Docket Numbers EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581
www.regulations.gov

Clothianidin and Thiamethoxam

Proposed Interim Registration Review Decision
Case Numbers 7620 and 7614

January 2020

Approved by: _____
Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

Date: 1-22-2020

Table of Contents

I. INTRODUCTION 4
A. Summary of Clothianidin and Thiamethoxam Registration Review 5
B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses 9
II. USE AND USAGE 17
III. SCIENTIFIC ASSESSMENTS 18
A. Human Health Risks 18
1. Risk Summary and Characterization 19
2. Human Incidents and Epidemiology 24
3. Tolerances 25
4. Human Health Data Needs 27
B. Ecological Risks 27
1. Risk Summary and Characterization 28
2. Ecological Incidents 41
i. Pollinator Incidents 41
ii. Aquatic and Non-Pollinator Terrestrial Incidents 42
3. Ecological and Environmental Fate Data Needs 43
C. Benefits Assessment 43
IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION 50
A. Proposed Risk Mitigation and Regulatory Rationale 50
1. Cancellation of Clothianidin Uses on Bulb Vegetables 52
2. Thiamethoxam Use Restrictions for Risks to Occupational Handlers 52
3. Glove and Respirator Requirements for Certain Occupational Handlers 53
4. Closed System Requirement for Thiamethoxam Corn Seed Treatments 56
5. Poultry House Use Requirements for Clothianidin 56
6. Application Rate Reductions 57
i. Clothianidin 57
ii. Thiamethoxam 60
7. Crop Stage Restrictions 62
i. Clothianidin 62
ii. Thiamethoxam 64
8. Advisory Statements for Clothianidin and Thiamethoxam Seed Treatment Uses 67
9. Residential Ornamental Advisory 67

10. Spray Drift Reduction and Runoff Reduction 68
11. Pesticide Resistance Management 73
B. Stewardship 74
C. Tolerance Actions 75
D. Proposed Interim Registration Review Decision 76
E. Data Requirements 76
V. NEXT STEPS AND TIMELINE 76
A. Proposed Interim Registration Review Decision 76
B. Implementation of Mitigation Measures 77
Appendix A: Summary of Proposed Actions for Clothianidin and Thiamethoxam 78
Table 1: Summary of Proposed Actions for Clothianidin 78
Table 2: Summary of Proposed Actions for Thiamethoxam 79
Appendix B: Proposed Labeling Changes for Clothianidin and Thiamethoxam Products 80
Table 1: Proposed Labeling Changes for Clothianidin Products 80
Table 2: Proposed Labeling Changes for Thiamethoxam Products 91
Appendix C: Endangered Species Assessment 103
Appendix D: Endocrine Disruptor Screening Program 104
Appendix E: Summary of Proposed Tolerance Actions 106

ED_006569J_00013068-00003

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the agency) Proposed Interim Registration Review Decision (PID) for clothianidin and thiamethoxam (PC Codes 044309 and 060109, case numbers 7620 and 7614, respectively), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. Clothianidin is a registered pesticide active ingredient but is also a major metabolite and degradate of thiamethoxam. Therefore, the ecological risks for these two chemicals were assessed together and both are included in this combined PID. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on clothianidin and thiamethoxam, can be found in the EPA's public docket (EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing a PID for clothianidin and thiamethoxam so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the Services) to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the EPA has not yet fully evaluated risks to listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for clothianidin and thiamethoxam prior to completing the clothianidin and thiamethoxam registration review. Likewise, the agency will complete endocrine screening for clothianidin and thiamethoxam, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the clothianidin and thiamethoxam registration review.

Clothianidin and thiamethoxam are systemic, neonicotinoid insecticides with unique spectrums of activity that act on the nicotinic acetylcholine receptors (nAChRs) of the central nervous system of insects. They are in the N-nitroguanidine group of neonicotinoids, in subclass 4A of the Insecticide Resistance Action Committee (IRAC) mode of action classification scheme. The target pests for clothianidin and thiamethoxam products include a diverse set of insect pests, such as aphids, whiteflies, thrips, caterpillars, beetles, flies, stinkbugs, and others. Clothianidin and thiamethoxam products are registered for use on a wide variety of crops (*e.g.* corn, cotton, soybeans, root and tuber vegetables, pome fruit, stone fruit, berries, tree nuts, legumes, cereal grains, and oilseed crops and herbs). They are also registered on non-agricultural use sites such as turf, poultry houses, and ornamental plants. Products containing clothianidin and thiamethoxam can be applied via methods such as aerial, ground foliar sprays, soil treatments, chemigation and as a seed treatment. There are currently 45 active registered Section 3 end-use products containing clothianidin and 77 containing thiamethoxam. Products containing clothianidin were first registered in 2003 and products containing thiamethoxam were first registered in 1999, and therefore, neither were subject to reregistration.

This document is organized into five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why clothianidin and thiamethoxam are used and summarizes data on their respective uses; *Scientific Assessments*, which summarizes the EPA's risks, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; *Benefits Assessments*, which describes the utility of the chemical along with any potential impacts of mitigation; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA's PID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

While this PID focuses on the specific risks, benefits, and mitigation measures for clothianidin and thiamethoxam, the EPA is issuing PIDs for all of the currently registered N-nitroguanidine neonicotinoid pesticides concurrently to ensure consistency across the class. The PIDs and supporting documents for the other N-nitroguanidine neonicotinoid pesticides (i.e., dinotefuran and imidacloprid) are available in the public dockets established for these cases.

A. Summary of Clothianidin and Thiamethoxam Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for clothianidin and thiamethoxam with the opening of a registration review docket for each of these cases. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of clothianidin and thiamethoxam. The registration review docket ID for clothianidin is EPA-HQ-OPP-2011-0865 and the registration review docket ID for thiamethoxam is EPA-HQ-OPP-2011-0581.

- December 2011 - The clothianidin and thiamethoxam Preliminary Work Plans (PWPs) and supporting documents were posted to the docket for a 60-day public comment period, which was extended for 7 days. The following is a list of those documents:
    - *Clothianidin Summary Document Registration Review*

- *Thiamethoxam Summary Document Registration Review*
- *Clothianidin. Human Health Assessment Scoping Document in Support of Registration Review*
- *Thiamethoxam. Human Health Assessment Scoping Document in Support of Registration Review*
- *Thiamethoxam Registration Review: Human Health Scoping Information Regarding the Wood Preservative Uses (Post Peer Review Update)*
- *Registration Review: Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments of Clothianidin,*
- *Registration Review: Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments of Thiamethoxam*
- *Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments in Support of the Registration Review of Thiamethoxam Antimicrobial Uses*

- June 2012 - The Final Work Plans (FWPs) for clothianidin and thiamethoxam (*Clothianidin Final Work Plan for Registration Review* and *Thiamethoxam Final Work Plan for Registration Review*) were issued. During the 60-day public comment period for the clothianidin and thiamethoxam PWPs, the agency received 175 and 14 public comments, respectively. The clothianidin and thiamethoxam FWPs included corrections to the list of data requirements needed to conduct a risk assessment to support a proposed registration review decision pursuant to 40 CFR § 155.53(b).

- July 2012 - The agency announced the availability of a petition received on March 20, 2012 entitled *Emergency Petition to Suspend: Clothianidin* from the Center for Food Safety (CFS) acting on behalf of 27 beekeeper and honey producers, and 4 environmental and consumer organizations. The petition and the agency's partial response to the petition were posted on July 27, 2012 in a new docket (EPA-HQ-OPP-2012-0334) and opened a 60-day public comment period that closed on September 25, 2012. The petition's remaining claims, as well as the 1,363 comments posted in response to the petition, will be addressed separately from this PID.

- March 2013 - Generic Data Call-Ins (GDCIs) for clothianidin (GDCI-044309-1185) and thiamethoxam (GDCI-060109-1309) were issued for data needed to conduct the registration review risk assessments. For both clothianidin and thiamethoxam, all data requirements have either been satisfied or waived; there are no outstanding GDCI requirements.

- January 2017 - The agency announced the availability of the *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* for a 60-day public comment period.

- December 2017 – The agency announced the availability of the following assessments to support Registration Review for a 60-day public comment period:

- *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review.* September 7, 2017.
- *Thiamethoxam. Draft Human Health Risk Assessment in Support of Registration Review.* December 5, 2017.
- *Clothianidin. Occupational and Residential Exposure Assessment for Registration Review.* September 7, 2017.
- *Clothianidin – Drinking Water Exposure Assessment for Registration Review of All Registered Uses.* July 12, 2017.
- *Clothianidin Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Registration Review.* August 31, 2017.
- *Thiamethoxam: Tier II Drinking Water Exposure Assessment to Support Registration Review.* July 13, 2017.
- *Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure Assessments for Registration Review.* August 31, 2017.
- *Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review*. November 27, 2017.
- *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review*. November 29, 2017.
- *Biological and Economic Analysis Division (BEAD) Response to Public Comments Submitted in Response to BEAD's Assessment entitled "Benefits of Neonicotinoid Seed Treatments to Soybean Production."* December 5, 2017.
- *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Cotton*. November 21, 2017.
- *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Citrus*. November 21, 2017.

- January 2020 – The agency is now announcing the availability of the PID and the *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* in the clothianidin and thiamethoxam dockets for a 60-day public comment period. Along with the PID, the following documents are also being posted to the clothianidin and/or thiamethoxam dockets:
  - *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam).* December 6, 2019.
  - *Biological and Economic Analysis Division's (BEAD) Response to Comments on the Preliminary Risk Assessments and Benefit Assessments for Citrus, Cotton, Soybean Seed Treatment, and Other Crops Not Assessed for Neonicotinoid Insecticides.* December 23, 2019.
  - *Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops.* August 30, 2018.
  - *Benefits of Neonicotinoid Insecticide Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit.* December 20, 2019.

- *Benefits of Neonicotinoid Insecticide Use in Berries (Strawberry, Caneberry, Cranberry, and Blueberry) and Impacts of Potential Mitigation.* December 6, 2019.
- *Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation.* December 11, 2019.
- *Benefits of Neonicotinoid Insecticides Usage in Grapes and Impacts of Potential Mitigation.* October 23, 2019.
- *Clothianidin (044309) Screening Level Usage Analysis (SLUA).* July 8, 2019.
- *Estimate of Area Treated per Day for Insecticides in Poultry Houses and Amount of Clothianidin Handled per Day When Using a Mechanically Pressurized Handgun.* July 9, 2019.
- *Review of "The Value of Neonicotinoids in North American Agriculture" prepared by AgInfomatics, LLC, for Bayer CropScience L.P., Mitsui Chemicals Agro, Inc., Syngenta Crop Protection, LLC, and Valent U.S.A. LLC.* November 4, 2019.
- *Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent.* December 11, 2019.
- *Thiamethoxam (060109) Screening Level Usage Analysis (SLUA).* July 25, 2019.
- *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments.* April 22, 2019.
- *Usage, Pest Management Benefits, and Possible Impacts of the Potential Mitigations of the Use of Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear).* December 11, 2019.
- *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment.* October 30, 2019.
- *Thiamethoxam. Revised Response to Comments on the Thiamethoxam Human Health Draft Risk Assessments for Registration Review.* January 14, 2020.
- *EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran).* January 6, 2020.
- *Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoids using Raby et al. (2018) toxicity data.* January 7, 2020.
- *Clothianidin: Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments.* January 8, 2020.
- *Thiamethoxam: Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments Received on the Bee and Non-Pollinator DRAs.* January 6, 2020.
- *Attachment 1 to the Neonicotinoid Final Bee Risk Assessments: Tier II Method for Assessing Combined Nectar and Pollen Exposure to Honey Bee Colonies.* January 14, 2020.

- *Attachment 2 to the Neonicotinoid Final Bee Risk Assessments: Residue Bridging Analysis of Foliar and Soil Agricultural Uses of Neonicotinoids.* January 14, 2020.
- *Attachment 3 to the Neonicotinoid Final Bee Risk Assessments: Residue Bridging Analysis for Foliar and Soil Non-Agricultural Uses of Neonicotinoids.* January 14, 2020.
- *Attachment 4 to the Neonicotinoid Final Bee Risk Assessments: Residue Bridging Analysis for Seed Treatment Uses of Neonicotinoids.* January 14, 2020.
- *NOTE TO READER: Documents Supporting the Registration Review of Clothianidin*. January 17, 2020.
- *NOTE TO READER: Documents Supporting the Registration Review of Thiamethoxam*. January 17, 2020.

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

As specified in section I.A., the clothianidin and thiamethoxam risk assessment documents were released in conjunction with two separate comment periods in 2017. The combined preliminary bee risk assessment for clothianidin and thiamethoxam was published on May 25, 2017 for a public comment period ending on July 24, 2017. The draft human health and non-pollinator ecological risk assessments for clothianidin and thiamethoxam, as well as various supporting benefits-related registration review documents, published on December 21, 2017 for a 60-day public comment period, which was extended by an additional 60 days, totaling 120 days in length and ending on April 21, 2018.

Across these two comment periods, the agency received a total of 996 distinct public comments. In addition, the comments included approximately 400,000 mass mailer campaign submissions. Comments were submitted by various individuals, organizations, and companies. Comments of a broader regulatory nature, and the agency's responses to those comments, are provided in the memorandum *Response from OPP's Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments of the 4 Nitroguanidine-substituted Neonicotinoid Insecticides*. Responses to comments on the topics of neonicotinoid benefits, ecological effects and human health effects are captured in the following documents:

- *Biological and Economic Analysis Division's (BEAD) Response to Comments on the Preliminary Risk Assessments and Benefit Assessments for Citrus, Cotton, Soybean Seed Treatment, and Other Crops Not Assessed for Neonicotinoid Insecticides.* December 23, 2019.
- *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment.* October 30, 2019.
- *Thiamethoxam. Revised Response to Comments on the Thiamethoxam Human Health Draft Risk Assessments for Registration Review.* January 14, 2020.

- *EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran).* January 6, 2020.
- *Clothianidin: Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments.* January 8, 2020.
- *Thiamethoxam: Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments Received on the Bee and Non-Pollinator DRAs.* January 6, 2020.

Additionally, the agency received comments on the preliminary risk assessments that resulted in revised risk assessments and/or adjustments to EPA's risk management approach. These comments are captured below, along with the agency's responses to those comments. The agency thanks all commenters for their comments.

Comments Submitted by Syngenta Regarding the Thiamethoxam Draft Human Health Risk Assessment in EPA-HQ-OPP-2011-0581-0227

Comment: Syngenta noted that the Cruiser 5FS (100-941) label currently includes the following use restriction, 'Do not apply more than 38 gallons of Cruiser 5FS per 8-hour day for seed treatments utilizing an open system,' and requested the EPA to include this restriction in the risk assessment for the liquid product, open system seed treatment scenarios.

EPA Response: The agency agrees that the seed treatment exposure calculations using application rates from EPA Reg. # 100-941 should also include the gallons per day restriction noted on the label. However, the agency identified labels (*e.g.,* EPA Reg. # 100-1184) that did not include a gallons per day restriction. Additionally, the agency determined risks of concern for seed crop uses (specifically field, pop and sweet corn) identified on these labels, even when the maximum personal protection equipment (PPE; double-layer clothing and gloves and a respirator) were considered. As a result, the agency is proposing a requirement that commercial facilities perform thiamethoxam corn seed treatments only in closed loading systems. For more information, please refer to Section III.A.1 and IV.A.3 of this PID, as well as *Thiamethoxam. Revised Response to Public Comments on the Thiamethoxam Human Health Draft Risk Assessment for Registration Review,* available in the thiamethoxam docket.

Comment: Syngenta noted that the agency's occupational risk assessment for onion seed handlers used an onion seed throughput rate of 5,000 lb. seed treated/day. This value is inconsistent with EPA's SOP 15.1, where the onion seed throughput rate is defined as 3,000 lb. seed treated/day. The SOP value is also consistent with throughput rate of 3,000 lb. seed treated/day EPA used for onions in the *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review.* Based on this finding, Syngenta asked the agency to refine the thiamethoxam assessment to align with EPA's SOP and the clothianidin assessment.

EPA Response: The agency agrees that the value of 3,000 lbs. seed treated/day should have been used for the assessment of onion seed. After refining the assessment, the agency determined that there are no risks of concern for activities associated with treating onion seed (margin of errors (MOEs) range from 130 to 950; LOC = 100).

Comment: Syngenta noted that the seeding rate of 4 lb. seed/A for bulb onions should have been used in the risk assessment.

EPA Response: The agency agrees that the seeding rate of 4 lbs. seed/A, which results in 320 lbs. seed planted/day, should have been used for the assessment of onion seed. After refining the model, the agency determined that there are no risks of concern for activities associated with planting onion seed.

Comment: Syngenta noted the Cruiser 5FS (100-941) and Cruiser Maxx Rice (100-1369) labels currently include the following use restriction, 'Do not exceed 120 lb. seed per acre,' and requested this maximum rate be used in the agency's risk assessment.

EPA Response: The agency agrees that the identified labels include a restriction of 120 lbs. seed/A for rice. After modifying the rate used, based on this restriction, the agency determined that there are no risks of concern for activities associated with rice seed.

Comment Submitted by ELANCO Regarding Thiamethoxam's Draft Human Health Risk Assessment (EPA-HQ-OPP-2011-0581-0233)

Comment: ELANCO expressed concerns over an occupational exposure scenario in the draft human health risk assessment for thiamethoxam. The agency modeled the mixer/loader/applicator exposure scenario for dry flowable formulations via mechanically pressurized handgun (for poultry/livestock/horse barn sites) using an assumption of 1,000 gallons of product application volume per day. ELANCO did not believe the assumption of 1,000 gallons/day of product applied by mechanically pressurized handgun for these sites reflects actual use practices and asked the agency to refine this assessment.

EPA Response: The agency agrees that since the product label specifies spot treatment of poultry houses only, the assumption of 1,000 gallons/day is an overestimate for the mechanically-pressurized handgun scenario. The agency updated the area treatment assumptions for poultry houses and determined that 12,300 sq. ft. for a perimeter/feed line treatment of one house is appropriate. The agency also determined that the maximum number of poultry houses treated by one worker per day is 10, which resulted in a maximum area of 123,000 sq. ft. feedline/perimeter treated per day.

Using these refined assumptions for both clothianidin and thiamethoxam, the agency determined that the risk estimates changed substantially. For clothianidin, there are no longer risks of concern for poultry house treatments (MOEs range from 370 to 69,000), though there are still risks of concern for other livestock housing scenarios. For thiamethoxam, there is no risk of concern to mixers/loaders/applicators of dry flowable (DF) formulations using a mechanically-pressurized handgun in poultry houses with PPE (single-layer clothing and gloves, and a

respirator; MOE = 160). However, the refined assessments identified new exceedances for mixers/loaders/applicators of DF formulations of thiamethoxam using a backpack sprayer, even if the maximum PPE is considered (*e.g.,* double-layer of clothing and gloves, and a respirator; MOE = 75). For more detailed information, refer to Section III.A.1 of this PID, and *Estimate of Area Treated per Day for Insecticides in Poultry Houses and Amount of Clothianidin Handled per Day When Using a Mechanically Pressurized Handgun*; *Thiamethoxam. Revised Response to Public Comments on the Thiamethoxam Human Health Draft Risk Assessment for Registration Review*; and *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment*; available in the dockets.

Comment Submitted by the Massachusetts Office of the Attorney General (EPA-HQ-OPP-2011-0920-0725):

Comment: The Massachusetts Office of the Attorney General (MA-OAG) expressed concerns regarding risks to pollinators from residential homeowner applications of neonicotinoids on gardens, lawns and ornamentals. MA-OAG also highlighted that many retailers have voluntarily committed to phasing out the sale of plants and other products containing neonicotinoid insecticides. MA-OAG suggests that the agency severely curtail the use of neonicotinoids.

EPA Response: The agency recognizes the potential risks to pollinators from homeowner applications of neonicotinoids on gardens, lawns and ornamentals. In response, the agency is proposing to require advisory label language that states, "Intended for use by professional applicators". Please refer to Section IV.A of this PID for additional details regarding the proposed label changes.

Comments Submitted Concerning the Preliminary Pollinator Risk Assessments:
The agency also received a number of comments regarding the preliminary pollinator risk assessments, including those concerning the scientific methodology or rationale in these assessments. These comments were considered in the preparation of the final pollinator risk assessments. The agency's responses can be found below. These comments were received from Academia, Beekeepers (BK), Beyond Pesticides (BP), the Center for Biological Diversity (CBD), California Citrus Mutual (CCM), the Center for Food Safety (CFS), CropLife America (CLA), Dancing Bee Gardens (DBG), GreenCAPE (GC), the National Corn Growers Association (NCGA), the National Cotton Council (NCC), the Natural Resources Defense Council (NRDC), the National Wildlife Federation (NWF), the Pesticide Policy Coalition (PPC), the Pollinator Stewardship Council (PSC), the San Francisco Estuary Institute (SFEI), the University of California – Riverside (UCR), the University of California – San Diego (UCSD), the United States Department of Agriculture (USDA), and Xerces Society for Invertebrate Conservation (XSIC).

For a more comprehensive account of the comments related to the preliminary pollinator risk assessments, including those summarized in this PID, refer to *EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran), Clothianidin Non-pollinator Addendum and*

Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments and *Thiamethoxam: Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments Received on the Bee and Non-Pollinator DRAs*, which are available in the public dockets.

Summary of Comments (BK, BP, CBD, CCM, CFS, DBG, GC, NCC, NRDC, NWF, SFEI, UCR, UCSD): Several commenters asked the agency to refer to open literature studies for data and/or methodologies to be incorporated into the EPA's pollinator assessment. These studies covered a range of considerations including, but not limited to, assessing risk to additional pollinator species (*e.g.* non-*Apis*), sub-lethal effects, and toxicity endpoints.

EPA Response: EPA relies on the best available science at the time of conducting its assessments. In the risk assessment process, numerous studies are considered and evaluated for inclusion in the assessments based on the agency's open literature guidance. Open literature studies that meet the guidance criteria are then selected for inclusion in the risk assessments. The selected studies are then weighted based on the scientific evaluation. EPA acknowledges the growing body of studies/data/methodologies and has considered additional studies in the final pollinator assessments that were brought to the agency's attention as comments received on the preliminary pollinator assessments.

Summary of Comments (Academia, BK, CBD, CFS, CLA, DBG, NRDC, NWF, PSC, USDA, XSIC): Several commenters suggested the Tier II colony feeding studies were inadequate, claiming design or conduct flaws (*e.g.* lack of overwintering, removal of colonies due to supersedure, failure to consider genetic variability).

EPA Response: The agency reviewed the study protocols prior to test initiation and determined that the study designs were appropriate for generating data for use in a regulatory risk assessment. While EPA reviewed protocols and determined that the studies were appropriate for risk assessment, the agency acknowledges that there were some issues with the initial studies. Therefore, EPA incorporated revised studies into the final pollinator assessments. These new studies all included successful overwintering control hive components such as colony strength, number of broods, food stores, etc., however, the agency notes that the treatment-related effects measured after overwintering were equal to or less sensitive than those measured prior to overwintering; since endpoints were based on effects observed during the season of the application, they were also protective of effects that may occur after overwintering. Data evaluation records for these studies are publicly available (regulations.gov; EPA-HQ-OPP-2011-0581-0040 and EPA-HQ-OPP-2011-0865-0179) and list the perceived strengths and limitations of these studies.

Summary of Comments: Several commenters expressed concerns that the agency did not implement a consistent methodology for the four nitroguanidine-substituted neonicotinoids in the preliminary pollinator risk assessments.

EPA Response: The initial registrations for the four nitroguanidine-substituted neonicotinoids were not concurrent, and, as a result, the registration review schedule for these chemicals were

not concurrent. As such, the preparation of the initial risk assessments for these four chemicals occurred at different times, where imidacloprid was assessed prior to the remaining three nitroguanidine-substituted neonicotinoids. However, since the release of the preliminary pollinator assessments, the agency has made a programmatic decision to align the registration review schedules for all four nitroguanidine-substituted neonicotinoids. Consequently, the final pollinator assessments are now aligned in methodology and consistency to the greatest extent possible.

Summary of Comments: Several comments were submitted on the bee bread method to evaluate pollen exposure, specifically that an unvetted method should not be used (NCC, CBD, PPC); the bee bread method overestimates exposures to pollen in the hive, and that these estimates should be converted to nectar equivalents that can be compared to the sucrose no observed adverse effect concentration (NOAEC; CLA, NCGA). In addition, the USDA had several specific comments on use of the bee bread method (*e.g.*, unvetted methodology, seasonality, carbohydrate and protein tracking, foraging assumptions, etc.) to evaluate pollen exposure in the clothianidin and thiamethoxam preliminary bee risk assessments. For more detail on USDA's concerns, reference EPA-HQ-OPP-2011-0865-0220.

EPA Response: Based on the public comments received, and new data available, including new colony feeding studies with spiked pollen and a supplement of an expanded suite of available empirical residue in pollen and nectar studies, the method to evaluate the pollen route of exposure has been updated in the final pollinator risk assessments. In short, the updated approach considers exposure via residues in pollen (and nectar) on a total dietary basis by converting pollen concentrations into nectar equivalents and summing the residues from both matrices (where appropriate) to estimate a single exposure number for comparison to a sucrose-based endpoint (NOAEC). See *Attachment 1. Tier II Method for Assessing Combined Nectar and Pollen Exposure to Honey Bee Colonies,* within each chemical-specific docket for a full explanation of the revised pollen method.

Comments Submitted by Syngenta Regarding Pollen Residues Used in the Preliminary Bee Risk Assessment (EPA-HQ-OPP-2011-0581-0075):

Comment: Syngenta expressed concerns that the canola study (MRID 49819502) cited in the *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* did not effectively identify the source (soil vs. treated seeds) of thiamethoxam residues in pollen. Syngenta was also concerned that the chronic EECs were based on a single sampling interval. Syngenta requested that the agency use the pollen and nectar residue data from another canola study (MRID 49775702) to refine the bee risk assessment.

EPA Response: The agency updated the seed treatment risk assessment analysis to include MRID 49775702. Please refer to the *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, available in the clothianidin and thiamethoxam dockets.

