**Thiamethoxam Executive Summary for Biological Evaluation**

A biological evaluation (BE) is a generic term for an analysis that a federal agency conducts when it takes action subject to review under the Endangered Species Act (ESA). EPA prepares a BE to evaluate the potential effects of an agency’s action (here, registered uses of thiamethoxam (PC code 060109)) on federally threatened and endangered species and designated critical habitat. This BE encompasses the review of all the registered uses and the approved product labels for all pesticide products containing thiamethoxam.

Under its current approach for registration review for conventional pesticides, EPA meets its ESA obligations through a three-step process. EPA’s development of this BE includes two steps. In Step 1, for each listed species and each designated critical habitat, EPA evaluates whether the registered uses of thiamethoxam will have No Effect (NE) or if the registered uses May Affect (MA) an individual of such species or habitat (separate determinations made for each species and critical habitat). More specifically, Step 1 is intended to be a conservative screen that is heavily reliant upon overlap of (1) areas where an environmentally discernable effect could occur from any labeled use of the pesticide being assessed (assumes the pesticide could be used in all areas allowable on the label) with (2) areas where species range/designated critical habitat occurs. It uses conservative assumptions and is intended to screen out species that are not reasonably expected to be exposed to the pesticide because they are outside of the pesticide use area. If EPA determines there is no effect, that is the end of the analysis for that particular species.

In Step 2, for those species and critical habitats that EPA determines an individual may be affected, EPA uses additional information to determine if thiamethoxam may affect but is Not Likely to Adversely Affect (NLAA) or may affect and is Likely to Adversely Affect (LAA) each individual species or critical habitat. Step 2 uses a more refined spatial overlap with specific pesticide use sites to calculate the portion of the population exposed, considers life history information, considers actual pesticide applications (usage data), additional toxicity data, and a range of potential exposure concentrations. If EPA makes a NLAA determination, then EPA must informally consult with the Services. Otherwise, if EPA makes a LAA determination, EPA must engage in formal consultation with the Services. Details on the method, models and tools used for making NE, NLAA and LAA determinations are provided in the Revised Method document.[[1]](#footnote-2)

Practically, the LAA threshold for a BE is very conservative as the likely “take” of even one individual of a species triggers LAA (even if that species is almost recovered). This often results in a high number of May Affect determinations in a BE. An LAA determination in the BE, however, should not be interpreted to mean that EPA has made a determination that thiamethoxam is putting a species in jeopardy. Those determinations are made in the course of Step 3 by the National Marine Fisheries Service and the Fish and Wildlife Service (referred to as The Services).

Step 3 is part of the formal consultation process. Here, the Services prepare a biological opinion (BiOp), which builds upon EPA’s BE to determine whether the potential adverse effect will jeopardize the continued existence of a species or destroy or adversely modify critical habitat. The analysis in Step 3 considers whether the anticipated adverse effects to individuals described in the BE will negatively affect populations and the species they comprise such that they jeopardize the continued existence of the species.

# General Information

Thiamethoxam is a systemic, neonicotinoid insecticide which acts on the insect nicotinic acetylcholine receptors (nAChRs) of the central nervous system via competitive modulation[[2]](#footnote-3). Thiamethoxam is in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) along with imidacloprid, clothianidin, and dinotefuran. The 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 higher 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.

This BE assesses all currently registered labels. Maximum application rates and minimum application retreatment intervals are based on the use defined by the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review[[5]](#footnote-6) and addendum[[6]](#footnote-7), unless otherwise noted. **APPENDIX 1-2** provides the use information as further refined by EPA, summarizing details relevant for modeling the maximum use patterns. **APPENDICES 1-2** and **3-1** provide additional details on how these uses were modeled.

Thiamethoxam is formulated as granule (G), water-dispersible granule (WDG), emulsifiable concentrate (EC), flowable concentrate (FC), ready to use (RTU), soluble concentrate/solid (SC/S), wettable powder (WP), agar gel (bait stations) and dust (D) for seed coatings/treatment. Applications occur from aircraft and ground vehicles (*e.g.*, tractors). Application equipment includes various sprayers (boom, airblast, hose-end, trigger, mist), spreaders, drenchers, injectors, irrigators (sprinkler and solid set), seed treaters, paintbrushes and syringes (crack and crevice and spot treatments) and the traditional watering can. Single application rates are up to 0.266 pounds active ingredient/acre (a.i./A) but are generally 0.05-0.086 lb a.i./A for foliar applications and 0.10-0.266 lb a.i./A for soil applications. Maximum combined annual application rates for agricultural and non-agricultural uses are not to exceed 0.266 lbs a.i./A.

