OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 17, 2024

Response to Public Comments on EPA's Registration of the New Active Ingredient, Glufosinate-P (Docket IDs: EPA-HQ-OPP-2020-0250 and EPA-HQ-OPP-2020-0533)

This document summarizes the U.S. Environmental Protection Agency's (EPA) responses to public comments received in response to the Notice of Receipt (NOR) of an application to register pesticide products containing the new active ingredient glufosinate-P and the proposed decision to unconditionally register products containing glufosinate-P under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(5).

BASF Application

On February 25, 2020, the EPA received an application from AgriMetis LLC to register pesticide products containing glufosinate-P ammonium (also referred to as L-glufosinate ammonium), an active ingredient not included in any currently registered pesticide products. On September 24, 2020, the EPA published a NOR in the Federal Register (Docket ID: EPA-HQ-OPP-2020-0250) notifying that EPA was in receipt of an application to register pesticide products containing a new active ingredient isomer not included in any currently registered pesticide products (glufosinate-P ammonium) and announced a public comment period of 30 days. EPA received one comment on the NOR from the Center for Biological Diversity.

On September 3, 2020, BASF acquired all applications under the pending L-glufosinate ammonium registration action from AgriMetis, LLC. Later, on December 9, 2022, BASF informed the Agency that they wished to voluntarily withdraw some of the initially requested uses leaving only canola, field corn, sweet corn, cotton, and soybean for the pending L-glufosinate ammonium registration. Subsequently on March 24, 2023, the EPA published a NOF in the Federal Register announcing that EPA had received a petition under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting that EPA establish tolerances for residues of glufosinate-p-ammonium on various commodities and provided a 30-day public comment period. No comments were received on the notice of filing.

Later BASF withdrew all end use products that were initially included in the package. Subsequently, BASF submitted additional applications for one technical product, one manufacturing use product and one end use product. On November 28, 2023, EPA published another NOR in the Federal Register (Docket ID: EPA-HQ-OPP-2020-0250) notifying that EPA was in receipt of an application to register pesticide products containing an active ingredient not included in any currently registered pesticide products (glufosinate-P ammonium) and announced a public comment period of 30 days. No comments relevant to this chemical were received on this notice of receipt.

MITSUI application
On May 26, 2020, EPA received an application from Meiji Seika Pharma Co., Ltd. (now MITSUI) to register new products containing glufosinate-P (also referred to as L-glufosinate acid). On February 8, 2021, the EPA published a NOR in the Federal Register (Docket ID: EPA-HQ-OPP-2020-0533) notifying that EPA was in receipt of an application to register pesticide products containing a new active ingredient isomer not included in any currently registered pesticide products (glufosinate-P) and announced a public comment period of 30 days. EPA received one comment on the NOR from the Center for Biological Diversity.

On November 21, 2023, the EPA published a NOF in the Federal Register announcing the receipt of the initial filing of the L-glufosinate acid petition under the FFDCA requesting the establishment of regulations for residues of L-glufosinate acid on various commodities. This publication also announced a public comment period of 30 days. One comment was received on the notice of filing and the response to this comment is addressed on Federal Register, establishing tolerances on glufosinate-P.

Glufosinate-P-ammonium is the ammonium salt of glufosinate-P and shares all the herbicidal properties for glufosinate-P as mentioned in the document entitled Memorandum Supporting Final Decision to Approve Registration for the New Active Ingredient Isomer, Glufosinate-P (Docket ID: EPA-HQ-OPP-2020-0533). Thus, the Agency considers glufosinate-P ammonium and glufosinate-P as functionally equivalent as glufosinate-P (the parent acid) is the active ingredient for both forms under typical environmental conditions. On May 9, 2024, the Agency announced the proposed decision to grant the registrations for two technical products, one manufacturing use product and one end-use product for the new active ingredient glufosinate-P ammonium, and one technical and one end use product for glufosinate-P under Section 3(c)(5) of FIFRA. A public comment period was held for 30 days, closing on June 08, 2024. The Agency received eleven comments to the docket: Three comments were from BASF; one from the U.S. Canola Association (USCA); one from American Soybean Association (ASA); one from Frank Rademacher, an agronomist, and Illinois farmer; one from National Agricultural Aviation Association (NAAA); one from National Cotton Council (NCC); one from Tennessee Farm Bureau Federation (TFBF); and one from the Center for Biological Diversity (CBD). The Agency also received an irrelevant comment from National Corn Growers Association. The comment from National Corn Growers Association only incorporated the Agency memorandum authorizing the posting of EPA-HQ-OPP-2020-0250 and EPA-HQ-OPP-2020-0533 to Regulations.gov for public access.

Comments on the BASF and MITSUI NORs and EPA's Responses

A. Center for Biological Diversity Comments

1. **CBD comment #1: Comply with duties under Section 7 of the Endangered Species Act (ESA), including completion of consultation.**: "As a separate, discretionary action that may affect endangered and threatened species, the EPA cannot approve new active ingredients prior to the completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service ("the Services"). Without such consultation, the EPA cannot satisfy its duty to

insure that its action does not jeopardize the continued existence of imperiled species across the country or adversely modify or destroy their critical habitat. Moreover, unless and until the EPA completes ESA consultation, any taking of protected species from the use of this pesticide is unlawful."

EPA Response: EPA initiated formal consultation with both Services prior to granting these registrations because the final Biological Evaluation[1]) has determined that the proposed uses of glufosinate-P on conventional and glufosinate-resistant corn, cotton, canola, and soybean may affect, and are Likely to Adversely Affect (LAA), multiple federally listed threatened or endangered species and their designated critical habitats. Additionally, under the ESA counterpart regulations, EPA predicted that the mitigation measures on the registrations and labeling reduce the effects on listed species and their designated critical habitats to the extent that the registration of products containing glufosinate-P would not result in a potential likelihood of future jeopardy for any listed species or likelihood of adverse modification for any designated critical habitats. See 50 C.F.R. § 402.40(b)(1). At the end of the consultation process, the Services will make determinations on whether the registration of products containing glufosinate-P is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of designated critical habitat. The Services provide their determinations in their biological opinions and may determine that additional mitigations are necessary.

