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Glyphosate

Proposed Interim Registration Review Decision
Case Number 0178

April 2019

Approved by: _____

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Date: 4/23/19

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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) *Proposed Interim Registration Review Decision* (PID) for glyphosate acid and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, 103613, and 417300, 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 as 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 a PID 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, B, and C). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, 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 listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for glyphosate prior to completing the glyphosate's 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. Last, the EPA will determine whether pollinator exposure and effects data are necessary to make a final registration review decision for glyphosate and issue a data call-in (DCI) to obtain any such data prior to completing the glyphosate registration review case. See Appendices D and E, respectively, for additional information on the listed species assessment and the endocrine screening for the glyphosate's registration review.

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 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 ways, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate is also registered for use on glyphosate-resistant crops such as 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 is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why glyphosate is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA's proposed interim registration review decision; and, last, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Glyphosate's Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for glyphosate with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of glyphosate.

- July 2009 - The *Glyphosate Preliminary Work Plan (PWP)*, Human Health Scoping Document, and Environmental Fate and Effects Problem Formulation 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.

- 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), the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* (dated September 8, 2015) online (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 US Department of Agriculture (USDA). These comments and the agency's responses are summarized below. 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. summitted a petition to the agency. The petition requested that the EPA lower the tolerance for oats and explicitly prohibit preharvest use on oats on glyphosate US labels. The agency is still reviewing this petition and has issued a Federal Register Notice of Filing for public comment in docket EPA-HQ-OPP-2019-0066. The agency intends to respond to this petition concurrently with the issuance of the *Interim Registration Review Decision* for glyphosate.

- March 2019 - The agency is now announcing the availability of the *Proposed Interim Registration Review Decision* (PID) in the docket for glyphosate, for a 60-day public comment period. Along with the PID, the following documents are also posted to the glyphosate 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)

B. Updates Since the Issuance of the Glyphosate Risk Assessments

The Agency received on September 27, 2018 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. The petitioners request 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 assert that the current tolerance level for oat is not protective enough when taking into consideration the actual dietary exposure to glyphosate in oats and the potential carcinogenicity of glyphosate. The agency is still reviewing this petition. Since this petition was submitted outside of the public comment period for the human health and ecological risk assessments, which closed on April 30, 2018, EPA has not considered it as a public comment on the risk assessments in preparation of this Proposed Interim Registration Review Decision. However, the Agency will treat this petition as a public comment on this Proposed Interim Registration Review Decision; a copy of the petition will be posted to the glyphosate registration review docket. The EPA intends to address this petition concurrently with the development of the Interim Registration Review Decision for glyphosate, taking into consideration issues raised in the petition and any comments the agency receives on its Notice of Filing.

In accordance with FFDCA section 408(d)(3), EPA is publishing EWG's petition for public comment; the public comment period will close 30 days after publication. The full petition is posted in docket EPA-HQ-OPP-2019-0066 at www.regulations.gov. This Proposed Interim Decision reflects the conclusions of EPA's most recent risk assessments and does not address the claims raised in the petition.

C. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the glyphosate preliminary risk assessments, which opened on February 27, 2018 and closed on April 30, 2018, the agency received 238,290 comments. Approximately 2,244 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, and the US Department of Agriculture. Most comments came from mass mail campaigns, and approximately 200 substantive comments were received from various stakeholders. Comments relating to widespread concerns, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below. Due to the high volume of comments received for glyphosate, the agency has combined comments by topic instead of responding to individual stakeholders and has focused its responses on comments that have not been addressed previously via the FIFRA SAP meeting or in previous registration

review documents for glyphosate. The comments did not result in changes to the agency's risk assessments. The agency thanks all commenters for their comments and has considered them in developing this PID.

For more detailed responses to comments relating to the human health risk assessment, see the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment*. For more detailed responses to 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*. All responses to comments documents are available in the public docket for glyphosate.

Comments About the EPA's Cancer Evaluation:

Many commenters expressed disagreement with the EPA's cancer conclusion, citing the International Agency for Research on Cancer's (IARC's) 2015 classification of glyphosate as "probably carcinogenic to humans." Comments were also received regarding the EPA's weight of evidence evaluation of the animal carcinogenicity data.

The EPA Response: The EPA conducted an independent evaluation of the carcinogenic potential of glyphosate and has determined that glyphosate is "not likely to be carcinogenic to humans." The agency's cancer classification is based on a thorough weight-of-evidence review of all relevant data and is in accordance with the agency's 2005 *Guidelines for Carcinogen Risk Assessment*.[1] The agency presented its draft cancer evaluation to the FIFRA Scientific Advisory Panel (SAP) in December 2016. Although the SAP did not reach consensus on several questions, none of the panelists believed that glyphosate should be classified as "likely to be carcinogenic to humans" or "carcinogenic to humans." Given the variety of opinions expressed, the agency revised its cancer evaluation and addressed comments from the SAP where consensus appeared to be reached. EPA's full weight-of-evidence evaluation can be found in the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, available in the glyphosate public docket (EPA-HQ-OPP-2009-0361).

Comments received from stakeholders concerning the weight of evidence evaluation were previously addressed in 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* (also available in the glyphosate public docket).

EPA's cancer evaluation is more robust than IARC's evaluation. IARC's evaluation only considers data that have been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered a subset of the studies included in the EPA's evaluation. For instance, IARC only considered 8 animal carcinogenicity studies while the agency used 15 acceptable carcinogenicity studies in its evaluation. The EPA also excluded some studies that were not appropriate for determining the human carcinogenic potential of glyphosate, such as studies in non-mammalian species (*i.e.*, worms, fish, reptiles, and plants) which IARC used in its evaluation.

[1] https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment

The Agency's cancer evaluation for glyphosate is also more transparent. EPA's draft cancer evaluation was presented to a FIFRA SAP for external peer review. EPA solicited public comment on the carcinogenic potential of glyphosate as part of the SAP process, which is well-documented with an agenda, transcript, meeting notes, and final SAP report. EPA responded to the SAP report, addressed panel recommendations, and made revisions to its cancer assessment that were transparent and provided to the public. EPA also solicited public comment on its full human health and ecological risk assessment for glyphosate in February 2018. In contrast, IARC meetings are not accessible to the public. Its deliberations are closed, its process does not allow for public comments to be submitted for consideration, there are no materials provided in advance of the meeting, and IARC's reports are final without an external peer review.

The EPA has not identified any new information received during the public comment period which ended on April 30, 2018 that would result in changes to the conclusion of its cancer assessment. The agency's cancer conclusion is consistent with other regulatory authorities and international organizations, including the Canadian Pest Management Regulatory Agency, the Australian Pesticide and Veterinary Medicines Authority, the European Food Safety Authority, the European Chemicals Agency, the German Federal Institute for Occupational Safety and Health, the Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

Comments on the EPA's Use of Open Literature Studies:

Many commenters asserted that the EPA relies too heavily on industry-funded studies and that these studies are not accessible to the public. Commenters requested that the EPA use open literature studies to assess glyphosate and point to various open literature studies describing various human health and ecological effects.

The EPA Response: The EPA requires a substantial amount of data to be collected and submitted for pesticide registration and registration review (see 40 CFR part 158 data requirements, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration). The required data provide a wide range of information and include the following: product chemistry, product performance, studies that determine hazard to humans and domestic animals, studies that determine hazard to non-target organisms, post-application exposure studies, applicator/user exposure studies, pesticide spray drift studies, environmental fate, and residue chemistry studies. Although many of these studies are submitted by pesticide producers, the EPA has rigorous guidelines for how studies should be conducted (https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic). The agency independently evaluates required studies for scientific acceptability. Laboratories conducting studies must address Good Laboratory Practices (GLP) designed to ensure data quality and integrity. The EPA's Office of Enforcement and Compliance Assurance (OECA) periodically inspects labs that conduct required studies to ensure that labs are in compliance with GLP regulations.

When studies are submitted to the agency for review, test reports must summarize and supply all the individual data obtained as part of the study. An independent evaluation is prepared for each study and a Data Evaluation Record (DER) is generated to summarize the study methods, results, and conclusions. DERs are subject to an internal peer review process and scientific review

committees within the Office of Pesticide Programs to ensure accuracy and consistency of interpretation prior to finalization.

Registrant-submitted studies are proprietary, and under FIFRA, cannot be released to any representative of a multinational pesticide producer or to anyone who intends to deliver such information to a multinational pesticide producer. Anyone not associated with a multinational pesticide producer may file Freedom of Information Act (FOIA) requests to access studies evaluated by the agency. For information on how to submit FOIA requests to access certain glyphosate studies, visit the EPA's website: https://www.epa.gov/foia/foia-request-process.

The EPA also reviewed the open literature to conduct both human health and ecological risk assessments.

The open literature review conducted for human health risk assessment is described in the document *Glyphosate—Systematic Review of Open Literature*. For its cancer evaluation, the EPA conducted an additional fit-for-purpose systematic review to obtain relevant and appropriate open literature studies with the potential to inform the human carcinogenic potential of glyphosate. This additional review is described in the agency's *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* which is available in the public docket. The extensive list of journal citations provided by some commenters was screened for new studies not previously considered in the EPA's search of the open literature and did not turn up any studies that would impact the conclusions the EPA reached in its human health risk assessment.