Comments Submitted Concerning the Preliminary Non-Pollinator Risk Assessments:

The agency received numerous comments in response to the preliminary non-pollinator risk assessments conducted for the four nitroguanidine-substituted neonicotinoids, including comments concerning the scientific methodology or rationale in these assessments. These comments were considered in the preparation of the final non-pollinator risk assessments. These comments were received from the AVAAZ, the Bay Area Clean Water Agencies (BACWA), Bayer CropScience, the California Department of Pesticide Regulation (CDPR), CropLife America (CLA), the San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), the Vermont Agency of Agriculture Food and Markets (VAAFM), and Xerces Society for Invertebrate Conservation (XSIC). The agency's response can be found below.

For a more comprehensive account of the comments related to the preliminary non-pollinator risk assessments and their responses, including those summarized in this PID, refer to *EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran), Clothianidin Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments* and *Thiamethoxam: Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments Received on the Bee and Non-Pollinator DRAs*, which are available in the public dockets.

Summary of Comment (CDPR and VAAFM): CDPR asserted that the neonicotinoid assessments did not adequately consider the potential runoff from treated seeds planted greater than 2 cm below the soil surface as the EPA's Pesticide Water Calculator (PWC) model used in the assessment does not quantitatively estimate pesticide residues from treated seeds planted below 2 cm (EPA-HQ-OPP-2008-0844-1116). However, CDPR referenced monitoring data (Hladik *et. al.,* 2014) that found that pesticide detections in surface water can be associated with rainfall events following planting of treated seeds, suggesting a link between seed treatments and pesticide detections in surface water. It was noted, though, that this study does not identify the depth at which the seed treatments in question were planted. Additionally, VAAFM reported maximum concentrations of neonicotinoids in the streams receiving effluent from tile drains (see EPA-HQ-OPP-2008-0844-1175 for additional details). CDPR suggested employing refined future modeling efforts to include soil runoff modeling to account for subsurface flow such as tile drains commonly used in agriculture.

EPA Response: The agency recently re-evaluated its surface water modeling for seed treatments. The agency no longer models applications "at depth", which could potentially overlook pesticide residues in runoff from treated seeds planted at depths below 2 cm. Instead, the agency has elected to use the "increasing with depth" application of the PWC model, which assumes that some portion of the applied chemical will be available to runoff, even when planted at depth. These assumptions were implemented in the models included in the comparative aquatic neonicotinoid risk assessment and associated documents, which identified acute and chronic risk exceedances for aquatic invertebrates (see Section III.B.1 of this PID).

The agency is proposing label language to mitigate potential risks from runoff. The proposed label language covers treated seeds, but also includes statements for spray and foliar

applications. For a detailed description of the proposed label language please refer to Sections IV.A.7 and IV.A.8, and Appendix B.

Summary of Comments (AVAAZ, BACWA, CDPR, CLA, SFBRWQCB, XSIC): Several commenters (EPA-HQ-OPP-2008-0844-1192, EPA-HQ-OPP-2011-0865-1068, EPA-HQ-OPP-2008-0844-1116) assert that ample evidence exists in the literature to show that relatively small concentrations of neonicotinoids can trigger harmful effects; that invertebrates are harmed at levels well below the current aquatic life benchmarks, and that these benchmarks should be revised. The commenters also felt that the following studies should be considered in the assessments:

- Maloney, E. M., Morrissey, C. A., Headley, J. V., Peru, K. M., & Liber, K. (2017). Cumulative toxicity of neonicotinoid insecticide mixtures to *Chironomus dilutus* under acute exposure scenarios. *Environmental Toxicology and Chemistry*, 36(11), 3091-3101.
- Miles, J. C., Hua, J., Sepulveda, M. S., Krupke, C. H., & Hoverman, J. T. (2017). Effects of clothianidin on aquatic communities: Evaluating the impacts of lethal and sublethal exposure to neonicotinoids. *PloS One*, 12(3), e0174171.
- Raby, M., Nowierski, M., Perlov, D., Zhao, X., Hao, C., Poirier, D. G., & Sibley, P. K. (2018). Acute toxicity of 6 neonicotinoid insecticides to freshwater invertebrates. *Environmental Toxicology and Chemistry*, 37(5), 1430-1445.

Conversely, CLA (EPA-HQ-OPP-2008-0844-1562) asserted that the application of the most conservative endpoint to assess risk to all aquatic invertebrates is overly conservative and does not account for diversity of aquatic invertebrate communities.

EPA Response: The agency has considered the additional information provided from the above studies. Raby *et. al.* conducted a comparative analysis by testing the four nitroguanidine-substituted neonicotinoids on 7 aquatic invertebrate species in a controlled laboratory environment. The agency also performed a cursory review of Maloney *et. al.* and Miles *et.al.*, which report lethal concentrations (LC_{50}) similar to those reported in *Raby et. al.* Overall, the agency found the Raby *et. al.* study acceptable for quantitative use in risk assessment, however, the agency concluded that the study does not change the risk conclusions for aquatic invertebrates as described in the preliminary ecological risk assessments. For more information, refer to the *Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoids using Raby et al. (2018) toxicity data* available in each docket.

Comment Submitted by Syngenta Regarding the Avian Endpoints Used in the Preliminary Aquatic and Non-Pollinator Risk Assessment for Thiamethoxam (EPA-HQ-OPP-2011-0581-0228):

Comment: Syngenta noted that the endpoints reported for the mallard reproduction study were expressed in milligrams of active ingredient per kilogram of bodyweight (mg a.i./kg-bw), but should have been reported in milligrams of active ingredient per kilogram of diet (mg a.i./kg-diet; p. 82 of *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review)*. Syngenta asked that the agency review the reported figures and provide the daily dose calculations.

EPA Response: The agency confirmed that there was a typographical error in the endpoints reported for the mallard reproduction study, and that these figures should have been expressed as mg a.i./kg-diet. Please refer to *Thiamethoxam: Addendum to the Non-Pollinator Draft Risk Assessment (DRA) and Response to Public Comments Received on the Bee and Non-Pollinator DRAs*, available in the thiamethoxam docket, for the daily dose conversion calculation and further details.

II. USE AND USAGE

Clothianidin

Clothianidin is a nitroguanidine-substituted neonicotinoid insecticide, which was first registered for use as pesticide in the United States in 2003. Clothianidin is used to target a wide variety of insect pests including, but not limited to piercing sucking pests such as aphids, mealybugs, sharpshooters, Asian citrus and pear psyllids and stinkbugs; coleopteran pests such as corn rootworm, billbugs, white grubs, and plum curculio; and a variety of sporadic pests such seed maggots and symphylans. Products containing clothianidin are formulated as granular, dust, seed treatment, solid agar, pressurized liquid, emulsifiable concentrate, soluble concentrate, and ready-to-use solutions on a variety of agricultural and non-agricultural use sites. Agricultural sites include vegetable crops, tree fruits, tree nuts, and field crops. Applications can also be made to poultry litter manure in chicken houses for darkling beetles and other poultry houses pests and later utilized as outdoor fertilizer. Non-agricultural uses include turf and ornamental plants, and indoor and outdoor residential, commercial, and industrial sites.

The largest agricultural use for clothianidin, in terms of lbs. a.i. applied, has been in the form of seed treatments. On average, between 2005 and 2014, over 1,400,000 lbs. a.i. of clothianidin were used annually for seed treatments on various field crops including corn, cotton, soybean, and wheat.[1] There are also seed treatments registered for various vegetable crops. More recent data on seed treatment usage are not available.

From 2007-2016, soil and foliar usage (together) averaged about 300,000 lbs. a.i.[2], applied to approximately 400 million acres annually.[3] Agricultural sites with the highest usage of clothianidin in average pounds applied per year are cotton (10,000), rice (6,000), and soybean (5,000).[2] The highest percent crop treated (PCT) values are reported for table grapes (20%), broccoli (15%), and figs (10%).

The agency has limited usage data on non-agricultural use sites. In 2016, approximately 9,000 lbs. a.i. of clothianidin was used by pest management professionals for outdoor pest control (*i.e.*,

[1] *Clothianidin (044309) Screening Level Usage Analysis (SLUA), December 30, 2015.*
[2] *Clothianidin (044309) Screening Level Usage Analysis (SLUA), July 8, 2019*
[3] *Agricultural Market Research Data (AMRD). 2007-2017.*

turf and ornamental plants, including in residential areas) and over 4,000 lbs. a.i. for indoor pest control.[4]

Thiamethoxam

Thiamethoxam was first registered for use as a pesticide in the United States in 1999. Thiamethoxam is commonly used to target piercing sucking pests such as aphids, leafhoppers, and whitefly in addition to certain hard to kill pests such as pepper weevil and thrips. Products containing clothianidin are formulated as wettable powder, dust, granular, microencapsulated, solid agar, soluble concentrate/solid, flowable concentrate, emulsifiable concentrate, and ready-to-use solutions. Thiamethoxam is registered to control various insects on a wide variety of agricultural use sites (*e.g.* field, forage, fruit, spice, and vegetable crops) and non-agricultural use sites (*e.g.* in and around residential/domestic dwellings, food handling establishments, commercial/ institutional/industrial areas, livestock pens, poultry houses, wood or wooden structures, and transportation vehicles).

As an antimicrobial pesticide, thiamethoxam was also registered for use as a wood preservative, however, these registrations were cancelled on September 18, 2013.[5]

The largest agricultural use for thiamethoxam, in terms of lbs. a.i. applied, has been in the form of seed treatments. On average, between 2005 and 2014, approximately 800,000 lbs. a.i. of thiamethoxam were used annually for seed treatments on various field crops including corn, cotton, soybean, potato, and wheat.[6] There are also seed treatments registered for various vegetable crops. More recent data on seed treatment usage are not available.

From 2007-2017, soil and foliar usage (together) averaged about 100,000 lbs. a.i.[7], applied to approximately 1.7 million acres annually.[3] Agricultural sites with the highest usage of thiamethoxam in average pounds applied per year are cotton (36,000 lbs.), soybean (15,000 lbs.), and potatoes (10,000 lbs.).[6] The highest percent crop treated (PCT) values are reported for grapefruit (30%), lettuce (20%), peppers (20%), and strawberry (20%).

The agency has limited usage data on non-agricultural use sites. Usage of thiamethoxam by pest management professionals has not been reported in recent years.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessments for clothianidin and thiamethoxam are presented below. The agency used the most current science policies and risk assessment

[4] *Non-agricultural Market Research Data (NMRD), 2017.*
[5] *78 FR 57379.*
[6] *Thiamethoxam (*060109*) Screening Level Usage Analysis (SLUA), January 26, 2016.*
[7] *Thiamethoxam (*060109*) Screening Level Usage Analysis (SLUA), July 25, 2019.*

methodologies to prepare risk assessments in support of the registration review of clothianidin and thiamethoxam. For additional details on the human health assessment for clothianidin, see the *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review*, available in the public docket for clothianidin: EPA-HQ-OPP-2011-0865. For additional details on the human health assessment for thiamethoxam, see the following documents: *Thiamethoxam. Draft Human Health Risk Assessment for Registration Review;* and *Thiamethoxam Registration Review: Human Health Scoping Information Regarding the Wood Preservative Uses (Post Peer Review Update)*. Both documents are available on regulations.gov in the thiamethoxam docket: EPA-HQ-OPP-2011-0581.

1. Risk Summary and Characterization

The toxicology databases for both clothianidin and thiamethoxam are complete. Studies for clothianidin were performed via the oral, inhalation, and dermal routes of exposure. For thiamethoxam, studies were only conducted for oral and dermal routes of exposure, where the agency's Hazard and Science Policy Council (HASPOC) found that the inhalation toxicity study could be waived based on a weight-of-evidence (WOE) approach (TXR# 0057630, M. Lewis, 09/22/17). The risk assessments for each of these two active ingredients use conservative assumptions, and the most sensitive endpoint from the respective toxicity databases, and are therefore protective of all potential reproductive, developmental and neurotoxic effects. Given the completeness of the toxicity database; clear reproductive and developmental NOAELs; and protective neurotoxic endpoints, the agency determined that reductions of the Food Quality Protection Act (FQPA) safety factors to 1X are appropriate for both clothianidin and thiamethoxam. In addition, both clothianidin and thiamethoxam are classified as "not likely to be carcinogenic to humans" and therefore no quantitative cancer risk assessment was conducted for either chemical.

There are no adverse effects observed in the route-specific dermal toxicity studies up to the limit dose in any tissue or organ for either clothianidin or thiamethoxam. However, since increased susceptibility was observed, oral points-of-departure (PODs) were selected for dermal exposure scenarios because the dermal toxicity studies did not evaluate developmental or reproductive endpoints. For clothianidin, oral PODs were also selected for the inhalation routes of exposure because the inhalation toxicity study did not evaluate developmental or reproductive endpoints. For thiamethoxam, a route-specific subchronic inhalation study was not recommended (TXR# 0057630, M. Lewis, 09/22/17).

Residues of thiamethoxam are expressed in terms of the combined residues of the insecticide thiamethoxam and its metabolite CGA-322704, also referred to as clothianidin; *N*-[(2-chloro-thiazol-5-yl)methyl]-*N'*-methyl-*N''*-nitro-guanidine. As noted previously, clothianidin is a registered pesticide active ingredient but is also a major degradate of thiamethoxam. The agency conducted separate risk assessments for thiamethoxam and for clothianidin, which included residues resulting from application of thiamethoxam.

There were no dietary, residential, aggregate or bystander risks of concern identified for either clothianidin or thiamethoxam. However, the agency's human health risk assessments identified

potential risks of concern for certain occupational handler scenarios, which is described in further detail below, as well as in *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review* and *Thiamethoxam. Draft Human Health Risk Assessment for Registration Review,* which are available in the chemical-specific docket.

Clothianidin

Dietary Risk
There are no acute or chronic dietary (food and drinking water combined) exposure estimates of concern, as they are all below the agency's level of concern (*i.e.,*100% of the acute or chronic population adjusted dose (aPAD or cPAD, respectively)) using conservative assumptions such as 100% crop treated for all commodities, tolerance-level residues (acute), field-trial-average residues (chronic), high-end estimates for drinking water derived using the highest application rates and modeling based on the most vulnerable areas. The clothianidin acute risk estimate for the most highly exposed population subgroup, children 1 – 2 years old, was 29% of the aPAD. The chronic dietary estimate for the most highly exposed population subgroup (infants) was 9% of the cPAD.

Residential Handler, Residential Post-Application, and Non-Occupational Spray Drift Risk
There are no residential risk estimates of concern for handlers, as all scenarios (combined dermal and inhalation) resulted in margins of exposure (MOEs) greater than the EPA's level of concern (LOC) of 100, ranging from 460 to 27,000,000. There are also no post-application residential risks of concern for adults or children; all combined estimates (dermal, inhalation and incidental oral) are greater than the LOC of 100, with MOEs ranging from 160 to 1,400,000. While there is the potential for bystander exposure to drift from sprays applied to agricultural areas, exposures resulting from spray drift were not quantitatively assessed because the turf exposure assessment is considered to be protective.

Aggregate Risk
There is potential for aggregate exposure to clothianidin from combined exposure through dietary and residential sources. The EPA assessed potential aggregate risks for all exposure durations. The acute aggregate assessment is equivalent to the dietary risk assessment which, as mentioned previously, found no risks of concern. All short-term aggregate exposures are also not of concern (MOEs range from 150 to 390; LOC = 100). Chronic exposure to clothianidin (*i.e.*, continuous exposure for > 6 months) is not expected to occur, therefore, chronic aggregate risk estimates are equivalent to the dietary risk estimates, which are not of concern.

Occupational Handler and Occupational Post-Application Risk
Except for seed treatment use on corn, there are no agricultural use occupational handler scenarios that result in risk estimates of concern; MOEs for other agricultural uses range from 510 to 1,200,000 (LOC = 100). The MOE for occupational handlers performing multiple activities (loading/applying, sewing, bagging, *etc.*) for corn seed treatment is 71 with the currently label-required personal protective equipment (PPE) of single layer clothing (*i.e.,* long sleeves and pants) and gloves. With the addition of a respirator, the risk would no longer be of concern (MOE = 190). All other seed treatment scenarios did not result in risk estimates of concern, with MOEs ranging from 110 to 250,000.

Two non-agricultural scenarios resulted in risk estimates of concern (MOEs < LOC of 100). The first is for mixers/loaders/applicators of liquid formulations via mechanically-pressurized handguns in poultry houses and other livestock housing (i.e., barns/feedlots), with an MOE of 54. In the 2019 memorandum *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment*, the agency updated some of its risk conclusions for non-agricultural use scenarios. On the basis of updated area treatment assumptions, the agency concluded that there are no longer occupational risk estimates of concern for use of clothianidin in poultry houses, with risk estimates (MOEs) ranging from 370 to 69,000 (LOC = 100). However, EPA also noted in the response-to-comments memo that uses on other livestock housing (i.e., barns/feedlots) are still assessed assuming the original use assumptions because the updated poultry house treatment area is not applicable to these scenarios. For scenarios in these other livestock houses, there are potential risks of concern for barn/feedlot uses with mechanically-pressurized handguns (MOE = 80). The addition of gloves to these use scenarios results in a MOE of 97.

The second non-agricultural scenario is for an applicator treating commercial buildings using liquid aerosol cans, which resulted in an MOE of 48. Adding gloves and a respirator would raise the MOE to 140, and the scenario would no longer be of concern. There were no other non-agricultural scenarios that resulted in risk estimates of concern, with MOEs ranging from 130 to 150,000. In addition, there are no occupational post-application risk estimates of concern, with all MOEs greater than the LOC of 100.

Thiamethoxam

Dietary Risk
There are no acute or chronic dietary risk estimates of concern for thiamethoxam, as they are all below 100% of the thiamethoxam aPAD and cPAD, respectively. Children 1 – 2 years old are the most highly exposed population subgroup for both acute dietary risk (8% of the aPAD) and chronic dietary risk (48% of the cPAD).

Residential Handler, Residential Post-Application, and Non-Occupational Spray Drift Risk
There are no residential risk estimates of concern for handlers (combined dermal and inhalation MOEs range from 770 to 260,000; LOC = 100). There are also no post-application residential risks of concern for adults or children; all estimates (dermal, inhalation and/or incidental oral MOEs range from 180 to 9.4×10^8). While there is the potential for bystander exposure to drift from sprays applied to agricultural areas, exposures resulting from spray drift were not quantitatively assessed because the turf exposure assessment is considered to be protective.

Aggregate Risk
There is potential for aggregate exposure to thiamethoxam from combined dietary and residential sources. The EPA assessed potential aggregate risks for all exposure durations. The acute aggregate assessment is equivalent to the dietary risk assessment, which, as mentioned previously, identified no risks of concern. There are no short-term aggregate risks of concern (MOEs range 140 to 610; LOC = 100). Chronic aggregate risk estimates for thiamethoxam are equivalent to the dietary risk estimates, which are not of concern.
Occupational Risks

The *Thiamethoxam. Draft Human Health Risk Assessment in Support of Registration Review* included an analysis of 92 different agricultural and non-agricultural occupational handler exposure scenarios. Of those 92 scenarios, 79 are not be of concern (*i.e.*, combined dermal + inhalation MOEs ≥ 100 with baseline attire, or engineering controls in the case of aerial applications).

For the 13 scenarios where the MOEs do not reach the target LOC of 100:

- Gloves mitigate potential risks of concern for:
  - mixing/loading liquid formulations for aerial applications to high-acreage field crops[8] (MOE increases from 98 to 520);
  - mixing/loading/applying liquid formulations for crack and crevice (C&C) via manually-pressurized handwand for applications in warehouses (MOE increases from 91 to 150);
  - mixing/loading/applying liquid formulations for crack and crevice (C&C) via manually-pressurized handwand for applications in childcare centers, schools and institutions (MOE increases from 91 to 150);
  - mixing/loading/applying liquid formulations for crack and crevice (C&C) via manually-pressurized handwand for applications in residential living spaces (MOE increases from 91 to 150);
  - mixing/loading/applying liquid formulations for crack and crevice (C&C) via manually-pressurized handwand for applications to mounds or nests (MOE increases from 6.7 to 630);
  - mixing/loading/applying DF formulations via manually-pressurized handwand to mounds or nests (MOE increases from 87 to 8,600); and
  - mixing/loading/applying DF formulations via mechanically-pressurized handgun for applications to landscaping trees, shrubs and bushes (MOE increases from 65 to 180).
- Gloves and a respirator would mitigate potential risks of concern for:
  - mixing/loading DF formulations for aerial application on sod (MOE increases from 44 to 200);
  - mixing/loading DF formulations for aerial application on high-acreage field crops (MOE increases from 53 to 250);
  - mixing/loading/applying DF formulations via mechanically-pressurized handgun for poultry-house applications (MOE increases from 57 to 160); and
  - mixing/loading/applying liquids with a mechanically-pressurized handgun for warehouse applications (MOE increases from 55 to 190).
- MOEs do not reach the target LOC for the following scenarios:
  - mixing/loading/applying DF formulations via mechanically-pressurized handgun to poultry/livestock house/horse barn/feed lots (MOE is 29 with double layer of protective clothing, gloves, and a respirator); and
  - commercial seed treatment for corn (field, pop, and sweet), safflower, and sorghum (MOEs ranged from 13 to 82).

[8] High-acreage crops include, but are not limited to barley, wheat, rice, cotton, corn, and other crops where 1,200 acres or more are treated per day.

During the public comment period on the draft risk assessment, Elanco contended that the agency's risk estimate was overly conservative because it assumed 1,000 gallons of product application volume per day.

In the 2019 response-to-comments memorandum *Thiamethoxam. Revised Response to Public Comments on the Thiamethoxam Human Health Draft Risk Assessment for Registration Review*, EPA determined that a treatment assumption of 12,300 ft^2 for a perimeter/feed line treatment of one poultry house, with at most 10 poultry houses treated in a day by one worker, is appropriate for assessing potential risks from applications in poultry houses with handheld equipment. Using these updated assumptions, and assuming the use of PPE consisting of gloves and a respirator, the risk estimate for mixing/loading/applying DF formulations using a mechanically-pressurized handgun in poultry houses reaches a combined (dermal plus inhalation) MOE of 160, which is not of concern to the agency.

The response-to-comments memo adds that the revised assumptions for poultry houses also result in a new risk exceedance for mixing/loading/applying DF formulations of thiamethoxam using a backpack sprayer. In this poultry house use scenario, the combined MOE for occupational handler risks is now of concern to the agency even considering maximum PPE (*e.g.*, double layer of clothing and a respirator; combined MOE = 75).

The agency also received comments from Syngenta that facilitated refinements to some of the risk calculations presented in the draft human health risk assessment. After incorporating the volumetric use restriction currently on the label for EPA Reg. #100-941 (Cruiser 5FS) limiting the gallons of product that may be handled per 8-hour day, EPA found that there are no risks of concern (*i.e.*, MOEs are above the LOC) for the seed crops listed on this label (including field corn, popcorn, sweet corn, cotton, flax, mustard, rice, safflower, and sunflower) for all seed treatment activities. However, other labels exist with corn (field, pop, and sweet) seed treatment which do not include volumetric use restrictions, and occupational risks for these labels remain of concern.

Syngenta also provided comments on onion seeding rates. Based on these comments, EPA is revising its assumptions for onion seed treatment rates, which resulted in no risks of concern for activities associated with treating onion seed (MOEs range from 130 to 950).

In addition, there are now no risks of concern for activities associated with planting treated onion seed (MOE= 280).

The EPA has also updated the assumption for the amount of rice seed handled per day. After incorporating a restriction currently on labels[9] capping the allowable amount of rice that may be planted at 120 lbs. seed/A, the MOE for activities associated with rice seed is no longer of concern (MOE =120).

[9] EPA Reg. numbers 100-941 (Cruiser 5FS) and 100-1369 (Cruiser Maxx Rice).

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding as to clothianidin or thiamethoxam and any other substance, and they do not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that either clothianidin or thiamethoxam have a common mechanism of toxicity with other substances.

2. Human Incidents and Epidemiology

The agency reviewed incidents for clothianidin and thiamethoxam using the OPP Incident Data System (IDS) and the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk Pesticides (SENSOR) databases.

Clothianidin
In Main IDS, from January 1, 2012 to July 13, 2017,17 cases were reported involving clothianidin, all of which reported multiple active ingredients. For Aggregate IDS, from January 1, 2012 to April 28, 2017, 52 incidents were reported involving clothianidin and were classified as minor severity.

A query of SENSOR-Pesticides (1998 – 2013) identified four cases involving clothianidin. Of the clothianidin cases reported, three cases involved multiple active ingredients and the fourth case involved only clothianidin. One case was classified as moderate severity and three cases were classified as low severity. All clothianidin cases were occupational in nature.

Based on the continued low frequency of thiamethoxam and clothianidin incidents reported to both IDS and SENSOR-Pesticides, there does not appear to be a concern at this time. The agency will continue to monitor the incident information available for thiamethoxam and clothianidin and additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

Thiamethoxam
In Main IDS, from January 1, 2012 to July 13, 2017, 45 cases were reported involving the active ingredient thiamethoxam. Of these 45 case reports, thiamethoxam was the only pesticidal active ingredient in nine incidents, each classified as moderate severity. The remaining 36 thiamethoxam incidents reported involved multiple active ingredients. In Aggregate IDS, from January 1, 2012 to July 13, 2017, 110 thiamethoxam incidents were reported. These thiamethoxam incidents were all classified as minor severity.

A query of SENSOR-Pesticides (1998 – 2013) identified 16 cases involving thiamethoxam. Eleven cases involved multiple active ingredients and five cases involved a single active ingredient. One case was high in severity, three cases were moderate in severity, and 12 cases were low in severity. Four of the cases were coded as occupational in nature. The one high severity thiamethoxam incident occurred in Michigan in 2011 and involved an adult male who

was not wearing the required PPE (gloves). He experienced a rash that lasted for more than 1.5 months and swelling in his neck that altered his voice.

3. Tolerances

Clothianidin

Tolerances for residues of clothianidin, including its metabolites, are established in 40 CFR §180.586. The tolerance expression for clothianidin contains a coverage and compliance statement and is therefore in accordance with current practices. There are clothianidin tolerance listings for several crop groups that have undergone revisions including Crop Groups/Subgroups 4, 5, 8 and 14, and these changes are summarized in **Table 1** below. The analytical reference standard for clothianidin expired in April 2018, and the registrant is responsible for maintaining reasonable amounts of this standard as long as tolerances remain published in 40 CFR §180.586. See Section 2.2.1 of the *Clothianidin. Draft Human Health Risk Assessment in Support of Registration* for directions on submitting an analytical reference standard for clothianidin.

