**Chapter 1 –** **Draft Glyphosate Problem Formulation**

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Introduction

This draft Biological Evaluation (BE) makes effects determinations for all federally listed endangered and threatened species, as well as those that are proposed and candidates for listing and experimental populations (in sum referred to as “listed species”). This BE also includes an analysis of designated critical habitats. The methods employed in this BE follow the Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (referred to as the “Revised Method”)[[[1]](#footnote-2)].

This chapter describes the problem formulation. Problem formulation is the first step of ecological risk assessment and establishes the goals, scope, and focus of the assessment. It is a systematic planning step that identifies major factors to be considered in a particular assessment.

Included in this chapter is a description of the federal action, the mode and mechanism of action of glyphosate, summaries of its uses (based on registered product labels), usage, overview of environmental fate, identification of the residue of concern, and an analysis plan for how the BE will be conducted.

Description of the Federal Action

In 2006, the U.S. Environmental Protection Agency (EPA) initiated Registration Review to reevaluate all registered pesticide active ingredients on a regular cycle. EPA is required to review each pesticide active ingredient at least every 15 years to make sure that it has the ability to assess risks to human health and the environment as science evolves and policies and practices may change, all pesticide products in the marketplace continue to meet the standard of registration. Registration Review includes labels registered under Sections 3, 24(c), and 18 of FIFRA. The federal action relevant to this BE is the Registration Review for glyphosate, which encompasses the review of all the registered uses and the approved product labels for all pesticide products containing glyphosate.

Mode and Mechanism of Action

Glyphosate [*N*-(phosphonomethyl)glycine] is an acid, and it can also be associated with different counter cations to form salts. Several salts of glyphosate are currently marketed, as well as the acid, and are considered as the active ingredient in end-use products. The parent acid is the chemical species that exhibits herbicidal activity and so is the actual chemical stressor considered in this risk assessment regardless of the salt, unless otherwise specified. In order to have comparable results, each salt is considered in terms of its glyphosate equivalent, (acid equivalent; a.e.), determined by multiplying the application rate by the acid equivalence ratio, defined as the ratio of the molecular weight of *N*‑(phosphonomethyl)glycine to the molecular weight of the salt. Table 1-1shows the salts of glyphosate that may be used as the source of the actual herbicide-active chemical species. For the purpose of this assessment, the acid and all of its salts are referred to collectively as “glyphosate” throughout this document.

Table 1-. Identification of Glyphosate and its Salts

|  |  |  |  |
| --- | --- | --- | --- |
| **Counter Cation** | **PC Code** | **CAS No.** | **Acid Equivalence Ratio** |
| Glyphosate acid(no counter cation) | 417300 | 1071-83-6 | 1 |
| Isopropyl amine | 103601 | 38641-94-0 | 0.74 |
| Monoammonium | 103604 | 114370-14-8 | 0.94 |
| Ethanolamine | 103605 | 40465-76-7 | 0.73 |
| Diammonium | 103607 | 40465-66-5 | 0.83 |
| *N*-methylmethanamine | 103608 | 34494-07-7 | 0.79 |
| Potassium | 103613 | 39600-42-5;70901-20-1 | 0.81 |

Glyphosate acid (CAS number 1071-83-6) [*N*-(phosphonomethyl)glycine] is an herbicide belonging to the phosphono amino acid class of pesticides. Glyphosate is a foliar, non-selective, systemic herbicide widely used to control weeds in agricultural crops and non-agricultural sites. Glyphosate is a potent and specific inhibitor of the enzyme 5-enolpyruvylshikimate 3-phosphate (ESPS) synthase. This enzyme is the sixth enzyme on the shikimate pathway and it is essential for the biosynthesis of aromatic amino acids (e.g., tyrosine, tryptophan, and phenylalanine) and other aromatic compounds in algae, higher plants, bacteria and fungi. Inhibition of this enzyme leads to plant cell death.

While the shikimate pathway is absent in mammals, acute and chronic exposure of animals has shown significant reduction in body weight and organ weights across multiple mammal and bird species if exposure levels are sufficient.

Use and Usage Characterization

Use data are based on registered product labels and include pesticide application information relevant to a treatment site (e.g., an orchard). EPA determines the uses based on registered labels and define crop or non-crop sites to which a pesticide may be applied. Use data also describe the maximum application rates, method (e.g., aerial or ground spray), re-treatment intervals and number of applications that may occur according to registered product labels.