The open literature data evaluated for ecological risk assessment is described in the agency's *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* and also in *Appendix G Bibliography of Ecotox Papers*. The extensive list of journal citations provided by some commenters was screened for potential new information relevant to the ecological risk assessment. The information submitted generally support the conclusions the EPA reached in its ecological risk assessment and do not warrant any changes.

The EPA's criteria for evaluating open literature data for both human health and ecological risk assessment are available online (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open).

Comments on Glyphosate Residues in Foods and Beverages:

Many commenters pointed to reports of glyphosate residues being detected in food/beverage commodities such as cereal, wine, orange juice, and others and express concerns about consumer safety. Others pointed to use of glyphosate as a pre-harvest desiccant for wheat as a source of glyphosate residues in cereal products.

The EPA Response: The EPA is aware of reports of glyphosate residues being detected in various foods and beverages. Due to its widespread use, trace amounts of glyphosate residues may be found in various food/beverage commodities. However, these trace amounts are below maximum residue levels established by the agency for those commodities and are not expected to pose risks of concern to consumers. For example, EPA has received results of testing of glyphosate residues in orange juice at a maximum of 26 parts per billion (ppb). At this

concentration, a 10 kg child would have to consumer approximately 385 liters of orange juice every day to reach the chronic reference dose of 1 mg/kg/day (the maximum acceptable oral dose that is the threshold of concern).

EPA evaluated dietary exposure to all population subgroups, including children, infants, and women of child-bearing age. There were no dietary risks of concern for glyphosate using an unrefined analysis, which (1) assumes that all food commodities contain maximum legal residues (*i.e.*, tolerance-level residues) and all registered food crops have been treated with glyphosate, and (2) uses high-end estimates of glyphosate in drinking water.

Commenters point to the use of glyphosate as a pre-harvest desiccant for wheat as a source of glyphosate residues in cereal products. The wheat desiccant use was considered in the agency's dietary risk assessment; EPA assumed maximum legal residues in wheat and other cereal grains. Taking exposures from those residues into consideration in its most recent human health risk assessment, EPA's estimation of risk from aggregate exposure to glyphosate, even including residues from pre-harvest desiccant use on wheat, is below the agency's level of concern. However, the agency has received a petition from the Environmental Working Group concerning the tolerance for oats and pre-harvest use on oats for which the agency is taking public comment. Additional information is described in section I.B of this document.

Comments on Formulations Toxicity:

Many commenters expressed concerns 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.

The EPA 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 pesticide product is first registered, including for glyphosate products. Since there are over 500 glyphosate products registered at different times in the US, the agency has assessed new inert ingredients at multiple points over the years for different formulations of glyphosate. The EPA evaluates the active and inert ingredients' hazard potential (*i.e.*, toxicity) with a battery of toxicity data. Any contaminants or impurities associated with formulation components must be reported to the agency and evaluated on a case-by-case basis. The agency reviews the amount in the formulation, the manufacturing information, and information on what steps are taken to limit or remove impurities. EPA can require that any inert ingredients of toxicological concern be listed in the ingredients statement of the label if determined to pose a hazard to humans or the environment (CFR § 156.10(g)(7)).

Glyphosate has been studied in a multitude of studies, including on multiple formulations that contain glyphosate. All studies of adequate scientific caliber that the Agency was aware of were incorporated into the risk assessment. For the glyphosate ecological risk assessment, ecotoxicity data on glyphosate formulations were reviewed in addition to data on glyphosate alone and relevant studies were summarized in the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts*.

For human health risk assessment, the EPA searched the open literature to find glyphosate formulations toxicity data but there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design. Furthermore, there are even fewer instances of studies comparing toxicity across formulations. Most studies using commercial formulations identified as part of EPA's review were *in vitro* studies, which are difficult to translate into *in vivo* effects where metabolism and clearance would play a large role in potential toxicity. EPA gave *in vivo* studies greater weight, however none of the *in vivo* studies with commercial formulations were found to be of adequate quality for use in human risk assessment. Common limitations observed in *in vivo* formulations studies include: lack of test material information, exposure conditions not adequately described/documented, data were presented only as graphs and measures of variability were not included, samples sizes were too small or not reported, only one dose was tested, age/health of study animals were not reported, and a mode of action/adverse outcome pathway was not established.

The EPA has been collaborating with the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences to develop research intended to evaluate the role of glyphosate in product formulations and the differences in formulation toxicity. The results of this research will be considered when available. Additional information on the NTP research plan for glyphosate is available online: https://ntp.niehs.nih.gov/results/areas/glyphosate/index.html.

If at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, the EPA intends to review it and determine the appropriate regulatory action.

Comments About the Monarch Butterfly:

Many commenters such as the Center for Food Safety, Center for Biological Diversity, Natural Resource Defense Council, and Beyond Pesticides expressed concerns 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.

The EPA Response: Monarch butterfly conservation is an important issue for the agency. While herbicides like glyphosate have been implicated in the decline of the monarch butterfly population, it is not known to what extent pesticides in general may play a role. It is important to note that threats to the monarch butterfly population are multi-pronged and include loss of breeding habitat, loss of overwintering habitat in Mexico,[2] changes in weather patterns (including winter storms), disease, and other factors.[3]

[2] Vidal, O., Lopez-Garcia, J., and Rendon-Salinas, E. (2014), Trends in Deforestation and Forest Degradation after a Decade of Monitoring in the Monarch Butterfly Biosphere Reserve in Mexico. *Conservation Biology*, 28: 177-186.
[3] Agrawal, A. and Inamine, H. (2018), Mechanisms behind the monarch's decline. *Science*, 22: vol. 360, Issue 6395, pp.1294-1296.

A holistic approach is needed for monarch conservation and such an approach should consider herbicides in general as well as other factors that may play a role in the monarch decline. In addition, it is important to balance weed management needs with monarch conservation needs. To that end, the EPA published the *Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly* for public comment in 2015 (available in docket EPA-HQ-OPP-2015-0389 at www.regulations.gov). In this document, the EPA sought feedback from stakeholders on strategies for managing risks to monarch butterflies and sought specific information on factors affecting the monarch population, including information such as:

i. volume of use of various herbicides in areas critical to the monarch butterfly and where milkweed species are commonly found;
ii. information on the monarch butterfly lifecycle, seasonal distribution, its population demographics over time, and any modeling analysis relevant to critical life stage parameters;
iii. availability of laboratory or field data that specifically relates to the effects of various herbicides on the milkweed plant species;
iv. information on both spatial and temporal parameters of weed management needs particularly where herbicide use may overlap with habitat of the monarch butterfly development, reproduction, and migration; and
v. information on existing practices that promote co-occurrence of agricultural production with maintenance of milkweed populations.

Overall, the EPA received good suggestions from stakeholders on how to manage risks to monarch butterflies. Suggestions from stakeholders include the following:

i. broad stakeholder involvement, outreach, and partnering;
ii. focusing on voluntary, incentive-based, and locally-led initiatives;
iii. promotion and use of best management practices to reduce pesticide exposure;
iv. promotion and use of integrated pest management;
v. development of label language to protect the monarch butterfly;
vi. supporting milkweed habitat in non-agricultural areas;
vii. more communication, education, and outreach on the monarch butterfly;
viii. continue to better understand monarch biology and needs; and
ix. ensure that any actions taken are done in a manner that balances monarch conservation priorities with other priorities such as native and invasive weed control.

In general, the EPA has focused its monarch conservation efforts on activities that are within the purview of the Office of Pesticide Programs (OPP) and are possible to implement through OPP's registration review, registration, and stakeholder outreach activities. The EPA is focused on four main areas: label language; cooperative efforts between the EPA and other federal, state, and private partners/stakeholders; outreach and communication; promoting best management practices and integrated pest management; and science and risk assessment. In the last several years, the EPA has made progress in many of these focus areas. Major milestones achieved include the following:

- In 2017, the EPA promoted pollinator/monarch conservation activities at the state level by finalizing the *2018-2021 FIFRA Cooperative Agreement Guidance*[4] for states. The

[4] https://www.epa.gov/compliance/fiscal-year-2018-2021-fifra-cooperative-agreement-guidance

2018-2021 Cooperative Agreement Guidance was modified to include the following monarch conservation activities:

- Establish/maintain relationships with federal, state, tribal and local agencies, beekeeper organizations, grower organizations (e.g., commodity groups), crop advisors, pesticide manufacturers (registrants), and other stakeholder groups within the region to assist where needed in combined pollinator protection activities.
- Providing continuing education opportunities to keep growers, applicators, and handlers up-to-date on the most recent methods to protect pollinators (including monarchs), such as integrated pest management, best management practices, and integrated vegetation management.
- Developing and implementing managed pollinator protection plans focusing on managed bees, as well as monarch butterflies and other native pollinators.
- Work with co-regulators and stakeholders to develop measures to determine the effectiveness of these plans in reducing pesticide risk to pollinators.
- Provide technical assistance, education and outreach to support habitat restoration efforts to enhance/supplement forage for bees and other pollinators, such as the monarch butterfly.
- Promote the use of best management practices, integrated roadside vegetation management, and mowing best practices in roadsides, rights-of-ways, or managed natural areas which may support pollinator habitat and in turn support foraging honeybees, monarch butterflies, and other pollinators.

