonia Provisions, PCC Community Markets and Stonyfield Farm, Inc., petition the U.S. Environmental Protection Agency (EPA) to modify the registered conditions of use for glyphosate by reducing the tolerance level of glyphosate in oats from 30 ppm to 0.1 ppm and to require glyphosate-containing product labels to explicitly prohibit the use of glyphosate as a preharvest desiccant on oats. This petition is filed pursuant to 21 U.S.C. § 346a(d) and concurrently as a Citizen's Petition under 5 U.S.C. §553(e). This document also serves as public comment to the agency to be considered with the registration review of glyphosate pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. § 136a(g). EWG does not have any financial interest in the modification of the glyphosate residual tolerance level in oat crops.

I. Introduction

The Environmental Working Group (EWG) is a public interest, nonprofit, nonpartisan organization, with offices in Washington, D.C., San Francisco and Sacramento, California, and Minneapolis, Minnesota. EWG's mission is to empower people to live healthier lives in a healthier environment. For more than two decades, EWG has strived to protect human health and the environment through breakthrough research and education, driving consumer choice and civic action. This includes substantial work to support safe, sustainable agriculture.

Glyphosate has been in use in the United States since the 1970s. It is the most widely used pesticide in the world.[1] In the past decade, the use of glyphosate has soared, with more than 250 million pounds sprayed in the U.S. annually according to data from the U.S. Geological Survey.[2] In 1996, the Agency approved the use of genetically engineered crops that could withstand direct application of glyphosate. Glyphosate is also now used for crop management, applied preharvest to a variety of non-genetically engineered crops, including oats outside of the U.S.[3] Presently, the EPA and the U.S. Department of Agriculture do not monitor glyphosate residues on most food crops. Yet, by all indications, Americans' exposures have increased dramatically.

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[1] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[2] USGS, PESTICIDE NAT'L SYNTHESIS PROJECT, ESTIMATED ANNUAL AGRIC. PESTICIDE USE, PESTICIDE USE MAPS – GLYPHOSATE (2015), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2015&map=GLYPHOSATE&hilo=L&disp=Glyphosate

[3] Monsanto, *Preharvest Staging Guide*, http://www.roundup.ca/_uploads/documents/MON-Preharvest%20Staging%20Guide.pdf

Between 2014 and 2016, at least 70 percent of American adults surveyed had detectable traces of glyphosate in their bodies, compared to 12 percent of American adults between 1993 and 1996.[4] The actual current exposure levels may be higher because glyphosate has not been included in nationwide biomonitoring studies, and there are no comprehensive datasets on glyphosate intake for young children and teenagers.

Under FIFRA, pesticides are required to be registered with the EPA. 7 U.S.C. § 136 (a). The agency reviews registration applications submitted by industry to determine tolerance levels and conditions of use. By law, the agency must consider human health and environmental costs in the pesticide approval process.[5] However, the current tolerance level for food residue in oats is less protective than EWG believes necessary to protect children's health based on independent studies on dietary exposure, international findings of cancer risk, and possible reproductive toxicity.

Americans' widespread exposure to glyphosate is of growing concern, particularly in the context of children's health, because of the potential risk of cancer. Yet, EPA deviated from its own established risk assessment guidelines, and took the position that glyphosate is "unlikely to cause cancer."[6] As a result, the high food tolerance levels of glyphosate remain set without an evaluation of carcinogenicity as an endpoint. In contrast, the International Agency for Research on Cancer, an agency of the World Health Organization, determined that glyphosate is a probable human carcinogen.[7] Based in part on the IARC classification, California's Office of Environmental Health Hazard Assessment recently finalized its No Significant Risk Level for Glyphosate, which is roughly 50 to 70 times lower than EPA's proposed Population Adjusted Dose for an adult.[8] California also added glyphosate to its official Proposition 65 list of chemicals known to the state to cause cancer.[9]

There have been at least 14 multiyear studies of glyphosate's ability to cause cancer in laboratory animals, most of which were conducted by the pesticide industry.[10] More than half of the studies the EPA reviewed detected elevated rates of cancer in study animals.[11] EPA's own Science

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[4] Mills PJ et al., *Excretion of the Herbicide Glyphosate in Older Adults Between 1993 and 2016*, 318(16) JAMA 1610-1611 (2017), 10.1001/jama.2017.11726; EWG, *Comments on the EPA's Assessment of Herbicide Glyphosate*, EPA-HQ-OPP-2009-0361(April 30, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1689

[5] 7 U.S.C. § 136(bb); EPA, LAWS & REGS., SUMMARY OF FOOD QUALITY PROT. ACT, (Last visited Sept. 26, 2018), https://www.epa.gov/laws-regulations/summary-food-quality-protection-act

[6] EPA, Glyphosate Draft Human Health Risk Assessment for Registration Review, Docket EPA-HQ-OPP-2009-0361-0068 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068; EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[7] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[8] CA, Notice of Proposed Rulemaking: Amendment to Section 25705, Specific Regulatory Levels Posing No Significant Risk: Glyphosate (Mar 28, 2017), https://oehha.ca.gov/proposition-65/crnr/notice-proposed-rulemaking-amendment-section-25705-specific-regulatory-levels

[9] CA, Glyphosate Listed Effective July 7, 2017, as Known to the State of CA to Cause Cancer, CAS No. 1071-83-6 (Jun 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer#_ftn1

[10] EWG, *Comments on the EPA's Assessment of Herbicide Glyphosate*, EPA-HQ-OPP-2009-0361(April 30, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1689

[11] *Id.*

Advisory Panel met in 2016 to review the Agency's assessment of the cancer evidence, and split over its assessment of the strength of the evidence.[12]

EWG contends that the EPA Office of Pesticide Programs incorrectly dismissed many study findings that showed statistically significant dose-response trends for glyphosate carcinogenicity. EPA's dismissal of those studies has enabled the continued approval of increasingly high tolerance levels of glyphosate as a residue on common foods. Specifically, the tolerance level for glyphosate in oat grain has been increased from 0.1 ppm in 1993 to current tolerance of 30 ppm.[13] The higher tolerance for oats and certain other grains was first raised to 20 ppm in 1997 and then increased to 30 ppm in 2008 to be consistent with the CODEX maximum residue limit (MRL) recommendations upon petition by Monsanto Inc.[14]

Oat products are widely consumed by children in the United States in cereals, breakfast bars, cookies, and other various foods. In 2018, EWG tested oatmeal or oat-based cereal, granola and snack bar products, and detected glyphosate in all but two of 45 samples of products.[15] In addition, the levels detected were at higher concentrations than glyphosate levels found in other studies for common foods such as wheat and corn.[16] These results suggest that children are likely consuming potentially harmful levels of glyphosate daily, as real dietary exposure is not limited to the oat products sampled. While all levels were within legal tolerance limits established by the Agency, the omission of cancer risk in the EPA's assessment of glyphosate undermines the credibility of current tolerance limits. EWG urges the agency to reduce the current tolerance limit of oats from 30 ppm back to the 1993 level of 0.1 ppm.

II. Legal Framework

The EPA regulates pesticides under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), 7 U.S.C §136 et seq. and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346(a). A pesticide includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," including any "weed," and thus includes chemicals commonly known as herbicides. 7 U.S.C. § 136(t)-(u). FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" as defined to include "(1) the economic, social, and environmental costs and benefits of the use of any pesticide, and (2) a human dietary risk from residues that result from a use of a pesticide in or on any food

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[12] *Id.*; EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[13] 40 C.F.R. § 180.364 (July 1, 2017)

[14] *Id., see also* EPA Rule, Glyphosate; Tolerance Actions, EPA-HQ-OPP-2007-1170 FRL-8379-3 (Sept 10, 2008), https://www.federalregister.gov/documents/2008/09/10/E8-20993/benfluralin-carbaryl-diazinon-dicrotophos-fluometuron-formetanate-hydrochloride-glyphosate; EPA Rule, Glyphosate; Pesticide Tolerances at 6 (April 11, 1997), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/tred_PC-417300_11-Apr-97.pdf; EPA OPP, Review PP No. 6E04645 Glyphosate in or on Imported Oats (May 8, 1996), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-285.pdf

[15] Alexis Temkin, EWG, CHILDREN'S HEALTH INITIATIVE, *Breakfast with a dose of Roundup?* (Aug 15, 2018), https://www.ewg.org/childrenshealth/glyphosateincereal/#.W6wWYxNKiRY attached as Exhibit 1

[16] *Id.*

inconsistent with the standard under 21 U.S.C. § 346(a)." 7 U.S.C. § 136(bb); *accord* 40 CFR §152.112(e).

EPA must periodically review the registration to make sure it is still considered safe in light of new science. 7 U.S.C. § 136a(g). EPA must complete its review of each existing pesticide registration by either October 2022 or within fifteen years after the date on which a pesticide containing a new active ingredient is first registered, whichever is later. *Id*. § 136a(g)(1)(A)(iii). Thereafter, EPA is required to conduct subsequent reviews of each pesticide registration every fifteen years. *Id*. § 136a(g)(1)(A)(iv).

The Food Quality Protection Act of 1996 (FQPA) amended both the FFDCA and FIFRA by requiring the EPA to consider health-based and child-protective standards when defining acceptable levels of pesticide residues in food and the environment. 7 U.S.C. 136; accord 21 U.S.C. § 346(b)(2)(C).[17] Tolerances for a pesticide chemical residue in or on a food may only be established or left in effect if that tolerance is "safe." 21 U.S.C. § 346(b)(2)(A). "Safe" means that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures. 21 U.S.C. § 346 (b)(2)(A).

The EPA may establish, modify or revoke a tolerance for a pesticide chemical residue at its own initiative or in response to a petition filed under 21 U.S.C. § 346(d). Any interested party may file such a petition upon showing of reasonable grounds for a modification or revocation of a pesticide tolerance when the party has a substantial interest in the action sought. 40 C.F.R. §180.32.

In addition, the Administrative Procedure Act provides that "each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C § 553(e).

The Environmental Working Group, and co-petitioners, file this petition concurrently as both

(1) a tolerance modification petition under 21 U.S.C. § 346(d) requesting that the EPA reduce the established tolerance of glyphosate in oat grain from 30ppm to 0.1ppm, and
(2) a citizen petition pursuant to 40 C.F.R. § 180.32 requesting a label clarification on glyphosate-containing products that explicitly prohibits preharvest application to oats as a desiccant in the United States.

Petitioners request a fee waiver pursuant to 40 C.F.R § 180.33(l) due to the substantial public interest in the reduction of dietary exposure to glyphosate from oats.

III. Glyphosate Production, Use, and Residue Monitoring

Glyphosate has the highest production volume of all herbicides in the U.S. and is currently used worldwide in agriculture, forestry, urban, and home applications.[18] Glyphosate was first synthesized and tested as an herbicide in 1970 and EPA registered the first products for use in

[17] 7 U.S.C. §136; *see* EPA, LAWS & REGS., SUMMARY OF FOOD QUALITY PROT. ACT, (Last visited Sept. 26, 2018), https://www.epa.gov/laws-regulations/summary-food-quality-protection-act
[18] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

the United States in 1974.[19] Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites.[20] Globally, glyphosate use has risen almost 15-fold since genetically engineered glyphosate-tolerant crops were introduced in 1996.[21]

There are approximately 800 EPA registered pesticide products containing glyphosate, however not all may be for sale or use at any one time.[22] Glyphosate was registered in over 130 countries as of 2010 and is likely the most commonly used herbicide in the world.[23] Since 1974 in the U.S., over 3.5 billion pounds of glyphosate active ingredient have been applied to crop and non-crop land, or 19 percent of the estimated global use of glyphosate.[24] Two-thirds of the total volume of glyphosate applied in the U.S. from 1974 to 2014 has been sprayed in just the last 10 years.[25]

Widespread adoption of no-till and conservation-till practices and the introduction of transgenic crop varieties engineered to be resistant to glyphosate have transformed glyphosate to a post-emergent, selective herbicide for use on some annual crops.[26] When applied at lower rates, glyphosate is a plant-growth regulator and desiccant.[27] While alternative drying methods exist, glyphosate offers a cheap and rapid option and has been widely adopted for oat crop management in recent years.[28] Although preharvest and desiccant applications of glyphosate are minor uses, the timing of these applications results in higher residuals on food crops. Preharvest and desiccant use are not approved for oat crops in the United States, however these applications are registered on label uses in other nations, including Canada a large supplier of oats to the U.S.

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[19] SZÉKÁCS & DARVAS, *Forty Years with Glyphosate*, in HERBICIDES – PROPERTIES, SYNTHESIS, AND CONTROL OF WEEDS (2012), 10.5772/32491

[20] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf; *see generally* USDA PESTICIDE DATA PROGRAM https://www.ams.usda.gov/datasets/pdp.

[21] ***Id.;*** Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[22] See generally EPA, PESTICIDE PRODUCT AND LABEL SYSTEM (PPLS), Glyphosate (Last visited Sept 27, 2018), https://iaspub.epa.gov/apex/pesticides/f?p=113:1:::NO:RP,1::; ***see also*** USGS PESTICIDE NAT'L SYNTHESIS PROJECT, Estimated Annual Agric. Pesticide Use Glyphosate (2018), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=GLYPHOSATE&hilo=L&disp=Glyphosate

[23] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf; DILL ET AL., *Glyphosate: Discovery, Development, Applications, and Properties*, in GLYPHOSATE RESISTANCE IN CROPS AND WEEDS: HISTORY, DEV., AND MGMT. (July 21 2010), https://doi.org/10.1002/9780470634394.ch1

[24] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[25] ***Id.***

[26] Duke & Powles, *Glyphosate Resistant Crops and Weeds, Now and in the Future,* 12 Agro Bio Forum, 346- 357 (2009); DILL ET AL., *Glyphosate: Discovery, Development, Applications, and Properties*, in GLYPHOSATE RESISTANCE IN CROPS AND WEEDS: HISTORY, DEV., AND MGMT. (July 21 2010), https://doi.org/10.1002/9780470634394.ch1

[27] GLYPHOSATE FACTS, ***Clarification of Pre-harvest uses of glyphosate,*** Transparency on safety aspects and use of glyphosate-containing herbicides in Eur. (Last visited Sept 25, 2018), https://www.glyphosate.eu/system/files/sidebox-files/clarification_of_pre-harvest_uses_of_glyphsate_en_0.pdf

[28] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

market.[29] The existing tolerance level for glyphosate in oats was set to achieve international harmonization to reduce barriers for agricultural imports.[30]

FDA has begun testing glyphosate in a limited number of foods, however, results have yet to be published.[31] In a 2016 presentation at the North American Chemical Residue Workshop, an FDA scientist showed data indicating the presence of glyphosate in several oat-based food products, but the full results have not been made public.[32]

In recent years, European and Canadian authorities have sampled glyphosate residues in foods. Canadian assessments did not test oats but detected glyphosate in over 30 percent of tested infant food and infant cereal.[33] In 2015, 9.1 percent of oat-based cereals surveyed in Europe had detectable levels of glyphosate, however, only 22 samples were analyzed.[34] In 2016, the non-profit Food Democracy Now tested single samples of a variety of popular American food items. Most notably, the highest levels of glyphosate were detected in Cheerios, but over 30 percent of samples had only "estimated" values due to uncertainties with the analytical method used in the study.[35]

EWG's independent lab results found that oat products have more concentrated levels of glyphosate compared to other common grains including wheat and corn.[36] While the detected glyphosate levels in oat products were all within federal legal limits, EWG asserts that these levels are inappropriately high based on EPA's omission of critical health data when setting tolerance limits.