Thiamethoxam is registered for use on a variety of agricultural and non-agricultural use sites. Between 2014 and 2018, over 185,000 pounds of thiamethoxam were applied annually via foliar or soil treatment to over 3 million acres of agricultural crops. Cotton and soybeans were the leading agricultural crops in thiamethoxam usage, receiving 49% of pounds thiamethoxam applied and 67% of acres treated. The remaining thiamethoxam applications are spread over 100 other crop varieties. While the vast majority of thiamethoxam is only applied to a few crops, examination of the percent of individual crops grown by state that are treated with thiamethoxam indicates that it is an important pest control tool for certain crops in certain states. Nearly less than 2,500 pounds of thiamethoxam were applied to non-agricultural use sites, including building premises and contents (including structural/perimeter pest control (indoors and outdoors in warehouses, schools, apartments, *etc.*) and indoor environments for the control of bed bugs) and livestock pens and poultry houses. Further information on agricultural and non-agricultural sites treated with thiamethoxam is available in **APPENDIX 1-4**.

The main routes of dissipation of thiamethoxam are spray drift, runoff, microbial degradation under aerobic and anaerobic aquatic conditions and aqueous photolysis. Thiamethoxam is expected to reach surface water primarily through spray drift and transport through runoff of the dissolved phase of thiamethoxam. Thiamethoxam is water soluble with a low octanol-water partitioning coefficient, low vapor pressure, and low Henry’s Law Constant. These data suggest that thiamethoxam has a low potential for volatilization and bioaccumulation.

Thiamethoxam degrades to clothianidin, a separate active ingredient (a.i.) in the neonicotinoid class of chemicals which is subject to its own BE. Both thiamethoxam and clothianidin share similar environmental fate characteristics and show similar behavior in the environment. Available fate and residue data of thiamethoxam 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 in this BE. Additional details on the fate of thiamethoxam are provided in **Chapter 3** of the Biological Evaluation.

# Toxicity Summary

On an acute exposure basis, thiamethoxam and clothianidin are very highly toxic to aquatic invertebrates. Tested insect species (class Insecta) are more sensitive on an acute exposure basis compared to tested species in other classes (*e.g.,* daphnids). By comparison, fish are several orders of magnitude less sensitive following acute exposure. On a chronic exposure basis, a decrease in survival was observed in aquatic insects for thiamethoxam, with effects to reproduction and development observed for clothianidin. As with acute exposure, daphnids are orders of magnitude less sensitive compared to insects when chronically exposed to thiamethoxam and clothianidin. Fish are also orders of magnitude less sensitive than aquatic insects on a chronic basis, with no effects observed for thiamethoxam and effects on growth observed for clothianidin. Aquatic plants are several orders of magnitude less sensitive to thiamethoxam compared to aquatic invertebrates, while effects on yield were observed for clothianidin (at relatively high concentrations).

In terrestrial organisms, thiamethoxam and clothianidin are characterized as highly toxic to bees on an acute exposure basis. Available data suggest potential effects to honey bee and bumble bee colonies that manifest as impacts to numbers of adults and decreases in brood. Thiamethoxam is characterized as slightly toxic to birds and mammals on an acute exposure basis, while clothianidin is characterized as moderately toxic to birds and mammals on an acute exposure basis. Chronic exposures to birds and mammals lead to decreases in body weight for thiamethoxam and eggshell thinning and decreased growth and maturation for clothianidin. Generally, minimal effects are seen in terrestrial plant studies; however, some effects on plant height were observed in some species of dicots for thiamethoxam. Generally, clothianidin has similar toxicity to or is more toxic than thiamethoxam. More details on the available toxicity data are provided in **Chapter 2**.