Usage data describe how the pesticide has been applied to multiple use sites within a state, region or the US. EPA also reviews actual usage data that documents the actual applications of a pesticide, including information such as actual application rates and timing, and spatial distribution of applications across multiple sites (usually based on survey data). The key difference between use and usage is potential applications vs. actual applications.

## Use Data (as Defined on Registered Product Labels)

The label on a pesticide package or container is legally enforceable. The label provides information about how to handle and safely use the pesticide product. Using a pesticide in a manner that is inconsistent with the use directions on the label is a violation of FIFRA and can result in enforcement actions to correct the violations. Glyphosate is one of the most widely used herbicides in North America. It is a non-selective systemic herbicide that is currently registered in the U.S. to control a broad spectrum of emerged annual and perennial broadleaf and grass weeds in a wide range of agricultural and non-agricultural use sites (**APPENDIX 1-1**). This BE assesses all currently registered labels.

Glyphosate is used on a wide variety of agricultural food and feed crops, non-food/feed crops, for plantation/silviculture uses, and for nursery/greenhouse use. Important non-agricultural uses include applications for noxious and invasive weed control in aquatic systems, pastures/rangelands, public lands, forestry, and rights-of-way applications. Glyphosate is also used for general weed control or for lawn replacement/renovation in commercial, industrial, and residential areas (by homeowners, landscaping operators, etc.) (**APPENDIX 1-2** provides the use information as further by EPA, summarizing details relevant for modeling the maximum use patterns**;** additional details on uses modeled described in **APPENDIX 1-3 and 3-1**).

Glyphosate is formulated as water-dispersible granules (WG) (80% active ingredient), emulsifiable concentrate (EC) (13.4% - 36.5% active ingredient), water-dispersible liquids (L) (5% - 14.6% active ingredient), ready to use (RTU) (0.81% active ingredient), and soluble concentrate/solid (SC/S) (95.2% - 96.7% active ingredient). Application equipment includes aircraft and various ground equipment (boom sprayer, hand held hydraulic sprayer, hand held sprayer, high volume ground sprayer, hooded sprayer, hose-end sprayer, low volume ground sprayer, low volume sprayer, motor driven sprayer, product container, ready-to-use spray container, shielded applicator, sprayer, tank-type sprayer, wick applicator, and wiper applicator). Application is via band treatment, broadcast, crack and crevice treatment, directed spray, edging treatment, ground spray, high volume spray (dilute), low volume spray (concentrate), perimeter treatment, soil broadcast treatment, spot treatment, spray, strip treatment, stump treatment, and wipe-on/wiper treatment. Single application rates are up to 8 pounds active ingredient (as acid equivalents)/acre (lb a.e./A) but are generally 1.55 lb a.e./A for aerial applications and 3.75 lb a.e./A for ground application. Maximum combined annual application rates are up to generally 6 to 8 lbs a.e./A. For some non-agricultural uses, the single application rates were calculated at rates up to 40 lbs a.e./A. These higher rates of 40 lbs a.e./A are calculated by extrapolating up from a smaller area as is expressed on the label (*e.g.,* rate expressed per 150 sq. feet instead of per acre). These rates are interpreted to be relevant for a wide variety of non-crop areas where total vegetation control is desired. In the absence of a pound a.e/acre rate, these calculated rates were selected for modelling and it is noted that this is an area that may lead to refinement should the labels be revised in the future.

## Usage Data

Between 2013 and 2018, the national annual total agricultural usage averaged approximately 280 million pounds of glyphosate whereas the average total treated acreage was 285 million. During this time frame, the crops with the most usage in terms of annual average total pounds of active ingredient applied were soybeans (114 million lbs), corn (90 million lbs), and cotton (20 million lbs). The crops with the most usage in terms of total treated acreage were the same with 114, 93 and 19 million acres treated for soybeans, corn and cotton, respectively. On average, the states with the most agricultural usage in terms of pounds applied per year were Iowa with 24 million pounds, Illinois with 23 million pounds and Nebraska with 20 million pounds. Other states with between 10 and 20 million pounds applied annually included Nebraska, Kansas, North Dakota, Texas, South Dakota, Minnesota, Indiana and Missouri. **(APPENDIX 1-4**).