Of the 45 product samples purchased and tested by EWG, 31 had glyphosate concentrations of 0.160 ppm and greater. The highest levels of glyphosate, greater than 1.0 ppm, were detected in two samples of Quaker Old Fashioned Oats. Only two product samples had no detectable glyphosate and 12 out of 45 product samples contained lower levels of glyphosate, from 0.01 to 0.120 ppm. Glyphosate was also detected, at concentrations of 0.010 to 0.030 ppm in five of 16

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[29] USDA, World Markets and Trade at 33 (Sept 2018), https://apps.fas.usda.gov/psdonline/circulars/grain.pdf; *see also* Monsanto Inc., *Preharvest Staging Guide*, http://www.roundup.ca/_uploads/documents/MON-Preharvest%20Staging%20Guide.pdf; Monsanto Inc. Roundup WeatherMax with Transorb 2 Technology Registration NO. 27487 (Feb 20 2018) http://www.roundup.ca/_uploads/documents/27487_WeatherMax_Approved%20All%20Uses_ENG_Re-eval_20Feb2018.pdf

[30] Roni A. Neff et al., *A comparative study of allowable pesticide residue levels on produce in the U.S.*, 8 Global Health 2 (2012), 10.1186/1744-8603-8-2

[31] GAO, Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations, GAO-15-38 (Oct 7, 2014), https://www.gao.gov/products/GAO-15-38

[32] Narong Chamkasem, FDA, Method Dev. Validation of the direct determination of glyphosate, glufosinate, and AMPA in Food by LC/MS (2016), https://www.nacrw.org/2016/presentations/O-27.pdf

[33] European Food Safety Authority (EFSA), The 2015 European Union report on pesticide residues in food, (April 7, 2017) doi:10.2903/j.efsa.2017.4791; Canada Food Inspection Agency (CFIA) Science Branch Survey Report, Safegaurding with Science: Glyphosate Testing in 2015-2016, http://www.inspection.gc.ca/food/chemical-residues-microbiology/food-safety-testing-bulletins/2017-04-13/executive-summary/glyphosate-testing/eng/1491846907641/1491846907985

[34] John Peterson Meyers et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, 15 Envtl. Health 19 (2016), 10.1186/s12940-016-0117-0

[35] FOOD DEMOCRACY NOW! *Glyphosate: Unsafe on any plate* (2016), https://usrtk.org/wp-content/uploads/2016/11/FDN_Glyphosate_FoodTesting_Report_p2016-3.pdf

[36] *Id., see also* Alexis Temkin, EWG, CHILDREN'S HEALTH INITIATIVE, *Breakfast with a dose of Roundup?* (Aug 15, 2018), https://www.ewg.org/childrenshealth/glyphosateincereal/#.W6wWYxNKiRY

organic product samples tested. These five samples came from two brands of organic rolled oats, Bob's Red Mill and Nature's Path. A third brand of organic rolled oats and all other organic oat products tested did not contain detectable concentrations of glyphosate. Glyphosate contamination of organic brand products could potentially come from glyphosate drift from conventional oats grown next to organically grown oats, or cross-contamination during food production.[37] This finding underscores the need for more data on actual dietary exposure to glyphosate. Without an accurate account of exposure the risk assessment by EPA cannot adequately consider lifetime exposure risk nor make a definitive finding that there is a reasonable certainty of no harm under the current tolerance level of 30 ppm. Full results are provided in the following table:

Type of Food	Product Name	Glyphosate (ppm)		
		Sample 1	Sample 2	Sample 3
Granola	Nature's Path Organic Honey Almond Granola	ND	ND	
	Back to Nature Granola Clusters - classic	.620	.170	
	Quaker Simply Granola Oats, Honey, Raisins & Almonds	.430	.400	
	Back to Nature Granola Clusters - Banana and Walnut	.030	.030	.340
	Nature Valley Granola Protein Oats 'n Honey	.220	.170	
	Kind Granola, Vanilla, Blueberry Clusters	.050	.060	
Instant Oats	Simple Truth Organic Instant Oatmeal	ND	ND	
	Quaker Instant Oats, Dinosaur Egg	.620	.780	
	Great Value Instant Oats	.450	.760	
	Umpqua Oats - Maple Pecan	.220	.220	
	Target Market Pantry Instant Oat - Strawberries + Cream	.120	.520	
Oat Breakfast Cereal	Kashi Organic Heart to Heart oat cereal	ND	ND	
	Cheerios	.490	.470	.530
	Lucky Charms**	.400	.230	
	Barbara's Multigrain Spoonfuls	.340	.300	
	Crackling Oat Bran	.250	.120	
Snack Bar	Cascadian Farm Organic Harvest Berry Granola Bar	ND	ND	
	KIND Oats & Honey Granola Bar	ND	.120	
	Nature Valley Crunchy Granola Bars Oats 'n Honey	.340	.420	
	Quaker Chewy Chocolate Chip Granola Bar	.120	.160	
	Nutrigrain Strawberry Cereal Bars	.030	.080	
Whole Oats	365 Organic Rolled Oats	ND	ND	
	Quaker Steel Cut Oats	.530	.290	
	Old Fashioned Oats	.390	1.10	1.30
	Bob's Red Mill (non-organic) Steel Cut Oats	.300	ND	
	Nature's Path Organic Rolled Oats	.030	.020	
	Bulk Bin (non-organic) Rolled Oats	.010	.040	
	Bob's Red Mill Organic Rolled Oats (4 samples tested)	ND	.010	.020, .020*

[37] Sarah West, NATURE'S PATH, ORGANIC NEWS & ENVT., *Are you eating glyphosate? How organic farming can help* (Jan 23, 2018), https://www.naturespath.com/en-us/blog/are-you-eating-glyphosate-organic-farming-can-help/

Source: EWG, from tests by Eurofin Analytical Laboratories

ND = none detected

**Two product samples tested both had 20 ppb glyphosate concentration.*

***Lucky Charms Frosted Toasted Oat Cereal with Marshmallows. Marshmallows were manually removed from the samples prior to shipping to the lab and testing for glyphosate.*

IV. Glyphosate is a Possible Carcinogen

Concerns have been raised about glyphosate's potential to cause cancer, particularly non-Hodgkin's lymphoma and other blood cancers.[38] Glyphosate exposure has also been associated with harm to the developing fetus, the reproductive system, liver, and kidney.[39] In 2015, the International Agency for Research on Cancer, a subdivision of the World Health Organization, reviewed existing data on glyphosate toxicity from epidemiological studies in people and research on laboratory animals and classified the chemical as "probably carcinogenic to humans" under Group 2A.[40] The Group 2A category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.[41] Limited evidence means that a positive association has been observed between exposure to the agent and cancer but that other explanations for the observations (called chance, bias, or confounding) could not be ruled out.[42] This evaluation considered the significant findings from the original 1984 U.S. EPA report [43] and several more recent positive results in concluding that there is sufficient evidence of carcinogenicity in experimental animals.[44]

Since then, additional reviews have contradicted the classification. In November 2015, the European Food Safety Authority (EFSA) concluded that glyphosate was unlikely to pose a carcinogenic hazard to humans. In May 2016, the Joint Food and Agriculture Organization (FAO) / WHO Meeting on Pesticide Residues (JMPR), another subdivision of the WHO, concluded that glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet. The EPA also reviewed the literature and found glyphosate to be "not likely to be carcinogenic to humans at doses relevant to human health risk assessment." After comments from the FIFRA Scientific Advisory Panel (SAP), they revised their determination to "not likely to be carcinogenic to humans," dropping the modifier.[45]

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[38] John Peterson Meyers et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, 15 Envtl. Health 19 (2016), 10.1186/s12940-016-0117-0

[39] *Id.*

[40] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[41] *Id.*

[42] *Id.*

[43] EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Sept 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf US EPA originally classified glyphosate as possibly carcinogenic to humans (Group C) in 1985. After a re-evaluation of that mouse study, the US EPA changed its classification to evidence of non-carcinogenicity in humans (Group E) in 1991. The US EPA Scientific Advisory Panel noted that the re-evaluated glyphosate results were still significant using two statistical tests recommended in the IARC Preamble.

[44] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[45] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, EPA-HQ-OPP-2009-0361-0073 at 144 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073

The EPA's Office of Research and Development epidemiologists agree with IARC that there is "limited evidence" of carcinogenicity in humans and understand IARC's definition of "limited evidence" as "a positive association has been observed" for which a causal association is "[c]redible, but chance, bias, or confounding could not be ruled out with reasonable confidence [IARC Preamble, section B6]." [46] Critically however, OPP decided to dichotomize the epidemiological evidence to be either "causal" or "not causal," resulting in different positions between EPA OPP and IARC. Generally, the data analysis and causal determinations in use for risk assessments include gradations of causality, however the OPP risk assessment did not follow this approach. Rather, it utilized a yes/no approach that does not provide for the possibility of carcinogenicity, despite the limited yet present data suggesting a possible causality. [47]

However, the EPA identified significant data gaps and internal disagreement on the implications of the science. In particular the SAP found that EPA did not adhere to the EPA Guidelines for Carcinogen Risk Assessment.[48] Some panel members found the weight of evidence, based on EPA's 2005 Guidelines, suggests potential carcinogenic effects. In their view, epidemiologic and rodent studies contain findings that together (coherence and consistency) suggest a potential for glyphosate to affect cancer incidence."[49]

These panel members felt that EPA's discussion of the epidemiological evidence appeared to discount statistical findings and overemphasize non-statistical criteria, and concluded that there is limited but suggestive evidence of a positive association between glyphosate exposure and risk of cancer, emphasizing the value and importance of the findings reported from several dose-response analyses and meta-analyses. [50] They recommended the Agency revise its conclusion along the lines of:

> "Based on the weight-of-evidence from epidemiological studies and meta-analyses, the Agency cannot exclude the possibility that observed positive associations between glyphosate exposure and risk of NHL suggest human carcinogenic potential of glyphosate, even though study limitations and concerns about potential biases remain."[51]

In addition, the panel identified critical data gaps due to limited epidemiological studies and no studies on glyphosate for highly exposed populations including children and manufacturers.[52]

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[46] EPA, Summary of ORD comments on OPP's glyphosate cancer assessment (Dec 14, 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf

[47] *Id.*

[48] *see generally* EPA, Guidelines for Carcinogen Risk Assessment (March 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf; *compare* EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[49] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 88 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[50] *Id.* at 16

[51] *Id.* EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 16-17 (Mar 16, 2017)

[52] *Id.* at 15, 29 "Even the estimated highest exposures experienced by glyphosate mixers and loaders of 0.03-7 mg/kg/day overlap with those potentially experienced by children. Thus applicators' occupational exposures may

The panel also identified remaining areas of uncertainty related to the potential for glyphosate-induced inflammation and genotoxic effects secondary to toxicity caused by high dose exposures (i.e., glyphosate-induced inflammation, oxidative stress, 8-OH-dG, and sister chromatid exchanges or 20 SCE) and whether the glyphosate-containing formulations have genotoxic potential.[53] Considered together, these data gaps undermine EPA's conclusion that glyphosate poses a reasonable certainty of no harm.

There have been many studies attempting to characterize the carcinogenic potential of glyphosate, using both human epidemiological data and experimental animal models. However, issues concerning the reproducibility of the results, the utilization of different animal strains, the difficulties comparing research published decades ago with recent work, the association of farming with increased incidence of some cancers, recall biases and co-exposure with other pesticides, and the latency of disease onset contribute to the difficulty of analyzing the (both positive and negative) findings.

a. Human studies demonstrate likely link between glyphosate exposure and non-Hodgkin lymphoma

Review of human epidemiological studies suggests an association between glyphosate and non-Hodgkin lymphoma (NHL). Although individual studies may not be statistically significant, when the data are merged, the relationship becomes evident.

Meta-analysis is used to combine results from different studies, to increase the power of the analysis. Specifically, for NHL and occupational exposure to glyphosate, IARC cites a 2014 study which combined six human epidemiological studies to find a meta risk-ratio of 1.5 (95% CI, 1.1–2.0). IARC added two additional epidemiological studies to the analysis and found a meta risk-ratio of 1.3 (95% CI, 1.03–1.65).[54] IARC also noted that case-control studies in three countries reported an increased risk of NHL resulting from glyphosate exposure.[55] These data lead IARC to conclude that there is "limited evidence in humans for the carcinogenicity of glyphosate."[56]

EPA's Science Advisory Panel (SAP) noted a third, more recent meta-analysis examining the relationship between glyphosate and NHL. The third meta-analysis created four different models that varied which studies were included in the analysis and the statistical method used. The lower bound for the 95 percent confidence interval for all four meta risk-ratios was 1.00 or greater, suggesting a positive association between NHL and glyphosate.[57] Because of this, some panelists noted that "since all the studies evaluated for NHL were of acceptable quality and three meta-analyses included by EPA show similar positive meta-RRs with uncertainties suggesting the risk estimates are above 1.0, the evidence from human data is suggestive of the carcinogenic potential

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not distinguish them from the general population with regard to absorbed doses of glyphosate, and it is not clear then that epidemiologic studies of such users are of much probative value."

[53] *Id.* at 18

[54] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017) at 30, https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[55] *Id.* at 75.

[56] *Id.* at 78.

[57] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 42-45 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

of glyphosate. All potential biases described . . . [were] plausible, but not sufficient . . . to disregard the meta-analyses findings."[58]

EPA performed its own meta-analysis and calculated a meta-effect estimate of 1.27 (95 percent CI, 1.01–1.59).[59] However, EPA immediately discounts this finding and the other meta-analyses because "Any of the meta-analysis estimates that were statistically significant were all borderline with the lower limit of the 95% CI just slightly over 1."[60] EPA advises that the number of studies in the meta-analysis is low and suggests that there could be bias and confounding variables influencing the results.[61] The Agency concludes that "Based on the weight-of-evidence, the agency cannot exclude chance and/or bias as an explanation for observed associations in the database. Due to study limitations and contradictory results across studies of at least equal quality, a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data."[62]At the earlier SAP meeting, some panelists, knowing the EPA was inclined to make this statement, expressed concern that "EPA's overall discussion appeared to focus on weaknesses and limitations of epidemiology in general as well as in each of the specific studies. It appeared to some Panel members that the Agency did not provide any alternative perspective that the evidence could be suggestive of an underlying effect of glyphosate on NHL."[63] It was proffered that the descriptor "Suggestive Evidence of Carcinogenic Potential" would be a better fit with the meta-analyses results.[64]

In 2017, a new analysis of the AHS cohort demonstrated an increased risk of acute myeloid leukemia in the most highly exposed pesticide applicators (relative to those who did not use glyphosate) that did not reach statistical significance ($P_{trend}T_{rend}$ = .11).[65] The EPA included these results in its Final Issue Paper by stating, "This study reported no association between glyphosate exposure and all lymphohematopoietic cancers, NHL, or any of its subtypes across exposure metrics," which may be an overstatement based on the suggestive trend finding.[66]

b. Despite discrepancies, animal models, when viewed in toto, suggest glyphosate is a rodent carcinogen

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[58] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 45 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[59] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017) (DP Barcode: D444689), at 64, https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487; EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 43 (Mar 16, 2017) , https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[60] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 64 (Dec. 12, 2017) (DP Barcode: D444689), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487

[61] *Id*. at 64-68.

[62] *Id*. at 68; EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 68 (Sept. 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf

[63] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 46 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[64] *Id.* at 48.

[65] Andreotti G, Koutros S, Hofmann JN, et al., Glyphosate Use and Cancer Incidence in the Agricultural Health Study, 110(5) J Nat'l Cancer Inst. 509-516 (2018).

[66] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 67 (Dec. 12, 2017) (DP Barcode: D444689), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487

After reviewing studies of rat and mouse models exposed to different doses of glyphosate, IARC concluded that "there is sufficient evidence in experimental animals for the carcinogenicity of glyphosate."[67] The EPA, in its analysis of the data, evaluated 14 animal studies. Of six mouse studies, three revealed a glyphosate-related trend in tumor incidence in "hemangiosarcomas, malignant lymphomas, or hemangiomas following adjustment for multiple comparisons."[68] Of eight rat studies, four demonstrated "a statistically significant trend . . . for tumor incidences in the testes, liver, or mammary gland following adjustment for multiple comparisons."[69] However, the agency immediately discounted these findings if the pairwise comparisons also were not significant, if there was not a monotonic dose response, if there was no evidence of tumor progression or pre-neoplastic lesions, or if the incidence of tumors was within historical controls.[70] EPA noted that the positive results were not reproducible.[71] The agency concluded that "based on the weight-of-evidence evaluations . . . none of the tumors evaluated in individual rat and mouse carcinogenicity studies are treatment-related . . ."[72]

During the earlier SAP meeting, some panelists agreed with the EPA's proposed conclusion (which mirrored its final conclusion closely), although others believed that the agency was giving disproportionate significance to certain factors such as the historical tumor rates.[73] Some panelists also did not agree with the EPA's downplaying of significant trends that were not monotonic, and thought that this was a violation of the 2005 Guidelines for Carcinogen Risk Assessment.[74] Other criticisms were that the EPA discounted doses above the limit dosage and did not explain why it chose to use historical controls in some comparisons.[75] The requirement for pairwise significance in addition to trend significance was also incongruent with the 2005 Guidelines.[76]

Some SAP panelists argued that the question was whether, individually, there is evidence of carcinogenic potential in any endpoint in a species or gender, not whether there is consistency between genders or among species and endpoints.[77] These panelists referred to comments submitted by Dr. Christopher Portier suggesting a pooled analysis and demonstrating that such an analysis revealed carcinogenic potential for some endpoints (see below for greater discussion

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[67] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans, at 78 (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf
[68] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 90 (Dec. 12, 2017) (DP Barcode: D444689) https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487
[69] *Id*. at 82.
[70] *Id*. at 82, 90; EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 82, 90-91, (Sept. 12, 2016) https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf
[71] *Id*. at 97.
[72] *Id.* at 97.
[73] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 18 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf
[74] *Id.* at 18, 50.
[75] *Id*. at 50.
[76] *Id*. at 53.
[77] *Id.* at 56.

of Dr. Portier's analysis of the animal carcinogenicity data).[78] Based on the "totality of tumor data," some panelists believed there was evidence that glyphosate is a rodent carcinogen.[79]

c. Open letter from former director of NCEH/ATSDR suggests analyses of glyphosate animal studies were flawed, and that the incidence of tumors is higher than reported

The data behind the analyses by the European Food Safety Authority (EFSA) and European Chemicals Agency (EChA) of the carcinogenic potential of glyphosate were made available to the public. This allowed Dr. Portier to examine the data more carefully, and, upon doing so, he found additional instances of tumor formation which had been missed by the earlier analyses.[80] He calls for the agencies to comprehensively re-evaluate their data in light of his findings to identify all the tumor sites.[81] Accordingly, the new results should be incorporated into their conclusions about glyphosate.

