**Chapter 4 – Clothianidin Effects Determinations**

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# Introduction

In this BE, either a “No Effect” (NE), “Not Likely to Adversely Affect” (NLAA) or a “Likely to Adversely Affect” (LAA) determination is made for 1821 listed species (including endangered, threatened, candidate, proposed species: and experimental populations) and 791 designated critical habitats. For each species and designated critical habitat, the effects determination is based on the methodology previously described in **Chapter 1** and the Revised Methods[[1]](#footnote-2). These determinations are described further below according to the Steps of the methodology in which a determination was made (*e.g.*, Step 1b, Step 2c) although some steps are combined as appropriate. Summary tables are provided within the chapter with more detailed tables and individual species determinations provided in appendices.

# Summary of Effects Determinations

**Tables 4-1 and 4-2** below summarize the effects determinations for all species and designated critical habitats, including a count of the number of species determinations by taxon. In addition, **Table 4-3** summarizes the step of the analysis in which each effects determination was made for the species and designated critical habitat while **Table 4-4** includes a summary of the strength of evidence associated with each LAA determination (discussed in more detail in **Section 3**). Effects determinations are summarized for each individual species and critical habitat in **APPENDIX 4-1**. **APPENDIX 4-1 (“Summary Table All Calls” tab)** is organized into 8 major taxa: birds, mammals, amphibians, reptiles, terrestrial invertebrates, fish, aquatic invertebrates and plants. Species are organized by taxon, then alphabetically according to scientific name, then by species identification number. For each species, the table includes an effects determination for both the species and its critical habitat, if applicable, as the table also has an indication of how the effects determination was reached (*e.g.,* terrestrial weight-of-evidence analysis, qualitative).

Table 4-1. Summary of Species Effects Determinations for Clothianidin (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 | 46 | 55 | 102 |
| Birds | 6 | 102 | 31 | 71 | 108 |
| Amphibians | 0 | 39 | 0 | 39 | 39 |
| Reptiles | 8 | 39 | 13 | 26 | 47 |
| Fish | 4 | 187 | 13 | 174 | 191 |
| Plants | 72 | 878 | 175 | 703 | 950 |
| Aquatic Invertebrates | 151 | 72 | 34 | 38 | 223 |
| Terrestrial Invertebrates | 17 | 144 | 25 | 119 | 161 |
| Total | 259 | 1562 | 337 | 1225 | 1821 |
| Percent of total | 14% | 86% | 19% | 67% |   |

Table 4-2. Summary of Critical Habitat Effects Determinations for Clothianidin (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 | 26 | 0 | 26 | 26 |
| Reptiles | 5 | 11 | 5 | 6 | 16 |
| Fish | 3 | 102 | 5 | 97 | 105 |
| Plants | 64 | 396 | 165 | 231 | 460 |
| Aquatic Invertebrates | 50 | 21 | 3 | 18 | 71 |
| Terrestrial Invertebrates | 7 | 42 | 16 | 26 | 49 |
| Total | 131 | 660 | 214 | 446 | 791 |
| Percent of total | 17% | 83% | 27% | 56% |   |

Table 4-3. Summary of Species Effects Determinations by Step (and part) in the Process

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Step 1A** | **Step 1B/C** | **Step 2A** | **Step 2B** | **Step 2C** | **Step 2D** | **Step 2E** | **Step 2F** | **Step 2G/H/I** |
|
| **Outside of the action area** | **No toxicity effects** | **Incomplete exposure pathway** | **Extinct** | **Unreliable overlap based on range** | **Exposure models unreliable** | **<1% overlap** | **<1 exposed and pop. >100** | **Weight of evidence**  |
| **NE** | **NE** | **NLAA** | **NLAA** | **NLAA** | **LAA** | **NLAA** | **LAA** | **NLAA** | **NLAA** | **NLAA** | **LAA** |
| # of species in category | 43 | 216 | 52 | 17 | 10 | 7 | 56 | 1 | 29 | 28 | 145 | 1217 |
| # of critical habitats in category | 60 | 71 | 18 | 2 | 0 | 4 | 15 | 1 | 59 | 35 | 85 | 441 |

Table 4-4. 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 | 994 | 81% | 349 | 78% |
| Weakest evidence of LAA | 231 | 19% | 97 | 22% |

