**Chapter 1 –** **Thiamethoxam Problem Formulation**

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# Introduction

This Biological Evaluation (BE) for thiamethoxam 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 (PF), which is the first step of ecological risk assessment. The PF 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 thiamethoxam, 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 thiamethoxam, which encompasses the review of all the registered uses and the approved product labels for all pesticide products containing thiamethoxam.

Mode and Mechanism of Action

Thiamethoxam is a systemic, neonicotinoid insecticide which acts on the insect nicotinic acetylcholine receptors (nAChRs) of the nervous system via competitive modulation (IRAC 2016). Thiamethoxam is in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) along with clothianidin, imidacloprid and dinotefuran[[2]](#footnote-3). Its mode of action on target insects (terrestrial and aquatic) involves out-competing the neurotransmitter acetylcholine for available binding sites on the nAChRs (Zhang et al. 2008)[[3]](#footnote-4). At low concentrations, neonicotinoids cause excessive nervous stimulation and at high concentrations, insect paralysis and death will occur (Tomizawa and Casida 2005)[[4]](#footnote-5). Thiamethoxam is systemic in plants; as such, it kills feeding insects via ingestion or direct contact routes of exposure. Target pests include the chewing and sucking pests such as aphids, whiteflies, thrips, leafhoppers, scales, and leaf miners.

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Use and Usage Characterization<http://epa.gov/pesticides/fifra6a2/>

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 defined 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. There are currently 80 registered Section 3 end-use products for thiamethoxam. Registered uses include a wide array of agricultural crops, including (but not limited to): root and tuber vegetables, leafy vegetables, brassica, cucurbits, fruiting vegetables, cereal grains, citrus fruit, pome fruit, stone fruit, berries, tree nuts, beans and other legumes, herbs, oilseed crops (*e.g.,* canola, cotton), and tobacco. Thiamethoxam is also registered for several non-agricultural uses, including ornamentals (Christmas trees), turf, poultry litter as well as perimeter/spot treatments. Applications may be made via a variety of methods including aerial and ground foliar sprays, soil treatment (*e.g.*, drench), chemigation (*e.g.*, soil incorporation or foliar), and as a seed treatment. Maximum single foliar application rates for thiamethoxam range from 0.05-0.266 lb a.i./A. This BE assesses all currently registered labels (**APPENDIX 1-1**). **APPENDIX 1-2** provides the use information, summarizing details relevant for modeling the maximum use patterns**;** additional details on uses modeled are described in **APPENDICES 1-3 and 3-1**.

## Usage Data

Between 2014 and 2018, the national annual total agricultural usage averaged approximately 180,000 pounds of thiamethoxam over 3.1 million acres (including foliar and soil applications). During this time frame, the crops with the most usage in terms of annual average total pounds of active ingredient applied via foliar or soil treatment were cotton (50,000 lbs), soybeans (40,000 lbs), potatoes (20,000 lbs) and oranges (20,000 lbs). The treated areas of cotton, soybeans, potatoes and oranges, were 1.1, 1, 0.2 and 0.2 million acres, respectively. On average, the states with the most agricultural usage in terms of pounds applied per year were California (38,000 lbs), Florida (14,000 lbs), Minnesota (12,000 lbs), and Arkansas (11,000 lbs) **(APPENDIX 1-4**).

Seed treatment with thiamethoxam is generally considered to be widespread in terms of the number of crops and the percentage of the crop planted with treated seed. However, quantitative seed treatment usage data are difficult to obtain due to the complexities of capturing this usage information from growers. While verifiable quantitative usage data that indicate the total pounds of active ingredient used to treat seed or the location and the number of acres planted with treated seed are not currently available, applications of thiamethoxam to seed and seed pieces may be generally characterized as commonly used on a wide variety of crop seeds and seed pieces for planting based on extension recommendations and other information. There are no quantified usage data available for non-agricultural uses of thiamethoxam. Available information indicates that <2000 lbs was applied to food related establishments (*e.g.*, restaurants, warehouses) and <500 lbs was applied per year to poultry houses (see **APPENDIX 1-4** for details).

# Overview of Environmental Fate

Thiamethoxam’s primary transport routes from treated sites to non-target areas include spray drift (for foliar applications) and runoff (for all application methods). Thiamethoxam is mobile to moderately mobile in soil and is soluble in water. Volatilization is not considered a major dissipation route and bioaccumulation is not expected. In terrestrial habitats, thiamethoxam is persistent, with half-lives on the orders of months to years. In aquatic habitats, thiamethoxam is less persistent, with aerobic aquatic metabolism half-lives on the order of weeks. In clear or basic water bodies, thiamethoxam may break down more quickly. Additional details on the fate of thiamethoxam are provided in **Chapter 3** of the Biological Evaluation.

# Residue of Concern

Thiamethoxam degrades into clothianidin, a separate active ingredient (a.i.) in the neonicotinoid class of chemicals which is subject to its own BE. Available fate and residue data indicate that the major route of formation of clothianidin (as a degradate) is from metabolism of thiamethoxam within plants. Clothianidin is also a major degradate in three of eight aerobic soil metabolism studies and one of two anaerobic soil metabolism studies. Clothianidin is also formed under field conditions as it is detected in terrestrial field dissipation studies. Therefore, both thiamethoxam and clothianidin are considered residues of concern for terrestrial and aquatic organisms. There were no other major residues of concern of thiamethoxam.