EPA is choosing to grant these registrations before consultation is complete since ESA section 7(d) provides that "[a]fter initiation of consultation required under [ESA section 7(a)(2)], the Federal agency and the permit or license applicant shall not make any irreversible or irretrievable commitments of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternative measures which would not violate [ESA section 7(a)(2)]."

2. **CBD comment #2: The EPA must consult on all synergistic and cumulative uses:** The EPA must ensure that all uses of this pesticide do not jeopardize species protected by the ESA or adversely modify or destroy their critical habitat, including uses with other ingredients or other pesticides. Absent information or data to determine whether this pesticide will act synergistically with other ingredients, such uncertainty requires that the EPA decline to re-register any end use products containing more than one active ingredient and prohibit tank mixing on the labels.

   At a minimum, where a product may affect listed species, all product labels must contain the following language: This product may have effects on federally listed

[1] Glufosinate-P and Glufosinate-P Ammonium: Final Environmental Fate and Ecological Risk Assessment (ERA) for the Proposed FIFRA Section 3 Registration and Biological Evaluation (BE) with Associated Effects Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat; EPA-HQ-OPP-2020-0250-0045

threatened or endangered species or their critical habitat in some locations. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county or parish in which you are applying the pesticide. To determine whether your county or parish has a Bulletin, and to obtain that Bulletin, consult http://www.epa.gov/espp/, or call 1-800-447-3813 no more than 6 months before using this product. Applicators must use Bulletins that are in effect in the month in which the pesticide will be applied. New Bulletins will generally be available from the above sources 6 months prior to their effective dates.

EPA response: The applications EPA is granting did not contain any products with active ingredients other than glufosinate-P. However, to determine whether there may be chemicals that when combined with glufosinate-P result in greater than additive (*e.g.*, synergistic) effects compared to glufosinate-P alone, EPA evaluated potential synergy between glufosinate-p and other active ingredients. EPA has developed an interim process to evaluate effects of mixtures of active ingredients based on patents granted by the U.S. Patent and Trademark Office (USPTO) based on the applicant showing the combined effects of the mixture are synergistic (*i.e.*, the effect of a mixture of pesticides is greater than the sum of the individual effects). Both BASF and MITSUI conducted an analysis of U.S. patents to identify any incidence of greater-than-additive (GTA; synergy) claims for glufosinate-P with other agricultural chemicals. The registrants based their analysis on the EPA interim guidance document entitled "*Process for Receiving and Evaluating Data Supporting Assertions of Greater Than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants*" (USEPA 2019). Based on the information provided through the analysis of U.S. patents, EFED found that no identified patents contained claims relevant to the ecological risk assessment of glufosinate-P and that there are no data at this time suggesting there are synergistic effects of glufosinate-P with other active ingredients and so EPA is not prohibiting tank mixes on glufosinate-P labels.

To address the potential effects to non-target vulnerable species, specifically the listed plant species Spring Creek bladderpod (*Lesquerella perforata*) and Whorled Sunflower (*Helianthus verticillatus)*, EPA developed pesticide use limitation areas and published Bulletins in the "Bulletins Live! Two" web-based system (BLT). To make the Bulletins enforceable, the product labeling directs all users to access the BLT prior to application according to the label statement below: "ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product

in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."

Additionally, the Services have included this BLT labeling language as necessary in their recent Biological Opinions.

3. **CBD comment #3: Require that that the registrant provide all necessary data and studies:** The EPA must have substantial evidence to register this pesticide. To do so, the EPA must require all necessary data and studies, including, but not limited to any previously identified data or study gaps, additional studies to evaluate effects on pollinators in accordance with the Guidance for Assessing Pesticide Risks to Bees, information concerning estrogen or other endocrine disruption effects, and any information that this pesticide or products containing this pesticide may have synergistic effects. This is information that the EPA must require from the applicant in the first instance pursuant to 40 C.F.R. § 159.195(a), which require registrants to submit information that they reasonably should know that EPA might regard as raising concerns about the appropriate terms and conditions of registration of a product. The applicant may have information regarding synergy, whether in a U.S. Patent Application or as a result of its research and development. Failure to require any of the above information will result in the EPA underestimating adverse effects and lacking substantial evidence to support registration.

   EPA response: All data requirements specified in Title 40 Part 158 of the Code of Federal Regulations (40 CFR Part 158) have been satisfied either by being completed, waived, or not triggered for glufosinate-P. Specifically, Table 3 – Table 5 and Appendix C of "Glufosinate-P and Glufosinate-P Ammonium: Final Environmental Fate and Ecological Risk Assessment (ERA) for the Proposed FIFRA Section 3 Registration and Biological Evaluation (BE) with Associated Effects Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat" provides the status of the required environmental fate and ecological effects studies. For more information on the status of human health studies refer to section 2.1 and section 12.0 of "Glufosinate-P**.** Human Health Risk Assessment for New Active Ingredient Isomer".

4. **CBD Comment #4: Incorporate necessary factors into evaluation and any proposed decision**: These factors should include the following, at a minimum:
   - **a.** effects on species listed as protected under the ESA and their critical habitat,
   - **b.** effects on pollinators and other beneficial insects, including indirect effects,
   - **c.** effects on human health or environmental safety concerning endocrine disruption, and
   - **d.** any additive, cumulative or synergistic effects of the use of this pesticide.

