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Dinotefuran

Proposed Interim Registration Review Decision
Case Number 7441

January 2020

Approved by: ______________________________

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Date: ___ 1-22-2020 ___

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the agency) Proposed Interim Registration Review Decision (PID) for dinotefuran (PC Code 044312, case 7441), 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 dinotefuran, can be found in the EPA's public docket (EPA-HQ-OPP-2011-0920) 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 dinotefuran 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 dinotefuran prior to completing the dinotefuran registration review. Likewise, the agency will complete endocrine screening for dinotefuran, 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 dinotefuran registration review.

Dinotefuran is a broad-spectrum systemic, neonicotinoid insecticide (in the nitroguanidine subclass), which acts on the neonicotinoid acetylcholine receptors (nAChRs) of the central nervous system of insects. Dinotefuran is categorized in the Mode of Action subclass 4A by the

Insecticide Resistance Action Committee (IRAC), a specialist technical group of the agrochemical industry association CropLife. Dinotefuran is used to target a variety of pests including aphids, whiteflies, thrips, leafhoppers, stinkbugs, mole crickets, white grubs, beetles and lacebugs. Products containing dinotefuran can be applied in both agricultural and non-agricultural settings. Agricultural use sites include, but are not limited to, cucurbit vegetables, grapes, nut trees, fruiting vegetables, brassica vegetables and leafy vegetables. Non-agricultural use sites include forest trees, ornamental plants, turf, animal and pet premises, and commercial/industrial buildings. There are 58 Section 3 product registrations, 12 Section 24 (c) Special Local Needs Registrations (SLN), and 13 Section 18 Emergency Exemptions containing dinotefuran. The first dinotefuran product was registered in the United States in 2004, and therefore dinotefuran was not subject to the reregistration process under FIFRA.

This document is organized into five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why dinotefuran is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; 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 dinotefuran, 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 Dinotefuran Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for dinotefuran 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 dinotefuran.

- December 2011 - The Dinotefuran 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 2012 - The *Dinotefuran Final Work Plan* (FWP) was issued. During the comment period for the Dinotefuran Summary Document the agency received one public comment, which did not result in changes to the work plan, data requirements or timeline in the PWP.

- March 2013 - Generic Data Call-In (GDCI) for dinotefuran was issued for data needed to conduct the registration review risk assessments. For dinotefuran, all data requirements were satisfied.

- January 2017 - The agency announced the early availability of the *Draft Assessment of the Potential Effects of Dinotefuran on Bees,* a 60-day public comment period was later opened to coincide with the other neonicotinoids starting May 25, 2017 and ending July 24, 2017.

- December 2017 – The agency announced the availability of the following documents to support Registration Review for 120-day public comment period which included a 60-day comment period extension:
  - *Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran*
  - *Dinotefuran: Registration Review Drinking Water Assessment and the Dinotefuran: Human Health Draft Risk Assessment for Registration Review*
  - *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Cotton*
  - *Benefits of Neonicotinoid Insecticide Use in Pre-Bloom and Bloom Periods of Citrus*

- January 2020 – The agency is now announcing the availability of the PID and the *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran* in the docket, for a 60-day public comment period. Along with the PID, the following documents are also posted in the dinotefuran 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
  - *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, 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
- *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran*, January 14, 2020
- *Note to Reader: Documents Supporting the Registration Review of Dinotefuran*

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

Two separate comment periods were held in 2017 for the dinotefuran risk assessment documents. The *Draft Assessment of the Potential Effects of Dinotefuran on Bees* was published on January 12, 2017 for a 60-day public comment period. The draft human health and non-pollinator ecological risk assessments for dinotefuran, and various supporting benefits-related registration review documents, published on December 21, 2017 for a 120-day public comment period. Although the initial comment deadline for these registration review documents was February 20, 2018, the comment period was extended for an additional 60 days, resulting in a revised comment submission deadline of April 21, 2018.

Across these two comment periods, the agency received a total of 727 public comments. Comments were submitted by various individuals, organizations, and companies. Comments of a broader regulatory nature, and the agency's responses to those comments, are provided in the memorandum *Response from OPP's Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments of 4 Neonicotinoid Insecticides* available in the public docket. 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.
- *Dinotefuran: Response to Public Comments Regarding the Draft Bee and Non-Bee Ecological Risk Assessments for the Registration Review of Dinotefuran.* January 7, 2020.
- *Dinotefuran: Response to Comments on the Human Health Risk Assessment for Registration Review (EPA-HQ-OPP-2011-0920-0753)*, October 5, 2018.