There is a time-limited tolerance for rice which expired in 2012 for residues of clothianidin on rice seed, which the agency proposes to remove from the 40 CFR 180.586 (a) (2), because there is a permanent tolerance already for clothianidin on rice (grain). In addition, there are opportunities for international harmonization with the tolerances for clothianidin. Some listings are harmonized with Canadian MRLs and others with Codex MRLs. In the case of updates to Crop Groups 4 and 5, some commodities have moved to different crop groups. EPA recommends revising US tolerances to harmonize with Codex MRLs for subgroup 13-07H, Group 15 (except rice), and Group 16 (except rice straw). Additionally, EPA is proposing eliminating trailing zeros listed in tolerances consistent with agency policy. For a full list of proposed clothianidin tolerance changes, please refer to Appendix E Table 1 in this PID.

Table 1: Clothianidin 40 CFR § 180.586: Summary of Proposed Tolerance Actions

Current Commodity Listing	Current Tolerance (ppm)	Proposed Commodity Listing	Proposed Tolerance (ppm)
Vegetable, leafy, except *Brassica*, Group 4	3.0	Separate listings for: Leafy greens Subgroup 4-16A, Leafy petiole vegetable Subgroup 22B, Celtuce, and Florence fennel	3
Vegetable, *Brassica*, leafy, Group 5	1.9	Separate listings for: Brassica leafy greens Subgroup 4-16B; Vegetable, *Brassica*, head and stem, Group 5-16; and Kohlrabi	1.9 (No change)

Table 1: Clothianidin 40 CFR § 180.586: Summary of Proposed Tolerance Actions			
Current Commodity Listing	Current Tolerance (ppm)	Proposed Commodity Listing	Proposed Tolerance (ppm)
Vegetable, fruiting, Group 8, except pepper	0.2	Remove	--
Pepper	0.8	Remove	--
(Addition)	--	Tomato Subgroup 8-10A	0.2
(Addition)	--	Pepper/eggplant Subgroup 8-10B	0.8
Nut, tree, Group 14	0.01	Nut, tree, Group 14-12	0.01 (No change)
Berry, low-growing, Subgroup 13-07H, except strawberry	0.01	Berry, low-growing, Subgroup 13-07H, except strawberry (No change)	0.07
Grain, cereal, Group 15, except rice	0.01	Grain, cereal, Group 15, except rice (No change)	0.04
Grain, cereal, forage, fodder and straw, Group 16, except rice, straw	0.05	Grain, cereal, forage, fodder and straw, Group 16, except rice, straw (No change)	0.2

Thiamethoxam

Tolerances for residues of thiamethoxam, including its metabolites, are established in 40 CFR §180.565. The tolerance expression for thiamethoxam contains both a coverage and compliance statement and is, therefore, in accordance with current practices. There are tolerance listings for thiamethoxam in several crop groups that have undergone revisions including Crop Groups/Subgroups 4, 5A, 5B, 8, 10, 11, 12, and 14. Generally, crop group updates primarily reflect expansions to include additional commodities in the group (for example, inclusion of pistachio in the tree nut crop group). Tolerance actions being proposed for thiamethoxam are summarized in **Table 2** below.

An analytical reference standard for thiamethoxam will expire on October 31, 2020 and the analytical reference standard for CGA-322704 expired on April 1, 2018. The registrant is responsible for maintaining reasonable amounts of this standard as long as tolerances remain published in 40 CFR §180.565. See Section 2.2.1 of the *Thiamethoxam. Draft Human Health Risk Assessment in Support of Registration* for directions on submitting analytical reference standards.

Adequate data have been submitted to support the established tolerances for residues of thiamethoxam in or on food commodities. There are no outstanding data with respect to tolerances. In addition, there are opportunities for international harmonization with the tolerances for thiamethoxam. Some listings are harmonized with Canadian MRLs and others with Codex MRLs. In one instance (Subgroup 13-07A), Canadian and Codex MRLs are harmonized (0.5 ppm) and are greater than the US tolerance (0.35 ppm). For this case, the proposed increase to the US thiamethoxam tolerance is minor and supported by available data. Therefore, EPA is proposing a tolerance revision for harmonization purposes. In the case of updates to Crop Groups 4 and 5, some commodities have moved to different crop groups. Additionally, EPA is proposing

eliminating trailing zeros listed in tolerances consistent with agency policy. For a full list of proposed thiamethoxam tolerance changes, please refer to Appendix E Table 2 in this PID.

Table 2: Thiamethoxam 40 CFR § 180.565: Summary of Proposed Tolerance Actions			
Current Commodity Listing	Current Tolerance (ppm)	Proposed Commodity Listing	Proposed Tolerance (ppm)
Vegetable, leafy, except *Brassica*, Group 4	4.0	Separate listings for: Leafy greens Subgroup 4-16A, Leafy petiole vegetable Subgroup 22B, Celtuce, and Florence fennel	4
Brassica, head and stem, Subgroup 5A	4.5	Separate listings for: Vegetable, *Brassica*, head and stem, Group 5-16; and Kohlrabi	4.5 (No change)
Brassica, leafy greens, Subgroup 5B	3.0	*Brassica* leafy greens Subgroup 4-16B	3
Vegetables, fruiting, Group 8	0.25	Vegetables, fruiting, Group 8-10	0.25 (No change)
Fruit, citrus, Group 10	0.4	Fruit, citrus, Group 10-10	0.4 (No change)
Fruit, pome, Group 11	0.2	Fruit, pome, Group 11-10	0.2
Fruit, stone, Group 12	0.5	Fruit, stone, Group 12-12	0.5
Nut, tree, Group 14	0.02	Nut, tree, Group 14-12	0.02
Pistachio	0.02	Remove	--
Caneberry, Subgroup 13-07A	0.35	Caneberry, Subgroup 13-07A (No change)	0.5

4. Human Health Data Needs

The human health database is complete for both clothianidin and thiamethoxam, and there are no data deficiencies at this time. As noted in the thiamethoxam draft human health risk assessment for registration review, an inhalation toxicity study is not available for thiamethoxam; however, the agency's HASPOC recommended, based on a WOE approach, that the study could be waived (TXR# 0057630, M. Lewis, 09/22/17).

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of clothianidin and thiamethoxam. For additional details on the ecological assessment for clothianidin and thiamethoxam, see the following documents, which

are available in the public dockets for clothianidin and thiamethoxam EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581) at www.regulations.gov.

- *Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review.*
- *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review.*
- *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.*
- *Comparative Analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoids using Raby et al. (2018) toxicity data.*

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. After the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its listed species assessments for clothianidin and thiamethoxam. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

Both clothianidin and thiamethoxam are water-soluble chemicals with low vapor pressure and Henry's Law Constants, indicating that these compounds are unlikely to volatilize in field conditions. Additionally, both active ingredients have low octanol: water partitioning coefficients, which suggests that clothianidin and thiamethoxam are unlikely to bioaccumulate.

Terrestrial Exposure and Risk - Overview

Thiamethoxam is applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, and seed treatments. Clothianidin is applied via the same application methods, but also includes basal bark treatments and spot treatments. For terrestrial wildlife, the agency modeled potential dietary exposure based on consumption of clothianidin and thiamethoxam residues on food items following spray (foliar or soil) applications as well as from possible dietary ingestion of residues on treated seeds. For treated seeds, different seed sizes and planting rates could result in a range of exposures. For clothianidin, potential dietary exposure was also considered from fields where applied manure from poultry house operations may contain clothianidin residues resulting in potential contamination of potential food items (*e.g.*, insects) and/or incidental ingestion of contaminated soil particles.

Overall, acute risks to avian and mammalian species from foliar and soil treatments of clothianidin and thiamethoxam appear to be low. Soil incorporation following soil treatments (or following soil amendment applications of poultry litter with clothianidin residues) decreases potential risks from this use pattern considerably. Exposures from treated seeds result in the highest acute and chronic risks to terrestrial organisms. However, the risks vary considerably. A low number of small treated seeds (*e.g.* lettuce and sugar beets) are required to reach levels of concern for smaller birds and mammals because the surface of these seeds have higher

concentrations of a.i. applied. Also, these smaller seeds are easier for small birds and mammals to consume because of their small size. However, larger seeds (*e.g.* corn and soybean) pose far lower risks to birds and mammals because lower concentrations of a.i. are applied to the seed surface. Also, the larger size of these seeds prevents smaller birds and mammals from consuming them.

For terrestrial invertebrates, the primary routes of exposure assessed include contact of bees with spray droplets and oral ingestion via pollen and nectar. Additionally, exposure can occur from seed treatment dust. Exposure can vary based on use patterns and the attractiveness of a treated crop.

Terrestrial and semi-aquatic (*i.e.* wetland) plant exposure estimates typically include plants that reside near a use area that may be exposed via runoff and/or spray drift from ground and/or aerial applications of a pesticide. For clothianidin and thiamethoxam, the agency only modeled the maximum single foliar (ground) applications (0.4 lbs. a.i./A and 0.265 lbs. a.i./A, respectively) of each active ingredient to turf and/or ornamentals. Aerial applications are not prevalent based on clothianidin and thiamethoxam use patterns for turf or ornamentals, and, therefore, are not considered in these assessments. Risks of thiamethoxam and clothianidin are considered low for terrestrial and semi-aquatic plants.

Mammals – Risk Estimates

Clothianidin is classified as moderately toxic to mammals on an acute oral exposure basis. Chronic exposure with the Norway rat (*Rattus norvegicus*) resulted in effects on growth and maturation in offspring. The chronic mammalian risk quotients (RQs) calculated for clothianidin are based on the chronic mammalian rat no observed adverse effect level (NOAEL) of 9.8 mg/kg-bw/day. Thiamethoxam is considered slightly toxic to mammals (LD_{50} = 1563 mg/kg-bw) on an acute oral basis, and in a chronic exposure reproduction test reduced weight gain was seen in offspring at 158 mg/kg-bw/day (NOAEL 61 mg/kg-bw/day). Potential risk was evaluated at three different weight classes of mammal: small (15 g), medium (35 g), and large (1000 g). Further details on ecological risks are provided below in separate sub-sections for clothianidin and thiamethoxam.

Clothianidin:

Foliar Applications: There are no acute risks of concern via foliar applications for mammalian species of any weight class even when assessed using the maximum registered single application rate of 0.4 lbs. a.i./A (RQs <0.01 – 0.20; LOC = 0.5). Acute RQs are highest for small mammals feeding on short grass.

There are no chronic mammalian LOC exceedances on a chronic dietary basis for all application rates (highest RQ = 0.49; LOC = 1.0), but there are exceedances for dose-based RQs based on single application rates. Risk estimates rose with increases in the modeled application rate. For single applications at the 0.1 lbs. a.i./A rate, there was only a marginal exceedance of the chronic LOC (1.0) for small mammals consuming short grass (RQ = 1.06). At that same application rate but with an assumption of two applications per year, chronic dose-based RQs exceeded the LOC for small mammals consuming short grass and/or broadleaf plants (RQs = 1.99 and 1.12,

respectively) as well as medium-sized mammals consuming short grass (RQ = 1.70). Potential risks of concern are also identified for both small and medium mammals consuming short grass and/or broadleaf plants (highest RQ = 2.12) at an application rate of 0.2 lbs. a.i./A. At the single foliar application rate of 0.4 lbs. a.i./A, chronic dose-based risks of concern are identified for all mammal size classes depending on the dietary item (highest RQ = 4.24), with exception of fruits/pods/seeds and grains.

Soil Applications: Based on the acute analysis (LD_{50}/ft^2; herein referred to as "area-based analysis") for soil applications, the acute LOC (0.5) is exceeded for small mammals only at the highest two application rates assessed: 0.4 lbs. a.i./A (RQ = 0.61), which represents the highest soil application rate, and 0.49 lbs. a.i./A (RQ = 0.75), which represents residues in fields following soil amendment applications of manure pulled from clothianidin-treated poultry houses.

A second way in which the agency assessed potential risks of soil applications of clothianidin to mammals was by using the upper bound Kenaga EECs in arthropods following soil applications as a surrogate for potential exposures of likely dietary items following soil exposures. Based on this analysis, there are no acute risks of concern for mammals (LOC = 0.5; highest RQ = 0.10 for the scenario of exposed poultry litter used as a soil amendment). However, four chronic risk estimates exceed the LOC (1.0; highest RQ = 2.04), indicating chronic risks of concern to small-medium mammals from soil applications at the application rate of 0.4 lbs. a.i./A, as well as exposure to residues from poultry litter soil amendment applications on agricultural fields (0.49 lbs. a.i./A).

Treated Seed Applications: RQs were calculated for six crops (corn, soybean, cotton, sugar beet and lettuce) when assessing potential risks to mammals from clothianidin-treated seeds. Modeled uses were selected to be representative of high-acreage crops (*e.g.* corn, soybean, cotton), to provide a range of application rates (*e.g.* cotton 0.071 lbs. a.i./A to lettuce 0.198 lbs. a.i./A), and present a range of application rate to seed size ratios (*e.g.* lettuce and corn).

For all size classes of mammals, the acute LOC was exceeded (RQs ranged from 0.22 to 174) for dose-based exposures to any of the assessed seeds other than soybeans. Moreover, for all size classes of mammals, acute exceedances occur where less than 10% of the animal's diet consists of treated lettuce or sugar beet seeds (or crops for which lettuce and sugar beets serve as surrogates). Area-based analysis identified no risks of concern for mammals (RQs <0.01 to 0.31).

The chronic LOC was exceeded for all size classes of mammals consuming any of the assessed treated seed (RQs ranged from 4.57 to 3655). The highest chronic RQ exceedances for treated seed was for lettuce.

Thiamethoxam:

Foliar and Soil Applications: There were no acute or chronic risks of concern identified for mammals from any foliar or soil applications. Estimates presented in the agency's *Preliminary Risk Assessment to Support the Registration Review of Thiamethoxam* were based on an upper-

bound application rate for both foliar agricultural (0.086 lbs. a.i./A) and soil agricultural/non-agricultural uses (0.265 lbs. a.i./A). Modeling accounted for up to three applications of thiamethoxam are made per growing season.

Treated Seed Applications: There were potential acute risks of concern identified for mammals from certain thiamethoxam seed treatment uses. Sugar beets were the only crop assessed where there was an acute LOC exceedance for thiamethoxam-treated seeds. These exceedances were identified for all size classes of mammals (RQs = 0.99 – 2.16).

There were chronic risk exceedances for corn, cotton, and sugar beet (RQs = 2.73 – 55.33). There were no chronic LOC exceedances for soybean. Chronic LOC exceedances were an order of magnitude greater for sugar beet (RQs = 25.33 – 55.33) than for corn (2.79 – 6.08) or cotton (2.73 – 5.97). For both acute and chronic risks, RQs increased as mammal size decreased.

Mammals – Risk Characterization

Clothianidin and Thiamethoxam

There are several variables impacting potential risks to mammals from seed treatments, such as how far apart and how many seeds are available at a given time, the amount of cover provided by field conditions (newly planted fields are likely to be open and provide less cover than no till fields, making them less attractive as a forage location for smaller mammals), and whether or not seeds are on the surface of a field vs. incorporated into the soil. Seeds buried below the soil surface are not as easily found by foraging mammals, reducing the potential for exposure and increasing the amount of time required to find them, which in turn decreases the likelihood of potential chronic exposure. However, some mammals are highly capable of burrowing in soil and acquiring buried seeds and may cache them for later consumption. In addition, in the case of chronic risks, the impact of consuming treated seeds may vary by life stage. It is currently an uncertainty whether effects seen in laboratory-based reproduction studies occur at a sensitive life stage or are due to the entire exposure period.

Another source of uncertainty are the scaling factors used to predict toxicity in different size mammals. This is important because the number of seeds a mammal needs to consume before toxicological effects are expected vary by the size of the mammal, with larger mammals expected to be more sensitive based on standard scaling factors.

- For clothianidin:
  - the number of treated seeds required to reach the lowest observed adverse effect concentration (LOAEC; *e.g.* decreased body weight, stillbirths, delayed sexual maturation) for chronic effects would be 1 – 6 corn seeds, 1 – 10 lettuce seeds, 1 – 12 sugar beet seeds, 1 – 21 cotton seeds, and 2 – 58 soybean seeds, depending on mammal size; and
  - chronic exceedances occur when less than 10% of the animal's (all size classes of mammals) diet consists of clothianidin treated seeds (all evaluated treated seeds except soybean).

- For thiamethoxam:
  - there were reduced offspring body weight gains reported during the lactation period (NOAEL = 61 mg/kg-bw/day; LOAEL = 158 mg/kg-bw/day) in the chronic mammalian reproductive study;
  - based on the NOAEL, the number of seeds required to reach this chronic effect for corn, cotton, and sugar beet ranges from 2 – 37, 5 – 123, and 3 – 64, respectively; and
  - based on the LOAEL, the required number of seeds for these crops are 4 – 96, 14 – 320, and 7 – 166, respectively.

Although there are potential acute risks of concern for clothianidin (all seeds evaluated except soybean) and thiamethoxam (sugar beet) treated seeds, the uncertainties discussed above limit the likelihood that an animal will consume acutely toxic levels of treated seeds. Overall, for clothianidin and thiamethoxam, potential risk is associated with chronic consumption of treated seeds, where the estimated number of seeds required for chronic effects is low.

Birds, Reptiles, and Terrestrial-Phase Amphibians – Risk Estimates
Clothianidin is characterized as moderately toxic to birds on an acute oral exposure basis and practically nontoxic on a subacute dietary exposure basis. Northern bobwhite quail (*Colinus virginianus*) represented the most sensitive chronic toxicity endpoint (NOAEC: 205 mg/kg-diet; LOAEC: 525 mg/kg-diet), with effects on reduced eggshell thickness. Thiamethoxam is characterized as slightly toxic to birds on an acute oral exposure basis (LC_{50} = 576 mg/kg-bw/day) and practically non-toxic on a subacute dietary exposure basis (LC_{50} > 5200 mg/kg-diet). Weight loss was seen in a chronic avian reproductive study in parental males at 900 mg/kg-diet (NOAEC 300 mg/kg-diet). The most sensitive avian species assessed for thiamethoxam is the mallard duck for both acute and chronic exposures. Note that birds are used as surrogates for potential risks to terrestrial-phase amphibians and reptiles.

Clothianidin:

Foliar Applications: For foliar applications of clothianidin, there are no acute or chronic risks of concern for birds even when calculated using the maximum registered foliar single application rate of 0.4 lbs. a.i./A (RQs <0.01 – 0.33; LOCs = 0.5 for acute risks and 1.0 for chronic risks). RQs decreased with avian weight class and are highest (0.33) for small birds feeding on short grass.

Soil Applications: Area-based analysis identified LOC exceedances for small birds only at the highest soil application rate of 0.4 lbs. a.i./A (RQ = 0.63). Acute risks of concern are also identified following field applications of manure from clothianidin-treated poultry houses. This scenario is assumed to be equivalent to a soil application rate of clothianidin at 0.49 lbs. a.i./A and resulted in an RQ of 0.77.

Based on an analysis of using the upper bound Kenaga EECs in arthropods following soil applications as a surrogate for potential exposures of likely dietary items following soil exposures, there are no acute risks of concern for species of birds (highest RQ = 0.16 for the

scenario of spent poultry litter use). Similarly, chronic exposures for birds are below any effect level thresholds (highest chronic RQ = 0.22 for the scenario of spent poultry litter use).
Seed Treatment Formulations: As mentioned previously in the clothianidin mammal section, RQs are calculated for various crops when assessing potential risks to birds from treated seeds. Expected risks are highest for small birds and decreases with increasing avian body weight. For small and medium birds, there are acute dose-based species LOC exceedances for all crops (RQs range from 1.20 – 284). For large birds, there are acute dose-based species LOC exceedances for birds feeding on corn, sugar beets and lettuce (or for crops for which corn, sugar beets and lettuce serve as surrogates). Area-based analysis identified no risks of concern for avian species, but there is a chronic LOC exceedance for birds consuming any of the assessed treated seeds (RQs ranged from 5.0 to 1813). Moreover, for all size classes of birds, acute exceedances occur where less than 10% of the animal's diet consists of treated lettuce or sugar beet seeds.

Thiamethoxam:

Foliar and Soil Applications: There were no acute or chronic RQ exceedances identified for birds (acute LOC = 0.5; chronic LOC = 1.0) either directly from any foliar or soil applications, or from birds consuming arthropods with residues resulting from either a foliar or soil treatment. Therefore, there are no risks of concern for birds from foliar or soil applications.

Seed Treatment Formulations: RQs were calculated for corn, cotton, soy, and sugar beet when assessing potential risks to birds from thiamethoxam-treated seeds. No RQ exceedances were identified using an area-based analysis of potential risks, but there were acute dose-based exceedances for all crops except soybean, and chronic exceedances for all modeled crops and size classes. Chronic RQ exceedances range from 12.6 – 117. Both acute and chronic exceedances were highest for sugar beet (highest acute RQ = 29.6; chronic RQ = 117). Risk estimates were highest for small birds and decrease with increasing avian body weight.

Birds, Reptiles, and Terrestrial-Phase Amphibians – Risk Characterization
In field conditions, the exposure of birds to clothianidin-treated seed is dependent upon many variables beyond the amount of active ingredient on a given treated seed. These factors include whether or not the treated seed is buried or on the surface of a field (as in the case of an accidental seed spill), the depth at which buried seed is buried, the number and density of treated areas across the landscape, and the seed size relative to the size and foraging patterns of birds. For birds of any size, the attractiveness of the treated seed as a source of food is relative to the color or size of other available food sources. The size of a bird is also important in predicting effects expected from exposure, because larger birds generally need to consume more treated seeds before toxicological effects are observed. Using the chronic avian reproduction toxicity endpoint associated with diminished eggshell thickness, the number of treated seeds required to reach this level would be 1 – 19 corn seeds, 1 – 32 lettuce seeds, 1 – 39 sugar beet seeds, 1 – 69 cotton seeds, and 4 – 186 soybean seeds.

The size of a treated seed relative to the size of a given bird is another important variable to consider when characterizing potential risks from clothianidin-treated seed. In the case of small birds, treated seeds which are large either due to pelleting or the size of an individual seed may be too big for a small (20g) passerine bird to swallow. Based on minimum weights of field corn

seed (~225 mg), and cotton seed (~100 mg), these seeds are considered too big for most small passerine birds to consume. Therefore, acute and dietary risks from consumption of these seeds can be discounted for these size classes of passerines. Field corn seed is also considered too big for medium-sized passerine birds to consume. Other types of corn seed (*e.g.* sweet, pop, etc.) exhibit a size range such that the average seed size is below the weight threshold for medium-sized passerines. Consequently, medium-sized passerines could still potentially be affected by consuming other corn varieties.

The largest birds would physically be able to consume a wider range of treated seeds, due to their size, but would need to consume a greater number of seeds than their smaller counterparts to experience negative health effects. For large birds foraging in corn fields, nearly their entire diet (99%) would have to be made up of the treated seed in order to reach the acute LOC. Given the potential availability of other seed sources (*i.e.* remaining waste grain or seeds from weed species on the field), this may be more likely in instances of treated seed spillage than through normal foraging behavior.

Terrestrial Invertebrates – Risk Estimates

This section incorporates information provided in the *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* as well as the more recent *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, which are available on the public docket. The initial preliminary bee assessment in 2017 evaluated the risk of the registered agricultural uses of clothianidin and/or thiamethoxam to bees alone. The 2017 assessment utilized available data at the time. For clothianidin and thiamethoxam this included a robust registrant-submitted dataset to help characterize the acute and chronic toxicity of clothianidin and/or thiamethoxam to adult and larval honeybees at the Tier I (individual) level. In each assessment, available open literature data was also reviewed in addition to the required data.

The final 2019 bee risk assessment updates the preliminary bee assessment and incorporates additional information, submitted to the EPA since the previous assessment. This new assessment also includes additional residue study data, which provide residues of clothianidin and/or thiamethoxam in nectar, pollen, and other plant matrices for registered crop uses; as well as a residue bridging strategy to extrapolate, where appropriate, residue data among crops, chemicals, and plant matrices to address lack of residue data for certain crops between the neonicotinoids. This additional information includes higher tiered, Tier II and III (colony) level data. Tier II data included both semi-field tunnel (rate-response) and feeding (dose-response) studies to help better evaluate potential colony-level effects, and tier III data included whole colony full field studies to better evaluate colony-level effects. For clothianidin, there were Tier III field studies conducted on canola or maize seeds. Thiamethoxam had available Tier III field studies conducted on sunflower seed-treated fields, oilseed rape seed-treated fields, and a foliar-treated apple orchard. These Tier III studies were all included in the most recent assessment. Data was requested based on a tiered approach, as lower tiered data could trigger the need for higher tiered data.

During the scoping of the registration review for clothianidin and thiamethoxam, the agency identified the need to assess risk to terrestrial invertebrates. As a result, the agency issued

requirements for a robust set of pollinator data, which included both exposure and toxicity data, along with higher tiered pollinator tests such as Tier II (semi-field) and Tier III tests (full field). During testing, honeybees (*Apis mellifera*) were used as a surrogate for other species of bees (*e.g.* bumble bees, solitary bees). Risks to these other non-*Apis* bees are evaluated qualitatively based on available information. As the bee risk assessment framework used by the EPA indicates, honeybees are considered to be reasonable surrogates for other bee species and conclusions from the weight of evidence for the honeybee can be used to help inform about potential risks to other non-*Apis* species. An exception is noted based on the differences in attractiveness of crops to different bee species.

Among the four neonicotinoids (imidacloprid, clothianidin, thiamethoxam, dinotefuran), robust data sets of pollen and nectar residue data available for foliar and/or soil applications to the following bee-attractive crops and crop groups: cotton, cucurbits, citrus, stone fruit, pome fruit, tree nuts, berries/small fruits, and ornamentals. Surrogates were used in some areas where limited or no residue data was available. Generally, this risk assessment finds that foliar and/or soil applications of clothianidin and thiamethoxam to honeybee attractive crops which are not harvested prior to bloom result in a potential for colony-level risk. Robust data are also available for seed treatments of imidacloprid, clothianidin and thiamethoxam to several crops, including corn. In general, risks of neonicotinoid seed treatments to honeybee colonies are considered low.