EPA cannot satisfy its legal duties unless it requires sufficient information and evaluates it for adverse effects before reaching any conclusions. Congress tasked the EPA with regulation of pesticides for safe use. FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." The EPA cannot meet this standard without requiring, evaluating, and considering all information that causes adverse effects from the additional use of this pesticide. Pollinator Stewardship Council v. U.S. E.P.A., Case No. 13- 72346, Dkt. No. 58-1 at 6, 2015 WL 5255016, *1.

EPA response: EPA has determined that all relevant data requirements specified in 40 CFR Part 158 based on the proposed use patterns for glufosinate-P have been satisfied (completed, waived, or not triggered). EPA has completed analyses on the potential effects on listed species and their designated critical habitat, direct and indirect effects on pollinators and other beneficial insects, human health effects/environmental safety, and potential greater than additive effects from the use of glufosinate-P.

EPA has identified mitigation measures for the proposed registrations to avoid the potential likelihood of future jeopardy to Federally listed threatened or endangered species and/or adverse modification of their designated critical habitats (CHs) associated with the registration of products containing glufosinate-P. However, the Services have the sole authority to make a final determination of whether these registration actions result in jeopardy for any listed species or adverse modification of any designated CHs. The Services provide their determinations in their biological opinions and may determine that additional mitigations are necessary. (Also refer to CBD comment #1, CBD comment #2 and CBD comment #3).

5. **CBD comment #5**: **Place appropriate restrictions on uses to avoid and minimize adverse effects.**

EPA response: The products as registered include multiple mitigation measures to reduce exposure to non-target organisms. The mitigation measure mentioned on the label include measures to minimize spray drift and run off. EPA is also imposing avoidance measures like pesticide use limitation areas consistent with recent FWS biological opinions issued for pesticides with similar environmental fate properties and application methods to avoid unreasonable adverse effects on listed species.

6. **CBD Comment #6: The EPA must support any assertion that products with new active ingredients are "safer" or that they will actually replace older pesticide use.** In recent registrations of products with new active ingredients, the EPA has stated that the new products will replace applications of older chemistries that present a greater risk to human health and the environment. It is unclear how the agency is actually making this determination. Older chemistries have undergone multiple decades of scientific scrutiny from a wide array of different scientific laboratories that newer ones simply have not.

   EPA response: EPA did not state that glufosinate-P and glufosinate-P ammonium would replace application of older chemistries that present greater risk to human health and the environment. Glufosinate-P, glufosinate-P ammonium, and racemic glufosinate contain the same herbicidally active ingredient. The glufosinate-P products achieve equivalent herbicidal control as the racemic product through use of the same amount of active isomer along with essentially no inactive isomer. In contrast, the racemic product contains equivalent amounts of active and inactive isomers, resulting in a total application rate that is approximately twice that of the glufosinate-P (*i.e.*, chirally enriched) products. If registered, glufosinate-P products could be used in place of racemic glufosinate in existing weed control programs, including as a part of Herbicide Resistance Management (HRM) and Integrated Pest Management (IPM) programs.

7. **CBD Comment #7: The EPA must take into account real-world scenarios.**

   EPA Response: EPA's risk assessments consider real-world scenarios from both ecological and human health perspectives. While EPA acknowledges that illegal use or accidental spills could potentially occur, based on the evidence before the Agency (including the data submitted by CBD and data on incidents involving racemic glufosinate), EPA considers the evidence that such exposures are likely to occur for glufosinate-P are speculative at this time based on, among other things, differences in methods of application and the spectrum of sophistication across different pesticide applicators. Therefore, EPA has not specifically modelled such exposures. However, to the extent that CBD's concern proves to be founded and misuse occurs, both state and federal agencies have authority to enforce pesticide label requirements and such enforcement actions are reported to EPA (consistent with the FIFRA Cooperative Agreement Guidance). Further, after registration, if registrants have "additional factual information regarding unreasonable adverse effects on the environment," they must report it to EPA under FIFRA § 6(a)(2). This includes, among other things, information about adverse effect incidents (which would include incidents stemming from misuse or accidental exposure) and new information derived from scientific studies (*e.g.*, unexpected levels of toxicity). See also 40 C.F.R. part 159. EPA maintains the Incident Data System (IDS), which records incidents involving both registered uses and misuses that are reported by applicants/registrants, states, tribes, and the general public. EPA uses these data as lines of evidence when assessing risks to non-target organisms as part of the maintenance of registered products.

8. **CBD Comment #8: The EPA must assess the enhanced toxicity of pesticide mixtures:** The protocol that is currently being used to identify claims of synergy and place restrictions on pesticide use is a step above how the agency has utilized synergy data in the past, yet many steps in the process appear arbitrary and poorly executed.

   EPA Response: The EPA has developed an interim guidance document entitled "Process for Receiving and Evaluating Data Supporting Assertions of Greater Than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants" (USEPA 2019). This interim guidance has a process to evaluate effects of mixtures of active ingredients based on patents granted by the U.S. Patent and Trademark Office (PTO) based on the applicant showing the combined effects of the mixture are synergistic (*i.e.*, the effect of a mixture of pesticides is greater than the sum of the individual effects). To ensure that effects data of the mixture that may be relevant to ecological risk assessments are considered, the EPA requested that registrants of new chemicals submit mixture toxicity data. The EPA provided guidance to assist registrants in identifying relevant data for submission.

   In response to the request and guidance, BASF Corporation and MITSUI conducted independent analyses of U.S. patents (Cain and Lorenz 2022; Pennino and Setliff 2022) to identify any incidence of greater-than-additive (GTA; synergy) claims for glufosinate-P with other agricultural chemicals. Based on the registrants' analyses of the patent search results, none of the identified patents met all the conditions discussed in the EPA guidance document. Therefore, based on the information provided through the analyses of U.S. patents, there are no data at this time to support claims of GTA or synergistic interactions of glufosinate-P with other active ingredients.