# Methodology for Making Effects Determinations

As discussed in **Chapter 1** and the Revised Method, effects determinations are made in a tiered manner, transitioning from more conservative, screening level assumptions to more refinement. As discussed in the Revised Method document, the MAGtool combines toxicological information, exposure analysis and results of the spatial analysis. The spatial footprint of the action area includes the pesticide footprint based on all labeled uses for the chemical and offsite transport due to spray drift. Additional information on how the action area was developed can also be found in **APPENDIX 1-6** and in the **Use Site Generation** tool documentation**.**

For each species and critical habitat, the MAGtool provides output for each step (and part) of the method, proceeding from Step 1a to Step 2f. In Steps 2f-2g/h/i, output is provided as the number of individuals predicted to be impacted under the assumptions of the analysis. It is important to note that the output generated is the potential number of individuals that could be impacted (based on the assumptions of the simulation), not a prediction that they will be impacted. Throughout this analysis, the BE maintains conservative assumptions and may overstate the number of species exposed to and impacted by a pesticide (see Table 5 in the Revised Method). At Step 2g through 2i, EPA applies a weight of evidence analysis to make the final effects determinations as outlined in **ATTACHMENT 4-1**. Effects determinations utilized probabilistic methods for a subset of species, including the use of the Excel Add-In, Oracle Crystal Ball. The output from these final steps is either an NLAA or LAA determination, with all LAA determinations receiving a strongest, moderate, or weakest evidence of LAA designation (further described in **Section 5.7**). Additional technical information on the MAGtool, can be found in the Revised Methods and the model documentation[[2]](#footnote-3).

The basis of the inputs used in the MAGtool to make effects determinations, including spatial analysis results, toxicity data and estimated environmental concentrations (EECs) are described in **Chapters 1 to 3.** Spreadsheets containing the inputs to the MAGtool are provided in **APPENDIX 4-2.** Additional details and output from the aquatic model parameter variation analyses (*i.e*., for curve number and application date) are provided in **APPENDICES 4-3 and 4-4.**

MAGtool outputs are based on foliar spray applications of clothianidin because these are generally protective of exposures to non-target organisms from any other type of application. In addition to the information included in the MAGtool output, consideration was also given to any additional non-spray uses that may be relevant to a use site that has overlap with a species range or critical habitat. Clothianidin is registered for seed treatment and soil applications on a number of use sites. A discussion and analysis of the methods for assessing these uses for terrestrial species and the predicted impacts are described in **APPENDIX 4-5**.

In addition to the MAGtool analysis, after an aquatic species or a terrestrial species that relies on aquatic dietary items has been given a NE or NLAA determination, EPA conducted a final analysis to evaluate sources upstream of a species range or critical habitat that could affect the species. To do this, EPA evaluated monitoring data upstream and downstream of the species range/critical habitat to determine if any detections of the pesticide had occurred. Details of this analysis method are provided in **APPENDIX 4-6** and the analysis used to derive the results in **APPENDIX 4-7.**

# Step 1: No Effect/May Effect Determinations

In Step 1a, a “No Effect” determination is made if a listed species range or its designated critical habitat are outside of the action area. Forty-three species and 60 critical habitats met these criteria for clothianidin.

In Steps 1b and 1c, a “No Effect” determination is made for a species and its critical habitat if no effect to a listed species or its prey, pollination, habitat, and/or dispersal (PPHD) is anticipated based on screening conservative toxicity endpoints against the highest EEC predicted. Two hundred and sixteen species and 71 critical habitats met these criteria for clothianidin. Due to the specific mode of action of neonicotinoid insecticides on insects, most of the NE determinations were for species that do not rely on insects (terrestrial or aquatic) as part of PPHD items.

Overall, “May Affect” (MA) determinations were made for 1562 species and 660 critical habitats. Specific species determinations are provided in **APPENDIX 4-1.** All species given a May Affect determination at Step 1 progressed to the Step 2 analysis where a NLAA or LAA determination is made.

# Step 2: NLAA/LAA Determinations

## Step 2a: Is the species exposure pathway incomplete?

In Step 2a, the assessor considers whether the pathway to pesticide exposure is complete for an individual of a listed species or the taxa upon which it depends (*i.e.,* PPHD). In general, exposures to non-target animals and plants may occur through contact, consumption or inhalation. The pathways of exposure that are relevant to a given pesticide are dependent upon the application parameters and fate properties of a pesticide. An exposure pathway is considered incomplete when there is no reasonable expectation of continuity between the source of pesticide exposure and an individual organism of a listed species. In other words, the exposure pathway is considered incomplete if an individual of a listed species or organisms upon which it depends are not expected to be exposed through contact, consumption or inhalation. When the exposure pathway is incomplete, effects are not reasonably expected to occur. Therefore, a NLAA determination is made for species for which exposure pathways are incomplete.

