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OFFICE OF
CHEMICAL SAFETY AND
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MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate

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The Environmental Fate and Effects Division (EFED) has completed its review of public comments received on the Preliminary Ecological Risk Assessment (PRA; USEPA 2015¹) for the herbicide, glyphosate and its salts (PC Code 417300, 103601, 103604, 103607, 103608, 103613, 103605) developed in support of Registration Review. The glyphosate PRA was published in the docket on February 28, 2018 (Docket Number: EPA-HQ-OPP-2009-0361). Comments on the PRA were received by many different stakeholders including: the U.S. Department of Agriculture, the Joint Glyphosate Task Force (JGTF), Non-governmental Organizations (e.g., Pesticide Action Network, Beyond Pesticides, Pollinator Stewardship Council, Center for Food Safety, GMO Free USA, Natural Resources Defense Council, Center for Biological Diversity, Napa County Green Party, Colorado State Beekeepers Association), other industry groups (e.g., CropLife America, National Agricultural Aviation Association (NAAA)), and private citizens. The comments were considered in the context of potential impacts on the risk conclusions presented in the ecological risk assessment. Many of the submitted public comments discussed similar topics

¹ USEPA 2015. Registration Review: Preliminary Ecological Risk Assessment for Glyphosate and Its Salts. DP Barcode 417701.

regarding the PRA, and as such, the summary of the comments received and EFED's responses are grouped by topic.

1. Use and Usage Information

Comment: Comments were received from the JGTF on the uses and use rate in the use tables in the PRA (Tables 4 and 5). In some cases, the comments indicated that the typical rates are lower than reported in the use tables. The commenter also indicated there are errors in the tables. Commenters such as the USDA also offered additional use information on the benefits of glyphosate for control of invasive weeds in non-cropped areas, aquatic uses, and pastures and submitted additional information to characterize the use sites where higher RQs were calculated (non-food tree crops, aquatic areas, pasture and natural lands, and non-crop sites).

EFED Response: EFED appreciates additional information and clarification on the use summary information, as well as additional information on typical use rates. EFED uses the registered maximum labeled rate when calculating risk quotients (RQs), and considers additional information when characterizing potential risk. In the PRA, EFED included additional analyses to characterize the LOC exceedances, based on available information on typical rates (*e.g.*, chronic RQs based on exposure at the *typical* rate of 3.75 lb a.e./A for mammals are just below the LOC), as well as considering the effects observed in toxicity studies.

2. Evaluating Technical Grade Active Ingredient (TGAI) vs. Glyphosate Formulations and Surfactants

Comment: Commenters such as Center for Food Safety, Beyond Pesticides, and Food & Water Watch indicated that the agency needs to consider toxicity and exposure from multiple exposure routes for glyphosate formulations as well as TGAI. Additionally, several commenters noted that while EPA evaluated the surfactant, polyoxyethylene tallow amine (POEA), EPA did not appear to consider POEA exposure in aquatic environments or only evaluated its exposure via spray drift. Information contained in the public comments on the fate of POEA indicated that it may degrade in the environment rather quickly, whereas other commenters cited data that indicated it may persist longer. Other commenters disagreed with the position that EPA only evaluated POEA when there are additional surfactants that may also pose a potential risk.

EFED Response: The conduct of the glyphosate ecological risk assessment uses the current approach as described in the Overview of the Ecological Risk Assessment Process (EPA, 2004), evaluating the pesticide (*i.e.*, glyphosate) based on available environmental fate and ecotoxicity data, relative to the registered uses. Inert ingredients are assessed separately when proposed for use as part of a pesticide formulation, and additional product labeling may be needed (*i.e.*, additional Environmental Hazard statements based on toxicity). As part of reregistration for glyphosate, products labeled for direct aquatic uses that contain inert ingredients with known toxicity to fish needed to include this statement on their labels. In the PRA, EFED did conduct several analyses based on exposure that can occur from labeled uses, and available toxicity data (glyphosate-only or formulation) in order to assess potential exposure and risk from glyphosate-containing products, including the POEA surfactant (known to be toxic to fish). The exposure analysis for both TGAI and glyphosate formulations is consistent with EFED's standard practices and guidance for exposure modeling. As discussed in the PRA, exposure to aquatic non-target organisms was evaluated from:

- Glyphosate TGAI (spray drift, spray drift plus runoff, direct application to water)
- Glyphosate formulations (spray drift, direct application to water); and
- Surfactant only (POEA) (spray drift)

Evaluation of potential risk to terrestrial non-target organisms was assessed by estimating exposure from:

- Glyphosate TGAI (spray drift, direct contact)
- Glyphosate formulations (spray drift, direct contact)

With regard to modeled exposure, evaluating potential POEA exposure (either as POEA-only or as part of a glyphosate formulation) via spray drift from an application to a terrestrial use site is consistent with EFED exposure modeling approaches. EFED notes there are uncertainties in evaluating POEA exposure in aquatic environments *via runoff* given that 1) POEA is a mixture of compounds that differ in the number of the ethoxy units, and 2) limited fate data to show how the respective components in a glyphosate formulation (including POEA), would degrade in the environment and/or be transported in run-off. EFED focused on the evaluation of POEA in aquatic habitats because it poses greater toxicity to aquatic animals than glyphosate. Additionally, while limited toxicity data are available for other surfactants, such as those that may be used in glyphosate formulations, the amount of toxicity information available for evaluation was greater for POEA.

3. Spray Drift Analysis

Comment: There were several comments from the JGTF and the NAAA regarding the spray drift analysis conducted in the PRA, particularly concerning the spray drift model, AgDrift, the inputs used in the model (*e.g.*, drift fraction, application rates, droplet sizes), exposure assumptions, and the uses modeled (*e.g.*, the non-agricultural uses at 8 lb a.e/A).

EFED Response: AgDrift is the currently approved model for evaluating potential spray drift from a pesticide application. The agency appreciates the additional information on application practices (both ground and aerial) and continues to work with industry to update and improve modeling methods to better reflect these practices. It is noted, however, that modeling is also based on maximum application rates as listed on the glyphosate labels or as listed in the JGTF's use summary matrix, and in the absence of specific use directions and application requirements across all product labels, default assumptions (based on empirical data) are used. EFED agrees that, overall, exposure from drift will be lower when using lower application rates and larger droplet sizes. Additionally, the risk assessment provided outputs for risks associated with ground and aerial applications, which will allow risk managers to understand the range of risks associated with different application methods.

4. Monitoring Data

Comment: Several commenters, such as Beyond Pesticides and Friends of the Earth, indicated that glyphosate has been detected in aquatic systems, and cite a publication by the U.S. Geological Survey (https://toxics.usgs.gov/highlights/glyphosate_wastewater.html).

EFED Response: EFED appreciates the notification of these monitoring data. EFED agrees that quality monitoring data can be a useful line of evidence. However, since these are ambient monitoring data and

not targeted, either spatially or temporally, to glyphosate use, the extent to which the monitoring detections directly correlate to certain glyphosate applications is uncertain. Thus, use of monitoring results for any risk calculations, in this case, is limited. Even with these uncertainties, the occurrence of glyphosate in some waterbodies is consistent with our analysis completed in the 2015 PRA (refer to Section 3.4 for discussion on surface water monitoring data), and these data sources referenced in the public comments shows that glyphosate can reach and is detected in aquatic systems.

Comment: The JGTF points out that the maximum concentration of glyphosate observed for an overland flow site does not represent concentration in surface water.

EFED Response: The reported concentration was not used to quantify risk, as was clearly noted in the assessment; however, these higher concentrations can be relevant to exposure characterization for some organisms.

5. Glyphosate Fate Parameters and Aquatic and Terrestrial Exposure Modeling

Comment: The JGTF noted that use of the aquatic model GENECC is outdated and that Pesticide in Water (PWC) model would produce lower estimated environmental concentrations (EECs).

EFED Response: EFED acknowledges that the Tier I screening model GENECC has been replaced with PWC. While lower EECs may be achieved with PWC versus GENECC, risk conclusions would remain the same given that there were no LOC exceedances for fish or aquatic invertebrates based on prior aquatic modeling using GENECC; therefore, updated, refined modeling was not warranted.

Comment: Various editorial comments were received from the JGTF regarding the environmental fate parameters reported in the risk assessment.

