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Imidacloprid

Proposed Interim Registration Review Decision
Case Number 7605

January 2020

Approved by: ___________________________

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Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the agency) Proposed Interim Registration Review Decision (PID) for imidacloprid (PC Code 129099) and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. 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 imidacloprid, can be found in the EPA's public docket (EPA-HQ-OPP-2008-0844) 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 imidacloprid 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 imidacloprid prior to completing the imidacloprid registration review. Likewise, the agency will complete endocrine screening for imidacloprid, 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 endangered species assessment and the endocrine screening for the imidacloprid registration review.

Imidacloprid is an N-nitroguanidine neonicotinoid insecticide, which causes irreversible blockage of the postsynaptic nicotinic acetylcholine receptors. It is a xylem and phloem-mobile systemic compound that is readily taken up by the roots of the plants and translocated through the plant via transpiration. There are over five hundred FIFRA § 3 and § 24(c) (Special Local Needs) products containing imidacloprid registered in the United States. Products containing imidacloprid can be formulated as granules, ready-to-use solutions, emulsifiable concentrates, flowable concentrates, water soluble packages (WSP), dust, impregnated materials, etc. Products can be applied via liquid spray of drench, broadcast granules, baits, and as seed treatment. Imidacloprid products can be applied to a variety of agricultural crops, including but not limited to, root and tuber vegetables, fruiting vegetables, oilseed crops, citrus fruit, leafy green vegetables, cucurbit vegetables and tropical and subtropical fruits. Imidacloprid products are also registered on non-agricultural use sites including but not limited to, turf and ornamentals, forestry, Christmas tree plantations, pet spot-on and collar products, baits and pellets, and in farm/residential/commercial areas. The first imidacloprid product was registered for use in 1994, and as a result, imidacloprid was not reviewed under the reregistration process.

This document is organized in 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 imidacloprid is used and summarizes data on its use; *Scientific Assessments,* which summarizes the EPA's risks, and 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 imidacloprid, 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 clothianidin, dinotefuran, and thiamethoxam are available in the public dockets established for each of these cases.

A. Summary of Imidacloprid Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for imidacloprid with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of imidacloprid.

- December 2008 – The imidacloprid *Summary Document*, Human Health Scoping Document, and Environmental Fate and Effects Problem Formulation were posted to the docket for a 60-day public comment period.

- June 2009 – The *Final Work Plan* (FWP) for Imidacloprid was issued. During the comment period the agency received one comment concerning trade irritants. The Final Work Plan was amended in July 2010 to include additional data necessary to support the registration review of imidacloprid.

- November 2010 – A Generic Data Call-In (GDCI) for imidacloprid was issued for data needed to conduct the registration review risk assessments; all data requirements have been satisfied.

- January 2016 – The agency announced the availability of the *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* for a 60-day public comment period which was then extended 30-days.

- January 2017 – The agency announced the availability of the *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid* for a 60-day public comment period.

- September 2017 – The agency announced the availability of the *Imidacloprid: Human Health Draft Risk Assessment for Registration Review*, *Imidacloprid. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment.*, and *Imidacloprid. Occupational and Residential Exposure Assessment for Registration Review.* for a 60-day public comment period.

- December 2017 – The agency announced the availability of the following documents to support Registration Review for a 60-day public comment period which was then extended for an additional 60 days to April 21, 2018:
    - *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" Dated October 15, 2014, OPP Docket: EPA-HQ-OPP-2014-0737*, December 5, 2017
    - *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Cotton*, December 5, 2017
    - *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Citrus*, November 21, 2017
    - *Imidacloprid Transmittal of the Preliminary Terrestrial Risk Assessment to Support Registration Review*, November 28, 2017

- January 2020 – The agency is now announcing the availability of the PID in the docket for imidacloprid, for a 60-day public comment period. Along with the PID, the following documents are also posted to the imidacloprid docket:
    - *Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation*, December 11, 2019
    - *Benefits of Neonicotinoid Insecticide Usage in Grapes and Impacts of Potential Mitigation*, October 23, 2019
    - *Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops*, August 30, 2018
    - *Usage, Pest Management Benefits, and Possible Impacts of the Potential Mitigation of the Use of the Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear)*, December 11, 2019

- *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
- *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments,* April 22, 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 and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit.* December 20, 2019
- *Review of "The Value of Neonicotinoids in North American Agriculture" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent,* 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
- *Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoids using Raby et al. (2018) toxicity data,* January 7, 2020
- *Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision*[1], September 17, 2019
- *Imidacloprid. Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments.*, February 11, 2019
- *Imidacloprid. Updated Non-Occupational Spray Drift Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments*, January 10, 2020
- *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid,* January 14, 2020
- *Note to Reader: Documents Supporting the Registration Review of Imidacloprid*

The agency will be posting a reader's guide in the docket to assist with navigation of the imidacloprid supporting documents.

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

Two separate comment periods were held for imidacloprid risk assessment documents. The *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* was published January 4, 2016 for for an initial 60-day public comment period. The comment period for the draft human health and non-pollinator ecological risk assessments for imidacloprid, as well as various supporting benefits-related registration review documents, opened on December 21, 2017 for an initial 60-day public comment period.

[1] Flumethrin updated human incident assessment composed of only incidents related to the combined imidacloprid and flumethrin product.

Across these comment periods, the agency received a total of 1,433 unique/distinct public comments to the imidacloprid docket. In addition, the neonicotinoids received approximately 400,000 mass mail 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 the Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments and Benefits Assessments Supporting the Registration Review of the Nitroguanidine-substituted Neonicotinoid Insecticides*. Comments on the topics of neonicotinoid benefits, ecological effects and human health effects are noted and responded to in the following memoranda:

- *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.
- *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
- *Imidacloprid: Response to Public Comments Related to the Preliminary Risk Assessments and Addendum to the Non-Pollinator Risk Assessments in Support of Registration Review (Docket No. EPA-HQ-OPP-2008-0844),* January 8, 2020
- *Imidacloprid: Draft Human Health Risk Assessment (DRA) for Registration Review – Response to Comments,* November 12, 2019

Additionally, the agency received comments to 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.

Comment Submitted by Bayer Healthcare, LLC. in EPA-HQ-OPP-2008-0844-1247

Comment: In response to EPA's identification of data gaps in the TTR and dermal absorption studies used in the imidacloprid human health risk assessment, Bayer CropScience (BCS) submitted the results of an imidacloprid-specific TTR study and a formulation-specific *in vivo* dermal absorption study to refine the EPA's imidacloprid human health risk assessment.

EPA Response: The agency thanks BCS for its comment and study submissions. The agency reviewed these studies and determined that the TTR and dermal absorption data deficiencies are now satisfied and that the dermal absorption factor (DAF) can be reduced from 7.2% to 4.8%. The agency refined the residential handler and post-application risk estimates using these studies and determined that there are no residential handler or post-application risks of concern associated with the pet collar use. EPA also identified with the newly available data new potential risks of concern associated with use on turf in non-irrigated plots, however, there are no remaining residential post-application exposure risks of concern associated with use on turf in irrigated plots. For a more detailed description of the updated risk estimates, please refer to

Imidacloprid. Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments, available in the public docket.

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: EPA thanks the Massachusetts Office of the Attorney General for its comment. The agency recognizes the potential risks to pollinators from homeowner applications of neonicotinoids on gardens, lawns, and ornamentals. In response, the agency is proposing certain rate reductions and require advisory label language for residential ornamental labels stating, "Intended for use by professional applicators". Please refer to Section IV.A of this PID for additional details regarding the proposed label changes.

Comment Submitted by the National Association of State Departments of Agriculture (EPA-HQ-OPP-2008-0844-1043):

Comment: The National Association of State Departments of Agriculture (NASDA) encourages the agency to fully articulate risk mitigation measures with state lead agencies, registrants, producers, users, and the agricultural stakeholder community to facilitate an informed risk assessment. Furthermore, NASDA is concerned that the agency did not articulate the benefits in the *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid.*

EPA Response: The agency continues to encourage public/stakeholder participation through the public comment period. Moreover, the agency prepared refined risk assessments in response to substantive comments, and also provided several additional benefits assessments (see Section I.A) to support the registration review of all the neonicotinoids, including imidacloprid. The agency carefully considered the risks and benefits described in these assessments to develop the risk mitigation proposals, which are detailed in this PID. In accordance with EPA policy, the agency is opening a 60-day public comment period for the proposed mitigation described in this PID prior to issuing a final decision.

Comments Submitted Concerning the Preliminary Pollinator Risk Assessments:

The agency received numerous comments in response to publication of the preliminary pollinator risk assessments for clothianidin, dinotefuran, imidacloprid, and thiamethoxam, which were considered in the preparation of the final pollinator risk assessments. The agency's responses can be found below. These comments were received from BCS, 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 San Francisco Estuary Institute (SFEI), the University of California – Riverside (UCR), the University of California – San Diego (UCSD), and the United States Department of Agriculture (USDA).

The agency also received abundant generalized comments regarding the preliminary pollinator risk assessments, including those concerning the scientific methodology or rationale in these assessments. 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),* available in the public dockets.

Summary of Comment (BCS): Bayer CropScience, commenting on behalf of the Imidacloprid EPA DCI cost-sharing consortium (Bayer, Nufarm, Ensystex, Helena, UPI, and Albaugh), expressed concerns over the kinetics model half-life estimates for imidacloprid. BCS asks that the agency provide more accurate half-life estimates for imidacloprid.

EPA Response: The preliminary pollinator assessment for imidacloprid reported a half-life range of 305 days to > 2,000 days. The agency has considered additional information since the assessment was published and identified a half-life range of 139 days to 608 days. This refined half-life range has a mean half-life of 254 days, which the agency used as the modeling input in the final pollinator assessment (available in the docket).

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: The agency thanks the commenters for their comments. 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 agency thanks the commenters for their feedback. The initial registrations for the four nitroguanidine-substituted neonicotinoids were not concurrent, and, as a result, the registration review schedules 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 concerned the bee bread method to evaluate pollen exposure. The nature of these comments include: an unvetted method should not be used in this risk assessment (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 Effects Concentration (NOAEC) (CLA, NCGA).

EPA Response: The agency thanks the commenters for their comments. Based on the public comments received, and new data available, including a 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 contaminated 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.

<u>Comments Submitted Concerning the Preliminary Non-Pollinator Risk Assessments:</u>
The agency received numerous comments in response to the preliminary non-pollinator risk assessments conducted for the four nitroguanidine-substituted neonicotinoids, which were considered in the preparation of the final non-pollinator risk assessments and comments

concerned the scientific methodology or rationale in these assessments. These comments were received from the, AVAAZ, the Bay Area Clean Water Agencies (BACWA), Bayer CropScience (BCS), 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)* and *Imidacloprid: Response to Public Comments Related to the Preliminary Risk Assessments and Addendum to the Non-Pollinator Risk Assessments in Support of Registration Review (Docket No. EPA-HQ-OPP-2008-0844),* available in the public dockets.

Summary of Comment (BCS): Bayer CropScience, on behalf of the imidacloprid EPA DCI cost-sharing consortium members (Bayer, Nufarm, Ensystex, Helena, UPI, and Albaugh) noted (EPA-HQ-OPP-2008-0844-1186) that the foliar rate for tobacco (0.561 kg a.i./ha) was incorrectly listed in the seed treatment column of Table 3-6, p. 38 in the *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid.*

EPA Response: The agency thanks BCS for their comment. The agency confirmed that there is a typographical error in Table 3-6. The application rate (0.561 kg a.i./ha) should have been listed under "soil application".

Summary of Comment (BCS): Bayer, on behalf of the imidacloprid EPA DCI cost-sharing consortium members, noted (EPA-HQ-OPP-2008-0844-1187) that the "Commercial (Perimeter Treatment): (0.5 lbs a.i./A, CA)" scenario in the *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid* (see Table 5-3, p. 89), incorrectly indicates a LOC exceedance for freshwater chronic risk.

EPA Response: The agency confirmed that there is a typographical error in Table 5-3. A chronic RQ of 0.9 is below the LOC (1), and not a risk of concern.

Summary of Comment (CPDR and VAAFM): CPDR 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. However, CPDR 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 crop-seeds, thus 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 tiles drains (see EPA-HQ-OPP-2008-0844-

1175 for detail). 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 thanks CDPR and VAAFM for their comments and submitting this monitoring data. 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).

Moreover, 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 Section IV.A.8 and Appendix B.

Summary of Comments (AVAAZ, BACWA, CDPR, CLA, SFBRWQCB, XSIC):
Commenters (EPA-HQ-OPP-2008-0844-1192, 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, one commenter (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 thanks the commenters for their feedback. 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 there are no significant changes in 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.

II. USE AND USAGE

Imidacloprid is a nitroguanidine neonicotinoid insecticide with the first product registered for use in the United States in 1994. Products containing imidacloprid are used to control a variety of sucking and piercing insect pests including thrips, aphids, and whiteflies, as well as soil insects such as beetles, grubs, and wireworms. Products containing imidacloprid are formulated as wettable powders, granules, seed treatment, trunk injection and soluble concentrates on a wide variety of agricultural and non-agricultural use sites. Agricultural sites include but are not limited to vegetable crops, tree fruits, tree nuts, and field crops as well as forestry (including lumber and pulp production; non-agricultural uses include but are not limited to turf and ornamental plants, and indoor and outdoor residential and commercial sites including pet products. There are over five hundred FIFRA § 3 and § 24 (c) registrations in the United States, including eighteen registrations for the technical grade active ingredient.

Agricultural Usage

The largest agricultural use for imidacloprid, in terms of pounds active ingredient (AI) applied, has been in the form of seed treatments. On average, between 2005 and 2015, over 700,000 lbs. of imidacloprid were used annually for seed treatments on various field crops including corn, cotton, soybean, potato, and wheat[2]. 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 averaged about 800,000 lbs. AI[3], applied to approximately 5.6 million acres[4] annually. Agricultural sites with the highest usage of imidacloprid in average pounds applied per year are cotton (100,000 lbs), oranges (80,000 lbs), and potatoes (80,000 lbs)[3]. The highest percent crop treated (PCT) values are reported for broccoli (70%), cauliflower (70%), and lettuce (70%)[3].

In 2016, approximately 5,000 pounds of imidacloprid was reported to be used for industrial vegetation management, including forestry[5].