For clothianidin, three types of species characteristics lead to a conclusion that the exposure pathway is incomplete: species or critical habitat that only occur on uninhabited islands, species that predominantly occur in the open ocean and terrestrial species that only occur in caves. Additional explanation of why the exposure pathway is incomplete for these three types of species habitats is provided in **APPENDIX 4-8**.

When considering the list of species, NLAA determinations were made for 52 species because they have incomplete exposure pathways for clothianidin. **APPENDIX 4-1** includes the species for which NLAA determinations are made because of incomplete exposure pathways. These species include those with ranges that are only on uninhabited islands, species that are located in the open ocean and only rely on the ocean for PPHD, and terrestrial invertebrate species that are obligate to caves (see **APPENDICES 4-1 and 4-8**).

Of the 52 species with incomplete exposure pathways, 18 have designated critical habitats. NLAA determinations are made for the designated critical habitats of species with incomplete exposure pathways (see **APPENDIX 4-1**).

## Step 2b: Is the species most likely extinct?

Species recommended for delisting due to extinction by the Services are presumed extinct and receive a NLAA determination. NLAA determinations are made for these species as exposure from the action is not reasonably certain to occur, and, therefore, effects on the species are not anticipated. Species are only presumed extinct after a recommendation to delist is made by the Services in a review document (*e.g.*, Recovery plan, 5-year review).

The US Fish Wildlife Service has recommended 17 species for delisting due to extinction. NLAA determinations are made for these 17 species because they are presumed extinct (see **APPENDIX 4-1** for the list of species). Two of these species have designated critical habitats.

## Step 2c: Is the range of species and resulting overlap considered unreliable?

As described in the Revised Method, in Step 2c, a review of the range data, provided by FWS, was completed for those that followed geopolitical boundaries (*e.g.,* counties or states), rather than natural ones. From that review, in cases where the ranges from ECOS and the field offices’ documentation differ substantially, a quantitative overlap analysis was not conducted and a LAA or a NLAA determination was based on a qualitative weight of evidence analysis.

Nine species were determined to have range data that differed substantially from the data provided in ECOS and as a result the overlap results would be unreliable. The weight of evidence included consideration of the size and unique traits of species range and life history (*e.g.,* exists only in very remote location) as well as any information from FWS documents on stressors to species (*i.e.,* pesticides) or proximity to potential use sites for clothianidin. Based on this analysis, a NLAA determination was made for 5 species and a LAA determination was made for 4 species. Three of the species were designated as moderate evidence of LAA and one was designated as weakest evidence of LAA. The specific species are provided in **APPENDIX 4-1** (tab marked as Step 2c)as well as additional information on the review of the data for each species and the factors considered in making the determinations.

Eight additional species and 4 critical habitats were also included in this Step of the analysis as either no spatial data were available and/or these species are considered extirpated based on communication with FWS. LAA determinations are made for 3 of these species and NLAA determinations were made for 5 of these species, while LAA determinations were made for all 4 critical habitats (see **APPENDIX 4-1** for the list of species). All of the species and critical habitats were designated as moderate evidence of LAA.

## Step 2d: Are exposure models considered unreliable for assessed species?

At this time, the current exposure models used in this assessment cannot estimate exposures for all types of pesticide applications, all habitat types, or for all potential exposure routes relevant to listed species. Therefore, there may be uncertainty in the exposure values being used for a particular species based on what potential uses its range or critical habitat may overlap with, what type of habitat the species is found in, or what the main potential exposure route(s) might be. For species and critical habitats that have not been determined to be NE or NLAA based on the above analyses, consideration is given to how well the conceptual model of the relevant exposure model(s) matches up with the specific species being assessed. If the model estimates are not considered representative of the exposure of the species (due to an inconsistency in the exposure model and assessed species’ habitat), a qualitative analysis is conducted.