As noted previously, clothianidin is a major degradate of thiamethoxam (in plants). As clothianidin and thiamethoxam have similar use patterns, and their toxic effects and the concentrations at which these toxic effects occur are similar for bees, the *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* expressed exposure and effects as "clothianidin equivalents" (c.e.), where thiamethoxam concentrations are converted using the molecular weight ratio of clothianidin to thiamethoxam (*i.e.*, ratio = 0.856)[2].

Based on the evaluated data, clothianidin and thiamethoxam are classified as toxic to adult honeybees with similar acute oral LD_{50} values (0.0037 µg c.e./bee and 0.0038 µg c.e./bee, respectively) and acute contact LD_{50} values (0.0275 µg c.e./bee and 0.021 µg c.e./bee, respectively). There are no acceptable definitive acute oral larval toxicity studies available for clothianidin and thiamethoxam. Therefore, acute dose-based RQs were not calculated for larvae. However, there is an acceptable larval chronic toxicity study for thiamethoxam, which was used to derive an acute oral toxicity estimate (> 0.03 µg c.e./larvae; 5% mortality). For clothianidin and thiamethoxam, there are acute contact risks to adult bees exposed to foliar applications (RQ = 52 and 5.1, respectively; LOC = 0.4). Also, for clothianidin and thiamethoxam, there are acute dose-based oral exposure risks from foliar use (RQs = 3,600 and 350, respectively); from soil (RQs ranged 1.2 – 7.0); and from seed treatment use (RQ = 79). The highest acute exceedances for clothianidin are from foliar uses on berries and small fruit, soil uses for cucurbits, and foliar uses for oilseed. For thiamethoxam, the highest acute exceedances are from foliar uses on ornamentals, soil uses for fruiting vegetables, and foliar uses for berries and small fruit.

For clothianidin and thiamethoxam, there were chronic oral toxicity exceedances (LOC = 1) for foliar and soil applications. Adult bee chronic RQs ranged from 3,600 – 36,000 for foliar applications, and 13 – 70 for soil applications. There were also chronic oral toxicity exceedances identified for larval bees (RQs ranged 300 to 1,500) from foliar uses of clothianidin and

thiamethoxam. For soil uses of clothianidin (non-agricultural), there were chronic exceedances to bee larvae (RQs ranged 2.1 to 2.3). There were also chronic oral exceedances for seed treatment uses for both adult and larval bees (RQ = 810 and 29, respectively). The highest chronic exceedances for clothianidin were from soil use for citrus and cucurbits, and foliar use on oilseed. For thiamethoxam, the highest chronic exceedances occurred from foliar use on ornamentals, berries and small fruit, and cucurbits.

Based on an analysis of Tier I data, for foliar applications, potential off-field dietary risks to individual bees exposed to spray drift extend >1000 feet from the edge of the treated field. There is uncertainty in this analysis including: assumptions on available attractive forage off field, use of individual level toxicity data, BeeREX default estimates for residues, and unrefined AgDRIFT™ modeling. Soil applications are assumed to have a low off-field risk because of low potential to drift. Off-field estimates of risk are based on screening-level exposure estimates, which cannot be refined with available residue data. Moreover, these estimates relied on assumptions regarding crop-attractiveness to bees, exposures, cultural practices (*i.e.* harvest cycles), environmental conditions (*i.e.* canopy coverage), wind conditions (*i.e.* unidirectional and constant), etc. Therefore, potential off-field risks may be overestimated. Additionally, exposure to individual bees from off-site movement of abraded seed dust during planting is noted as a potential exposure route of concern.

Due to neonicotinoid persistence in the environment, poultry litter usage estimates indicated potential risk to bees when applied at the maximum allowed rate (0.49 lbs. a.i./A; clothianidin only) when applied on multiple occasions (six whole house treatments) and then utilized as fertilizer on agricultural fields. Based on that maximum rate, RQs calculated using the Bee-REX model showed acute and chronic exceedances to adult bees (RQs 7 and 70, respectively) and chronic risk to larval bees (RQ of 2.3).

On a colony-level, potential risks were identified for several scenarios. Since risks to honey bees were identified at the Tier 1 (individual bee) level, the agency evaluated risks at the colony level (Tier II and Tier III). At the Tier II level, this involved comparing clothianidin and thiamethoxam residues measured in pollen and nectar in various crops to levels that affect honey bee colonies. At the Tier III level, this involved analysis of full field studies that were conducted for clothianidin and thiamethoxam seed treatments (various crops). In addition, this involved analysis of full field studies that were conducted on thiamethoxam foliar applications to orchards or melons. These Tier III studies contained significant uncertainties associated with the study design and availability of data which limited their utility. These uncertainties include the origin of the pollen and nectar brought back to the hives, high variability in the data collected (including in control hives), and inadequate replication or pseudo-replication (e.g. studies conducted using only one field). Ecological incidents were also considered as a line of evidence. For a detailed explanation of these risk estimates, please refer to the *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, available in the dockets. The findings of the higher tier assessment are summarized below.

Terrestrial Invertebrates – Risk Characterization

The agency utilized several lines of evidence to better refine the risk calls including: incorporating information on crop bee attractiveness, agronomic practices (*e.g.,* harvest time

relative to bloom) to determine if exposure was present, a comparison of residues to adverse effects levels for entire hives (residues above NOAEC and LOAEC), and major categories of incidents. For comparison of residues to adverse effects levels for entire hives, EPA considered duration and frequency of exceedance, the magnitude of exceedance (including the ration of max residue value to NOAEC/LOAEC and percent of diet from the treated field needed to reach the NOAEC/LOAEC), as well as consideration of usage and geographic scale/spatial distribution of exposure.

It is important to note that multiple factors can influence the strength and survival of bees whether they are solitary or social. These factors, including disease, pests (*e.g.,* mites), nutrition, and bee management practices, can confound the interpretation of studies intended to examine the relationship of the test chemical to a receptor (*i.e.*, larval or adult bee). Therefore, most studies attempt to minimize the extent to which these other factors impact the study; however, higher-tier studies afford less control over these other factors, and their role may become increasingly prominent as the duration of the study is extended. Although studies attempt to minimize the confounding effects of other environmental factors, there is uncertainty regarding the extent to which the effects of a chemical may be substantially different had these other factors been in place.

Strongest Evidence of On-field Risk: For foliar and soil applications of clothianidin and thiamethoxam, the lines of evidence are considered "strongest" for supporting the finding of colony-level risk resulting from applications to:

- For Clothianidin:
    - Cotton (foliar);
    - Cucurbits (foliar);
    - Grapes (foliar, pre-bloom); and
    - Ornamentals (foliar and soil).
- For Thiamethoxam:
    - Cotton (foliar);
    - Cucurbits (foliar);
    - Orchard crops (*i.e.*, citrus, pome, stone and tropical fruits, tree nuts; foliar, pre-bloom);
    - Citrus (soil, pre-bloom);
    - Berries (foliar and soil, pre-bloom;
    - Honeybee attractive fruiting vegetables (*i.e.*, okra, roselle, chilis and peppers; foliar); and
    - Ornamentals (foliar and soil).

These findings are supported by multiple lines evidence indicating residues exceed the clothianidin and/or thiamethoxam colony-level endpoints by a high magnitude, frequency and/or duration. In some cases, they are also supported by modeled residues or ecological incidents involving bees that are associated with the use.

Moderate Evidence of On-field Risk: For foliar and soil application of clothianidin and thiamethoxam, the strength of evidence is considered "moderate" in indicating a colony-level risk to honeybees for the following registered uses:

- Clothianidin and Thiamethoxam:
  - Citrus (soil, post-bloom);
  - Cucurbits (soil);
  - Residential lawns (foliar); and
  - Ornamentals (foliar and soil).
- Thiamethoxam only:
  - Honeybee attractive fruiting vegetables (soil).

These findings are supported by lines of evidence indicating residues exceed the clothianidin and/or thiamethoxam colony-level endpoints but the magnitude, frequency and/or duration of exceedance is limited.

Weakest Evidence of On-field Risk: For foliar, soil and seed treatment applications of clothianidin and thiamethoxam, the strength of evidence is considered "weakest" in indicating a colony-level risk to honeybees for the following registered uses:

- Clothianidin
  - Honeybee attractive root and tuber crops (*i.e.*, sweet potato, Jerusalem artichoke, edible burdock, dasheen, horseradish; foliar and soil); and
  - Turmeric (seed treatment).
- Thiamethoxam
  - Honeybee attractive root and tuber crops (foliar and soil);
  - Citrus (soil, post-bloom); and
  - Mint (foliar).

For thiamethoxam applications (foliar) to mint, the evidence is considered weakest because risk findings rely exclusively on residue data that are extrapolated (bridged) from other neonicotinoids or different crop groups where the influence of crop on the magnitude of the residue is highly uncertain. The clothianidin use for treated turmeric seed pieces, the evidence is considered weakest because risk findings rely on nectar and pollen exposures extrapolated from the size of treated seeds, but turmeric is planted as large seed pieces.

For clothianidin and thiamethoxam applications to honeybee attractive root and tuber crops, the evidence is considered weakest because of the following. Clothianidin residue data are available for potato pollen; however, this crop does not produce nectar like other crops in this group (*e.g.*, sweet potatoes). Residues in potato (*Solanum tuberosum*) pollen are below the colony level endpoints, however, the agency cannot conclude that nectar-producing honeybee attractive root and tuber crops pose a low risk because there are no residue data for nectars in this crop group. When considering residue data for other field crops (e.g., cotton, cucurbits), foliar and soil applications result in residues in nectar that are above the colony level endpoints. This suggests a potential concern for nectar-producing root and tuber crops. Available information suggests that several of these honeybee attractive root and tuber crops are cultivated primarily through their

roots and not through setting seed, however without further information on the timing of cultivation relative to bloom periods, honeybee exposure cannot be precluded.

Terrestrial Plants
No risks of concern to terrestrial plants are identified for either clothianidin or thiamethoxam. For further detail, please refer to *Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review* and *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review*, both available in their respective dockets.

Aquatic Risks

Although clothianidin and thiamethoxam were assessed together in one bee risk assessment, separate aquatic assessments were conducted. In terrestrial plants, clothianidin is observed as a major degradate of thiamethoxam. In other environmental fate studies (e.g., hydrolysis, aerobic soil metabolism), clothianidin is a minor degradate. Therefore, in the aquatic risk assessment of thiamethoxam, only the parent compound is considered as a residue of concern. This section describes the risks to aquatic organisms from clothianidin and thiamethoxam applications.

Freshwater Fish, Estuarine/Marine Fish, and Aquatic-Phase Amphibians
On an acute basis, clothianidin is characterized as practically non-toxic to freshwater fish and no more than slightly toxic for estuarine/marine fish. Thiamethoxam is also characterized as practically non-toxic to fish on an acute exposure basis. Clothianidin and thiamethoxam both had minor effects on fish growth after chronic exposure. There are no risks of concern to fish or aquatic-phase amphibians from either clothianidin or thiamethoxam. The acute and chronic RQs for fish (which were used as surrogates for aquatic-phase amphibians when calculating RQs) did not exceed the acute (0.5) or chronic (1.0) LOC for any uses (clothianidin RQs $\leq$ 0.001; thiamethoxam RQs $\leq$ 0.002). Potential risks to fish and aquatic-phase amphibians are therefore considered low for these chemicals.

Freshwater Invertebrates
For aquatic invertebrates, the level of sensitivity varies greatly among species on an acute toxicity basis. For example, clothianidin is practically non-toxic to water fleas (*Daphnia magna*), but is very highly toxic to other taxa, including shrimp and aquatic insects. Reproduction is affected in both freshwater and estuarine/marine invertebrates. Effects on development were also observed in benthic invertebrates.

On an acute exposure basis, thiamethoxam is very highly toxic (*i.e.*, LC_{50} < 100 µg a.i./L) to aquatic invertebrates. Tested insect species are more sensitive on an acute exposure basis compared to tested species in other classes (*e.g.*, daphnids and mysid shrimp). On a chronic exposure basis, a decrease in survival is observed in aquatic insects exposed to 2.23 µg a.i./L, resulting in a NOAEC of 0.74. As with acute exposure, daphnids and mysid shrimp are orders of magnitude less sensitive when exposed to thiamethoxam on a chronic exposure basis.

The agency generated a *Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoids using Raby et al. (2018) toxicity data*, which became available following

publication of the *Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review* (2017) and the *Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review* (2017).The studies, located in the docket, were used to determine risks quotients using acute and chronic toxicity data provided in the two open literature papers published by researchers from the University of Guelph.[10,11] With use of the available raw data, EPA determined the results could be used quantitatively for risk assessment purposes (*i.e.,* to derive RQs). Upon the review of the Raby data, risks of concern were identified for all four neonicotinoid insecticides (clothianidin, thiamethoxam, dinotefuran, and imidacloprid) to freshwater invertebrates on both an acute and chronic basis.

On an acute basis across all tested species, LC_{50} values for dinotefuran were similar, but slightly higher than imidacloprid. On average, LC_{50} values for clothianidin were 2.4 times higher than those of imidacloprid and dinotefuran, suggesting that clothianidin may be relatively less acutely toxic than imidacloprid and dinotefuran. Thiamethoxam's LC_{50} values were 5.6 times higher than those of imidacloprid across all tested species, which suggests that thiamethoxam is potentially the least acutely toxic.

All four neonicotinoids present chronic risks of concern to freshwater invertebrates, where clothianidin and imidacloprid have similar toxicities. Based on midge data (generally more sensitive than mayflies), dinotefuran and thiamethoxam are relatively less sensitive (decreased factors of ~2.3 and 5.3, respectively) than imidacloprid and clothianidin. There is a ~4X factor difference in sensitivity across the four neonicotinoids where dinotefuran is the least sensitive. Dinotefuran and thiamethoxam are also reported as the least sensitive in mayfly data as well.

Two notable uncertainties within the Raby *et. al.* data include: 1) inconsistent analytical verification of concentrations, and 2) different control performance in the imidacloprid testing.

For 1), not all test concentrations were confirmed through analytical verification. As a result, the LC_{50} and NOAEC values are based on nominal concentrations. From the limited subset of test concentrations that were analyzed, the measured values were similar to the nominal concentrations, and are not expected to have a substantial impact on the reliability of the acute and chronic toxicity values.

For 2), the chronic midge test showed a reduction in the performance of control organisms with regards to growth and reproductive endpoints, relative to controls in the other tests. Due to this, there is potential that the imidacloprid midge toxicity endpoints underestimate the actual toxicity of imidacloprid to midges. However, the chronic endpoint used for comparison of the neonicotinoids done by the agency was the percent emergence endpoint, which for the

---

[10] Raby, M; Nowierski, M.; Perlov, D; Zhao, X.; Hao, C; Poirier, D.G. and P.K. Sibley. 2018a. Acute Toxicity of 6 Neonicotinoid Insecticides to Freshwater Invertebrates. Environmental Toxicology and Chemistry, 37 (5): 1430–1445. MRID 50776401.

[11] Raby, M; Zhao, X.; Hao, C.; Poirier, D.G. and P.K. Sibley. 2018b. Chronic toxicity of 6 neonicotinoid insecticides to Chironomus dilutus and Neocloeon triangulifer. Environmental Toxicology and Chemistry, 37 (10): 2727-2739. MRID 50776201.

imidacloprid controls did meet EPA test method standards and was generally one of the most sensitive endpoints across chemicals.

Both mayfly and midge studies tested all four neonicotinoids, however when considering exposure, dinotefuran tended to have the highest estimated exposure concentrations (EECs) among the four chemicals. The other three neonicotinoids were estimated to have similar EECs to each other. On an acute basis, for the mayfly and midge acute RQs, the majority of clothianidin and dinotefuran RQs were greater than those of imidacloprid. Thiamethoxam appears to present a lower acute risk concern when considering the midge RQs. On a chronic basis more generally, clothianidin, dinotefuran, and imidacloprid, have similar chronic RQs with a few exceptions: tree fruit RQs for imidacloprid were eleven times higher than the other A.I.s; foliar nursery and soil forestry applications RQs for clothianidin were an order of magnitude higher than imidacloprid; foliar and soil applications as well as seed treatment RQs for imidacloprid were 13-220 times higher than thiamethoxam. Overall thiamethoxam was found to have lower exceedances to aquatic invertebrates than the other three nitroguanidine neonicotinoids.

Estuarine/Marine Invertebrates
For clothianidin foliar applications, there are no acute risks identified for all uses (RQs < 0.5) except for use on rice (RQs = 1.6; foliar and seed treatment). The chronic LOC (1) is only exceeded for foliar uses on fruit and nut trees, ornamentals/shade trees, and rice (RQs ranged from 1.1 – 5.2). The chronic LOC (1) for soil applications is exceeded for tree fruits and nuts, cucurbits, fruiting and leafy vegetables, and low growing berries (RQs ranged 1.6 – 1.9). For clothianidin seed treatments, there are no acute LOC (0.5) exceedances, except for the use on rice (RQ ≤ 1.4). There are also no chronic LOC (1) exceedances except for use on rice (RQ = 1.7). For the poultry house use of clothianidin (0.49 lbs. a.i./A), the acute LOC is not exceeded (RQs ≤ 0.31), however, the chronic LOC is exceeded (RQ ≤ 3.0).

None of the saltwater (SW) invertebrate acute or chronic RQs exceeded the LOCs for thiamethoxam uses with foliar, soil and seed treatments.

Aquatic Vascular and Non-Vascular Plants
There are no risks of concern to aquatic plants from either clothianidin or thiamethoxam. The RQs for aquatic vascular and non-vascular plants did not exceed the LOC (1) for any uses (clothianidin RQs ≤ 0.16; thiamethoxam (RQs <0.001). For clothianidin, effects on yield were observed in both aquatic vascular and non-vascular plants but only at high test concentrations (0.075 lbs. a.i./A; single application).

2. Ecological Incidents

i. Pollinator Incidents

The Office of Pesticide Programs (OPP) maintains a database called the Incident Database System (IDS) in which wildlife incidents reported to the agency from a variety of sources are maintained. The sources of information for incidents include registrant reports (aggregated incidents) submitted under the FIFRA §6(a)(2) reporting requirement, as well as reports from

local, state, national and international-level government reports on bee kills, news articles, and correspondence made to the EPA by phone or via email (through beekill@epa.gov) generally reported by homeowners and beekeepers. A search of IDS for aggregated incidents was conducted on May 2, 2019 for clothianidin and thiamethoxam. Incidents in IDS are classified as "not determined," "unlikely," "possible," "probable," and "highly probable".

There were 54 ecological incidents affecting bees in the United States associated with the use of clothianidin that were reported in the IDS between 2010 and 2018. Some incidents involved clothianidin and other chemicals. The majority of reported incidents involved commercial honeybees. The incident reports' classifications ranged from unlikely to highly probable, where 15 incidents were classified as "highly probable," and 16 incidents were classified as "probable". Considering all reported incidents, 19 of the incidents were attributed to registered uses of clothianidin (*i.e.*, corn, cotton, canola, and sugar beet) at the time of the incident, but the legality of use was not determined in 34 of the reported incidents, and a single incident was considered a misuse. There were 27 incidents where entire honeybee colonies were affected that were associated with corn, however, there was insufficient evidence to correlate clothianidin or the other neonicotinoids to these incidents. All but four of these 27 incidents occurred prior to 2015.

From 2002 – 2018, there were 22 incidents reported in the US for honeybees in association with agricultural uses of thiamethoxam. Seven of the incidents with certainties of highly probable or possible have been reported in association with corn planting in Indiana, Minnesota, and Illinois. Observations included hundreds to thousands of dead bees and bees with behavioral impacts. Twelve incidents considered probable or possible were reported by the state of Washington in 2002 in association with applications of thiamethoxam to orchards (as unspecified, or to pears or cherries). In most of these incidents, the bee hives were located within the treated orchards. In addition, an incident was reported in California in association with thiamethoxam applications to lemon trees. In 2018, an incident was reported in association with an application to watermelons. One additional incident was associated with applications to an "agricultural area".

ii. Aquatic and Non-Pollinator Terrestrial Incidents

A review of the IDS database for incidents involving wildlife including aquatic organisms as well as plants was completed on June 15, 2017. There was one incident submitted for clothianidin for the Poncho Beta formulation, which reported crop damage in Idaho in August 2014 from spray drift. However, that incident was also associated with several other insecticides, fungicides, and herbicides. There were four incidents submitted for thiamethoxam. Three of the four incidents involved plant crops (*i.e.* beans, corn, etc.), and one incident involved birds. All four incidents listed thiamethoxam as a "possible" cause for the reported incident, however, these incidents were also associated with other chemicals.

In addition to the incidents described above, additional incidents are reported to the agency in aggregated incident reports. Pesticide registrants report certain types of incidents to the agency as aggregate counts of incidents occurring per product per quarter. Ecological incidents reported in aggregate reports include those categorized as 'minor fish and wildlife' (W – B), 'minor plant' (P – B), and 'other non-target' (ONT) incidents. 'Other non-target' incidents include reports of

adverse effects to insects and other terrestrial invertebrates. No aggregate incident reports for W – B or P – B have been submitted to the agency for clothianidin or thiamethoxam.

Although there were limited or no incident reports received by the agency for clothianidin or thiamethoxam related to terrestrial wildlife and/or plants, the absence of reported incidents should not be construed as the absence of incidents. Incident reports for non-target organisms typically provide information only on mortality events and plant damage incidents. Except for phytotoxic effects in terrestrial plants, sublethal effects, such as reduced growth or impaired reproduction, are rarely reported. EPA's changes in the registrant reporting requirements for incidents in 1998 may account for a reduced number of reported incidents. Registrants are now only required to submit detailed information on 'major' fish, wildlife, and plant incidents. Minor fish, wildlife, and plant incidents, as well as all other nontarget incidents, are generally reported aggregately and are not included in the Ecological Incident Information System (EIIS). In addition, there have been changes in state monitoring efforts due to lack of resources.

The agency will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for clothianidin and thiamethoxam is complete. No additional fate data is needed for the clothianidin and thiamethoxam registration review.

C. Benefits Assessment

This section of the PID is organized to begin with a brief benefits overview for clothianidin and thiamethoxam, followed by a more detailed summary of their usage in several crop groups (*e.g.* berries, citrus, cucurbits, pome fruit, stone fruit, etc.). Crop groups described below were the subjects of in-depth benefits assessment memoranda that are part of the documents being released in the neonicotinoid dockets at www.regulations.gov for public comment.

The EPA conducted a number of use site-specific benefits assessments for the neonicotinoids as a pesticide class. Each assessment considered the advantages of the individual neonicotinoid active ingredients, including their use in targeting particular pests, average application rates, acres treated and potential alternatives, which are described in detail in the benefits assessments available in the docket (see Section I.A. for a full list of available benefits documents).

The agency found that as a group, the neonicotinoid insecticides:

- Can control a variety of piercing and sucking pests including those that vector plant diseases such as aphids and whitefly;
- Each show certain benefits for the control of different pests depending on the use setting;
- Offer both immediate, contact control and systemic, residual control of pests over an extended period of time; and
- Are comparatively less expensive and more effective than some alternatives.

Clothianidin is a nitroguanidine-substituted neonicotinoid insecticide used to control damaging pests of concern across a wide range of agricultural and non-agricultural use sites. Neonicotinoids act on the central nervous system of insects, causing irreversible blockage of the postsynaptic nicotinergic acetylcholine receptors (via a selective agonistic mechanism). The primary pests targeted for control with clothianidin include piercing and sucking pests such as aphids, mealybugs, sharpshooters, Asian citrus and pear psyllids and stinkbugs; coleopteran pests such as corn rootworm, billbugs, white grubs, and plum curculio; and a variety of sporadic pests such seed maggots and symphylans. Clothianidin is registered for use on root and tuber vegetables, bulb vegetables, leafy vegetables (brassica and non-brassica), legumes, fruiting vegetables, cucurbits, citrus fruit, pome fruit, stone fruit, berries and small fruit, tree nuts, cereal grains, oilseed crops, and other unclassified crops.

Thiamethoxam is a second-generation neonicotinoid insecticide, belonging to the thianicotinyl subclass. Thiamethoxam acts on the central nervous system of insects by binding to the postsynaptic nicotinic acetylcholine receptor and has systemic and contact activity. The primary pests targeted for control with thiamethoxam include piercing sucking pests such as aphids, leafhoppers, and whitefly in addition to certain hard to kill pests such as pepper weevil and thrips. Thiamethoxam is also highly water soluble and is readily translocated in plant tissue giving it good systemic activity. Registered uses for thiamethoxam encompass a wide range of agricultural use sites, which includes root and tuber vegetables, leafy vegetables (brassica and non-brassica), legumes, fruiting vegetables, cucurbits, citrus fruit, pome fruit, stone fruit, berries and small fruit, cereal grains, etc. There are also a number of non-agricultural use sites (*e.g.* warehouses, schools, residential living spaces, etc.).

The following are summaries of the benefits assessments available in the public docket. [12,13]

Berries
Berries refer to strawberry, caneberry (blackberry, raspberry, *etc.*), cranberry, and blueberry, as well as multiple other small soft fruit grown on very small acreage. Neonicotinoids, including clothianidin and thiamethoxam, provide both contact and systemic control of numerous economically significant pests in berry crops.

Clothianidin is registered for use on cranberry and blueberry. Clothianidin is recommended for control of cranberry girdler and weevils in cranberry production. Weevil damage can result in plant damage and cranberry feeding damage can result in plant death. Alternatives for the control of weevils include chlorpyrifos and indoxacarb as well as other neonicotinoids (such as imidacloprid, dinotefuran, and acetamiprid). Clothianidin is the only insecticide recommended for control of cranberry girdler.

Thiamethoxam is registered for soil and foliar applications on several berry crops including blueberry, caneberry (including raspberry and blackberry), strawberry and cranberry. Strawberry and caneberry growers rely heavily on thiamethoxam, treating around a third of the acres grown. It is less used in blueberry, where use of imidacloprid is more common. There are no usage data

[12] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2011-0865
[13] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2011-0581

available for cranberry production. Thiamethoxam is used for the control of aphids and whiteflies, but primarily for Lygus bug in strawberry; aphids, potato leafhopper, root weevils, and spotted wing drosophila in caneberry; cranberry flea beetle, leafhopper, and weevil in cranberry; and aphids, sharpnosed leafhopper, and Japanese beetle in blueberry production. These pests cause direct feeding damage (i.e. Japanese beetle and cranberry flea beetle) and transmit diseases (i.e. aphids and leafhoppers). Alternatives vary greatly by crop and target pest, but generally include: organophosphates, pyrethroids and other neonicotinoids (such as imidacloprid and acetamiprid)

For more information, refer to *Benefits of Neonicotinoid Insecticide Use in Berries (Strawberry, Caneberry, Cranberry, and Blueberry) and Impacts of Potential Mitigation* available in the docket.