EPA regulates the registration, distribution, sale, and use of pesticides. The states have primary authority for pesticide compliance monitoring and enforcement. EPA provides funds to the states for pesticide education and outreach as well as compliance monitoring and enforcement activities under the FIFRA State and Tribal Continuing Environmental Program cooperative agreements[4]. FIFRA Cooperative Agreement Guidances, which are periodically updated, outline areas of cooperation between the EPA and the states and tribes, and describe specific pesticide program activities where grant money may be disbursed. Adding monarch conservation activities to the 2018-2021 FIFRA Cooperative Agreement Guidance empowers states to prioritize pollinator/monarch conservation activities depending on each state's needs and priorities.

- In 2017, the EPA adopted advisory environmental hazards label language for pesticide products that are toxic to plants in its Interim Registration Review Decisions to alert pesticide users of potential effects 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 adjacent to the treated area. Protect the forage and habitat of non-target organisms by minimizing spray drift. For further guidance and instructions on how to minimize spray drift, refer to the Spray Drift Management section of this label."*

- In 2018, the EPA organized four webinars to educate stakeholders on ways to reduce pesticide spray drift and ways to use integrated pest management principles in managing agricultural lands. The webinars are as follows:

- *Strategies for Managing Pesticide Spray Drift Webinar*, covered the fundamentals of spray drift management.[5]
- *Integrated Pest Management: Strategies for Pollinator Habitat Promotion and Conservation in Agricultural Areas*, covered integrated pest management principles for managing agricultural lands.[6]
- *Best Practices for Aerial Application*, a more in-depth look at aerial application.[6]
- *Best Practices for Ground Application*, a more in-depth look at ground application.[6]

- The EPA is continuing to collaborate with states, federal agencies, and other stakeholders in order to coordinate on conservation efforts and aid in scientific risk assessment. For example, the EPA is currently working with the Fish and Wildlife Service on the assessment of the monarch butterfly species status, and is engaged in discussions with the US Department of Agriculture, the State FIFRA Issues Research And Evaluation Group (SFIREG), and the Association of American Pesticide Control Officials (AAPCO) on various pesticide policy issues, including pollinator/monarch protection efforts.

Stakeholders are encouraged to visit the EPA's new monarch butterfly website for resources and news on the monarch front: https://www.epa.gov/pollinator-protection/protecting-monarch-butterflies-pesticides. In this proposed interim registration review decision for glyphosate, the agency is proposing risk mitigation measures to manage off-target spray drift to protect non-target organisms. Further information on the EPA's proposed interim decision and the agency's rationale is described in Section IV of this document.

Comments About Pollinators:

Several commenters, including the Pollinator Stewardship Council and Colorado State Beekeepers Association, discussed potential direct effects to honey bees and their health, particularly as it related to sublethal effects on honey bee navigation and appetite and cited various open literature references about honey bee health.

The EPA Response: The agency appreciates this additional information concerning honey bee toxicity data. There is uncertainty regarding the relationship of sublethal effects such as inhibition of navigation and loss of appetite, relative to the EPA's standard assessment endpoints (*i.e.*, impaired survival; growth; development). Additionally, the ecological assessment included discussion about a study that tested for colony-level effects (Thompson et al, 2014), which did not show that glyphosate adversely affected adult or developing young (brood). The EPA may require additional pollinator data in order to complete its evaluation of risk to bees prior to a final decision for registration review.

[5] This webinar's materials are posted online at: https://www.epa.gov/reducing-pesticide-drift/strategies-managing-pesticide-spray-drift-webinar-materials
[6] EPA is working on posting the materials for this webinar.

Comments on the Presence of Glyphosate in Surface Water:

Several commenters such as Beyond Pesticides and Friends of the Earth cited a recent report from the US Geological Survey (USGS) indicating that glyphosate had been detected in aquatic systems.

The EPA Response: The agency is aware of the recent 2014 USGS report (https://toxics.usgs.gov/highlights/2014-04-23-glyphosate_2014.html). The USGS monitoring data were considered as part of the EPA's ecological risk assessment (see Section 3.4 of the ecological risk assessment). The USGS data are ambient monitoring data and not targeted spatially or temporally to glyphosate use, so the extent that monitoring detections directly correlate to certain glyphosate applications is uncertain. These data have limited use for risk calculation but are useful as an additional line of evidence. The occurrence of glyphosate in some waterbodies (aside from its uses that include direct applications to certain waterbodies) is consistent with the EPA's analysis and was factored into risk assessment.

Comments Relating to Endangered Species Risk Assessment and Synergy:

The Center for Biological Diversity (CBD) submitted comments which focus on the EPA's duty to consult with the Services on the registration review of glyphosate in accordance with the Endangered Species Act (ESA). The CBD's comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the agency's preliminary determinations regarding the effects of glyphosate on listed species and their designated critical habitat for the glyphosate registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

The EPA Response: The EPA plans to address many of the concerns regarding listed species as part of the implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. See Endangered Species Assessment in Appendix D of this document for more information. The EPA will address concerns specific to glyphosate particularly with regard to pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See Endocrine Disruptor Screening Program in Appendix E of this document for more information regarding endocrine disruption. 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.

Comments Relating to the EPA's Use Reports for Glyphosate:

A number of private citizens expressed concern that the EPA did not adequately assess the large volume of glyphosate use and the large number of use sites as part of registration review. Some commenters, such as Center for Food Safety, requested that the EPA update its use reports for glyphosate and provide more accurate estimates of use and usage.

The EPA Response: At various points in registration review, the EPA has provided estimates of agricultural usage for glyphosate. The following use reports were previously published in the glyphosate registration review docket: the 2008 *Screening Level Estimates of Agricultural Uses of the Case Glyphosate* and the 2015 *Updated Screening Level Usage Analysis (SLUA) Report for Glyphosate Case PC #s (103601, 103604, 103607, 103608, 103613, 417300)*. As part of this proposed interim registration review decision, the EPA is also providing updated agricultural and non-agricultural usage information, which are included in the *Glyphosate: Response to Comments, Usage, and Benefits*, also available in the public docket. A summary of all the current use sites for glyphosate along with current labeled applications rates and other application parameters are also available in the *Joint Glyphosate Task Force's Use Summary Matrix*, available in the glyphosate public docket.

Comments on Glyphosate's Connection to Resistant Weeds:

Many stakeholders (*e.g.*, Beyond Pesticides, Center for Food Safety, Center for Biological Diversity) 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. Commenters noted that there is potential for resistance to spread between herbicide resistant crops and related plants. Other stakeholders (*e.g.*, Kansas Agribusiness Retailers Association, Almond Alliance of California, Iowa Corn Growers Association) state that glyphosate is effective on weeds that are resistant to other herbicides and is still a useful tool for growers despite weed resistance issues.

The EPA Response: Whenever a herbicide is used, there is a potential for that use to contribute to the evolution of herbicide resistance, particularly if the population of a weed species is subjected to repeated sublethal doses of herbicide. Weed resistance commonly occurs but despite resistance problems, glyphosate remains an important weed management tool. Glyphosate is still effective on many weed species that have shown resistance to other herbicides. To combat weed resistance, EPA encourages tank-mixing herbicides, rotating different mechanisms of action, crop rotation, and the use of integrated pest management programs. To maintain some of the most important benefits of glyphosate, growers must use herbicides responsibly as part of an integrated weed control strategy and be proactive in employing good weed resistance management practices.

Herbicide resistance can occur through pollen-mediated gene flow from resistant crops to weedy relatives. Additionally, glyphosate-resistant biotypes of some weeds can rapidly disperse through pollen-mediated gene flow. The United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) regulates the planting, importation, or transportation of genetically engineered plant crops under the Plant Protection Act. Most genetically engineered plants are "regulated articles" and must receive prior approval from APHIS before introduction.

Helping to educate growers on how to manage weed resistance is a top priority for the agency. The EPA is proposing to require herbicide resistance management labeling as part of this Proposed Interim Registration Review Decision (see section IV of this document). The EPA has also published two Pesticide Registration Notices (PRNs) which address pest resistance management. PRN 2017-1[7] promotes mechanism of action labeling by pesticide registrants. PRN 2017-2[8] provides specific guidance for managing herbicide resistance, including labeling, education, training, and stewardship strategies for pesticide manufacturers, producers, formulators, states, grower groups, growers, and other interested stakeholders.

Comments from Mass Mail Campaigns:

The EPA received comments from nine mass mail campaigns. Two mass mail campaigns were organized by Bayer Crop Science and an unidentified organization and included comments from farmers, agricultural professionals, and general consumers urging the EPA to keep glyphosate accessible. Seven mass mail campaigns came from the following environmental non-governmental organizations: Friends of the Earth, Center for Food Safety, Environmental Action, Pesticide Action Network, Organics Consumer Association, Center for Biological Diversity, and an unidentified organization. These seven campaigns urged the EPA to restrict glyphosate, protect the monarch butterfly, and/or reconsider its cancer conclusion.