2 *Imidacloprid (129099) Screening Level Usage Analysis (SLUA), March 14, 2017*
3 *Imidacloprid (129099) Screening Level Usage Analysis (SLUA), December 9, 2019*
4 *Agricultural Market Research Data (AMRD). 2007-2017. Data collected and sold by a private market research firm. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statistically valid results, typically at the state level.*
5 *Non-agricultural Market Research Data (NMRD), 2017. Data on consumer and professional pest control markets collected and sold by a private market research firm.*

Non-Agricultural Usage

The agency has limited usage data on non-agricultural use sites. In 2016, approximately 300,000 lbs of imidacloprid was used by pest management professionals (*i.e.*, applicators who typically apply pesticides to turf and ornamental plants, including in residential areas)[5]. Additionally, approximately 40,000 lbs of imidacloprid was purchased in 2016 directly by consumers for indoor and outdoor use.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health 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 imidacloprid. For additional details on the human health assessment for imidacloprid, see the *Imidacloprid: Human Health Draft Risk Assessment for Registration Review, Imidacloprid: Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments,* and *Imidacloprid. Updated Non-Occupational Spray Drift Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments,* which are available in the public docket.

1. Risk Summary and Characterization

Humans may be exposed to imidacloprid in food and drinking water from crop uses, residential applications, in occupational settings, and from exposures to spray drift. The primary target system for mammals via the oral route is the nervous system; observed effects include tremors/trembling, decreased motor activity, etc., in multiple neurotoxicity studies in the dog and rat. No signs of toxicity were observed through the dermal and inhalation routes in the available studies and there was no evidence of carcinogenic potential in the database. Imidacloprid is classified as a Group E chemical ("Evidence of non-carcinogenicity for humans"), oral Toxicity Category II (high oral lethality), and dermal Toxicity Category IV (low lethality by the dermal and inhalation routes). Because the toxicology database is sufficient to support risk assessment, the assessments are unlikely to underestimate exposure, and the observed neurotoxic and fetal and offspring effects are well characterized and protected for, and the FQPA Safety Factor was reduced to 1X. Therefore, the level of concern (LOC) for all assessments is 100 based on the interspecies (10X) and intraspecies (10X) extrapolation. The toxic effects used by the agency to estimate risk in the human health assessment are based on evidence of neurotoxicity in the 90-day rat study. As a result of information received as part of public comments, EPA has drafted an updated assessment, *Imidacloprid: Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments,* which is available in the public docket.

Dietary (Food + Water) Risks

The acute dietary assessment assumed tolerance-level residues for most registered commodities, and all crops were assumed to have 100% of the crop treated. No acute dietary risks of concern were identified, as all populations resulted in acute population adjusted doses (aPAD) of less than 100% which is HED's level of concern. The highest exposed population subgroup was children 1-2 years old with an aPAD of 93%.

The chronic dietary assessment also assumed tolerance-level residues but incorporated average percent crop treated for several commodities. All chronic exposure analyses were below the level of concern. The most highly exposed population subgroup was children 1-2 years old at 12% of the chronic population adjusted dose (cPAD).

Residential Risks

Residential uses of imidacloprid include lawns and gardens, homes, commercial establishments, crack-and-crevice treatments, pet uses, structural pest control, and wood preservation. Generally, short-term dermal and incidental oral post-application exposures (short-term) are expected as a result of these residential uses, with the exception of intermediate- and long-term exposures from the pet collar and spot-on uses, as they present the potential for prolonged exposure via a continuous source and frequent contact (*i.e.*, playing with pets).

All residential handler scenarios resulted in margins of exposure (MOEs) greater than HED's LOC of 100, which makes these risks not of concern. MOEs ranged from 110 to 950,000; the lowest MOE was associated with applying pet collars to large dogs. Since the previous human health risk assessment, the combined residential post-application exposure risk estimates for the pet collar use have been updated and are no longer of concern (*i.e.*, MOEs ≥ the LOC of 100) for all scenarios.

The post-application residential MOEs (combined dermal and inhalation) for foliar spray and granular irrigated turf are not of concern (MOEs ≥ LOC of 100) however, there are risk estimates that indicate potential concern for adults (dermal exposure, high-contact activities), and children 1 to <2 years old (dermal exposure, high contact activities and hand-to-mouth) using additional turf transferable residue (TTR) data submitted during the public comments on the human health risk assessment from the foliar and granular non-irrigated plots. Following review of this data, the agency updated its exposure assumptions, resulting in these risks of concern. For children 1 to <2 years old, combined dermal and incidental oral estimates are of concern with an MOE of 25, dermal high-contact play on treated turf scenarios resulted in an MOE of concern of 36, and the hand to mouth scenario resulted in an MOE of concern of 83. For adults, the high-contact play modeled scenario resulted in an MOE of concern of 71. Detailed discussion of this data and the resulting risks of concern are in, *Imidacloprid: Human Health Draft Risk Assessment for Registration Review* and *Imidacloprid: Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments*, available in the imidacloprid docket.

Bystander Risks

Previously, a quantitative spray drift assessment for imidacloprid was not required because the residential turf post-application MOEs was not of concern and was protective of bystander risks. After review of the TTR data submitted during the public comment period, non-occupational spray drift exposure was reassessed and determined to not be of concern. For more information please see, *Imidacloprid. Updated Non-Occupational Spray Drift Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments*, available in the imidacloprid docket.

Occupational Risks

Most occupational handler risk estimates were not of concern (*i.e.*, MOEs $\geq$ 100) with current baseline attire (long-sleeved shirt, long pants, shoes and socks) or with personal protective equipment (PPE and gloves). The exception was for workers performing activities related to: on-farm seed treatment to barley, canola, cotton, millet, and wheat (MOEs ranged from 4 to 94); the handgun application for citrus (MOE = 58); and seed planter exposure for flax which showed a slight exceedance (MOE = 98). Workers conducting seed treatment on barley and cotton would need to wear double layer clothing and gloves to reach acceptable MOEs; for workers applying imidacloprid to citrus using handguns, only the addition of gloves would be needed; uses such as canola, millet, and wheat show lower MOEs ranging from 4 to 37, which would require further mitigation such as conducting applications in commercial seed treatment facilities, to reduce risks below EPA's level of concern.

The occupational post-application dermal exposure assessment resulted in MOEs greater than the LOC of 100 and were not of concern; MOEs ranged from 440 to 4,800.

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding for imidacloprid and any other substance, and it does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances for this assessment.

2. Human Incidents and Epidemiology

An incident review was conducted from January 1, 2000 to August 27, 2008 and there were a large number (436) of single chemical incidents involving imidacloprid reported in the Office of Pesticide Program's Incident Data System (IDS). In the most recent IDS analysis, including search results from January 1, 2011 to April 26, 2016, 44 incidents were reported for single chemical (exposure to imidacloprid only), and 518 incidents reported for multiple active ingredients (combined exposure to imidacloprid and other active ingredients). In the aggregate IDS, 2,828 incidents were reported involving imidacloprid. In addition, the Sentinel Event Notification System for Occupational Risk (SENSOR) was queried from 1998 to 2013, and 318 cases involved imidacloprid (114 involved only imidacloprid). A query of the National Pesticide

Information Center (NPIC) from January 1, 2010 to December 31, 2015, identified 111 incidents, and 96 of those were reported to the California's Pesticide Incident Surveillance Programs (PISP) involving imidacloprid and other chemicals (2010 to 2013).

Since the 2017 draft human health risk assessment, a new human health incident memo, *Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision*, was posted to the docket. Although the report was made as part of the flumethrin registration review, all incidents noted were from a single combined flumethrin-imidacloprid product (Seresto™ Collar, EPA Reg. No. 11556-155) and incorporate incidents from January 1, 2016 to August 27, 2019. During this time in the Main IDS there were 252 human health incidents reported that involved the active ingredient imidacloprid. Of these 252 incidents, 19 were classified as major severity and 233 were classified as moderate severity. In Aggregate IDS, there were 374 human health incidents reported involving imidacloprid. These incidents were classified as minor severity.

Of the 19 major severity incidents in main IDS that were further reviewed, the symptoms most often reported were dermal (8) and neurological (7). However, a patient could exhibit multiple symptoms. Dermal symptoms reported include rash, redness, skin lesions, hives, and pruritus. Neurological symptoms reported include headaches, numbness, tingling and one person reported seizures. The total number of imidacloprid incidents reported to IDS, from 2013 to 2018, appeared to be increasing over time. The agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

3. Tolerances

Tolerances for imidacloprid are established on a variety of raw agricultural and livestock commodities for the U.S.; for Canada, Mexico and Codex the residue definition is harmonized. However, there are many international tolerances that are not harmonized with the U.S. tolerance. Most cannot be harmonized because the U.S. uses have higher application rates, and thus higher tolerance levels. The agency proposes increasing the US tolerances for residues of imidacloprid on citrus fruits and coffee to harmonize with Canada and Codex MRLs. Additionally, EPA is proposing eliminating trailing zeros listed in tolerances consistent with agency policy. All proposed tolerance revisions for imidacloprid are listed in Appendix E: Summary of Proposed Tolerance Actions.

4. Human Health Data Needs

The human health database for imidacloprid is complete. No additional data is needed for the imidacloprid registration review.

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 imidacloprid. For additional details on the ecological assessment for imidacloprid, see the following documents, which is available in the public docket (EPA-HQ-OPP-2008-0844) at www.regulations.gov.

- *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid*
- *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review*
- *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid*
- *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. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for imidacloprid. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

5. Risk Summary and Characterization

Terrestrial Exposure

Imidacloprid is applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, and seed treatment. For terrestrial wildlife, the agency modeled potential dietary exposure based on consumption of imidacloprid residues on food items following spray (foliar or soil) applications as well as from ingestion of residues on treated seeds. For treated seeds, different seed sizes and planting rates could result in a range of exposures. EPA also considered potential bird and mammal dietary exposure from fields where applied manure from poultry house operations may contain imidacloprid residues resulting in contamination of 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 imidacloprid appear to be low. Soil incorporation following soil treatments, including incorporation of treated poultry litter, decreases potential risks from this use pattern considerably. Exposures from treated seed results 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.

For terrestrial plants, available data indicate they are not sensitive to imidacloprid up to 2X its maximum single foliar application rate of 0.25 lb a.i./A. Therefore, exposure modeling (and risk estimation) for terrestrial plants was not conducted.

Mammals – Risk Estimates
Imidacloprid is classified as moderately toxic to mammals on an acute oral exposure basis. Chronic exposure in the Norway rat (*Rattus norvegicus*) resulted in reductions in parental and offspring body weight. The chronic mammalian risk quotients (RQs) calculated for imidacloprid were based on the chronic mammalian rat 2-generation reproduction NOAEL of 16.5 mg/kg-bw/d. Potential risk was evaluated at three different weight classes of mammal: small (15 g), medium (35 g), and large (1000 g). Further details on mammalian risks are provided below.

Foliar Applications: There were 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 lb a.i./A (RQs <0.01 – 0.11; LOC = 0.5). Acute RQs were highest for small mammals feeding on short grass.

There were no chronic LOC exceedances on a chronic dietary basis for all application rates (highest RQ = 0.44; LOC = 1.0), but there were exceedances for dose-based RQs for 15 of 17 uses (highest RQ = 2.9 on citrus/pome). Expected risks rose with increases in the modeled application rate and for smaller sized mammals.

Soil Applications: There were no acute risks of concern via soil applications for mammalian species of any weight class even when assessed using the maximum registered single application rate of 0.4 lb a.i./A (RQs <0.01 – 0.37). Acute RQs decreased with weight class and were highest for small mammals feeding on short grass.

There were no chronic LOC exceedances on a chronic dietary bases for all application rates (highest RQ = 0.19), but there were dose-based risks of concern for 18 uses (highest RQ = 1.2). Expected risks rose with increases in the modeled application rate and for smaller mammals. No exceedances to mammals were noted from use on poultry litter.

Treated Seed Applications: RQs were calculated for six crops (corn, soybean, cotton, wheat, sorghum, and potato) when assessing potential risks to mammals from imidacloprid-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.*, sorghum 0.023 to potato 0.878 lb a.i./A) and present a range of application rate to seed size ratios. The acute species LOC was exceeded for four of the six scenarios (RQs ranged from <0.01 to 1.1; LOC = 0.5) for dose-based exposures. The highest acute RQ exceedances were for use on cotton.

The chronic LOC was exceeded for all size classes of mammals consuming each of the assessed treated seed with the exception of potato (RQs ranged from 0.3 to 29; LOC = 1.0), indicating potential chronic risk. The highest chronic RQ exceedances for treated seed was for cotton.

Mammals - Risk characterization
There are several variables impacting exposure 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 specific sensitive life stage or are due to exposure over 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 effect are expected varies by the size of the mammal, with larger mammals requiring a larger dosage for toxicological effects to be likely. According to the agency's *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review*, the percent of a mammals' diet that would need to be imidacloprid-treated seed in order to exceed the acute level of concern would be 34-78% for sorghum/wheat seed, 37-82% for corn seed, 160-331% for soybean seed, 47-96% for cotton seed, and 2200-3688% for potato seed, depending on mammal size. Dietary percentages greater than 100% indicate a low potential for risk while risk increases as the dietary percentage decreases below 100% since it is presumed more likely that a mammal would consume smaller fraction of its diet from the treated field. The highest potential risk scenario identified was small (≤15g) mammals consuming sorghum seed. In this example, an individual small sized mammal would need to consume 34% of its daily diet as treated sorghum/wheat seed in a day to exceed the acute level of concern.

Although our risk estimates indicate the potential for acute risks of concern, specifically for smaller sized mammals, there is uncertainty associated with the percentage of an individual mammal is likely ot be treated seed. Overall, risk of concern is more likely from chronic (long-term) consumption of treated seed.

Birds, Reptiles, and Terrestrial-Phase Amphibians – Risk Estimates
Imidacloprid is characterized as highly toxic to birds on an acute oral exposure basis and slightly toxic on a subacute dietary exposure basis. Japanese quail (*Coturnix coturnix japonica*) represents the most sensitive acute toxicity endpoint while mallard duck (*Anas platyrhynchos*) represents the most sensitive chronic toxicity endpoint with effects on egg production, egg hatchability, and adult body weight. Further details on ecological risks to birds, reptiles, and terrestrial phase amphibians from exposure to imidacloprid are provided below. Note that birds are used as surrogates for potential risks to terrestrial-phase amphibians and reptiles.