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

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-2011-0920-0583):

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 draft pollinator risk assessments.

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 dinotefuran. 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 Mitsui Chemicals Agro, Inc. (MCAG), 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) and *Dinotefuran: Response to Public Comments Regarding the Draft Bee and Non-Bee Ecological Risk Assessments for the Registration Review of Dinotefuran*, available in the public dockets.

Summary of MCAG Comments (EPA-HQ-OPP-2011-0920-0588):
MCAG Comment: MCAG stated "On pages 1, 9, 10, 14, 20, 21, 35, 63, 64, 66, 67, 69, 71, 72, 118, and 127, maximum application rates and risk assessment results and conclusions are presented for Crop Subgroup 14: Tree Nuts. There are no tolerances for dinotefuran on Crop Subgroup 14: Tree Nuts. Dinotefuran labels show use rates for Ornamental Non-bearing Nut Trees. As this assessment is not intended to include ornamental uses of dinotefuran, all mention of Tree Nuts should be removed."

EPA Response: EPA appreciates the clarification on the Crop Subgroup 14: Tree Nuts use. The final bee assessment includes ornamental non-bearing nut trees as part of the evaluation of ornamental uses of dinotefuran and removes reference to Crop Subgroup 14.

MCAG Comment: MCAG identified numerous errors throughout the document, including: reported endpoints, reported residues, and citations.

EPA Response: EPA appreciates the editorial corrections and has incorporated all changes as appropriate in the final bee risk assessment, which will be published along with the Proposed Interim Decision for dinotefuran. These corrections do not impact the analyses or conclusions presented in the final risk assessment.

MCAG Comment: MCAG provided several comments related to the clarification of Tier I risk conclusions for acute exposures to larval bees and requested EPA modify risk conclusion statements to clarify that risks from acute larval exposures are not anticipated for tuberous and corm vegetables or for any soil application.

EPA Response: EPA appreciates the clarification provided on risk conclusions and notes that conclusions presented in the final bee risk assessment are based on the available Tier I and II toxicity data as well as the submitted residue studies. The Tier I conclusions, which formed the basis for the draft bee risk assessment, are now summarized in Table 5.9 of the final assessment.

MCAG Comment: MCAG commented on the approach to estimating off-field exposure via spray drift described in the draft bee risk assessment and concludes "exposure to residues deposited off-site are not significant and given the uncertainties inherent in the risk assessment assumptions, no spray buffers are needed to protect honeybees."

EPA Response: EPA estimated off-field exposure via spray drift according to label directions, and current internal guidance and models.

MCAG Comment: MCAG stated "the chronic larval toxicity endpoint should be set at a no observed adverse effect concentration (NOAEC) of 0.33 μg/larva (corresponding to 0.0825 μg/larva/day) with a lowest observed adverse effect concentration (LOAEC) of 0.85 μg ai/larva (corresponding to 0.2125 μg/larva/day) based on the 22 -day observation."

EPA Response: EPA updated the statistics for the 8-d larval mortality, 15-d pupal mortality, and 21-d adult emergence endpoints using the Cochran-Armitage trend test (consistent with OECD guidance). The resulting NOAEC and LOAEC for 8-d larval mortality are <0.13 and 0.13 ug/larvae, respectively, based on statistically significant 14% effect (p = 0.01) at lowest concentration tested. The DER has been amended with updated statistics but did not change the most sensitive endpoint or resulting NOAEC/LOAEC values. This does not result in a change to the risk assessment or prior conclusions.

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

Summary of Comments: Several comments were submitted on the bee bread method to evaluate pollen exposure, specifically that an unvetted method should not be used (NCC, CBD, PPC); the bee bread method overestimates exposures to pollen in the hive, and that these estimates should be converted to nectar equivalents that can be compared to the sucrose 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 residues in pollen (and nectar) on a total dietary basis by converting pollen concentrations into nectar equivalents and summing the residues from both matrices (where appropriate) to estimate a single exposure number for comparison to a sucrose-based endpoint (NOAEC). See *Attachment* 1. *Tier II Method for Assessing Combined Nectar and Pollen Exposure to Honey Bee Colonies*, within each chemical-specific docket for a full explanation of the revised pollen method.