Citrus
On average from 2011 to 2015, there were 3,100 total citrus acres treated annually with clothianidin and 284,000 total citrus acres treated annually with thiamethoxam.[14] Data from 2014 to 2018 indicate substantial increases in usage, by 67% and 40% respectively.[15] In general, the Asian Citrus Psyllid (ACP) is the primary pest targeted by the neonicotinoids; thiamethoxam also targets rust mites and the Fuller rose beetle. ACP is an invasive species that transmits the pervasive bacterial disease Huanglongbing (HLB), also known as the citrus greening disease. Infected trees experience premature fruit drop, and the fruit available at harvest are smaller and have a bitter, metallic taste that impacts the quality of fruit produced. More than 90% of all Florida citrus acres are now affected by HLB. There is no cure for HLB and all infected trees eventually die; infected trees must be removed from commercial orchards to avoid contributing to the spread of the disease. Without thiamethoxam, growers would increase use of insecticides such as organophosphates (e.g., acephate, malathion) and pyrethroids (e.g., bifenthrin, lambda-cyhalothrin, cyfluthrin), as well as acetamiprid, a chloropyridinyl neonicotinoid. Control costs would increase, and control would likely be compromised as well, leading to an increased number of trees infected with HLB, which would have to be removed and replaced at substantial cost.

Thiamethoxam also targets citrus leafminer and mites, and, in California, the Fuller rose beetle. Alternatives for leafminer and mite include abamectin and spirotetramat. There do not appear to be good alternatives to thiamethoxam for the Fuller rose beetle.

For more information, see *Benefits of Neonicotinoid Insecticide Use in the Pre-Bloom and Bloom Periods of Citrus*.

Cotton
An average of 6.4 million acres of cotton are treated with a neonicotinoid insecticide. EPA estimates that almost 69% of acres receive at least one application of a neonicotinoid, primarily with imidacloprid and thiamethoxam. Accounting for multiple treatments per acre, nearly 9 million acres of cotton are treated with neonicotinoids annually. Seed treatments account for about 6 million acres, approximately 100,000 acres are treated at-plant, and over 2.8 million

[14] Market research data. 2011-2015.
[15] Market research data. 2014-2018.

acres are treated after crop emergence. Thiamethoxam accounts for more than 1.5 million acres of the area treated after crop emergence, clothianidin is used on just over 100,000 acres and the rest, about 1.2 million acres, is treated with imidacloprid.

Foliar usage of clothianidin and thiamethoxam in cotton most commonly targets plant and stink bugs. There are regional differences in usage and target pests. Clothianidin is rarely used in the Mid-South and Plains states. In the Plains states, the primary target pest of thiamethoxam is the flea hopper and there is some usage against aphids. These pests cause a variety of damage by piercing the boll to feed on developing seeds resulting in yield loss and loss of fiber quality. Without clothianidin, thiamethoxam, or other nitroguanidine neonicotinoids, growers would probably use a combination of an organophosphate with a pyrethroid, such as acephate or dicrotophos with lambda-cyhalothrin or bifenthrin, to control plant and stink bugs, which would increase costs – and lower income – by $3 to $7/acre, depending on the region, which could be as much as three percent of a grower's net operating revenue.

For more information, see *Benefits of Neonicotinoid Insecticide Use in the Pre-Bloom and Bloom Periods of Cotton*.

Cucurbits
Clothianidin has very limited use for foliar and soil applications on cucurbits, with 5,700 total acres treated annually, on average from 2011 – 2015. Thiamethoxam is primarily used as a soil or foliar application for cucumbers (12,000 total acres treated annually), but is also applied by other growers of other cucurbits (*e.g.* cantaloupes, squash, watermelon, pumpkins) via the same application methods. Nationally-targeted pests for cucurbits include the whitefly, aphid, thrips and cucumber beetle. There are several species of whiteflies and aphids that can vary by region, but these pests all threaten cucurbit crops by direct-feeding and by vectoring viruses or disorders. There are also several species of thrips that vary by region, and, these pests are known to cause leaf silvering, leaf curling, flower deformations, and fruit damage. Cucumber beetles occur nationally but are particularly a pest of concern in the northeast United States. Cucumber beetle larvae feed on the roots of cucurbit plants, while adults feed on leaves. The alternatives to neonicotinoids currently in use are bifenthrin, chlorpyrifos, permethrin, carbaryl and zeta-cypermethrin.

For more information, see *Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation.*

Fruiting Vegetables, Brassica Vegetables, Leafy Green Vegetables, Tree Nuts, Root & Tuber Vegetables, Bulb Vegetables, and Tropical and Subtropical Fruit
These crop groups account for approximately 35% of neonicotinoids used in agriculture and about 25% of the acreage treated with neonicotinoids, not including seed treatments. Growers of fruiting vegetables and *Brassica* vegetables rely relatively heavily on clothianidin and thiamethoxam with about 10 to 15 percent of the crop treated, on average.[6] Only about five percent of the leafy greens, tree nuts, and carrots are treated with clothianidin and thiamethoxam; imidacloprid generally is the dominant neonicotinoid for these crops, as well as for pest control in tropical/subtropical fruit. There is little usage of clothianidin and thiamethoxam, or of other neonicotinoids, in bulb vegetables.

In general, neonicotinoids, including clothianidin and thiamethoxam, are used in both soil and foliar applications to manage piercing and sucking pests that feed off the sap of plants, these pests may also vector diseases. While imidacloprid is often used against aphids and whiteflies, clothianidin and thiamethoxam often target bagrada bug, stink bugs, leafhoppers, and thrips, as well as a number of soil-dwelling pests such as springtail and root maggots. Alternatives for these pests tend to be contact insecticides like OPs and pyrethroids, but which do not provide the residual systemic control of the neonicotinoids and may have to be applied multiple times throughout the season. Extension guides discourage use of broad-spectrum insecticides like pyrethroids early in the season because it may reduce populations of predatory and parasitic insects and result in secondary pest outbreaks later.

For more information, see *Benefits of Neonicotinoid Use and Impacts of Potential Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, Tropical and Subtropical Fruit Crops*.

Grapes
Thiamethoxam has very limited use on grapes with an average of one percent of grape acreage treated or lower. Thiamethoxam is primarily used for the control of leafhoppers (which includes glassy-winged sharpshooter). Additionally, thiamethoxam is recommended for the control of grape pylloxera. These pests cause quality and yield impacts due to direct feeding damage and disease spread. Alternatives vary by target pest but consist generally of pyrethroids and organophosphate as well as other neonicotinoids (such as imidacloprid and acetamiprid).

Clothianidin accounts for 29,000 total acres treated (or 25PCT) in table grapes, 8,800 total acres treated (or 1PCT) in wine grapes, and 2,800 total acres treated (or 1PCT) in raisin grapes. Clothianidin is used almost exclusively for the control of mealybugs but is also recommended for the control of leafhoppers (which includes glassy-winged sharpshooters). These pests can cause quality and yield loss from direct feeding damage and disease transmission. Mealybugs contaminate fruit with egg clusters and honeydew produced by adults can render the fruit unmarketable. Grape mealybugs are also the primary vectors of the grapevine leafroll associated virus (GLRaV), which can spread across vineyards resulting in a 40% loss of crop yields. Alternative control options include spirotetramat and lime sulfur.

For more information, refer to *Benefits of Neonicotinoid Insecticides Usage in Grapes and Impacts of Potential Mitigation* available in the docket.

Pome Fruit
Clothianidin and thiamethoxam are registered for use in pome fruit crops (which includes apple and pear). Clothianidin accounts for 1,000 of the total acres treated (or 1PCT) in pear production; 20,300 of the total acres treated (or 13PCT) in eastern apple production; and there is no reported usage in western apple production. Clothianidin is used the control of pear psylla and mealybug in pear production and for the control of plum curculio and brown marmorated stinkbugs (BMSB) in apple production. These pests cause quality and yield impacts associated with direct feeding and mold growth due to honeydew secretion. Alternatives generally include pyrethroids, organophosphates, and other neonicotinoids (such as imidacloprid and acetamiprid).

Thiamethoxam accounts for 8,900 of the total acres treated (or 15PCT) in pear production; 80,800 of the total acres treated (or 50PCT) in eastern apple production; and 4,400 of the total acres treated (or 1PCT) in western apple production. Thiamethoxam is used for the control of pear psylla and mealybugs in pear production and plum curculio, aphid, and BMSB in apple production. These pests cause quality and yield impacts associated with direct feeding damage and mold growth due to honeydew secretions. Alternatives generally consist of pyrethroids, organophosphates, and other neonicotinoids (such as imidacloprid and acetamiprid).

For more information, refer to *Usage, Pest Management Benefits, and Possible Impacts of Potential Mitigation of the Use of the Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear)* available in the docket.

Rice
The primary use of thiamethoxam and clothianidin is via seed. Foliar applications of clothianidin target the many of the same early season pests as seed treatment applications (e.g., rice water weevil, chinch bugs, aphids); therefore, foliar applications likely only occur when seed treatments are not used. Foliar applications of clothianidin occur between emergence and early tillering on less than 1,000 acres of rice annually. Depending on the target pest, foliar alternatives to clothianidin include pyrethroids, diflubenzuron, and neonicotinoid and chlorantraniliprole seed treatments, depending on the target pest.

For more information, refer to *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments,* available in the docket.

Seed Treatments
Clothianidin and thiamethoxam are currently registered as a seed treatment for multiple field crops, such as canola, corn, cotton, soybean, sugarbeet, rice, and wheat, and vegetable crops, such as brassica, carrots, cucurbits, lettuce, and onion. The highest usage is on corn and soybean, simply by virtue of the large number of acres planted.

Clothianidin and thiamethoxam, along with imidacloprid, are some of only a few insecticidal seed treatments available. The neonicotinoids are valuable tools because they have both contact and systemic activity. Thus, they control both soil pests and above ground pests that attack early stages of the crop. Soil pests include corn rootworms, wireworms, grape colaspis, and maggots, but there are also many soil pests that are not well-identified. It is difficult to scout for soil pests in advance of planting and their presence is often hard to predict. Damage can be extensive; soil pests may attack the seed and/or developing roots and sprouts resulting in poor stand establishment and substantial yield reductions. Above ground pests such as aphids, leafhoppers, and thrips feed on newly emerged seedlings. In addition to direct feeding damage, such pests can transmit diseases. Depending on the crop, other pests include Hessian fly, leafminers, beetles, and the bagrada bug. As with soil pests, damage to seedlings can result in poor stands and substantial yield reductions.

Imidacloprid would be the most likely alternative for clothianidin and thiamethoxam seed treatments where imidacloprid is registered. A few other insecticides are available for a limited number of sites. For example, chlorpyrifos is registered for treating wheat, sorghum, and some

vegetable seeds; acetamiprid is registered for canola seed; and cyromazine is used to treat some vegetable seeds. Pyrethroids, such as permethrin and cyfluthrin, are registered for some sites as well. None of these, except for acetamiprid, has systemic activity and would only control soil pests. Chlorantraniliprole has limited systemic activity and only controls some of the insects controlled by noenicitinoid seed treatments in rice seed. At-plant soil applications may be used in lieu of seed treatments. Application rates are higher than for seed treatments, increasing chemical costs, but a larger zone around the seed may be protected from soil pests. Common insecticides applied at-plant include various carbamates, organophosphates, pyrethroids, and neonicotinoids. For above ground pests, insecticide applications immediately after the crop emerges. Compared to seed treatments, application rates and chemical costs are higher, and the growers are likely to incur additional equipment and labor costs to make the application.

For more information, refer to *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments*, and *Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops* available in the docket.

Stone Fruit
Clothianidin and thiamethoxam each account for about 6% of the peach/nectarine crop treated (9,000 and 11,500 total acres treated, respectively). Among stone fruit crops, clothianidin is registered only for peaches; thiamethoxam is registered for the entire crop group. Thiamethoxam is used to a fairly large extent in cherries (23% average annual crop treated at 49,300 total acres treated).

Important stone fruit pests targeted by clothianidin and thiamethoxam include the plum curculio, aphids, plant bugs, stink bugs, June beetles, and Oriental fruit moth. Treatments for all these pests is typically done soon after petal fall or close to harvest to avoid insect contamination of fruit. Alternative insecticides currently used or recommended include, carbamates, organophosphates, and pyrethroids, other nitroguanidine neonicotinoids (mainly imidacloprid), and the chloropyridinyl neonicotinoid acetamiprid. Use of these chemicals is likely to rise in the absence of clothianidin or thiamethoxam.

For more information, see *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam)*.

Turf and Ornamentals
Clothianidin and thiamethoxam have limited use on turf and ornamentals, where professional applicators reported that these two active ingredients were applied on approximately 3% of the acres treated. Clothianidin and thiamethoxam were reported to be important rotation partners for the management of southern chinch bugs in St. Augustine grass. Neonicotinoids are typically important to managing aphids, borers, white grubs, armored scales and whiteflies in the management of turf and ornamentals. Alternatives to clothianidin and thiamethoxam include other neonicotinoid chemistries (namely imidacloprid and dinotefuran), pyrethroids, organophosphates, avermectins, carbaryl and diamides.

For more information, see *Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent.*

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

As discussed previously, EPA recognizes that the neonicotinoids, including clothianidin and thiamethoxam, are a key tool for growers that provide unique and effective pest control. However, the agency has identified ecological risks of concern, particularly to pollinators and aquatic invertebrates, as a result of many of the same attributes that make the neonicotinoids effective pest management tools. Risk mitigation measures are being proposed to address ecological risks of concern identified for pollinators, birds, mammals, and to aquatic invertebrates; and human health risks of concern to occupational handlers from certain clothianidin and thiamethoxam uses, as described in Section III.

There are human health exceedances identified for several occupational use scenarios. EPA is proposing to mitigate these risks through the requirement of additional Personal Protection Equipment (PPE) such as gloves, respirators, or requiring closed loading systems for seed treatment on labels. Technical registrants are in general agreement with the proposed label changes that will significantly reduce, and eliminate in many scenarios, potential exposure to workers.

There are significant exceedances noted for honeybees. The protection of honeybee colonies is particularly important as, although honeybees are not native to the United States, they play a critical role in the pollination needs of many U.S. crops. While honeybees are often the focus, non-honeybees such as bumble bees, leafcutter bees, and blue orchard bees also play a unique and important role in commercial pollination services, and therefore are also important to protect both bees and agriculture. Additionally, it is important to put forth mitigation that reduces impact to wild native species of bees, as well as honeybees. Rate reductions for certain crops where bee exposure exists or crop stage restrictions that limit exposure during critical periods in the growing season, are expected to have the highest potential impact in reducing risks to all bees.

Due to the persistence of neonicotinoids in the environment, there are also potential exceedances to bees noted for clothianidin and thiamethoxam from usage on poultry litter in chicken houses at the maximum rate and number of applications annually. Once applied, this litter can be taken out of the chicken houses and utilized as fertilizer on agricultural fields, allowing for exposure to bees. The agency is proposing to mitigate these potential risks by reducing the number of poultry house (whole house) applications allowed annually for clothianidin and thiamethoxam.

There are potential risks to birds and small mammals associated with seeds that are coated with neonicotinoids. Mitigation was considered with the understanding of the high benefits associated with seed treatment uses (*e.g.,* early-stage crop protection from soil and above-ground pests), which have the potential to reduce overall neonicotinoid exposure and offer a lower overall risk profile compared to foliar uses. The agency is proposing additional advisory label language,

amplifying Best Management Practices (BMPs), and education programs to help inform farmers about the importance of picking up spilled seed, in order to reduce overall exposure to birds and mammals. High-tech planting equipment using GPS and computer controls is becoming increasingly common in the U.S., and these technologies also help decrease incidence of spills over older, human-operated equipment.

Potential risks to aquatic invertebrates, which fill a foundational role in ecological food webs, are a concern. EPA is proposing several measures for reducing overall exposure including targeted annual application rate reductions and drift and runoff mitigation.

Risks of concern were identified to honeybees in EPA's assessments. The protection of honeybee populations is particularly important as honeybees play a critical role in the pollination needs of many U.S. crops. In 2017 pollination services from operations with more than 5 colonies were valued at over 160 million dollars, and annual honey production in the US was valued at over 340 million dollars[16]. Although the focus of the pollinator risk assessments is on honeybees, the agency recognizes that numerous other species of bees occur in North America and that these non-*Apis* bees have ecological importance in addition to commercial importance in some cases. For example, it is important to note that several species of non-*Apis* bees are commercially managed for their pollination services, including bumble bees (*Bombus spp.)*, leaf cutting bees (*Megachile rotundata*), alkali bees (*Nomia melanderi*), blue orchard bees (*Osmia lignaria)*, and the Japanese horn-faced bee (*Osmia cornifrons*). Importantly, a growing body of information indicates native bees play an important role in crop and native plant pollination, in addition to their overall ecological importance via maintaining biological diversity. EPA is therefore proposing mitigation that reduces impact to honeybees that are also expected to benefit other pollinating insects. Of these measures, reductions in maximum application rates for certain crops where pollinator/bee exposure may occur, or crop stage restrictions which limit exposure during critical periods in the growing season, are expected to have the highest potential impact in reducing risks to all pollinators. These measures were developed in a manner intended to preserve the majority of pest management utility, while also considering risk reductions for bees.

EPA reached out to a variety of stakeholders while drafting its mitigation strategy in order to gain a better grasp of growing practices and potential benefits. EPA also conducted an analysis of common or rare application rates, which was helpful in identifying when conservative assumptions were made in the risk assessments regarding maximum rates. This analysis also allowed the agency to determine where targeted rate reductions would decrease overall potential risks, while minimizing potential impacts to users. Proposed mitigation measures were identified by evaluating each neonicotinoid active ingredient and each use scenario for each crop individually, to determine the best path forward.

Overall, EPA is proposing to address potential risks posed by current registered uses of clothianidin and/or thiamethoxam through the following risk mitigation measures:

- Cancelling certain clothianidin uses
- Restricting certain thiamethoxam uses
- Requiring additional PPE

[16] USDA, National Agricultural Statistics Service (NASS), Agricultural Statistics Board. (2018).

- Reducing maximum application rates or restricting applications during pre-bloom and/or bloom, targeting certain uses with potentially higher pollinator risks and lower benefits
- Preserving the current restrictions for application at-bloom
- Requiring additional label language reducing use by homeowners
- Applying targeted rate reductions for higher risk uses
- Requiring additional spray drift and runoff reduction label language
- Promoting voluntary stewardship efforts to encourage the use of best management practices, education, and outreach to applicators and beekeepers

In selecting appropriate mitigation, EPA considered the benefits of the use of clothianidin and/or thiamethoxam to determine whether any risks present unreasonable adverse effects. For many uses, the benefits are very high. In contrast, significant risks of concern were noted for certain crops. Due to the potential impact to growers' ability to address certain critical pest issues, in accordance with FIFRA's requirement to EPA to take into account the benefits of the use of pesticides in its decision-making, there are cases where the EPA is not proposing risk mitigation. An example of a crop in which the benefits of clothianidin and/or thiamethoxam were weighed against potential impacts of mitigation was citrus crops, where neonicotinoids, including clothianidin and thiamethoxam, are a key element in programs to control the ACP, an invasive pest that transmits HLB, a devastating and incurable disease. See section III.C. for more information. Additionally, EPA considered the overall extent and likelihood of exposure of certain risks of concern. For example, tree injections showed significant risk extending into the following growing season. However, they are an expensive and relatively infrequently used method to prevent tree loss. Due to the low amount of overall usage and strong benefits of the tree injection use, the agency is not proposing risk mitigation.

The proposed mitigation does not eliminate all potential risks of concern from the use of clothianidin or thiamethoxam, however, the proposed mitigation reduces the overall potential of risk and/or exposure. The agency finds the remaining risks to be reasonable under FIFRA, given the benefits of using clothianidin and thiamethoxam. The EPA is also proposing label changes to address general labeling improvements for all clothianidin and thiamethoxam products and uses.

1. Cancellation of Clothianidin Uses on Bulb Vegetables

The agency is proposing that cancellation of clothianidin use on bulbs is necessary in order to mitigate potential exceedances to aquatic invertebrates. The highest neonicotinoid exceedances to aquatic invertebrates from bulb use reached an RQ of 556. A benefits assessment was available for this use, which showed limited usage of neonicotinoids with no usage reported for clothianidin. Although the benefits assessment noted that there are some benefits of neonicotinoid use on bulbs in targeting thrips, alternatives to the neonicotinoids remain available for use on bulbs. In consideration of the high potential risk exceedances and the relatively low expected impacts to bulb growers, EPA is proposing that cancellation of these uses is necessary.

2. Thiamethoxam Use Restrictions for Risks to Occupational Handlers

As noted in Section III.A.1. of this PID, potential risks of concern have been identified for occupational handlers associated with:

- Mixing/loading/applying dry flowable formulations of thiamethoxam for application via backpack sprayer for poultry house applications
- Mixing/loading/applying dry flowable formulations of thiamethoxam for application via mechanically-pressurized handgun to livestock houses, horse barns, and feed lots

These potential risks exceed the EPA's level of concern even when maximum PPE is considered. Therefore, to protect the health of occupational handlers of thiamethoxam, the agency is proposing to restrict all uses for these two use scenarios: 1) DF formulations of thiamethoxam via backpack sprayer for poultry house applications, 2) DF formulations of thiamethoxam via mechanically-pressurized handgun for livestock houses, horse barns, and feed lot applications. It should be noted that even after these proposed restrictions, applicators would still have the option of making thiamethoxam applications in poultry houses, livestock houses, horse barns, and feed lots using alternative application technologies (*e.g.* manually-pressurized handwands) as allowed on labels, taking into account the various mitigation updates proposed in this PID.

3. Glove and Respirator Requirements for Certain Occupational Handlers

Human health exceedances are identified for clothianidin and thiamethoxam for several registered agricultural, seed treatment and non-agricultural (*e.g.* spray applications in commercial buildings) use scenarios. EPA is proposing to mitigate these risks by adding requirements for Personal Protection Equipment (PPE) such as gloves and/or respirator, along with requiring certain application restrictions for commercial facilities.

Most occupational handler risk estimates were not of concern with current baseline attire or with PPE, however, there were some scenarios where risks of concern were identified for workers performing activities (*e.g.*, mixing, loading and/or applying). To mitigate potential dermal and/or inhalation risks to handlers, the agency is proposing the following:

<u>For Clothianidin:</u>

- Proposed uses to add requirement for gloves and a respirator:
  - Corn – seed treatment use (*e.g.*, loading, applying, sewing, bagging, *etc.*)
  - Commercial Buildings – liquid (*i.e.* aerosol cans) application
- Proposed uses to add requirement for gloves:
  - Livestock housing (*i.e.*, non-poultry, barns/feedlots) – Mixing/loading/applying liquid formulation via mechanically-pressurized handgun

As stated in Section III.1 of this PID, there were several potential risks of concern to occupational handlers, including, dermal and inhalation scenarios for corn seed treatment handlers performing several activities (*e.g.* loading, applying, sewing, bagging, *etc.*). The MOE is 71 (LOC = 100) with the current label-required single layer. The agency is therefore proposing the use of a respirator and updating the glove statements for all handlers of clothianidin corn seed treatments. The MOE for the liquid application via aerosol can to treat for bed bugs in commercial buildings was 48. The agency is proposing a label requirement for gloves and a respirator, which results in no risk of concern. The MOE for mixers/loaders/applicators of liquid formulations via mechanically-pressurized handguns in livestock housing was 80. The agency proposes a glove requirement, which no longer results in a risk of concern.

For Thiamethoxam:

- Proposed uses to add requirement for gloves and a respirator:
  - Sod – Mixing/loading dry flowable (DF) formulations for aerial application
  - High-acreage field crops (*e.g.,* barley, wheat, rice, cotton, corn) – Mixing/loading DF formulations for aerial application
  - Warehouses – Mixing/loading/applying liquid formulations via mechanically-pressurized handgun
  - Poultry Houses – Mixing/loading/applying DF formulations via mechanically-pressurized handgun
- Proposed uses to add requirement for gloves:
  - Warehouses – Mixing/loading/applying liquid crack and crevice (C&C) treatment via manually-pressurized handwand
  - Childcare centers, schools and institutions – Mixing/loading/applying liquid C&C treatment via manually-pressurized handwand
  - Residential living spaces – Mixing/loading/applying liquid C&C treatment via manually-pressurized handwand
  - Mounds or nests – Mixing/loading/applying liquid formulations via manually-pressurized handwand
  - Mounds or nests – Mixing/loading/applying DF formulations via manually-pressurized handgun
  - Landscaping trees, shrubs and bushes – Mixing/loading/applying DF formulations via mechanically-pressurized handgun

As noted in Section III.1 of this PID, there were several potential risks of concern to occupational handlers from thiamethoxam uses. Potential risks of concern were identified for mixers/loaders of DF formulations for aerial applications to sod and high-acreage field crops (sod, MOE = 44; high-acreage field crops, MOE = 53). EPA proposes requiring gloves and a respirator, which resolves these potential risks of concern. The MOE for mixers/loaders/applicators of liquid formulations using a mechanically-pressurized handgun to warehouses was 55. This scenario no longer results in a risk of concern with the addition of gloves and a respirator. A potential risk of concern was identified for mixers/loaders/applicators of DF formulations via mechanically-pressurized handguns to poultry houses (MOE = 57), which is eliminated with the addition of gloves and a respirator.