The qualitative analysis considered whether exposures to clothianidin are reasonably certain to occur given the habitat of the listed species (*e.g.,* ocean, beach, and/or freshwater habitats) and, if exposures are expected to occur, whether impacts to an individual are likely. The analysis also considered the potential for effects to the PPHD of the species and whether those effects would rise to the level of impacting an individual of a listed species. Circumstances that led to a NLAA determination include:

* marine species where impacts to PPHD of the species would not rise to the level of impacting an individual and whose exposures to clothianidin are reasonably expected to be *de minimus* (e.g., whales that utilize open ocean);
* marine species that also utilize terrestrial environments (on a limited basis), because exposure to clothianidin is not reasonably expected to occur at levels that will impact an individual (*e.g.,* sea turtles and pinnipeds);
* marine species that rely on multiple dietary items because exposure to clothianidin is not reasonably expected to decrease prey populations; and
* terrestrial species that are predominantly located outside of the jurisdiction of the United States because use of clothianidin in the US is unlikely to result in exposure.

When considering the species information and the potential for exposure, LAA determinations with weakest evidence were made for one species and one critical habitat (killer whale) and NLAA determinations were made for 56 species and 15 critical habitats. Additional discussion on these determinations is provided in **APPENDIX 4-8**.

## Step 2e: Is the percent of species range/critical habitat that overlaps with the action area less than 1%?

As described in the Revised Method, the effects determination for any listed species or designated critical habitat whose range overlaps <1% with the area of effects, after considering the quantitative analyses, will be a NLAA determination. The cutoff of 1% is based on the precision of the available data. Twenty-nine species and fifty-nine critical habitats met these criteria for clothianidin.

## Step 2f: Based on conservative assumptions, is it likely that less than 1 individual is exposed?

Step 2f applies a more refined approach and considers available usage data when identifying the likely portion of a species range where pesticide exposure may occur; different approaches were employed for crop and non-crop uses due to differences in the nature of the available usage data. At this step in the method, the percent overlap analysis becomes a surrogate for the percentage of the population exposed; further description of the methodology is available in the Revised Method. In Step 2, the number of individuals exposed and impacted is considered using the likely exposure area. Additionally, the designation of a species likely being on or off a use site, based on the species life history, is applied at this step. In Step 2f, the maximum PCT and upper distribution of acres in the species range is used to represent the % overlap with the range and the number of individuals likely exposed. This approach is also applied to the critical habitat.

Based on this analysis, twenty-eight species and thirty-five critical habitats met these criteria for clothianidin.

## Step 2g/h/i: Weight of Evidence Analysis for final effects determinations

As described in the Revised Method, a weight of evidence analysis was used for any species reaching Step 2 parts g, h and i of the analysis. This included 1362 species and 526 critical habitats. The purpose of the weight of evidence was to consider multiple factors and scenarios in making the effects determination, including various percent crop treated (PCT)/acres distribution scenarios, alternative assumptions for species populations, potential alternative toxicity endpoints as well as typical application rates. Additionally, probabilistic components were introduced into the analysis at this step for a subset of species to allow for the use of distributions of potential EECs and toxicological responses.

In addition to making a NLAA or LAA determination for a species and critical habitat from the analyses, as part of the effects determination a degree of confidence was assigned to each LAA determination. This was denoted as “evidence in the LAA” determination and 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, impacts to both the species and PPHD as opposed to only one, the presence of reported incidents involving the species taxa or PPHD taxa, the presence of monitoring data that exceeds endpoints, exposure only due to spray drift and the likelihood of drift into a species habitat (*e.g.*, if the species inhabits forests). This is described in more detail in the Revised Method document and in **ATTACHMENT 4-1**. The three strength of evidence categories applied to LAA determinations are not used for NE or NLAA determinations. Given the conservative nature of the Step 1 and Step 2 analysis, EPA is confident that when a NE or NLAA determination is made, there will be no effects to an individual of the assessed species or an individual of a species is not likely to be adversely affected.

One uncertainty noted for some species is that the best available species range data do not accurately reflect where the species is expected to be located. An overlap scenario is considered in the weight of evidence for a subset of species based on a more refined analysis of the likely habitat of the species. This included a subset of 124 species, including plants, mammals, birds and terrestrial invertebrates. Under this scenario, the exposure area within the species range for each species is defined as the likely habitat, based on the GAP/Landfire layer[[3]](#footnote-4). NLAA determinations are made for species if the overlap of the action area and the preferred habitat layer is less than 1%, or a NLAA determination is made based on the complete WoE analysis with the habitat layer applied.

