



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response from the Pesticide Re-evaluation Division (PRD) to Comments on the Glyphosate Proposed Interim Decision

DATE: January 16, 2020

FROM: Dana L. Friedman
Chief, Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division

THROUGH: Elissa Reaves, PhD
Acting Director
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A handwritten signature in blue ink, appearing to read "Elissa Reaves", is written over the "THROUGH:" section.

DOCKET: Glyphosate (EPA-HQ-OPP-2009-0361)

Summary

On May 6, 2019, EPA issued a notice in the Federal Register concerning the opening of a public comment period for the proposed interim decision (PID) for glyphosate. This notice announced the publication of the PID, along with supporting documents, and opened a 60-day public comment period concluding on July 5, 2019. Based on multiple requests to extend the public comment period, the agency extended the comment period for an additional 60 days, which then closed on September 3, 2019. During the comment period, the agency received 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 US 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 interim registration review decision (ID), the agency is posting this document and the *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* document to address comments received on the PID. 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. This document combines comments by topic instead of responding to individual stakeholders and directs the public to

responses previously provided in EPA documents. See Section IV of this document for a complete list of supporting materials, which can be found in the EPA's public docket for glyphosate (EPA-HQ-OPP-2009-0361) at www.regulations.gov.

Comments specific to the glyphosate mitigation, comments of a broader regulatory nature, and the agency's responses to those comments are addressed in the *Glyphosate Interim Registration Review Decision Case Number 0178*, which is available on the docket. The comments did not result in changes to the agency's risk assessments; however, they did result in some changes to the mitigation that was proposed in the PID. In addition, comments received during the PID public comment period identified open literature studies for the agency's consideration. For more information, see the *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, which is available on the public docket. None of the open literature 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 thanks all commenters for their comments and has considered them in developing the glyphosate interim registration review decision.

Public Comments and Agency Responses

I. List of Glyphosate PID Public Commenters

- a) Academic / Extension: IR-4 Project, National and Regional Weed Science Societies (Weed Science Society of America, Aquatic Plant Management Society, North Central Weed Science Society, Northeastern Weed Science Society, Southern Weed Science Society, Western Society of Weed Science Society)
- b) Commodity Groups:
 - i) Alfalfa/Forage: California Alfalfa & Forage Association, National Alfalfa & Forage Alliance
 - ii) Grains: California Association of Wheat Growers, California Grain and Feed Association, National Association of Wheat Growers, National Barely Growers Association, North Dakota Grain Growers Association
 - iii) Corn: National Corn Growers Association, New York Corn & Soybean Growers Association, South Dakota Corn Growers Association
 - iv) Cotton: California Cotton Ginners & Growers Association, Georgia Cotton Commission, Plains Cotton Growers, Inc., South Texas Cotton & Grain Association
 - v) Soybean: American Soybean Association
 - vi) Sugar: American Sugarbeet Growers Association
 - vii) Specialty Crops: Almond Alliance of California, American Pistachio Growers, California Association of Winegrape Growers, California Citrus Mutual, California Citrus Quality Council, National Potato Council, USApple Association, Washington State Potato Commission
- c) Non-Governmental Organizations (NGO): American Mosquito Control Association (AMCA), Beyond Pesticides, Center for Food Safety (CFS), Center for Biological Diversity (CBD), Environmental Working Group (EWG), Food & Water Watch, Grassroots Environmental Education, Natural Resources Defense Council (NRDC),

Oregonians for Food and Shelter, Organic Consumers Association, Pesticide Action Network North America (PAN), Responsible Industry for a Sound Environment (RISE), US Public Interest Research Group (PIRG)