Comments on the Proposed Decision and EPA's Responses

A. **BASF comment:** BASF appreciates the efforts EPA has taken to review the complete data package and to reach the proposed decision for glufosinate-P-ammonium. BASF states that glufosinate-P-ammonium (isomer) products require less total glufosinate (active ingredient) to achieve the same efficacy of older (racemic) glufosinate ammonium products, allowing growers to use lower product use rates to control target weeds. They believe that a lower product use rate offers economic and environmental benefits, including smaller packaging sizes and a reduced carbon footprint associated with product transportation and application. BASF also states that they are prepared to accept the registrations as reflected in the proposed labels and risk assessments, and that they will explore possible refinements and corrections with EPA at a later date if necessary.

   EPA Response: The Agency acknowledges the comments from BASF and concludes they are supportive of this regulatory action**.** The glufosinate-P products would be applied

at use rates with approximately half the amount of total glufosinate as in racemic glufosinate products, but with the same amount of the herbicidally active glufosinate-P isomer applied. Glufosinate-P is functionally the same herbicide as racemic glufosinate. The chirally enriched glufosinate-P ammonium products from BASF could have a minor benefit over racemic glufosinate products because growers would need to purchase fewer containers of product for applications and incur reduced container rinsing and disposal costs; however, the concentration of the L-isomer in the single application rate is similar across currently registered and proposed BASF glufosinate products.

B. **U.S. Canola Association (USCA) comment**: The USCA strongly supports the registration of Liberty ULTRA (containing the new active ingredient glufosinate-p-ammonium). Liberty ULTRA represents an advance in herbicide technology that will benefit growers and other agricultural industry stakeholders. Liberty ULTRA provides foundational, broad spectrum weed control that can be used across millions of acres of glufosinate-tolerant canola, corn, cotton, and soybeans. Liberty ULTRA Herbicide would represent the first registration of the resolved isomer of glufosinate for use in the United States. It is our understanding that Liberty ULTRA will be registered in the same crops and crop use patterns as Liberty® 280. The Glu-L Technology utilized in Liberty ULTRA typically reduces the application use rate by 25% compared to the current racemic mixture of glufosinate marketed as Liberty® 280. The lower use rate provides several important economic and environmental benefits including less inactive material introduced to the environment while still maintaining a high level of efficacy on difficult weeds, like water hemp and palmer amaranth. We understand from the registrant that the carbon footprint associated with the transportation of Liberty ULTRA will also be reduced by 46% compared to racemic mixture versions of glufosinate. The Liberty ULTRA product also incorporates mitigation measures required by the EPA to protect endangered species.

   EPA Response: The Agency acknowledges the comments from USCA and concludes they are supportive of this regulatory action**.** The proposed glufosinate-P products would be applied at use rates with approximately half the amount of total glufosinate as in racemic glufosinate products, but with the same amount of the herbicidally active glufosinate-P isomer applied. Glufosinate-P is functionally the same herbicide as racemic glufosinate, and the benefits to users as a nonselective postemergence contact herbicide in both glufosinate-resistant and non-resistant crops would be almost identical to racemic glufosinate in these use sites.

C. **Tennessee Farm Bureau Federation (TFBF) comment:** TFBF supports the use of glufosinate-P to control weeds in non-tolerant and glufosinate-resistant corn, sweet corn, soybeans, cotton, and canola and encourage the Environmental Protection Agency (EPA) to approve this request. While TFBF supports the use of conservation practices to protect non-target species, TFBF also encourages EPA to ensure the recommended mitigation measures are workable, cost-effective, and flexible enough to work on different farm types, sizes, and locations.

EPA Response: The Agency acknowledges the comments from TFBF and concludes they are supportive of this regulatory action**.** The Agency-proposed mitigations to protect non-target species reflect practices that can be readily implemented by growers and identified by pesticide applicators. The proposed mitigations to reduce exposure from spray drift and runoff/erosion provide flexibility for growers to select combinations that work best for them while providing necessary protections for non-target species.

D. <u>American Soybean Association (ASA) comment:</u> ASA supports the proposed decision to approve a registration for the new enriched isomer glufosinate-p for use on conventional and glufosinate-resistant corn, cotton, canola, and soybean. Glufosinate-P, which is an isomer of traditional glufosinate (racemic) formulations but contains a higher concentration of herbicidal active ingredient relative to other commercially available products, will carry several important benefits for U.S. soybean farmers. Glufosinate has traditionally had challenging aspects with application because the racemic formulations contain a 50-50 mix of L- and D-isomers. D-isomers are not herbicidally active though, so farmers must apply higher total volumes of chemical to have the same herbicidal effect via present L-isomers. The new glufosinate-P formulation, however, contains higher levels of L-isomers, allowing farmers to use less product to have the same herbicidal effect.

EPA Response: The Agency acknowledges the comments from ASA and concludes they are supportive of this regulatory action**.** The proposed L-glufosinate products would be applied at use rates with approximately half the amount of total glufosinate as in racemic glufosinate products, but with the same amount of the herbicidally active L-glufosinate isomer applied. L-glufosinate is functionally the same herbicide as racemic glufosinate, and the benefits to users would be almost identical to racemic glufosinate in registered use sites.

E. <u>National Agricultural Aviation Association (NAAA) comment:</u>

1. **NAAA comment #1:** NAAA strongly objects to the prohibition of aerial applications of glufosinate-P on non glufosinate-resistant crops. The estimated risk to protected species and areas from aerial applications in the risk assessments is artificially inflated because of the inaccuracy of the Tier 1 AgDRIFT model. NAAA encourages EPA to use the Tier 3 model in AgDRIFT instead of the Tier 1 on the ecological risk assessments and ESA analysis for glufosinate-P. EPA OCSPP leadership has publicly stated they intend to update their atmospheric modeling, referencing NAAA's suggested use of Tier 3 of the AgDRIFT model. This was also confirmed in in the Herbicide Strategy update. Drift from aerial applications is more accurately estimated by using the Tier 3 model as proposed in a letter sent from NAAA to the Office of Pesticide Programs in June of 2020. A recent field study conducted at the University of Arkansas concluded the drift estimates from the Tier 1 model were “greatly over-predicting” the amount of drift physically measured in the field study.