The MAGtool technical documentation describes the algorithm used to assign an automated NLAA or LAA determination and the strength of evidence in the LAA and it is also provided for reference in **ATTACHMENT 4-1**. Lines of evidence were considered for each LAA determination in the weight of evidence. These lines of evidence were also reviewed by an assessor when appropriate to allow for individual refinement of the determination, if needed. Additionally, in the output, the contribution of each specific use site to the total number of individuals potentially impacted is provided, as well as other characterization of the effects determinations.

Based on the WoE analysis, a NLAA determination was made for 145 species and 85 species’ critical habitat and a LAA determination was made for 1217 species and 441 critical habitats (**Table 4-3 and Table 4-4**). As described above, 124 species were evaluated based on the application of the GAP/Landfire layer as part of the overlap analysis and was considered as part of the WoE. NE determinations were made for 5 of these species in the Step 1 analysis based on no anticipated toxicity and were not further evaluated. NLAA determinations were made for 18 of the species based on an overlap of the action area (to the fullest buffer extent) of <1% after the application of the habitat layer, 1 species based on less than 1 individual expected to be exposed and 4 species after the weight of evidence analysis. The remaining 96 species were found to be LAA, 74 with moderate evidence of risk and 22 with weakest evidence of risk. The overall determination or strength of evidence did not change for most of these species when compared to the analysis without the habitat layer, but the number of individuals predicted to be impacted tended to decrease. With the application of the refined habitat layer, although the number of individuals that could be impacted was reduced, there was greater confidence in the effects determination due to the restriction of the range to the habitat layer. The application of habitat layers and evaluating their impact on the confidence in LAA determinations will be further developed in the future. Specific species results are provided in **APPENDIX 4-1.**

For the strength of evidence of each LAA determination, the majority of species were found to be in the moderate evidence of LAA. LAA determinations were distributed across all taxa. Additional details on the distribution of the strength of determinations as well as additional characterization of the effects determinations is provided in **Tables 4-5 thru 4-8** below.

Table 4-5. Distribution of LAA Determinations Across Evidence Classes for Species Range and Critical Habitat

|  |  |  |
| --- | --- | --- |
| **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 | 994 | 81% | 349 | 78% |
| Weakest evidence of LAA | 231 | 19% | 97 | 22% |

Table 4-6. Distribution of LAA Determinations Across Taxonomic Groups for Species Range

|  |  |  |
| --- | --- | --- |
| **Taxa** | **Strength of evidence of LAA (counts)** | **Strength of evidence of LAA (%)** |
| **Strong** | **Moderate**  | **Weak** | **Total** | **Strong** | **Moderate** | **Weak** |
| Mammals | 0 | 45 | 10 | 55 | 0% | 82% | 18% |
| Birds | 0 | 65 | 6 | 71 | 0% | 92% | 8% |
| Amphibians | 0 | 39 | 0 | 39 | 0% | 100% | 0% |
| Reptiles | 0 | 15 | 11 | 26 | 0% | 58% | 42% |
| Fish | 0 | 171 | 3 | 174 | 0% | 98% | 2% |
| Plants | 0 | 512 | 191 | 703 | 0% | 73% | 27% |
| Aquatic Invertebrates | 0 | 32 | 6 | 38 | 0% | 84% | 16% |
| Terrestrial Invertebrates | 0 | 115 | 4 | 119 | 0% | 97% | 3% |

Table 4-7. Additional Characterization of LAA and NLAA Determinations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **LAA call based on Max Upper only?** | **LAA call with no impacts by alternative analysis?** | **LAA call based on drift only?** | **LAA call based on impacts to PPHD only?** | **LAA call based on one use only?** | **NLAA call with low population (<100)?** |
|  |
| 0 | 126 | 18 | 1057 | 146 | 116 |  |