The EPA Response: The agency has conducted comprehensive human health and ecological risk assessments for glyphosate and has not received any information from public comments that would warrant revising the conclusions of its risk assessments. The EPA did not identify any risks of concern for humans from exposure to glyphosate. In addition, the agency determined glyphosate is not likely to be carcinogenic to humans. The EPA has identified risks primarily from spray drift for non-target organisms. The agency has weighed the risks and benefits of glyphosate use as part of its proposed interim registration review decision. In general, the benefits that glyphosate confers to growers outweighs the geographically limited risks to non-target organisms. It is important to balance the needs of weed management with protections for non-target organisms and the agency is proposing risk mitigation measures to manage off-target spray drift and promote weed resistance management. Further information on the EPA's proposed interim decision and the agency's rationale is described in Section IV of this document.

Comments from USDA's Office of Pest Management Policy:

In its comments to the glyphosate registration review docket, USDA submitted information on the benefits of glyphosate, and furnished information on the non-agricultural uses of glyphosate, particularly in non-food tree crops, aquatic areas, and pasture/natural lands.

The EPA Response: The agency thanks USDA for its comments and especially appreciates the information on use of glyphosate in non-agricultural areas, as that information is not readily

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[7] *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling.* https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management

[8] *Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship.* https://www.epa.gov/pesticide-registration/prn-2017-2-guidance-herbicide-resistance-management-labeling-education

available. The benefits and information on application rate, timing, and typical practices for non-agricultural uses have been considered as part of this Proposed Interim Registration Review Decision.

II. USE AND USAGE

Glyphosate is a broad-spectrum, systemic glycine herbicide which inhibits the enzyme enolypyruvyl shikimate-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 is formulated 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 (ex. sugarcane), glyphosate is used as a plant growth regulator.

Glyphosate is 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 is also registered for use on glyphosate-resistant (transgenic) crops such as corn, soybean, cotton, canola, sugar beets, and alfalfa. Registered non-agricultural uses include: tree injections, residential spot treatments, aquatic areas, forests, rights of ways, 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, tree injection, stump treatment, 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.

The EPA completed a new 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. Most glyphosate was applied to soybean (approximately 117.4 million lbs applied annually), corn (approximately 94.9 million lbs applied annually), and cotton (approximately 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 for the homeowner market (approximately 5 million lbs applied annually), turf (approximately 4.9 million lbs applied annually), forestry

(approximately 3.6 million lbs applied annually), and roadways (approximately 3.3 million lbs applied annually).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. 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. 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. Risk Summary

The EPA thoroughly assessed risks to humans from exposure to glyphosate from all 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 different components of the EPA's human health risk assessment are described below.

Cancer Assessment

The EPA convened a FIFRA SAP meeting in December 2016 to consult on the carcinogenic potential of glyphosate. Recommendations from the Scientific Advisory Panel meeting were published in March 2017. The EPA revised its cancer assessment based on comments received from the SAP and responded to the SAP in 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*. The EPA's final cancer conclusion and its rationale for reaching this conclusion is described in the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*. The EPA's final cancer assessment includes the newly published analysis of glyphosate use and cancer incidence in the Agricultural Health Study (AHS). The AHS study is a long-term epidemiological study of over 54 thousand pesticide applicators to investigate the association between pesticide exposures and incidence of various types of cancer and non-cancer outcomes. The EPA's review of the AHS study is described in the *Summary Review of Recent Analysis of Glyphosate Use and Cancer Incidence in the Agricultural Health Study*. The agency has determined that glyphosate is not likely to be carcinogenic to humans and therefore a quantitative cancer assessment was not conducted.

All documents relating to the cancer evaluation for glyphosate are published in the public registration review docket for glyphosate (EPA-HQ-OPP-2009-0361). The deliberations of the glyphosate FIFRA SAP meeting, including 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 has received a September 27, 2018 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. 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 is still reviewing this petition and has issued a Federal Register Notice of Filing for public comment in docket EPA-HQ-OPP-2019-0066. The petition references EPA's cancer evaluation and includes the following arguments:

1) EPA's tolerance for oats is not adequately protective of children, due to the widespread use of glyphosate and a lack of glyphosate residue monitoring data. The petitioners submit results of residue testing from the EWG of glyphosate levels in various granola, instant oat, breakfast cereal, and snack commodities as evidence of this assertion.
2) Glyphosate is a possible carcinogen according to the International Agency for Research on Cancer (IARC), who classified glyphosate as "probably carcinogenic to humans" in 2015.
3) Human studies demonstrate a likely link between glyphosate exposure and non-Hodgkin lymphoma.
4) Animal models, when viewed in total, suggest glyphosate is a rodent carcinogen.
5) Analyses of glyphosate animal studies by the European Food Safety Authority and the European Chemicals Agency were flawed, and the incidence of tumors is higher than reported.
6) Petitioners point to comments sent from the Office of Research and Development, which were sent to the Office of Pesticide Programs (OPP) while the agency's cancer evaluation was being drafted in 2015, as a line of evidence, contending that OPP should have been more circumspect about rejecting IARC's cancer conclusion.
7) EWG calculated its own cancer risk level and proposed that the level protective of children's health is 0.01 milligrams of glyphosate per day. The petitioners contend that EPA's dietary risk assessment is not adequately protective of children.

Since this petition was submitted outside of the public comment period for the human health and ecological risk assessments, which closed on April 30, 2018, EPA has not considered it as a public comment in the preparation this Proposed Interim Registration Review Decision. EPA will respond to this petition concurrent with the development of its Interim Registration Review Decision for glyphosate. The risk findings described herein reflect the conclusions of EPA's December 12, 2017 human health risk assessment.

Dietary (Food + Water) Risks

An acute dietary assessment was not completed because an acute reference dose could not be established due to the absence of observable adverse effects seen in acute studies. A cancer dietary assessment was not conducted because glyphosate is classified as not likely to be carcinogenic to humans.
Long-term toxicity studies in mice, rats, and dogs demonstrate that glyphosate is of very low toxicity following repeated oral exposure. Rabbits were the most sensitive species tested and the endpoint chosen for chronic dietary assessment was based on diarrhea and few/no feces. A

conservative chronic dietary risk assessment was conducted assuming tolerance-level residues, modeled drinking water estimates from direct application to water scenarios, 100% crop treated assumptions, and default modeling parameters. The resulting chronic dietary risk estimates were not of concern. Children 1-2 years old were the most highly exposed population subgroup (chronic population adjusted dose [cPAD] = 23%, where a cPAD above 100% exceeds the agency's level of concern).

Breast Milk Analysis

In response to concerns from certain segments of the public related to the potential presence of glyphosate in human breast milk, the EPA analyzed human breast milk samples collected by the National Children's Study for residues of glyphosate and glyphosate metabolites (N-acetyl-glyphosate and AMPA). A total of 39 samples from 39 mothers were analyzed. Glyphosate and its metabolites were not detected in human breast milk samples. For additional details on the EPA's breast milk analysis and methodology, please view the following documents in the glyphosate registration review docket:

- *Analysis of Human Milk for Incurred Residues of Glyphosate and its Metabolites. ACB Project #B14-46—Updated from Report Dated September 18, 2015* (dated April 26, 2016)
- *Analytical Method for the Determination of N-Acetylglyphosate and Other Analytes in Various Animal Matrices Using LC/MS/MS* (undated)

The results of the EPA's breast milk analysis is consistent with the scientific literature for glyphosate, which indicates that glyphosate does not bioaccumulate in the human body.

Residential Handler Risks

The EPA considered the potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). A quantitative residential handler assessment was not completed due to lack of toxicity from short- and intermediate-term dermal and inhalation routes of exposure. Residential handler risks are not anticipated from currently registered uses of glyphosate.

Residential Post-Application Risks

Post-application dermal and inhalation assessments were not quantitatively assessed due to lack of toxicity. However, a short- and intermediate-term post-application incidental oral exposure assessment was conducted to assess potential risk from two scenarios: 1) for hand-to-mouth behavior on treated lawns and 2) for swimmers via short-term post-application incidental oral exposure to glyphosate from the aquatic use. Post-application incidental oral risk estimates for the turf use were not of concern, with Margins of Exposure (MOEs) ranging from 640 to 290,000, where MOEs below 100 are of concern. Post-application swimmer risk estimates for the aquatic use were not of concern (MOEs range from 210,000 to 2,200,000, where MOEs below 100 are of concern). Therefore, residential post-application risks are not anticipated from currently registered uses of glyphosate.