EPA Response: The Agency thanks NAAA for their comments regarding the AgDRIFT™ model and for the input which they along with others have provided to

further refine the model. EPA has updated the aerial spray drift analysis and mitigations for glufosinate-P to be consistent with Tier 3 AgDRIFT™ modeling as described in *Ecological Mitigation Support Document to Support Endangered Species Strategies Version 1.0* (hereafter referred to as the "mitigation support document"). The results of the analysis are given in **Appendix A** of this document and have been incorporated into decision document. The updated spray drift analysis resulted in a decrease in the distance to deposition below the adverse effects endpoints but did not eliminate the off-field effects for aerial applications. This supported the use of the minimum spray drift buffers included on the final label.

2. **NAAA comment #2:** NAAA objects to the 10-mph wind speed limit for aerial applications of glufosinate-P. In some parts of the country, wind speeds can commonly exceed 10 mph during critical portions of the application season. Limiting application to wind speeds below 10 mph would have a negative impact on the ability to make timely applications. There are existing labels that allow application in wind speeds up to 15 mph.

EPA Response: EPA thanks NAAA for their comments on the importance of wind speed restrictions to aerial applicators. The Agency updated the spray drift analysis in the BE to be consistent with the Tier 3 approach described in the mitigation support document, which includes an analysis of the effects of various factors, including wind speeds >10 mph, on spray drift deposition. The 15-mph wind speed limit have been incorporated into the label language.

3. **NAAA comment #3:** NAAA urges EPA to allow aerial applications of glufosinate-P on all crops, both glufosinate-resistant and non-glufosinate-resistant, and all non-crop sites that are allowed on the label. To further mitigate the risk of drift when making aerial applications non-glufosinate-resistant crops and non-crop areas, NAAA recommends the label restrict aerial applicators to using a very coarse or coarser droplet size and a maximum boom length of 65% of wingspan for fixed wing aircraft and 75% of rotor diameter for helicopters at all wind speeds. If EPA is concerned aerial applicators might not be aware of how to set their aircraft up and verify its performance, they could consider requiring aerial applicators to be certified by NAAA's C-PAASS program in order to make these types of applications.

EPA Response: The agency thanks NAAA for their comment and recommendation to restrict aerial applicators to using very coarse or coarser droplet size and a maximum boom length of 65% of wingspan for fixed wing aircraft and 75% of rotor diameter for helicopters at all wind speeds. However, the glufosinate-P assessment is based on instructions listed on the proposed labels submitted by the registrant. The label allows for application using ground boom or aerial equipment as proposed by the registrant and contains instructions that reflect measures needed to mitigate risks of concern.

4. **NAAA comment #4:** While burndown applications and applications to non-crop areas using glufosinate might not be commonly made by aerial

applications, this option is critical to growers during periods of prolonged rain or high winds. Growers who normally use ground rigs for glufosinate applications will not be able to get their sprayers in fields when they are wet. Nor can they spray when the winds are too high. While aerial applicators are also restricted by wind speed, for any given period of time when the wind speed permits applications, aerial applicators can treat far more acres. Matthews et al. notes that application timing is a key for Integrated Pest Management (IPM) and that aerial application has an advantage over ground application when and where large areas need to be treated quickly. The option of aerial application is also crucial during this time of weed resistance that is afflicting crop growth and yields.

EPA Response: EPA would like to thank NAAA for their comment regarding the importance of retaining aerial applications for non-crop areas and the importance of application timing to Integrated Pest Management programs. The glufosiante-P labels do not restrict aerial application on glufosinate-resistant crops for burndown.

5. **NAAA comment #5:** To compare the productivity between aerial application and ground application in a row crop agricultural setting, an aerial applicator and ground applicator from Mississippi were asked to provide details about the productivity of their application equipment. The aircraft was an Air Tractor AT-502B with a 60-foot swath width and the ground rig was a John Deer R4030 with a 90-foot boom. In both cases a 12-hour day of spraying was assumed, which is appropriate for the height of spraying season. According to the applicators, during an average 12-hour day, the aircraft treats 1,800 acres while the ground rig treats 450 acres, meaning aerial application is roughly 4 times as productive as ground application in this region. NAAA also believes this productivity reduces drift incidents because growers who utilize aerial application to make herbicide applications in a timely manner do not feel pressured to spray with a ground rig under high-wind weather conditions in order to get the application made. While acknowledging no data to prove it, NAAA hypothesizes that many of the drift incidents that have occurred with the newer formulations of herbicides intended for resistant crops are due to applications in unfavorable weather conditions. Growers are forced to apply in unfavorable weather in order to get all of their fields treated in the tight time period allowed to use some herbicides during the growing season.

EPA Response: EPA appreciates the information regarding the importance of aerial applications of herbicides to growers. This information will be considered as mitigation measures to reduce spray drift of pesticides are further refined.

