**Imidacloprid 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 imidacloprid (PC code 129099)) 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 imidacloprid.

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 imidacloprid 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 imidacloprid 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 imidacloprid 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

Imidacloprid is one of the most widely used insecticides in North America. It is a neonicotinoid insecticide registered in the U.S. to control piercing and sucking insects. Imidacloprid is used on several crops (orchard crops, cereal grains, berry/small fruits and vegetable crops), Christmas tree plantations and turf. Between 2014 and 2018, across states and all agricultural usage, the estimated cumulative usage of 891,400 pounds of imidacloprid was applied to agricultural crops. The agricultural use in a single state that had the highest annual average pounds active ingredient applied was grapes grown for vineyards (90,000 lb.). Across all states with agricultural uses of imidacloprid, cotton had the highest average pounds active ingredient applied annually (200,000 lb.) **(APPENDIX 1-4)**.

Imidacloprid has a high solubility, low octanol-water partitioning coefficient, low vapor pressure, and low Henry’s Constant . These data suggest that imidacloprid has a low potential for volatilization and bioaccumulation. However, the chemical will be readily soluble and thus available for leaching and movement with run-off water. The chemical will initially enter the environment via direct application (*e.g.*, as liquid sprays, dusts, seed coatings, granular formulations) to use sites (*e.g.*, seed treatment, soil, foliage).  It may move off-site via spray drift, dissolved in runoff, and/or as residue sorbed to eroded sediment. The chemical is highly susceptible to photodegradation in water with an observed half-life of 0.2 day. Aerobic and anaerobic aquatic transformation are expected to contribute to dissipation of imidacloprid reaching aquatic systems by run-off and drift. Persistence in soils may lead to accumulation over the years with repeated applications. However, the magnitude of soil accumulation is expected to be highly affected by other important routes of dissipation including leaching, run-off and plant up-take which are expected to reduce this accumulation.  Additional details on the fate of imidacloprid are provided in **Chapter 3** of the Biological Evaluation. Residues of concern are discussed in **APPENDIX 1-8**.

# Toxicity Summary

Similar to the other neonicotinoid insecticides with current registrations in the United States (imidacloprid, thiamethoxam, clothianidin, dinotefuran), imidacloprid works by acting on the insect nicotinic acetylcholine receptor (nAChRs) of the central nervous system via competitive modulation. Its mode of action on target insects involves out-competing the neurotransmitter, acetylcholine for available binding sies on the nAChRs (Zhang et al. 2008). At low concentrations, neonicotinoids cause excessive nervous stimulation and at high concentrations, insect paralysis and death (Tomizwa and Casida, 2005). Imidacloprid is a xylem-mobile systemic compound that is readily taken up by the roots of the plant and translocated throughout the plant via the transpiration stream (Sur and Stork, 2003).

On an acute exposure basis, imidacloprid is classified as very highly toxic to aquatic invertebrates. The available data suggest that aquatic insect species (class Insecta) are more sensitive on an acute exposure basis compared to other species of aquatic invertebrates (*e.g.*, crustaceans). By comparison, fish and aquatic plants are several orders of magnitude less sensitive following acute exposure to imidacloprid. On a chronic exposure basis, a decrease in survival was observed in aquatic insects. As with acute exposure, daphnids, mysid shrimp, and fish are orders of magnitude less sensitive compared to aquatic insects when chronically exposed to imidacloprid. For terrestrial organisms, imidacloprid is characterized as highly toxic to bees, highly toxic to birds and moderately toxic to mammals 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. Chronic exposures to birds and mammals lead to decreases in body weight and egg production in birds. Generally, no effects were observed in terrestrial plant studies that tested up to the currently registered single maximum application rate.  There are reported ecological incidents involving imidacloprid use for birds, fish, terrestrial plants, and terrestrial and aquatic invertebrates. More details on the available toxicity data and incident reports 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 imidacloprid 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)[[2]](#footnote-3) 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 imidacloprid. 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 imidacloprid uses and then buffering them out to the off-site transport distance estimated using the AgDRIFT model (**APPENDIX 1-6**). The overlaps of action area and individual species’ ranges or critical habitats were calculated. This analysis used spatial data of species’ ranges and critical habitats from the FWS and NMFS. In the contiguous United States (ConUS), agricultural potential use sites are represented using the USDA Crop Data Layer (CDL) (**APPENDIX 1-5**). 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 Imidacloprid

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 209 species and 78 critical habitats. EPA made MA determinations for 1612 species and 713 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 [[3]](#footnote-4). In Step 2, EPA made NLAA determinations for 167 species and 55 critical habitats. EPA made LAA determinations for 1445 species and 658 critical habitats. Specific species determinations are provided and described 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 (92% of species and 97% of critical habitats) were considered to have moderate evidence. Strongest evidence was found for none of the species or critical habitat LAA determinations. Weakest evidence was found for 8% of species and 3% of critical habitat LAA determinations. Developed, Open Space Developed and Managed Forests, were the use sites most frequently associated with impacts to species or critical habitats with LAA determinations. LAA determinations were made for species across all taxa.Because imidacloprid is highly toxic to terrestrial and aquatic invertebrates but is much less toxic to other vertebrate and plant taxa, 1107 of the 1444 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 imidacloprid 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 imidacloprid 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 Imidacloprid (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 | 32 | 69 | 102 |
| Birds | 0 | 108 | 31 | 77 | 108 |
| Amphibians | 0 | 38 | 0 | 38 | 38 |
| Reptiles | 1 | 46 | 16 | 30 | 47 |
| Fish | 4 | 188 | 13 | 175 | 192 |
| Plants | 49 | 901 | 17 | 884 | 950 |
| Aquatic Invertebrates | 151 | 72 | 33 | 39 | 223 |
| Terrestrial Invertebrates | 3 | 158 | 25 | 133 | 161 |
| **Total** | **209** | **1612** | **167** | **1445** | **1821** |
| **Percent of total** | **11%** | **89%** | **9%** | **79%** |  |

**Table 2. Summary of Critical Habitat Effects Determinations for Imidacloprid (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 | 14 | 19 | 33 |
| Birds | 0 | 31 | 5 | 26 | 31 |
| Amphibians | 0 | 25 | 0 | 25 | 25 |
| Reptiles | 2 | 14 | 8 | 6 | 16 |
| Fish | 3 | 103 | 5 | 98 | 106 |
| Plants | 22 | 438 | 9 | 429 | 460 |
| Aquatic Invertebrates | 50 | 21 | 3 | 18 | 71 |
| Terrestrial Invertebrates | 1 | 48 | 11 | 37 | 49 |
| **Total** | **78** | **713** | **55** | **658** | **791** |
| **Percent of total** | **10%** | **90%** | **7%** | **83%** |  |

**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 | 0 | 0% | 0 | 0% |
| Moderate evidence of LAA | 1336 | 92% | 635 | 97% |
| Weakest evidence of LAA | 109 | 8% | 23 | 3% |

1. https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf [↑](#footnote-ref-2)
2. The exposure models can be found at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment> [↑](#footnote-ref-3)
3. Available at: <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional> [↑](#footnote-ref-4)