Non-Occupational Bystander Spray Drift Risks

The EPA assessed the potential for risk to non-occupational bystanders from off-target movement of glyphosate via spray drift, to protect from indirect exposure (*e.g.*, children playing on lawns where residues have deposited next to treated fields). Since glyphosate is registered for use on turf, it was considered whether the existing turf post-application assessment was protective of bystander exposure via spray drift. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The currently registered maximum single agricultural application rate for glyphosate is 8 lbs ae/A (for use on pastures, forestry, non-food tree crops, etc.). The highest fraction of spray drift for any application method immediately adjacent to a treated field results in a deposition fraction of 0.26 of the application rate (from AgDrift modeling). The maximum application rate adjusted by the 0.26 adjustment factor for drift (8 lb ae/A x 0.26 lb ae/A=2.08 lb ae/A) is less than the assessed maximum direct spray residential turf application rate (10.5 lb ae/A). Therefore, the turf post-application assessment is protective for any potential bystander spray drift exposure, and a quantitative spray drift assessment for glyphosate was not required. Therefore, non-occupational bystander spray drift risks are not of concern for glyphosate.

Aggregate Risks

Aggregate risk assessment considers exposure from food, drinking water, and residential exposures combined. The EPA conducted short-term (food, water, residential) and chronic (food and water) aggregate risk assessments. Acute and cancer aggregate risk assessments were not conducted since an appropriate endpoint attributable to a single dose was not identified for the general U.S. population or any population subgroup and glyphosate is classified as not likely to be carcinogenic to humans, respectively. An intermediate-term assessment was not conducted since the short-term assessment is protective of intermediate-term exposure (the endpoints for these durations are identical). Short-term aggregate risks were not of concern (MOE for children = 260, MOE for adults = 1,300, where MOEs below 100 are of concern). The MOE for children represents exposure from chronic dietary (food and water) and incidental oral ingestion exposure from turf use, which was the highest exposure scenario. The MOE for adults represents chronic dietary exposure (food and water) and incidental oral ingestion exposure resulting from aquatic use, the highest exposure scenario.

Chronic aggregate risks were also not of concern. Chronic aggregate exposure is from dietary (food and water) exposure only, based on the use pattern, and are the same as the chronic dietary risk estimates (≤23% cPAD, see dietary section).

Cumulative Risks

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, the EPA did not assess cumulative risks for this assessment.
Occupational Risks

A quantitative occupational exposure assessment was not conducted due to lack of toxicity via the occupational handler and post-application dermal and inhalation routes of exposure. Therefore, occupational risks from currently registered uses of glyphosate are not of concern.

The current restricted entry interval (REI) on the labels is 12 hours or 4 hours, depending on the glyphosate formulation. The current human health risk assessment supports a 4 hour REI for glyphosate the active ingredient, but the different glyphosate formulations were not assessed. According to *PRN 95-3: Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) for Certain Low Risk Pesticides*, certain glyphosate formulations may qualify for a reduced 4 hour REI. Glyphosate registrants may use the existing label amendment process to request a reduction in the existing 12 hour REI to a 4 hour REI on the label, on a formulation by formulation basis.

2. Human Incidents and Epidemiological Analysis

The EPA conducted an extended incident search for glyphosate human health incidents in February 2014. Five pesticide incident data sources were reviewed: Office of Pesticide Programs Incident Data System (IDS; 2008-2012), National Pesticide Information Center (NPIC; 2007-2013), California's Pesticide Incident Surveillance Program (PISP; 2005-2010), National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH/SENSOR; 1998-2009), and the American Association of Poison Control Centers (AAPCC; 2001-2012). 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 by volume. Health effects reported in the incident databases include dermal, ocular, and respiratory symptoms and effects are generally mild and resolve rapidly. Data from IDS and NPIC suggest that homeowner mixing/loading/applying (usually due to human error and container leaks of glyphosate products) are responsible for almost half of reported incidents. Data from SENSOR-Pesticides are consistent with IDS and NPIC and show that glyphosate application results in the most reported incidents. Occupational handling of equipment is responsible for most incidents in California's PISP database due to equipment leaks and malfunction. Across SENSOR, IDS, and NPIC, children's exposure was due to post-application exposure, accidental ingestion, and tampering with the product.

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. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

An updated incident search was conducted in the IDS on October 26, 2018 for new human health incidents. From January 1, 2014 to October 25, 2018, 249 incidents were reported in the Main IDS involving glyphosate. Of these, there were 3 deaths, 24 incidents were classified as major

severity, 216 incidents were classified as moderate severity, 5 incidents were classified as minor severity, and 1 incident had no or unknown effects. Of the three reported deaths, two were suicides and one was described as a "Roundup overdose." From January 1, 2014 to October 25, 2018, 3,123 incidents were reported to Aggregate IDS involving glyphosate; most were classified as minor severity and the rest had no effects or unknown effects.

For more information on reported human incidents, see the *Glyphosate: Tier II Incident Report*, available in the in the public docket for glyphosate.

3. 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.

Table 1. Proposed Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.

Current		Proposed Change		Comment
Commodity	Tolerance (ppm)	Commodity	Tolerance (ppm)	
Soybean, forage	100.0	Soybean, forage	100	change in number of significant figures
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	

Table 1. Proposed Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.				
Current		Proposed Change		Comment
Commodity	Tolerance (ppm)	Commodity	Tolerance (ppm)	
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.

4. Human Health Data Needs

No human health data needs have been identified for glyphosate. The human health data required as part of the registration review DCI has been satisfied.

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. 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. 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.

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. See Appendix D for more details. As such, potential risks for non-listed species only are described below. See section III.C of this document for additional risk characterization.

1. Risk Summary

Terrestrial Risks

To assess risk to mammals, birds, terrestrial invertebrates, and terrestrial plants, the EPA reviewed both registrant-submitted studies and studies from the open literature. When available, formulation-specific data were also considered in addition to data on glyphosate alone.

Mammals

Acute risks to mammals are expected to be low for technical grade glyphosate. Acute risk quotients (RQs) were not calculated for mammals because the lethal dose sufficient to kill 50% of a population (LD_{50}) is greater than the highest concentrations tested (up to 4,800 milligrams acid equivalent per kilogram of bodyweight [mg ae/kg-bw]) in the available acute oral toxicity study. Estimated Environmental Concentrations (EEC)s for all uses except spot treatment are below the highest concentration tested in the available acute oral and acute dietary studies. However, the application rate for spot treatments is adjusted to a per acre basis and conservatively assumes that the entire area is treated at that high rate.

In addition to toxicity studies with technical grade glyphosate, acute dose-based toxicity studies were available for various formulations. RQs exceeded the level of concern (LOC) of 0.5 for one formulation (11.4% glyphosate; acute RQs ≤ 2.1) for labeled use on broadcast brush at a rate of 7.2 lb ae/A. Data for most formulations showed LD_{50} values greater than the highest dose tested.

Chronic dietary-based RQs for technical grade glyphosate did not exceed the LOC for any use patterns, except spot treatment (RQs ≤ 1.92, where the LOC=1). However, chronic dose-based RQs did exceed the LOC for the following scenarios:

i. application to sugarcane at rates of 2.25 lb ae/A and above (RQ=1.02),
ii. application to most conventional crops by ground at rates of 3.75 lb ae/A and above (RQ ≤ 1.21),
iii. application to Roundup-ready crops at the maximum annual rate of 6 lb ae/A (RQs ≤ 1.11),
iv. application to tree crops at a rate of 8 lb ae/A (RQs ≤ 1.03),
v. application to food trees and vine, berry, and small fruits at the maximum annual rate of 8 lb ae/A (RQs ≤ 1.60),
vi. application to forestry, pastures, non-crops areas at a rate of 8 lb ae/A (RQs ≤ 2.04),
vii. application as spot treatments assuming a rate of 40 lb ae/A (RQs ≤ 10.2).

Most chronic dose-based risk exceedances are slightly above the LOC, except for residential spot treatments. The application rate for spot treatment conservatively assumes that the entire acre is treated at a high rate of 40 lb ae/A. Potential risk to mammals from spot treatment use should be limited to residential areas and limited in area.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Potential acute risks to birds from exposure to technical grade glyphosate are likely to be nearer to the level of concern at application rates lower than 8 lb ae/A. There were no mortalities in any of the acute oral or acute dietary avian studies with technical glyphosate (LD_{50} values >3,196.3 mg ae/kg-bw and >4,971 mg ae/kg-diet, respectively). Since definitive LD or LC_{50} values were not determined, RQs were not calculated. EECs for all uses except spot treatment are below the highest concentration tested in the available acute oral and acute dietary studies. However, the application rate for spot treatments is adjusted to a per acre basis and conservatively assumes that the entire area is treated at that high rate.

Regarding the acute toxicity of glyphosate formulations, RQs exceeded the LOC of 0.5 for one formulation (68.5% glyphosate monoammonium salt; acute RQs $\leq$ 1.26, based on an LD_{50} value of 1,131 mg ae/kg-bw for bobwhite quail). Acute avian studies were available for the degradate AMPA and data show it is no more toxic than the parent glyphosate.

