**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)

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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A copy of the glyphosate ID, now vacated in part and the remainder withdrawn, is posted to the glyphosate registration review public docket (EPA-HQ-OPP-2009-0361) at https://www.regulations.gov.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.