# Analysis Plan

Listed species and designated critical habitats that were listed as of Nov 1, 2020 are considered in this BE (see **APPENDIX 4-1** for complete species lists). Effects determinations were made for 1821 listed species and 791 designated critical habitats.

As described in the Revised Method[[5]](#footnote-6), 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 thiamethoxam 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 thiamethoxam 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 thiamethoxam-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 thiamethoxam overlap analysis is conducted using ArcGIS version 10.8. All labeled uses for thiamethoxam 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 (and the associated off-site transport zone).

A number of spatial data sources are used to generate Use Data Layers (UDLs), which map the potential use sites for thiamethoxam. 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)[[6]](#footnote-7). 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 thiamethoxam’s registered agricultural crops and those UDLs. **APPENDIX 1-5** also defines how individual CDL layers are grouped into UDL categories[[7]](#footnote-8) 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 (see **APPENDIX 1-5** for additional information on the UDLs and **ATTACHMENT 1-3** for additional information on extracting the acres from the CoA). 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[[8]](#footnote-9)). In Alaska and Puerto Rico, the US Geological Survey’s 2016 and 2001 National Land Cover Dataset (NLCD)[[9]](#footnote-10) are used, respectively. In Hawaii, Guam, American Samoa, Virgin Islands and Northern Mariana Islands, the National Oceanic and Atmospheric Administration’s Coastal Change Analysis Program (C-CAP)[[10]](#footnote-11) data from 2004-2012 are used. For non-agricultural use patterns in ConUS and NL48 additional UDLs are created to represent thiamethoxam’s registered uses. The data sources used for these UDLs included but were not limited to the NLCD 2016, GAP Protected Areas Database, LandFire and NAVTEQ. A new non-agricultural layer representing possible poultry litter applications was developed for use in this BE. Due to the limited availability of GIS data in some of the NL48 regions, the Field Nurseries UDL could not be created in Commonwealth of the Northern Mariana Island, Guam, and America Samoa. **APPENDIX 1-6** summarizes all spatial data used to generate the agricultural and non-agricultural UDLs used for thiamethoxam’s potential use site footprints in the ConUS and NL48.

The Step 2 overlap analysis incorporates thiamethoxam usage data, which are provided in the SUUM (SIAB Use and Usage Matrix), combining it with information from the CoA 2017 (**APPENDIX 1-4, ATTACHMENT 1-4**). **APPENDIX 1-7 and 1-8** describe how the usage data for thiamethoxam, the CoA 2017, 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 updates include a refined exposure model for plants inhabiting terrestrial, wetland and aquatic habitats and updates to the MAGtool to improve accuracy, efficiency and transparency, as 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 the Pesticide in Water Calculator (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.

Since the publication of the Revised Methods, modifications were made to the MAGtool and an updated version was used in this analysis (MAGtool version 2.3.1). Updates to the tool incorporated continued efforts to improve the efficiency, accuracy, and refinement of the tool. These updates are outlined more fully in the MAGtool documentation included on the models[[11]](#footnote-12) website and included incorporation of a new batch function analysis, improvements to spray drift analysis methods and input options, as well as the ability to make effects determinations either deterministically or probabilistically. The model allows the user to make deterministic calculations using the upper and lower bounds of the exposure assumptions, or using a probabilistic analysis, to determine impacts to a species based on mortality effects, sublethal effect or effects to prey, pollination, habitat, and dispersal vectors (PPHD). This was done to provide more transparency to the results calculations and to streamline the calculations for shorter run times. For a subset of species, selected based on the potential to refine the effects analysis, probabilistic analysis was used in making effects determinations. For the majority of species, as impacts are predicted even at the minimum or lower bound of exposure assumptions, the probabilistic analysis does not change the effects determination and was not conducted.

**Chapter 2** of this BE includes thiamethoxam’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 thiamethoxam (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 thiamethoxam. For exposure in terrestrial habitats, the MAGtool[[12]](#footnote-13) (version 2.3.1) 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[[13]](#footnote-14)) and, where appropriate, the Pesticide in Flooded Applications Model (PFAM; version 2[[14]](#footnote-15))). 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. <http://www.irac-online.org/> [↑](#footnote-ref-3)
3. Zhang Y, Liu S, Gu J, Song f, Yao X, Liu Z. (2008). Imidacloprid acts as an antagonist on insect nicotinic-acetylcholine receptor containing the Y151M mutation. Neurosci. Let. 446: 97-100. [↑](#footnote-ref-4)
4. Tomizawa M, Casida J. (2005). Neonicotinoid insecticide toxicology: mechanisms of Selective Action. Annual Review of Pharmacology and Toxicology, 45, 247–268. [↑](#footnote-ref-5)
5. Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides. 2020. US EPA. Available at https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf [↑](#footnote-ref-6)
6. [] 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-7)
7. [] 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-8)
8. [] where NL is “non-lower” and 48 refers to the number of states in ConUS [↑](#footnote-ref-9)
9. [] Homer, C. G., Dewitz, J. A., Jin, S., Xian, G., Costello, C., Danielson, P., Gass, L., Funk, M., Wickham, J., Stehman, S., Auch, Roger F., Riitters, K. H. 2020. Conterminous United States land cover change patterns 2001–2016 from the 2016 National Land Cover Database: ISPRS Journal of Photogrammetry and Remote Sensing, v. 162, p. 184–199 [↑](#footnote-ref-10)
10. [] 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-11)
11. [] 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-12)
12. [] 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-13)
13. [] 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-14)
14. Ibid. [↑](#footnote-ref-15)