Foliar Applications: For foliar applications of imidacloprid, there were no acute or chronic risks of concern for birds on a dietary basis even when calculated using the maximum registered foliar single application rate of 0.4 lb a.i./A (RQs <0.01 – 0.86; LOCs = 0.5 for acute risks and 1.0 for chronic risks). Acute exceedances were identified on a dose basis with RQs ranging from <0.01 to 9.8 among all bird types, dietary items, and uses. Small and medium size herbivorous birds have the greatest frequency of exceeding the acute risk LOC, with exceedances in all 17 crop scenarios (representing 26 registered use patterns) for at least 3 of the 4 dietary categories. For large herbivorous birds, acute dose-based RQs range from 0.02 to 1.2, and LOC exceedances mainly occur for birds consuming short grass. For insectivores, acute dose-based RQ values range from 0.13 to 3.8 and exceed the acute LOC for small and medium insectivores, except for marginal exceedances for tree nuts and citrus/pome fruits. Lowest overall risk from foliar applications of imidacloprid is expected for granivores, with no exceedances of the acute risk LOC. RQs decreased with avian weight class and were highest for small birds feeding on short grass. In practice, given that most herbivorous avian species are expected to be classified as large birds (≥1,000 g), it is unlikely that herbivorous species will be at risk. However, it is possible that smaller omnivorous species that consume available foliage (e.g., seedlings) may be at risk.

Soil Applications: The potential for acute risk to birds consuming contaminated arthropods was identified for small and medium size birds for all crop exposure scenarios modeled (RQ range = 0.68 to 4.2). Chronic dose-based RQ values were not calculated for birds per the T-REX model. On a dietary basis, acute risk was not indicated (maximum acute RQ = 0.03). On a chronic dietary basis, risks to birds are not indicated since the chronic RQ values are below the LOC for all uses (RQs range from 0.14 to 0.38).

Based on an acute analysis (LD_{50}/ft^2) for soil applications of imidacloprid, the acute LOC was exceeded for small and medium size birds for all crop exposure scenarios modeled (acute RQ range from 1.2 to 20). For large birds, the crop uses with the highest application rates (*e.g.*, bulb vegetables, fruiting vegetables, citrus) slightly exceed the acute LOC of 0.2 with an RQs of 0.23. Potential risk to birds from use in poultry litter was not assessed in the terrestrial draft imidacloprid risk assessment.

Seed Treatment Formulations: As mentioned previously in the section for mammals, RQs representing potential risks to birds from imidacloprid-treated seeds were calculated for various crops and rates. Expected risks are highest for small birds and decrease with increasing avian body weight. For small and medium birds, there are acute dose-based LOC exceedances for all crops (RQs range from 0.15 to 99). For large birds, there are acute dose-based species LOC exceedances for birds feeding on soybean, wheat, corn, sorghum, and cotton seeds. On a chronic basis, the LOC was exceeded for birds consuming all of the assessed treated seeds (RQs ranged from 1.0 to 41). The highest chronic exceedances for all sizes of birds was from treated cotton seed with an RQ of 41.

Birds, Reptiles, and Terrestrial-Phase Amphibians - Risk characterization
In field conditions, the exposure of birds to imidacloprid 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.

Based on the agency's *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review*, the percent of which a bird's diet would need to consist of imidacloprid-treated seed in order to exceed the acute level of concern would be only 3% for field corn seed (risk only to large birds), 12% soybean seed (risk only to large birds), 1-4% cotton seed, and 1-3% sorghum/wheat seed, depending on bird size. The highest risk was identified for small size birds which would need to consume less than a single treated sorghum and wheat seed to exceed the acute level of concern, while with small or medium size birds consuming cotton, sorghum, and wheat seed, a bird would only need to consume 1-4 seeds [two (cotton) or four (sorghum and wheat)] to exceed the acute level of concern.

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 imidacloprid-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 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. Examples of seeds too large for small passerine (20g) bird consumption includes are field corn, soybean, cotton, and potato. Therefore, acute and dietary risks from consumption of these seeds can be discounted for these size classes of passerines. Field corn and potato seeds are 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. As an example, for large birds foraging in cotton fields, 4% of their diet would have to be made up of the imidacloprid-treated seed in order to reach the species acute LOC compared to 1% of a medium bird's diet. Given the potential availability of other seed sources (*i.e.* remaining waste grain or seeds from weed species on the field), eating diets made up entirely of a specific seed type is unlikely but may be more likely in instances of treated seed spillage than through normal foraging behavior.

<u>Terrestrial Invertebrates</u> – Risk Estimates

This section incorporates information provided in the *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* as well as the more recent *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid*, which are available in the public docket. The initial preliminary pollinator assessment published in 2016 evaluated the potential risk associated with the registered agricultural uses of imidacloprid to bees alone. The 2016 assessment utilized available data at the time. This included a robust registration review required dataset to help characterize the acute and chronic toxicity of imidacloprid to adult and larval honeybees at the Tier I (individual bee effects) level. In each assessment (2016 and 2019), a plethora of available open literature data were also reviewed in addition to the required data.

The final 2019 bee risk assessment then updates the preliminary pollinator assessment and incorporates additional information submitted to the EPA since the previous assessment. This new assessment also includes additional residue study data, which provide information on residues of imidacloprid in nectar, pollen, and other plant matrices for registered crop uses; as well as a residue bridging strategy to extrapolate residue data among crops, chemicals, and plant matrices to address lack of residue data for certain crops between the neonicotinoids where appropriate. This additional information includes higher tiered (Tier II and III) 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 evaluated colony-level effects which represented a more real-world scenario, however was associated with more uncertainty.

Imidacloprid is unique compared to the other neonicotinoids as it had the availability of Tier III full-field studies conducted on pumpkin and cotton, which were incorporated into the recent assessment. Data were 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 imidacloprid, 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.* bumblebees, solitary bees). Risks to these other non-*Apis* bees are evaluated qualitatively based on available information. As the pollinator risk assessment framework used by the EPA indicates, honeybees are intended 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, and dinotefuran), robust data sets of pollen and nectar residue data are 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. Surrogate residue data from the other neonicotinoids were used to represent uses on crops where limited or no residue data were available. Generally, the imidacloprid risk assessment found that foliar or soil applications of imidacloprid to honeybee attractive crops that are not harvested prior to bloom result in the potential for colony-level risks of concern. Risks associated with pre-bloom applications are generally greater than those associated with post-bloom applications.

Based on the evaluated data, imidacloprid is classified as very highly toxic to adult honeybees with acute oral and acute contact LD_{50} values of 0.0039 and 0.043 µg a.i/bee, respectively. For larval toxicity, there was no acute oral study available. At the Tier 1 (individual bee) level, acute contact RQs ranged from 2.5 to 31 (LOC = 0.4). Acute oral exposure to adult honey bees foraging on the treated field based on refined exposure (measured residues) from foliar applications resulted in RQ exceedances up to 32 (orange), soil use RQ exceedances up to 126 (ornamentals), and combined foliar and soil exceedances up to 208 (cotton). The highest acute exceedances were from uses on citrus, pome fruit, ornamentals and turf.

For chronic oral toxicity to adult bees, a 10-day study indicated a No Observed Adverse Effect Concentration (NOAEC), at 0.0011 µg a.i/bee/day. The Lowest Observed Adverse Effect Concentration (LOAEC) based on significant effects on food consumption for this study was 0.0018 µg a.i/bee/day. A 21-day chronic toxicity test did not show significant effects up to and including the highest concentration tested, 40 µg a.i/L (equivalent to 0.00183 µg a.i/bee). At the Tier 1 (individual bee) level, chronic adult oral RQ exceedances from on-field foliar use of imidacloprid based on refined exposure (measured residues) are up to 86 (orange), soil use exceedances are up to 224 (ornamental), foliar and seed exceedances are up to 7.7 (cotton) and, foliar and soil exceedances are up to 518 (cotton) (LOC = 1.0). Like with the acute risk exceedances, the highest chronic risk exceedances noted were from uses on citrus, pome fruit, ornamentals and turf.

Based on an analysis of Tier I data, for foliar applications, potential off-field dietary risks to individual bees exposed to spray drift extend greater than 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.

Imidacloprid exposure to pollinators also exists where applications are made to poultry litter manure in broiler houses which are later used as outdoor fertilizer. Due to neonicotinoid persistence in the environment, poultry litter use resulted in acute risks of concern for bees when applied at the maximum allowed rate (0.032 – 0.756 lb a.i./A) and number of applications (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 exceedances up to 5.5 (larval chronic) and up to 21 (adult chronic). For the lowest application rate of 0.032 lb ai/A, RQ values are 0.23 (larval chronic) and 0.91 (adult chronic); below the LOC of 1.

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 imidacloprid 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 pumpkin and cotton. 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 Imidacloprid*, available in the docket. The findings of the higher tier assessment are summarized below.

<u>Terrestrial Invertebrates</u> – 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 not been present.

<u>Strongest Evidence of Risk:</u> For foliar and soil applications of imidacloprid, the lines of evidence are considered "strongest" for supporting the finding of colony-level risk resulting from applications to (with corresponding application method and timing of application with highest level of concern):

- citrus, banana/plantain (foliar and soil, pre-bloom),
- cotton (combined foliar + soil)
- berries (foliar and soil, pre-bloom),
- cucurbits (soil)
- attractive fruiting vegetables (chilies, peppers, foliar and soil), and
- attractive ornamentals and forest trees (foliar, soil)

These findings are supported by multiple lines of evidence indicating that residues exceed the imidacloprid 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 Risk: For foliar, soil, and trunk injection application of imidacloprid, the strength of evidence is considered "moderate" in indicating a colony-level risk to honeybees for the following registered uses:

- citrus (soil, post-bloom),
- tree nuts (soil, post-bloom),
- cotton (foliar and soil),
- turf (including residential lawns), and
- ornamentals and forestry (trunk injection).

These findings are supported by lines evidence indicating that residues exceed the imidacloprid colony-level endpoints but the magnitude, frequency and/or duration of exceedance is limited. In some cases, residues exceed only for a subset of sites or crops, possibly due to the impact of soil type (*e.g.*, soil applications to cotton).

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

- root/tubers (foliar, soil),
- legumes (soil, seed, beans),
- citrus (foliar, post-bloom),
- pome and stone fruit (foliar & soil, post-bloom),
- herbs and spices (foliar, soil),
- tropical fruit (foliar & soil, post-bloom), and
- hops/peanut (foliar, soil, seed)

Terrestrial Plants

Imidacloprid was not found to be toxic to terrestrial plants when tested up to its maximum single application rate. Due to the low sensitivity of terrestrial plants to imidacloprid applications up to the maximum single rate, a quantitative risk assessment was not conducted for terrestrial plants.

Aquatic Risks

Imidacloprid is applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, and seed treatment. For aquatic wildlife, the agency modeled potential exposure based on the likelihood of imidacloprid residues reaching aquatic waterbodies. Imidacloprid's chemical properties indicate it is readily soluble in water and that volatilization and bioaccumulation in aquatic organisms are negligible. Imidacloprid is considered persistent in aquatic environments with the exception of conditions that favor aqueous photolysis. The major routes transporting imidacloprid from treatment sites to aquatic habitats include runoff and spray drift.

Freshwater Invertebrates

Based on the *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid* dated December 22, 2016, acute and chronic risks of concern to freshwater invertebrates for imidacloprid were identified for both agricultural and non-agricultural soil, foliar, and combined application method uses. All uses associated with foliar spray and combination application methods showed the potential for acute and chronic risks to freshwater invertebrates. Acute RQs ranged from <0.01 to 44 and exceeding the LOC of 0.5, while chronic RQs ranged from <0.01 to 2130 exceeding the chronic LOC of 1.0. Chronic freshwater RQ exceedances were generally highest for combined applications (39 to 2130), then foliar (82 to 1020), followed by soil (<0.01 to 699), and then seed (<0.01 to 84). A similar trend was seen with acute risks of concern.

<u>Comparative Analysis of Aquatic Invertebrate Risk Quotients</u>
While imidacloprid had a fairly comprehensive dataset for the agency to estimate potential aquatic risk, the other neonicotinoids in this group had much more limited dataset for the draft aquatic risk assessment. 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 *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid* (2016). The studies, located in the docket, were used to determine RQs using acute and chronic toxicity data provided in the two open literature papers published by researchers from the University of Guelph, Raby data (Raby *et al.* 2018a[6] and Raby *et al.* 2018b[7]). 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 (dinotefuran, clothianidin, thiamethoxam, 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. LC_{50} values for clothianidin on average were 2.4 times higher than those of imidacloprid and dinotefuran, suggesting that clothianidin may be somewhat less toxic on an acute basis than imidacloprid and dinotefuran. Thiamethoxam LC_{50} values were 5.6 times higher than those of imidacloprid across all tested species, suggesting that thiamethoxam is potentially the least toxic on an acute basis.

All four neonicotinoids present risks of concern to freshwater invertebrates on a chronic basis as well, with clothianidin and imidacloprid having similar toxicity, dinotefuran being ~2.3 times less sensitive, and thiamethoxam being ~5.3 times less sensitive than imidacloprid and clothianidin based on midge data (which was generally more sensitive than mayfly, the other tested species in the chronic test). There is a ~4 times difference in sensitivity across the four neonics with dinotefuran being the least sensitive; despite an almost 20 times difference between

[1] 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.

[7] 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.

mayfly toxic endpoints. There is a similar trend with the mayfly data with dinotefuran (and thiamethoxam) being the least sensitive.

Two notable uncertainties with the Raby data include: 1) inconsistent analytical verification of concentrations, and 2) differing 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 is 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 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

Acute risks were not identified for saltwater invertebrates. Chronic risks to saltwater invertebrates were identified for all application methods with RQs ranging from <0.01 to 131. The highest exceedances being identified from combined uses (2.4 to 131) followed by foliar (5.0 to 63), soil (<0.01 to 43), then seed treatment (<0.01 to 5.1) (LOC = 1.0).

Freshwater/Estuarine/Marine Fish and Aquatic-Phase Amphibians

The *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid,* dated December 22, 2016, noted no direct risks of concern to fish or aquatic phase amphibians from any of the agricultural or non-agricultural uses assessed. The limited number of aquatic incidents reported for imidacloprid indicate a lack of direct adverse impacts on fish. Furthermore, available monitoring data indicate detected concentrations of imidacloprid are several orders of magnitude below levels shown to cause adverse effects in fish and aquatic-phase amphibians. While the potential risk of direct effects of imidacloprid to fish and amphibians is considered low, the potential exists for indirect risks to fish and aquatic-phase amphibians through reduction in their invertebrate prey base.