Also, there were six non-agricultural use scenarios with potential risks of concern for mixers/loaders/applicators. For liquid formulations applied via manually-pressurized handwands, there were potential risks of concern associated with crack & crevice (C&C) applications in warehouses (MOE = 91); C&C applications in childcare centers, schools and institutions (MOE = 91); C&C applications to residential living spaces (MOE = 91); and applications to mounds or nests (MOE = 6.7). For these use scenarios, the agency proposes a glove requirement to the label, which eliminates these risks. The MOE for DF formulations applied via manually-pressurized handgun to mounds or nests was 87. The addition of gloves negates this potential risk. Finally, a potential risk of concern was identified for DF formulations applied via mechanically-pressurized handgun to landscaping trees, shrubs and bushes (MOE = 65). Therefore, the agency proposes requiring gloves, which results in no risk of concern.

In addition, the agency is proposing to update the glove statements currently on labels to be consistent with the Label Review Manual. The proposed new language does not fundamentally change the personal protective equipment that workers need to use, and therefore should impose no impacts on users. With cooperation from stakeholders, the proposed label changes would significantly reduce, and eliminate in many scenarios, risks of concern to workers.

The EPA has recently required fit testing, training, and medical evaluations[17] for all handlers who are required to wear respirators and whose work falls within the scope of the WPS.[18] If a clothianidin handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer, which includes the cost of the respirator plus, for WPS-covered products, the cost for a respirator fit test, training, and medical exam.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on available information that the EPA has, the average cost of a disposable particulate filtering face-piece respirator) is about $5 and an elastomeric half mask respirator is $35, with their replacement cartridges averaging around $19.[19] The agency expects that the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. The estimated cost of a respirator fit test, training and medical exam is about $180 annually.[20] The impact of the proposed respirator requirement is likely to be substantially lower for a clothianidin or thiamethoxam handler who is already using a respirator because the handler or handler's employer uses other chemicals requiring a respirator in the production system or as part of the business (*i.e.*, the handler or employer will only incur the cost of purchasing filters for the respirator on a more frequent basis). Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection.[21]

The EPA acknowledges that requiring a respirator and the associated fit testing, training, and medical evaluation places a burden on handlers or employers. However, the proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. In estimating the inhalation risks, and the risk reduction associated with different respirators, the EPA's human health risk assessments assume National Institute for Occupational Safety and Health (NIOSH) protection factors (*i.e.*, respirators are used according to OSHA's standards). If the respirator does not fit properly, use of clothianidin and thiamethoxam may cause unreasonable adverse effects on the pesticide handler.

---

[17] Fit testing, training, and medical evaluations must be conducted according to OSHA regulations 29 CFR § 1910.134, 29 CFR § 1910.134(k)(1)(i) through(vi), and 29 CFR § 1910.134, respectively.
[18] 40 CFR 170 (see also Appendix A of chapter 10 of the Label Review Manual, available at https://www.epa.gov/pesticide-registration/label-review-manual)
[19]Gempler's. 2016. Commercial-Grade Outdoor Work Gear Online Catalogue. Accessed online on August 26, 2016, at http://www.gemplers.com/respirators
[20] Economic Analysis of the Agricultural Worker Protection Standard Revisions. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 2015. p. 205. Available at www.regulations.gov, docket number EPA-HQ-OPP-2011-0184-2522
[21] 29 CFR § 1910.134

4. Closed System Requirement for Thiamethoxam Corn Seed Treatments

As noted in Section III.A.1. of this PID, potential risks of concern have been identified for occupational handlers from the use of thiamethoxam for corn seed treatments in commercial facilities. Even with maximum PPE (double layer of clothing, gloves, and an elastomeric half-mask respirator) required for these uses, certain field, pop, and sweet corn seed treatment scenarios still have MOEs of concern for certain activities, ranging from 13 – 43. These MOEs are well below the agency's level of concern of 100. To protect the health of workers involved in commercial seed treatments of corn using thiamethoxam, EPA is therefore proposing that the use of a closed loading system be required for all thiamethoxam corn seed treatments conducted in commercial facilities. With the addition of a closed loading system, EPA would no longer expect any potential risks of concern to human health for corn seed treatments of thiamethoxam in commercial facilities.

EPA is proposing that all thiamethoxam products registered for corn seed treatment uses must include the following statement on labels:

- "Must be applied by closed system seed treatment application processes when applied in commercial seed treatment facilities."

EPA identified no risk estimates of concern for corn seed treatment uses of thiamethoxam in the case of on-farm seed treatments, and mitigation is therefore not being proposed for that use scenario. The closed system requirement being proposed in this PID is for commercial facilities only.

5. Poultry House Use Requirements for Clothianidin

Ecological risks of concern for both bees and aquatic invertebrates have been identified as a result of poultry house uses of clothianidin. Single application rates associated with non-agricultural uses account for some of the highest application rates, where poultry house applications were up to 0.49 lbs. a.i./A. There is a potential chronic risk for aquatic invertebrates from the application of clothianidin to poultry houses (RQs $\leq$ 7.2). Additionally, soil amendments of clothianidin-treated poultry litter (from the use in poultry houses) pose a risk when applied to fields with honeybee attractive plants (*e.g.*, pasture). Screening level RQs for applications of poultry litter from treated poultry houses resulted in acute and chronic LOC exceedances for adult bees (RQs = 7 and 70, respectively).

To help mitigate these potential risks, EPA is proposing that the all clothianidin products registered for poultry house uses must include the following statements:

- "Limit applications to one whole house treatment and 5 perimeter (partial house) treatments per year."
- "Do not apply to more than 30,000 sq. ft. per year per house."

The goal of these proposed statements is to reduce the total environmental loading of clothianidin resulting from poultry house uses. Limiting both the number and square footage of allowable poultry house treatments per year will limit the amount of clothianidin entering the

environment, when treated poultry litter is removed from poultry houses and used as a soil amendment in agricultural fields, while still retaining the benefits of clothianidin for poultry producers as a treatment for darkling beetles and other poultry houses pests. These proposed limits on poultry house uses of clothianidin will also reduce the exposure of applicators to this pesticide.

6. Application Rate Reductions

Application rate reductions are being proposed for several uses in order to reduce risks to both bees and aquatic invertebrates. For pollinators, these rate reductions focus on certain crops with the highest potential reduction of risks to bees. For bees and aquatic invertebrates, measured rate reductions are a part of a multi-faceted approach to reducing overall exposure. The additional approaches include spray drift and runoff reduction language, current application timing restrictions, and pesticide education and outreach efforts. The goal of these proposed maximum annual application rate reductions is to reduce the total environmental loading of clothianidin and/or thiamethoxam resulting from the various uses specified, while still providing growers with the ability to use these tools as an effective means of pest control.

As part of the assessments of the benefits for the neonicotinoids, EPA also assessed the impacts of potential mitigation, including the effect of reducing rates. This information was critical in identifying sites and rates where rate reductions would achieve the greatest reduction in risk while minimizing the potential impacts on users of clothianidin and/or thiamethoxam. Although these proposed rate reductions do not eliminate all risks, they are expected to contribute to reducing risk overall. The benefits of these uses outweigh the remaining reduced risks of concern.

To help mitigate risks to non-target organisms, EPA is proposing the following reductions in the maximum allowable annual application rates for foliar and/or soil applications of clothianidin and thiamethoxam products:

i. Clothianidin

Table 3. Proposed Maximum Annual Application Rates for Clothianidin

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Rate (Max. Annual)
Berries and small fruit (excluding grape and strawberry)	Maximum combined annual application rate, regardless of formulation type: 0.20 lbs. a.i./A per year	Maximum combined annual application rate, regardless of formulation type: 0.16 lbs. a.i./A per year
Cotton	Maximum combined annual application rate, regardless of formulation type: 0.20 lbs. a.i./A per year	Maximum combined annual application rate, regardless of formulation type: 0.15 lbs. a.i./A per year
Fruiting Vegetables	Foliar: 0.20 lbs. a.i./A per year	Foliar: 0.17 lbs. a.i./A per year
Pome Fruit	Foliar: 0.20 lbs. a.i./A per year	Foliar: 0.16 lbs. a.i./A per year

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Rate (Max. Annual)
Production/Commercial Ornamentals	Foliar and soil: 0.40 lbs. a.i./A per year	Foliar and soil: 0.30 lbs. a.i./A per year
Tree Nuts	Foliar: 0.20 lbs. a.i./A per year Soil: 0.40 lbs. a.i./A per year	Foliar: 0.16 lbs. a.i./A per year Soil: 0.38 lbs. a.i./A per year
Turf	Foliar: 0.40 lbs. a.i./A per year	Foliar: 0.30 lbs. a.i./A per year

Berries and small fruits
In this crop group, clothianidin is registered for use only on cranberry and blueberry. EPA is proposing to reduce the current maximum annual application rate, regardless of the application method, from 0.20 lbs. a.i./A per year to 0.16 lbs. a.i./A per year. This mitigation is being proposed to address aquatic invertebrate exceedances.

Potential risks to aquatic invertebrates are noted for foliar applications of clothianidin to cranberries, with RQs up to 96. The agency is uncertain as to the impact this mitigation will have on growers. Clothianidin was registered for use on cranberries and blueberries in 2016 and usage data are not available. EPA encourages comment on the feasibility of pest control at these rates and the extent to which growers' production practices will be affected.

Cotton
For cotton, EPA is proposing reducing the current maximum combined rate of 0.20 lbs. a.i./A per year, regardless of formulation type, and reducing it to 0.15 lbs. a.i./A per year applied annually. This mitigation measure is being proposed to address pollinator and aquatic invertebrate risk exceedances.

Potential risks from cotton foliar use is considered under the strongest category of evidence for pollinator exceedances. Acute and chronic foliar exceedances are identified for adult bees (RQs = 346 and 2,729, respectively). Foliar applications of clothianidin resulted in chronic RQs that ranged from 30 to 59 for freshwater aquatic invertebrates. Cotton is considered one of the major drivers of potential pollinator risk. However, clothianidin is also considered highly beneficial to cotton growers throughout the growing season for a variety of pests.

Available usage data show that an average of 8,900 lbs. of clothianidin is applied as a foliar treatment each year; less than two percent of the cotton crop is treated with a foliar application of clothianidin, although over 12% of the cotton crop in California and Arizona receives foliar treatment. Nationally, the average annual application rate is 0.097 lbs. a.i./A per year, which is well below the proposed new annual rate of 0.15 lbs. a.i./A per year, however, annual application rates of 0.160 lbs. a.i./A per year are observed on about 13% of the acres treated with clothianidin. With consideration of current usage and typical rates, these rate reductions are expected to have impact on some users. The proposed rate would allow only one application at the maximum single application of 0.10 lb a.i./A per year. Growers who would normally make a second application may have to use alternative insecticides.

Fruiting Vegetables
For the fruiting vegetables crop group, EPA is proposing reducing the current maximum foliar annual application rate from 0.20 lbs. a.i./A per year to 0.17 lbs. a.i./A per year. This rate reduction is targeted at reducing potential risk to aquatic invertebrates.

Potential risks to aquatic invertebrates are noted for both foliar and soil applications of clothianidin from fruiting vegetable use, with RQs ranging up to 768 and the highest exceedances identified for foliar uses. The agency expects that the potential impacts to growers from this mitigation will be low. According to usage data, annual rates above 0.12 lbs. a.i./A per year are used on only about one percent of the area treated with clothianidin, inclusive of soil applications. The proposed rate allows at least two foliar applications of clothianidin per year.

Pome Fruit
For pome fruit, EPA is proposing to reduce the current maximum annual foliar application rate of 0.20 lbs. a.i./A per year to 0.16/year lbs. a.i./A. This mitigation is being proposed for aquatic invertebrate risk exceedances.

Potential risks to aquatic invertebrates are noted for applications of clothianidin from pome fruit use, with a chronic RQ of 108. A rate reduction of clothianidin in apple will impact about 11% of the Eastern apple crop acreage that use clothianidin to control plum curculio and brown marmorated stink bug. For apple orchards treated with clothianidin, approximately 90% of the base acres are treated with average annual rates of 0.16 lbs. a.i./A per year (MRD, 2013-2017). Thus, a reduction in the annual rate is likely to affect about 10% of Eastern apple crop acreage facing severe pest pressure. For pear, about 1% of the crop acreage is treated with clothianidin to control pear psylla and mealybug. Of the pear crop acreage treated with clothianidin, nearly 98% are treated at the maximum annual rate of 0.20 lbs. a.i./A per year. For these pear crops, a rate reduction is likely to have a significant impact on the use clothianidin. Benefits are considered high for pome fruit use of clothianidin. Alternatives to clothianidin in pome fruit include organophosphates, pyrethroids, and other neonicotinoids (such as imidacloprid and acetamiprid).

Production/Commercial Ornamentals
For production/commercial ornamentals, EPA is proposing a reduction of the current maximum annual foliar and soil application rate from 0.40 lbs. a.i./A per year to 0.30 lbs. a.i./A per year. This rate reduction is targeted at reducing potential risk to pollinators and aquatic invertebrates (nursery only). These rate reductions apply to ornamental ground cover, ornamental trees, forestry, ornamental woody shrubs and vines, and outdoor greenhouses/nurseries. This mitigation does not apply to indoor commercial nursery, Christmas trees, greenhouse uses, or forestry use on public land and quarantine application by USDA.

Potential risks from ornamentals are considered under the strongest category of evidence for pollinator exceedances based on bridged residue studies and three bee kill incident reports (see *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*). Also, potential risks to aquatic invertebrates are noted for foliar and soil applications, with chronic RQs ranging from 30 to 86 for foliar applications and from 29 to 83 for soil applications. Benefits are considered high for the use of neonicotinoids, however, clothianidin is one of the least used neonicotinoid active ingredients for these use sites (3%).

Other than the available 2014 AgInfomatics report and review, usage data is limited. This rate reduction is considered to have potentially moderate impacts on current usage.

Tree nut
For tree nuts, EPA proposes reducing the current maximum foliar annual application rate from 0.20 lbs. a.i./A per year to 0.166 lbs. a.i./A per year, and a reduction in the maximum soil annual application rate from 0.40 lbs. a.i./A per year to 0.38 lbs. a.i./A per year. This mitigation measure is being proposed for aquatic invertebrate exceedances.

Potential risks from tree nut uses are noted for aquatic invertebrates. Aquatic invertebrate exceedances for foliar applications ranged from 256 to 433 and for soil applications from 18 to 84. Highest benefits of clothianidin use on tree nuts are in pecans where PCTs may be as high as 10 and average around 5.[4] The average annual rate is 0.127 lbs. a.i./A per year. Therefore, the proposed annual foliar rate reduction is expected to have low impact on growers. Reductions in the annual soil application rates are expected to have low impacts on current usage; soil applications appear rare to nonexistent.

Turf
For turf, EPA is proposing reducing the current maximum annual foliar and soil application rate from 0.40 lbs. a.i./A per year to 0.30 lbs. a.i./A per year. This rate reduction is targeted at reducing potential risk to aquatic invertebrates.

Potential risks to aquatic invertebrates are noted for foliar applications of clothianidin on turf, where RQs ranged from 46 to 71. There is also moderate evidence (high initial residues and a bee kill incident) indicating that use of clothianidin on attractive flowering weed species presents potential risk to honeybee colonies. Benefits are considered high for the use of neonicotinoids, however, clothianidin is one of the least used neonicotinoid active ingredients for this use site. Other than the available 2014 AgInfomatics report and review, usage data is limited. AgInfomatics reported that clothianidin is important for southern chinch bug control in St. Augustine grass, and a rate reduction of clothianidin in turf may negatively impact turf management efficacy against southern chinch bugs in St. Augustine grass. Overall, this rate reduction is considered to have potentially moderate impact on turf given the current usage.

ii. Thiamethoxam

Table 4. Proposed Maximum Annual Application Rates for Thiamethoxam

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Rate (Max. Annual)
Berries and Small Fruit (Foliar Applications)	Bushberry Subgroup (including but not limited to highbush blueberry, gooseberry, etc.)	
	0.188 lbs. a.i./A per year	0.15 lbs. a.i./A per year
	Caneberry Subgroup (including but not limited to blackberry, raspberry, etc.)	
	0.094 lbs. a.i./A per year	0.07 lbs. a.i./A per year
	Low Growing Berry Subgroup (including but not limited to lowbush blueberry, strawberry, cranberry, etc.)	
	0.188 lbs. a.i./A per year	0.15 lbs. a.i./A per year

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Rate (Max. Annual)
	Small Fruit Vine Climbing Subgroup (including but not limited to maypop; excluding grape, fuzzy kiwi fruit and gooseberry)	
	0.109 lbs. a.i./A per year	0.09 lbs. a.i./A per year
Berries and Small Fruit (Soil Applications)	Bushberry Subgroup (including but not limited to highbush blueberry, gooseberry, etc.)	
	0.188 lbs. a.i./A per year	0.15 lbs. a.i./A per year
	Low Growing Berry Subgroup (including but not limited to lowbush blueberry, strawberry, cranberry, etc.)	
	0.188 lbs. a.i./A per year	0.15 lbs. a.i./A per year
	Small Fruit Vine Climbing Subgroup (including but not limited to maypop; excluding grape, fuzzy kiwi fruit and gooseberry)	
	0.266 lbs. a.i./A per year	0.22 lbs. a.i./A per year
Cotton	Maximum combined annual application rate, regardless of formulation type: 0.125 lbs. a.i./A per year	Maximum combined annual application rate, regardless of formulation type: 0.09 lbs. a.i./A per year

Berries and small fruits
The berries and small fruits group includes several subgroups of crops such as bushberry, caneberry, low growing berry, and vine climbing small fruit, but not including grape. EPA is proposing reducing the current maximum foliar annual application rate for the bushberry subgroup from 0.188 lbs. a.i./A per year to 0.15 lbs. a.i./A per year; the caneberry subgroup from 0.094 lbs. a.i./A per year to 0.07 lbs. a.i./A per year; the low growing berry subgroup from 0.188 lbs. a.i./A per year to 0.15 lbs. a.i./A per year; and the small fruit vine climbing subgroup from 0.109 lbs. a.i./A per year to 0.09 lbs. a.i./A per year.

The agency is also proposing reducing the current maximum soil annual application rate for the bushberry subgroup from 0.188 lbs. a.i./A per year to 0.15 lbs. a.i./A per year; the low growing berry subgroup from 0.188 lbs. a.i./A per year to 0.15 lbs. a.i./A per year; and the small fruit vine climbing subgroup from 0.266 lbs. a.i./A per year to 0.22 lbs. a.i./A per year. This mitigation is being proposed to reduce potential pollinator risk.

Potential risks from foliar and soil, pre-bloom applications to berries is considered under the strongest category of evidence for pollinator exceedances. Foliar exceedances for adult pollinators are identified with an acute RQ of 170 and a chronic RQ of 860. A foliar chronic exceedance is also identified for larval bees (RQ = 35). Soil exceedances to adult pollinators are identified with an acute RQ of 15 and a chronic RQ of 71. A soil exceedance is also identified for larval bees (Chronic RQ = 3.9). Benefits are also considered substantial for thiamethoxam's use on berries and small fruit, where PCTs ranged 7 – 32%. The agency expects a potential moderate impact on usage.

The agency expects variable impacts on growers, depending on the crop. Growers of caneberry are most likely to experience an impact; the average annual application rate is 0.092 lbs. a.i./A per year (*i.e.,* most users apply thiamethoxam at or near the current maximum application rate).

In some years, 10% of blueberry acres are treated at rates of 0.163 lbs. a.i./A per year, implying that some growers may face potential sporadic constraints. However, proposed rates would allow strawberry growers at least two applications per year and is likely to affect very few acres.

Cotton
For cotton, EPA is proposing to reduce the current maximum combined rate of 0.125 lbs. a.i./A per year, regardless of formulation type, and reducing it to 0.09 lbs. a.i./A per year applied annually. This mitigation is being proposed to reduce potential pollinator risk.

Potential risks from cotton foliar use is considered under the strongest category of evidence for pollinator exceedances. There are acute and chronic foliar exceedances for adult bees (RQs = 53 and 66, respectively). There is also a chronic foliar exceedance for larval bees (RQ = 2.7). Cotton is considered to be one of the major drivers of potential pollinator risk. Thiamethoxam is also considered highly beneficial to cotton growers throughout the growing season for a variety of pests.

Available usage data show that an average of 62,300 lbs. of thiamethoxam is applied as a foliar treatment each year to 1.5 million acres. Also, the average annual application rate is 0.065 lbs. a.i./A per year, which is well below the proposed new annual rate of 0.098 lbs. a.i./A; rates of 0.10 lbs. a.i./A per year are used on about 8% of the acres. With consideration of current usage and typical rates, these rate reductions may impact some users. The proposed rate would allow only one application at the maximum single application of 0.063 lbs. a.i./A. Growers who would normally make a second application may have to use alternative insecticides.

7. Crop Stage Restrictions

Crop stage restrictions can limit exposure during critical periods in the growing season when exposures to pollinators are more likely to occur. In its final bee risk assessment, the agency analyzed a large volume of scientific data showing residues of neonicotinoids in pollen and nectar over time. Through this analysis the agency calculated pre-bloom intervals to determine at what stage in the growing season risk exceedances went above the level of concern. By selecting application restrictions based on crop stage, the agency expects potential exposure can be significantly reduced. These proposed restrictions were preferable only in crops with distinct phenological stages which are easily identifiable by growers.

i. Clothianidin

Table 5. Proposed Crop Stage-based Application Restrictions for Clothianidin

Crop/Crop Group	Proposed Risk Mitigation
Cucurbits	The agency is proposing a crop stage restriction for both foliar and soil labels, to prohibit use from vining to harvest or after the emergence of the first true (non-cotyledon) leaf

Crop/Crop Group	Proposed Risk Mitigation
Avocado, banana, dates and olives	The agency is proposing a crop stage restriction for foliar labels, to prohibit foliar application pre-bloom until after flowering is complete and all petals have fallen off.

Cucurbits
For cucurbits, EPA is proposing a crop stage restriction for both foliar and soil labels, to prohibit use on vining to harvest or after the emergence of the first true (non-cotyledon) leaf. The applicator has a choice to either utilize crop stage frame of reference (*e.g.,* vining to harvest or first true (non-cotyledon) leaf). The agency encourages input from stakeholders regarding the best identifier for crop stage.

Potential risks to pollinators are noted under the strongest evidence of risk for cucurbit foliar uses, and under the moderate evidence of risk for cucurbit soil uses. Foliar RQ exceedances for adult pollinators are identified with an acute RQ of 0.5 and a chronic RQ of 4.1. RQ exceedances for adult pollinators from soil applications are identified for both acute and chronic (RQs = 5.2 and 53, respectively). Also, there is an RQ exceedance from soil application for larval pollinators (max larval RQ = 2.16). Neonicotinoid residue data indicate that residues remained in the plant at high levels for weeks after application as seen by the lowest observed adverse effect concentration (LOAEC) shown reached at 19 days after application for foliar and 47 days for soil. Available benefits information identified clothianidin's usage as mostly negligible, and neonicotinoids are not typically used after vining. Therefore, a restriction from vining to harvest is not likely to significantly impact current usage.

Tropical and Subtropical Fruit
For avocado, banana, dates, and olives; EPA is proposing a crop stage restriction for foliar use, to prohibit foliar application pre-bloom until after flowering is complete and all petals have fallen off. The agency is not proposing crop stage restrictions for other fruit trees in this crop group.

Potential risks to pollinators are noted under the weakest evidence of risk for foliar and soil post-bloom. Mitigation is being proposed on crops in this group that are considered to have higher acreage and to be pollinator attractive, and no mitigation is being done on low acreage or non-bee attractive crops. Clothianidin's usage varies across the crops in the tropical and subtropical fruit group, with relatively high usage on fig and pomegranate trees. From the information available on avocado, dates, and olives, the agency anticipates low impacts to users. California accounts for about 90% of total U.S. acreage of these crops and, based on data from California Pesticide Use Reports, usage of clothianidin is rare on avocado, dates, and olives. EPA is specifically requesting public comments to better understand potential impacts on banana production.

ii. Thiamethoxam

Table 6. Proposed Crop Stage-based Application Restrictions for Thiamethoxam

Crop/Crop Group	Proposed Mitigation
Cucurbits	The agency is proposing a crop stage restriction for foliar labels only, to prohibit use vining to harvest or after the emergence of the first true (non-cotyledon) leaf.
Fruiting Vegetables	The agency is proposing a crop stage restriction for both foliar and soil labels, to not apply after the appearance of the initial flower buds until flowering is complete and all petals have fallen off. Additionally, for tomatoes, peppers, chili peppers and okra only, EPA is also proposing to not apply after 5 days after planting or transplanting regardless of application method.
Pome Fruit	The agency is proposing crop stage restrictions for foliar labels only, to not apply from bud-break (also known as "swollen bud stage" in pear or "silver-tip stage" in apple) until after petal fall is complete.
Stone Fruit	The agency is proposing a crop stage restriction for foliar labels, to prohibit foliar application from bud break until after petal fall is complete.
Tree Nuts	The agency is proposing the following crop stage restrictions for foliar labels only: For walnuts and pecans: "Do not apply prior to bud break or until after petal fall is complete." For other tree nut crops: "Do not apply prior to bloom or until after petal fall is complete."
Avocado, banana, dates and olives	The agency is proposing a crop stage restriction for foliar labels, to prohibit foliar application pre-bloom until after flowering is complete and all petals have fallen off.

Cucurbits
For cucurbits, EPA is proposing a crop stage restriction for foliar labels, to prohibit use from vining to harvest or after the emergence of the first true (non-cotyledon) leaf. The applicator has a choice to utilize either crop stage frame of reference (*e.g.,* vining to harvest or first true (non-cotyledon) leaf). The agency encourages input from stakeholders regarding the best identifier for crop stage.

Potential risks to pollinators are noted under the strongest evidence of risk for cucurbit foliar uses, and under the strongest evidence of risk for cucurbit foliar uses. Foliar exceedances to adult pollinators are identified with an acute RQ of 23 and a chronic RQ of 1400. Acute and chronic

risk exceedances to adult pollinators from soil applications are identified (RQs = 4.6 and 23, respectively). Also, there are chronic foliar and soil RQ exceedances for larval pollinators (larval RQs = 56 and 1.2, respectively). Neonicotinoid residue data indicate that residues remained in the plant at high levels for weeks after application as seen by the lowest observed adverse effect concentration (LOAEC) shown reached at 19 days after application for foliar and 47 days for soil. According to EPA's assessment, thiamethoxam's usage is primarily at-plant or immediately after crop emergence. Therefore, a restriction from vining to harvest is likely to have a marginal impact on current usage.