Portier notes that some of the results, although positive, were categorized by EFSA and EChA as unrelated to glyphosate exposure. He points out that some of the proffered reasons for excluding positive data in animal studies are not scientifically appropriate. Investigators should not have concluded that studies' results were inconsistent with each other because they should not have been comparing studies which used different strains of animal models. Reviewers also should not have compared the results of studies that were of different durations, because the rate of spontaneous tumor formation in older rodents is much higher than in middle-aged rodents.[82] Moreover, the use of historical controls in place of concurrent controls to show that tumor incidence did not vary between groups also undermines the validity of the analysis—the outcome of a study is more robust when the animals are closely related genetically, eat the same food, and live in the same type of housing.[83] Reviewers also rejected positive findings if there was a sex difference in the rate of tumor formation, but Portier asserts this is not a valid analytical technique, and notes that there are known human carcinogens which have demonstrated discrepancies based on sex in tumor incidence in animal models.[84] Finally, he counters the

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[78] *Id*. at 59.
[79] *Id.* at 77; Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slides 13-15 (Oct. 11, 2017), https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 3, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf
[80] Dr. Portier states: "In the last two years, I have systematically gone through these data to identify any statistically significant findings that might have been missed in the other evaluations. I found three additional tumors [in mice studies] that had not been discussed in any of the previous evaluations . . . . [For rats,] there are 7 tumors not discussed in any of the evaluations . . . ." Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 3, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slides 13-15 (Oct. 11, 2017), https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf
[81] Letter from Christopher Portier, PhD, to Jean Claude Juncker, President, European Comm'n (May 28, 2017), at 5, https://www.nrdc.org/sites/default/files/open-letter-from-dr-christopher-portier.pdf
[82] Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slide 21 (Oct. 11, 2017),; https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 5-6, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf
[83] *Id.* slide 19; slide narrative at 4-5, 5-6.
[84] *Id.* slide 20.

argument that the animals in the highest dose exposure groups were suffering from general toxicity; thus, the effects observed at these exposure levels were likely due to glyphosate and should have been incorporated into EFSA's and EChA's assessments.[85]

d. Division within the EPA OPP's conclusion regarding carcinogenic potential of glyphosate

The EPA's Office of Research and Development (ORD) conducted an expedited review of OPP's conclusion that glyphosate was "not likely to be carcinogenic to humans." ORD points out that OPP seems to evaluate data in a binary (yes/no) manner: Epidemiological studies are categorized as either demonstrating carcinogenicity or not, ignoring the "gradations of causality" embodied in modern risk assessment approaches and the EPA Cancer Guidelines themselves.[86] IARC, in its review of glyphosate, and ORD utilize descriptors that may signify a plausible positive association between human cancer and glyphosate, without completely ruling out chance. OPP's failure to follow its own agency guidelines when evaluating the human epidemiological studies cast doubt on its conclusion that glyphosate is "not likely to be carcinogenic."

Another criticism that ORD made of OPP's evaluation is that OPP only used pairwise comparisons, while IARC used trend tests. The EPA Cancer Guidelines allow both tests to be used when evaluating the incidence of tumors, and state that a positive result using one test and a null effect in the other is still enough evidence to conclude that the relationship between exposure and tumors is not by chance. Under these circumstances, OPP should have been more circumspect about rejecting IARC's trend analyses and subsequent conclusions and concluding that glyphosate is "not likely to be carcinogenic."

Finally, ORD points out that OPP did not perform "an integrated analysis of the data" and instead reviewed each study individually. ORD also notes that the mutagenic potential of glyphosate was not thoroughly analyzed. Again, given that one office within EPA is pointing out the incompleteness of the analysis of another EPA office concerning their conclusions regarding glyphosate, and suggesting that a different conclusion is more appropriate, EPA should reduce the tolerance level to be more health-protective.[87]

V. Children's Health

Many common oat products are marketed to children, and the EPA has noted that children 1-2 years old have the highest dietary exposure to glyphosate.[88] As noted by the Scientific Advisory Panel, the epidemiologic data is limited and none of the studies addressed populations who have relatively high exposure.[89] However, because the EPA categorized glyphosate as "not likely to be carcinogenic," the greater vulnerability of children to this chemical remains inadequately

[85] Id; slide narrative at 5
[86] EPA, Summary of ORD comments on OPP's glyphosate cancer assessment (Dec 14, 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf
[87] *Id., see also* https://www.nrdc.org/experts/jennifer-sass/split-within-epa-glyphosate-carcinogenicity
[88] EPA OPP, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 15 (Sept 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf
[89] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 15 (Mar 16, 2017)

evaluated. In addition to excluding cancer risk from the equation, EPA also used incorrect toxicological endpoints in its assessment of the pesticide and failed to include human studies. Taken together, the standard applied by the agency failed to comprehensively capture the risk potential of glyphosate exposure in children and proceeded to set a food residue tolerance level that is not protective enough.[90]

As described by EPA

> "Children 1-2 years old are considered the most highly exposed subpopulation with oral exposures from dietary (food and water) ingestion and incidental oral ingestion (e.g., hand-to-mouth activities) in treated areas. There is also potential for dermal exposures in previously treated areas. Using HED's standard exposure assessment methodologies which are based on peer-reviewed and validated exposure data and models6 , a high-end estimate of combined exposure for children 1-2 years old is 0.47 mg/kg/day".[91]

The FFDCA explicitly requires that EPA, in establishing a tolerance, must assess the risk that a pesticide poses to infants and children. 21 U.S.C. § 346(a)(b)(2)(C). The agency shall "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the pesticide and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." §§ 346a(b)(2)(C)(ii)(I) & (II).

In ensuring that the statutory safety standard is met, EPA must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." §§ 346a(b)(2)(C)(i)(I) & (III). EPA must also base its tolerance decision on available information about "food consumption patterns unique to infants and children" and the "cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity." *Id*. §§ 346a(b)(2)(C)(i)(I) & (III).

Additionally, "a tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*

A tenfold safety factor for children's health is fully supported by both the national pesticide law and by the recommendations of the country's top experts. In 1993, the National Research Council Report "Pesticides in the Diets of Infants and Children," highlighted that children are exposed to more pesticides than adults and are more susceptible to the toxic effects of pesticides, particularly those that cause cancer.[92] In 2009, the National Research Council again emphasized

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[90] Mills PJ et al., *Excretion of the Herbicide Glyphosate in Older Adults Between 1993 and 2016*, 318(16) JAMA 1610-1611 (2017), 10.1001/jama.2017.11726; IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[91] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 15 (Mar 16, 2017)

[92] NAT'L RESEARCH COUNCIL ET AL., PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN (1993), https://doi.org/10.17226/2126

the importance of applying an adjustment factor to account for varying susceptibility to cancer among humans.[93]

A risk assessment for glyphosate should include a tenfold safety factor to account for glyphosate exposures to children and the developing fetus. A 2009 report from the State of California points out that existing risk assessment approaches do not "adequately address the possibility that risk from early-in-life exposures may differ from that associated with exposures occurring in adulthood."[94] The report also noted that an adjustment factor of 10 is appropriate for calculating lifetime cancer risk in humans arising from carcinogen exposures that occur in utero.[95] A safety factor of 10 would account for potential increased susceptibility to glyphosate exposures occurring before birth and in the early years of life.

EPA acknowledges the need for this heightened safety standard for children, yet the dietary risk assessment for glyphosate did not conduct acute or cancer risk assessments because of the preceding classification of "not likely to be a human carcinogen." In addition, the exposure scenarios relied only on animal studies and did not include comparable data based in human studies.[96] The chronic analysis assumed tolerance-level residues and 100 percent crop treatment.[97] The resulting chronic risk estimates were below 100 percent of the chronic population-adjusted dose (cPAD) and are therefore determined to be less than HED's level of concern.[98] However, the established cPAD is too high because it's not based on cancer data, thus any risk assessment even factoring for worst case scenarios like using tolerance-level residues and 100% crop treatment will result in chronic exposure estimates less than 100%. The resulting chronic risk estimates are incomplete as conducted for failing to consider the potential carcinogenicity of glyphosate.

In 2017, California listed glyphosate as "Known to the State to Cause Cancer" under the California Proposition 65 law that requires labeling of cancer-causing chemicals and proposed a No Significant Risk Level of 1.1 milligrams glyphosate per day, more than 60 times lower than the safety level set by the Environmental Protection Agency.[99] California's proposed limit under Proposition 65 is the dose of glyphosate expected to cause no more than one case of cancer in every 100,000 people who ingest it over a lifetime.[100] EWG strongly supports the state's move to set a health-protective limit for glyphosate based on cancer risk. But we believe the EPA should

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[93] NAT'L RESEARCH COUNCIL ET AL., SCIENCE AND DECISIONS; ADVANCING RISK ASSESSMENT (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment

[94] CA EPA OEHHA, IN UTERO AND EARLY LIFE SUSCEPTIBILITY TO CARCINOGENS: THE DERIVATION OF AGE-AT-EXPOSURE SENSITIVITY MEASURES, (May 2009), https://oehha.ca.gov/media/downloads/crnr/appendixjearly.pdf

[95] *Id.*

[96] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017)

[97] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, Appendix E, EPA-HQ-OPP-2009-0361-0073 at 200 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073; *compare to* actual U.S. treatment of oats with Glyphosate, USDA QUICK STATS, AVERAGE OF DATA ITEMS ACROSS TIME PERIODS (Last visted Sept 26 2018) https://quickstats.nass.usda.gov/data/maps/1F600EE4-9DCA-32F5-86C2-75F947786B68

[98] EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[99] CA, Glyphosate Listed Effective July 7, 2017, as Known to the State of CA to Cause Cancer, CAS No. 1071-83-6 (Jun 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer#_ftn1

[100] *Id.*

go further and set a much lower limit for glyphosate at no more than 0.01 milligrams per day consistent to the 1993 tolerance level of 0.1ppm.[101]

Following the approach for deriving a cancer-specific risk level used by California's Office of Environmental Health Hazard Assessment in California, EWG calculated that a one-in-one-million cancer risk, protective of children's health would be 0.01 milligrams of glyphosate per day.[102] Eating a cup of cereal with a glyphosate level of 0.160 ppm would result in ingesting this amount of glyphosate – without taking into account the presence of glyphosate in other foods. The widespread dietary exposure to glyphosate prompts petitioners to request the EPA reduces the tolerance level of glyphosate on oats back to the a more protective 0.1 ppm residual level and take action to prevent oat products that were treated with preharvest glyphosate from entering the U.S. consumer market.

VI. Conclusion

The widespread exposure to glyphosate in high concentrations in oat products requires immediate action. EWG urges the EPA to follow its own internal guidelines when reviewing the evidence of increased cancer risks from human and animal studies. It must also consider ways to pool data across studies for cancers where authors report statistically significant trend tests. Recognizing that international practices and market trade have prompted the higher tolerance levels of glyphosate in oat products entering the United States, however, these interests should not outweigh the need for robust safety standards for domestic consumers. The current tolerance levels are not protective enough in consideration of actual dietary exposure to glyphosate in oats with and the potential carcinogenicity of glyphosate.

EWG and co-petitioners request that EPA lower the tolerance limit of glyphosate in oats from 30 ppm to 0.1 ppm to account for the carcinogenic risk of the pesticide and high dietary exposure of children. In addition, petitioners request that the EPA clarify labeling requirements to explicitly prohibit preharvest application of glyphosate on oats as a desiccant.

Respectfully Submitted,

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[101] EWG, RETHINKING CANCER, *California's Proposed Limit vs. The Amount Allowed by EPA*, (2016) https://www.ewg.org/research/california-proposes-safe-level-roundup-more-100-times-lower-epa-limit/californias-proposed#.W5majthKj-Y; EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[102] *Id.*

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Docket Number EPA-HQ-OPP-2009-0361
www.regulations.gov

Glyphosate

Interim Registration Review Decision
Case Number 0178

January 2020

Approved by: _____
Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

Date: 1-22-2020

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) *Interim Registration Review Decision* (ID) for glyphosate acid (PC Code 417300) and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, and 103613; case 0178), and is being issued pursuant to 40 CFR § 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an Interim Registration Review Decision before completing registration review. Among other things, the Interim Registration Review Decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review case. Additional information on glyphosate can be found in the EPA's public docket (EPA-HQ-OPP-2009-0361) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing an ID for glyphosate so that it can (1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation (see Appendices A and B). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, the Services) to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the EPA has not yet fully evaluated risks to federally-listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for glyphosate prior to completing the glyphosate registration review. Likewise, the agency will complete endocrine screening for glyphosate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices D and E, respectively, for additional information on the listed species assessment and the endocrine screening for the glyphosate registration review.

In addition, in September 2018, the Environmental Working Group (EWG) along with several other stakeholders, collectively referred to as EWG et al. hereafter, petitioned the agency to

reduce the glyphosate tolerance in oats to 0.1 parts per million (ppm) and to require labels for registered glyphosate products to explicitly prohibit the use of glyphosate as a preharvest desiccant. The agency is in the process of reviewing comments submitted on the 2018 EWG et al. petition and responding to the EWG et al. petition; to the extent the issues in the petition impact the registration review case, EPA will incorporate its responses to the petition into its final registration review decision for glyphosate. To view the EWG et al. petition and related documents, visit docket ID: EPA-HQ-OPP-2019-0066 at regulations.gov.

The glyphosate registration review case covers glyphosate acid (PC code 417300) and the following salt forms with active pesticide registrations: isopropylamine salt (PC code 103601), ammonium salt (PC code 103604), ethanol amine salt (PC code 103605), diammonium salt (PC code 103607), dimethyl ammonium salt (PC code 103608), and the potassium salt (PC code 103613). Glyphosate is a non-selective, systemic herbicide with products registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, cereal grains, and other field crops. Non-agricultural uses include residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate products are also registered for use on the glyphosate-resistant crops, including alfalfa, corn, soybean, cotton, canola, and sugar beets. The first pesticide product containing glyphosate was registered in 1974; a Reregistration Eligibility Decision (RED) for glyphosate was completed in 1993. Since then, the EPA has reviewed the risk assessments for glyphosate to determine if updates were necessary when new uses were added to glyphosate labels.

This document describes any changes since the Proposed Interim Registration Review Decision (PID), includes a summary of public comments on the PID, and includes the agency's interim registration review decision and the agency's rationale. See the PID for a summary of glyphosate's registration review timeline, use and usage information describing how and why glyphosate is used, the EPA's risk and benefits assessments, and a discussion of risk characterization. The PID also describes the mitigation measures that were proposed to address risks of concern and the regulatory rationale for the EPA's proposed interim registration review decision.