Comments Submitted Concerning the Preliminary Non-Pollinator Risk Assessments:
The agency received numerous comments in response to the preliminary non-pollinator risk assessments conducted for the four nitroguanidine-substituted neonicotinoids, 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 a variety of stakeholders including, but not limited to, the Agricultural Retailers Association (ARA), AVAAZ, the Bay Area Clean Water Agencies (BACWA), MCAG, the California Department of Pesticide Regulation (CDPR), CropLife America (CLA), North Dakota Grain Growers Association (NDGGA), Louisiana State University Agricultural Center, the San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), the University of Minnesota (UMN). 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 *Dinotefuran: Response to Public Comments Regarding the Draft Bee and Non-Bee Ecological Risk Assessments for the Registration Review of Dinotefuran*, available in the public dockets.

Summary of Comments (AVAAZ, BACWA, CDPR, CLA, SFBRWQCB, XSIC):
Commenters (EPA-HQ-OPP-2008-0844-1192, EPA-HQ-2008-0844-1116, EPA-HQ-OPP-2011-0920-0750, EPA-HQ-OPP-0920-0712, EPA-HQ-OPP-2011-0920-0693) 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-2011-0920-0711) 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.

<u>**Comment Submitted by MCAG (EPA-HQ-OPP-2011-0920-0728):**</u>
MCAG provided information suggesting that dinotefuran is different than the other nitroguanidine substituted neonicotinoids (imidacloprid, clothianidin, and thiamethoxam), stating "based on the available toxicity data, dinotefuran is generally less acutely and chronically toxic than the other neonicotinoids".

EPA Response: In the ecological risk assessments for the nitroguanidine-substituted neonicotinoids (referred to as "neonicotinoids"), the aquatic invertebrate toxicity data available at the time of publication was characterized. The neonicotinoids evaluated include clothianidin, dinotefuran, imidacloprid and thiamethoxam. Of the four chemicals, imidacloprid has the largest database of aquatic invertebrate toxicity data. Although clothianidin and thiamethoxam had fewer data available than imidacloprid, there were still data for several different test species, including aquatic life stage insects. Dinotefuran had the smallest toxicity database of all four chemicals, relying heavily upon cladoceran data, which are not sensitive to the neonicotinoids relative to other tested aquatic invertebrate species.

There are some important notes relevant to the available toxicity databases. First, there is a difference in sensitivity among test species to the same neonicotinoid. Among different mayfly species, the neonicotinoids have 96-h LC_{50} values that span orders of magnitude. Therefore, the most sensitive toxicity endpoints used in risk assessment may be dependent upon which species are tested. In the case of imidacloprid, which has the largest database of toxicity data, the fact that this chemical has the lowest toxicity endpoints may not be a function of its lower toxicity but rather of the sensitivity of the tested species. The most sensitive test species for imidacloprid was *Cloeon dipterum* (a mayfly) for acute exposures and *Caenis horaria* (also a mayfly) for chronic exposures. At the time of the original risk assessments, none of the other three chemicals had toxicity data for this test species.

After the draft ecological risk assessments for the neonicotinoids were posted to the docket, two studies were published focusing on the toxicity of these compounds to aquatic invertebrates (Raby et al. 2018a and Raby et al. 2018b). EFED has reviewed these two studies and has determined that their results may be used quantitatively for risk assessment purposes, *i.e.*, to derive Risk Quotients (RQs). Given that the toxicity data generated by Raby et al. 2018 (a and b) were from the same lab, this data set allows for a unique opportunity to compare the toxicities of the neonicotinoids, decreasing the variability that may be due to tests from different labs. A complete discussion of the comparative risk of the four nitroguanidine substituted neonicotinoids can be found in the memorandum "Comparative analysis of Aquatic Invertebrate Risk Quotients Generated for Neonicotinoids using Raby et al. (2018) Toxicity Data" (US EPA, 2020).

As discussed in the analysis and considering the two most sensitive species tested, the four chemicals are relatively similar in toxicity on an acute and chronic exposure basis for the mayfly, but there were differences in sensitivities observed among the chemicals for the midge. When considering exposure, dinotefuran tends to have the highest EECs among the four chemicals. Overall, for the same uses, the chemicals represent a similar risk concern.

RQs for dinotefuran based on the acute and chronic toxicity data for the two most sensitive species presented in Raby et al. are provided in Table 1 of *Dinotefuran: Response to Comments Regarding the Draft Bee and Non-Bee Ecological Risk Assessments for the Registration Review of Dinotefuran*. Those RQs supersede those presented in the draft risk assessment.

