**Chapter 1 – Draft Propazine Problem Formulation**

Contents

[1 Introduction 2](#_Toc53023220)

[2 Description of the Federal Action 2](#_Toc53023221)

[3 Mode and Mechanism of Action 2](#_Toc53023222)

[4 Use and Usage Characterization 3](#_Toc53023223)

[4.1 Use Data (as Defined on Registered Product Labels) 3](#_Toc53023224)

[4.2 Usage Data 3](#_Toc53023225)

[5 Overview of Environmental Fate 4](#_Toc53023226)

[6 Residue of Concern 4](#_Toc53023227)

[7 Analysis Plan 5](#_Toc53023228)

Introduction

This problem formulation provides the foundation for the propazine Biological Evaluation (BE) 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). The assessment for propazine represents EPA’s Biological Evaluation (BE) for all listed species and designated critical habitats.

Included in this chapter is a description of the federal action; the mode and mechanism of action of propazine; summaries of its uses (based on registered product labels and commitment letters from all technical registrants), usage, and fate; definition of the residue of concern and an analysis plan for how the BE will be conducted. As part of the FIFRA registration review process, a detailed Problem Formulation for the FIFRA ecological risk assessment of propazine was finalized in February 2013[[2]](#footnote-3) (USEPA, 2013, DP Barcode D407255). The problem formulation considered data needs for both a FIFRA ecological risk assessment and an assessment for potential impacts on listed species.

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 propazine, which encompasses the review of all the registered uses, and the approved product labels for all pesticide products containing propazine.

Mode and Mechanism of Action

Three chlorotriazine herbicides have current registrations in the United States: propazine (6-chloro-N,N′-bis(1-methylethyl)-1,3,5-triazine-2,4-diamine; PC code 080808); atrazine (6-chloro-N-ethyl-N′-(1-methylethyl)-1,3,5-triazine-2,4-diamine; PC code 080803); and simazine (6-chloro-N,N′-diethyl-1,3,5-triazine-2,4-diamine; PC code 080807).  These three chemicals differ only in number and/or position of methyl groups on moieties branched in identical positions off the triazine ring, thus are structurally nearly identical.  Based upon the available guideline and non-guideline toxicity studies, these chlorotriazines result in similar herbicidal effects to terrestrial and aquatic plants.

In plants, these molecules bind with a protein complex of the photosystem II in chloroplast photosynthetic membranes (Schulz et al., 1990).  The result is an inhibition in the transfer of electrons through the light reactions of photosynthesis that in turn inhibits the formation and release of oxygen, production of adenosine triphosphate, and the fixation of carbon dioxide into sugars. Plant death results from starvation and oxidative damage caused by the breakdown in photosynthesis.

While this pathway is not found in animals, acute and chronic exposure of animals has shown significant reduction in body weight and organ weights across multiple mammal and bird species.

Use and Usage Characterization

Use data are based on registered product labels and include pesticide application information relevant to a treatment site (*i.e.*, sorghum). EPA determines the uses based on registered labels, including any agreed upon changes to these labels from the technical registrants (Appendix 1-2), and defines 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 and avoid harm to human health and the environment. 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. This BE assesses all currently registered labels and any agreed upon changes to these labels from the technical registrants (for implementation on all formulated product labels). While the current labels may not reflect all the agreed upon changes, the technical registrants have agreed in the form of commitment letters (see **APPENDIX 1-2**) to update the propazine formulated product labels to be reflective of these changes (uses summarized in **APPENDIX 1-3**). Major changes in the commitment letters include restriction of applications to sorghum in the states of Texas, Oklahoma, and Kansas (see **APPENDIX 1-2** for specific details). EPA plans to formalize these changes through the appropriate processes prior to finalizing the BEs.

Propazine is only registered for use on sorghum (**APPENDIX 1-1**). The single maximum propazine application rate does not exceed 1.2 lb a.i./A and multiple applications are not allowed.

Propazine is applied preplant or preemergence in grain sorghum (*Sorghum bicolor*) plantings in order to control broadleaf and grass weeds. Currently, there is only one end-use pesticide product registered for propazine.

## Usage Data

Based on usage data compiled by EPA’s Office of Pesticide Program’s Biological and Economic Analysis Division (BEAD), approximately 218,400 pounds of propazine are used each year on 308,800 acres of sorghum in Oklahoma, Kansas and Texas (based on a yearly average from 2015 to 2017) (see **APPENDIX 1-4** for details). The average rate applied is reported as 0.707 lbs ai/A. Although allowed per the product label, no aerial applications were reported.

# Overview of Environmental Fate

The major transport routes off the treated area for propazine include runoff and spray drift. Propazine is expected to be moderately persistent and mobile (according to the Food and Agricultural Organization (FAO) mobility classification system[[3]](#footnote-4)) in most soils, and it is resistant to breakdown by hydrolysis, photolysis, or biodegradation.

Studies suggest that propazine is stable to both abiotic processes of hydrolysis and aqueous photolysis. Propazine is also fairly stable under aerobic and anaerobic aquatic metabolism with half-lives ranging from 146 to 1240 days (extrapolated past the end of the study) and 69.3 to 122 days respectively. Batch equilibrium experiments suggest that propazine is mobile, with Freundlich Kd values ranging from 0.34 to 3.19 in two separate studies involving 8 soil textures. The Koc values ranged from 65 to 268 in these same studies.

