**Chapter 1 –** **Clothianidin Problem Formulation**

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# Introduction

This Biological Evaluation (BE) for clothianidin 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 clothianidin, summaries of its uses (based on registered product labels), usage, overview of environmental fate, identification of the residues 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 clothianidin, which encompasses the review of all the registered uses and the approved product labels for all pesticide products containing clothianidin.

Mode and Mechanism of Action

Clothianidin (IUPAC name: (*E*)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine) is a systemic, neonicotinoid insecticide which acts on the nicotinic acetylcholine receptors (nAChRs) of the central nervous system via competitive modulation (IRAC 2015). Clothianidin is in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) along with imidacloprid, thiamethoxam 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)). Clothianidin is a xylem and phloem-mobile systemic compound that is readily taken up by the roots of the plant and translocated throughout the plant via the transpiration stream. As such, they kill 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.

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 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. Clothianidin is an insecticide that is currently registered in the U.S. to control insects in a wide range of agricultural and non-agricultural use sites (**APPENDIX 1-1**). This BE assesses all currently registered labels.

There are currently 46 registered Section 3 end-use products for clothianidin. 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, cotton, and tobacco. Clothianidin is also registered for several non-agricultural uses, including commercial premises, outdoor residential, ornamentals trees, turf, and livestock areas. 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), seed treatment, and bait placement. Maximum single foliar application rates for clothianidin range from 0.05-0.2 lb a.i./A for agricultural uses. Maximum single application rates of 0.4 lb a.i./A are associated with the non-agricultural uses. 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 2013 and 2018, the national annual total agricultural broadcast usage averaged approximately 36,000 pounds of clothianidin. Nationally, among surveyed agricultural crops, clothianidin usage (both pounds applied, and total acres treated) has shown an overall increasing trend in pounds applied and acres treated since 2005 with a slight decrease in 2018. During the most recent five years of available survey data (2014 -2018), less than around 50,000 pounds of clothianidin were applied to less than 500,000 acres of agricultural crops annually, in 25 states. During this time frame, the crops with the most usage in terms of annual average total pounds of active ingredient applied were cotton (8,000 lbs), potatoes (5,000 lbs), and soybeans (5,000 lbs). The crops with the most usage in terms of total treated acreage were the same with 100,000, 90,000 and 40,000 acres treated for soybeans, cotton, and potatoes, respectively (see **APPENDIX 1-4** for details). Approximately 50% of pounds of clothianidin applied agriculturally are made to four crops (cotton, potatoes, soybeans and broccoli). In terms of total acres treated, approximately 50% of the acres treated with clothianidin are planted with two crops (cotton and soybeans). The remaining clothianidin applications are spread over 20 other crops. While the vast majority of clothianidin is only applied to a handful of crops, examination of the percent of individual crops grown by state that are treated with clothianidin indicates that usage is prevalent for certain crops in certain states. For instance, an average of 55% of peaches in South Carolina, 75% and 65% of apples in Virginia and West Virginia respectively and 75% of pumpkins in Texas are treated annually with clothianidin **(APPENDIX 1-4)**.

Over 9,000 pounds of clothianidin are applied to non-agricultural sites annually however, national non-agricultural usage data are more limited than agricultural data with many of the sites not surveyed at the national level. 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 broad spectrum treatment and bed bug treatment**.** Sites surveyed at the national level indicated no reported usage of clothianidin. Further information on non-agricultural sites treated with clothianidin is available in **APPENDIX 1-4**.

Seed treatment with clothianidin 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 active ingredient used to treat seed or the location and the number of acres planted with treated seed are not currently available, applications of clothianidin 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.

# Overview of Environmental Fate

The major transport routes off the treated area for clothianidin include runoff and spray drift for broadcast uses. Clothianidin has a high solubility, low octanol-water partitioning coefficient, low vapor pressure, and low Henry’s Constant. These data suggest that clothianidin has a low potential for volatilization and bioaccumulation. The major route of dissipation for clothianidin appears to be photolysis, with an aqueous photolysis half-life less than 1 day and a soil photolysis half-life of 34 days. The preponderance of clothianidin surface water detections are in agricultural areas and in the vicinity of local use areas. Additional details on the fate of clothianidin are provided in **Chapter 3** of the Biological Evaluation.

# Residue of Concern

Available toxicity data for aquatic taxa indicate that, in general, clothianidin degradates were similar to (non-toxic) or less toxic than clothianidin. However, TMG is of concern to benthic invertebrates. Because the mobility of clothianidin and its degradates indicate that they do not readily bind to soil or sediment, unextracted residues were not considered for further analysis. Therefore, the stressors of concern for the aquatic assessment are determined to be parent clothianidin as well as the degradate TMG. TMG forms via aerobic aquatic metabolism and occurs at up to 25% of applied clothianidin. Consideration of the potential increased toxicity of formulations is considered through the selection of toxicity endpoints and is discussed further in **Chapter 2**.

# 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 clothianidin 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 clothianidin 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 clothianidin-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 clothianidin overlap analysis is conducted using ArcGIS version 10.8. All labeled uses for clothianidin 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).

A number of spatial data sources are used to generate Use Data Layers (UDLs), which map the potential use sites for clothianidin. 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 clothianidin’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 clothianidin’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. **APPENDIX 1-6** summarizes all spatial data used to generate the agricultural and non-agricultural UDLs used for clothianidin’s potential use site footprints in the ConUS and NL48.

The Step 2 overlap analysis incorporates clothianidin 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 clothianidin, 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 clothianidin’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 clothianidin (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 clothianidin. 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: Cotton, Soybeans, Citrus, Grapes, Other Orchards, Other Row Crops, Other Crops, Rice, and Vegetables and Ground Fruit. [↑](#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., 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-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)