Aquatic Vascular and Non-Vascular Plants

Potential imidacloprid risk to aquatic plants is expected to be low. Aquatic plants were not assessed as available data for vascular and non-vascular aquatic plants indicate toxicity endpoints that are several orders of magnitude above the highest EECs in surface waters.

6. Ecological Incidents

Ecological incidents were noted as possibly stemming from imidacloprid usage for several taxa. The certainty of these incidents stemming directly from imidacloprid use varies. It is important to note incident information serves as one line of evidence, and that the absence of reports does not indicate an absence of general incidents or pollinator losses due to pesticides.

Terrestrial non-pollinator incidents

A review of the Environmental Information Incident System (EIIS) incident database yielded 16 reported terrestrial organism incidents from 1995 to 2017. These incidents are discussed in more detail in, *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review*. For incidents originating from foliar applications, the reports primarily concern plant damage to agricultural crops, but are all associated with either “unlikely” or “possible” certainty indices due to the presence of multiple pesticides or no confirmatory residue analysis to confirm the presence of imidacloprid.

For the soil or ground-applied related incidents reported, 4 of the 7 incidents (57%) were associated with a “possible” certainty. Three of these incidents involved deaths to birds, yet there was no confirmatory residue analysis conducted in any of these cases to implicate imidacloprid or any other chemical as the cause of the mortality. In two other reports associated with higher certainty, plant damage was the reported effect, although at least one of these reports cites a misuse of the chemical. As described previously, imidacloprid did not show significant effects to ten species of plants at the highest application rate (0.5 lbs. AI/A) permitted, therefore it is unlikely to be the cause of the incident. In a recent (2016) report, 25 American goldfinches were reported dead shortly following a soil drench application to elm trees with a product containing 75% imidacloprid. A subsequent residue analysis of the livers and stomachs detected imidacloprid residues at 2.1 and 2.2 ppm, respectively, which indicates imidacloprid’s presence in the bird. The pathology report also noted grass seeds in the stomachs of the birds.

For the sole report associated with a seed treatment application, although a large number of birds were reported as allegedly dying due to ingestion of imidacloprid-treated wheat seeds, a subsequent residue analysis did not detect imidacloprid in the birds. This incident was categorized as “possible.”

For 3 of the 4 incidents in the unknown method of application category, the incidents appear to be associated with homeowner lawn care products, specifically grub control products. Although these incidents list damage to the homeowner lawns, the relevancy of these incidents relative to others where agricultural crops and or avian and mammalian wildlife is concerned is low given that homeowner-applied products are subject to a greater chance of misuse relative to those made by certified applicators.

Aquatic incidents

The incident database (1995 to 2017) also noted two wildlife incident reports concerning aquatic organisms (*i.e.*, fish and invertebrates). Both incidents were associated with non-agricultural uses of imidacloprid on turf. One of these incidents was notably a misuse, which in addition to imidacloprid, also contained the pesticides thiophanate-methyl and deltamethrin, the latter of which is known to be more toxic to fish which was the affected species in the incident report. These two aquatic incidents are categorized in more detail in, *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid*.

Pollinator incidents

The source of pollinator incidents includes not only EIIS but registrant reports submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) §6(a)(2) reporting requirement, as well as reports from local, state, national and international level government reports on bee kill incidents, news articles, and correspondence made to the agency by phone or via email (through beekill@epa.gov) generally reported by homeowners and beekeepers. These incidents are described in more detail in, *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid*, in the imidacloprid docket.

14 of the 19 incidents summarized either included a follow-up investigation that confirmed through residue analysis the presence of imidacloprid in at least one matrix (dead bees, floral pollen, nectar), or were submitted by the registrant under FIFRA 6(a)(2), which provides a higher confidence of imidacloprid being associated with these incidents. Ten of these incidents originated from an agricultural use while others were mainly from residential and commercial use on ornamentals. In some of these instances, other chemicals (including other neonicotinoid chemicals) were also detected. For others, the incident was determined to originate from a misuse of imidacloprid.

Of the ten incidents reported on agricultural crops, half were from soil applications and half were from seed treatment applications. Of the soil applications, four reported dead honeybees near citrus and soybean fields, while one reported dead bumble bees in greenhouse tomatoes. Most non-agricultural incidents involved applications to ornamental tree species; linden, arbutus, and laurel.

Several other incident reports were more anecdotal in the narrative, as they provided information without a confirmatory residue analysis such as news reports and beekeeper organization newsletters. Of the incidents that provided a residue analysis, imidacloprid concentrations of dead bee samples were quantified as high as 2,456 µg/L.

Pet incidents

The EPA has received and evaluated numerous pet incidents since imidacloprid's registration in 1994; however, a comparative assessment of pet incidents across all registered pet products based on usage data is not available. The agency is conducting similar analyses on other pesticides registered for direct treatments to pets, such as spot-ons, and may consider conducting such analyses for other active ingredients with products registered for direct treatments to pets, such as collars. EPA has been engaged with stakeholders on a variety of different actions to address potential risks to pets from the use of pet spot-on products; additional information on this project can be found here: https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects. As additional information is gathered through this project, EPA will be evaluating the use of pet products generally, including those that contain imidacloprid, to determine if additional changes are needed to pet product registrations.

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.

7. Ecological and Environmental Fate Data Needs

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

C. Benefits Assessment

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 1.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 particular pests;
- offer both immediate, contact control and systemic, residual control of pests over an extended period of time;
- are comparatively less expensive and more effective than some alternatives;

For imidacloprid specifically, the agency found benefits of usage includes selective activity, a unique mode of action for resistance management, systemic and translaminar activity, minimal toxicity to most predatory or parasitoid insects, and the capacity to target hard-to-control pests. Imidacloprid usage suggests it provides superior control of aphids and whitefly (while other neonicotinoids are beneficial for control of other insects). Alternatives to imidacloprid, depending on the crop or use site and target pest, include organophosphates, pyrethroids, and carbamates, as well as alternative nitroguanidine and chloropyridinyl neonicotinoids such as thiamethoxam and acetamiprid, respectively.

The following are summaries of the benefits assessments available in the public docket[8]:

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; imidacloprid accounts for about 35% of these acres. Imidacloprid is applied primarily via seed treatment but is also registered for foliar and soil treatments. An average total of 3.2 million acres are treated with imidacloprid annually with a total of 192,000 average pounds of active ingredient applied at an average application rate of 0.060 lbs. AI/A. The vast majority of treated cotton acreage is via seed treatment at rates below the overall average. Rates of at-plant soil applications and in-season foliar applications average 0.169 lbs AI/A and 0.071 lbs AI/A, respectively. Of cotton foliar applications (both via ground and aerial applications), imidacloprid accounts for over half of the neonicotinoid use in terms of pounds applied but less than 40% of the acres treated.

Foliar usage of imidacloprid in cotton most commonly targets plant bugs, aphids, and stink bugs. There are regional differences in pest pressure. Stink bugs are somewhat more common targets in the Southeast than in the Mid-South and Plains states. In the Plains states, the primary target pest is the fleahopper. These pests cause a variety of damage throughout the growing season and can account for not only early season yield losses but in the case of “sticky cotton”, when lint and other contaminants adhere to cotton processing equipment, caused by late season whiteflies and aphids, limiting the viability and sale of final product. Without imidacloprid 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, which would increase costs – and lower income – by $3 to $7/acre, depending on the region.

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

Citrus

Based on information from market research data, imidacloprid and thiamethoxam were the main neonicotinoid active ingredients used on citrus groves nationally from 2011 – 2015. On average, 104,000 pounds of imidacloprid were used annually on 274,000 acres of citrus with over 417,000 total acres treated with imidacloprid for an average of 1.5 applications per year. Neonicotinoids are used on citrus as part of programs to control the Asian citrus psyllid (ACP), a vector for Huanglongbing bacterial disease (HLB), also known as citrus greening disease. HLB is currently incurable; it negatively affects both the quantity and quality of fruit and may kill trees within a few years. Without imidacloprid, used in conjunction with other neonicotinoids, growers would increase use of other insecticides such as organophosphates and pyrethroids like acephate,

[8] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0844

dicrotophos, bifenthrin, lambda-cyhalothrin, and 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.

In citrus production, neonicotinoids are also used to control a variety of other insect pests such as aphids, leafminers, citrus rust mite, fuller rose beetle, and scale insects, that occur outside the bloom period.

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

Grape

Pesticide usage data from 2013 – 2017 indicate that over 500,000 acres of grapes are treated annually in the U.S. with imidacloprid, or around 50% of table, raisin, and wine grapes. Applications are most often made post-bloom, but imidacloprid is also a leading insecticide prior to and during bloom. Extension guides recommend imidacloprid in a regiment for most grape insect pests. The primary target pests are leafhoppers, including sharpshooters, and mealy bugs, with the grape berry moth and Japanese beetle being important pests of grapes in the northeast. Damage from these pests can result in quality and yield reductions. Sharpshooters vector Pierce’s Disease which is a fatal bacterial disease for grapes that can result in 100% yield loss. Imidacloprid provides rapid control via contact activity and residual control through systemic activity. More generally, neonicotinoids are important rotation partners for resistance management.

Neonicotinoids provide substantial benefits to grape growers, given that the alternative insecticides are limited and/or more expensive depending on target pest. If imidacloprid and other neonicotinoids were unavailable, yield and quality loss, including losses from disease, would be likely.

For more information, see *Benefits of Neonicotinoid Insecticide Use in Grapes and Impacts of Potential Mitigation,* available in the public docket.

Rice

While EPA conducted a benefits assessment for rice, imidacloprid is not registered for use in rice and thus was not included in the rice benefits assessment.

Stone Fruit

The stone fruit benefits assessment included apricot, sweet and tart cherries, peaches/nectarines, and plums/prunes as well as several other varieties and hybrids. The proportion of U.S. cherry crop treated with either imidacloprid (40%) or thiamethoxam (23%) is substantial while applications to peach/nectarine crop treated with neonicotinoids is far less, imidacloprid makes up the most with 8%. For apricot and plums/prune, about 5% of the crop is treated with imidacloprid, while use of other neonicotinoids is negligible. Thus, the focus of the benefits assessment was on cherry and peach.

Pests on stone fruit for which imidacloprid may be used include plum curculio, aphids, cherry fruit fly, stink bugs, plant bugs, oriental fruit moth, and spotted wing Drosophila. Of these, plum curculio is a significant pest for which post-bloom control is critical. However, among the nitroguanidine neonicotinoids, thiamethoxam is considered more efficacious than imidacloprid for this pest. Plum curculio is a beetle which deposits eggs on or near developing fruit. Its larvae feed inside fruit and this can lead to fruit drop or cosmetic damage to larger fruit (USDA 2011). In addition, buyers and processors have a zero-tolerance policy for infestations, and detection of a single larva will result in rejection of the entire harvest from a given orchard block. Imidacloprid is more often utilized to manage fruit flies, another critical pest in terms of both yield/quality loss and the threat of harvest rejection, as any fly infestation in harvested fruits also faces a ‘zero tolerance’ policy among buyers. Aphids targeted by imidacloprid use can be occasionally serious pests, particularly to young trees. The spotted wing Drosophila is a tiny “vinegar” fly, native to east Asia, which was accidentally introduced into the United States in 2009. It prefers soft-skinned fruit for oviposition and (unlike fruit flies) has the ability to lay eggs in undamaged fruit. Like the curculio and fruit flies, Drosophila larvae are internal fruit feeders, and feeding increases the incidence of fungal and bacterial diseases in the affected fruit. Among stone fruit, however, cherries are most vulnerable to this pest, though it can be found on ripe plums and peaches as well. Due in part to the difficulty of detecting this tiny insect, its damage, and the zero tolerance among buyers for any infestation in the harvest, cherry growers in particular rely on frequent treatments of multiple insecticides in affected areas. Imidacloprid is one of these options.

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)*, available in the public docket.

Pome Fruit

Imidacloprid is applied to approximately 158,200 total acres of pome fruit with a total of approximately 18,700 pounds applied (2013-2017). Imidacloprid use on Western apples accounts for approximately 95% of the total acres treated with nitroguanidine neonicotinoids. Imidacloprid is applied at an average rate of 0.106 lbs. AI/A for Western apples and 0.128 lbs. AI/A for Eastern apples. Imidacloprid is also used on pear, about 11% of the acres grown are treated at an average rate of 0.204 lbs. AI/A.

Imidacloprid is used for the control of pear psylla and mealybugs in pear and aphids and brown marmorated stink bug (BMSB) in apple production. These target pests can result in quality and yield loss. The majority of imidacloprid use is during the post-bloom to harvest periods of the pome fruit production cycle. However, 20-30% of the pome fruit crop is treated with neonicotinoids during the pre-bloom and bloom periods. For aphid control in Western apple production, imidacloprid is the second most used insecticide, following chlorpyrifos, during the pre-bloom and bloom periods, and the number one control option post-bloom. Early season control can be important to manage early season pests that can build up to high population densities if not controlled early season.

For more information, see *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 public docket.

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, of which imidacloprid is often the most commonly used, provide both contact and systemic control of numerous economically significant pests in berry crops. Imidacloprid is used for the control of strawberry aphids, spittlebug, potato leafhopper, and whiteflies in strawberry; aphids, potato leafhopper, spotted wing drosophila (SWD), and thrips in caneberry; blackheaded fireworm, cranberry flea beetle, rootgrubs/rootworms, and weevils in cranberry; and aphids, sharpnosed leafhopper, blueberry maggot, and Japanese beetle in blueberry. These target pests cause direct feeding damage which can cause reductions in the aesthetic quality of harvested fruit (*e.g.*, Japanese beetle), transmit diseases which can result in plant death and/or crop loss (*e.g.*, aphids, leafhoppers, whiteflies), and can present damage during harvest that can potentially result in complete crop rejection, of a grower's entire field (*e.g.*, blueberry maggot).