EFED Response: EFED appreciates the identification of the noted typographical errors, reporting inconsistencies in reference temperatures and pH; however, given that tier 1 exposure modeling was used in the PRA, these factors would not change the risk assessment conclusions. As appropriate, corrections to any input parameters will be incorporated in any future risk assessment.

Comment: In the terrestrial exposure modeling for birds and mammals, the default foliar dissipation half-life input is 35-days. The JGTF suggested using an alternative foliar dissipation half-life of 2.8 days on grasses, based on 22 residue trials (as cited in the European Food Safety Authority's (EFSA) peer review of glyphosate (EFSA Journal (2015) 13(11):4302). Additionally, the JGTF noted that the use of the Kenaga residue values are considered worst-case and additional residue data for glyphosate should be considered (EFSA Guidance Document on Risk assessment for Birds and Mammals, 2009).

EFED Response: The Kenaga residue values used in the T-REX model are the standard residue values used in calculating risk quotients. To further characterize potential exposures from a shorter foliar dissipation half-life, in the PRA, a foliar dissipation half-life of 12 days was used as the model input and was based on residue data for alfalfa and forest foliage (page 33 of the PRA). Since both the acute and chronic RQs are based on the peak EEC, the influence of the foliar dissipation rate depends on the number of applications and the timing between multiple applications. In cases where there is more than one application (*i.e.*, 2 applications at 1.55 lb a.e./A for the Roundup Ready crops), the use of an alternative rate may influence the eventual peak EEC, and could lower that resulting RQ value. However, it is noted that for a single maximum application rate of 8 lb a.e./A, the EECs are still greater than the

lowest toxicity value for both birds and mammals (RQ>LOC), as the dissipation rate does not influence the peak EEC. Additionally, the PRA noted that for a single application at 3.75 lb a.e./A, the estimated exposure concentrations (up to 900 mg a.e./kg-diet) would be greater than NOAEC value from the bobwhite quail reproduction study (830 mg a.e./kg-diet; page 86 of the PRA), and would also be greater than the non-definitive NOAEC observed in the mallard duck reproduction study (<501 mg a.e./kg-diet).

Comment: The JGTF noted that glyphosate residues in nectar and pollen from the crop, Phacelia, are approximately 10 times lower than the default exposure concentrations in the Tier 1 assessment for honey bees.

EFED Response: EFED appreciates the information regarding glyphosate residue data in nectar and pollen and will consider using this additional residue data if it is appropriate in any future assessment of risk to bees.

Comment: Some commenters remarked about the persistence of glyphosate in soil, and the potential for glyphosate to reach groundwater sources.

EFED Response: The glyphosate salts dissociate rapidly to form glyphosate acid and the counter ion. Because glyphosate acid will be a zwitterion (presence of both negative (anionic) and positive (cationic) electrostatic charges) in the environment, it is expected to speciate into dissociated species of glyphosate acid as well as glyphosate-metal complexes in soil, sediment, and aquatic environments. The available laboratory data indicate that both glyphosate and its primary metabolite, AMPA, sorb strongly to soil, which can be attributed to processes including pesticide binding to the organic matter fraction of the soil, as well as the propensity for glyphosate and AMPA to form metal-ligand complexes on surfaces of iron and aluminum oxides. The aquatic modeling considered accounting for sorption on both mineral and organic constituents in soils and sediments. Based on measured Koc values, glyphosate is classified as slightly mobile to hardly mobile according to the FAO classification scheme and would not be expected to leach to groundwater or to move to surface water at high levels through dissolved runoff. However, glyphosate does have the potential to contaminate surface water from spray drift or transport of residues adsorbed to soil particles suspended in runoff. It is expected to be persistent in anaerobic sediments.

Overall, the monitoring data indicate that neither glyphosate nor AMPA are typically detected in groundwater sources. Although the PWC modeling indicate no glyphosate breakthrough in groundwater during a 100-year simulation, groundwater monitoring data showed one site with a very high peak (285 µg/L) and annual average concentration (20.6 µg/L) for glyphosate, which is a subsurface drain and not representative of groundwater source drinking water. The highest AMPA concentration (397 µg/L) in groundwater is from a site in Iowa (Coupe et al., 2011). These represent highly vulnerable groundwater wells. The median detection frequency of glyphosate was <0.1%. These data indicate that glyphosate or AMPA are not typically detected in groundwater.