II. USE AND USAGE

Dinotefuran is a neonicotinoid insecticide (in the nitroguanidine subclass) that has contact and systemic activity used to control a variety of insects. Dinotefuran has numerous agricultural and non-agricultural uses. Agricultural use sites include field crops, fruits, and vegetables as well as Christmas tree plantations, and dinotefuran can be applied via soil and foliar applications methods (both ground and by air) as well as a tree/trunk injection. Non-agricultural uses include indoor residential and commercial sites, including food handling establishments, outdoor residential and commercial sites such as gardens, lawns, and ornamental plantings; and pets and livestock. It is applied by both professional pest control operators and homeowners with surface, space, and directed crack and crevice sprayers, and aerosol sprays. End-use formulations include ready-to-use, pressurized liquids, dust, emulsifiable concentrates, granules, soluble concentrates, pellets/tablets, impregnated material, and water-soluble packaging.

Agricultural Usage

From 2007-2017, dinotefuran usage averaged about 32,000 pounds AI[1], applied to approximately 230,000 acres[2]. Usage has been increasing over time. Major agricultural uses in terms of total average pounds applied include rice, cotton, cucurbits, and fruiting vegetables[1]. In terms of percent crop treated (PCT), cantaloupes and celery are the highest with an average of 25 percent; around 10 percent of the acreage in brassica vegetables and other cucurbits are treated with dinotefuran.

In 2016, usage of dinotefuran was reported to be used for industrial vegetation management, including forestry, but quantitative estimates were not reported[3]. In 2012, approximately 10,000 lbs AI of dinotefuran was estimated to have been used in horticultural nurseries and greenhouses[4].

Non-Agricultural Use

The agency has limited usage data on non-agricultural use sites. In 2014, approximately 37,000 lbs AI of dinotefuran was used in and around food handling establishments[5]. There was also usage by professional pest control operations in and around other commercial establishments and

[1] *Dinotefuran (044312) Screening Level Usage Analysis (SLUA), July 8, 2019*

[2] *Agricultural Market Research Data (AMRD). various years. 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.*

[3] *Non-Agricultural Market Research Proprietary Data. 2017b. Studies conducted and sold by a consulting and research firm. Report on vegetation management. [Accessed June 2019.]*

[4] *Kline and Company, 2013. Professional Turf and Ornamental Markets for Pesticides and Fertilizers, 2012.*

[5] *Kline and Company, 2015. Pest Control in Food Handling Establishments 2014: U.S. Market Analysis and Opportunities. [Accessed June 2019.]*

residential buildings reported in 2016, but quantitative estimates are not available[6]. Direct to consumer sales are not reported in available usage data[7].

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 dinotefuran. For additional details on the human health assessment for dinotefuran, see the *Dinotefuran: Human Health Draft Risk Assessment for Registration Review*, which is available in the public docket.

1. Risk Summary and Characterization

There are no residue chemistry, toxicology, or occupational/residential exposure data gaps for dinotefuran. Acute and chronic dietary exposure and risk estimates are not of concern for dinotefuran. Dinotefuran is classified as "not likely to be carcinogenic to humans" based on lack of evidence of carcinogenicity in rats and mice and there is no evidence of mutagenicity. Dinotefuran has low acute toxicity by oral, dermal, or inhalation exposure routes (Toxicity Category III or IV). It does not irritate the eye (Toxicity Category IV), but causes a low level of skin irritation (Toxicity Category IV); it is not a dermal sensitizer. The Food Quality Protection Act (FQPA) Safety Factor (SF) for dinotefuran has been reduced to 1X because (1) there is an adequate toxicity database for dinotefuran; (2) the prenatal developmental studies in rabbits and rats and the 2-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* and/or postnatal exposure to dinotefuran; (3) the neurotoxic potential of dinotefuran has been adequately considered; and (4) there are no residual uncertainties identified in the exposure databases. Therefore, the level of concern (LOC) = 100.

No hazard was identified for the short- and intermediate-term dermal and inhalation routes of exposure, residential handler, occupational handler, and occupational post-application exposures were not assessed. The only potential non-dietary exposure pathway that was quantitatively assessed is the incidental oral exposure pathway for children 1 to <2 years old and the resulting MOEs are greater than HED's level of concern (LOC = 100); however, although the exposure pathway potentially exists, incidental oral post-application risk estimates did not result in risk estimates of concern (MOEs ≥ 100). Additionally, there were no aggregate risks of concern identified.