Chronic avian RQs were not calculated because the most sensitive endpoint in the avian reproduction study resulted in a non-definitive NOAEC. However, EECs for multiple uses are greater than the lowest concentration tested in the mallard study where effects on body weight were observed (NOAEC <501 mg ae/kg; MRID 48876602). To further characterize the potential for chronic risk from exposure to glyphosate, RQs were calculated using the non-definitive NOAEC from the avian reproduction study with the bobwhite quail where no effects were observed at the highest concentration tested, 830 mg ae/kg-diet. The following scenarios exceed the LOC of 1:

i. application to most conventional crops at the maximum single aerial rate (1.55 lb ae/A), the maximum single ground rate (3.75 lb ae/A), or above,
ii. application to Roundup ready crops by ground at the maximum single rate of 3.75 lb ae/A or above,
iii. application to sugarcane at rates of 2.25 lb ae/A or above,
iv. application to tree crops at rates of 8 lb ae/A,
v. application to food trees and vine, berry, and small fruits at 8 lb ae/A, and
vi. application to forestry, pasture, and non-crop areas at a rate of 8 lb ae/A.

RQs for the scenarios above were marginal (RQs ranged from approximately 1 to $\leq$ 2.5). Given that there were no reported effects up to the highest concentration tested in the bobwhite quail avian reproduction study, these RQs may be conservative for most uses, but to a lesser extent for use on forests, pastures, and non-crop areas. Application as spot treatment at a rate of 40 lb ae/A resulted in higher risk exceedances, but this scenario was conservatively assessed (RQ $\leq$ 11.6). Evidence from multiple studies suggest that exposure to glyphosate may result in decreases in body weight, but reproductive parameters such as number of eggs laid, embryo viability, and eggshell thickness may not be impacted.

Terrestrial Invertebrates (honeybees)

Potential risk to terrestrial invertebrates is uncertain, as acute contact and oral honeybee LD_{50} values are greater than the highest doses tested (103 µg ai/bee for contact, 182 µg ai/bee for oral exposure). Application rates higher than 5.7 lb ae/A exceed the highest tested oral concentrations. Risks to individual bees at application rates lower than 5.7 lb ae/A are expected to be low, but risks are uncertain at rates above 5.7 lb ae/A.

In a colony-level study, no adverse effects were reported based on exposure to residues from an application at a rate of 1.92 lb ae/A.

Data are available for other types of terrestrial invertebrates (predatory mites, earthworms, parasitic wasps) where no effects are reported up to the highest dose tested. The most sensitive endpoint was for predatory mite, and data suggest possible effects up to 69 ft from the edge of

the field for an application rate at 8 lb ae/A, and 16 ft from the edge of the field for an application rate at 3.75 lb ae/A.

Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although the EPA identified the need for certain data to evaluate potential effects on pollinators when initially scoping the registration review for glyphosate, the problem formulation and registration review DCI for glyphosate, were both issued prior to the EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[9]. This 2014 guidance lists additional pollinator studies that were not included in the glyphosate registration review DCI. Therefore, the EPA is currently determining whether additional pollinator data are needed for glyphosate. If the agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for glyphosate, then the EPA will issue a DCI to obtain these data. The pollinator studies that could be required for glyphosate are listed in Table 2 below.

Table 2. Potential Pollinator Data Requirements for Glyphosate

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	Honey bee adult chronic oral toxicity
Non-Guideline	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.

Terrestrial Plants

Exposure to glyphosate may impact non-target terrestrial plants. Risks from runoff due to glyphosate applications are anticipated to be low. Runoff estimated environmental concentrations were lower than the no observable adverse effect level for plants (based on seedling emergence data).

Potential risks to terrestrial plants are primarily from spray drift. Based on vegetative vigor data, dicots are generally more sensitive to glyphosate than monocots. The most sensitive species tested was cucumber, based on vegetative vigor data for a glyphosate formulation where phytotoxicity was observed (leaf discoloration). A spray drift analysis was completed for both ground and aerial application of glyphosate at various application rates up to 8 lb ae/A, assuming

[9] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

default droplet size parameters. Fine to medium droplets were assessed for aerial application and very fine to fine droplets were assessed for ground application (based on the American Society of Agricultural and Biological Engineers' [ASABE] droplet size classification standard). Results for the most sensitive species tested, cucumber, are presented in Table 3.

Given its importance as a critical food resource for the monarch butterfly, the agency also completed a spray drift analysis for common milkweed. Reported toxicity endpoints in the literature for common milkweed are similar to the vegetative vigor endpoints for cucumber, the most sensitive species tested (IC_{25} for cucumber is 0.074 lb ae/A; IC_{25} for common milkweed is 0.126 lb ae/A). Distances from the edge of the field to be below toxicity threshold (i.e., buffer distances) for both cucumber and milkweed are listed in Table 3.

Table 3. Results of spray drift assessment for terrestrial plants for both aerial and ground application of glyphosate at various application rates

Application rate (lb ae/A), assuming 1 application at each rate	Distance from the edge of the field to be below toxicity threshold for most sensitive species tested (cucumber)	Distance from the edge of the field to be below toxicity threshold for the common milkweed	Spray method
1.55	190	118	Aerial (fine to medium droplets)
2.25	282	171	
3.75	466	279	
8	>1,000	620	
1.55	52	33	Ground (very fine to fine droplets)
2.25	79	46	
3.75	128	75	
8	253	157	

Ground applications result in less spray drift than aerial applications in general. For the most sensitive species, cucumber, applications at 8 lb ae/A result in buffer distances of 253 ft for ground application and over 1,000 ft for aerial application. Applications at rates of 3.75 lb ae/A result in much lower buffer distances (128 ft for ground application and 466 ft for aerial application).

Aquatic Risks

To assess potential risk to aquatic organisms, the EPA reviewed both registrant-submitted studies and open literature studies. The EPA also assessed risk from exposure to technical grade glyphosate and for formulated glyphosate, including formulations containing polyoxyethylene tallow amine (POEA). While POEA is not used in glyphosate formulations labeled for aquatic use sites, terrestrial formulations may still contain POEA and may contribute to exposure via runoff. Risk from runoff and spray drift were assessed. Exposure from both terrestrial and aquatic applications were considered.

Data on the degradate aminomethylphosphonic acid (AMPA) were available for fish and aquatic invertebrates and were reviewed as part of the aquatic assessment. Based on existing data,

AMPA appears to be less acutely toxic to aquatic organisms than the parent glyphosate and the existing aquatic assessment is considered protective for exposure to AMPA.

Fish, Aquatic Invertebrates, and Aquatic-Phase Amphibians

Risks to fish, aquatic invertebrates, and aquatic-phase amphibians did not exceed the LOC for exposure to glyphosate alone (acute RQs < 0.01, where the acute LOC = 0.5; chronic RQs ≤ 0.12, where the chronic LOC = 1). Risks are also likely to be low for exposure to formulations containing POEA (acute RQs ≤ 0.07). Formulations that do not contain POEA similarly did not show risks of concern (acute RQs < 0.01).

Aquatic Vascular and Non-Vascular Plants

Risks to aquatic plants did not exceed the level of concern for exposure to glyphosate alone (acute RQs ≤ 0.17, where the LOC=1). Risks are likely to be low for exposure to formulations containing POEA via terrestrial applications (acute RQs ≤ 0.68). Risks exceed the level of concern for exposure to formulations without POEA for applications to aquatic environments (acute RQs ≤ 2.6). This is not surprising, given that some glyphosate formulations are tailored to treat aquatic weeds.

Evaluation of risk to terrestrial plants from exposure to spray drift via glyphosate formulations is described in the terrestrial plant section, and the calculated distances off-field to be below toxicity threshold would apply to emergent aquatic vegetation as well as terrestrial plants. For emergent aquatic vascular plants, there is potential for risk from exposure to spray drift from terrestrial uses (distance from the edge of the field to below toxicity threshold is over 1,000 ft, for application rates at 8 lb ae/A, see table 2).

2. Ecological Incidents

A review of the Ecological Incident Information System (EIIS) and the Avian Monitoring Information System (AIMS) was conducted on February 21, 2014. A search of the Office of Pesticide Incident Data system (IDS) for aggregated incidents (i.e., registrant-reported incidents) was conducted on February 27, 2014. Incidents in EIIS are classified as "possible," "probable," and "highly probable." Incidents in AIMS are classified as "possible," "probable," "likely," "highly likely," and "certain." The majority of the glyphosate incidents are for terrestrial plants, fewer incidents were reported for terrestrial and aquatic wildlife.

Terrestrial plant incidents

Plant incidents for glyphosate and its various salt forms involved either direct treatment or spray drift and resulted in either plant damage or mortality. Approximately 602 individual plant incidents were reported, and 724 aggregate incidents were reported. Reports were classified from "possible" to "highly probable." Most plant incidents involved spray drift onto adjacent agricultural crops and grass. There were a few incidents of trees being damaged or killed. There was one incident which involved use on a right-of-way that was classified as highly probable.

Terrestrial wildlife incidents

Five wildlife incidents were reported for glyphosate for uses on rangeland/pasture, home/lawn, and a tree farm. One consisted of accidental misuse on corn where an unknown bird was reported as dead. Two incidents classified as "possible" involved mortality to three birds from drift and mortality to several dogs from runoff. No additional details were provided for the dog mortalities. For the bird mortalities, other chemicals were applied at the same time, including atrazine, s-metolachlor, and permethrin. One incident involved honeybees and was classified as "possible" where it was reported that an herbicide containing sulfometuron methyl and glyphosate was applied near flowering areas and twitching or dead bees were observed near three hives. One "probable" incident reported incapacitation of two iguanas following ingestion of dandelions sprayed with glyphosate. In the IDS aggregate database, there were 38 reports of wildlife incidents, but additional details were not available.