A. Updates Since the Proposed Interim Registration Review Decision was Issued

In April 2019, the EPA published the PID for glyphosate. Since that time, the agency has reviewed public comments and has made changes to the spray drift management labeling and rotational crop timing language that was proposed in the PID. The changes for spray drift management labeling are as follows: changes in droplet size restrictions, the removal of advisory spray drift statements for airblast applications, and the incorporation of updated swath displacement language for aerial applications. In addition, the agency has updated the language regarding rotational crop timing to provide clearer directions for use. For more information on the changes made to the mitigation proposed in the PID, please refer to Section IV.A. and Appendix A. There have been no additional updates to what was proposed in the PID, nor any updates to the draft risk assessments (DRAs). This document thus finalizes the agency's draft supporting documents *Glyphosate Draft Human Health Risk Assessment for Registration Review* and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*,

which are available in the public docket. Along with the ID, the following documents are also posted to the glyphosate docket:

- *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision*, dated January 16, 2019
- *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, dated January 13, 2019

B. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period for the PID, which opened on May 6, 2019, the agency received comments requesting an extension of the public comment period from the original deadline of July 5, 2019. The agency extended the comment period for 60 days, which then closed on September 3, 2019. During the 120-day comment period, the agency received roughly 283,300 comments. Over 12,000 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, the U.S. Department of Agriculture and members of the general public. Most comments came from mass mailer campaigns, and approximately 120 unique substantive comments were received from various stakeholders.

Along with the ID, the agency is posting the following documents that address comments received on the PID: *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* and *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*. Most of the comments received on the PID are substantively the same as comments received during previous glyphosate comment periods on the agency's risk assessments. The *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* responds to comments that have not been addressed previously via the December 2016 FIFRA Scientific Advisory Panel (SAP) meeting to discuss the carcinogenic potential of glyphosate[1] or in previous registration review documents for glyphosate. These comments did not result in changes to the agency's risk assessments.

EPA's *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* document combined comments by topic instead of responding to individual stakeholders and directs the public to responses previously provided in EPA documents. Comments specific to the glyphosate mitigation, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below, and some resulted in changes to the mitigation proposed in the PID.

For more detailed responses to comments relating to the human health risk assessment, and EPA's cancer evaluation for glyphosate, see the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* and *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*. For more detailed responses to

[1] Materials from the December 13-16, 2016 FIFRA SAP are posted in docket EPA-HQ-OPP-2016-0385. The final report, the transcript, charge questions, and other materials are also available online: https://www.epa.gov/sap/meeting-materials-december-13-16-2016-scientific-advisory-panel

comments relating to the ecological risk assessment, see the *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate*. For detailed responses to comments on the use/usage of glyphosate and the benefits, see the *Glyphosate: Response to Comments, Usage, and Benefits (PC Codes: 103601, 103604, 103605, 103607, 103613, 417300)*. All response to comments documents are available in the public docket for glyphosate (EPA-HQ-OPP-2009-0361) and published online[2]. The agency thanks all commenters for their comments and has considered them in developing this ID.

Comments Regarding the Environmental Working Group (EWG) Petition

Comment: On September 27, 2018, the agency received a petition from the Environmental Working Group, Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farms, Inc (EWG et al.). The petitioners requested that the agency reduce the tolerance of the pesticide glyphosate in or on oats from 30 ppm to 0.1 ppm and modify labels to explicitly prohibit preharvest use on oats. The petitioners asserted that the current tolerance level for oats is not protective enough when assessing people's dietary exposure to glyphosate in oats and the potential carcinogenicity of glyphosate. Numerous members of the general public commented in support of the EWG et al. petition. Various stakeholders and numerous farmers commented in opposition of the petition. EWG et al. also provided comments on the PID that were similar in nature to the issues raised in the petition.

EPA Response: In accordance with FFDCA section 408(d)(3), EPA published EWG et al.'s petition for a 30-day public comment period on May 6, 2019; the public comment period closed on June 5, 2019. The full petition is posted in docket EPA-HQ-OPP-2019-0066 at www.regulations.gov. The agency is still reviewing the 103,447 comments that were received on the petition. This Interim Decision reflects the conclusions of EPA's most recent risk assessments and does not address the claims raised in the petition, or constitute EPA's response to the petition. The agency anticipates issuing the response to the petition in 2020.

Comments Regarding the Human Health Risk Assessment

Comment: The agency received comments regarding the human health risk assessment from a wide array of stakeholders. Topics included concerns with the cancer assessment, toxicological studies, protection of children, and detections of glyphosate. Additionally, open literature studies were also identified for the agency's consideration.

EPA Response: Comments received regarding the human health risk assessment for glyphosate have been previously addressed in the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (EPA-HQ-OPP-2009-0361-2343). Many of the open literature studies were previously identified and considered by the agency as part of two open literature searches. The remaining studies identified during the public comment period were primarily journal articles published since these searches were conducted. None of the open literature

[2] https://www.epa.gov/ingredients-used-pesticide-products/proposed-interim-registration-review-decision-and-responses-0

studies identified for the agency's consideration were found to have an impact on the glyphosate hazard characterization, cancer assessment, or human health risk assessment. The agency will continue to monitor the open literature for studies that use scientifically sound and appropriate methodology and relevant routes of exposure that have the potential to impact the risk evaluation of glyphosate. For more information, please see the *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, which is available on the public docket.

Comments Regarding Spray Drift Management

Comment: Several stakeholders, including USDA and NAAA, provided comments on the proposed droplet size requirement of "fine or coarser," suggesting that a larger droplet size may be more appropriate for glyphosate products where glyphosate is the only active ingredient. The commenters expressed concern that using a fine droplet size might increase the risk of drift while providing no improvement on efficacy, due to the fact that glyphosate is a systemic herbicide that needs less coverage than contact pesticides. Commenters also noted that glyphosate is often tank-mixed with other pesticides and that fine droplet size may be appropriate in those cases to allow greater flexibility for tank mixing.

EPA Response: The agency is requiring label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all products containing glyphosate. The agency's goal is to manage off-target spray drift from application of glyphosate while continuing to preserve glyphosate's utility for growers and allow growers continued flexibility when making applications. Since glyphosate is a systemic herbicide, the agency agrees that "medium" or coarser droplet size is appropriate when glyphosate is sprayed as the sole active ingredient, or when tank-mixed with other systemic herbicides. Since glyphosate is a compound that is frequently tank-mixed with other pesticides (*e.g.* when used with an insecticide in a burndown treatment), the agency agrees that a "fine" droplet size is appropriate when tank-mixing with a pesticide product that requires a fine droplet size. The agency is revising the droplet size labeling based on the comments received. Refer to Section IV.A.1. and Appendix B of this Interim Decision for additional information on the required droplet size language.

Comment: Commenters noted that it is not appropriate to require enforceable spray drift management language for airblast applications, given that herbicides are not applied via airblast to orchards and vineyards.

EPA Response: The agency agrees that airblast application is not an approved application method for glyphosate and has removed this language from the required labeling in Appendix B.

Comments Regarding Rotational Crop Timing

Comment: The Joint Glyphosate Task Force (JGTF), consisting of 26 member companies, commented on the proposed labeling changes for rotational crop timing, suggesting language that provides clearer directions for use.

EPA Response: The agency thanks the JGTF for their comment. The agency has reviewed the suggested language and agrees that the language is more informative and clarifies the directions for use regarding rotational crop timing. Updated label clarification language for rotational crop timing has been included in Appendix B.

Comments Regarding the JGTF "Glyphosate Master Reference Label"

Comment: The JGTF submitted to the agency a document titled "Glyphosate Master Reference Label," which is intended to be used by registrants to aid in the creation and review of product labels containing glyphosate. The "Glyphosate Master Reference Label" intends to define key elements of a glyphosate end-use product label, including precautionary and other label statements, approved crop and non-crop uses, maximum application rates, methods of application, and application restrictions for specific uses.

EPA Response: The agency appreciates the registrant collaboration in identifying currently registered uses of glyphosate in the JGTF's "Glyphosate Master Reference Label". The task force developed this tool as a reference for registrants. While the JGTF's "Glyphosate Master Reference Label" may be used by registrants to aid in label submission, EPA emphasizes that the existing EPA process for reviewing labels as part of registration review still applies.

II. USE AND USAGE

Glyphosate is a broad-spectrum, systemic glycine herbicide which inhibits the enzyme 5-enolypyruvylshikimate-3-phosphate (EPSP) synthase in plants and inhibits aromatic amino acid synthesis. It is the only herbicide in the Weed Science Society of America's (WSSA) group 9 class and it has a unique mode of action. Glyphosate products are registered as ready-to-use solution, water-dispersible granules, soluble concentrate, emulsifiable concentrate, flowable concentrate, water soluble packaging, pressurized liquid, pellets/tablets, and tree injection shells. It can be applied as a pre-emergent, post-emergent, or as a pre-harvest application to the crop to treat a variety of emerged grass and broadleaf weeds. In a few crops (*e.g.* sugarcane), glyphosate is used as a plant growth regulator.

Glyphosate products are registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, legumes, cereal grains, and other field crops. Glyphosate products are also registered for use on the following glyphosate-resistant (transgenic) crops: corn, soybean, cotton, canola, sugar beets, and alfalfa. Registered non-agricultural uses include: tree injections, residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land.

Application methods vary for glyphosate and include aircraft, various ground equipment, and various handheld equipment. Application types include: aerial spray, ground boom spray, strip treatment, band treatment, broadcast spray, spot treatment, stump treatment, tree injection, and wipe-on/wiper treatments. The maximum single application rate on labels is up to 8 pounds acid equivalent per acre (lb ae/A) (acid equivalents or ae are used to assess the different acid and salt forms of glyphosate) for the following uses: pastures, non-food tree crops, forestry, aquatic

areas, and non-crop. However, for agricultural row crop uses, maximum single application rates are 1.55 lb ae/A for aerial applications and 3.75 lb ae/A for ground applications. Maximum annual application rates are generally 6 to 8 lbs ae/A, except for residential spot treatments.

The EPA completed a usage analysis for glyphosate by analyzing agricultural market research data from 2012 to 2016. Approximately 281 million pounds of glyphosate was applied to 298 million acres annually in agricultural settings, on average. Most glyphosate was applied to soybean (117.4 million lbs applied annually), corn (94.9 million lbs applied annually), and cotton (20 million lbs applied annually). Many citrus fruits (*e.g.*, grapefruit, oranges, lemons), field crops (*e.g.*, soybean, corn, cotton), and tree nuts (*e.g.*, almonds, walnuts, pistachios) have the highest percentage of their acres treated with glyphosate.

Approximately 24 million pounds of glyphosate are applied to non-agricultural sites annually, on average. The majority of non-agricultural use is in the homeowner market (5 million lbs applied annually), turf (4.9 million lbs applied annually), forestry (3.6 million lbs applied annually), and roadways (3.3 million lbs applied annually).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment was presented in the glyphosate PID. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate. The EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern.

Both non-cancer and cancer effects were evaluated for glyphosate and its metabolites, aminomethyl phosphonic acid (AMPA) and N-acetyl-glyphosate. The human health risk assessment for glyphosate and supporting documents, including the agency's revised issue paper on the carcinogenic potential of glyphosate, are published in the public registration review docket for glyphosate (EPA-HQ-OPP-2009-0361) at www.regulations.gov. The deliberations of the glyphosate FIFRA SAP meeting on the carcinogenic potential of glyphosate, including the agenda, meeting notes, SAP recommendations, the EPA's presentation to the FIFRA SAP, and other supporting documents are published in the glyphosate FIFRA SAP docket (EPA-HQ-OPP-2016-0385) at www.regulations.gov.

The agency concluded that there are no dietary risks of concern for any segment of the population, even with the most conservative assumptions applied in its assessments (*e.g.*, tolerance-level residues, direct application to water, and 100% crop treated). The agency also concluded that there are no residential, non-occupational bystander, aggregate, or occupational risks of concern.

The EPA has not made a common mechanism of toxicity to humans finding as to glyphosate and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, it was not appropriate for EPA to assess cumulative risks.

For additional details on the human health assessment for glyphosate, see the *Glyphosate Draft Human Health Risk Assessment for Registration Review*, which is available in the public docket.

1. Human Incidents and Epidemiological Analysis

The EPA conducted human health incident reviews for glyphosate in February 2014 and in October 2018. Thousands of glyphosate incidents were reported but most reported incidents were minor in severity. The high number of reported incidents across the databases is likely a result of glyphosate being among the most widely-used pesticides in the United States by volume. Health effects reported in the incident databases included dermal, ocular, and respiratory symptoms and effects were generally mild and resolved rapidly. While the agency recently received information regarding litigation related to glyphosate human health incident claims, submitted under the FIFRA 6(a)2 adverse event reporting requirement, the agency does not comment on private litigation. EPA has thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans. The agency will continue to monitor incident information and additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

The medical-case literature was reviewed, and most accidental ingestion of glyphosate formulations result in mild symptoms. Intentional ingestions caused moderate to severe symptoms and involved multiple organ systems.

The epidemiological literature was also reviewed but most studies were hypothesis-generating in nature. The EPA found there was insufficient evidence to conclude that glyphosate plays a role in any human diseases. Since the last EPA review of the epidemiological literature, two studies regarding the association between glyphosate exposure and non-Hodgkin's Lymphoma (NHL) were identified for detailed review by the agency; however, these studies did not impact the agency's assessment. For more information, refer to *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, which is available on the public docket.

For more information on reported human incidents, see the *Glyphosate: Tier II Incident Report*, available in the in the public docket for glyphosate.

2. Tolerances

Tolerances are established for residues of glyphosate in/on numerous plant commodities in 40 CFR § 180.364. Glyphosate tolerances range from 0.2 to 400 ppm. The EPA evaluated the glyphosate residue chemistry database to determine if the established tolerances conform to current practices and to determine whether updates were necessary for current crop group/subgroup definitions. The EPA intends to establish new tolerances for various vegetable and fruit groups and subgroups, as listed in Table 1. Upon establishment of these new crop group tolerances, EPA intends to remove the following individual tolerances, since they will no longer be needed: acerola; aloe vera; ambarella; asparagus; atemoya; avocado; bamboo, shoots; banana; biriba; breadfruit; cactus, fruit; cactus, pads; canistel; cherimoya; custard apple; date, dried fruit;

durian; feijoa; fig; fruit, stone, group 12; guava; ilama; imbe; imbu; jaboticaba; jackfruit; longan; lychee; mamey apple; mango; mangosteen; marmaladebox; noni; nut, tree, group 14; olive; palm heart; papaya; papaya, mountain; passionfruit; pawpaw; persimmon; pineapple; pistachio; pomegranate; pulasan; rambutan; rose apple; sapodilla; sapote, black; sapote, mamey; sapote, white; soursop; Spanish lime; star apple; starfruit; sugar apple; Surinam cherry; tamarind; vegetable, leafy, brassica, group 5; vegetable, leafy, except brassica, group 4; watercress, upland; and wax jambu. Additionally, EPA is requiring eliminating trailing zeros listed in tolerances consistent with agency policy.

Table 1. Required Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.

Current		Required Change		Comment
Commodity	**Tolerance (ppm)**	**Commodity**	**Tolerance (ppm)**	
Soybean, forage	100.0	Soybean, forage	100	Correct number of significant figures to be consistent with EPA policy
Soybean, hay	200.0	Soybean, hay	200	
Soybean, hulls	120.0	Soybean, hulls	120	
Soybean, seed	20.0	Soybean, seed	20	
Fruit, stone, group 12	0.2	Fruit, stone, group 12-12	0.2	Update to the current crop group definitions; coconut was excluded from the tree nut crop group tolerances as the residues were not within 5x (coconut tolerance at 0.1 ppm)
Nut, tree, group 14	1.0	Nut, tree, group 14-12 (except coconut)	1.0	
Vegetable, leafy, except brassica, group 4	0.2	Vegetable, leafy, group 4-16	0.2	Update to the current crop group definitions
Vegetable, leafy, brassica, group 5	0.2	Vegetable, *Brassica*, head and stem, group 5-16	0.2	
Several	0.2-0.5--	Vegetable, stalk and stem, subgroup 22A	0.5	
	0.2	Vegetable, leaf petiole, subgroup 22B	0.2	
	0.2	Fruit, tropical and subtropical, edible peel, group 23	0.2	
	0.2	Fruit, tropical and subtropical, small fruit, inedible peel, group 24A	0.2	
	0.2	Fruit, tropical and subtropical, medium to large fruit, smooth, inedible peel, group 24B	0.2	
	0.2	Fruit, tropical and subtropical, large fruit, rough or hairy, inedible peel, group 24C	0.2	
	0.2	Fruit, tropical and subtropical, vine, inedible peel, group 24E	0.2	

In accordance with FFDCA, the agency will be conducting rulemaking to implement any tolerance changes identified for glyphosate.