- d) Federal, State, or Local Governments: National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (US Department of Health and Human Services, Sacramento River Source Water Protection Program, US Department of Agriculture (USDA) Office of Pest Management Policy (OPMP)
- e) Agricultural Businesses: Delta Council, Far West Agribusiness Association, Kansas Agribusiness Retailers Association, PennAg Industries Association, South Dakota Agribusiness Association, Virginia Agribusiness Council
- f) Pesticide Registrants: Bayer, Joint Glyphosate Task Force, LLC, Monsanto
- g) Farm Bureaus: American Farm Bureau Federation, Arizona Farm Bureau Federation, California Farm Bureau Federation, Colorado Farm Bureau, Georgia Farm Bureau, Hawaii Farm Bureau, Kentucky Farm Bureau, Louisiana Farm Bureau Federation, Montana Farm Bureau Federation, Nebraska Farm Bureau, New Jersey Farm Bureau, New York Farm Bureau, Oklahoma Farm Bureau, Pike-Scott Farm Bureau, South Valley California County Farm Bureaus, Tennessee Farm Bureau Federation, Virginia Farm Bureau Federation
- h) Trade Organizations: Agricultural Council of Arkansas, Agricultural Retailers Association, AmericanHort and Horticultural Research Institute Foundation, Bio Nebraska Life Sciences Association, California Seed Association, California Specialty Crops Council, Golf Course Superintendents Association of America, Grower-Shipper Association of Central California, Organic & Natural Health Association, Southern Crop Production Association, Western Agricultural Processors Association, Western Growers, Western Plant Health Association
- i) Other Commenters: Public Awareness for Preventative Health Care, Inc., private citizens, anonymous commenters

II. List of Mass Comment Campaigns

- a) American Farm Bureau Federation (1,639 signatures)
- b) Beyond Pesticides (4,345 signatures)
- c) Center for Biological Diversity (4,984 signatures)
- d) Center for Food Safety (15,972 signatures)
- e) CREDO Action (75,475 signatures)
- f) Environmental Action (15,841 signatures)
- g) Environmental Working Group (79,537 signatures)
- h) Green America (10,098 signatures)
- i) Monsanto (5,462 signatures)
- j) Natural Resources Defense Council (2,568 signatures)
- k) Pesticide Action Network North America (26,720 signatures)
- l) Sierra Club (21,449 signatures)
- m) US Public Interest Research Group (14,294 signatures)

III. Responses to General Comments:

- a) General support of the registration review of glyphosate.
 - i) Description of Comments: The agency received comments from a broad range of stakeholders, including comments from mass mail campaigns, that provided use/usage information and attested to the general benefits of glyphosate's agricultural and non-agricultural uses. These uses include glyphosate-resistant field crops, conventional field crops, vegetable and other crops, tree and vine crops, residential sites, pasture and rangeland, forestry, rights of way, aquatic systems, and turf. Comments from the mass mail campaigns urged the EPA to keep glyphosate accessible for users.
 - ii) Agency Response: The agency agrees that glyphosate is an important herbicide for many growers and that there are many benefits associated with glyphosate. For more detailed responses to comments regarding the use/usage of glyphosate and the benefits, see *Glyphosate: Response to Comments, Usage, and Benefits (PC Codes: 103601, 103604, 103605, 103607, 103613, 417300)* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*, which are available on the docket.
- b) General opposition to the registration review of glyphosate/ban the use of glyphosate.
 - i) Description of Comments: Multiple comments from stakeholders, including mass mail campaigns, implored the EPA to ban or severely restrict the use of glyphosate claiming adverse effects to human health and the environment. These campaigns urged EPA to restrict glyphosate, protect the monarch butterfly, and/or reconsider its human health risk assessment.
 - ii) Agency Response: The agency has 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. EPA has conducted comprehensive human health and ecological risk assessments for glyphosate and has not received any information that would change the conclusions of its risk assessments. Under section 3(c)(5), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that a pesticide not cause "unreasonable adverse effects on the environment" in order to be registered. FIFRA 7 U.S.C. § 136a(c)(5). Section 2(bb) defines "unreasonable adverse effects on the environment" as, among other things, "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide...". This standard is a "risk benefit" standard that requires the agency to compare the potential risks from a pesticide with the benefits to users of the pesticide. The agency carefully considered the risks and benefits of glyphosate in the *Glyphosate Proposed Interim Registration Review Decision Case 0178* and *Glyphosate Interim Registration Review Decision Case 0178*, which are available in the dockets for each case.
- c) Comments relating to human health and the agency's human health risk assessment.
 - i) Description of Comments: Several commenters expressed concern on a wide array of topics relating to the human health risk assessments and associated issues including: EPA's cancer assessment, toxicological studies, protection of children, detections of