Over 21 million pounds of glyphosate are applied to non-agricultural sites annually. Most recent non-agricultural usage data from 2013 or 2016 depending on the use site (see **APPENDIX 1-4** for details) shows that the largest use in terms of average annual pounds applied is consumer application to outdoor premises of household/domestic dwellings (5 million pounds a.e.), followed by application to roadways (4.7 million pounds a.e.) and forestry sites (4.2 million pounds a.e.)**.** Other use sites with greater than 1 million pounds per year include nursery and greenhouse ornamentals, institutional turf facilities and application by lawn care operators. Use sites with less than a million pounds per year include railways, utility/pipeline rights-of-way (ROWs), sod farms, applications by landscape contractors, direct application to water and golf courses.

# Overview of Environmental Fate

The major transport routes off the treated area for glyphosate include runoff and spray drift. Glyphosate has a high solubility, low octanol-water partitioning coefficient, low vapor pressure, and low Henry’s Constant. These data suggest that glyphosate has a low potential for volatilization and bioaccumulation. It is assumed that 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. Glyphosate can form various metal complexes (Popov et al., 2001).The formation of glyphosate-metal complexes with iron and aluminum promotes a high sorption affinity of glyphosate on the surfaces of Fe and Al oxides in soils and sediments (McBride, 1994).The main routes of dissipation are microbial degradation under aerobic conditions, and runoff. Glyphosate is expected to reach surface water primarily through spray drift; however, transport in runoff may also occur primarily via sorption of glyphosate-metal complexes to eroded sediment. The highest concentrations of glyphosate in surface water are in urban environments and in the vicinity of local use areas. Additional details on the fate of glyphosate are provided in **Chapter 3** of the Biological Evaluation.

# Residue of Concern

Along with significant mineralization to carbon dioxide, the major metabolite of glyphosate is aminomethylphosphonic acid (AMPA). It was detected in all laboratory studies except for the abiotic hydrolysis studies. The laboratory and field dissipation data indicate that AMPA is substantially more persistent than glyphosate. Formation of transformation products is further discussed in **Chapter 3**.

Although AMPA is a major degradation product from glyphosate, it is not considered a residue of toxicological concern in aquatic environments based on available toxicity data. A group of surfactants, the polyethoxylated tallow amines (POEA), are included in some formulations and have been shown to be more toxic to aquatic animals than glyphosate alone. Consideration of the potential increased toxicity of formulations is considered through the selection of toxicity endpoints and is discussed further in **Chapter 2**. Estimated aquatic exposure concentrations are based on the parent glyphosate. This is based on available data as limited fate data are available to model POEA.

# Analysis Plan

Listed species and designated critical habitats that were listed as of Jan 30, 2019 are considered in this BE (see **APPENDIX 4-1** for complete species lists). Effects determinations were made for 1795 listed species and 792 designated critical habitats.

As described in the Revised Method, listed species risk assessments for pesticides include three steps. Steps 1 and 2 are represented by the BE, which evaluates whether an individual of a listed species is reasonably expected to be exposed to a pesticide, and, if so, distinguishes effects that are likely to adversely affect an individual of a species from those that are not likely to adversely affect an individual. This process is also applied to the designated critical habitat of listed species (when available). In Step 1, for every listed species and designated critical habitat, EPA determines whether glyphosate will have No Effect (NE) or May Affect (MA) (separate determinations made for each species and critical habitat). For those species and critical habitats with MA determinations in Step 1, EPA will determine if glyphosate is Not Likely to Adversely Affect (NLAA) or Likely to Adversely Affect (LAA) each individual species or critical habitat.

Details on the method, models and tools used for making NE, NLAA and LAA determinations are provided in the Revised Method. This analysis plan identifies glyphosate specific information that is used in the Revised Method to complete this BE.

Step 1 begins with an analysis of the potential overlap of the action area and individual species ranges or critical habitat. For species or critical habitats with no overlap (*i.e.,* species found outside of the action area), NE determinations are made. The currently registered uses (summarized in **Section 4, APPENDIX 1-2** and **APPENDIX 1-3**) include agricultural and non-agricultural uses. The glyphosate overlap analysis is conducted using ArcGIS version 10.7. All labeled uses for glyphosate are represented by one or more of the agricultural or non-agricultural Use Data Layers (UDL) created from a variety of landcover, land use and supplemental data sources (see **APPENDIX 1-6** for details**)**. Agricultural and non-agricultural use sites are combined to derive the action area (along with the associated off-site transport zone). Due to the overlapping extents of the individual UDLs, the action area only includes direct overlap. For this reason, the spatial extent of drift from use sites was considered by creating a separate drift layer represented by the minimum distance from a use site across all UDLs for a location.