6. **NAAA comment #6:** Regarding the BASF label for glufosinate-P, NAAA strongly disagrees with several statements from Section 9.3 *Controlling Droplet Size – Aircraf*t and Section 9.2 *Techniques for Controlling Droplet Size.*

- Number of nozzles: while using a larger orifice may be a good recommendation for a ground sprayer, it does not always apply to agricultural aircraft. For the 40-degree flat fan nozzles, there is an increase in droplet size from the 0.6 GPM orifice to the 1.2 GPM orifice at both 40 and 60 psi. However, for the straight stream nozzles, using the larger 1.2 GPM orifice decreases droplet size, thus increasing the risk of drift. Since the straight stream nozzle creates a larger droplet size, this would be the preferred option for applying glufosinate-P and other herbicides.
- Nozzle orientation: NAAA agrees that orienting the nozzle straight back will produce the largest droplet size. However, locking an aerial applicator into only orienting the nozzle straight back means they can't create a medium droplet size if they select a straight stream nozzle.
- Nozzle type: If an aerial applicator chooses to use a medium droplet size, as is allowed by the label, they may need to use a flat fan, or deflect a straight stream nozzle, both of which are not allowed by this section.
- Pressure: while this section is not under the section specific for aircraft, it does not clearly differentiate the intended application platform. The fact that boom height in section 9.3, which is specific to aircraft, has a recommendation for ground equipment adds to the confusion. The data in the table above shows that no matter what nozzle type or size is used, increasing pressure increases the droplet size for aerial applications.
- NAAA urges both the EPA and registrants to write technology neutral label language. When labels are written with outdated technical information, professional aerial applicators can't take advantage of the latest technology and techniques to maximize efficacy and reduce the risk of drift. The label should only dictate the required droplet size classification –how that is achieved should be left to the professional aerial.

EPA Response: The Agency appreciates the additional information and recommendations provided by NAAA regarding spray nozzles and controlling droplet size. The spray drift advisory language on the label has been updated to improve clarity and to increase consistency across all glufosinate-P pesticide labels. The EPA will continue to work with the industry and other stakeholders to ensure that labels contain clear, concise, and up to date information.

7. **NAAA comment #7:** NAAA also disagrees with a minimum spray application rate of 10 GPA. This recommendation is frequently made under the erroneous assumption it increases efficacy while also reducing drift. In terms of efficacy, there is research that shows lower spray application rates can achieve the same level or better efficacy than higher spray application rates.

EPA Response: The Agency appreciates the additional information provided by NAAA regarding efficacy associated with a minimum spray application rate of 10 GPA. The minimum spray volume is established by the registrant-submitted labels and is not based on EPA recommendations. The Agency would consider any future proposed alterations in the application parameters to determine if the change would affect the understanding of the transport of or exposure to the of the compound.

F. <u>Center for Biological Diversity (CBD) comment:</u>

1. **CBD comment #1:** Initiating ESA-consultation is not ESA-consultation. We oppose any pesticide approvals that have not undergone a full ESA-consultation and complied with the terms and conditions to implement the Reasonable and Prudent Measures (RPMs) or Reasonable Prudent Alternatives (RPAs) or minimized incidental take in accordance with the U.S. Fish and Wildlife Service (U.S. FWS) and National Marine Fisheries Service (collectively "the Services") during formal ESA-consultation. Furthermore, the EPA does not possess the statutory authority or scientific expertise to correctly assess or make "predictive" determinations regarding jeopardy to any listed species, as such determinations can only be made by the Services during formal consultations under the ESA.

EPA Response: EPA initiated formal consultation with both Services prior to granting these registrations because the final Biological Evaluation has determined that the proposed uses of glufosinate-P on conventional and glufosinate-resistant corn, cotton, canola, and soybean may affect, and are Likely to Adversely Affect (LAA), multiple federally listed threatened or endangered species and their designated critical habitats. Additionally, under the ESA counterpart regulations, EPA predicted potential likelihood of future jeopardy of listed species and adverse modification of designated critical habitat. . EPA predicted a potential likelihood of future jeopardy (J) from glufosinate-P labeled uses for 60 listed species. EPA also predicted a potential likelihood of future adverse modification (AM) of 38 CHs from labeled uses. The mitigation measures added to these registrations and labeling reduce the effects on listed species and their designated critical habitats to the extent that the proposed registration of products containing glufosinate-P would not result in a potential likelihood of future jeopardy for any listed species or likelihood of adverse modification for any designated critical habitats. See 50 C.F.R. § 402.40(b)(1). At the end of the consultation process, the Services will make determinations on whether the registration of products containing glufosinate-P is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of designated critical habitat. The Services provide their determinations in their biological opinions and may determine that additional mitigations are necessary.

Although formal consultation has not been completed prior to granting these registrations, EPA has met its obligations under ESA section 7(d). EPA has determined that issuing these registrations will not result in irretrievable or irreversible commitment of resources that would foreclose the Services' development and EPA's implementation of any ESA reasonable and prudent alternatives (RPAs) as required by ESA section 7(d)

that states "[a]fter initiation of consultation required under [ESA section 7(a)(2)], the Federal agency and the permit or license applicant shall not make any irreversible or irretrievable commitments of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternative measures which would not violate [ESA section 7(a)(2)]."

2. **CBD comment #2:** CBD fails to see how that mitigation strategy can possibly prevent jeopardy to 60 species and adverse modification to 38 critical habitats. Furthermore, there is nothing in here that will appreciably minimize incidental take for 382 listed animal species and 197 listed plant species. CBD cannot think of any scenario where a pesticide that can be used on this scale and where jeopardy is predicted to 60 species can possibly be mitigated with just a single Bulletin. CBD understands that broad label changes can reduce the number of Bulletins needed, but there are still going to be individual species' needs that are not adequately addressed by general label changes. What this plan for L-glufosinate resembles to CBD is what the agency did for dicamba's new use on genetically engineered cotton and soybean in 2020. There the EPA put in place mitigation that the agency believed would result in no off-field movement and put in one Bulletin for the Spring Creek Bladderpod and called it good. It should be evident at this point that the assumption of no off-field movement is not a valid scientific assumption. This is an assumption built on the 2004 Overview of the Ecological Risk Assessment Process: Endangered and Threatened Species Effects Determinations (Hereafter "2004 Overview") and became widely used in the Enlist Duo and Xtendimax approvals a decade ago. However, EPA revisited the Enlist Duo ESA-mitigations more recently and identified many additional mitigations than it initially added under its original approach, and the Xtendimax endangered species mitigations have been a noted failure, even by EPA itself.