- glyphosate, endocrine disruption, effects on the gut microbiome, residues in food and beverages, and the presence of glyphosate in surface water.
- ii) Agency Response: The agency has reviewed these comments and determined that many of the comments are substantively the same as comments received during previous glyphosate comment periods on the agency's risk assessments. For the agency's response to comments regarding endocrine disruption, effects on the gut microbiome, residues in food and beverages, and the presence of glyphosate in surface water, see the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*. For the agency's response to comments regarding EPA's cancer assessment, toxicological studies, protection of children, and detections of glyphosate, see *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment, Response to Comments on the Human Health Draft Risk Assessment* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*.
- d) Comments relating to the environment and the agency's ecological risk assessment.
- i) Description of Comments: Several commenters expressed concern on a variety of topics relating to the ecological risk assessment and associated issues including: risk to wildlife, endangered species risk assessment, and synergy.
 - ii) Agency Response: In the interim registration review decision for glyphosate, the agency is requiring risk mitigation measures to manage off-target spray drift to protect non-target organisms. Additionally, 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. As noted in the glyphosate PID, the EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. The EPA intends to release this policy for public comment. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's registration review decision for glyphosate. For more information, see *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*.
- e) Comments about pollinators.
- i) Description of Comments: Several commenters expressed concern regarding potential direct effects to honeybees and their health and potential indirect effects to honeybees including loss of forage and/or other habitat resources. Some commenters cited various open literature references about honey bee health.
 - ii) Agency Response: In the interim registration review decision for glyphosate, the agency is requiring risk mitigation measures, including a non-target organism advisory statement, to manage off-target spray drift to protect non-target organisms.

- The agency may require additional pollinator data in order to complete its evaluation of risks to bees prior to a final decision for registration review. For more information, see *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*.
- f) Comments about the monarch butterfly.
 - i) Description of Comments: Several commenters expressed concern that the EPA’s risk assessment is not protective of monarch butterflies and plant resources for monarchs, such as milkweed. In general, commenters asserted that the EPA has not done enough to protect monarch butterflies when monarch populations have been in decline in recent decades. Commenters urged the EPA to restrict or ban glyphosate on the grounds that it is killing milkweed, a key resource for monarch butterfly larvae.
 - ii) Agency Response: Monarch butterfly conservation is an important issue for the agency and stakeholders are encouraged to visit EPA’s monarch butterfly website¹ for related resources and information. In the interim registration review decision for glyphosate, the agency is requiring risk mitigation measures including a non-target organism advisory statement to manage off-target spray drift. These mitigation measures to protect non-target organisms are expected to reduce exposure to pollinators, including monarchs. For more detailed responses to comments regarding monarchs, see the *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*.
 - g) Comments about the toxicity of different formulations, including the technical grade active ingredient, toxicity of inert compounds, and surfactants.
 - i) Description of Comments: Several commenters expressed that glyphosate formulations are more toxic than glyphosate alone and questioned the toxicity of inert ingredients and the lack of transparency for inert ingredients and other contaminants in pesticide products.
 - ii) Agency Response: Most pesticide products contain substances in addition to the active ingredient (known as inert ingredients) which aid in the performance and effectiveness of the pesticide product. All active and inert ingredients must be approved by the agency when a product is first registered. The agency has evaluated the hazard potential (*i.e.*, toxicity) of glyphosate and any inert ingredients with a battery of toxicity data from a multitude of studies throughout the risk assessment process. For more detailed responses to comments regarding EPA’s evaluation of the glyphosate technical grade active ingredient and the toxicity of inert compounds including surfactants, see the *Glyphosate Proposed Interim Registration Review Decision Case 0178*, *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* and *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment*, which are available on the public docket.
 - h) Comments about EPA’s use of open literature studies.