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[6] *Non-Agricultural Market Research Proprietary Data. 2017a. Studies conducted and sold by a consulting and research firm. Report on professional turf and ornamental plants and professional pest control pesticide usage. [Accessed June 2019.]*

[7] *Non-Agricultural Market Research Proprietary Data. 2017a. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. [Accessed June 2019.]*

Dietary, Residential Handler, Residential Post-Application, Aggregate, Bystander, and Occupational Handler and Post-Application Risks

No risks of concern were identified for dietary, residential handler, residential post-application, aggregate, or occupational handler or post-application exposures. The only potential post-application exposure pathway that was quantitatively assessed is the incidental oral exposure pathway for children 1 to <2 years old. The resulting MOEs range from 1,200 to 5,500,000 and are significantly greater than the LOC of 100; therefore, there are no post-application risks of concern. A quantitative bystander spray drift assessment for dinotefuran was not needed because the potential residues from direct applications to residential turf are greater than the potential residues resulting from drift from nearby agricultural endpoints (i.e., the residential post-application risk assessment is protective of potential bystander risks.

Since no hazard was identified for the short-term and intermediate-term dermal and inhalation routes of exposure, occupational handler and post-application exposures were not assessed, and there are no expected risks of concern.

Cumulative Risks

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

2. Human Incidents and Epidemiology

One hundred and two dinotefuran incidents were previously reviewed in 2011, and based on the low severity and frequency of cases reported to IDS, further analysis was not warranted. In the current analysis covering incidents reported from January 1, 2012 to July 11, 2017, five cases involving a single active ingredient and 45 cases involving multiple active ingredients were reported to Main IDS; another 810 cases are recorded in the Aggregate IDS (these incidents are typically of low severity). A query of SENSOR-Pesticides 1998-2013 identified 31 cases involving dinotefuran. Based on the continued low severity of dinotefuran incidents reported to both IDS and SENSOR-Pesticides, there does not appear to be a concern at this time.

The agency will continue to monitor the incident data. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

3. Tolerances

Tolerances are established under 40 CFR § 180.603 for residues of dinotefuran, including its metabolites and degradates, for plants and livestock commodities as well as food handling establishments. There are/were time-limited tolerances for stone and pome fruits (expires 12/31/2021) and fuzzy kiwifruit (expires 12/31/2022). EPA intends to update crop group definitions for several commodities, revoke individual tolerances for some commodities that will be covered in the appropriate crop groupings, and increase some tolerances to harmonize with

Codex Maximum Residue Limits (MRLs); there are no MRLs established in Canada and Mexico for dinotefuran.

Revisions are proposed at this time to include updated crop group definitions, update tolerances per the EPA's guidance on trailing zeros, as well as increased tolerance levels for international harmonization. Only the proposed tolerance revisions are presented in below. The agency will use its FFDCA rulemaking authority to undertake the needed tolerance changes.

Dinotefuran 40 CFR § 180.603: Summary of Proposed Tolerance Actions			
Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
40 CFR 180.603 (a)(1) Plant Commodities			
Brassica leafy greens subgroup 4-16B	--	15	1) Crop group conversion/revision 2) Correct number of significant figures to be consistent with EPA policy
Brassica, head and stem, subgroup 5A	1.4	--	Tolerance should be revoked upon establishment of Vegetable, Head and Stem *Brassica*, Group 5-16 and kohlrabi
Brassica, leafy greens, subgroup 5B	15.0	--	Tolerance should be revoked upon establishment of *Brassica* leafy greens subgroup 4-16B
Celtuce	5.0[8]	5	1) Separate tolerance for celtuce is needed as it is left out when crop group 4 is converted to 4-16A and 4-16B 2) Correct number of significant figures to be consistent with EPA policy
Cotton, gin byproducts	8.0	8	Correct number of significant figures to be consistent with EPA policy
Florence fennel	5.0[1]	5	1) Separate tolerance for Florence fennel is needed as it is left out when crop group 4 is converted to 4-16A and 4-16B 2) Correct number of significant figures to be consistent with EPA policy
Grape, raisin	2.5	3	1) Harmonization with Codex MRL 2) Correct number of significant figures to be consistent with EPA policy
Kohlrabi	1.4[9]	2	1) Separate tolerance for kohlrabi is needed as it is left out when crop group 5 is converted to 5-16 and 22B 2) Harmonization with Codex MRL (increase from 1.4 to 2.0 ppm) 3) Correct number of significant figures to be consistent with EPA policy
Leaf Petiole Vegetable Subgroup 22B	--	5	Crop group conversion/revision
Leafy greens subgroup 4-16A	--	5	Crop group conversion/revision and correct number of significant figures to be consistent with EPA policy
Onion, green, subgroup 3-07B	5.0	5	Correct number of significant figures to be consistent with EPA policy
Peach	1.0	1	
Rice, grain	9.0	9	
Tomato, paste	1.0	1	
Turnip, greens	15.0	15	
Vegetable, fruiting, group 8	0.7	--	Tolerance should be revoked upon establishment of Vegetable, fruiting, group 8-10
Vegetable, fruiting, group 8-10	--	0.7	Crop group conversion/revision
Vegetable, Head and Stem *Brassica*, Group 5-16	--	2	1) Crop group conversion/revision