6. Ecological Effects Toxicity Data

Comment: Several commenters, such as Moms Across America and GMO Free USA, provided extensive citations to journals relating to glyphosate, including links to general webpage articles that are not specific to glyphosate (or pesticides), and potential impacts to wildlife. Some of these citations in the open literature include possible toxicity data (including effects beyond survival, growth, and

reproduction) for several different aquatic (*e.g.*, fish, amphibians, aquatic invertebrates) and terrestrial taxa.

EFED Response: Based on a screen of the citations (as relevant to the ecological risk assessment), information generally supports the conclusions drawn in the assessment. Generally, the available toxicity data (both registrant-submitted and in the open literature) that were evaluated in the 2015 PRA indicated that glyphosate poses low toxicity to aquatic animals, although some formulations that can contain POEA may pose greater relative (acute) toxicity to sensitive species. Similarly, for terrestrial habitats, glyphosate has the potential to impact sensitive plants (as expected for an herbicide); while glyphosate may not pose direct toxicity to terrestrial animals, there is the potential for indirect effects due to habitat loss.

a. Aquatic Toxicity

Comment: The JGTF noted that the chronic toxicity value for the estuarine/marine invertebrates, which was calculated using an acute-to-chronic ratio, was calculated incorrectly and should be approximately 2X lower than what was used in the PRA.

EFED Response: EFED confirmed the endpoint and acknowledges that the endpoint was incorrectly reported in Tables 30 and 35 (*i.e.*, 13.7 mg a.e./L) in the PRA. However, the endpoint was correctly calculated as presented in Table 18 in the PRA (6.11 mg a.e./L). This endpoint is based on the acute amphipod toxicity data (35.5 mg a.e./L) and not the acute oyster endpoint (40 mg a.e./L) due to the inclusion of development in the acute oyster endpoint. The risk quotients presented in Tables 30 and 35 are based on the 6.11 mg a.e./L endpoint and not the incorrect 13.7 mg a.e./L and are below levels of concern.

b. Terrestrial Toxicity

Comment: The JGTF questioned the use of the vegetative vigor terrestrial plant toxicity endpoint for dicots (EC₂₅ of 0.074 lb a.e./A for cucumber; MRID 44320636), and asserted that a quantitatively determined endpoint, such as weight or height, rather than a qualitative endpoint such as phytotoxicity, be used for risk characterization.

EFED Response: EFED notes that based on the Data Evaluation Record (DER) for MRID 44320636, the EC₂₅ for cucumber is reported to be based on phytotoxicity. Toxicity values on endpoints such as growth from other submitted terrestrial plant toxicity data as well as studies in the open literature are similar to the cucumber endpoint. As such, the reported next most sensitive vegetative vigor endpoint is for radish (*Rhaphanus sativus*) with an endpoint value of 0.09 lb a.e./A, which is based on dry weight (MRID 44125715/45045101). The commenter stated that multiple species had the same NOEL value as the cucumber, which EFED confirms is correct. In the study that tested the cucumber, the next most sensitive dicot is for soybean with an EC₂₅ value of 0.126 lb a.e./A, based on dry weight. The use of the 0.09 or 0.126 lb a.e./A endpoint value would still indicate potential effects to terrestrial plants based on the exposure estimates (see Table 48 in the PRA). Furthermore, available incident data indicate that glyphosate has the potential to adversely affect terrestrial plants.

Comment: The JGTF disagreed with the use of the chronic avian toxicity endpoint reported in the chronic avian toxicity study with mallard ducks (growth endpoint; MRID 48876602). The commenter stated that the study authors concluded no effects on growth in the study, whereas EPA's re-evaluation

indicated that a NOAEC could not be established due to effects on growth at the lowest test concentration (*i.e.*, male body weight gain and offspring weight).

EFED Response: While EFED has considered the comment, EFED continues to support the use of the non-definitive endpoint as the most sensitive chronic avian endpoint. EFED does note that the PRA discussed species differences among the different chronic avian toxicity studies, as well as indicating that there is evidence to suggest that glyphosate does not appear to impact reproductive parameters.