EPA Response: Before issuing these registrations, EPA made effects determinations and initiated formal consultation under ESA section 7 and its implementing regulations at 50 CFR Part 402. EPA used the Herbicide Strategy to inform the mitigations identified to address predictions of the potential likelihood of future jeopardy or adverse modification. During the development of the Herbicide Strategy, EPA worked closely with the U.S. Fish and Wildlife Service. EPA took comment on the draft BE which discussed each of the proposed uses, the extent of overlap with listed species ranges and designated critical habitat and the magnitude of effect for each listed species and designated critical habitat. Contrary to CBD's interpretation, EPA made effects determinations and identified mitigation measures that would address predictions of the potential likelihood for jeopardy or adverse modification.

3. **CBD comment #3:** Full compliance with the ESA must begin with a biological evaluation (BE) conducted in accordance with the available methodology for assessing risk to ESA-listed species from pesticides. At this time, that methodology is the "Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides". This Method was

finalized with extensive stakeholder feedback and applied many of the principles endorsed by the National Academies of Sciences ("NAS"). While CBD does not agree with, or endorse, every single aspect of the Revised Methods, it is currently the methodology EPA has in place to assess risk to ESA-listed species from pesticides. Efforts to somehow reduce the pesticide use footprint to only the treated fields and slap on a Bulletin for one species have not worked for widely used herbicides in the past and CBD does not believe it works here. Its only purpose appears to be to bypass the Revised Methods, which CBD strongly oppose.

EPA Response: EPA appreciates CBD's comments but disagrees that the Agency's intention was to bypass the Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticide. EPA conducted its assessment of glufosinate-P consistent with the methodologies outlined in the Revised Methods. Although the Revised Method pertains to registration review and not new actives, it identifies approaches which are applicable to both types of actions. The Agency has continued to work with the Services to ensure that the methods used are also consistent with those used by the Services in their Biological Opinions.

4. **CBD comment #4:** Of the nine potential jeopardy conclusions for terrestrial invertebrates, at least six are pollinators. In EPA's risk assessment, the agency found significant chronic risks to adult foraging bees and other terrestrial invertebrates. Risks of concern remained for aerial applications 105-203 ft off the treated field. A 50 ft wind-directional, aerial buffer is not enough, especially when wind directionality can change quickly, and adequate compliance cannot be reasonably assumed. This is even more important given the sheer amount of overlap between potential use footprints and species' range. The Poweshiek skipperling range has a 75% overlap with both the corn and soy use data layer (UDL). The Karner blue butterfly and Mitchell's satyr butterfly range have between 20-40% overlap with both the corn and soy UDL. The rusty patched bumble bee has 22% range overlap with the corn UDL. These are significant overlaps, especially when the buffer distances can include roads. Often the thin slivers of land between fields and roads can be the only pollinator foraging habitat for miles in many areas CBD is worried about the impacts of L-glufosinate (or any other herbicide for that matter) on the health of these dangerously imperiled pollinators. CBD does not believe that EPA's proposal adequately protects these species and believe that there should be either 1) more extensive general label changes, or 2) Bulletins for many, if not all of them – incorporating ground-application buffers, larger aerial-application buffers, and additional runoff credits.

EPA Response: EPA thanks CBD for their comments. The justifications for the determinations of not likely to adversely affect (NLAA) or likely to adversely affect (LAA) and subsequent predictions of the potential likelihood of future jeopardy (J) or adverse modification (AM) are presented in the Microsoft™ Excel spreadsheet which accompany the BE. As noted in the BE, these determinations and predictions are

informed not only by the extent of overlap but also by the magnitude of effect, the species' vulnerability, and various modifiers associated with the life history of the species. For the spray drift buffers, while effects to individual adult bees and other non-bee terrestrial invertebrates were identified out to 105-203 feet from the treated field, this exposure is not expected to result in community- or population-level effects off the treated field (Refer to section 8.4.7 of BE for more information). Terrestrial plants are the only taxa where the EPA determined that population-level effects were likely off field. The updated spray drift analysis in Appendix A indicates that a 50-ft-wide buffer is sufficient to reduce exposure below the population and community toxicity endpoints for terrestrial plants. Based on these factors, EPA believes that the mitigation measures outlined will be sufficient to avoid the potential likelihood of future J/AM. As noted in earlier responses, EPA initiated formal consultation with the Services and provided the BE and the underlying data used to support the analyses; they will have the opportunity during the consultation process to independently evaluate EPA's determinations and predictions.

5. **CBD comment #5:** L-glufosinate has a high runoff potential given that it is considered mobile to highly-mobile in soil. Given that L-glufosinate is proposed to be used on crops that are grown in areas of the U.S. that have "high" runoff vulnerability and comparing to the case studies in the Herbicide Strategy, one runoff mitigation point does seem to us to be an adequate runoff mitigation to prevent jeopardy findings to 60 species. This is especially worrisome to ESA-listed plants that can be found near agricultural fields and non-listed plants that ESA-listed animals rely on for forage. Again, overlaps with range and UDL can be quite high – particularly for species like the lakeside daisy, Minnesota dwarf trout lily, and northeastern bulrush. These plants will not be found on treated fields, but all exist near water sources and floodplains – the areas that runoff will reach. The specifics of how the Herbicide Strategy is going to be updated are still unknown to the public. If the L-glufosinate mitigation strategy aligns with how the Herbicide Strategy will be updated, we may begin to question the effectiveness of that Strategy moving forward – particularly if Bulletins continue to be used sparingly.