The mobility of propazine is also noted in the supplemental terrestrial field dissipation studies, suggesting that propazine persists in the upper 6 inches and may leach to ground water. Therefore, the use of propazine may result in groundwater and/or surface water contamination in areas where soils are highly permeable, the water table is shallow, or where there is irrigation and/or high rainfall which promote runoff. Volatility and air photolysis are not expected to be major routes of dissipation due to the low vapor pressure (2.9 x 10-8 torr at 20 °C). Additional details on the fate of propazine are provided in **Chapter 3** of the Biological Evaluation.

# Residue of Concern

The residue of concern is parent propazine. The major soil metabolite was 2-hydroxy propazine (2-hydroxy-4,6-bis(isopropylamino)-s-triazine) and comprised a maximum of 31% of the total applied radioactivity (TAR) after one year. Minor degradates consist of desethylatrazine (2-chloro-4-isopropylamino-6-amino-s-triazine or DEA) (<2% of TAR) and 2-hydroxy desethylatrazine (<5% of TAR).

Five transformation products were identified in aerobic and anaerobic aquatic studies: 2-chloro-4,6-diamino-1,3,5-triazine (DACT); atrazin-desethyldeisopropyl-2-hydroxy (ammeline); propazine-2-hydroxy (2-hydroxy propazine); atrazin-desethyl-2-hydroxy (deisopropyl hydroxy propazine); and atrazin-desethyl (DEA). In the aerobic aquatic study, DACT was a major transformation product (maximum of 11.7% at Day 46) in the Golden Lake water-loamy sand sediment system and a minor transformation product in the Goose River water-clay loam sediment system. All other compounds were minor transformation products in both systems. In the anaerobic aquatic study, no major transformation products were identified.

The major laboratory soil degradate, 2-hydroxy propazine was seen in the 0-3” and 3-6” soil layers of the terrestrial field studies at approximately 15% of parent at day 1 and decreased to less than 5% of parent by day 93. The other two minor degradates desethylatrazine (DEA) and 2,4-diamino-6 chloro-s-triazine (DACT), which are common to atrazine and simazine, were detected only in the 0-3" soil layer, each at less than 5% of parent at day 1, however decreasing to less than 1% by day 28.

The major degradates (2-hydroxy propazine and DACT) are not considered to be of toxicological concern because toxicity studies and ECOSAR suggest lower toxicity than parent propazine. It should be noted that no studies were submitted on the fate of any degradates (both major and minor) in the environment. Therefore, propazine alone is the residue of concern for the ecological risk assessment (see **Chapter 3**).

# Analysis Plan

Listed species and designated critical habitats that were listed as of January 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 propazine 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 propazine 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 propazine 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 propazine overlap analysis is conducted using ArcGIS version 10.7. The action area is derived using potential use sites and the off-site transport zone. The currently registered uses, incorporating changes based on commitment letters (summarized in **Section 3** and **APPENDIX 1-3**) include one agricultural use (*i.e.,* sorghum). For propazine, agricultural use site is used to derive the action area (along with the associated off-site transport zone).

A number of spatial data sources were used to generate Use Data Layers (UDLs), which map the potential use sites for propazine. In the contiguous United States (ConUS), agricultural use patterns UDLs are represented by using the US Department of Agriculture’s (USDA) Crop Data Layer (CDL)[[4]](#footnote-5). This analysis utilizes data from 2013-2017. As the commitment letters restrict the use of propazine to the states of Texas, Oklahoma, and Kansas, areas outside of ConUS (*e.g.,* Hawaii, Puerto Rico, etc.) were not included in the analysis. **APPENDIX 1-6** includes a crosswalk between propazine’s registered agricultural crops and the CDL. **APPENDIX 1-6** also defines how individual CDL layers are grouped into UDL categories[[5]](#footnote-6) and temporally combined to account for the accuracy of the data. USDA’s 2012 Census of Agriculture (CoA) is also used to improve accuracy by expanding the agricultural UDLs to meet or exceed the reported acres in the CoA (**ATTACHMENT 1-3**).

The Step 2 overlap analysis incorporates propazine 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 propazine, the CoA and the potential use sites are combined to estimate the number of treated acres relevant to a given species located in ConUS. 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 plants 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 1-1**; 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 1-1** Presents the ICx values that will be used as the Step 1 and 2 thresholds when a reliable NOAEC value is not available.

**Table 1-1.** 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 propazine’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 propazine (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 propazine. For exposure in terrestrial habitats, the MAGtool[[6]](#footnote-7) (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[[7]](#footnote-8)) and, where appropriate, the Pesticide in Flooded Applications Model (PFAM, version 2[[8]](#footnote-9)). 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. Propazine Registration Review Docket Folder. <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2010-0230> [↑](#footnote-ref-3)
3. The FAO mobility classification system is recommended for use in exposure assessments in the Office of Pesticide Programs in “*Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in the Problem Formulation for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*” (USEPA, 2010). <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-reporting-environmental-fate-and-transport>. [↑](#footnote-ref-4)
4. 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-5)
5. 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-6)
6. 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-7)
7. 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-8)
8. Ibid. [↑](#footnote-ref-9)