Fruiting Vegetables
For the fruiting vegetables crop group, EPA is proposing a crop stage restriction for both foliar and soil labels, to not apply after the appearance of the initial flower buds until flowering is complete and all petals have fallen off. For tomatoes, peppers, chili peppers and okra, EPA is also proposing to restrict application after 5 days after planting or transplanting regardless of application method.

Potential risks to pollinators are noted under the strongest evidence of risk for foliar and under the moderate evidence of risk for soil uses of pollinator attractive fruiting vegetables. Pollinator risk exceedances from foliar application are identified with an adult bee acute RQ of 38 and a chronic RQ of 240; soil application risk exceedances for adult bees are identified for both acute (RQ = 109) and chronic (RQ = 430). Chronic risk exceedances are also identified for larval bees from foliar and soil applications (RQs = 1.3 and 18, respectively). Benefits are considered to be high for thiamethoxam's use on fruiting vegetables, where PCTs ranged from 19 – 31%. Thiamethoxam is particularly important to pepper growers. Applications after crop emergence or transplanting account for around two-thirds of the neonicotinoid-treated acres of peppers and tomato acres. Thiamethoxam targets season-long pests. Thrips and leafhopper can target fruit directly and viral diseases vectored by these pests can seriously impact the development, quality and/or yield of the harvested fruit. Aside from neonicotinoids, California extension only recommends carbaryl for leafhopper control; it is not systemic and may have to be applied multiple times to achieve control throughout the season. Alternatives for thrips include pyrethroids, OPs, acetamiprid, and cyantraniliprole; oxamyl might provide good systemic control but EPA has previously proposed cancelling use of oxamyl on tomato.

Pome Fruit
For pome fruit, the agency is proposing crop stage restrictions for foliar labels only. For pears, the agency proposes to prohibit foliar applications from swollen bud stage until after petal fall is complete. For non-pear pome fruit (including but not limited to apple), the agency proposes a prohibition on foliar applications from the silver-tip stage until after petal fall is complete.

Potential risks to pollinators are noted under the strongest evidence of risk for foliar, pre-bloom applications of thiamethoxam to pome fruit. Acute and chronic foliar exceedances are identified for adult bees (RQs = 52 and 400, respectively). Additionally, a chronic exceedance is identified for larval bees (RQ = 18). Foliar exceedances are also identified for freshwater invertebrates (RQs ranged 5.2 to 5.6). Benefits are also considered to be low to high for thiamethoxam's use on pome fruit, where PCTs ranged from 1 – 50%. Thiamethoxam is particularly important to eastern apple growers. Available benefits information identified thiamethoxam as most used

post-bloom (65 – 80%), therefore, the proposed restrictions are likely to have low to moderate impact on current usage. Thiamethoxam is the primary control option of plum curculio during the pre-bloom and bloom period in eastern apple production (accounting for 17 PCT). The prohibition of thiamethoxam use during this time period will likely lead to an increase in the use of the leading alternatives, lambda-cyhalothrin and phosmet. There is likely a limited impact to pear and western apple growers from this restriction.

Stone Fruit
For stone fruit, the agency is proposing crop stage restriction for foliar labels, to prohibit foliar application from bud break until after petal fall is complete.

Potential risks to pollinators are noted under the strongest evidence of risk for foliar, pre-bloom applications of thiamethoxam to stone fruit. Acute and chronic foliar exceedances are identified for adult bees (RQs = 1.1 and 5.2, respectively). Foliar RQ exceedances are also identified for freshwater invertebrates (RQs ranged 5.2 to 5.6). Available benefits information identified thiamethoxam as most used post-bloom (>80%), therefore, the proposed restrictions are likely to have low impact on current usage.

Tree Nuts
For tree nuts, EPA is proposing crop stage restrictions for foliar labels. For walnuts and pecans, the agency proposes to prohibit use prior to bud break or until after petal fall is complete, and for other tree nut crops, the agency proposes to prohibit use prior to bloom or until after petal fall is complete. The applicator has a choice to utilize either crop stage frame of reference (*e.g.,* prior to bud break or until after petal fall is complete). EPA is specifically requesting public comments to better understand potential impacts from these proposed crop stage restrictions. Available data for pecans indicates that almost 20% of total acres treated with neonicotinoids occurs prior to or around bloom although this time period includes a period after bloom and prior to nut swell. The proposal would allow dormant season applications of thiamethoxam prior to bud break.

Potential risks to pollinators are noted under the strongest evidence of risk for foliar, pre-bloom applications of thiamethoxam to tree nuts. Residue studies report residue exceedances, where residues persisted for 13 – 21 days before exceeding the LOAEC, and 21 days before exceeding the NOAEC. Benefits are also considered low for thiamethoxam's use on tree nuts, where PCTs are about 1% or less for pecans and pistachios. Given thiamethoxam's minimal use on tree nut crops, the agency anticipates low impacts on growers.

Tropical and Subtropical Fruit – Avocado, Banana, Dates and Olives
For avocado, banana, dates and olives; EPA is proposing a crop stage restriction for foliar labels, to prohibit foliar application pre-bloom until after flowering is complete and all petals have fallen off. The agency is not proposing crop stage restrictions for other fruit trees in this crop group.

Potential risks to pollinators are noted under the strongest evidence of risk for foliar, pre-bloom applications of thiamethoxam. Mitigation is being proposed on crops in this group that are considered both higher acreage and pollinator attractive, no mitigation is being done on low usage or non-bee attractive crops. Neonicotinoids are generally considered important to

pomegranate production (PCT = ~46%, neonicotinoids). From the information available on avocado, dates, and olives, the agency anticipates low impacts to users. California accounts for about 90% of total U.S. acreage of these crops and, based on data from California Pesticide Use Reports, usage of thiamethoxam is rare on avocado, dates, and olives. EPA is specifically requesting public comments to better understand potential impacts on banana production.

8. Advisory Statements for Clothianidin and Thiamethoxam Seed Treatment Uses

Acute and chronic dietary risks of concern have been identified for birds and mammals exposed to clothianidin and/or thiamethoxam treated seeds. The potential for risk depends on the size of the animal and the treated seed. However, the risk potential is also dependent on factors affecting exposure (*e.g.* application rates, timing, seed depth).

To help mitigate these risks, EPA is proposing that all pesticide products that contain either clothianidin and/or thiamethoxam and are registered for seed treatment uses must include the following advisory statements:

- "Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)."
- "Dispose of all excess treated seed by burying seed away from bodies of water."
- "Do not contaminate bodies of water when disposing of planting equipment wash water."

The purpose of these required advisory statements is to encourage the adoption of best management practices when handling and planting clothianidin- and/or thiamethoxam-treated seeds that will reduce the exposure of birds and mammals to treated seeds. Covering or collecting spilled seed and burying excess seed are measures that will reduce the likelihood that animals will find and consume treated seeds. Water bodies tend to be gathering points for birds and mammals. Therefore, disposing of equipment wash-water away from these water bodies will decrease the chance of contaminating these water bodies with neonicotinoid residues. Likewise, disposing of excess seeds away from these water bodies will decrease the likelihood of animals incidentally ingesting treated seeds while visiting a body of water. Finally, although these advisory statements were developed with the primary intention of reducing the exposure of birds and mammals to neonicotinoid-treated seed, adding these statements to labels is also expected to benefit aquatic organisms by reducing neonicotinoid loading in aquatic systems.

9. Residential Ornamental Advisory

For application to ornamental plants, the agency identified significant risks of concern. In the agency's final bee risk assessment, ornamentals are designated under the strongest evidence for potential pollinator risk. Potential risks to aquatic invertebrates are also identified, with RQs ranging up to 86. Clothianidin and thiamethoxam use on ornamentals is limited, with both chemistries applied to approximately 3% of the crop acreage treated. However, other than the available 2014 AgInfomatics report and review, usage data is limited. To help mitigate these risks, the agency is proposing the following advisory language for residential uses:

- "Intended for use by professional applicators."

This is due to the high risks of concern, the potential extent of exposure, particularly to bees, and to decrease the likelihood of misapplication or overapplication where significant risks of concern have been identified for these uses.

10. Spray Drift Reduction and Runoff Reduction

EPA is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all clothianidin and thiamethoxam products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of clothianidin or thiamethoxam.

The agency is proposing the following spray drift mitigation language be included on all clothianidin and thiamethoxam product labels. The proposed spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is providing recommendations which allow clothianidin and thiamethoxam registrants to standardize all advisory language on clothianidin and thiamethoxam product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this proposed interim decision once effective.

These mandatory spray drift mitigation measures are proposed for aerial applications for all products delivered via liquid spray:

- Applicators must not spray during temperature inversions.
- For aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- Specify spray droplet size of medium or coarser (ASABE S572.1)
- Do not apply by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.

These mandatory spray drift mitigation measures are proposed for ground applications delivered via liquid spray:

- Applicators must not spray during temperature inversions.

- Do not apply when wind speeds exceed 15 mph at the application site.
- User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy.
- Specify spray droplet size of medium or coarser (ASABE S572.1)
- For air blast applications, nozzles directed out of the orchard must be turned off in the outer row.
- For air blast applications, applications must be directed into the canopy foliage.
- Do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.

To reduce the amount of clothianidin and thiamethoxam that can enter waterbodies from runoff, EPA is proposing a vegetative filter strip (VFS) requirement for all clothianidin and thiamethoxam agricultural products of 10 feet. Currently some clothianidin and thiamethoxam product labels already have a VFS requirement of 10 feet on labels. VFS are intended to reduce sediment loads to adjacent water bodies, and also show some efficacy in reducing runoff volume as well. As a consequence, they may have some utility in reducing movement of pesticides, particularly those bound to sediments into natural waters.

They are somewhat expensive to implement and maintain, and they must be maintained, or they will lose efficacy and channelized flow across the VFS will develop after a few years. VFS are most effective at removing non-source point pollutants (e.g., pesticides) from runoff water sources. However, the effectiveness of a VFS is influenced by various land management practices (e.g., flood and furrow irrigated fields, etc.) which may impact their utility. The agency has considered several additional sources of research which contextualize the benefits of VFS and has determined that proposing the use of VFS is appropriate mitigation to reduce clothianidin and thiamethoxam residues in aquatic habitats. EPA is not proposing a VFS requirement in Western irrigated agriculture because a VFS would be more expensive to maintain, and runoff is less likely. In the west, areas where agriculture is irrigated would likely require irrigation to maintain a VFS, and on fields where water is managed carefully there is less likely to be runoff and erosion into a waterbody.

The following proposed mitigation measure applies to all agricultural uses of clothianidin and thiamethoxam. This proposed mitigation requirement is separate and in addition to the spray drift buffer zones described above; spray drift buffer zones are still proposed to be required if a vegetated filter strip is present. The proposed vegetative filter strip requirement reads as follows:

- Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (e.g., lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, commercial fish farm ponds).
    - Only apply products onto fields where a maintained vegetative filter strip of at least 10 feet exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 10 feet may be reduced under the following conditions:
        - Western irrigated agriculture is exempt from this requirement. Western irrigated agriculture is defined as irrigated farmland in the following

states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35).

In addition to the drift reduction measures and VFS discussed above, EPA is proposing measures to reduce the perimeter treatment area and increase label clarity and consistency, thus reducing the overall amount of clothianidin and thiamethoxam that enters waterbodies and outdoor drainage systems. Specific measures are intended to ensure areas sprayed are permeable and less runoff-prone, reduce offsite-drift to waterbodies, as well as to reduce the potential for over-spraying. Although potential risks to aquatic organisms are expected to remain after the implementation of the measures, these proposed label changes are directionally correct with respect to reducing the amount of environmental exposure. The following mandatory and advisory mitigation measures for all clothianidin and thiamethoxam outdoor residential and commercial use sites to reduce the amount of runoff entering waterbodies and drainage systems:

- Band and perimeter treatment is limited to an area of application no more than 7' out x 2' feet up maximum around buildings or structures.
- Spot treatment is application to limited areas on which insects are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls, and bases or undersides of equipment. For this purpose, a "spot treatment" will not exceed 2' x 1' square feet.
- Do not apply to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack and crevice treatment.
- Do not apply to the point of runoff.
- Do not apply during rainfall.
- Avoid applying when rain is expected within 24 hours except when product requires watering in.

<u>Impacts of Spray Drift and Runoff Mitigation</u>

Wind Speed, Boom Length/Swath Displacement, and Release Height
Current requirements for aerial applications are:

- Do not apply thiamethoxam when wind speeds exceed 10 mph at the application site. The boom length must be 75% or less of the wingspan or rotor diameter.
- Do not apply clothianidin when wind speeds exceed 10 and 15 mph at the application site (the label provides conflicting directions). The boom length must be 75% or less of the wingspan and 90% of rotor diameter.
- The release height of both active ingredients must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- There are no requirements for swath displacement on current labels.

There are no proposed changes for release height. Proposed changes will allow applications of thiamethoxam at higher wind speed, which will provide growers with greater flexibility to make applications in a timely manner. Further, at wind speeds of 10 mph or less, the boom length for helicopter is increased to 90 percent of the rotor diameter, which may necessitate fewer passes to

complete an application, likely decreasing application costs. The proposed changes will provide clarity to clothianidin users. To the extent that users make applications at wind speeds between 10 and 15 mph, boom lengths will be reduced under the proposal, which may necessitate more passes to complete an application, potentially increasing application costs. Currently, there are no requirements for swath displacement. The agency has not assessed the impacts of a ½ or ¾ swath displacement upwind at the downwind edge of the field. The agency invites comments if this mitigation would impact growers.

Current requirements for ground applications are:

- Do not apply thiamethoxam when wind speeds exceed 10 mph at the application site.
- The release height for thiamethoxam must be no higher than 10 feet from the top of the crop canopy or ground (*i.e.*, same as for aerial applications)
- Do not apply clothianidin when wind speeds exceed 15 mph at the application site.
- The release height for thiamethoxam must be no higher than 4 feet from the top of the crop canopy or ground

Proposed changes will allow thiamethoxam applications at higher wind speed, which will increase the flexibility growers have to make applications in a timely manner.

Proposed changes will allow applications of thiamethoxam at higher wind speed, which will provide growers with greater flexibility to make applications in a timely manner. Based on previous reviews of recommended release heights for optimal coverage across common nozzle types, a release height of 4 feet or less should not impact growers when making applications of clothianidin or thiamethoxam.

Temperature Inversions (Ground and Aerial Applications)
Labels are currently silent on inversions or have advisory language to discourage applying during inversions. The proposed requirement could result in delays to intended applications and, more generally, reduce the amount of time users have to apply clothianidin and thiamethoxam. Management of production activities will be more complex. Potentially, growers could switch to a different active ingredient that does not have this restriction, but that would be costly and potentially difficult in a short period of time. Moreover, temperature inversions are more likely to occur a couple of hours before sunset and after sunrise, which is also when applications may be timed to avoid spraying when pollinators are active, complicating growers' ability to follow good stewardship programs.

Droplet Size
Currently, growers are advised to apply using medium or coarser droplets or the largest droplet that provides effective control.

The agency is establishing a mandatory droplet size of medium or coarser for all neonicotinoids to address the potential risks of neonicotinoids to terrestrial and aquatic invertebrates. Components of applications, including droplet size, are complex, but essentially insects need to come into contact with, or ingest, a lethal dose of insecticide to be effectively controlled which requires proper coverage throughout the plant or foliage. Systemic insecticides, like clothianidin

and thiamethoxam, control some insects regardless of droplet size due to the systemic movement within the plant. However, neonicotinoids, including clothianidin and thiamethoxam, are valuable because they also have immediate, contact activity, especially when applied to the foliage.

Generally, entomologists accept that good coverage is required for maximum efficacy during an application and that fine droplets provide better coverage than medium or coarser droplets. Requiring larger droplet size than a grower would normally use could decrease the immediate, control of pests, which could result in reduced yields or quality of produce. Furthermore, higher rates of survival of the target pest(s) could undermine resistance management efforts by selecting for more tolerant biotypes. To compensate, growers could use higher application rates than they otherwise would, if allowed; make more frequent applications; and/or select alternative products. These actions would likely increase pest control costs.

Requirements for Air Blast Sprayers
There are currently no specific requirements air blast applications. The agency does not anticipate impacts to the users of clothianidin or thiamethoxam from requirements to direct spray into the canopy and to turn off nozzles that would treat the outer orchard rows as this corresponds to good application practices. The agency invites comments if this mitigation would impact applicators.

Buffers and Vegetative Filter Strips
Currently, users of clothianidin and thiamethoxam are not to cultivate or plant crops within 25-foot of aquatic areas to provide a VFS. The proposed requirement for would reduce the size of the VFS to 10 feet or less for irrigated agriculture, but maintain the 25-foot area as a buffer. Reducing the size of the VFS could reduce the costs growers incur to maintain the VFS and potentially increase the cultivated area of their fields, although they could not apply thiamethoxam or clothianidin within the area previously part of the VFS due to the proposed buffer.

However, the proposed 150-foot buffer from aquatic habitats for aerial applications represents a substantial change that could impact usage of thiamethoxam and clothianidin. Currently, aerial applications are used for nearly 30% of the area treated with clothianidin and almost 20% of the area treated with thiamethoxam. Aerial applications are most common in soybean, in terms of total acres and the proportion of acres treated by air, but aerial applications are relatively common in some small acreage crops including lettuce, and *brassica* vegetables.[22] Aerial applications account for over 10% of the Florida orange acreage treated with clothianidin.

If growing areas are adjacent to water bodies, buffers may require growers to leave a portion of the land dedicated to crops untreated or remove land from production. The impact of this mitigation can be highly localized and depends on the size and shape of a field. Leaving an area untreated in a field can harbor insects and serve as a source of re-infestation, requiring subsequent applications.

[22] Market Research Data. 2013-2017.

Removing land from production can decrease revenue from lost crop area. EPA previously estimated impacts of lost productive lands from increasing vegetative filter strips for pyrethroids, which also restrict application near water bodies. Buffers do not need to be maintained like vegetative filter strips, but the value of lost cropped area is likely to be similar. For the earlier BEAD analysis, lost crop areas were presented for increases in lost are of 15 and 25 feet. However, the proposed buffer for aerial applications is 150 feet, an increase of 125 feet over the existing vegetative filter strip. Using the same method that was used for pyrethroids, the value of the potential lost crop area from the increased buffer can also be estimated. The estimated impacts disproportionally affect growers producing crops from small acreage fields, as a greater portion of the total field is lost to a buffer. For example, clothianidin and thiamethoxam have significant aerial applications to soybeans and cotton. The median size soybean field is 13.6 acres, and if that field is assumed to be rectangular with a waterbody along the long side, the lost crop value is estimated to be $116 per acre for the increase in lost cropped area from a buffer change to 150 feet from 25 feet. The impacts are greater for smaller fields as is typical for vegetable production. For example, ten percent of tomato fields are 2.2 acres or smaller and a 150-foot buffer for clothianidin and thiamethoxam could mean that almost 68% of the field could be lost to a buffer if the field were adjacent to a water body.

The greatest impacts may be incurred by Florida orange growers who may be constrained from making aerial applications of clothianidin for ACP control. Aerial applications may be part of coordinated treatment programs among multiple growers. EPA encourages comments on the impacts the buffer may have. Instead of taking land out of production, a grower could switch to a different chemical that does not have a buffer requirement, apply an alternative to only those areas of the field that is within the buffer or accept pest damage in the buffered areas. Leaving an area untreated in a field can harbor insects and serve as a source of re-infestation, requiring subsequent applications.

Impacts of Mitigation Measures for Residential and Commercial Use Sites
The agency did not assess the impacts of runoff mitigation measures for residential and commercial use sites, in particular the definition of 'spot treatment'. In general, however, these measures appear consistent with good application practices. The agency invites comments if this mitigation would impact applicators.

11. Pesticide Resistance Management

Pesticide resistance occurs when genetic or behavioral changes enable a portion of a pest population to tolerate or survive what would otherwise be lethal doses of a given pesticide. The development of such resistance is influenced by a number of factors. One important factor is the repeated use of pesticides with the same mode (or mechanism) of action. This practice kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers. These individuals will eventually be unaffected by the repeated pesticide applications and may become a substantial portion of the pest population. An alternative approach, recommended by resistance management experts as part of integrated pest management (IPM) programs, is to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population. This approach may delay and/or prevent the development of resistance to a particular mode (or mechanism) of action without

resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

The EPA is proposing resistance-management labeling, as listed in Appendix B, for products containing clothianidin and thiamethoxam, in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides. Additional information on the EPA's guidance for resistance management can be found at the following website: https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management.

B. Stewardship

In addition to establishing both advisory and compulsory language for product labels, EPA's registration review provides an opportunity to inform stakeholders and the general public about opportunities to minimize potential ecological risks and promote pollinator health more generally. Beyond the mitigation measures proposed above, voluntary stewardship activities and use of best management practices (BMPs) can be effective in further reducing pesticide exposure to at risk taxa. Examples of these activities include:

- promoting the creation of additional pollinator habitat;
- improving pesticide users' understanding and adherence to label directions which advise users on seed spill clean-clean up, reduction in drift/runoff, and minimizing exposure to pollinators;
- promoting integrated pest management (IPM) solutions;
- encouraging growers to take care when planting treated seed to reduce the amount of exposed seed; and,
- increasing awareness of potential impacts of pesticides through education (*e.g.,* training courses, pamphlets, workshops/conferences, and through tv, radio, social media and other communication platforms).

Habitat loss is a significant issue with negative impacts on the health of bees. With access to a healthy and diverse diet through a thriving habitat, bees may be better able to tolerate stressors such as pests, disease, and exposure to pesticides. As a healthy diet is crucial to maintaining flourishing pollinator populations, and the protection of pollinator habitat is not something that can be directly addressed on a pesticide product label, EPA and other federal/state/tribal and local government agencies and non-government organizations (NGOs) promote pollinator habitat through active education and outreach programs. Helpful guidance on pollinator protection can be found on the EPA's pollinator protection webpage[23].

Users should take several precautions while using neonicotinoid products to minimize potential exposure to pollinators. First, users should not apply neonicotinoids when bees and other pollinators are actively foraging on pollinator-attractive plants during bloom. Secondly, users should consider a pesticide's ability to drift to other non-target areas and be aware of the presence of bee colonies or highly bee-attractive plants nearby an application site. With

[23] https://www.epa.gov/pollinator-protection

applications to lawns, its beneficial to mow prior to applications, as this reduces the potential for pollinator attractive weeds that could expose bees to pesticides. Although the cultivation and protection of pollinator habitat is typically encouraged, in this case, taking steps to ensure a lawn is mowed prior to neonicotinoid applications can reduce potential direct exposure for visiting pollinators. Other things the public can do to minimize potential exposure of pollinators are listed on EPA's, *What You Can Do to Protect Honey Bees and Other Pollinators* webpage[24].

Treated seed is most likely to become available to birds and mammals through accidental spills, excess unplanted seed on the edges of the field, shallow planted seed, and the improper disposal of treated seed. An effective method to reduce exposure would be encouraging growers to take additional care when planting treated seed to ensure any exposed seed is retrieved. The American Seed Trade Organization has published a guide[25] to help educate applicators on practices to help reduce potential risks to the environment from seed treatments. The agency encourages public and private participation in creating tools and fostering effective communication to help reach applicators and educate them on practices that can reduce risks to the environment.

The technical registrants for the neonicotinoids, including Bayer, BASF, Mitsui, Syngenta, and Valent, coordinated to develop a voluntary proposal to promote product stewardship for their product seed treatments and applications in agricultural crops, production and landscape ornamental plants, turfgrass and pest-management setting (structural, commercial and residential). Their proposal includes a summary of the current neonicotinoid stewardship program, as well as their proposal for an enhanced registrant-initiated stewardship program for expansion and amplification of stewardship efforts. This document, *Neonicotinoid Stewardship Program – Current Summary and Proposal,* is included in the public docket for each of the neonicotinoids along with their PIDs.

The agency encourages strong pollinator protection stewardship in both the public and private sector. EPA will continue to work with its partners at the federal, state, tribal, and local levels, along with non-governmental organizations to promote pollinator protection, education, and outreach. This includes coordinating with states and tribes on pollinator protection plans (*i.e.;* managed pollinator protection plans), coordinating with stakeholders on extension of, and education around, existing BMPs, and continued education and outreach to the public on pollinator protection. In addition, the agency plans on continuing conversations with the registrants on the *Neonicotinoid Stewardship Program*.

C. Tolerance Actions

Tolerance actions are proposed for clothianidin and thiamethoxam. The agency plans to modify several established tolerances, mainly in response to revisions to the uses included in various crop groups and subgroups. There are also opportunities for international harmonization with the tolerances for clothianidin and thiamethoxam. Some listings are proposed to be harmonized with Canadian MRLs and others with Codex MRLs. Additionally, EPA is proposing eliminating

[24] https://www.epa.gov/pollinator-protection/what-you-can-do-protect-honey-bees-and-other-pollinators
[25] https://seed-treatment-guide.com/

trailing zeros listed in tolerances consistent with agency policy. All proposed tolerance revisions for clothianidin and thiamethoxam are listed in Section III.A.3 and Appendix E.

D. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP), the Endangered Species Act (ESA) components of this case, the agency has made the following PID:

(1) no additional data are required at this time; and (2) changes to the affected registrations or their labeling are needed at this time, as described in Section IV.A and Appendices A and B.

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of clothianidin and thiamethoxam, nor is it making a complete endangered species finding. Although the agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of clothianidin and thiamethoxam. The agency's final registration review decision for clothianidin and thiamethoxam will be dependent upon the result of the agency's ESA assessment and any needed § 7 consultation with the Services, and an EDSP FFDCA § 408(p) determination.

E. Data Requirements

- *Reference Standards:*
  - The analytical reference standard for clothianidin has expired and must be submitted to the EPA's National Pesticide Standards Repository (see https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository).
  - An analytical reference standard for thiamethoxam is available at the EPA's National Pesticide Standards Repository (see https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository). However, the agency proposes to require analytical reference standards for thiamethoxam's metabolite CGA-322704 to be submitted to National Pesticides Standards Repository. Note that the current analytical reference standard for thiamethoxam will expire on October 31, 2020.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for clothianidin and thiamethoxam and will allow a 60-day comment period on the PID. If there are no significant comments or additional information submitted to the docket during the comment period that

leads the agency to change its PID, the EPA may issue an interim registration review decision for clothianidin and thiamethoxam. However, a final decision for clothianidin and thiamethoxam may be issued without the agency having previously issued an interim decision. A final decision on the clothianidin and thiamethoxam registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination, and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the clothianidin and thiamethoxam registrants must submit amended labels that include the label changes described in Appendix B. The revised labels and registration amendments must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the clothianidin and thiamethoxam dockets.