A number of spatial data sources were used to generate Use Data Layers (UDLs), which map the potential use sites for glyphosate. In the contiguous United States (ConUS), agricultural use pattern UDLs are represented by using the US Department of Agriculture’s (USDA) Crop Data Layer (CDL)[[2]](#footnote-3). This analysis utilizes data from 2013-2017. **APPENDIX 1-5** includes a crosswalk between crops found in the CDL and the resulting UDL while **APPENDIX 1-6** includes a crosswalk between glyphosate’s registered agricultural crops and those UDLs. **APPENDIX 1-6** also defines how individual CDL layers are grouped into UDL categories[[3]](#footnote-4) and temporally combined to account for the accuracy of the data. USDA’s 2012 Census of Agriculture (CoA) is also used to improve accuracy of the individual UDLs by expanding the agricultural UDLs to meet or exceed the reported acres in the CoA as needed (**ATTACHMENT 1-3**). The CDL is only available for ConUS, so other data sources are used to represent agricultural areas in states and US territories outside of ConUS (referred to as NL48[[4]](#footnote-5)). In Alaska and Puerto Rico, the US Geological Survey’s 2011 National Land Cover Dataset (NLCD)[[5]](#footnote-6) is used. In Hawaii, Guam, American Samoa, Virgin Islands and Northern Mariana Islands, the National Oceanic and Atmospheric Administration’s Costal Change Analysis Program (C-CAP)[[6]](#footnote-7) data from 2010-2012 are used. For non-agricultural use patterns in ConUS additional UDLs were created to represent glyphosate’s registered uses. The data sources used for these UDLs included but are not limited to the NLCD 2011, GAP Protected Areas Database, LandFire and NAVTEQ; for additional details see **APPENDIX 1-6** which summarizes all spatial data used to generate the agricultural and non-agricultural UDLs used for glyphosate’s potential use site footprints. Due to the limited availability of GIS data in some of the NL48 regions, the Nurseries UDL could not be created in Commonwealth of the Northern Mariana Island, Guam, and America Samoa and the Forest Trees UDL could not be created in America Samoa. A separate UDL specific to fallow area was not created in the NL48 regions because it would be identical to the agricultural UDL. **APPENDIX 1-6** summarizes all spatial data used to generate the agricultural and non-agricultural UDLs used for glyphosate’s potential use site footprints in the ConUS and NL48.

The Step 2 overlap analysis incorporates glyphosate usage data, which are provided in the SUUM (SIAB Use and Usage Matrix), combining it with information from the CoA (**APPENDIX 1-4, ATTACHMENT 1-4**). **APPENDIX 1-7** describe how the usage data for glyphosate, the CoA, and the potential use sites are combined to estimate the number of treated acres relevant to a given species located in ConUS or NL48 (respectively). These appendices also explain how the off-site transport zone (specifically spray drift) is adjusted based on available usage data.

The Revised Method document stated “Over time, EPA expects to update the MAGtool and other models and tools described in this document. When a pesticide BE is conducted, it will incorporate the most current versions of models and tools intended for use in the BEs.” This BE is consistent with the Revised Method and includes two method updates that are intended to improve the methods for assessing exposure and effects to plants. First, this BE utilizes a refined exposure model for plants inhabiting terrestrial, wetland and aquatic habitats. Second, this BE incorporates surrogate endpoints for plants when No Observed Adverse Effects Concentrations (NOAEC) values are not available. These approaches are discussed below.

To estimate exposures to plants in aquatic, wetland, and terrestrial habitats, this BE uses the Plant Assessment Tool (PAT), a new tool designed to refine screening-level exposure estimates to plants typically generated using TerrPlant. PAT employs mechanistic representations of fate (e.g., degradation) and transport (e.g., runoff), using data that are typically available for pesticides, to model runoff and spray drift exposure to terrestrial and wetland environments. For terrestrial plants, runoff and erosion are modeled using the Pesticide Root Zone Model (PRZM; which is part of PWC) and spray drift is modeled using AgDRIFT deposition values (also incorporated into the MAGtool).  The model uses a mixing cell approach to represent water within the active root zone area of soil, and accounts for flow through the terrestrial plant exposure zone (T-PEZ) caused by both treated field runoff and direct precipitation onto the T-PEZ.  Pesticide losses from the T-PEZ occur from transport (i.e., washout and infiltration below the active root zone) and degradation. Wetlands are modeled using PRZM and the Variable Volume Water Model (VVWM) and are then processed in PAT to estimate aquatic (mass per volume of water) and terrestrial (mass per area) concentrations. Aquatic plant exposure is modeled using the PRZM/VVWM models and the standard pond. The results from PAT are summarized for use in the MAGtool in the same way as the results from PWC.