[8] At present, celtuce and Florence fennel are covered by crop group 4 tolerance.
[9] At present, kohlrabi is covered by crop group 5A tolerance.

Dinotefuran 40 CFR § 180.603: Summary of Proposed Tolerance Actions			
Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments (*correct commodity definition*)
			2) Harmonization with Codex MRL (increase from 1.4 to 2.0 ppm) 3) Correct number of significant figures to be consistent with EPA policy
Vegetable, leafy, except *Brassica*, group 4	5.0	--	Tolerance should be revoked upon establishment of Leafy greens subgroup 4-16A, Leaf Petiole Vegetable Subgroup 22B, celtuce, and Florence fennel
40 CFR 180.603 (b)-Section 18			
Fruit, pome, group 11-10	--	2[3]	1) Commodity definition correction 2) Correct number of significant figures to be consistent with EPA policy
Fruit pome, group 11	2.0	Remove	
Fruit stone, group 12	2.0	Remove	

4. Human Health Data Needs

There are no residue chemistry, toxicology, or occupational/residential exposure data gaps for dinotefuran. No additional human health data are anticipated to be needed to support this registration review at this time.

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 dinotefuran. For additional details on the ecological assessment for dinotefuran, see the following documents, which are available in the public docket (EPA-HQ-OPP-2011-0920) at www.regulations.gov.

- *Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran*
- *Draft Assessment of the Potential Effects of Dinotefuran on Bees*
- *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran*
- *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 dinotefuran. 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

Dinotefuran is applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching. For terrestrial wildlife, the agency modeled potential dietary exposure based on consumption of dinotefuran residues on food items following spray (foliar or soil) applications. Overall, acute risks to avian and mammalian species from foliar and soil treatments of dinotefuran are not expected. Soil incorporation following soil treatments, decreases potential risks from this use pattern considerably.

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

Mammals, Birds, Reptiles, and Terrestrial-Phase Amphibians

Dinotefuran is practically non-toxic to moderately toxic to birds (and to terrestrial-phase amphibians and reptiles for which birds serve as surrogates) and practically non-toxic to mammals on an acute basis. Overall, potential acute risks to birds and mammals from foliar and trunk injection treatments appear to be low. There is the potential for acute effects to birds from soil (spray) treatments at the highest application rate (0.54 lb AI/A; ornamentals including non-bearing nut trees), with Risk Quotients (RQs) ranging from 0.01 to 0.83[10] (soil incorporation following soil treatments decreases potential risks from this use pattern considerably). Unlike the other nitroguanidine substituted neonicotinoids, dinotefuran is not registered as a seed treatment and thus, not a route of exposure.

Although the possibility of exposure exists for terrestrial wildlife such as mammals, birds, reptiles, and terrestrial-phase amphibians, acute and chronic risks of concern have not been identified for any of the assessed dinotefuran uses or application methods.

Terrestrial Invertebrates (honeybees) – *Risk Estimates*

This section incorporates information provided in the *Draft Assessment of the Potential Effects of Dinotefuran on Bees* as well as the more recent *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran*, which are available in the public docket. The 2017 draft pollinator assessment utilized available data to evaluate potential risk associated with the registered agricultural uses of dinotefuran to bees alone. The available data included a registration review required Tier I (individual bee) level dataset to help characterize the acute and chronic toxicity of dinotefuran to adult and larval honeybees. In both assessments, available open literature data were also reviewed.