A very high proportion of caneberries and blueberries are treated with imidacloprid while about ten percent of strawberry acreage is treated with imidacloprid. Data are not available for insecticide usage in cranberry. The alternatives to imidacloprid vary by crop and target pest and consist primarily of organophosphates, pyrethroids, flupyradifurone and acetamiprid in strawberry; organophosphates and pyrethroids in caneberry; organophosphates and spinosyns in cranberry; and acetamiprid, pyrethroids, organophosphates, and carbamates in blueberries. Imidacloprid, compared to its alternatives, offers flexibility of application method, cheaper cost compared to some alternatives, superior control compared to some alternatives, and longer residual control which reduces the number of applications needed resulting in further reduction of application costs.

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

Cucurbits

The cucurbits benefits assessment for the neonicotinoids includes usage in cantaloupes, watermelon, squash, cucumber, and pumpkin from emergence to harvest in the Western, Southern, and Northern production regions. Key pests treated by neonicotinoids include whiteflies and aphids. Imidacloprid is the most utilized neonicotinoid active ingredient on cucurbits followed by dinotefuran. Imidacloprid is applied most to cantaloupe (8,600 lbs. AI/A annually); however, in total, an average of 26,000 pounds of imidacloprid are applied annually to cucurbits.

According to pesticide market research data (2013-2017), imidacloprid is the most commonly-used insecticide prior to crop emergence. Imidacloprid is most commonly used on cucurbits to target aphids both prior-to-crop emergence and crop emergence-to-vining followed closely by its use to target cucumber beetle.

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

Other Crops: Fruiting vegetables, Brassica vegetables, Leafy Green vegetables, Tree Nuts, Root & Tuber vegetables, Bulb vegetables, Herbs, Peanut, Legume Vegetables, and Tropical and Subtropical Fruit

Neonicotinoids provide both contact and residual control of several important insect pests, primarily piercing and sucking pests that feed off the sap of plants and that may vector disease. Because they are systemic, both soil and foliar applications can be used, permitting growers flexibility in terms of application timing and method. Neonicotinoids are less widely used in production of bulb vegetables, succulent and dried legumes, peanut, and certain tropical fruits like avocados, dates, and olives. In these crops, target pests may be uncommon or rarely damaging and/or there are cost effective alternatives. Data for some small-acreage crops, such as herbs, are not available from which to draw conclusions.

In general, usage of imidacloprid is highest among the neonicotinoids. Most of the neonicotinoid usage in tree nuts is associated with imidacloprid although relatively little is used in almond production. Imidacloprid is also the primary neonicotinoid used in production of tropical fruits, for which acreage in the continental United States is generally very small. Of the crops grown on more than 10,000 acres, usage of imidacloprid is high in pomegranate, but low in avocado, dates, and olive. On peppers and tomatoes, 32% and 65% of the acreage is treated with imidacloprid, respectively. Similarly, the percent of acres treated with imidacloprid is high in most of the leafy vegetables and *Brassica* vegetables, ranging from nearly 35% to 75%. Imidacloprid is also the primary neonicotinoid used in production of root and tuber crops; over 20% of carrot acreage and over 35% of potato acreage are treated with imidacloprid, often by chemigation. However, 10% or less of peanut, dry and succulent beans and peas, and bulb vegetables are treated with imidacloprid.

To some extent, other neonicotinoids could be used as alternatives to imidacloprid. However, the pest spectrum is slightly different; imidacloprid tends to provide control over a greater range of sucking and piercing insects. Dinotefuran is not registered for use in tree crops; thiamethoxam is the only other nitroguanidine neonicotinoid registered for foliar application in carrot and imidacloprid is the only neonicotinoid registered for soil and foliar applications in legumes and peanut. Absent imidacloprid, alternative pest control strategies would vary widely across these crops and pests. Broad-spectrum insecticides such as organophosphates and pyrethroids may be used in some situations; more selective insecticides possibly in conjunction with insect growth regulators might be feasible in other situations. Few, if any, of these options have systemic activity and multiple applications may be needed to provide similar control to a single imidacloprid application.

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

Turf and Ornamentals
The registrants of neonicotinoid insecticides commissioned a series of reports, prepared by the agricultural consulting firm AgInfomatics in 2014 on the value of neonicotinoids, or equivalently the impacts of a ban on their use on turf and ornamentals in the United States and Canada. The reports quantified the agronomic, environmental, and socio-economic values of neonicotinoids using a Choice Experiment to homeowners and professionals who manage turf and ornamentals. The turf and ornamentals industries in the U.S. account for over 400,000 businesses, millions of jobs, and billions in annual revenues. Turf and ornamentals add value to the homes of consumers through various means such as aesthetics, recreation, energy and water conservation. Insects can damage areas with turf and ornamentals, and thus reduce their value to consumers. Over 19,000 homeowners were surveyed by AgInfomatics and segmented into three markets based on the predominate “homescape” type: “flowers and shrubs,” “lawns,” and “trees.” Over 700 turf and ornamentals professionals were surveyed through various professional associations and segmented into five business types: trees, greenhouse, lawn, nursery, and landscape ornamentals. The results of the homeowner survey showed that homeowners value neonicotinoid insecticides. The top concerns of homeowners applying insecticides to their homescape center around efficacy and safety (humans, pets, wildlife and bees) according to the data gathered in the choice experiment. The results show that when given a choice between two options, both of which are efficacious and safe for humans, the homeowners preferred the option that had the additional attribute of being safe on bees.

The results of the professional survey showed that professionals value neonicotinoids because professionals reported that neonicotinoids offer systemic properties; exhibit long-term efficacy; and provide a low-risk to the applicators, customers and their pets. The most used neonicotinoid active ingredient was imidacloprid (75% of survey respondents), followed by dinotefuran (17%), clothianidin (3%) and thiamethoxam (3%). Based on the results of this report, the most difficult pests to manage in the absence of neonicotinoids would be aphids, borers, white grubs, armored scales and whiteflies, respectively. Professionals stated that the negative business impacts from the absence of neonicotinoids would be driven mostly by the cost increases associated with the use of alternatives (*e.g.*, chemical and labor costs) and lower customer satisfaction. The possible alternatives in the absence of the neonicotinoids in order of preference are pyrethroids, organophosphates, avermectins, carbamates, and diamides.

Results from the econometric analysis using the Choice Experiment indicated that homeowners had different willingness to pay for pesticides based on their attributes. Although the authors used a rigorous approach, there were inconsistencies between model results and interpretation of results in the text. For example, AgInfomatics’ survey omitted pertinent information relevant to the decision-making process of consumers. These omissions resulted in conclusions where AgInfomatics overvalued or undervalued the benefits of neonicotinoids within certain homeowner market segments relative to alternatives.

In addition to the homeowner and professionals’ surveys, there were three case studies completed by AgInfomatics highlighting the benefits of neonicotinoids to control Southern chinch bugs in turf, silverleaf whiteflies in ornamentals, and emerald ash borers in trees. The emerald ash borer case study provided additional support on the value of neonicotinoids, including imidacloprid in USDA pest management programs for additional invasive species (*e.g.*, spotted lanternfly, Asian longhorned beetle) attacking trees on federal lands.

Although there were areas for improvement in the report's methodology, results, and general conclusions; EPA agrees with AgInfomatics that neonicotinoids are a useful tool and often a top choice for pest control in the turf and ornamental industries.

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*, available in the public docket.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

As discussed previously, EPA recognizes that the neonicotinoids, including imidacloprid, 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 human health risks of concern from imidacloprid to occupational handler and residential post-application scenarios; and ecological risks of concern identified for pollinators, birds, mammals, and to aquatic invertebrates, as described in Section III.

Risks of concern were identified to aquatic invertebrates, which play a foundational role in aquatic ecosystems. The agency is proposing several risk mitigation measures for reducing exposure to aquatic invertebrates, including targeted annual application rate reductions, along with spray drift and runoff management measures.

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[9]. 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

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

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 developing the mitigation strategy in order to gain a better grasp of growing practices and potential benefits. As part of its assessments of the impacts of potential mitigation, EPA reviewed available information on the distribution of application rates used by applicators, and this information contributed to identifying when assumptions were made in the risk assessments regarding maximum rates may have overestimated certain risks. These analyses also allowed the EPA to determine where targeted rate reductions would decrease overall potential risks, while minimizing potential impacts to users. Proposed risk 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 addressing risk posed by current registered uses of imidacloprid uses through the following risk mitigation measures:

- Cancel residential spray applications to turf, on-farm seed treatment (of canola, millet, and wheat), and use on bulb vegetables;
- Require additional PPE;
- Reduce maximum application rates or restricting applications during pre-bloom and/or bloom, targeting certain uses with potentially higher pollinator risks and lower benefits;
- Preserve the current restrictions for application at-bloom;
- Require advisory language for residential ornamental uses;
- Apply targeted application rate reductions for higher risk uses;
- Require additional spray drift and runoff reduction label language; and,
- Promote voluntary stewardship efforts to encourage employment of best management practices, education, and outreach to applicators and beekeepers.

In selecting appropriate mitigation, EPA considered both the risks and benefits of imidacloprid use. Due to the potential impact to growers’ ability to address certain critical pest issues, the agency did not propose risk mitigation on several uses, including citrus and grapes. For citrus crops, the neonicotinoids are a key element in programs to control the ACP, an invasive pest that transmits HLB, a devastating and incurable disease. In grapes, the neonicotinoids are used similarly to combat sharpshooters which vector Pierce’s Disease, a fatal bacterial disease for grapes that can result in 100% yield loss. For other uses where mitigation was proposed, the mitigation does not completely eliminate all risks of concern from the use of imidacloprid, however does reduce overall risk and/or exposure. The agency finds the remaining risks to be reasonable under FIFRA given the benefits of the use of imidacloprid. The EPA is also proposing label changes to address general labeling improvements for all imidacloprid products.

1. Cancellation of Uses

The agency is proposing cancellation of imidacloprid residential spray applications to turf. This cancellation would eliminate risks of concern to both children and adults from the residential turf use. Although this use has potentially high benefits to homeowners, EPA is required to address non-occupational residential risks of concern under FQPA to ensure, "reasonable certainty that no harm will result from aggregate exposure" from each pesticide from dietary or other sources such as food, drinking water, and residential uses. Therefore, cancellation of the residential turf use is necessary and is being proposed.

The agency is also proposing cancellation of imidacloprid use on bulb vegetables to mitigate risks of concern to aquatic invertebrates. The highest risk estimates to aquatic invertebrates from bulb vegetable use were up to an RQ of 556. A benefits assessment was conducted for this use which showed limited usage of neonicotinoids, with an average of approximately 2,000 lbs. applied annually and a percent crop treated of 2-3% for imidacloprid. Although the benefits assessment noted that there were some benefits of neonicotinoids to target thrips, effective alternatives to the neonicotinoids remain available for use on bulbs. Cancellation of this use would also eliminate the risks identified for birds from foliar use of bulbs. In consideration of the potential risks and the relatively low expected benefits, EPA is proposing cancellation of this use.

2. Prohibition of On-farm Seed Treatment for Canola, Millet, and Wheat

As noted in Section III.A.1. of this PID, risks of concern have been identified for occupational handlers for the use on canola, millet, and wheat via on-farm seed treatment activities. Even with the maximum PPE (double layer of clothing, gloves, and an elastomeric half-mask respirator) required for these uses, MOEs ranged from 2 – 25, (LOC= 100). To address potential occupational risk concerns for workers involved in on-farm seed treatments of canola, millet, and wheat using imidacloprid, EPA is proposing prohibiting use of on-farm treatment facilities for these crops, and a requirement that treatment be conducted in commercial seed treatment facilities only. EPA is proposing that all imidacloprid products registered for canola, millet, and wheat seed treatment uses must include the following statement:

- "Must be applied in commercial seed treatment facilities only."

The aggregate impacts of this prohibition are uncertain because data on the extent of on-farm treatment of canola, millet, and wheat seed are unknown.

3. Personal Protection Equipment

Human health risks of concern were identified for several registered agricultural, seed treatment and liquid/foliar citrus handgun spray application use scenarios. EPA is proposing to mitigate these risks through cancellation of certain uses, where necessary, and adding requirements for Personal Protection Equipment (PPE) such as gloves, along with requiring certain applications take place in commercial seed treatment facilities. With cooperation from stakeholders there was mutual agreement on the proposed label changes that would significantly reduce, and eliminate in many scenarios, risks of concern to workers.

Most occupational handler risk estimates were not of concern with current baseline attire or with personal protective equipment, however, several scenarios for workers performing activities related to: on-farm seed treatment to barley, cotton, and citrus were of concern. As stated in Section III.1 of this PID, there were several potential risks of concern to occupational handlers, including, short- and intermediate-term combined dermal and inhalation scenarios for barley and cotton seed treatment use and citrus handgun application. MOEs for seed treatment uses included barley and cotton, both with an MOE of 39 (LOC=100) with the current label-required single layer clothing and gloves. The agency is therefore proposing adding double-layer clothing and gloves for all handlers of imidacloprid barley and cotton on-farm seed treatments. The MOE for the liquid/foliar handgun application use on citrus was 58 without the current label language which does not require gloves. With the addition of single-layer gloves the MOE would be 160 and not of concern. The agency does not anticipate any risks of concern to handlers of imidacloprid with the addition of this risk mitigation.

Therefore, to mitigate potential dermal and/or inhalation risks to handlers, the agency is proposing requiring double-layer clothing and gloves for certain uses.

- Proposed uses to add requirement for double-layer clothing and gloves:
  - Barley – on-farm seed treatment use
  - Cotton – on-farm seed treatment use
- Proposed uses to add requirement for gloves:
  - Citrus – liquid/foliar handgun application

In addition, the agency is proposing to update the glove statements currently on labels to be consistent with the Label Review Manual[10]. 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, there was mutual agreement on the proposed label changes that would significantly reduce, and eliminate in many scenarios, risks of concern to workers.

4. Application Rate Reductions

Ecological risks of concern were identified for terrestrial and aquatic invertebrates as well as to birds and mammals, described in more detail in the draft risk assessments. To help mitigate these risks, EPA is proposing the following reductions in the maximum allowable annual application rates for foliar and soil applications of imidacloprid products.