As noted in the PID, the agency received a September 27, 2018 petition from the Environmental Working Group et al., requesting that the agency reduce the tolerance of the pesticide glyphosate in or on oats and modify labels to explicitly prohibit preharvest use on oats. The agency issued a Federal Register Notice of Filing for public comment in a separate docket, EPA-HQ-OPP-2019-0066. This Interim Decision reflects the conclusions of EPA's most recent risk assessments and

does not address the claims raised in the petition or provide EPA's response to the petition. The agency anticipates issuing the response to the petition in 2020.

3. Human Health Data Needs

No additional human health data needs have been identified for the glyphosate registration review beyond the human health data required as part of the registration review DCI, which has been satisfied.

B. Ecological Risks

A summary of the agency's ecological risk assessment was presented in the PID. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate.

The agency did not identify potential risks of concern for fish, aquatic invertebrates, or aquatic-phase amphibians. Low or limited potential risks of concern were identified for mammals and birds. Consistent with its mode of action as an herbicide, potential risks to non-target terrestrial and aquatic plants were primarily from spray drift and the resulting distances from the edge of the field to below toxicity threshold were heavily dependent on the application rate used. Given its importance as a critical food resource for the monarch butterfly, the agency also completed a spray drift analysis for common milkweed, with those results being similar to distances calculated for other terrestrial plants tested in ecotoxicity tests (*i.e.*, cucumber).

Based on an adult honey bee acute contact and oral toxicity tests, the likelihood of acute adverse effects to adult bees is considered low at application rates up to 5.7 lb a.e./A; however, it is uncertain if effects would occur at higher application rates (i.e., up to 8 lb a.e./A). In a colony-level study, no adverse effects (acute or sublethal) were reported based on exposure to residues from an application at a rate of 1.92 lb ae/A. However, the full suite of Tier I toxicity studies are unavailable to fully assess potential risk to bees at the individual and/or colony level.

The agency believes that additional data may be necessary to fully evaluate risks to bees. Although the agency did not identify the need for these additional data to evaluate potential effects to bees when initially scoping the registration review for glyphosate, the Problem Formulation and registration review generic data call-in (GDCI) for glyphosate were both issued prior to publication of the June 2014 harmonized *Guidance for Assessing Pesticide Risks to Bees*[3]. This 2014 guidance lists additional laboratory-based studies of individual bees and based on the results of those studies, possible colony-level studies, that were not included in the glyphosate registration review GDCI. Therefore, the agency is currently determining whether additional bee toxicity and exposure data are needed for glyphosate. If the agency determines that additional data are necessary to help make a final registration review decision for glyphosate, then EPA will issue a GDCI to obtain these data. The pollinator studies that could be required for glyphosate are listed in Table 2.

[3] http://www2.epa.gov/sites/production/files/201406/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Table 2: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline (OECD 245)	Honey bee adult chronic oral toxicity
Non-Guideline OECD 239)	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for glyphosate. The draft biological evaluation for glyphosate is anticipated in 2020.

The agency conducted a review of ecological incidents and determined the majority of the glyphosate incidents are for terrestrial plants. Most plant incidents involved spray drift onto adjacent agricultural crops and grass. Fewer incidents were reported for terrestrial and aquatic wildlife.

For additional details on the ecological assessment for glyphosate, see the *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*, which is available in the public docket.

1. Ecological and Environmental Fate Data Needs

The ecological effects data required as part of the glyphosate registration review DCI were received and found to be adequate for risk assessment. The agency will issue a DCI for additional pollinator data as part of a separate action if it determines that additional pollinator data are necessary to help make a final registration review decision for glyphosate.

C. Benefits Assessment

Glyphosate is the most commonly used agricultural herbicide in the United States. It is a broad-spectrum herbicide that provides postemergence control of broadleaf, sedge, and grass weeds with minimal residual toxicity to crops or non-target vegetation. Glyphosate is a unique herbicide as it is the only herbicide classified as a Group 9 herbicide by the WSSA, which acts by inhibiting the enzyme EDSP synthase in plants and inhibiting aromatic amino acid synthesis.

Glyphosate is a relatively inexpensive herbicide to apply in agricultural situations, with the cost of applications to most crops ranging $1 to $13 per acre.

Glyphosate products are registered for use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial, and residential areas. Current glyphosate-resistant field crops are soybean, corn, cotton, canola, alfalfa, and sugar beet. Many of these crops, such as corn, cotton, soybean, and sugar beet, have exceptionally high percentages of their acreage treated with glyphosate (approximately 90 percent of acres treated in each crop). Genetically-engineered (transgenic) glyphosate-resistant (GR) varieties of these crops can be sprayed over-the-top with minimal or no crop phytotoxicity, and glyphosate may also be used as a pre-plant burndown in many of these crops. On average, 84 percent of glyphosate applied in agricultural settings, in terms of pounds, is applied to soybeans, corn, or cotton per year.

Glyphosate is also beneficial as part of weed control programs in orchards and specialty crops. Glyphosate use is prevalent in orchards and vineyards, and most acres of crops such as tree nuts, citrus, and grapes are treated with glyphosate. Glyphosate is the most versatile herbicide in orchard floor management because it may be used for under tree weed control, chemical wiping, chemical mowing, and spot treatment. Since glyphosate controls a broad spectrum of weeds and does not have residual soil activity, it can be used to control emerged weeds prior to planting high value crops such as fruits and vegetables, for which growers sometimes have limited weed control options.

Glyphosate is also important for noxious and invasive weed control in aquatic systems, pastures/rangelands, public lands, forestry, and rights-of-way. Invasive weeds controlled by glyphosate include cattails and water hyacinth, which can impede water flow and irrigation. Improper weed management can cause water to stagnate, providing a breeding habitat for mosquitos. Therefore, effective weed control is important for controlling mosquito-borne diseases. Glyphosate is also important for habitat restoration efforts. It is used to control invasive annual, perennial, and woody plants in riparian habitats and rangeland. Glyphosate use in rights-of-way helps keep roadways and railroad tracks safe by protecting the stability of the surface, maintaining visibility for operators, and allowing for the distribution of goods, services, and utilities (gas and electric). Glyphosate is the most frequently used active ingredient used to control invasive species in the United States.

Glyphosate is a versatile active ingredient and can be applied with many different types of application equipment depending on the needs of the user. In addition to the broadcast spray applications, it can be applied via application methods such as cut stump treatment, stem/tree injection, wick applications, spot treatment, and as a directed spray.

For more information on the benefits of glyphosate, see the *Glyphosate: Response to Comments, Usage, and Benefits*. In addition, the USDA provided non-agricultural usage information as a 2018 comment in the glyphosate public docket (EPA-HQ-OPP-2009-0361-1618), which furthered the agency's understanding of the benefits of glyphosate to this sector.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

The EPA did not identify any human health risks from exposure to glyphosate. The agency identified potential ecological risk to mammals and birds, but these risks are expected to be limited to the application area or areas near the application area. The EPA also identified potential risk to terrestrial and aquatic plants from off-site spray drift, consistent with glyphosate's use as an herbicide.

Glyphosate is a versatile herbicide that provides a broad spectrum of weed control across numerous agricultural and non-agricultural sites. Glyphosate is generally inexpensive in agricultural settings. Glyphosate is important in the management of invasive/noxious weeds and is a critical tool for habitat restoration efforts for rangeland and pastures. It is used for weed management for rights-of-way, forestry, industrial settings, residential areas, and aquatic environments.

The EPA concludes that the benefits outweigh the potential ecological risks when glyphosate is used according to label directions. To reduce off-site spray drift to non-target organisms, the agency is requiring spray drift management labeling. Since the PID was issued and in response to comments, the agency has made changes to the spray drift management language relating to droplet size, updated the swath displacement language based on current EPA policy, and removed the proposed advisory spray drift language for application via airblast, as airblast is not an application method used for glyphosate. In addition, EPA has adjusted the required language for rotational crop timing information based on the comments received. All required mitigation measures are detailed in Appendices A and B.

1. Spray Drift Management

The agency is requiring label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all glyphosate products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate.

The agency is requiring the following spray drift mitigation language to be included on all glyphosate product labels for products applied by liquid spray application. The required spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is providing recommendations which allow glyphosate registrants to standardize all advisory language on glyphosate product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements required in this ID once added to the labels.

- Applicators must not spray during temperature inversions.

- For aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor blade diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the ground or crop canopy, unless a greater application height is required for pilot safety.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground and/or aerial applications, select nozzle and pressure that deliver Medium or coarser droplets as indicated in nozzle manufacturer's catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1), unless tank-mixing with a pesticide product that requires use of a finer droplet size (ASABE S572.1). If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1).

The agency's goal is to manage off-target spray drift from applications of glyphosate while continuing to preserve glyphosate's utility for growers and allow growers continued flexibility when making applications. The agency assessed the potential impact on growers of the required spray drift management restrictions and has determined that these measures are not expected to substantially reduce the benefits of glyphosate to users. Prohibiting glyphosate applications during temperature inversions may impact the usability of glyphosate products by reducing the amount of time users have to apply glyphosate, but growers can switch to other products if they encounter temperature inversions.

For the PID, the EPA considered the impact of requiring "fine" or coarser droplets (*i.e.*, requiring growers to deliver droplets no smaller than "fine") on glyphosate labels and determined that such a requirement was not likely to affect the efficacy of glyphosate when used alone since it is a systemic herbicide. The agency is now requiring "medium" or coarser droplet size where glyphosate is the sole active ingredient being applied in order to further reduce drift. Efficacy is anticipated to be unaffected based on comments received from the public. Glyphosate is a compound that is frequently tank-mixed with other herbicides. Given that the language provides flexibility with droplet size for tank-mixed partners, the EPA does not expect there would be concerns for tank mixing with other herbicides. However, since glyphosate can be applied as a burndown treatment, insecticides may be included in the tank mix. Insecticides are generally considered to provide better efficacy with smaller droplets, therefore EPA is allowing "fine" droplets for use in tank mixes with active ingredients that require "fine" or coarser droplets. The EPA is uncertain if requiring "fine" droplets will impact the efficacy of insecticides tank-mixed with glyphosate because some insecticides could be more effective at droplet sizes smaller than "fine" (such as "very fine" or "extremely fine"). If reduced efficacy occurred, the agency would expect growers to respond by increasing the application rates (if allowed by the label), increasing

the number of applications, increasing the application rates of tank-mix partners, making additional applications, or switching to a different active ingredient.

In addition to including the spray drift restrictions on glyphosate labels, all references to volumetric mean diameter (VMD) information for spray droplets are required to be removed from all glyphosate labels where such information currently appears. The new language above, which cites ASABE S572.1, eliminates the need for VMD information.

2. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN or Notice) on herbicide resistance management.[4] Consistent with the Notice, the EPA is requiring the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID and ID.

The development and spread of herbicide-resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide-resistant weeds have been known since the 1950s, the number of species and their geographical extent has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide-resistant weeds, both in controlling established herbicide-resistant weeds and in slowing or preventing the development of new herbicide-resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

The EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

3. Non-target Organism Advisory

The protection of pollinators and other non-target organisms is a priority for the agency. While the agency did not identify risks to individual bees from glyphosate applications at rates below 5.7 lb ae/A, risks to terrestrial invertebrates at higher application rates are uncertain. In addition, glyphosate may impact non-target plants via spray drift and impact nectar sources and habitat for pollinators and other non-target organisms. EPA is requiring a non-target organism advisory to alert users of potential impact to non-target organisms: “This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas

[4] PRN 2017-2, “Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship”

adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."

4. Label Consistency Measures

There are currently 557 Section 3 registrations and 37 Section 24(c) registrations for glyphosate. Label directions for glyphosate vary significantly from label to label, and newer stamped labels in general have more comprehensive instructions than older labels. The EPA is requiring all glyphosate labels to be updated to modern standards. The specific components of the label that require updates are as follows: the maximum application parameters, the environmental hazards statement for aquatic use, and clarification on rotational crop timing. In addition, the agency is providing guidance to glyphosate registrants on acceptable marketing statements.

Maximum Application Parameters

In 2013, at the agency's request and in preparation for risk assessment, the Joint Glyphosate Task Force, a consortium of glyphosate registrants, created a *Use Summary Matrix*, which was intended to summarize all use sites being supported as part of registration review and outline important application parameters such as maximum single and yearly application rates. EPA's risk assessments for glyphosate were based on maximum application parameters as described in the *Use Summary Matrix*. The maximum application rates on glyphosate labels must be consistent with the maximum application rates that were assessed by the agency and supported by the Joint Glyphosate Task Force. These maximum application parameters are described in Appendix C of this document.

Many older glyphosate labels do not define any maximum application parameters. EPA is requiring that maximum application parameters be clearly defined on all glyphosate labels and must not exceed the maximum application parameters as described in Appendix C. It is not EPA's intention to change the current application rates on glyphosate labels, but the agency is requiring defined rate limits in order to establish better consistency and clarity on labels. Appendix C lists the maximum application parameters by use site for both aerial and ground application.

Statements for Aquatic Uses

The EPA is requiring updated environmental hazards statements for aquatic use products to be consistent with modern standards and to be in line with newer pesticide labels. The glyphosate Reregistration Eligibility Decision (RED) issued in 1993 specified that glyphosate labels formulated for aquatic use have language intended to warn users of potential fish suffocation from aquatic applications. The EPA is requiring updates to the existing language to be consistent with current labeling guidance (see the EPA's Label Review Manual, and Table 4 below).

An additional statement under "directions for use" for aquatic use labels is required to instruct users to apply in strips to help avoid oxygen depletion when emerged weed infestations cover the total surface area of an impounded water body (see Table 4 below).

Table 4. Statements Required for Glyphosate for Aquatic Use

Product Type	Statement
Environmental hazards: for labels with terrestrial uses only	"Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with aquatic uses only	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with both aquatic and terrestrial uses	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Directions for use for aquatic uses	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."

Clarification on Rotational Crop Timing

Many glyphosate labels lack instructions for crop rotation. The EPA is requiring the clarification that treated fields may be rotated to a labeled crop at any time. For fields being rotated to a non-labeled crop, any glyphosate application must be made a minimum of 30 days prior to planting. EPA is updating the language that was proposed in the PID to further clarify the instructions on rotational crop timing based on public comments received.

Label Claims

During meetings with the agency in 2018, the Joint Glyphosate Task Force proposed to clarify on existing labels a statement about how glyphosate works. The following statement is being required: "Glyphosate works by targeting an enzyme that is essential for plant growth." The revision is consistent with the requirements of 40 CFR § 156.10(a)(5). Registrants may use alternate claims, as long as alternate claims meet labeling requirements. Registrants can refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims prior to submitting updated labels for registration review.

B. Tolerance Actions

The EPA is requiring the following revisions for glyphosate tolerances: adjusting the number of significant figures, establishing new tolerances for various vegetable and fruit groups/subgroups, and deleting certain older tolerances which are no longer needed due to the new tolerance

groupings. Refer to Section III.A.3 of this document for the required tolerance changes. The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances. The agency intends to address the tolerance revisions requested by the EWG et al. petitioners in its response to their petition and has not addressed them in this document.

C. Interim Registration Review Decision

In accordance with 40 CFR § 155.56 and 155.58, the agency is issuing this Interim Registration Review Decision. Except for the EDSP, ESA, and resolution of the EWG et al. petition, the agency has made the following Interim Registration Review Decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed, as described in Section IV. A. and Appendices B and C. This document finalizes the agency's draft supporting documents: *Glyphosate Draft Human Health Risk Assessment for Registration Review*, and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts.*

In this interim registration review decision, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate, nor is it making a complete endangered species finding. This interim registration review decision does not address the specific claims raised in the EWG et al. petition, nor does it constitute EPA's response to the petition. Although the agency is not making a complete endangered species finding at this time, the mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate. The agency's final registration review decision for glyphosate will be dependent upon the result of the agency's ESA assessment and any needed section 7 consultation with the Services, an EDSP FFDCA section 408(p) determination, and after a resolution of the EWG et al. petition.