¹ <https://www.epa.gov/pollinator-protection/protecting-monarch-butterflies-pesticides>

- i) Description of Comments: Several commenters asserted that the EPA relies too heavily on industry-funded studies and that these studies are not accessible to the public. Commenters request that the EPA use open literature studies to assess glyphosate and point to various open literature studies describing various human health and ecological effects.
 - ii) Agency Response: The agency requires a substantial amount of data to be collected and submitted for pesticide registration and registration review (see 40 CFR part 158 data requirements). It is EPA's policy to use the best available science; numerous studies are considered and evaluated for inclusion in the risk assessments based on the agency's open literature guidance. EPA's criteria for evaluating open literature data for consideration in both human health and ecological risk assessment are available online². For more detailed responses to comments regarding the agency's use of open literature studies for glyphosate, see the *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, *Glyphosate Proposed Interim Registration Review Decision Case 0178*, *Evaluation Guidelines for Ecological Toxicity Data in the Open Literature*, *Glyphosate – Systematic Review of Open Literature*, *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment*, *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment*, and *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate*.
- i) Concerns about herbicide resistance.
 - i) Description of Comments: Several stakeholders commented on glyphosate's connection to weed resistance, stating that widespread use of glyphosate has resulted in increased weed resistance, particularly in glyphosate-resistant crops.
 - ii) Agency Response: Whenever a herbicide is used, there is a potential for that use to contribute to the evolution of herbicide resistance. The agency recognizes that glyphosate remains an important weed management tool when used in accordance with the label. To preserve glyphosate as a viable tool for growers and combat weed resistance, EPA is requiring that herbicide resistance management language be added to all glyphosate labels. For more detailed responses to comments regarding herbicide resistance, see the *Glyphosate: Response to Comments, Usage, and Benefits (PC Codes: 103601, 103604, 103605, 103607, 103613, 417300)* and *Glyphosate Proposed Interim Registration Review Decision Case Number 0178*.

IV. List of Documents Supporting Glyphosate Registration Review

Human Health Risk Assessment:

- *Glyphosate – Systematic Review of Open Literature*
(<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0067>)

² <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open>

- *Glyphosate Draft Human Health Risk Assessment for Registration Review* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068>)
- *Glyphosate Tier II Incident Report* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0069>)
- *Glyphosate. Amended Residential Exposure Assessment for a Registration Review* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0070>)
- *Glyphosate. Dietary Exposure Analysis in Support of Registration Review* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0071>)
- *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* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0072>)
- *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073>)
- *Summary Review of Recent Analysis of Glyphosate Use and Cancer Incidence in the Agricultural Health Study* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0074>)
- *Updated Statistics Performed on Animal Carcinogenicity Study Data for Glyphosate* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0075>)
- *Drinking Water Assessment for the Registration Review of Glyphosate* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0076>)
- *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0081>)
- *Analysis of Human Milk for Incurred Residues of Glyphosate and its Metabolites. ACB Project #B14-46 – Updated from report dated September 18, 2015* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0085>)
- *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2343>)

Ecological Risk Assessment:

- *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0077>)
- *Appendix G. Bibliography of ECOTOX Papers* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0078>)
- *Appendix H. Data Table for Accepted ECOTOX Papers* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0079>)
- *Evaluation Guidelines for Ecological Toxicity Data in the Open Literature* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0080>)
- *Appendix B. Ecological Effects Data with Mammalian Data* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0084>)

- *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2341>)

Registration Review and Risk Management:

- *Glyphosate Generic Data Call In (GDCI-417300-886)* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0046>)
- *Glyphosate: Weight of Evidence Analysis of Potential Interaction with the Estrogen, Androgen, or Thyroid Pathways* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0047>)
- *Glyphosate: Data Evaluation Records (DERs) for EDSP Tier 1 Assays* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0048>)
- *Glyphosate: Full Bibliography of Submitted Studies (Organized by Guideline Number)* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0080>)
- *Glyphosate Proposed Interim Registration Review Decision Case Number 0178* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344>)

Use, Usage, and Benefits:

- *Updated Screening Level Usage Analysis (SLUA) Report in Support of Registration Review of Glyphosate* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0045>)
- *Joint Glyphosate Task Force – Use Summary Matrix* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0082>)
- *Updated Screening Level Usage Analysis (SLUA) Report for Glyphosate Case* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0083>)
- *Glyphosate: Response to Comments, Usage, and Benefits (PC Codes: 103601, 103604, 103605, 103607, 103613, 417300)* (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2342>)