The final 2019 bee risk assessment updates the draft pollinator assessment and incorporates additional information submitted to the EPA since the time of the previous draft assessment. This

[10] RQs exceeding the LOC represent potential risks of concern. The LOC for acute risks is 0.5.

new assessment includes data on residues of dinotefuran in nectar, pollen, and other plant matrices associated with registered crop uses. It utilizes a residue bridging strategy to extrapolate between 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 (colony) level) pollinator studies. Tier II data included a sucrose colony feeding (dose-response) study to better evaluate potential colony level effects. Data were required based on a tiered approach, as lower tiered data could trigger the need for higher tiered data.

The agency is concerned about potential risks from neonicotinoid use to all pollinators. During testing, honeybees (*Apis mellifera*) were used as a surrogate for other species of pollinators (*e.g.* bumblebees, monarchs, etc.). 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, the honeybees (*Apis mellifera*) are considered to be reasonable surrogates (in the absence of data to the contrary) 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 nitroguanidine neonicotinoids (imidacloprid, clothianidin, thiamethoxam, 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, berries/small fruits, and ornamentals (including non-bearing nut trees). Surrogate data were used where limited or no residue dinotefuran data were available. Generally, the dinotefuran risk assessment finds that applications of dinotefuran to honeybee attractive crops that are not harvested prior to bloom result in a potential for colony-level risk.

Dinotefuran is highly toxic to adult bees on an acute contact (48-hr LD_{50} = 0.024 µg a.i./bee) and oral (48-hr LD_{50} = 0.0076 µg a.i./bee) basis. Dinotefuran is classified as non-toxic with endpoints up to 3.3 µg a.i./larva (111 mg a.i./kg diet) to honey bee larvae on an acute (single dose dietary) exposure basis. RQ exceedances for larvae are orders of magnitude lower than those of adults, with acute contact RQs ranging from 7.4 to 20. Acute RQ exceedances associated with on-field foliar use of dinotefuran range from <0.3 to 760 and soil use exceedances range from <0.1 to 12 (LOC = 0.4). The highest acute foliar RQ exceedances noted are associated with use on brassica head and stem vegetables, fruiting vegetables, cucurbit vegetables, bulb vegetables, stone fruit, and low growing berries (except strawberry); while the highest soil-applied RQ exceedances result from use on potatoes, leafy vegetables, brassica head and stem vegetables, fruiting vegetables, cucurbits, kiwi, tuberous and corm vegetables, and small fruit vine climbing subgroup (except kiwi).

One study is available that examines the chronic toxicity of dinotefuran for adult honeybees through dietary exposure. The NOAEC and the LOAEC based on mortality are 0.0015 and 0.0035 µg a.i./bee, respectively. In a larval chronic 21-day study, individual honeybee (*Apis mellifera*) larvae were exposed *in vitro* to technical grade dinotefuran. No statistically significant differences were detected between the negative control and treatment groups for pupal mortality, adult emergence, or growth (body weight of emerged bees); however, high mortality in the control group observed at Day 14 limits the extent to which the study can detect treatment effects. The NOAEC is less than the lowest dinotefuran treatment level (*i.e*., NOAEC: <0.0325 µg a.i./larva/day). As with the acute data, RQ exceedances for honeybee larvae are orders of magnitude lower than those of adults. Chronic RQ exceedances associated with on-field foliar use of dinotefuran range from 28 to 3900 and soil use RQ exceedances range from 0.9 to 60.

Based on an analysis of Tier I data, for foliar applications, potential off-field dietary risks to individual bees exposed to spray drift extend 1000 feet from the edge of the treated field. There is uncertainty in this analysis including: assumption of 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.

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 dinotefuran residues measured in pollen and nectar in various crops to levels that affect honey bee colonies. These analyses may not reasonably represent non-*Apis* bees (e.g., bumblebees), due to different crop attractiveness. 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, which are conducted outside the laboratory, afford less control over these other factors, and their role may become increasingly prominent as the duration of the study is extended. Although study protocols attempt to minimize the confounding effects of other environmental factors, there is uncertainty regarding the extent to which the effects of a chemical may be substantially different had these other factors been not be in place.