D. Data Requirements

No additional data are required for this registration review at this time. The EPA will consider requiring the glyphosate registrants to submit pollinator data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for glyphosate. A final decision on the glyphosate registration review case will occur after: (1) an EDSP FFDCA §408(p) determination, (2) an endangered species determination under the ESA and any needed §7 consultation with the Services, and (3) a resolution of the EWG et al. petition. This document finalizes the agency's draft supporting documents: *Glyphosate Draft Human Health Risk Assessment for Registration Review*, and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts.*

B. Implementation of Mitigation Measures

Given the anticipated timeframe for the agency's response to the EWG et al. petition in 2020, labels should not be submitted at this time. Once the agency completes its response to the petition, it will issue letters to glyphosate registrants requesting label submission to incorporate the glyphosate required interim risk mitigation (see Appendices A, B, and C), which will be posted to the docket. Revised labels and requests for amendment of registrations will be required for submission to the agency for review within 60 days following the issuance of letters.

Appendix A: Summary of Required Actions for Glyphosate

Registration Review Case#: 0178
PC Codes: 103601, 103604, 103605, 103607, 103608, 103613, 417300
Chemical Type: herbicide
Chemical Family: glycine derivative
Mode of Action: targets the 5-enolpyruvyl-3-shikimate phosphate synthase enzyme

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions	Comment
Terrestrial and aquatic plants	Spray drift	Foliar absorption	Acute Chronic	Survival, biomass	Require enforceable spray drift management language; updated environmental hazards language	
Birds	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth	Require enforceable spray drift management language	Risks are likely limited to the field and areas near the application field.
Mammals	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth and reproduction	Require enforceable spray drift management language	Risks to are likely limited to the field and areas near the application field.
Terrestrial invertebrates	Residues on nectar sources (via deposition or spray drift)	Dietary	Acute Chronic	Effects on nectar sources of terrestrial invertebrates	Non-target organism environmental hazards language	Risks to bees are uncertain at application rates higher than 1.9 lb ae/A. The agency may require additional pollinator data to fully assess risk to terrestrial invertebrates.

Appendix B: Required Labeling Changes for Glyphosate Products

Description	Required Label Language for Glyphosate Products	Placement on Label
	End Use Products	
Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide (*i.e.*, **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE)** in the fourth column. **Glyphosate** | **GROUP** | **9** | **HERBICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Non-target Organism Advisory	"NON-TARGET ORGANISM ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
Environmental Hazards Statement for Aquatic Use	*For labels without aquatic uses:* "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with aquatic uses only:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with both aquatic and terrestrial uses:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your	Environmental Hazards

Description	Required Label Language for Glyphosate Products	Placement on Label
	State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."	
Aquatic Use Statement	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."	Directions for Use
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action (Applies to all products delivered via liquid spray applications)	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Rotational crop information	"This product may be applied during fallow intervals preceding planting, prior to planting or transplanting, at-planting, or preemergence to annual and perennial crops listed on this label, except where specifically limited. For any crop not listed on this label, application must be made a minimum of 30 days prior to planting."	Directions for Use
Label claims	"Glyphosate works by targeting an enzyme that is essential for plant growth." [Alternate claims, if used, must meet labeling requirements. Refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims.]	Product Information
Clarification of application rates	Ground and aerial applications rates on the labels must not exceed the maximum application parameters as noted in Appendix C of this document, which were maximum application parameters assessed by the EPA. Application rates may only be clarified for uses that are currently approved on labels.	Directions for Use

Description	Required Label Language for Glyphosate Products	Placement on Label
Spray Drift Management Application Restrictions for all products that are delivered via liquid spray applications and allow aerial application	**"MANDATORY SPRAY DRIFT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Aerial Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and allow ground boom applications	**"MANDATORY SPRAY DRIFT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and allow boomless ground sprayer applications	**"MANDATORY SPRAY DRIFT** **Boomless Ground Applications:** • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Boomless Applications"

Description	Required Label Language for Glyphosate Products	Placement on Label
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Required Label Language for Glyphosate Products	Placement on Label
	Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which can cause small droplets to remain suspended in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They can begin to form in late afternoon/early evening and often continue into the morning. Their presence can be indicated by ground fog. If fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for products that are delivered via liquid spray applications and allow boomless ground sprayer applications	**"SPRAY DRIFT ADVISORIES** **Boomless Ground Applications:** • Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C: Maximum Application Rates for Glyphosate Ground and Aerial Application[5]

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Round-up Ready 2 Yield Soybeans	3.75	1.55	6
Root Tuber Vegetables: arracacha, arrowroot, carrot, chinese artichoke, Jerusalem artichoke, beet (garden), burdock, canna, cassava (bitter and sweet), celeriac, chayote (root), chervil (turnip-rooted), chicory, chufa, dasheen (taro), galangal, ginger, ginseng, horseradish, leren, kava (turn-rooted), parsley (turnip-rooted), parsnip, potato, radish, rutabaga, oriental radish, salsify, skirret, sweet potato, tanier, turmeric, turnip, wasabi, yacon, yam bean, true yam	3.75	1.55	6
Rangelands	0.38	0.38	2.25
Pome Fruits: including apple, crabapple, loquat, mayhaw, pear, oriental pear, quince	3.75	1.55	8
Pastures	8	8	8
Oilseed Crops: borage, buffalo gourd, calendula, canola, castor oil plant, chinese tallow tree, crambe, cuphea, echium, euphorbia, evening primrose, flax (seed), gold of pleasure, hare's ear mustard, jojoba, lesquerella, meadow foam, milkweed, mustard (seed), niger (seed), oil radish, poppy seed, rapeseed, rose hip, safflower, sesame, stokes aster, sunflower, sweet rocket, tallow wood, tea oil plant, veronia.	3.75	1.55	6
Non-Food Tree Crops: pine, poplar, eucalyptus, christmas trees, other non-food tree crops	8	8	8
Miscellaneous Tree Food Crops: cactus (fruit and pads), palm (heart, leaves, oil)	3.75	1.55	8
Miscellaneous Crops: aloe vera, bamboo shoots, globe artichoke, okra, peanut (ground nut), strawberry, sugar beet, asparagus, pineapple	3.75	1.55	6
Legume Vegetables: Succulent varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, field pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea; Soybean (immature seed); Sword bean. Dry varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean,	3.75	1.55	6

[5] It is not EPA's intention to change the current application rates on glyphosate labels, but the agency is requiring defined rate limits on labels in order to establish better consistency and clarity on labels.

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Soybean (immature seed); Sword bean Dry varieties of Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea			
Leafy Vegetables: Amaranth (Chinese spinach); Arugula (roquette); Beet greens; Cardoon; Celery; Chinese celery; Celtuce; Chaya; Chervil; Edible-leaved chrysanthemum; Garland chrysanthemum; Corn salad; Cress (garden and upland); Dandelion; Dock (sorrel); Dokudami; Endive (escarole); Florence fennel; Gow kee; Lettuce (head and leaf); Orach, Parsley; Purslane (garden and winter); Radicchio (red chicory); Rhubarb; Spinach; New Zealand spinach; Vine spinach; Swiss chard; Watercress (upland); Water spinach	3.75	1.55	6
Herbs and Spices: Allspice, Angelica, Star anise, Annatto (seed), Balm, Basil, Corage, Burnet, camomile, Caper buds, Caraway, Black caraway, Cardamom, Cassia bark, Cassia buds, Catnip, Celery seed, Chervil (dried), Chive, Chinese chive, Cilantro (leaf), Cilantro (seed), Cinnamon, Clary, Clove buds, Coriander leaf (cilantro or Chinese parsley), Coriander seed (cilantro), Costmary, Cumin, Curry (leaf), Dill (dillweed), Dill (seed), Epazote, Fennel seed (common and Florence), Fenugreek, White ginger flower, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage (leaf and seed), Mace, Marigold, Marjoram (including oregano), Mexican oregano, Mioga flower, Mustard (seed), Nasturtium, Nutmeg, Parsley (dried), Pennyroyal, Pepper (black and white), Pepper leaves, Peppermint, Perilla, Poppy (seed), Rosemary, Rue, Saffron, Sage, Savory (summer and winter), Spearmint, Stevia levaes, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood	3.75	1.55	6
Grass/Turfgrass/Sod Production	3.75	1.55	6
Grain Sorghum	3.75	1.55	6
Fruiting Vegetables: Eggplant; Groundcherry (Physalis spp); Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato	3.75	1.55	6
Forestry	8	8	8
Fallow	3.75	1.55	6
Cucurbits Vegetables/Fruit: Chayote (fruit); Chinese waxgourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Edible gourd (includes hyotan, cucuzza, hechima, Chinese okra); Melons (all); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); Muskmelon (includes cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey ball melon, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon); Pumpkin; Summer squash	3.75	1.55	6

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
(includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); Winter squash (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); Watermelon			
Cotton	3.75	1.55	6
Corn (Field, Seed, Silage, Popcorn)	3.75	1.55	6
Conservation Reserve Program	3.75	1.55	6
Citrus Fruit Crop: All cultivars, varieties and/or hybrids of Calamondin; Chironja; Citron; Citrus hybrids; Grapefruit (including Japanese summer); Kumquat; Lemon; Lime (including Australian desert lime, Australian finger lime, Australian round lime, Brown river finger lime, Mount white, New Guinea wild, Russell river, sweet, and Tahiti); Mandarin (including Mediterranean and Satsuma); Orange (all); Pummelo; Tangelo; Tangerine (Mandarin); Tangor; Uniq Fruit (ugli)	3.75	1.55	8
Cereal and Grain Crop: barley, buckwheat, millet, oats, rye, quinoa, teff, teosinte, triticale, wild rice, rice, feed barley, wheat	3.75	1.55	6
Bulb Vegetables: All cultivars, varieties and/or hybrids of Chive (fresh leaves, including Chinese chive); Daylily (bulb); Elegans hosta; Fritillaria (bulb and leaves); Garlic (bulb, including great-headed and serpent garlic); Kurrant, Leek (including lady's and wild leek); Lily (bulb); Onion (including Beltsville bunching, bulb, Chinese bulb, fresh, green, macrostem, pearl, potato bulb, tree tops and Welsh onion tops); Shallot (bulb and fresh leaves)	3.75	1.55	6
Brassica Vegetable: Broccoli; Chinese broccoli (gai lon); Broccoli raab (rapini); Brussels sprouts; Cabbage; Chinese cabbage (bok choy); Chinese cabbage (napa); Chinese mustard cabbage (gai choy); Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens	3.75	1.55	6
Round-up Ready Flex Cotton	3.75	1.55	6
Round-up Ready Cotton	3.75	1.55	6
Round-up Ready Corn (GA-21)	3.75	1.55	6
Round-up Ready Corn 2 (NK603)	3.75	1.55	6
Round-up Ready Alfalfa	1.55	1.55	6
Round-up Ready Sugarbeets	3.75	1.55	6
Tropical/Subtropical Trees/Fruits: Ambarella; Atemoya; Avocado; Banana; Barbados cherry (acerola); Biriba; Blimbe; Breadfruit; Cacao (cocoa) bean; Canistel; Carambola (starfruit); Cherimoya; Coffee; Custard apple; Dates; Durian; Feijoa; Figs; Governor's plum; Guava; Ilama; Imbe; Imbu; Jaboticaba; Jackfruit; Longan; Lychee; Mamey apple; Mango; Mangosteen; Marmaladebox (genip); Mountain papaya; Noni	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
(Indian mulberry); Papaya; Pawpaw; Plantain; Persimmon; Pomegranate; Pulasan; Rambuttan; Rose apple; Sapodilla; Sapote (black, mamey, white); Spanish lime; Soursop; Star apple; Sugar apple; Surinam cherry; Tamarind; Tea; Ti (roots and leaves); Wax jambu			
Tree Nut Crops: Cultivars, varieties, and/or hybrids of African nut-tree; Almond; Beechnut; Brazil nut; Brazilian pine; Bunya; Burr oak; Butternut; Cajou nut; Candlenut; Cashew; Chestnut; Chinquapin; Coconut; Coquito nut; Dika nut; Ginkgo; Guiana chestnut; Hazelnut (Filbert); Heartnut; Hickory nut; Japanese horse-chestnut; Macadamia nut; Mongongo nut; Monkey-pot; Monkey puzzle nut; Okari nut; Pachira nut; Peach palm nut; Pecan; Pequi; Pili nut; Pine nut; Pistachio; Sapucaia nut; Tropical almond; Walnut (black, English); Yellowhorn	3.75	1.55	8
Sweet Corn	3.75	1.55	6
Sugar Cane	3.75	2.25	6
Stone Fruit: All cultivars, varieties and/or hybrids of Apricot; Cherry (sweet and tart); Nectarine; Olive; Peach; Plum/Prune (all types); Plumcot	3.75	1.55	8
Round-Up Ready Canola (Winter Varieties)	1.55	1.55	6
Soybeans	3.75	1.55	6
Sweet Corn with Round-Up Ready 2 Technology	3.75	1.55	6
Round-Up Ready Canola (Spring Varieties)	1.55	1.55	6
Vine Crops: grapes (raisin, table, wine), hops, passion fruit, kiwi	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Non-Crop: Airports, airfields, apartment complexes, commercial sites, ditch banks, driveways, ramps, alleys, lanes, paths, trails, sidewalks, walkways, access roads, farm roads, highways (including aprons, medians, guardrails, and rights-of-way), paved areas and prior to paving, dry ditches, dry canals, fences and fencerows, golf courses, greenhouses, industrial sites, landscape areas, lumber yards, manufacturing sites, municipal sites, natural areas, office complexes, ornamentals, parks, campgrounds, sports areas, tennis courts, parking areas, cemeteries, petroleum or other tank farms and pumping installations, refineries, around telephone and communications equipment, public areas, drive-in theaters, railroads (including ballasts, shoulders, crossings and spot treatments), recreation areas, residential areas, rights-of-way, roadsides, firebreaks, schools, shadehouses, sports complexes, storage areas, substations, construction and pre-construction sites, turfgrass areas, around ornamental gardens, around ornamental trees and shrubs, power and utility sites, around commercial or industrial outbuildings, warehouse areas, bare ground, gravel yards, mulched areas, beaches, habitat restoration and management areas, uncropped farmstead areas, uncultivated non-agricultural areas, vacant lots, wastelands, shelter belts, and wildlife management areas. Natural Woodlands, including Wildlife and Habitat Management Areas, Wildlife Openings, Natural Areas (such as Wildlands and Wildlife Refuge), Campgrounds, Parks and Recreational Areas in Natural Forests, and Reforestation Treatments in Natural Forests	8	8	8
Aquatic	8	8	8
Alfalfa, Clover, and Other Forage Legumes, including: kudzu, lespedeza, lupin, sainfoin, trefoil, velvet bean, vetch, kenaf, leucaena	3.75	1.55	6
Berry and Small Fruit Crops: All cultivars, varieties and/or hybrids of Amur River grape; Aronia berry; Bayberry; Bearberry; Bilberry; Blackberry (including Andean blackberry, arctic blackberry, bingleberry, black satin berry, boysenberry, brombeere, California blackberry, Chesterberry, Cherokee blackberry, Cheyenne blackberry, common blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, evergreen blackberry, Himalayaberry, hullberry, lavacaberry, loganberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, mora, mures deronce, nectarberry, Northern dewberry, olallieberry, Orgeon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, Southern dewberry, tayberry, youngberry, zarzamora); Blueberry (highbush and lowbush); Buffaloberry; Che; Chilean guava; Chokecherry; Cloudberry; Cranberry (including highbush); Currant (black, Buffalo, red, native); Elderberry; European barberry; Gooseberry; Grape; Honeysuckle (edible); Huckleberry; Jostaberry; Juneberry (Saskatoon berry); Kiwifruit (fuzzy and hardy); Ligonberry; Maypop; Mountain pepper berries; Mulberry; Muntries; Partridgeberry; Phalsa; Pincherry; Raspberry (black, red and wild); Riberry; Salal; Schisandra berry; Sea buckthorn; Serviceberry	3.75	1.55	8

Appendix D: Endangered Species Assessment

This Appendix provides general background about the Agency's assessment of risks from pesticides to endangered and threatened (listed) species under the Endangered Species Act. Additional background specific to glyphosate appears at the conclusion of this Appendix.

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides[6]. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been proposed based on experience conducting the first three pilot BEs. Public input on those proposed revisions is currently being considered.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, 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 specific species or habitats, 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. This will allow the EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for glyphosate as part of completing this registration review.

[6] https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process

Glyphosate is one of the chemicals in stipulated partial settlement agreement in the case of Center for Biological Diversity et al., v. United States Environmental Protection Agency et al., No. 3:11 cv 0293 (N.D. Cal.). Among other provisions, this agreement sets an August 14, 2021, deadline for EPA to complete nationwide ESA section 7(a)(2) effects determination for glyphosate and, as appropriate, request initiation of any ESA section 7(a)(2) consultations with the Services that EPA may determine to be necessary as a result of those effects determinations.