[10] https://www.epa.gov/pesticide-registration/label-review-manual

Table 1. Proposed Maximum Annual Application Rates for Imidacloprid

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Rate (Max. Annual)
Berries and small fruits (non-grapes)	Foliar and soil: 0.50 lbs. AI/A/yr	Maximum combined annual application rate for any berries regardless of formulation type should not exceed 0.40 lbs. AI/A/yr.
Brassica/Cole	Foliar: 0.23 lbs. AI/A/yr	Foliar: 0.20 lbs. AI/A/yr
Leafy Vegetables	Foliar: 0.23 lbs. AI/A/yr	Foliar: 0.20 lbs. AI/A/yr
Fruiting Vegetables	Foliar: 0.23 lbs. AI/A/yr	Foliar: 0.20 lbs. AI/A/yr
Root and tuber (not including potato)	Foliar: 0.12 lbs. AI/A/yr Soil: 0.38 lbs. AI/A/yr	Foliar: 0.10 lbs. AI/A/yr Soil: 0.31 lbs. AI/A/yr
Legumes (not including soybeans or peanuts)	Foliar: 0.13 lbs. AI/A	Foliar: 0.11 lbs. AI/A
Peanuts	Foliar: 0.13 lbs. AI/A	Foliar: 0.12 lbs. AI/A
Stone Fruit	Foliar: 0.50 lbs. AI/A Soil: 0.38 lbs. AI/A	Foliar: 0.40 lbs. AI/A Soil: 0.34 lbs. AI/A
Pome Fruit	Foliar: 0.50 lbs. AI/A	Foliar: 0.40 lbs. AI/A
Tree Nuts	Foliar: 0.36 lbs. AI/A Soil: 0.50 lbs. AI/A	Foliar: to 0.30 lbs. AI/A Soil: 0.36 lbs. AI/A
Cotton	Maximum combined annual application rate regardless of formulation type: 0.50 lbs. AI/A	Maximum combined annual application rate regardless of formulation type: 0.37 lbs. AI/A
Turf	Foliar and soil: 0.40 lbs. AI/A	Foliar and soil: 0.30 lbs. AI/A.
Production/Commercial Ornamentals	Foliar and soil: 0.40 lbs. AI/A	Foliar and soil: 0.30 lbs. AI/A

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 imidacloprid 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 imidacloprid. 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.

Berries and small fruits (non-grape)

The berries and small fruits crop group includes crops such as, strawberries, cranberry, caneberry, and other berries and small fruit for which benefits and impacts have not been assessed by the agency. EPA is proposing reducing the current maximum annual application rate of 0.5 lbs. AI/A, to not exceed a combined annual application rate of 0.40 lbs. AI/A/yr for any berries regardless of formulation type. This mitigation is being proposed to address both pollinator and aquatic invertebrate risks.

Risks from the berries and small fruits category were considered in the category, strongest evidence of potential pollinator risk pre-bloom, in the agency's bee risk assessment. Both acute and chronic risks of concern were identified to aquatic invertebrates with risk estimates up to an RQ of 172. In addition to addressing risks of concern to bees, rate reductions also help reduce potential aquatic invertebrate risk. Available data indicates that 90% of blueberry acres were treated at 0.20 lbs. AI/A/year or less and the other 10% are treated at the higher 0.48 lbs AI/A/year rate. The average annual application rate for imidacloprid is 0.11 lbs. AI/A on caneberries and 0.42 lbs. AI/A on strawberry, therefore for cases like caneberries, limited impacts of the proposed mitigation are expected. However, it is uncertain whether there may be greater impacts to use of imidacloprid on strawberries. The agency does not have information on application rates for cranberry and blueberry and therefore the potential impacts of this mitigation for those crops could not be assessed.

Brassica/Cole

For the brassica/cole crop group, which includes broccoli, EPA is proposing reducing the current maximum annual application rate from 0.23 lbs. AI/A to 0.20 lbs. AI/A annually for foliar applications. This rate reduction is targeted at reducing potential risk to aquatic invertebrates and represents a reduction in the foliar rate to align closer with the average rate.

Potential risk to aquatic invertebrates was noted for both foliar and soil applications of imidacloprid to brassica/cole, with RQs up to 680 with the highest risk identified for foliar use. Benefits were considered to be high for imidacloprid's use on brassica/cole crops, with PCT's ranging from 10 – 67%. Imidacloprid is particularly important to broccoli growers for general control whitefly in brassica. The average annual application rates of imidacloprid applied nationally to brassica/cole is 0.206 lbs. AI/A, slightly above the proposed rate. Potential impacts to growers from this mitigation could vary. Data show that over 25% of the brassica and leafy vegetable acres treated with imidacloprid utilize annual application rates of 0.304 lbs AI/A/year, but this figure includes soil applications. Nearly 40% of the vegetable acres treated with imidacloprid are treated at rates above 0.20 lbs AI/A/year. Thus, there are likely some situations where growers make multiple applications of imidacloprid and would have to use an alternative insecticide or insecticides for one of those applications.

Leafy vegetables

For the leafy vegetables, EPA is proposing to reduce the current maximum annual foliar application rate from 0.23 lbs. AI/A to 0.20 lbs. AI/A. This rate reduction is targeted at reducing potential risk to aquatic invertebrates only and represents a reduction in rates to align closer with the average rate.

Potential risk to aquatic invertebrates was noted for both foliar and soil applications of imidacloprid to leafy vegetables, with RQs up to 989 with the highest risk identified for foliar use. The benefits were considered to be high for imidacloprid's use on leafy vegetables with PCTs ranging from 33 – 74%. Imidacloprid is particularly important to lettuce growers to combat contamination issues at harvest. The average annual rate for imidacloprid to leafy vegetables is 0.206 lbs. AI/A, just above the proposed rate. Potential impacts to growers from this mitigation could vary. Data show that over 25% of the brassica and leafy vegetable acres treated with imidacloprid utilize annual application rates of 0.304 lbs AI/A/year, but this figure accounts includes soil applications. Nearly 40% of the vegetable acres treated with imidacloprid are treated at rates above 0.20 lbs AI/A/year. Thus, there are likely some situations where growers make multiple applications of imidacloprid and would have to use an alternative insecticide or insecticides for one of those applications.

Fruiting Vegetables
For fruiting vegetables, EPA is proposing reducing the current maximum annual foliar application rate from 0.23 lbs. AI/A to 0.20 lbs. AI/A. This rate reduction is targeted at reducing potential risk to aquatic invertebrates.

Potential risk to aquatic invertebrates was noted for both foliar and soil applications of imidacloprid to fruiting vegetables, with RQs ranging up to 768 with the highest risk identified for foliar use. Imidacloprid plays an important role in early season crop protection in carrots, and based on usage on potato, it is likely important for use on other root and tubers. The PCT is 23% for carrots and is primarily applied by chemigation. The average annual application rate for imidacloprid on carrots is 0.277 lb AI/A/year and around 90% of acres are treated at rates of 0.304 lb AI/A/year or more. 74% of the treated carrot acres are treated at a single application rate of 0.304 lb AI/A or more. EPA would expect a decrease in product performance at the lower rate. Foliar applications are less important in carrots; however, they may be a valuable method for other root and tuber crops. However, based on the magnitude of the risk exceedance for carrots, a rate reduction is being proposed.

Root and tuber (not including potato)
For the root and tuber crop group (not including potato), EPA is proposing reducing the current maximum annual foliar application rate from 0.12 lbs. AI/A to 0.10 lbs. AI/A and the maximum annual soil application rate from 0.38 to 0.31. These rate reductions are targeted at reducing potential risk to aquatic invertebrates.

Potential risk to aquatic invertebrates was noted for both foliar and soil applications from root and tuber use, with foliar RQs ranging up to 2130, and soil RQs up to 998. Benefits were considered moderate for imidacloprid's use on root and tubers, with PCTs as high as 23%. Imidacloprid is particularly important to carrot growers. The average annual rate for imidacloprid on root and tuber is 0.277, however due to substantial aquatic invertebrate risk, a rate reduction is being proposed.

Legumes (not including soybeans or peanuts)
For the legumes crop group (dry and succulent beans and peas, not including soybeans or peanuts), EPA is proposing reducing the current maximum annual foliar application rate from 0.13 lbs. AI/A to 0.11 lbs. AI/A. This rate reduction is targeted at reducing potential risk to aquatic invertebrates only and represents a reduction in the foliar rate to align closer with the average rate.

Potential risk to aquatic invertebrates was identified for both foliar applications of imidacloprid to legumes (not including soybeans or peanuts), with RQs ranging up to 400. Benefits were considered low for imidacloprid's use on legumes (not including soybeans or peanuts), with PCTs ranging from 4 – 6%. The average annual rate for imidacloprid to this crop group is 0.087 lbs. AI/A, below the proposed rate so potential impacts to growers from this mitigation are considered likely to be low.

Peanuts
For peanuts, EPA is proposing reducing the current maximum annual foliar application rate from 0.13 lbs. AI/A to 0.12 lbs. AI/A. This rate reduction is targeted at reducing potential risk to aquatic invertebrates.

Potential risk to aquatic invertebrates was noted for foliar applications of imidacloprid to peanuts, with RQs up to 149. Benefits were considered high for this use as it is the only neonicotinoid registered for peanuts, however, the PCT was less than 1% with a total of 41,000 lbs. applied annually. This rate reduction is likely to have very low impacts to growers on current usage, which is primarily soil applications prior to crop emergence.

Stone Fruit
For stone fruit, EPA is proposing reducing the current maximum soil annual application rate of 0.38 lbs. AI/A to 0.34 lbs. AI/A, and a reduction in the maximum foliar annual application rate from 0.50 lbs. AI/A to 0.40. This mitigation is being proposed both for pollinator and aquatic invertebrate risk.

Risks from stone fruit use were assigned the category, weakest evidence of potential pollinator exceedances post-bloom, in the agency's bee risk assessment. The systemic fate properties of imidacloprid contributed to risks of concern both after bloom and before harvest. Foliar RQs ranged up to 824 on an acute basis and 2920 on a chronic basis. Aquatic invertebrate risk for foliar applications ranged up to 330. Soil risks were identified for pollinators with RQs up to 11. For soil application, the agency expects little impact on the growers from a 10% reduction in the current maximum annual application rate as soil treatment to stone fruit is rare. For foliar application, a 20% reduction in the current maximum annual application rate is likely to affect a sizeable number of cherry acres. As discussed in Section III C, the agency's stone fruit assessment focuses on cherries and peaches, because imidacloprid is little used on peaches, the agency did not assess potential impacts to growers for peaches. Other neonicotinoid alternatives are available for stone fruit however impacts to growers could vary.

Pome Fruit
For pome fruit, EPA is proposing reducing the current maximum foliar annual application rate of 0.50 lbs. AI/A to 0.40. This mitigation is being proposed both for pollinator and aquatic invertebrate risks.

Risk from pome fruit use assigned the category, weakest evidence of potential pollinator risk post-bloom, in the agency's bee risk assessment. The systemic fate properties of imidacloprid contributed to risks of concern both after bloom and before harvest. Foliar adult honeybee RQs ranged up to 7301. Aquatic invertebrate risk for foliar applications ranged up to 743. These risks of concern represent some of the greatest risks compared to other agricultural uses. Benefits are considered high for pome fruit use of imidacloprid post-bloom and medium for pre- and at-bloom usage. Other neonicotinoid alternatives are available for pome fruit however impacts to growers is considered moderate.

Tree nut

For tree nuts, EPA is proposing reducing the current maximum soil annual application rate of 0.50 lbs. AI/A to 0.36 lbs. AI/A; and a reduction in the maximum foliar annual application rate from 0.36 lbs. AI/A to 0.30. This mitigation is being proposed both for pollinator and aquatic invertebrate risks.

Risks from tree nut use were assigned the category moderate category of evidence for pollinator risk from soil applications post-bloom in the agency’s bee risk assessment, and aquatic risk from primarily foliar usage. Adult honeybee RQs ranged up to 14. Aquatic invertebrate risks ranged up to 433. The proposed soil rate was based on a safety finding for current tolerances of no greater than 0.36 lbs. AI/A per year, while the proposed foliar rate was below this requirement. These rate reductions are expected to have low impacts on current usage because, across all application methods, around 5-10% of acres are treated at rates greater than 0.30 lbs. AI/A/year.

Cotton

For cotton, EPA is proposing reducing the current maximum combined rate of 0.50 lbs. AI/A regardless of formulation type and reducing it to 0.37 lbs. AI/A applied annually. This mitigation is being proposed for pollinator risk.

Potential risks from cotton combined foliar and soil use was considered under the strongest category of evidence for pollinator risk. Soil adult honeybee RQs ranged reached 2.6 on an acute basis and 9.3 on a chronic basis to adults, while foliar adult honeybee RQs reached up to 494 on an acute basis and 1752 chronic. Cotton is considered one of the major drivers of potential pollinator risk. Imidacloprid is considered highly beneficial to cotton growers throughout the growing season for a variety of pests.

Available usage data show that the average annual application rate is 0.151 lbs. AI/A per year with less than 3% of acres treated with rates of 0.37 lbs. AI/A annually or more. The majority of growers were found to apply imidacloprid to cotton at an average of less than 0.3 lbs. AI/A annually, well below the proposed annual rate of 0.37 lbs. AI/A. Affected users may have to switch to alternative insecticides or mix additional insecticides with imidacloprid to maintain pest control. With consideration of current usage and typical rates, these rate reductions are considered to have potentially low to medium impacts to users.

Turf

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

Potential risk to aquatic invertebrates was noted for applications of imidacloprid from turf, with RQs ranging up to 236. Risk to bees assigned the category, moderate evidence of potential pollinator risk, in the agency’s bee risk assessment. Benefits were considered high for this use for imidacloprid, as it accounts for 75% of turf treated with neonicotinoids. Other than the available 2014 AgInfomatics report and review, current usage data was limited. This rate reduction is considered to potentially have moderate impacts on usage.

Production and Commercial Ornamentals
For production and commercial ornamentals, EPA is proposing reducing the current maximum annual foliar and soil application rate from 0.40 lbs. AI/A to 0.30. 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 greenhouse/nursery. This risk mitigation does not include indoor commercial nursery, Christmas trees, greenhouse uses, or forestry use on public land and quarantine application by USDA.

Potential risks from use on ornamentals assigned the category, strongest evidence of potential pollinator risk, in the agency’s bee risk assessment. Risk to aquatic invertebrates were identified, with RQs ranging up to 1020. Benefits were considered high for this use, as 75% of neonicotinoid usage on ornamentals is with imidacloprid. Other than the available 2014 AgInfomatics report and review, usage data was limited. This rate reduction is considered to have potentially moderate impacts on current usage.