Aquatic incidents

One "possible" 2003 incident involved 10 dead goldfish, 2 incapacitated fish, and other fish observed "gasping" at the water surface; investigators reported it was not possible to determine a reason for the fish kill due to lack of water measurements. Eleven fish incidents were reported from 1990 to 2003 with classifications ranging from "possible" to "highly probable." One "highly probable" incident involved misuse where thousands of shad were killed. Four other incidents of misuse were also reported. Two fish kill incidents were reported where glyphosate was applied directly to the fish pond, in both cases investigations indicated that elevated ammonia and reduced dissolved oxygen may have been reason for the fish kill. One incident involved glyphosate being applied to the perimeter of a pond and fish kills were reported 2 months later; the report indicated that overstocking and improper disolved oxygen may have killed the fish. In one incident, glyphosate was applied to 80 acres next to a fish pond, when it rained the next day, 700 fish were found dead, but no other details were provided.

Incident update

As of 2017, all ecological incidents are migrated and combined into IDS. An updated search for new ecological incidents since 2014 was conducted in IDS on November 26, 2018. There were 24 reported incidents of on-site crop damage from application of glyphosate in combination with other pesticides. Twelve incidents were on treated corn and were classified as "possible" to "probable"; the adverse effects observed in corn included crop injury, discoloration, or death. There were 12 incidents of crop damage on soybean, incident classifications ranged from "possible" to "probable" and adverse effects observed were browning/death or discoloration/bleaching.

There were 5 reported incidents of off-target spray drift damage. One "probable" incident in 2014 involved drift onto a nearby vineyard from a non-crop area application nearby and resulted in the withering and yellowing of grape leaves. Another "possible" incident in 2014 involved dead or dying bees on a sidewalk from application of glyphosate and pendimethalin in the area; no further details were provided. A "possible" incident in 2015 involved drift from a glyphosate ditch area application which resulted in death in 7 bee hives nearby a week later; the beekeeper reported loss of over 100,000 bees. Another "probable" incident in 2015 involved drift from a

field corn application which resulted in phytotoxicity in a garden nearby. A "possible" incident in 2017 involved drift damage to 20 acres of roses and 22 thousand potted roses; multiple herbicide applications were reported nearby by multiple growers.

3. 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. As noted in Table 1, pollinator data may still be needed. The agency will issue a DCI for 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. Risk Characterization

Birds and Mammals

Potential risks were identified for mammals and birds feeding on foliar dietary items treated with glyphosate. There were marginal risk exceedances for applications at the maximum single aerial application rate of 1.55 lb ae/A, the maximum single ground application rate of 3.75 lb ae/A, application to sugarcane, and applications to tree crops, forests, pastures, and non-crop areas at 8 lb ae/A. Risks from these scenarios are likely limited to the treated field and areas near the treated field. Risk to mammals and birds were primarily for application as spot treatment. Spot treatments are limited to residential areas and limited to small areas, so risks from this use are likely spatially limited. In addition, the risk assessment assumes that birds and mammals will consume food items treated with glyphosate as 100% of their diet, this is unlikely to occur from spot treatment application.

According to USDA, use on non-food tree crops, forestry, pastures, and non-crop areas are also geographically limited.[10] The high application rate of 8 lb ae/A intended for these uses are for small spot treatments in highly concentrated and localized areas for management of invasive weeds and for conservation purposes on non-agricultural lands. The application methods used for these sites are unlikely to drive drift, as application is usually by small mechanically-pressurized or handheld equipment. Exposure to birds and mammals under such conditions are likely to be localized and minimal.

Non-food tree crop applications are intended for private forestry management. According to USDA, glyphosate is applied in this setting as part of a tank mix for weed resistance management, and the rate used is no more than 4.5 or 5 lbs ae/A. Application for forestry management is usually made by helicopter equipped with drift control technologies, including micro-foil boom and raindrop nozzles which allow for precise applications. Glyphosate is also applied to conifer and hybrid cottonwood establishments in the Pacific Northwest, and recommended use rates for site preparation range from 1.5 to 3 lb ae/A.

[10] See USDA's comments on the glyphosate ecological risk assessment in the glyphosate registration review docket at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1618

Glyphosate use in pastures is for renovation and habitat restoration efforts. According to USDA, glyphosate is applied at 2.25 lb ae/A for forage renovation (to convert common bermudagrass to hybrid bermudagrass) with 2 consecutive fall applications. In natural areas or utility rights of way, glyphosate rates may reach 4 lb ae/A. Application above 4 lb ae/A is usually applied by handgun for spot treatment of invasive weeds, such as cogon grass, and are not likely to drive risk concerns.

Since these uses are very localized and application to these use sites are either with lower application rates than assessed or done with application equipment that is unlikely to contribute to spray drift, risk to mammals and birds from these uses is expected to be lower than estimated.

Terrestrial and Aquatic Plants

Consistent with its mode of action as an herbicide, risk to non-target terrestrial and aquatic plants were primarily from spray drift and the resulting buffer distances were heavily dependent on the application rate used (Table 2). The maximum labeled single application rate for ground application to agricultural row crops is 3.75 lb ae/A; at this rate, the distance from the edge of the field to get below toxicity threshold is 128 ft. The maximum labeled single application rate for aerial application to agricultural row crops is 1.55 lb ae/A; at this rate, the distance from the edge of the field to get below toxicity threshold is 190 ft.

The EPA recently completed an updated analysis of glyphosate usage (see the *Glyphosate: Response to Comments, Usage, and Benefits* document), and data from 2012 to 2016 indicate that for many crops, the average single application rates used by growers are even lower than the application rates assessed by the EPA for ground and aerial row crop applications. Average single application rates used by growers vary from crop to crop but range from 0.67 lb ae/A for canola to 1.84 lb ae/A for table grapes. The majority of glyphosate is applied to corn (approximately 94.9 million lb ae applied annually) and soybean (approximately 113.9 million lb ae applied annually). The average single application rate used for corn is 0.95 lb ae/A and the average single application rate used for soybean is 0.97 lb ae/A. If average application rates are close to typical grower practices, spray drift risk to non-target terrestrial and aquatic plants from row crop applications is expected to be lower than estimated.

For detailed crop by crop usage and rate information, see the *Glyphosate: Response to Comments, Usage, and Benefits* document in the glyphosate docket at www.regulations.gov.

Aquatic Uses

USDA submitted additional information on aquatic applications of glyphosate (2018). Application of glyphosate in aquatic use sites at rates of 8 lb ae/A are for perennial grass control (ex., the invasive torpedograss in Florida). Application at the 8 lb ae/A rate occurs only once per site per year, and aerial applications in such instances are atypical. Perennial grasses like *Arundo* (giant reed) and *Phragmites* (common reed) can be controlled with lower rates and with one application per year. Programs to control giant salvinia (an invasive aquatic fern) in Louisiana involve multiple applications of glyphosate at 1-2 lb ae/A, up to the yearly maximum of 8 lb ae/A. As such, risk to non-target organisms from application to aquatic use sites would be geographically limited.

To view the information submitted from USDA on the non-agricultural uses described previously, please visit the glyphosate public docket at www.regulations.gov (EPA-HQ-OPP-2009-0361-1618).

D. Benefits Assessment

Glyphosate is the most commonly used agricultural herbicide in the United States, in terms of area treated. It is a broad-spectrum herbicide that controls 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 Weed Science Society of America (WSSA). Glyphosate is a relatively inexpensive herbicide to apply in agricultural situations, with the cost of applications to most crops ranging $1to $13 per acre.

Glyphosate is 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 include 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 orchard and vineyards floor management and most acres of crops such as tree nuts, citrus, and grapes are treated with glyphosate. Glyphosate is the most diverse 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, where 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-ways. Invasive weeds controlled by glyphosate include cattails and water hyacinth, which can impede water flow and impede irrigation. Improper weed management can cause water to stagnate, which provides 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 ways 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 top 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, under hooded sprayers, and as a directed spray.

For more information on the benefits of glyphosate, see the *Glyphosate: Response to Comments, Usage, and Benefits* and the 2018 comment from USDA in the glyphosate public docket (EPA-HQ-OPP-2009-0361-1618).

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The EPA did not identify any human health risks from exposure to any use of glyphosate. The agency identified potential risk to mammals and birds, however these risks are expected to be limited to the application area or areas near the application area. The EPA identified potential risk to terrestrial and aquatic plants from off-site spray drift, consistent with glyphosate's use as a 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 essential in habitat restoration efforts for rangeland and pastures. It is used for weed management for rights-of-ways, 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 EPA is proposing certain spray drift management measures. To preserve glyphosate as a viable tool for growers and combat weed resistance, the EPA is also proposing that herbicide resistance management language be added to all glyphosate labels. The EPA is also proposing certain labeling clean-up/consistency efforts to bring all glyphosate labels up to modern standards. The EPA has discussed these measures with the Joint Glyphosate Task Force, a registrant consortium, which does not oppose the proposed risk mitigation outlined herein.