Appendix A: Summary of Proposed Actions for Clothianidin and Thiamethoxam

Table 1: Summary of Proposed Actions for Clothianidin

Registration Review Case#: 7620
PC Code: 044309
Chemical Type: insecticide
Chemical Family: nitroguanidine-substituted neonicotinoid
[Mode or Mechanism (for herbicides)] of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Occupational Handlers	Aerial and ground application, treated seeds	Dermal and inhalation	Short and intermediate term	Systemic effects	• Require additional PPE (*e.g.*, gloves and respirators) • Precautionary statements • Use Restrictions
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Crop stage restrictions • Use deletions • Use restrictions • Buffers • Spray drift reduction
Aquatic Invertebrates	Runoff from treated sites	Contact and ingestion	Acute and chronic	Acute and chronic toxicity	• Spray drift reduction • Prevent runoff • Vegetative filter strips • Reduce perimeter treatment applications
Birds and Mammals	Residues on ingested seeds	Dietary and ingestion	Acute and chronic	Acute and chronic toxicity	• Clean up spills of treated seeds

Table 2: Summary of Proposed Actions for Thiamethoxam

Registration Review Case#: 7614 PC Code: 060109 Chemical Type: insecticide Chemical Family: nitroguanidine-substituted neonicotinoid [Mode or Mechanism (for herbicides)] of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Occupational Handlers	Aerial and ground application	Dermal and inhalation	Short and intermediate term	Systemic effects	• Require additional PPE (gloves and respirators) • Precautionary statements • Require closed loading for seed treatment • Cancel equipment/application uses
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Bloom restrictions • Use deletions • Use restrictions • Buffers • Spray drift reduction
Aquatic Invertebrates	Runoff from treated sites	Contact and ingestion	Acute and chronic	Acute and chronic toxicity	• Spray drift reduction • Prevent runoff • Vegetative filter strips • Reduce perimeter treatment applications
Birds and Mammals	Residues on ingested seeds	Dietary and ingestion	Acute and chronic	Acute and chronic toxicity	• Clean up spills of treated seeds

Appendix B: Proposed Labeling Changes for Clothianidin and Thiamethoxam Products

Table 1: Proposed Labeling Changes for Clothianidin Products

Description	Proposed Label Language for Clothianidin Products	Placement on Label
Technical Products		
For any product that allows use on bulb vegetables	Delete foliar and soil use on bulbs.	Directions for Use
End Use Products		
Mode/Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide in the fourth column. **CLOTHIANIDIN** | **GROUP** | **4A** | **INSECTICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves and a respirator) for seed treatments to corn	"Handlers must wear chemical resistant gloves and a respirator while handling (*e.g.,* loading, applying, sewing, bagging, etc.) treated corn seeds."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and

Description	Proposed Label Language for Clothianidin Products	Placement on Label
		Agricultural Use Requirements, if applicable
Additional PPE (gloves and a respirator) for liquid aerosol application to commercial buildings	"Applicators must wear chemical resistant gloves and a respirator while treating commercial buildings with liquid aerosol formulations."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves) for liquid/foliar application to barn/feedlot applied via mechanically-pressurized handgun	"Applicators and handlers must wear chemical resistant gloves while mixing, loading, or applying liquid foliar formulations for a mechanically-pressurized handgun for livestock houses (Note: This does not include poultry houses. Only non-poultry livestock houses (*i.e.,* barns/feedlots))."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Requirements for Non-WPS Uses, including the use of any products requiring respirators for in-field, seed, or post-harvest treatments.	Respirator fit testing, medical qualification, and training Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements.	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"

Description	Proposed Label Language for Clothianidin Products	Placement on Label
Directions for mixing/loading products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)]. Handling Instructions Follow these steps when handling pesticide products in WSPs. 1. Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions. 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP.	Directions for Use for mixing/loading WSP

Description	Proposed Label Language for Clothianidin Products	Placement on Label
	6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as in case of a spill or equipment break-down."	
All outdoor foliar spray uses	Update the bee advisory box according to the following: https://www.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides	Follows directly after the Environmental Hazard statement
All outdoor foliar spray uses	For foliar spray application to crops under contract pollinator services: "Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless the following condition has been met. If an application must be made when managed bees are at the treatment site, the beekeeper providing the	Directions for Use

Description	Proposed Label Language for Clothianidin Products	Placement on Label
	pollination services must be notified no less than 48 hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying." For foliar spray application to crops not under contract pollinator services: "Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen off unless the application is made in response to a public health emergency declared by appropriate State or Federal authorities."	
All outdoor foliar spray uses	"Do not apply by ground within 25 feet, or by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for use
Resistance-management labeling statements for insecticides and acaricides	Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year).	Directions for Use, prior to directions for specific crops
Additional Required Labeling Action Applies to all products delivered via liquid spray applications	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Berries and small fruit, excluding grape and strawberry, set maximum annual rate	Maximum annual application rate for berries, regardless of application method, is not to exceed 0.16 lbs. a.i./A per year.	Directions for Use
Cotton, set maximum annual rate	Regardless of application method, apply no more than 0.15 lbs. a.i./A per year, including seed treatment, soil drench and foliar sprays.	Directions for Use
Fruiting Vegetables, set maximum annual rate for foliar spray	For foliar spray only: maximum annual application rate is not to exceed 0.17 lbs. a.i./A per year.	Directions for Use
Ornamentals, which includes ornamental trees, forestry, ornamental woody shrubs and vines, and outdoor greenhouse/nursery. This mitigation does not include	For both foliar spray and soil drench: maximum annual application rate is not to exceed 0.30 lbs. a.i./A per year.	Directions for Use

Description	Proposed Label Language for Clothianidin Products	Placement on Label
indoor commercial nursery, Christmas trees, greenhouse uses, or forestry use on public land and quarantine application by USDA.		
Pome fruit, set maximum annual rate for foliar spray	For foliar spray only: maximum annual application rate is not to exceed 0.16 lbs. a.i./A per year.	Directions for Use
Tree nuts, set maximum annual rate for foliar spray and soil drench	For foliar spray only: maximum annual application rate is not to exceed 0.16 lbs. a.i./A per year. Soil drench: maximum annual application rate is not to exceed 0.38 lbs. a.i./A per year.	Directions for Use
Turf, set maximum annual rate for foliar spray	For foliar spray only: maximum annual application rate is not to exceed 0.30 lbs. a.i./A per year.	Directions for Use
Avocado, banana, dates, and olives, add application timing restriction based on crop stage	For foliar spray only: "Do not apply before bloom until after flowering is complete and all petals have fallen off."	Directions for Use
Cucurbit, add application timing restriction based on crop stage	For foliar spray and soil drench: "Do not apply after vining or appearance of the first true (non-cotyledon) leaf until harvest."	Directions for Use
All agricultural foliar spray uses	"VEGETATIVE FILTER STRIPS Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds). Only apply products containing clothianidin onto fields where a maintained vegetative filter strip of at **least 10 feet** exists between the field edge and where a down gradient aquatic habitat exists. Western irrigated agriculture is exempt from this requirement. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35). For further guidance on vegetated filter strips, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs144p2_030970.pdf"	Directions for Use

Description	Proposed Label Language for Clothianidin Products	Placement on Label
Ornamentals, which includes Ornamental ground cover, Christmas tree plantations, Ornamental and/or shade trees, ornamental herbaceous plants, ornamental nonflowering plants, and ornamental woody shrubs and vines	"Intended for use by professional applicators."	Directions for Use
Poultry houses set maximum number of applications and add maximum application area	"Do not apply more than one whole house treatment and 5 perimeter (partial house) treatments per year." "Do not apply to more than 30,000 sq. ft. per year per house."	Directions for Use
Seed treatments, add to seed bad tag	Add the following statements to tags to clean up spills, dispose of excess seed to avoid contamination of water bodies: "Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)." "Dispose of all excess treated seed by burying seed away from bodies of water." "Do not contaminate bodies of water when disposing of planting equipment wash water."	Directions for use
All outdoor non-agricultural spray applications	"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: 1. Application to soil, lawn, turf, and other vegetation; 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (*e.g.*, soil, mulch, or lawn) 3. Applications to the side of a man-made structure, up to 2 feet above ground level; 4. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure; 5. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch;	Directions for Use

Description	Proposed Label Language for Clothianidin Products	Placement on Label
	6. Applications to vertical surfaces directly above pervious surfaces such as bare soil, lawn, turf, mulch or other vegetation, and not over a hard impervious surface (e.g., driveways, sidewalks), drainage, or other condition that could result in runoff into storm drains, drainage ditches, gutters, or surface waters, to control occasional invaders or aggregating pests."	
Outdoor non-agricultural spray applications	"Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate to the point of run-off."	Directions for Use
Outdoor non-agricultural spray applications – rain related statements (except for products that require watering-in)	"Do not make applications during rain. Avoid making applications when rainfall is expected within 24 hours to allow product sufficient time to dry." "Excessive rainfall within 24 hours after application may cause unintended run-off of pesticide application."	Directions for Use
Outdoor non-agricultural spot treatments	"Spot treatment is application to limited areas on which insects are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls, and bases or undersides of equipment. Spot treatments must not exceed two square feet in size (2ft. by 1 ft.), not to exceed 10 % of the entire treatment area"	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a medium or coarser (ASABE S572.1) droplet size. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Aerial Applications"

Description	Proposed Label Language for Clothianidin Products	Placement on Label
Spray Drift Management Application Restrictions for products that are delivered via spray applications and that allow airblast applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Airblast applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Airblast Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and allow ground boom applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and that allow boom-less ground sprayer applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Boomless Ground Applications:** • Applicators are required to use a medium or coarser droplet size (ASABE S572.1) for all applications. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Boomless Applications"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** *(**note to registrants:** remove if ground boom is prohibited on product labels)*	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Clothianidin Products	Placement on Label
	• Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion,	

Description	Proposed Label Language for Clothianidin Products	Placement on Label
	while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	**"SPRAY DRIFT ADVISORIES** **Boomless Ground Applications:** • Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Table 2: Proposed Labeling Changes for Thiamethoxam Products

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	End Use Products	
Mode/Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide in the fourth column. **THIAMETHOXAM** | **GROUP** | **4A** | **INSECTICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves and a respirator) for mixing/loading/applying dry flowable formulations for poultry houses and warehouses	"Handlers and applicators must wear chemical resistant gloves and a respirator while mixing, loading, or applying using a mechanically pressurized handgun."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves) for mixing/loading liquids for aerial applications to barley, beans (dry),	"Handlers must wear chemical resistant gloves while mixing or loading."	In the Personal Protective Equipment (PPE) within the Precautionary

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
canola/rapeseed, corn (field), cotton, cowpea/blackeyed pea, flax, garbanzos (including chick peas), lentils, lupine (grain), mustard, peas (field), potato, rice, sorghum, soybeans, sugar beet, sunflower, tobacco, triticale, and wheat		Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves) for mixing/loading/applying dry flowable formulations with a manually-pressurized handwand to poultry/livestock house/ horse barn/feed lot, and mounds/nests	"Handlers and applicators must wear chemical resistant gloves while mixing, loading, or applying with a manually-pressurized handwand."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves) for mixing /loading/applying liquids with a manually-pressurized handwand to mounds/nests	"Handlers and applicators must wear chemical resistant gloves while mixing, loading, or applying with a manually-pressurized handwand."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Additional PPE (gloves) for mixing/loading/applying dry flowable formulations with a mechanically-pressurized handgun to landscaping, trees/shrubs/bushes	"Handlers and applicators must wear chemical resistant gloves while mixing, loading, or applying with a mechanically-pressurized handgun."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
Additional PPE (gloves) for mixing/loading/applying crack and crevice treatments with a manually-pressurized handwand to warehouses, childcare center/schools/institutions, and residential living spaces	"Handlers and applicators must wear chemical resistant gloves while mixing, loading, or applying crack and crevice treatments with a manually-pressurized handwand."	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Requirements for Non-WPS Uses requiring respirators	"Respirator fit testing, medical qualification, and training: Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
Directions for mixing/loading products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)]. Handling Instructions Follow these steps when handling pesticide products in WSPs.	Directions for Use for mixing/loading WSP

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	1. Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions. 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.	

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as in case of a spill or equipment break-down."	
All outdoor foliar spray uses	Update the bee advisory box according to the following: https://www.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides	Follows directly after the Environmental Hazard statement
All outdoor foliar spray uses	For foliar application to crops under contract pollinator services: "Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless the following condition has been met. If an application must be made when managed bees are at the treatment site, the beekeeper providing the pollination services must be notified no less than 48 hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying." For foliar application to crops not under contract pollinator services: "Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen off unless the application is made in response to a public health emergency declared by appropriate State or Federal authorities."	Directions for use
All outdoor foliar spray uses	"Do not apply by ground within 25 feet, or by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Resistance-management labeling statements for insecticides and acaricides	Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
Additional Required Labeling Action Applies to all products delivered via liquid spray applications	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Seed treatments to corn	"Must be applied by closed system seed treatment application processes in a commercial seed treatment facility."	Directions for Use
Berries and small fruits, not including grapes, set maximum annual rate for foliar spray and soil drench uses	**Foliar Sprays:** Bushberry Subgroup (including but not limited to highbush blueberry, gooseberry, red currant, etc.): maximum annual application rate is not to exceed to 0.15 lbs. a.i./A per year. Caneberry Subgroup (including but not limited to blackberry, raspberry, etc.): maximum annual application rate is not to exceed 0.07 lbs. a.i./A per year. Low Growing Berry Subgroup (including but not limited to lowbush blueberry, strawberry, cranberry, etc.): maximum annual application rate is not to exceed 0.15 lbs. a.i./A per year. Small Fruit Vine Climbing Subgroup (including but not limited to maypop; excluding grape, fuzzy kiwi fruit and gooseberry): maximum annual application rate is not to exceed 0.09 lbs. a.i./A per year. **Soil Drench:** Bushberry Subgroup (including but not limited to highbush blueberry, gooseberry, red currant, etc.): maximum annual application rate is not to exceed 0.15 lbs. a.i./A per year. Low Growing Berry Subgroup (including but not limited to lowbush blueberry, strawberry, cranberry, etc.): maximum annual application rate is not to exceed 0.15 lbs. a.i./A per year. Small Fruit Vine Climbing Subgroup (including but not limited to maypop; excluding grape, fuzzy kiwi fruit and gooseberry): maximum annual application rate is not to exceed 0.22 lbs. a.i./A per year.	Directions for Use
Cotton, set maximum annual rate	Regardless of formulation or method of application, apply no more than 0.09 lbs. a.i./A per year, including seed treatment, soil drench and foliar spray uses.	Directions for Use
Avocado, banana, dates, and olives, add application	For foliar spray only: "Do not apply before bloom until after flowering is complete and all petals have fallen off."	Directions for Use

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
timing restriction based on crop stage		
Cucurbit, add application timing restriction based on crop stage for foliar spray uses	For foliar spray only: "Do not apply after vining or appearance of the first true (non-cotyledon) leaf until harvest."	Directions for Use
Fruiting vegetables, set maximum annual rate for foliar spray, and add application timing restriction based on crop stage	For foliar spray only: "Do not apply after the appearance of the initial flower buds until flowering is complete and all petals have fallen off." For soil drench only: "For tomatoes, peppers, chili peppers and okra only, do not apply after 5 days after planting or transplanting regardless of application method."	Directions for Use
Pome fruit, add application timing restriction for foliar spray uses	For foliar spray only: "Do not apply from bud break (also known as "swollen bud stage" in pear, or "silver-tip stage" in apple) until after flowering is complete and all petals have fallen off."	Directions for Use
Stone Fruit, add application timing restriction for foliar spray uses	For foliar spray only: "Do not apply from bud break until after flowering is complete and all petals have fallen off."	Directions for Use
Tree nut, add application timing restriction for foliar spray uses	For walnuts and pecans: "Do not apply prior to bud break until after flowering is complete and all petals have fallen off." For other tree nuts crops: "Do not apply prior to bloom until after flowering is complete and all petals have fallen off."	Directions for Use
All agricultural foliar spray uses	"VEGETATIVE FILTER STRIPS Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds). Only apply products containing thiamethoxam onto fields where a maintained vegetative filter strip of at **least 10 feet** exists between the field edge and where a down gradient aquatic habitat exists.	Directions for Use

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	Western irrigated agriculture is exempt from this requirement. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35). For further guidance on vegetated filter strips, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs144p2_030970.pdf"	
Ornamentals, which includes Ornamental ground cover, Christmas tree plantations, Ornamental and/or shade trees, ornamental herbaceous plants, ornamental nonflowering plants, and ornamental woody shrubs and vines	"Intended for use by professional applicators."	Directions for Use
All outdoor non-agricultural spray applications	"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: 1. Application to soil, lawn, turf, and other vegetation; 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (*e.g.*, soil, mulch, or lawn) 3. Applications to the side of a man-made structure, up to 2 feet above ground level; 4. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure; 5. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch; 6. Applications to vertical surfaces directly above pervious surfaces such as bare soil, lawn, turf, mulch or other vegetation, and not over a hard impervious surface (e.g., driveways, sidewalks),	Directions for Use

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	drainage, or other condition that could result in runoff into storm drains, drainage ditches, gutters, or surface waters, to control occasional invaders or aggregating pests."	
Outdoor non-agricultural spray applications	"Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate to the point of run-off."	Directions for Use
Outdoor non-agricultural spray applications – rain related statements (except for products that require watering-in)	"Do not make applications during rain. Avoid making applications when rainfall is expected within 24 hours to allow product sufficient time to dry." "Excessive rainfall within 24 hours after application may cause unintended run-off of pesticide application."	Directions for Use
Outdoor non-agricultural spot treatments	"Spot treatment is application to limited areas on which insects are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls, and bases or undersides of equipment. Spot treatments must not exceed two square feet in size (2ft. by 1 ft.), not to exceed 10 % of the entire treatment area."	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a medium or coarser (ASABE S572.1) droplet size. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Aerial Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and that allow airblast applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Airblast applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 miles per hour at the application site.	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Airblast Applications"

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	• User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions."	
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and that allow ground boom applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and that allow boom-less ground sprayer applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Boomless Ground Applications:** • Applicators are required to use a medium or coarser droplet size (ASABE S572.1) for all applications. • Do not apply when wind speeds exceed 15 miles per hour at the application site. Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Boomless Applications"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
	Controlling Droplet Size – Aircraft ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	

Description	Proposed Label Language for Thiamethoxam Products	Placement on Label
Advisory Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	**"SPRAY DRIFT ADVISORIES** **Boomless Ground Applications:** Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C: Endangered Species Assessment

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been proposed based on experience conducting the first three pilot BEs. Public input on those proposed revisions is currently being considered.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for clothianidin and thiamethoxam does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although the EPA has not yet completed effects determinations for specific species or habitats, for this PID, the EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of clothianidin or thiamethoxam. This will allow the EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for clothianidin and thiamethoxam as part of completing this registration review.

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for Clothianidin, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), clothianidin and and thiamethoxam are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[26] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Neither clothianidin nor thiamethoxam are on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[27]

[26] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[27] https://www.epa.gov/endocrine-disruption

In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of clothianidin and thiamethoxam. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

Appendix E: Summary of Proposed Tolerance Actions

Table 1: Clothianidin

Clothianidin 40 CFR §180.586, Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments *(correct commodity definition)*
§180.586(a) General			
Barley, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Barley, hay	None	0.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Barley, straw	None	0.3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Berry, low-growing, Subgroup 13-07H, except strawberry	0.01	0.07	Update to harmonize with Codex MRLs.
Brassica leafy greens Subgroup 4-16B	None	1.9	Commodity displaced by crop group conversion.
Celtuce	None	3	Commodity displaced by crop group conversion.
Corn, field, forage	None	0.6	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, field, stover	None	0.3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, pop, stover	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, sweet, forage	None	0.7	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, sweet, stover	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Cotton, undelinted seed	0.20	0.2	Correct number of significant figures to be consistent with EPA policy.
Florence fennel	None	3	Commodity displaced by crop group conversion.
Fruit, pome	1.0	1	Correct number of significant figures to be consistent with EPA policy.
Grain, cereal, forage, fodder and straw, Group 16, except rice, straw	0.05	0.2	Update to harmonize with Codex MRLs.
Grain, cereal, Group 15, except rice	0.01	0.04	Update to harmonize with Codex MRLs.
Grape	0.60	0.6	Correct number of significant figures to be consistent with EPA policy.
Kohlrabi	None	1.9	Commodity displaced by crop group conversion.

Clothianidin 40 CFR §180.586. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Leafy greens Subgroup 4-16A	None	3	Commodity displaced by crop group conversion.
Leafy petiole vegetable Subgroup 22B	None	3	Commodity displaced by crop group conversion.
Oat, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Peach	0.80	0.8	Correct number of significant figures to be consistent with EPA policy.
Pepper	0.8	Remove	Change definition to: Pepper/eggplant Subgroup 8-10B
Pepper/eggplant Subgroup 8-10B	None	0.8	Commodity displaced by crop group conversion.
Pomegranate	0.20	0.2	Correct number of significant figures to be consistent with EPA policy.
Potato, chips	0.6	0.8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Potato, granules/flakes	1.5	2	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Rice, grain	None	0.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Rice, seed	0.01	Remove	Expired June 23, 2012.
Rye, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, forage	None	1	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, stover	None	0.8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Tomato Subgroup 8-10A	None	0.2	Commodity displaced by crop group conversion.
Triticale, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Vegetable, brassica, leafy, Group 5	1.9	Remove	Divide into separate listings: *Brassica* leafy greens Subgroup 4-16B; Vegetable, *Brassica*, head and stem, Group 5-16; and Kohlrabi.
Vegetable, fruiting, Group 8, except pepper	0.2	Remove	Divide into separate listings: Tomato Subgroup 8-10A; Pepper/eggplant Subgroup 8-10B.

Clothianidin 40 CFR §180.586. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Vegetable, head and stem *Brassica* Group 5-16	None	1.9	Commodity displaced by crop group conversion.
Vegetable, leafy, except brassica, Group 4	3	Remove	Divide into separate listings: Leafy green Subgroup 4-16A; Correct number of significant figures to be consistent with EPA policy.
Vegetable, tuberous and corm, Subgroup 1C	0.3	0.4	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, forage	None	0.8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, grain	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, hay	None	1.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, straw	None	0.8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.

Table 2. Thiamethoxam

Thiamethoxam 40 CFR §180.565. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
§180.565(a) General			
Alfalfa, forage	0.05	10	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Alfalfa, hay	0.12	8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Alfalfa, seed	None	1	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Barley, grain	0.4	0.9	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Barley, hay	0.4	1.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Barley, straw	0.4	3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Brassica leafy greens Subgroup 4-16B	None	3	Update definition, and correct number of significant figures to be consistent with EPA policy.

Thiamethoxam 40 CFR §180.565. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Brassica, head and stem, Subgroup 5-A	4.5	Remove	Divide into separate listings: Vegetable, *Brassica*, head and stem, Group 5-16; and Kohlrabi.
Brassica, leafy greens, Subgroup 5-B	3	Remove	See *Brassica* leafy greens Subgroup 4-16B.
Caneberry Subgroup 13-07A	0.35	0.5	Update to harmonize with Codex MRLs.
Cattle meat byproducts	0.04	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Celtuce	None	4	Commodity displaced by group conversion.
Corn, field, forage	0.1	0.7	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, field, stover	0.05	1	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, pop, forage	0.1	0.7	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, pop, stover	0.05	0.7	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, sweet, forage	0.1	5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Corn, sweet, stover	0.05	0.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Florence fennel	None	4	Commodity displaced by group conversion.
Fruit, citrus, Group 10	0.4	Remove	See Fruit, citrus, Group 10-10.
Fruit, citrus, Group 10-10	None	0.4	Update definition.
Fruit, pome, Group 11	0.2	Remove	See Fruit, pome, Group 11-10.
Fruit, pome, Group 11-10	None	0.2	Update definition.
Fruit, stone, Group 12	0.5	Remove	See Fruit, stone, Group 12-12.
Fruit, stone, Group 12-12	None	0.5	Update definition.
Goat meat byproducts	0.04	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Horse meat byproducts	0.04	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Kohlrabi	None	4.5	Commodity displaced by group conversion.
Leafy greens Subgroup 4-16A	None	4	Commodity displaced by group conversion.

Thiamethoxam 40 CFR §180.565. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments *(correct commodity definition)*
Leafy petiole Subgroup 22B	None	4	Commodity displaced by group conversion.
Milk	0.02	0.07	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Nut, tree, Group 14	0.02	Remove	See Nut, tree, Group 14-12.
Nut, tree, Group 14-12	None	0.02	Update definition.
Oat, grain	None	0.9	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Pistachio	0.02	Remove	See Nut, tree, Group 14-12.
Potato	None	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Rice, grain	None	6	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Rice, straw	None	2	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Rye, grain	None	0.9	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sheep meat byproducts	0.05	0.15	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, forage	0.02	0.9	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, grain	None	0.6	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, grain, stover	0.02	1.5	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sorghum, sweet, stalk	None	0.7	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Sugarcane	None	0.2	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Triticale, grain	None	0.3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Vegetable, fruiting, Group 8	0.25	Remove	See Vegetables, fruiting, Group 8-10
Vegetable, head and stem Brassica Group 5-16	None	4.5	Commodity displaced by group conversion.

Thiamethoxam 40 CFR §180.565. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments *(correct commodity definition)*
Vegetable, leafy, except brassica, Group 4	4.0	Remove	Divide into separate listings: Leafy greens Subgroup 4-16A, Leafy petiole vegetable Subgroup 22B, Celtuce, and Florence fennel
Vegetables, fruiting, Group 8-10	None	0.25	Commodity displaced by group conversion.
Wheat, bran	None	0.4	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, forage	0.5	3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, grain	None	0.3	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, hay	0.02	8	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.
Wheat, straw	0.02	6	Based on new uses of thiamethoxam. Recommended tolerance levels from HED, 30 January 2019, D446686.