Appendix E: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for glyphosate, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), glyphosate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. Glyphosate is on List 1 and the review conclusions are available in the glyphosate public docket (see EPA-HQ-OPP-2009-0361). A second list of chemicals identified for EDSP screening was published on June 14, 2013,[7] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[8]

[7] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[8] https://www.epa.gov/endocrine-disruption

In this ID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION PREVENTION

September 21, 2022

MEMORANDUM

SUBJECT: Withdrawal of the *Glyphosate Interim Registration Review Decision*

TO: Glyphosate Registration Review Docket (EPA-HQ-OPP-2009-0361)

FROM: Cathryn Britton, Branch Chief
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division

THRU: Mary Elissa Reaves, Director
Pesticide Re-evaluation Division
Office of Pesticide Programs

On June 17, 2022, the United States Court of Appeals for the Ninth Circuit vacated and remanded the human health portion of EPA's interim registration review decision for glyphosate (ID), held that EPA's failure to make an effects determination before issuing the ID violated the Endangered Species Act (ESA), and remanded without vacating the ecological portion of the ID but imposed an October 1, 2022 deadline for EPA to complete the remand. *Natural Resources Defense Council et al. v. EPA*, 38 F.4th 34 (9th Cir. 2022). In light of the court's decision, this memorandum announces EPA's withdrawal of all remaining portions of the glyphosate ID, including the remanded ecological portion.

A copy of the glyphosate ID, now vacated in part and the remainder withdrawn, is posted to the glyphosate registration review public docket (EPA-HQ-OPP-2009-0361) at https://www.regulations.gov.

Background

Issuance of the Glyphosate Interim Registration Review Decision

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide registration continues to satisfy the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

EPA regulations establish procedures for the registration review program required in FIFRA section 3(g). Under 40 C.F.R. § 155.56, EPA may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. Procedures for issuing an interim registration review decision are set forth in § 155.58.

On February 3, 2020, EPA published a notice in the Federal Register (85 Fed. Reg. 5957) announcing the availability of the glyphosate ID. EPA issued the ID pursuant to 40 C.F.R. §§ 155.56 and 155.58, explaining that it was doing so to "(1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation." The ID finalized EPA's draft risk assessments supporting registration review, *Glyphosate Draft Human Health Risk Assessment for Registration Review* and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*. The ID did not identify any human health risks of concern from exposure to glyphosate but did identify potential ecological risks. It also identified interim risk mitigation measures, in the form of label changes, including spray drift management language, herbicide resistance management language, a non-target organism advisory, and certain label consistency measures. It concluded that, under FIFRA, the benefits of glyphosate outweigh the potential ecological risks when glyphosate is used in accordance with labels.

The glyphosate ID did not make findings under section 7 of the ESA or under the Endocrine Disruptor Screening Program (EDSP) pursuant to section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), nor did it respond to a 2018 administrative petition submitted by the Environmental Working Group and others (EWG et al.) to reduce the tolerance level for glyphosate residues on oats and require certain label changes based on concerns regarding dietary exposure and carcinogenicity. EPA explained that it would do so before completing registration review for glyphosate, and that the "final registration review decision for glyphosate will be dependent upon the result of the agency's ESA assessment and any needed section 7 consultation with the [U.S. Fish and Wildlife Service and the National Marine Fisheries Service], an EDSP FFDCA section 408(p) determination, and after a resolution of the EWG et al. petition." The glyphosate ID also did not solicit label changes from registrants to implement the interim risk mitigation measures. EPA explained that it would do so once it responded to the EWG et al. petition.

For further background on glyphosate and its registration review history, see the end of this memorandum.

Endangered Species Act Assessment for Glyphosate

ESA section 7(a)(2) requires that federal agencies ensure that the actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of species listed as

threatened or endangered under the ESA (listed species) or destroy or adversely modify their designated critical habitat. For pesticides in registration review, EPA's responsibility includes evaluating potential effects to listed species and their designated critical habitat, often through a biological evaluation (BE). If EPA determines that a pesticide's registration "may affect" and is "likely to adversely affect" listed species or designated critical habitat, the Agency initiates formal consultation with the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (together, the Services). The Services prepare their respective biological opinions (BiOps) regarding whether the pesticide's registration is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of designated critical habitats and describing any reasonable and prudent measures or reasonable and prudent alternatives. EPA then uses its authorities under FIFRA to implement, as necessary, any such measures or alternatives described in the BiOps.

On November 25, 2020, EPA released the draft BE for glyphosate for public comment. On November 12, 2021, EPA released the final BE for glyphosate, which found that glyphosate may affect 1,795 listed species and 792 critical habitats and is likely to adversely affect 1,676 of those species and 759 of those habitats. EPA initiated formal consultation with the Services in November 2021. As noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision, discussed below, consultation with the Services is ongoing.

For further information on EPA's ESA assessment for glyphosate, see https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-glyphosate.

Challenges to Glyphosate Interim Registration Review Decision

On March 20, 2020, two groups of petitioners filed petitions for review of the glyphosate ID in the Ninth Circuit. *See Natural Resources Defense Council et al. v. EPA*, No. 20-70787 and *Rural Coalition et al. v. EPA*, No. 20-70801. Together these petitions challenged EPA's analysis of the human health and ecological risks and costs of glyphosate, weighing of such risks against the benefits of glyphosate, and the interim risk mitigation measures identified in the ID, and alleged that EPA violated the ESA by issuing the ID before completing consultation with the Services.

While EPA defended its analysis of human health risks and the alleged ESA violation, it moved for partial voluntary remand without vacatur of its analysis of ecological risks and costs, weighing of such risks against benefits, and interim risk mitigation measures. EPA sought remand to:

- Consider how the glyphosate ID may be impacted by the (then) draft BE and whether additional or different risk mitigation measures may be necessary.
- Reconsider its analysis of ecological risks as it relates to in-field effects of glyphosate on monarch butterfly habitat in light of the court decision in *National Family Farm Coalition v. EPA*, 966 F.3d 893 (9th Cir. 2020).

- Consider whether the court decision in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020) regarding EPA's analysis of spray drift risks and other potential costs of another pesticide (dicamba) affected EPA's analysis of glyphosate.
- Evaluate the glyphosate ID in light of the change in Administration and policy priorities, as reflected in the January 20, 2021 "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" (86 FR 7037, 1/25/21) and, in particular, consider whether there are other aspects of its analysis of ecological risks and costs related to glyphosate that should be reassessed or for which additional explanation should be provided.
- Consider what risk mitigation measures may be necessary to reduce potential risks following completion of analyses left outstanding in the ID.

The Ninth Circuit heard oral argument on these challenges on January 10, 2022 and issued its decision on June 17, 2022. The court vacated and remanded the human health portion of the glyphosate ID, held that EPA's failure to make an effects determination before issuing the ID violated the ESA, and granted EPA's motion for partial voluntary remand but imposed an October 1, 2022 deadline for EPA "to issue a new ecological portion." *Natural Resources Defense Council et al. v. EPA*, 38 F.4th 34 (9th Cir. 2022).

On August 1, 2022, EPA filed a petition for panel rehearing that sought relief only from the court's imposition of a deadline to complete remand of the ecological portion of the ID. EPA explained that, while the court did not define what it meant by "issue a new ecological portion," the Agency would not be able to finalize a new ecological portion in a registration review decision for glyphosate by the October 1, 2022 deadline because of the time needed to address the issues for which EPA sought remand and to complete consultation under the ESA. In a declaration filed in support of the petition, EPA set forth its anticipated schedule for completing registration review for glyphosate. EPA also stated that if the court did not lift the deadline, the Agency might exercise its discretion to withdraw the remanded ecological portion of the ID and focus its efforts on the required final registration review decision for glyphosate. A copy of EPA's August 1, 2022 petition for panel rehearing and declaration filed in support of the petition is posted to the glyphosate registration review public docket (EPA-HQ-OPP-2009-0361) at https://www.regulations.gov.

On August 5, 2022, the court denied EPA's petition for panel rehearing without opinion.

Withdrawal

In its June 17, 2022 decision, the Ninth Circuit vacated and remanded the human health portion of the glyphosate ID. EPA is now withdrawing all remaining portions of the ID, including the remanded ecological portion consisting of the Agency's analysis of the ecological risks and costs of glyphosate, the weighing of such risks against the benefits of glyphosate, and interim risk mitigation measures. Because the ID is an informal adjudication that EPA issued at its discretion, EPA may withdraw all or a portion of it without public comment. Moreover, it would be impracticable for EPA to take public

comment here because of the October 1, 2022 deadline imposed by the court to complete remand of the ecological portion of the ID.

EPA has determined that withdrawal is appropriate in light of the Ninth Circuit's June 17, 2022 decision and the particular circumstances of glyphosate's registration review and ESA assessment. Insofar as the court has ordered EPA to finalize a "new ecological portion," doing so through another interim registration review decision or a final registration review decision would involve significant and lengthy steps. As detailed in EPA's August 1, 2022 petition for panel rehearing and declaration filed in support of the petition, the Agency is unable to finalize a new ecological portion in a registration review decision for glyphosate by the court-imposed October 1, 2022 deadline because of the time needed to address the issues for which EPA sought remand and to complete consultation under ESA. Moreover, before issuing such a decision, EPA must first prepare a proposed decision, make it available for a period of public comment of at least 60 days, and consider any comments received. 40 C.F.R. § 155.58. For reference, EPA received approximately 283,300 public comments comprising over 12,000 unique submissions when it published the glyphosate proposed ID in May 2019, and it then took nine months to finalize and publish the ID in February 2020. EPA cannot complete these processes by the court-imposed October 1, 2022 deadline.

To date, EPA has not solicited label changes from registrants to implement the interim risk mitigation measures identified in the ID. The Agency has not solicited such label changes because EPA's continued work towards completing registration review for glyphosate could affect what risk mitigation measures EPA may determine are necessary, as noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision. Moreover, the Agency continues to work on a response to the EWG et al. petition, which asks EPA to reduce the tolerance level for glyphosate residues on oats and require certain label changes based on concerns regarding dietary exposure and carcinogenicity. Because of the court's vacatur and remand of the human health portion of the ID, EPA believes it would be appropriate to respond to the EWG et al. petition once it completes its review on remand. To avoid multiple, and potentially conflicting, rounds of label changes, EPA expects to defer solicitation of label changes until it issues a final registration review decision for glyphosate.

For these reasons, EPA believes it is appropriate to withdraw all remaining portions of the glyphosate ID, including the remanded ecological portion, and focus its efforts on completing the required final registration review decision for glyphosate.

Although the glyphosate ID is now vacated in part and the remainder withdrawn, that does not automatically mean that EPA's underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, are either incorrect or cannot be used as support for a future decision following reconsideration in accordance with the court's decision.

Next Steps

With respect to the vacated human health portion of the ID, in accordance with the Ninth Circuit's June 17, 2022 decision, EPA intends to revisit and better explain its evaluation of the carcinogenic potential of glyphosate and to consider whether to do so for other aspects of its human health analysis. With respect to the withdrawn ecological portion of the ID, EPA intends to address the issues for which it sought remand, including:

- Consider whether additional or different risk mitigation measures may be necessary based on the outcome of ESA consultation for glyphosate.
- Prepare an analysis of in-field effects of glyphosate on monarch butterfly habitat.
- Consider whether EPA's analysis of spray drift risks and other potential costs of dicamba are relevant to EPA's analysis of glyphosate's risk from spray drift.
- Consider whether there are other aspects of EPA's analysis of ecological risks and costs related to glyphosate that should be reassessed or for which additional explanation should be provided.
- Consider what risk mitigation measures may be necessary to reduce potential risks following completion of analyses left outstanding in the ID.

EPA also intends to complete ESA consultation with the Services, respond to the EWG et al. petition, and make an FFDCA section 408(p) EDSP determination before issuing a final registration review decision for glyphosate. As noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision, EPA anticipates issuing a final registration review decision for glyphosate in 2026.

Glyphosate Background and Registration Review History

Glyphosate is a non-selective, systemic herbicide with products registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, cereal grains, and other field crops. Non-agricultural uses include residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate products are also registered for use on the glyphosate-resistant crops, including alfalfa, corn, soybean, cotton, canola, and sugar beets.

EPA formally initiated registration review for glyphosate in 2009 with the opening of the registration review docket for the case. The following summary highlights significant milestones that have occurred during the registration review of glyphosate

- July 2009 - The *Glyphosate Preliminary Work Plan (PWP)*, the *Glyphosate Human-Health Assessment Scoping Document in Support of Registration Review*, and the *Registration Review–Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and Its Salts* were posted to the docket for a 60-day public comment period.

- December 2009 - The *Glyphosate Final Work Plan (FWP)* was issued. Comments received on the PWP covered the following topics: opposition to the use of glyphosate, the toxicity of glyphosate formulations and inert ingredients, use and usage trends, human health risks, ecological risks, endocrine disruption, and the benefits of glyphosate. The public comments received did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- September 2010 - A Generic Data Call-In (GDCI) for glyphosate was issued for data needed to conduct the registration review risk assessments. All required data were submitted and reviewed. The registration review GDCI for glyphosate is considered satisfied.

- September 2015 – The Agency completed its evaluation of Tier 1 endocrine data submitted under the EDSP and published the *Glyphosate: Weight of Evidence Analysis of Potential Interaction with the Estrogen, Androgen, or Thyroid Pathways*. EPA found no convincing evidence of potential interaction with the estrogen, androgen, or thyroid pathways and glyphosate was not recommended for further EDSP testing.

- December 2016 – The agency convened a FIFRA Scientific Advisory Panel meeting to consider and review a set of scientific issues related to the EPA's evaluation of the carcinogenic potential of glyphosate. The meeting agenda, the agency's cancer issue paper, charge questions for the panel, transcript, and final report are available on EPA's website: https://www.epa.gov/sap/meeting-materials-december-13-16-2016-scientific-advisory-panel. Additional supporting materials and comments received from the public can be found in docket EPA-HQ-OPP-2016-0385 at www.regulations.gov.

- December 2017 – The agency published the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (dated December 12, 2017), the *Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate* (dated December 12, 2017), the *Glyphosate Draft Human Health Risk Assessment for Registration Review* (dated December 12, 2017), and the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* (dated September 8, 2015) on EPA's website: https://www.epa.gov/ingredients-used-pesticide-products/draft-human-health-and-ecological-risk-assessments-glyphosate.

- February 2018 - The agency announced the availability of the human health and ecological risk assessments for a 60-day public comment period. Over 238,000 comments were received during the comment period, most of which came from various mass mail campaigns. Approximately 2,244 unique submissions were received from various stakeholders, including pesticide registrants, industry groups, farmers, grower groups, private citizens, non-governmental organizations, states, and the U.S. Department of Agriculture. The comments did not change the risk assessments or registration review timeline for glyphosate.

- September 2018 – The Environmental Working Group, joined by Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farm, Inc. submitted an administrative petition to the Agency. The petition requested that EPA lower the tolerance for residues of glyphosate on oats and require label changes to prohibit the preharvest use of glyphosate on oats. On May 6, 2019, the Agency published a Notice of Filing of the petition in the Federal Register for a 30-day public comment period in docket EPA-HQ-OPP-2019-0066. 103,447 comments were received on the petition, most of which came from mass mail campaigns and 419 of which represented unique comments. The Agency continues to work on its response to the petition.

- May 2019 - The Agency announced the availability of the *Glyphosate Proposed Interim Registration Review Decision* (PID) for a 60-day public comment period, which was later extended to 120 days. Along with the PID, the following documents were posted to the docket:

    - *Glyphosate: Response to Comments, Usage, and Benefits* (dated April 18, 2018)
    - *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (dated April 23, 2019)
    - *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* (dated November 21, 2018)

    During the 120-day comment period on the PID, the agency received roughly 283,300 comments. Over 12,000 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, the U.S. Department of Agriculture and members of the general public. Most comments came from mass mailer campaigns, and approximately 120 unique substantive comments were received from various stakeholders. Public comments did not change the Agency's risk conclusions but resulted in changes to the spray drift management labeling and rotational crop instructions.