EPA Response: EPA thanks CBD for their comments regarding the mobility of glufosinate-P and the effectiveness of mitigation measures. The mitigations for glufosinate-P to address predictions of potential likelihood of future jeopardy or adverse modification were informed by the final Herbicide Strategy. The number of mitigation points identified are based on the magnitude of difference (MOD), which is a function of both the estimated exposure and toxicity of the compound at the population and/or community level. While a chemical is classified as mobile to highly mobile, that is not the only factor used to calculate the exposure component of the MOD. The MOD for glufosinate-P incorporates persistence, mobility, application rate and method, use site, and toxicity of the compound. Isolating a single variable (*e.g.,* only considering mobility) can result in a misleading interpretation of the potential risks of the compound in the environment. While the aquatic modeling indicates that glufosinate-P may reach off-target waterbodies, as would be expected of a highly mobile compound, the

estimated concentrations were within one order of magnitude of the relevant population- and community-level toxicity endpoints. Therefore, only three points of mitigation were identified to address the predictions of potential likelihood of future jeopardy or adverse modification. The necessary mitigations and level of mitigation are on the final labeling provided by the registrants.

Although the mitigations are informed by the strategy, EPA made effect determinations and initiated formal consultation with the Services. EPA also made a consistency determination under ESA section 7(d) before granting these registrations. EPA will continue to work with the Services to determine whether additional mitigation measures are needed. The registrations include a term on them that provides for a process to get the registrants to expeditiously amend their registrations and product labeling if the Services find that addition mitigation are needed to avoid future jeopardy and/or adverse modification of designated habitat from the registered uses of glufosinate-P.

EPA's intent is not to minimize the use of Bulletins but rather to ensure effective mitigations are included on the FIFRA label to more broadly reduce exposure and impacts to non-target organisms (*i.e.*, minimization) and more specifically leverage temporally/spatially explicit measures (*e.g.*, avoidance) through the use of Bulletins.

Appendix A: Revised Aerial Spray Drift Analysis for Glufosinate-P

Since the publication of the draft ecological risk assessment, EPA re-examined some of the input parameters for AgDRIFT™ by considering comments made by NAAA as well as other sources of information and developed updated recommendations on the use of Tier III aerial modeling in AgDRIFT™ with input parameters that reflect current, common aerial application practices.[2] This appendix describes updates to the Tier III aerial modeling and the effects on the estimated offsite transport distances for population/community level effects to terrestrial plants. The analysis only considers effects to terrestrial plants, as they were the only taxa for which population-level impacts were determined to be likely off-field.

Table A1 summarizes the previously modeled and updated AgDRIFT™ parameters. EPA selected a medium spray droplet size distribution based on the label instructions and standard aerial application practices. The rationale for the other updated input parameters can be found in the mitigation support document. **Table A2** provides the spray drift distances to no effect for population- and community-level effects to terrestrial plants based on aerial and ground applications. The updated aerial spray drift analysis reduced the off-site distance to population-level effects from 46 to 36 ft and the distance to community-level effects from 30 to 13 feet.

A 1. Comparison between previous and current recommended input parameters in Tier III AgDRIFT™.

Parameter Group and Parameter		Previous Default Input Parameter	Current Recommended Default Input Parameter
Aircraft > Aircraft	Aircraft Type	Air Tractor AT-401	Air Tractor AT-802A
Aircraft > Nozzles and Droplet Size Distribution (DSD)	Drop Size Distribution	Fine to Medium	Medium*
	Generate Regular Distribution	Extent:76.32% Nozzle Spacing: 0.912 ft	Extent**: 75% Nozzle Spacing: 1 ft
Aircraft	Boom Height	10 ft.	10 ft.
	Flight Lines	20	15
Swath	Swath Width Definition	Fixed Width	Fixed Width
	Swath Width	60	80
	Swath Width Displacement as Fraction of Swath Width	0.3722	0.5
	Half Boom Effect	No entry	No entry
Atmospheric Stability	Stability	Night/Overcast Cloud Cover	Day/Slight Solar Insolation
Advanced Settings	Height for Wind Speed Measurement	6.56 ft	10 ft
Terrain	Surface Roughness	0.0246 ft	0.0246 ft

* Droplet Size Distribution (DSD) selected based on label instructions. For glufosinate-P, the labeled DSD is medium to coarse. The EPA used a medium DSD in the updated modeling to generate a conservative estimate of the spray drift distances based on the smallest allowable droplet size.
** Extent defines the length of the spray boom relative to the airplane wingspan

[2] Described in *Ecological Mitigation Support Document to Support Endangered Species Strategies Version 1.0* (also referred to as the "mitigation support document").

A 2. Spray Drift Distances Based on Highest Application Rate Used to Establish the Exposure Area for Evaluating Adverse Effects to Listed Species Populations and Communities of Plants

Taxa	Population/Community Adverse Effects Endpoint	Use/Use Site	Highest App Rate[1]	Fraction of Applied to No Effect[2]	Application Method	Boom Height	Distance from the Field Edge to Deposition Below Adverse Effects Endpoint (ft)[3]	
							2024 BE	Revised Aerial Inputs
Terrestrial Plants	HC_{05} = 0.0417 lbs ae/A (Population)	GMO/Non-GMO-Soybean, Field Corn, Canola, Cotton	0.359	0.116	Ground	Low	3	3
						High	7	7
					Aerial	NA	46	36
	HC_{25} = 0.058 lbs ae/A (Community)		0.359	0.162	Ground	Low	3	3
						High	3	3
					Aerial	NA	30	13

BE= Biological Evaluation; GMO=Genetically modified Organism; HC_{xx} = XX percentile hazard concentration; NA= not applicable.

[1] Spray drift distance for terrestrial plants is based on the maximum single application rate which is reported in this column.

[2] Calculated as the ratio of the associated adverse effects endpoint to the highest app rate.

[3] Distance from field edge at which exposure no longer exceeds the endpoint. The distance was estimated assuming ground application with low (20 inches above the ground) or high (50 inches above the ground) boom height and ASAE fine to medium/coarse droplet size distribution and aerial application with nozzles that produce ASAE medium to coarse droplet size distribution with 10 mph windspeed.