For listed terrestrial and wetland plant species, NOAECs from seedling emergence and vegetative vigor studies are used to represent toxicity endpoints. There are often cases where NOAECs are not available (*e.g*., statistically significant effects occurred at all test concentrations) or are considered unreliable. Consistent with OPP’s longstanding practice, in cases where NOAECs are not available or reliable, an ICx value is used as a surrogate. Based on an analysis of the variability in the dry weight and height data of the controls of commonly tested species in vegetative vigor and seedling emergence studies, x values were assigned based on test type and endpoint (Table 1-2; supporting details in **ATTACHMENT 1-5**). This analysis does not consider the biological significance of the percent effect but rather identifies an ICx value at which we have confidence the measured effect is discernible.Table 1-2presents the ICx values that will be used as the Step 1 and 2 thresholds when a reliable NOAEC value is not available.

Table 1-. Alternate Step 1 and 2 thresholds.

|  |  |  |
| --- | --- | --- |
| **Test Type** | **Dry Weight** | **Shoot Height** |
| Vegetative Vigor | IC15 | IC10 |
| Seedling Emergence | IC20 | IC10 |

**Chapter 2** of this BE includes glyphosate’s toxicity endpoints and **Chapter 3** includes the exposure analysis. These toxicity endpoints and exposure estimates are used in Steps 1 and 2. **Chapter 2** also summarizes incident reports that are associated with applications of glyphosate (incident reports associated with illegal uses or misuses are not included in the assessment). **Chapter 3** summarizes available monitoring data. **Chapter 4** includes the species and critical habitat-specific determinations for glyphosate. For exposure in terrestrial habitats, the MAGtool[[7]](#footnote-8) (version 2.2) is used (additional details in **ATTACHMENT 1-1** and tool documentation). For aquatic habitats, exposure is estimated using the Pesticide in Water Calculator (PWC; version 1.52[[8]](#footnote-9)) and, where appropriate, the Pesticide in Flooded Applications Model (PFAM, version 2[[9]](#footnote-10)). Aquatic scenarios (referred to as “bins”) used to estimate exposures for each listed species with aquatic habitats are provided in **ATTACHMENT 1-2**. For plants, exposure is estimated using PAT. The MAGtool is used to integrate exposure, effects, and listed species life history information in order to make NE, NLAA and LAA determinations.

1. [] Available at: <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional> [↑](#footnote-ref-2)
2. [] USDA National Agricultural Statistics Service Cropland Data Layer. 2013-2017. Published crop-specific data layer [Online]. Available at <https://www.nass.usda.gov/Research_and_Science/Cropland/SARS1a.php> (accessed 3/2018; verified 2/2020). USDA-NASS, Washington, DC. [↑](#footnote-ref-3)
3. [] Categories include: corn, cotton, rice, soybeans, wheat, vegetables and ground fruit, other grains, other row crops, other crops, pasture/hay, citrus, vineyards and other orchards. [↑](#footnote-ref-4)
4. [] where NL is “non-lower” and 48 refers to the number of states in ConUS [↑](#footnote-ref-5)
5. [] Homer, C.G., Dewitz, J.A., Yang, L., Jin, S., Danielson, P., Xian, G., Coulston, J., Herold, N.D., Wickham, J.D., and Megown, K., 2015, Completion of the 2011 National Land Cover Database for the conterminous United States-Representing a decade of land cover change information. Photogrammetric Engineering and Remote Sensing, v. 81, no. 5, p. 345-354 [↑](#footnote-ref-6)
6. [] National Oceanic and Atmospheric Administration, Coastal Services Center. 1995-present. The Coastal Change Analysis Program (C-CAP) Regional Land Cover. Charleston, SC: NOAA Coastal Services Center. Accessed at <https://coast.noaa.gov/digitalcoast/data/ccapregional.html> (accessed 3/2020). [↑](#footnote-ref-7)
7. [] Information on the models and tools used to support this biological evaluation are available at: <https://www.epa.gov/endangered-species/models-and-tools-endangered-species-pesticide-assessments> (Accessed September 2020). [↑](#footnote-ref-8)
8. [] Available online at: [https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic](https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment%23aquatic) (Accessed September 2020). [↑](#footnote-ref-9)
9. [] Ibid. [↑](#footnote-ref-10)