- February 2020 – The Agency announced the availability of the ID. Along with the ID, the following documents were published in the docket:
    - *Response from the Pesticide Reevaluation Division to Comments on the Glyphosate Proposed Interim Decision* (dated January 16, 2020)
    - *Glyphosate Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* (dated January 13, 2019)
    - *Glyphosate: Epidemiological Review of Zhang et al. (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed Interim Decision* (dated January 6, 2020)

- November 2020 - The Agency released the draft BE for glyphosate for public comment. Approximately 870 comments that pertained to the draft BE for

glyphosate were submitted, including 11 requests for extensions of the public comment period. Additionally, six mass mail campaigns were submitted with approximately 110,000 signatures.

- November 2021 - The Agency released the final BE for glyphosate evaluating potential effects to listed species and critical habitats.

DECLARATION OF DAVID ANDREWS

I, Dr. David Andrews, declare that I have personal knowledge of the facts set forth in this declaration

1. My name is David Andrews. I am the Chief Science Officer at the Environmental Working Group ("EWG"). I am familiar with the scientific evidence and analysis supporting EWG's 2018 petition to the Environmental Protection Agency ("EPA"), which requested that EPA reduce the tolerance for glyphosate residues on oats and prohibit the use of glyphosate as a pre-harvest desiccant.
2. I received a Bachelor of Arts in Chemistry from Wesleyan University and a Ph.D. in Chemistry from Northwestern University. I have worked at EWG since 2008 and have extensive experience evaluating environmental contaminants and their impacts on human health. In my role, I oversee EWG's scientific research programs, including data analysis, peer-reviewed research, and the scientific foundations of EWG's consumer databases and public-facing resources, including pesticides and dietary exposure pathways. I also work closely with policymakers, researchers, and other stakeholders to translate complex scientific information into accessible and actionable guidance.

3. Pesticides, including glyphosate, are a priority area for EWG because they are widely used in food production and can contribute to routine dietary exposure, including among infants and young children. EWG conducts research and testing to better understand these pesticide exposures and their potential health implications, and to inform both the public and policymakers about risks associated with pesticide residues in food.
4. In my work, I have reviewed scientific literature, government assessments, and testing data related to glyphosate exposure through food, including oat-based products.
5. Glyphosate is the most widely used herbicide in the United States and globally. Its use extends beyond weed control during crop growth and includes pre-harvest applications on certain crops, including oats, often for weed control immediately prior to the harvest. When applied at this stage of the growing cycle, glyphosate can function to accelerate crop dry-down and facilitate harvest, resulting in residues in harvested grain and in foods made from those grains. Because these applications occur shortly before harvest, glyphosate can be directly transported into the edible portion of the plants where it does not readily break down.
6. As a result of this late-stage use, dietary exposure to glyphosate through food is pervasive. Multiple testing efforts, including those conducted by

EWG and others, have detected glyphosate residues in a wide range of commonly consumed foods, such as oat-based cereals, snacks, and other products frequently marketed to and consumed by children. EWG's testing detected glyphosate residues in 43 of 45 oat-based food products tested, including products specifically marketed to children. In 31 of those products, glyphosate levels exceeded 0.16 parts per million, an EWG scientists' calculated benchmark derived from the California's proposed No Significant Risk Level of 1.1 milligrams/day with added Food Quality Protection Act safety factors, and several products contained residues exceeding 1.0 part per million.

7. Oats are a particularly significant source of dietary exposure for infants and young children. Oat-based products are widely used in infant cereals, breakfast foods, and snack products consumed regularly, often daily, by young children. Because children consume more food per unit of body weight than adults, repeated consumption of oat-based foods containing glyphosate residues can contribute disproportionately to aggregate dietary exposure during early developmental periods.
8. EPA has acknowledged that young children experience the highest body weight adjusted dietary exposure to glyphosate. In its own risk assessments, EPA has identified children aged one to two years as the population

subgroup with the greatest exposure relative to body weight. EPA has further recognized that this elevated exposure reflects differences in consumption patterns and body weight, which can result in higher exposure on a per-body-weight basis for infants and young children.

9. EPA has also recognized that infants and young children may be more susceptible to the effects of chemical exposure during critical windows of developmental periods, a concern Congress codified in the Food Quality Protection Act, which requires EPA to consider the special susceptibility of children when evaluating pesticide risk.

10. Dietary exposure to glyphosate results in measurable internal exposure. Biomonitoring studies cited in the petition detected glyphosate or its primary metabolite in a majority of tested urine samples, with detection frequencies increasing over time**.** One longitudinal analysis cited in the petition found that detection rates for glyphosate in American adults increased from approximately 12 percent of samples in the early 1990s to more than 70 percent by 2016. These findings confirm that glyphosate exposure is not theoretical or episodic, but widespread, and that dietary intake results in measurable body burden.

11. Scientific concern regarding glyphosate exposure leading to health harm has existed for decades. In 2015, the International Agency for Research on

Cancer classified glyphosate as "probably carcinogenic to humans," based on "sufficient" evidence of carcinogenicity in experimental animals and "limited" evidence of carcinogenicity in humans. The human evidence included epidemiological studies showing positive associations between glyphosate exposure and non-Hodgkin lymphoma. Additional human epidemiological studies cited in the petition suggest an association between glyphosate exposure and non-Hodgkin lymphoma, with multiple meta-analyses reporting elevated risk estimates when data from individual studies are combined.

12. EPA's assessments of glyphosate's potential carcinogenicity have reflected differing interpretations of the available scientific evidence over time. EPA scientists and advisory panels have identified statistically significant findings of health harm in animal carcinogenicity studies, including increased tumor incidence and dose-response relationships, dose-response trends, and epidemiological associations that warrant further consideration in EPA's cancer risk assessments and registration review process. The EPA Scientific Advisory Panel has also noted inconsistencies in the evaluation of conflicting data and dismissal of positive finding trends within EPA's risk assessment framework.

13. At the same time, EPA has characterized portions of the epidemiological evidence as insufficient to support a carcinogenic risk determination, despite acknowledging some positive associations between glyphosate exposure and cancer outcomes.

14. Based on my review of the scientific literature and EPA's prior assessments, there have been differing interpretations of data relevant to glyphosate's potential health effects, including statistically significant dose-response findings in certain studies. Some EPA scientists and advisory bodies have described portions of this evidence as "limited but suggestive" of carcinogenicity.

15. The tolerance for glyphosate residues in oat grain was originally set at 0.1 parts per million in 1993. In 1997, EPA increased the tolerance to 20 parts per million, and in 2008 increased it again to 30 parts per million. The tolerance remains at 30 parts per million today. As described in the petition, prior increases to the tolerance were associated with efforts to harmonize U.S. standards with international residue limits.

16. Because glyphosate is so widely used, and because oats and oat-derived products are a common component of the American diet, particularly for infants and young children, for many consumers it can be difficult to avoid dietary exposure to glyphosate through food. Individuals cannot reasonably

eliminate exposure through personal choice alone, especially where foods perceived as healthy or appropriate for children are among the primary sources of exposure.

17. Based on these concerns regarding dietary exposure, EWG submitted a formal administrative petition to EPA on September 27, 2018, pursuant to the FFDCA, 21 U.S.C. § 346a(d). EWG amended the petition on March 28, 2019. The petition was intended to prompt EPA to evaluate whether existing tolerances adequately protect against the levels of dietary exposure described above.

18. First, the petition requested that EPA modify the tolerance for glyphosate residues on oats. The petition requested that EPA reduce the tolerance to 0.1 ppm, the level that applied prior to the 1997 and 2008 increases, and evaluate whether any higher tolerance could be shown to meet the FFDCA's safety standard, particularly for infants and children.

19. Second, the petition requested that EPA prohibit the use of glyphosate as a pre-harvest desiccant on oats. The petition explained that this agricultural practice involves application of glyphosate shortly before harvest and results in significantly higher residues in harvested grain and finished food products. The petition further explained that pre-harvest desiccation is not

necessary for weed control and that its primary effect is to facilitate harvesting, rather than to protect crop yield.

20. In support of these requests, the petition presented scientific evidence concerning dietary exposure to glyphosate, including data showing that oat-based foods frequently consumed by children contain higher glyphosate residues than many other staple grains. The petition emphasized that young children experience the highest dietary exposure to glyphosate and that the existing tolerance does not adequately account for the potential health risks associated with that level of exposure, including carcinogenic risks.

21. In January 2020, EPA issued an Interim Registration Review Decision for glyphosate. In that decision, EPA acknowledged the pending petition but stated that it was not addressing the petition in that document and that the Interim Decision did not constitute EPA's response. EPA also indicated that it anticipated issuing a response to the petition in 2020.

22. To my knowledge, EPA has acknowledged the petition and its subject matter but has not issued a decision resolving the requested actions. EPA has not communicated a date certain for response and has not explained what additional analysis, if any, is required before issuing a decision.

23. Based on my experience reviewing EPA regulatory processes, a response to a tolerance petition typically involves evaluating the evidence presented and

issuing a determination addressing the requested relief. EPA has not indicated to EWG why the issues raised in the petition cannot be addressed through such a process.

24. During the time EPA has not acted on the petition, glyphosate has continued to be used in food production, including on oats, and consumers have continued to be exposed through commonly consumed foods.

25. As a result, EWG continues to evaluate and communicate about glyphosate exposure without the benefit of a final, reviewable agency determination addressing the safety of the challenged tolerance and use.

26. Based on my experience working with scientific and regulatory processes related to pesticide exposure, it is not in the public interest for a petition of this nature to remain unresolved for this length of time without a clear explanation or timeline for decision.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 20th day of April, 2026.

Dr. David Andrews

DECLARATION OF MAURA WALSH

I, Maura Walsh, declare as follows:

1. My name is Maura Walsh. I am the Executive Vice President for Marketing & Communications at the Environmental Working Group ("EWG"). I have held this position for approximately ten years and have worked at EWG for more than a decade.

2. In my role, I oversee EWG's communications, public engagement, and supporter programs, including individual donations, EWG's national email program, social media platforms, and traditional media outreach. I am personally familiar with EWG's organizational structure, supporter base, and the ways in which EWG engages with and represents the people who rely on its work.

3. EWG is a 501(c)(3) nonprofit, nonpartisan organization dedicated to empowering people to live healthier lives in a healthier environment. A core part of EWG's mission is to conduct scientific research and translate that research into accessible consumer-facing tools, databases, and reports that help people understand and reduce exposure to harmful chemicals in food, water, and consumer products—particularly exposures affecting infants and children.

4. Although EWG is not a formal membership organization, it functions in many respects like one. EWG maintains a large, identifiable base of supporters who

regularly engage with the organization, rely on its research and advocacy, and provide financial support to advance its mission.

5. EWG communicates directly and regularly with millions of supporters nationwide through email, social media, and other outreach channels. EWG's email program alone reaches hundreds of thousands of active supporters who receive frequent updates about food safety, pesticide residues, toxic chemicals, and related public health issues. These communications often prompt feedback, participation in surveys, and engagement with EWG's policy and advocacy efforts.

6. EWG also receives financial support from individuals across the country who donate to support its research, consumer guidance, and advocacy on issues such as pesticide residues in food and chemical exposures affecting children. In 2025 alone, EWG generated approximately $3.8 million in grassroots revenue through its digital channels, reflecting sustained financial backing from supporters who rely on EWG's work. These supporters choose to donate because they rely on EWG to represent their interests in regulatory and policy processes and to provide independent, science-based information they cannot obtain elsewhere.

7. Many of EWG's supporters are parents and caregivers who are particularly concerned about chemical exposures in foods consumed by infants and young children. Through surveys, direct communications, and supporter feedback,

EWG regularly hears from families who rely on EWG's research to guide food purchasing decisions and to advocate for stronger regulatory protections where individual consumer choice is insufficient to eliminate exposure.

8. EWG's work on glyphosate residues in food, including oat-based foods commonly consumed by children and agricultural practices such as pre-harvest desiccation, is central to its mission and directly responsive to the concerns of its supporters. EWG's research and testing regarding glyphosate have been widely disseminated through its consumer guides, reports, and media outreach, and have generated substantial engagement from supporters seeking clarity about the safety of foods their children consume.

9. EPA's prolonged failure to respond to EWG's glyphosate petition has directly impaired EWG's ability to carry out its core organizational functions. Without a final agency decision addressing whether existing glyphosate tolerances on oats are safe for infants and children, EWG cannot accurately inform its supporters about the adequacy of federal protections or assess EPA's regulatory position. This regulatory silence creates confusion among EWG's supporters and undermines EWG's ability to fulfill its mission of providing clear, science-based guidance.

10. EPA's inaction has also forced EWG to devote additional staff time and organizational resources to explaining regulatory uncertainty and responding to supporter concerns that should have been resolved through timely agency

action. This diversion of resources impairs EWG's advocacy, communications, and educational activities.

11. EWG brings this petition both to protect its own organizational interests and to represent the interests of its supporters, including parents and caregivers concerned about dietary exposure to glyphosate through foods routinely consumed by children. EWG's supporters look to EWG to act on their behalf in regulatory processes affecting food safety and public health.

12. Based on my experience overseeing EWG's communications and supporter engagement, EWG has a defined and engaged constituency that relies on EWG's advocacy, supports its activities financially and otherwise, and is the intended beneficiary of the relief sought in this action.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 20th day of April, 2026.

Maura Walsh
Washington, DC

DECLARATION OF GARY HIRSHBERG

I, Gary Hirshberg, declare as follows:

1. My name is Gary Hirshberg and I have personal knowledge of the facts stated in this declaration.
2. I am the Co-Founder and former CEO of Stonyfield Farm, the world's largest organic yogurt producer, and I currently serve as CEO of the Hirshberg Entrepreneurship Institute. I am also the Founder and Co-Chair of Organic Voices and the Northeast Organic Family Farm Partnership, two nonprofit organizations that advocate for organic agriculture and food system reform.
3. I have spent decades working at the intersection of agriculture, environmental health, and consumer transparency. I am the author of *Stirring It Up: How to Make Money and Save the World* and have frequently spoken and written on issues related to sustainability, organic agriculture, and the business case for environmentally responsible practices.
4. I am a grandparent of four grandchildren, and I am deeply concerned about the risks that environmental contaminants, including glyphosate, pose to children, including my own grandchildren, particularly given children's heightened vulnerability to toxic exposures.

5. I am a supporter of the Environmental Working Group ("EWG"). I regularly receive EWG's emails, reports, and consumer guidance concerning food safety, pesticide residues, toxic chemicals, and public health. I rely on EWG's research and educational materials to help me make informed decisions about the food I purchase for myself and my family, particularly for my grandchildren.

6. I have also provided financial support to EWG to help advance its work on food safety, toxic chemicals, and public health. I choose to support EWG because I rely on its research and advocacy to represent my interests and the interests of families like mine in regulatory decision-making.

7. I am concerned about chemical exposures in food, especially exposures that may affect infants and young children during critical stages of development. I try, when possible, to reduce my family's exposure to harmful chemicals through food choices.

8. My grandchildren regularly consume oat-based foods, including oatmeal, snack bars, crackers, and cereals. These foods are a routine part of my grandchildrens' diets because they are affordable, widely available, and generally marketed as healthy options for children.

9. I am aware that glyphosate is widely used in agriculture and that residues have been detected in oat-based foods commonly consumed by children. I

am particularly concerned about glyphosate exposure because it may be difficult or impossible for families to avoid through individual consumer choice alone.

10. I am aware that in 2018, EWG submitted a petition to the U.S. Environmental Protection Agency ("EPA") requesting that EPA reevaluate and reduce the tolerance level of glyphosate residues on oats and prohibit the use of glyphosate as a pre-harvest desiccant. I also understand that EPA has not issued a final response to that petition.

11. EPA's failure to respond to EWG's petition concerns me because it leaves unresolved whether existing glyphosate tolerances for oats adequately protect infants and young children. Without a final decision from EPA, I cannot know whether the foods my grandchildren eat regularly are adequately protected by federal safety standards.

12. There is only so much I can do as an individual consumer to reduce my grandchildren's exposures to glyphosate. I believe that protecting children from unsafe pesticide residues should not depend solely on individual consumer choices, but on effective and timely action by EPA.

13. I support EWG's efforts to ensure that EPA fulfills its statutory obligation to evaluate and regulate pesticide residues in food in a manner that protects infants and children. I have authorized EWG to represent my interests in

seeking a court order requiring EPA to issue a final response to EWG's glyphosate petition.

14. EPA's continued delay in responding to the petition directly affects my family by prolonging uncertainty and allowing continued exposure to glyphosate in foods my grandchildren consume regularly. A court order requiring EPA to act would help ensure that my grandchildren's health and safety are protected consistent with federal law.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this18th day of April, 2026.

Gary Hirshberg
Holderness, NH