# Exposure Methods

Exposure estimates are based primarily on fate and transport model results. Aquatic exposures (surface water and benthic sediment pore water) are quantitatively estimated for representative thiamethoxam uses in specific geographic regions within generic habitats (referred to as bins) using the Pesticide Root Zone Model (PRZM5) and the Variable Volume Water Model (VVWM)[[7]](#footnote-8) in the Pesticides in Water Calculator (PWC). Aquatic exposure results for the bin(s) most appropriate for the species and/or critical habitat are discussed in **Chapter 3**. Also discussed in **Chapter 3** are available water monitoring data for thiamethoxam. For terrestrial exposures, existing models [*i.e.*, AgDRIFT, earthworm fugacity model, Terrestrial Herpetofaunal Exposure Residue Program Simulation (T-HERPS), Terrestrial Residue Exposure model (T-REX) and portions of the Terrestrial Investigation Model (TIM)] were combined and modified into a single tool that is referred to as the MAGTool (**Chapter 4**). This assessment replaces EPA’s TerrPlant model with the Plant Assessment Tool (PAT). The latter is a more refined exposure model for terrestrial, wetland and aquatic plants.

# Overlap Analyses

Step 1 of the BE involves an analysis of the potential overlap of the action area and individual species ranges and critical habitat. The action area was derived in ArcGIS 10.8 by combining the data layers representative of thiamethoxam potential uses plus off-site transport. The overlaps of action area and individual species’ ranges or critical habitats were calculated. This analysis used spatial data of species’ ranges and habitats from the Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS). In the contiguous United States (ConUS), agricultural potential use sites are represented using the USDA Crop Data Layer (CDL) (**APPENDIX 1-5**). Other data sources are used to represent agricultural areas in states and US territories outside of the contiguous United States, for which the CDL is not available (**APPENDIX 1-6)**. All species or critical habitats with some overlap of the action area and their range or designated critical habitat, or with some overlap on species that the listed species depends on (**Chapter 4**) move on to step 2 and are assessed to make LAA/NLAA determinations.

# Summary of Effects Determinations for Thiamethoxam

This BE makes effects determinations (NE, NLAA or LAA) for 1821 listed species, and 791 designated critical habitats. Under Step 1, EPA made NE determinations for 221 species and 89 critical habitats. EPA made MA determinations for 1600 species and 702 critical habitats. As explained above, all species and critical habitats with a MA determination progressed to the Step 2 analysis where an NLAA or LAA determination is made[[8]](#footnote-9). In Step 2, EPA made NLAA determinations for 204 species and 58 critical habitats. EPA made LAA determinations for 1396 species and 644 critical habitats. Specific species determinations are provided in **APPENDIX 4-1.**

For each LAA determination, EPA also characterized these determinations into three categories (*i.e.,* strongest, moderate and weakest) which characterizes the strength of the weight of evidence. Each species or critical habitat was assigned a weak, moderate or strong evidence in the LAA determination based on multiple factors, including: the impact of using less conservative assumptions in the analysis, the quality of the species range or usage data, whether impacts could occur due to direct toxicity to the species or to both direct toxicity and to its prey, pollination, habitat, and dispersal (PPHD), the presence of reported incidents involving the species taxa or PPHD taxa, the presence of monitoring data that exceeds endpoints, whether species’ habitats are potential use sites or if they could only be exposed from spray drift, and the likelihood of drift into a species habitat (*e.g*., if the species inhabits forests).

Of the LAA determinations, the majority (82% of species and 86% of critical habitats) were considered to have moderate evidence. Strongest evidence was found for <1% of species and <1% of critical habitat LAA determinations. Weakest evidence was found for 18% of species and 14% of critical habitat LAA determinations. Open Space Developed, Developed, Field Nurseries, Poultry Litter and Managed Forests (NL48) were the use sites most frequently associated with predicted impacts to species or critical habitats with LAA determinations, although numerous other non-agricultural and agricultural UDLs may also impact species. LAA determinations were made for species across all taxa. Because thiamethoxam is highly toxic to terrestrial and aquatic invertebrates but is much less toxic to other vertebrate and plant taxa, 1208 of the 1396 LAA determinations were based on effects to PPHD alone (see **Table 4-7** in **Chapter 4**). Having impacts only to PPHD also contributes to the high number of moderate strength of evidence classifications.For certain species, there were uncertainties in the thiamethoxam effects determinations based on the resolution of spatial data. For species and critical habitats, there were uncertainties in the resolution of usage data and the threshold for assessing impacts on PPHD (detailed in **Chapter 4**).**Table 1** and **Table 2** summarize the NE, NLAA and LAA determinations for species and critical habitats. **Table 3** summarizes the strength of evidence classifications for the LAA determinations.