5. Crop Stage Restrictions

As noted in section four, risks were identified for several taxa described in the draft risk assessments. 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 assessing 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 were easily identifiable by growers.

Table 2. Proposed Crop Stage-based application Restrictions for Imidacloprid

Crop/Crop Group	Proposed Risk Mitigation
Fruiting Vegetables	For both foliar and soil applications: prohibit application 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 only: Do not apply after 5 days after planting or transplanting regardless of application method.
Cucurbits	For both foliar and soil applications: prohibit use from vining to harvest or after the emergence of the first true (non-cotyledon) leaf
Tropical and Subtropical Fruit (avocado, banana, dates, and olives only)	For foliar applications: prohibit foliar application pre-bloom until after flowering is complete and all petals have fallen off; and For soil applications: prohibit post-bloom application.

Fruiting Vegetables

For the fruiting vegetables crop group, EPA is proposing a crop stage restriction for both foliar and soil applications, to prohibit application 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 proposing to prohibit application after 5 days after planting or transplanting regardless of application method for all crops in the crop group.

Potential risk to pollinators was assigned the category, strongest evidence of potential pollinator risk, in the agency's bee risk assessment for foliar and soil uses of pollinator attractive fruiting vegetables. Benefits were considered high for imidacloprid's use on fruiting vegetables, though PCTs ranged from 32% to 65%. Imidacloprid is considered particularly important to tomato growers. Applications after crop emergence or transplanting account for around two-thirds of the treated acres of peppers and tomato acres. Imidacloprid targets season-long pests. Thrips, stinkbug and pepper weevil can target fruit directly and viral diseases vectored by aphids and whitefly can seriously impact the development, quality and/or yield of the harvested fruit. The proposed changes are expected to potentially impact growers.

Cucurbits

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

Risk to pollinators was assigned the category, strongest evidence of potential pollinator risk, in the agency's bee risk assessment for cucurbit soil uses. Based on available residue data, imidacloprid remained in the plant matrices at high levels for months after application. Residues exceeded the lowest observed effect concentration (LOEC) at 65 days after application for foliar applications and 67 days for soil applications. Available benefits information identified imidacloprid usage to most commonly occur prior to crop emergence, therefore, a restriction from vining to harvest is likely to not significantly impact current usage.

Tropical and Subtropical Fruit

For avocado, banana, dates, and olives, EPA is proposing a crop stage restriction for foliar labels to prohibit foliar application from pre-bloom until after flowering is complete and all petals have fallen off; and to prohibit post-bloom application for soil applications. No mitigation is proposed for other fruit trees in this crop group.

Risk to pollinators was assigned the category, weakest evidence of potential pollinator risk, in the agency's bee risk assessment for foliar and soil post-bloom applications. Risk mitigation is being proposed on crops in this group considered to have higher usage and to be pollinator attractive, however, no risk mitigation is being proposed for lower acreage or non-bee attractive crops. An exception is provided for pomegranate as well, due to available usage data showing imidacloprid use on pomegranate as particularly beneficial. 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 imidacloprid is rare on avocado, dates, and olives. EPA is specifically requesting public comments to better understand potential impacts on banana production.

6. Residential Ornamental Advisory

For application to ornamental plants, the agency identified significant risks of concern. Potential risks from use on ornamentals was assigned the category, strongest evidence of potential pollinator risk, in the agency's bee risk assessment. Risk to aquatic invertebrates was also identified, with RQs ranging up to 1020. Benefits were considered high for this use, as 75% of neonicotinoid usage on ornamentals is with imidacloprid. However, other than the available 2014 AgInfomatics report and review, usage data was limited. The agency is proposing adding language to residential labels advising that ornamental products are, "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.

7. Label Language Improvements

EPA is proposing several advisory label language changes intended to better inform and/or discourage the applicator from creating exposures that may lead to increased risks of concern. This includes updates to the current advisory bee language, water soluble packaging, and language to better clarify whether products are for indoor or outdoor use. For more information, please see Appendix B.

The agency is also proposing revising the PHI to 7-days on the Admire® 2F label to reflect other pomegranate labels, based on information listed in the 2008 scoping document (PP# 5E6920, J. Tyler, 14-JUN-2006; D322834).

Risks of concern were identified to birds and small mammals associated with seeds that are treated with imidacloprid for which EPA is proposing additional advisory label language, encouraging the promotion of Best Management Practices (BMPs) and education programs to help inform users about the importance of picking up spilled seed in order to reduce exposure to birds and mammals. The agency's understanding of these risks includes characterization that indicate only a portion of birds and mammals are likely to be impacted. Risk mitigation measures were considered with the understanding of the high benefits associated with seed treatment uses, which through their use, have the potential to reduce overall neonicotinoid exposure and offer a lower overall ecological risk compared to foliar uses.

8. Restrictions to Poultry House Uses

Due to the persistence of neonicotinoids in the environment, potential risks of concern to honeybees were also identified for imidacloprid from use on poultry litter in broiler houses at the maximum annual application rate. Once applied, the litter can be applied as a fertilizer on agricultural fields, contributing to ecological exposure. EPA is proposing to reduce risk from this use by reducing the number of whole house applications allowed annually for imidacloprid.

In order to reduce exposure to pollinators, EPA is proposing that all imidacloprid 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 imidacloprid resulting from poultry house uses. Limiting both the number and square footage of allowable poultry house treatments per year will limit the amount of imidacloprid entering the environment when treated poultry litter is removed from poultry houses and used as a soil amendment in agricultural fields. The proposed mitigation retains the use of imidacloprid for poultry producers, recognizing its importance in treating for darkling beetles and other poultry house pests.

9. Spray Drift 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 imidacloprid 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 imidacloprid.

The agency is proposing the following spray drift mitigation language be included on all imidacloprid 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 imidacloprid registrants to standardize all advisory language on imidacloprid 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 imidacloprid that can enter waterbodies from runoff, EPA is proposing a vegetative filter strip (VFS) requirement for all imidacloprid agricultural products of 10 feet. Currently some imidacloprid 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 imidacloprid 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 imidacloprid. 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).

Impacts of Spray Drift and Runoff Mitigation

EPA examined a subset of labels from single AI products of imidacloprid (EPA Reg # 264-827, 34704-931). These labels represent more than 40% of all imidacloprid applied to agricultural crops (MRD 2013-2017). This was not an exhaustive label review, but this was preformed to have an idea of the spray drift statements currently on labels to determine if any of the changes would lead to an impact to growers.

<u>Wind Speed, Percent Usable Boom Length, Swath Displacement and Release Height (aerial applications)</u>
Labels reviewed have a wind speed restriction of 15 mph and the boom length must not exceed 75% of the wing span or rotor diameter. Therefore, there should be little impact when applications are made when wind speed is 15 mph when applications are made with fixed wing aircraft. Additionally, there would be increased percent usable boom length (90% or less) of the rotor diameter for helicopters which could mean more area can be covered in less time. However, when wind speeds are between 10 and 15 mph, applicators using fixed wing aircraft, will need to reduce the swath width. This will lead to more passes being made and will cause applications to take longer which is likely to be more expensive. Another option would be to use a different, more expensive chemical that does not have this restriction.

Labels reviewed do not address swath displacement based upon wind speed. The agency has not assessed the impacts of windspeed restrictions for aerial applications and the requirement 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.

Labels reviewed currently require applicators to release imidacloprid at a height no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety. Therefore, the agency does not expect an impact for requiring this language as mandatory for all imidacloprid labels.

<u>Wind Speed and Release Heights (ground applications)</u>
Labels reviewed have a mandatory wind speed restriction of 15-mph, and one of the labels reviewed indicate wind speed restrictions do not apply to applications made in-furrow or below

soil-level (EPA Reg # 264-827). Therefore, the agency does not anticipate an impact of a 15-mph wind speed restriction.

Labels reviewed currently do not specify a release height for ground application. However, previous analysis for release heights for most nozzles indicate a release height of 4ft should not impact grower when making applications of imidacloprid.

Temperature Inversions (ground and aerial applications)
Labels reviewed have a mandatory language prohibiting applications during inversions; therefore, the agency does not anticipate an impact in restricting applications during temperature inversions. The agency notes that some applicators may make applications in the evening hours to avoid spraying during the daytime to avoid making applications when pollinators are active. Temperature inversions are generally considered to be more likely to occur a couple of hours before and after sunset and sunrise. These growers would likely switch to a different active ingredient that does not have this restriction.

Droplet Size (aerial and ground applications, excluding airblast sprayers)
The Agency is considering establishing a mandatory droplet size of medium to 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. Hypothetically, systemic insecticides, like neonicotinoids, might control some insects with a larger droplet size due to the systemic movement within the plant, but systemic activity alone does not mean effective control will still occur. Buchholz and Nauen (2001)[11] showed that the control from neonicotinoids was more complex than an active ingredient being systemic, i.e., control was a “combination of systemic and contact properties.” The authors indicate that factors such as the cuticular properties of leaves, metabolism and stage of insect (e.g., mobile versus quiescent stages), and the physio-chemical properties of the insecticide contribute to the performance of neonicotinoids. Furthermore, Basso et al. (2016)[12] showed that contact with neonicotinoids was needed to control insects on large plants compared with smaller plants, presumably due to poor translocation in large plants.

The labels reviewed provide advisory language that suggests growers should apply with the largest droplet that provides effective control. Generally, entomologists accept that good coverage is required for maximum efficacy during an application and that fine droplets provide better coverage than coarse droplets. BEAD expects that droplet size restrictions could decrease the control of pests with contact neonicotinoids. If control was reduced, BEAD anticipates growers would increase rates, make more frequent applications, and/or select alternative products (pyrethroids, carbaryl, diflubenzuron, etc., depending on the target pest). Additionally, growers may face financial impacts due to increased cost of applications and/or reduced yields or

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[11] Buchholz, A. and R. Nauen. 2001. Translocation and translaminar bioavailability of two neonicotinoid insecticides after foliar application to cabbage and cotton. Pest Mgmt. Sci. 58: 10-16.
[12] Basso, C.J., C.C. Kuss, O.H. de Castro Pias, D.S. Muraro, and L. Cutti. 2016. Neonicotinoid insecticide systemicity in soybean plants and its effect on brown stink bugs. Pesq. Agropec. Trop., Goiânia 46: 96-101.

quality due to poor control. Furthermore, mandatory droplet size could lead to reduced rates being successfully delivered to the target pest(s) via poor coverage and undermine resistance management efforts.

<u>Buffers (ground and aerial applications)</u>
Labels reviewed prohibit applications within 25 feet (ground), or within 150 feet (aerially) of lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries and commercial fish farm ponds. Therefore, the agency does not anticipate an impact with buffer requirements. However, the agency did not assess this mitigation on a crop by crop basis or review labels for specific crops that may be impacted by this mitigation. 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. If a grower were using an imidacloprid product that does not currently have this restriction, the grower would likely switch to a different chemical that does not have this restriction. These impacts will disproportionally affect growers producing crops from small acreage fields.

<u>Requirements for Air Blast Sprayers</u>
Labels reviewed have mandatory language requiring that spray is only directed in the canopy, is prohibited from going beyond the edge of the cultivated area and is directed inward, toward the orchard/vineyard when treating the outer row. Therefore, the agency does not expect impacts associated with the proposed mitigation.

<u>Impacts of Vegetative Filter Strips</u>
Labels reviewed require a 10-foot VFS. Therefore, the agency does not anticipate an impact with VFS requirements. However, the agency did not assess this mitigation on a crop by crop basis or review labels for specific crops that may be impacted by this mitigation. The impact of this mitigation can be highly localized and depends on the size and shape of a field. In some situations, VFS may require growers to remove land from production thus decreasing revenue. These impacts will disproportionally affect growers producing crops from small acreage fields. If a grower were using an imidacloprid product that does not currently have this restriction, the grower would likely switch to a different chemical that does not have this restriction.

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 imidacloprid 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 overspraying. 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 imidacloprid 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.

Impacts of Mitigation Measures for Residential and Commercial Use Sites
The agency did not assess the impacts of runoff mitigation measures residential and commercial use sites; however, the agency considers these measures are consistent with application practices. The agency invites comments if this mitigation would impact applicators.

In addition to including the following spray drift restrictions on imidacloprid labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all imidacloprid labels where such information currently appears and to establish label consistency by requiring standardized spray drift advisory language. The proposed new language below, which cites American Society of Agricultural & Biological Engineers (ASABE) S572.1, eliminates the need for VMD information.

10. 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 imidacloprid, 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[13].

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 applications to lawns, its beneficial to mow prior to applications. 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[14].

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

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[13] https://www.epa.gov/pollinator-protection
[14] https://www.epa.gov/pollinator-protection/what-you-can-do-protect-honey-bees-and-other-pollinators

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[15] 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

The agency proposes increasing the tolerances for residues of imidacloprid on citrus fruits and coffee to harmonize with Canada and Codex MRLs. Tolerances are proposed to be revoked for apple, okra, pecan, pistachio, watercress, watercress (upland), and vegetable legume group 6. Tolerances are proposed to be established for celtuce, fennel/florence/fresh leaves and stalk, kohlrabi, and soybean vegetable. Additionally, EPA is proposing eliminating trailing zeros listed in tolerances consistent with agency policy. All proposed tolerance revisions for imidacloprid are listed in Section III.A.3 for more details. The agency will use its FFDCA rulemaking authority to undertake needed tolerances changes.

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) and 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 and their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

[15] https://seed-treatment-guide.com/

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of imidacloprid, 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 imidacloprid. The agency's final registration review decision for imidacloprid 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

The agency does not anticipate calling-in additional data for the imidacloprid registration review at this time.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for imidacloprid 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 imidacloprid. However, a final decision for imidacloprid may be issued without the agency having previously issued an interim decision. A final decision on the imidacloprid 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 imidacloprid 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.