Table 4-8. Impact of All UDLs on LAA Effects Determinations

|  |  |  |
| --- | --- | --- |
| **UDL1** | **Number of times UDL predicted to impact a species1** | **Rank** |
|
| **CONUS** |
| CONUS\_Open Space Developed | 830 | 1 |
| CONUS\_Developed | 749 | 2 |
| CONUS\_Poultry Litter | 516 | 3 |
| CONUS\_Other Crops | 419 | 4 |
| CONUS\_Vegetables and ground fruit | 295 | 5 |
| CONUS\_Other Orchards | 256 | 6 |
| CONUS\_Cotton | 166 | 7 |
| CONUS\_Soybeans | 153 | 8 |
| CONUS\_Grapes | 143 | 9 |
| CONUS\_Rice | 59 | 10 |
| CONUS\_Citrus | 46 | 11 |
| CONUS\_Other Row Crops | 43 | 12 |
| **NL48 Layers** |
| NL48\_Developed | 352 | 1 |
| NL48\_Open Space Developed | 277 | 2 |
| NL48\_Poultry Litter | 104 | 3 |
| NL48\_Ag | 102 | 4 |
| 1 Counts terrestrial and aquatic impacts separately, one species could be impacted twice by same use in both terrestrial and aquatic environment |

The number of and strength of LAA determinations found for clothianidin is expected given the action area of the chemical and the toxicity profile. Clothianidin is an insecticide with a large number of uses and less than 50,000 pounds are applied to crops and 9,000 pounds are applied to non-agricultural sites each year. Open Space Developed, Developed, and Poultry Litter (considered a non-agricultural use as it relates to the application of manure contaminated with clothianidin rather than a direct application of clothianidin) were the most frequent UDLs predicted to impact a species.

Due to the lack of availability for all UDLs with non-agricultural use sites except Developed and uncertainty in usage data associated with the non-agricultural use sites, strength of evidence was moderate at best when these uses were the main contributors to risk, reflected in the 81% and 78% of LAA effects determinations associated with moderate evidence. Clothianidin is highly toxic to terrestrial and aquatic invertebrates but is much less toxic to other vertebrate and plant taxa. This fact, and the reliance of a large number of species on invertebrate species as prey or pollinators is reflected in the results of the LAA determinations. Of the 1225 LAA determinations, 1057 were based on effects to PPHD alone (see **Table 4-7**). Having impacts only to PPHD also contributes to the high number of moderate strength of evidence. Although each species analysis is unique, these factors may help to explain the general trend seen in the data of many species with a LAA determination. Nineteen percent of species were associated with weakest evidence of risk, while none were associated with strongest evidence of risk. Twenty-two percent of species’ critical habitats were associated with weakest evidence of risk, while none were associated with strongest evidence of risk.

It is notable that despite the high toxicity of clothianidin to invertebrate species, even those species were largely classified as moderate evidence of risk. As discussed above, this is based on the criteria for determining strength of evidence. With the non-agricultural use layers impacting the largest number of individuals for most species, these were most often considered the top drivers of risk, and strength of evidence was moderate at best. If an analysis was conducted considering only agricultural uses, where labeled uses can be mapped more specifically and better usage data is available, the strength of evidence may increase.

Summary results for the species determinations are contained in **APPENDIX 4-1 (“Summary” tab)** and are denoted as either “TerrWoE”, “AquaWoE” or “TerrWoE and AquaWoE” as the source of the effects determination. Additional worksheets in **APPENDIX 4-1** include total determination counts for species and a key to file locations for each species. Detailed weight of evidence output for all species are located in **APPENDIX 4-9**, organized according to the file key in **APPENDIX 4-1**.

# Upstream Monitoring Data Analysis

As previously discussed, as part of the analysis any species that was classified as a NE or NLAA was reviewed to ensure that no sources upstream of a species range or critical habitat would affect the species. To do this, EPA evaluated the monitoring data with regards to the location to the species range/critical habitat (*e.g.,* upstream or downstream) to determine if any detections of the pesticide had occurred. Only monitoring sites upstream of or in the species range/critical habitat were considered relevant for the downstream transport analysis, as there is uncertainty in the downstream monitoring sites as to where the pesticide originated (*i.e.*, was pesticide used in the species range/critical habitat, or outside where the species would not be exposed).

Results of the analysis are described in **APPENDIX 4-6.** One hundred species and 154 critical habitat determinations were NE (outside action area) or NLAA (< 1 exposed or < 1% overlap) based on quantitative analysis. No effects determinations were revised based on the monitoring data analysis. Monitoring data analysis results are included in the weight of evidence output for each species.