EPA makes an LAA determination when there is the potential for a single individual of a species to be affected by the labeled use of a pesticide, which is a conservative threshold. This often results in a high number of LAA determinations. An LAA determination in the BE should not be interpreted to mean that EPA has determined that the registered use of thiamethoxam is putting a listed species in jeopardy. The National Marine Fisheries Service and the Fish and Wildlife Service make those determinations.

**Table 1. Summary of Species Effects Determinations for Thiamethoxam (Counts by Taxon).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Taxon** | **Step 1 Effects Determinations** | **Step 2 Effects Determinations** | **Totals** |
| **No Effect** | **May Affect** | **Not Likely to Adversely Affect** | **Likely to Adversely Affect** |
| Mammals | 1 | 101 | 48 | 53 | 102 |
| Birds | 5 | 103 | 32 | 71 | 108 |
| Amphibians | 0 | 38 | 0 | 38 | 38 |
| Reptiles | 8 | 39 | 13 | 26 | 47 |
| Fish | 4 | 190 | 13 | 177 | 194 |
| Plants | 49 | 901 | 41 | 860 | 950 |
| Aquatic Invertebrates | 151 | 70 | 34 | 36 | 221 |
| Terrestrial Invertebrates | 3 | 158 | 23 | 135 | 161 |
| **Total** | **221** | **1600** | **204** | **1396** | **1821** |
| **Percent of total** | **12%** | **88%** | **11%** | **77%** |  |

**Table 2. Summary of Critical Habitat Effects Determinations for Thiamethoxam (Counts by Taxon).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Taxon** | **Step 1 Effects Determinations** | **Step 2 Effects Determinations** | **Totals** |
| **No Effect** | **May Affect** | **Not Likely to Adversely Affect** | **Likely to Adversely Affect** |
| Mammals | 0 | 33 | 17 | 16 | 33 |
| Birds | 2 | 29 | 3 | 26 | 31 |
| Amphibians | 0 | 25 | 0 | 25 | 25 |
| Reptiles | 5 | 11 | 5 | 6 | 16 |
| Fish | 3 | 103 | 5 | 98 | 106 |
| Plants | 28 | 432 | 13 | 419 | 460 |
| Aquatic Invertebrates | 50 | 21 | 3 | 18 | 71 |
| Terrestrial Invertebrates | 1 | 48 | 12 | 36 | 49 |
| **Total** | **89** | **702** | **58** | **644** | **791** |
| **Percent of total** | **11%** | **89%** | **7%** | **81%** |  |

**Table 3. Classification of LAA Determinations by Strength of Evidence.**

|  |  |  |
| --- | --- | --- |
| **Strength of LAA call** | **Species range** | **Critical Habitat** |
| **Number** | **% of LAA determinations** | **Number** | **% of LAA determinations** |
| Strongest evidence of LAA | 6 | <1% | 1 | <1% |
| Moderate evidence of LAA | 1145 | 82% | 556 | 86% |
| Weakest evidence of LAA | 245 | 18% | 87 | 14% |

1. https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf [↑](#footnote-ref-2)
2. <http://www.irac-online.org/modes-of-action/> [↑](#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. Neuroscience Letters. 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. *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessments to*

 *Support Registration Review*. Environmental Protection Agency, Office of Pesticide Programs, Environmental

Fate and Effects Division, November 29, 2017. [↑](#footnote-ref-6)
6. *Thiamethoxam - Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments*

 *Received on the Bee and Non-Pollinator DRAs.* Environmental Protection Agency, Office of Pesticide Programs,

 Environmental Fate and Effects Division, January 06, 2020. [↑](#footnote-ref-7)
7. The exposure models can be found at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment> [↑](#footnote-ref-8)
8. Available at: <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional> [↑](#footnote-ref-9)