Appendix A: Summary of Proposed Actions for Imidacloprid

Registration Review Case#: 7605
PC Code: 129099
Chemical Type: Insecticide
Chemical Family: Neonicotinoids
Mode 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
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Crop stage restrictions • General other use restrictions • Spray drift reduction
Occupational Handlers	Aerial and ground application	Dermal and inhalation	Short and intermediate term	Portal of entry effects	• Require additional PPE (e.g., double layer clothing, gloves) • Precautionary statements • Prohibition of on-farm seed treatments for canola, millet, and wheat
Residential post-application (adults and children)	Ground application	Dermal and inhalation	Short and intermediate term	Portal of entry effects	• Use deletion for residential spray applications to turf
Aquatic Invertebrates	Runoff from treated sites	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Spray drift and runoff reduction • Vegetative filter strips • Use deletion for bulb vegetables • 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 Imidacloprid Products

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
	Technical Products	
Residential turf use	Delete residential spray use on turf.	Directions for Use
Foliar spray and soil drench use on bulb vegetables	Delete foliar spray and soil drench use on bulb vegetables.	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. **Imidacloprid** | **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 (double layer clothes and gloves) for seed treatments to barley and cotton	"Applicators must wear two layers of clothing and chemical resistant gloves while applying on-farm seed treatments to barley and cotton."	Personal Protective Equipment (PPE) within the Precautionary Statements
Additional PPE (gloves) for liquid spray applications to citrus by handgun	"Applicators must wear chemical resistant gloves for liquid spray applications by handgun."	PPE within the Precautionary Statements
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 Imidacloprid Products	Placement on Label
Additional Required Labelling 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 canola, millet, and wheat	"Apply in a commercial seed treatment facility."	Directions for Use
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.	Directions for Use for mixing/loading WSP

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
	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. 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

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
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 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."	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
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 fruits, not including grapes, set maximum annual rate	Maximum annual application rate for berries regardless of application method is not exceed 0.40 lbs. AI/A/yr.	Directions for use
Brassica (cole) leafy vegetables, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.20 lbs. AI/A/yr.	Directions for use
Leafy vegetables, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.20 lbs. AI/A/yr.	Directions for use
Fruiting vegetables, set maximum annual rate for	Foliar spray only: maximum annual application rate is not to exceed 0.20 lbs. AI/A/yr.	Directions for use

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
foliar spray, and add application timing restriction based on crop stage	All: "Do 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 only: "Do not apply after 5 days after planting or transplanting regardless of application method."	
Root and tuber vegetables, not including potatoes, set maximum annual rate for foliar spray and soil drench	Foliar spray: maximum annual application rate is not to exceed 0.10 lbs. AI/A/yr. Soil drench: maximum annual application rate is not to exceed 0.31 lbs AI/A/yr.	Directions for use
Legumes, not including soybeans and peanuts, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.11 lbs. AI/A/yr.	Directions for use
Peanuts, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.12 lbs. AI/A/yr.	Directions for use
Stone fruit, set maximum annual rate for foliar spray and soil drench	Foliar spray: maximum annual application rate is not to exceed 0.40 lbs. AI/A/yr. Soil drench: maximum annual application rate is not to exceed 0.34 lbs. AI/A/yr.	Directions for use
Pome fruit, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.40 lbs. AI/A/yr.	Directions for use
Tree nut set maximum annual rate for foliar spray and soil drench	Foliar spray: maximum annual application rate is not to exceed 0.30 lbs. AI/A/yr. Soil drench: maximum annual application rate is not to exceed 0.36 lbs. AI/A/yr.	Directions for use
Cotton set maximum annual rate	Regardless of application method, apply no more than 0.37 lbs. active ingredient per acre per year, including seed treatment, soil drench and foliar sprays.	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
Avocado, banana, dates, and olives, add application timing restriction based on crop stage	Foliar spray: "Do not apply before bloom until after flowering is complete and all petals have fallen off." Soil drench: "Do not apply once bloom has occurred until the next growing season."	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).	Directions for use

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
	Only apply products containing imidacloprid 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"	
Ornamentals, which includes ornamental ground cover, Christmas trees, ornamental and/or shade trees, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines	"Intended for use by professional applicators."	Directions for use
Ornamentals, which includes ornamental trees, forestry, ornamental woody shrubs and vines, and outdoor greenhouse/nursery set maximum annual rate for foliar spray and soil drench. Does not include indoor commercial nursery, Christmas trees, greenhouse uses, or forestry use on public land and quarantine application by USDA.	For both foliar spray and soil drench: maximum annual application rate is not to exceed 0.30 lbs. AI/A/yr.	Directions for use
Turf/sod set maximum annual rate	Maximum annual application rate regardless of application method is not to exceed 0.34 lbs. AI/A/yr.	Directions for use

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
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 labels 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; 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."	Directions for Use
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

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
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** **<u>Aerial Applications</u>**: • 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 Managment" under the heading "Aerial Applications"
Spray Drift Management Application Restrictions for products that allow airblast applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **<u>Airblast applications:</u>** • Sprays must be directed into the canopy foliage. • 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 Management" under the heading "Airblast Applications"

Description	Proposed Label Language for Imidacloprid 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 applied as liquids and allow ground boom applications	**“MANDATORY SPRAY DRIFT MANGEMENT** **<u>Ground Boom Applications:</u>** • 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 Management” under the heading “Ground Boom Applications”
Spray Drift Management Application Restrictions for products that are applied as liquids and allow boom-less ground sprayer applications	**“MANDATORY SPRAY DRIFT MANAGEMENT** **<u>Boomless Ground Applications:</u>** • 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 Management” 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 Imidacloprid 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.	

Description	Proposed Label Language for Imidacloprid Products	Placement on Label
	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** **<u>Boomless Ground Applications:</u>** • 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** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift.”	Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”
Admire® 2F (EPA Registration Number 264-758) label change		
PHI revision for pomegranate	PHI for pomegranate is 7-days.	Directions for use

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[16]. 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 imidacloprid 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 imidacloprid. 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 imidacloprid as part of completing this registration review.

[16] https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process

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 imidacloprid, 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), imidacloprid is 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,[17] 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. Imidacloprid is not 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.[18]

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

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

[18] https://www.epa.gov/endocrine-disruption

Appendix E: Summary of Proposed Tolerance Actions

Imidacloprid 40 CFR §180.472. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
§180.472(a) General			
Acerola	1.0	1	Correct number of significant figures to be consistent with EPA policy
Almond, hulls	4.0	4	Correct number of significant figures to be consistent with EPA policy
Apple	0.5	-	Tolerance should be revoked upon establishment of Fruit, pome, group 11-10
Apple, wet pomace	3.0	3	Correct number of significant figures to be consistent with EPA policy
Aspirated grain fractions	240	240	Grain, aspirated fractions
Atemoya	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Avocado	1.0	1	Correct number of significant figures to be consistent with EPA policy
Banana	0.50	0.5	Correct number of significant figures to be consistent with EPA policy
Beet, sugar, molasses	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Beet, sugar, tops	0.50	0.5	Correct number of significant figures to be consistent with EPA policy
Biriba	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Caneberry, subgroup 13-A	2.5	2.5	Caneberry subgroup 13-07A
Canistel	1.0	1	Correct number of significant figures to be consistent with EPA policy
Cattle, fat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Cattle, meat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Cattle, meat byproducts	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Celtuce	-	6	Commodity displaced by the crop group conversion.
Cherimoya	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Citrus, dried pulp	5.0	5	Correct number of significant figures to be consistent with EPA policy
Coffee, green bean	0.8	1	Harmonize with Codex MRL
Cotton, gin byproducts	4.0	4	Correct number of significant figures to be consistent with EPA policy
Cotton, meal	8.0	8	Correct number of significant figures to be consistent with EPA policy
Cotton, undelinted seed	6.0	6	Correct number of significant figures to be consistent with EPA policy
Custard apple	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Feijoa	1.0	1	Correct number of significant figures to be consistent with EPA policy
Fennel, florence, fresh leaves and stalk	-	6	Commodity displaced by the crop group conversion.
Fruit, citrus, group 10	0.7	1	Fruit, citrus, group 10-10, Harmonize with Codex MRL

Imidacloprid 40 CFR §180.472. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Fruit, pome, group 11	0.60	0.6	Corrected value to be consistent with EPA Rounding Class Practice. Fruit, pome, group 11-10
Fruit, stone, group 12	3.0	3	Corrected value to be consistent with EPA Rounding Class Practice. Fruit, stone, group 12-12
Goat, fat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Goat, meat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Goat, meat byproducts	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Grain, cereal, forage, fodder and straw, group 16, forage, except rice	7.0	7	Correct number of significant figures to be consistent with EPA policy
Grain, cereal, forage, fodder and straw, group 16, hay, except rice	6.0	6	Correct number of significant figures to be consistent with EPA policy
Grain, cereal, forage, fodder and straw, group 16, stover, except rice	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Grain, cereal, forage, fodder and straw, group 16, straw, except rice	3.0	3	Correct number of significant figures to be consistent with EPA policy
Grape	1.0	1	Correct number of significant figures to be consistent with EPA policy
Grape, juice	1.0	1	Correct number of significant figures to be consistent with EPA policy
Grape, raisin	1.0	1	Correct number of significant figures to be consistent with EPA policy
Guava	1.0	1	Correct number of significant figures to be consistent with EPA policy
Herbs subgroup 19A, dried herbs	48.0	48	Herb subgroup 19A, dried herbs. Correct number of significant figures to be consistent with EPA policy
Herbs subgroup 19-A, fresh herbs	8.0	8	Corrected value to be consistent with EPA Rounding Class Practice. Herb subgroup 19A, fresh herbs
Hog, fat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Hog, meat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Hog, meat byproducts	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Hop, dried cones	6.0	6	Correct number of significant figures to be consistent with EPA policy
Horse, fat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Horse, meat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Horse, meat byproducts	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Ilama	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Jaboticaba	1.0	1	Correct number of significant figures to be consistent with EPA policy

Imidacloprid 40 CFR §180.472. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Kava, leaves	4.0	4	Correct number of significant figures to be consistent with EPA policy
Kava, roots	0.40	0.4	Correct number of significant figures to be consistent with EPA policy
Kohlrabi	-	6	Commodity displaced by the crop group conversion.
Leaf petioles subgroup 4B	6.0	6	Correct number of significant figures to be consistent with EPA policy
Leaf petioles subgroup 4B	6.0	6	Corrected value to be consistent with EPA Rounding Class Practice. Leaf petiole vegetable subgroup 22B
Leafy greens subgroup 4A	3.5	3.5	Leafy greens subgroup 4-16
Lettuce, head	3.5	-	See Leafy greens subgroup 4-16
Lettuce, leaf	3.5	-	See Leafy greens subgroup 4-16
Longan	3.0	3	Correct number of significant figures to be consistent with EPA policy
Lychee	3.0	3	Correct number of significant figures to be consistent with EPA policy
Mango	1.0	1	Correct number of significant figures to be consistent with EPA policy
Milk	0.10	0.1	Correct number of significant figures to be consistent with EPA policy
Nut, tree, group 14	0.05	0.05	Nut, tree, group 14-12
Okra	1	-	Tolerance should be revoked upon establishment of Vegetable, fruiting, group 8-10
Onion, dry bulbs, subgroup 3-07A	0.15	0.15	Onion, bulb, subgroup 3-07A
Papaya	1.0	1	Correct number of significant figures to be consistent with EPA policy
Passionfruit	1.0	1	Correct number of significant figures to be consistent with EPA policy
Pecan	0.05	-	Tolerance should be revoked upon establishment of Nut, tree, group 14-12
Persimmon	3.0	3	Correct number of significant figures to be consistent with EPA policy
Pistachio	0.05	-	Tolerance should be revoked upon establishment of Nut, tree, group 14-12
Pomegranate	0.90	0.9	Correct number of significant figures to be consistent with EPA policy
Potato, chip	0.40	0.4	Corrected value to be consistent with EPA Rounding Class Practice. Potato, chips
Potato, processed potato waste	0.90	0.9	Correct number of significant figures to be consistent with EPA policy
Pulasan	3.0	3	Correct number of significant figures to be consistent with EPA policy
Rambutan	3.0	3	Correct number of significant figures to be consistent with EPA policy
Sapodilla	1.0	1	Correct number of significant figures to be consistent with EPA policy
Sapote, black	1.0	1	Correct number of significant figures to be consistent with EPA policy
Sapote, mamey	1.0	1	Correct number of significant figures to be consistent with EPA policy
Sheep, fat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy

Imidacloprid 40 CFR §180.472. Summary of Proposed Tolerance Actions			
Commodity	Currently Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
Sheep, meat	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Sheep, meat byproducts	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Soursop	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Soybean, forage	8.0	8	Correct number of significant figures to be consistent with EPA policy
Soybean, meal	4.0	4	Correct number of significant figures to be consistent with EPA policy
Spanish lime	3.0	3	Correct number of significant figures to be consistent with EPA policy
Star apple	1.0	1	Correct number of significant figures to be consistent with EPA policy
Starfruit	1.0	1	Correct number of significant figures to be consistent with EPA policy
Strawberry	0.50	0.5	Correct number of significant figures to be consistent with EPA policy
Sugar apple	0.30	0.3	Correct number of significant figures to be consistent with EPA policy
Tomato, paste	6.0	6	Correct number of significant figures to be consistent with EPA policy
Tomato, puree	3.0	3	Correct number of significant figures to be consistent with EPA policy
Vegetable, brassica leafy, group 5	3.5	3.5	Brassica head and stem vegetable group 5-16
Vegetable, cucurbit, group 9	0.50	0.5	Corrected value to be consistent with EPA Rounding Class Practice.
Vegetable, fruiting, group 8	1.0	1	Corrected value to be consistent with EPA Rounding Class Practice. Vegetable, fruiting, group 8-10
Vegetable, leaves of root and tuber, group 2	4.0	4	Correct number of significant figures to be consistent with EPA policy
Vegetable, legume, group 6, except soybean	4.0	4	Correct number of significant figures to be consistent with EPA policy
Vegetable, root and tuber, group 1, except sugar beet	0.40	0.4	Correct number of significant figures to be consistent with EPA policy
Vegetable, root and tuber, group 1, except sugar beet	0.40	0.4	Corrected value to be consistent with EPA Rounding Class Practice. Vegetable, root and tuber (except sugar beet), subgroup 1B
Watercress	3.5	-	Tolerance should be revoked upon establishment of Leafy greens subgroup 4-16
Watercress, upland	3.5	-	Tolerance should be revoked upon establishment of Leafy greens subgroup 4-16
Wax jambu	1.0	1	Correct number of significant figures to be consistent with EPA policy
§180.472(d) Indirect or inadvertent residues			
Soybean, vegetable	-	0.3	Only commodity not covered by vegetable, legume, group 6, except soybean tolerance in (a).
Vegetable, legume, group 6	0.3	-	Covered by vegetable, legume, group 6, except soybean tolerance in (a) and soybean, vegetable in (d).