# Additional Characterization of Effects Determinations, Uncertainties and Refinements

These effects determinations were developed based on refinements to the methods for evaluating risks to listed species, such as inclusion of usage data and probabilistic modeling. There are several areas of the analysis that could be further refined to increase confidence in the effects determinations. See **ATTACHMENT 4-1** for details on how these uncertainties influence the confidence of the effects determinations. Any refinements in the following areas would potentially increase the EPA’s confidence in the LAA determinations:

* Resolution of spatial data. There are uncertainties in the spatial footprint associated with the non-agricultural uses of clothianidin and there are limited data available to inform the extent of usage in any given area for these types of uses. Another important uncertainty is that the available range data for some listed species are at the sub-county level, with boundaries that are biological in nature, while others follow geopolitical boundaries, such as county or state lines. Species with overly broad ranges that include habitats the species would not utilize lead to uncertainties in effects determinations.
* Resolution of usage data. Usage data are available at the state, regional, or national level while species’ range or critical habitat information is at the sub-state level. To address the difference in scale, we made several assumptions with respect to where pesticide-treated acres could occur relative to a species’ habitat (*e.g.,* all treated acres occur within the habitat, evenly dispersed throughout the state, or primarily outside of a species habitat).
* Threshold for assessing impacts on PPHD of a species. There are uncertainties associated with the magnitude of impact to a particular species’ prey base or habitat for a given pesticide that could result in a discernible effect to that listed species.
* Poultry litter use. Clothianidin can be used in poultry houses to control darkling and hide beetles. The litter collected from these treated poultry houses can be later used on agricultural fields as a soil amendment. The UDLs for fields that typically use poultry litter soil amendments, as described in **APPENDIX 1-6**, include: CONUS\_Corn, CONUS\_Soybeans, CONUS\_Cotton, CONUS\_Other Grains, CONUS\_Other Row Crops, CONUS\_Rice, CONUS\_Vegetables and ground fruit, CONUS\_Wheat, CONUS\_Alfalfa, and NL48\_Ag. The inclusion of all of these uses in counties where poultry operations occur could potentially overestimate the acreage where poultry litter is applied and overestimate the overlap with species ranges/critical habitats.
* Toxicity endpoint selection. Some data sets had a large amount of toxicity data, while for other taxa, data were sparse. When data were sparse, conservative assumptions were made based on the available data for the taxon. As a consideration of other toxicity data, an alternative less conservative assumption was made and included as part of the alternative analysis scenario. The results of the alternative analysis should be considered when evaluating the uncertainty and potential outcomes of the analysis due to the variability in the available toxicity data, as well as the influence of other input parameter assumptions (*e.g.,* application rate, population size).
* Monitoring data. There is a significant body of monitoring data available for clothianidin. Effects determinations were made based largely on the results of modeling. Monitoring data were considered as part of the weight of evidence and in the determination of an NE or NLAA (any NE or NLAA determinations were screened for the presence of monitoring data before that effects determination was made; however, no species matched these criteria for clothianidin). Monitoring data results were included in the weight of evidence output for each aquatic species.

# Conclusions

For 1,821 listed species, including endangered, threatened, candidate, proposed species, and experimental populations; and 791 designated critical habitats, a NE, NLAA or a LAA determination was made for clothianidin. The weight of evidence for each LAA determination was also characterized as either strongest, moderate, or weakest. All of Steps 1 (parts a-c) and 2 (parts a-i) were applied for the majority of listed species and critical habitats.

NE determinations were made for 259 species and 131 designated critical habitats. NLAA determinations were made for 338 species and 215 species’ critical habitat and LAA determinations were made for 1225 species and 446 critical habitats. Approximately 67% of all species and 56% of all critical habitats were given a LAA determination and these species were distributed across all taxa. Of those LAA determinations, none were considered to have strongest evidence, 81% were considered to have moderate evidence, and 19% were considered to have weakest evidence for species and 0% were considered to have strongest evidence, 78% were considered to have moderate evidence, and 22% were considered to have weakest evidence for critical habitat. Open Space Developed, Developed, and Poultry Litter UDLs were the use sites most frequently associated with impacts to species or critical habitats with LAA determinations.

1. Available online at: <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional> [↑](#footnote-ref-2)
2. Available online at: <https://www.epa.gov/endangered-species/models-and-tools-endangered-species-pesticide-assessments> [↑](#footnote-ref-3)
3. U.S. Geological Survey Gap Analysis Program, 20160513, GAP/LANDFIRE National Terrestrial Ecosystems 2011: U.S. Geological Survey: Boise, ID, <https://www.sciencebase.gov/catalog/item/573cc51be4b0dae0d5e4b0c5>. [↑](#footnote-ref-4)