1. Spray Drift Management

The agency is proposing 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 proposing the following spray drift mitigation language to be included on all glyphosate product labels for products applied by liquid spray application. The proposed 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 proposed in this PID, once effective.

- 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 applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, 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 aerial applications, select nozzle and pressure that deliver "fine" or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (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 proposed spray drift management restrictions and has determined that these measures are not expected to substantially reduce the benefit 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.

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 has determined that such a requirement is not likely to affect the efficacy of glyphosate when used alone since it is systemic. Glyphosate is a compound that is frequently tank mixed with other herbicides. Because the proposed 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. The EPA is uncertain if requiring "fine" or coarser 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 proposed to be removed from all glyphosate labels where such information currently appears. The proposed new language above, which cites ASABE S572.1, eliminates the need for VMD information. The agency is also proposing the addition of a non-target organism advisory statement. The protection of pollinating organisms is a priority for the agency. It is possible that pollinators and other non-target organisms may be indirectly impacted from effects on forage and habitat. It is the agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, the EPA is proposing non-target organism advisory language to be placed on glyphosate labels to address this potential concern.

2. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.[11] Consistent with the Notice, the EPA is proposing 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.

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 mitigating 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 Statement

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,

[11] PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship"

glyphosate may impact non-target plants via spray drift and impact nectar sources and habitat for pollinators and other non-target organisms. EPA is proposing a non-target organism advisory statement 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 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 555 Section 3 registrations and 37 Section 24(c) registrations for glyphosate. Labels directions for glyphosate vary significantly from label to label, and newer stamped labels in general have better instructions than older labels. The EPA is proposing to update all glyphosate labels to modern standards. The components of the label the agency proposes to update 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*. EPA is proposing that maximum labeled rates on current labels 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 proposes that maximum application parameters be clearly defined 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 proposing to define the 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 proposing to update the 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 for aquatic applications. The EPA is proposing to update the existing language to be consistent with current labeling guidelines (see the EPA's Label Review Manual). Proposed environmental hazards statements are listed in table 4.

In addition, the agency is proposing an additional statement under "directions for use" for aquatic use labels 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; the proposed statement also appears in table 4. These statements already appear on some newer labels and the agency is proposing to apply these statements to all labels.

Table 4. Proposed Statements for Glyphosate for Aquatic Use

Product Type	Proposed 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 proposing to clarify 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.

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 proposed: "Glyphosate works by targeting an enzyme that is essential for plant growth." The proposed 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 proposing that the number of significant figures be modified for several tolerances, and that new tolerances be established for various vegetable and fruit groups and subgroups. The new tolerance groupings remove the need for certain older tolerances, which are proposed to be deleted. The Agency will issue a Federal Register notice announcing these proposed tolerance changes under FFDCA following issuance of an Interim Decision for glyphosate. Refer to section III.A.3 of this document for the proposed tolerance changes.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR § 155.56 and 155.58, the agency is issuing this Proposed Interim Registration Review Decision. Except for the EDSP, ESA and pollinator components of this case, the agency has made the following Proposed 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 at this time, as described in Section IV. A. and Appendices B and C.

In this proposed 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 or a complete assessment of effects to pollinators. Although the agency is not making a complete endangered species finding at this time, the proposed 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 an assessment of non-target exposure to pollinators (bees).

D. Data Requirements

No additional data are required as part of this proposed interim registration review decision. The EPA will consider requesting the glyphosate registrants to submit pollinator data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this proposed interim registration review decision for glyphosate and will allow a 60-day comment period on the proposed interim decision. If there are no significant comments or additional information submitted to the docket during the comment period that leads the agency to change its proposed interim decision, the EPA may issue an interim registration review decision for glyphosate. However, a final decision for glyphosate may be issued without the agency having previously issued an interim decision. A

final decision on the glyphosate registration review case will occur after: 1) an EDSP FFDCA section 408(p) determination, 2) an endangered species determination under the ESA and any needed Section 7 consultation with the Services, and 3) a more in-depth assessment of non-target exposure to pollinators, if determined to be necessary.

B. Implementation of Mitigation Measures

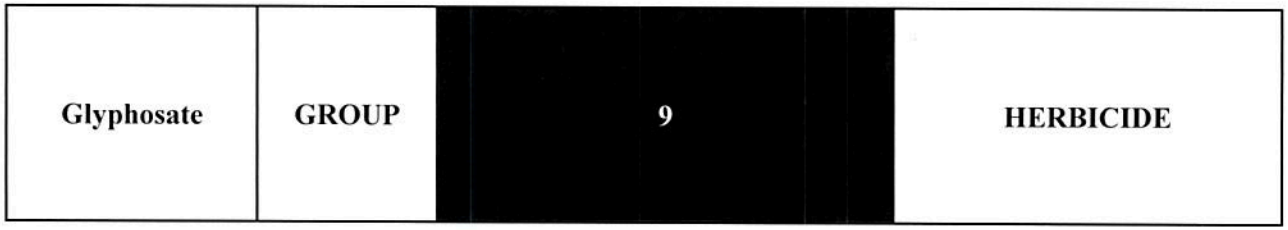
Once the Interim Registration Review Decision is issued the glyphosate registrants must submit amended labels that include the label changes described in Appendices A, B, and C. The revised labels must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision.

Appendix A: Summary of Proposed 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	Proposed Actions	Comment (used to briefly clarify or elaborate on risk or mitigation)
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 5.7 lb ae/A. The agency may require additional pollinator data to fully assess risk to terrestrial invertebrates.

Appendix B: Proposed Labeling Changes for Glyphosate Products

Description	Proposed Label Language for Glyphosate Products	Placement on Label
	End Use Products	
Mode/Mechanism of Action Group Number		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 Statement	"NON-TARGET ORGANISM ADVISORY STATEMENT: 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 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	Environmental Hazards

Description	Proposed Label Language for Glyphosate Products	Placement on Label
	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	"Treated fields may be rotated to a labeled crop at any time. For treated fields being rotated to a non-labeled crop, 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

Description	Proposed Label Language for Glyphosate Products	Placement on Label
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
Mandatory Spray Drift Management Language for all products delivered via liquid spray application and allow aerial application	**"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 fine or coarser droplet size (ASABE S572.1). • Applicators must use ½ 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 "Spray Drift" under the heading "Aerial Applications," and before use rates and or application instructions
Enforceable Spray Drift Management Language for products that allow airblast applications	**"SPRAY DRIFT** **Airblast Applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer rows. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Airblast Applications"
Enforceable Spray Drift Management Language for products that are applied as liquids and allow ground boom applications	**"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 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 "Spray Drift" under the heading "Ground Boom Applications"

Enforceable Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	**"SPRAY DRIFT** **<u>Boom-less Ground Applications:</u>** • Applicators are required to use a fine or coarser droplet size (ASABE S572.1) for all applications. • 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 "Spray Drift" under the heading "Boom-less Applications"
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**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	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** 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 applied as liquids and allow boom-less ground sprayer applications	"**SPRAY DRIFT** **Boom-less 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** **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. Proposed Maximum Application Rates for Glyphosate Ground and Aerial Application

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, 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);	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)
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 (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); Winter squash (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); Watermelon	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)
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 (Indian mulberry); Papaya; Pawpaw; Plantain; Persimmon; Pomegranate; Pulasan; Rambuttan; Rose apple;	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)
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

Consistent with EPA's responsibility under the Endangered Species Act (ESA), EPA intends to complete national-level endangered species Biological Evaluations for glyphosate to assess risks to federally threatened and endangered (listed) species from registered uses of pesticides. This Biological Evaluation will be completed in accordance with the joint Interim Approaches developed to implement the recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*. The NAS report[12] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct to meet their obligations under the ESA. The methods developed as part of the joint Interim Approaches will continue to be vetted before EPA utilizes these methods broadly to meet its ESA obligations.

In November 2013, the U.S. Fish and Wildlife Service, the National Marine Fisheries Service (together, the Services), EPA, and the U.S. Department of Agriculture released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.* [13]

The ecological risk assessment supporting this Proposed Interim Registration Review for glyphosate does not contain a complete, national-level ESA analysis, including effects determinations for specific listed species or designated critical habitat. The agency intends to complete an assessment of risk to listed species prior to completing its final registration review decision for glyphosate. Final Biological Opinions for glyphosate will be developed by the Services. EPA intends to address risks to listed species identified in the Biological Opinions for glyphosate as part of its final registration review decision for glyphosate, and implement geographically-specific risk mitigation for listed species and designated critical habitats, as necessary, via *Bulletins Live! Two.* More information on *Bulletins Live! Two* is accessible at https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins.

[12] http://www.nap.edu/catalog.php?record_id=18344
[13] http://www.epa.gov/espp/2013/nas.html

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,[14] 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.[15] In this PID, 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.

[14] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[15] https://www.epa.gov/endocrine-disruption