Comment: The JGTF noted that the acute mammalian endpoint used in the assessment was from a study conducted with a glyphosate formulation (MRID 43728003). They indicated that risk characterization is typically conducted using a study conducted with technical material.

EFED Response: Evaluation of acute mammalian toxicity data used in the assessment is consistent with what is described in the OPP's Overview Document² in that formulated product effects data can be evaluated and included in the risk assessment when available and appropriate. If there is formulation data that suggests greater toxicity than toxicity data using only technical material, then it can be used to evaluate potential risk to terrestrial animals. This is because terrestrial animals (*i.e.*, birds and mammals) may consume treated dietary items (*e.g.*, grasses, seeds) shortly after application which may contain the technical material as well as the components of the formulation. As discussed in the assessment, available data shows that glyphosate alone poses low acute toxicity to mammals; however, there are formulation toxicity data showing that some formulations may pose greater toxicity (acute RQs ≤ 2.1). Based on TGA toxicity data, there is the low potential for risk of sublethal effects, with the exception of small/medium mammals (short grass) for uses at the combined max annual rate (chronic RQs ≤ 10.02).

7. Monarchs and other Pollinators

Comment: 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.

EFED Response: EFED appreciates this additional information concerning honey bee toxicity data. With regard to sublethal effects such as navigation or appetite, there is uncertainty regarding the relationship of effects to EPA's assessment endpoints (*i.e.*, impaired survival; growth; development). Additionally, the study that tested for colony-level effects (Thompson et al, 2014) did not show that glyphosate adversely affected adult or developing young (brood).

Comment: Several comments were also received (from Natural Resources Defense Council, private citizens, and others) regarding potential indirect effects to honey bees and other pollinators (*e.g.*, Monarch butterflies) due to loss of forage and/or other habitat resources. Other comments also stated

² USEPA 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. [Office of Chemical Safety and Pollution Prevention formerly the Office of Prevention, Pesticides and Toxic Substances. Office of Pesticide Programs, Washington D.C. January 23, 2004. <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>

that glyphosate is not directly toxic to monarch butterflies, and that general consideration to overall breeding habitat loss and effects of climate on the availability of habitat at important breeding points of their complex life cycle and migration routes have been identified as substantial drivers for monarch butterfly populations.

EFED Response: The PRA did indicate potential effects to terrestrial plants, which could lead to potential indirect effects to other organisms that rely on terrestrial plants for food or habitat. Based on available open literature data for common milkweed, important for monarch butterfly breeding habitat, the reported effective dose and inhibition concentrations are similar to the most sensitive vegetative vigor terrestrial plant toxicity tests (for cucumber); therefore, the predicted extent of risk to sensitive terrestrial plants in the PRA are likely representative for potential adverse effects to common milkweed.

Comment: The JGTF indicated in their comments, that while there were no laboratory studies with honey bee larvae, there are additional laboratory studies with adult honey bees and bumble bees, specifically a chronic toxicity test with adult honey bees and an acute toxicity test with bumble bees (*Bombus terrestris*) and solitary bees (*Osmia bicornis*). The JGTF later submitted these studies to the agency (MRIDs 50603801, 50603802, 50603803, 50603805).

EFED Response: EFED has received the new pollinator studies and acknowledges that these additional data would be helpful when evaluating potential risks to honey bees and other non-*Apis* bees. EPA will review these studies in a future assessment to evaluate potential effects to pollinators.

8. Soil Microbial Communities

Comment: Several commenters (including Napa County Green Party, GMOScience, and Pesticide Action Network) indicated that glyphosate may potentially harm soil microbes given they share the same pathway as plants that is targeted by glyphosate.

EFED Response: Information provided by some of the public comments suggested potential effects to soil microbial communities (*e.g.*, fungi, microbes), whereas other reported information suggested that adverse impacts to soil organisms is anticipated to be low. Potential effects to soil microbes/communities is not currently assessed in EFED's ecological risk assessments.

9. Typographical Errors or Clarifications in the PRA

Comment: The Joint Glyphosate Task Force (JGTF) noted several apparent typographical errors (*i.e.*, MRID reference numbers) or clarifications in the PRA including label use information, ecological toxicity studies, and fate studies.

EFED Response: EFED appreciates the JGTF noting these potential discrepancies, for which EFED has made note of for future risk assessments.