Strongest Evidence of Risk: For foliar, soil, and trunk injection applications of dinotefuran, 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):

- cotton (foliar)
- stone fruit (foliar, pre-bloom)
- berries (foliar, pre-bloom),
- pollinator-attractive fruiting vegetables (foliar), and
- pollinator-attractive ornamentals and forest trees (foliar, soil, trunk injection)

These findings are supported by multiple lines of evidence indicating that residues exceed the dinotefuran colony-level NOAEC 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 and soil application of dinotefuran, the strength of evidence is considered "moderate" in indicating a colony-level risk to honey bees for the following registered uses:

- cucurbits (foliar),
- berries (soil, pre-bloom), and
- turf (residential lawns with bee-attractive blooming weeds).

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

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

- pollinator-attractive root/tubers (foliar, soil),
- pollinator-attractive fruiting vegetables (soil), and
- stone fruit (soil, pre-bloom)

Honeybees in particular play an important role in commercial pollination services for certain crops. 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.

Off-field drift of dinotefuran (from foliar spray applications) is another potential route of exposure which can present risks to bees. Off-field drift was calculated via the AgDRIFT model which considers a variety of factors including wind speed, spray nozzle type, release height, etc. Spray drift from foliar treatments resulted in risks at greater than 1,000 feet from the field for honey bees. Off-field estimates of risk are based on exposure estimates which cannot be refined with available residue data. Moreover, these estimates relied on conservative 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, adult chronic endpoints were considered very sensitive, even with the additional modeling (section 5.1.3 of the final pollinator assessment) using coarser droplet sizes, the drift distances were not appreciably affected.

Terrestrial Plants

No risks of concern are identified for terrestrial plants. No effects were observed in the available vegetative vigor and seedling emergence studies, which tested the maximum application rate for dinotefuran. RQs were not calculated because the highest test concentrations did not yield adverse effects.

Aquatic Risks

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

Freshwater Invertebrates

From the initial *Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran*, meaningful acute and chronic RQs for dinotefuran to freshwater invertebrates could not be calculated because definitive toxicity endpoints were not available for data classified as quantitative. The RQs available were calculated based on available qualitative data. EECs were highest for rice with a 1-day average water column level of 349 μg/L from combined (soil and foliar) applications. The use of dinotefuran on rice yielded the highest chronic RQ for freshwater invertebrates (84, LOC = 1). Chronic RQs for all other crops were at least an order of magnitude lower, ranging from 1.38 – 8.23. The acute RQ exceedance for rice was highest at 34.9; with all other acute RQs ranging from 0.48 – 6.52 based on the most sensitive species (*trichoptera*) data. Aquatic invertebrate exposure from the rice use is expected; however, potential impacts could be limited based on available use practice information, limited national geographic footprint, and best management practices such as increased water holding times, water conservation practices, and in-furrow/row rice (non-flooded field) usage. These factors, along with current buffer and spray drift label language, have the potential to significantly reduce the potential for dinotefuran runoff to adjacent aquatic water bodies from the aquatic risk driver, rice.

<u>Comparative Analysis of Aquatic Invertebrate Risk Quotients</u>
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 Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran*. 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[11] and Raby *et al.* 2018b[12]). 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 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.

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[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.

[12] 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.

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 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 RQs for estuarine/marine invertebrates in the initial dinotefuran non-pollinator draft risk assessment did not show exceedances. Meaningful RQs could not be calculated for estuarine/marine invertebrates on a chronic exposure basis because the available study showed effects at all test concentration, resulting in a non-definitive NOAEC of < 44 µg/L, the lowest concentration tested. At this lowest test concentration, effects on female dry weight were seen, up to 17% decrease. This LOAEC of 44 ug/L was lower than modeled concentration for maximum exposure scenario (rice) and within an order of magnitude of all other scenarios (EECs range from 4.14 to 24.7 for all uses except rice, which is 252 ppb), suggesting that risk to estuarine/marine invertebrates from chronic exposure to dinotefuran is uncertain, but cannot be precluded.

Fish and Aquatic-Phase Amphibians

No effects were observed at the highest treatment levels tested for freshwater and estuarine/marine fish (surrogate for aquatic-phase amphibians), RQ values therefore were not particularly meaningful. As estimated environmental concentrations (EECs) do not approach these treatment levels, direct risk to fish is not a concern.

While the potential risk of direct effects of dinotefuran 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

No risks of concern were identified for aquatic plants. Non-listed species RQs for vascular and non-vascular aquatic plants could not be calculated because definitive toxicity endpoints are not available for the tested species.

6. Ecological Incidents

There are no incidents reported for plants, aquatic or terrestrial vertebrates, or aquatic insects. All of the available incidents reported are regarding bees. The search reflects reported incidents since the initial registration of dinotefuran and includes any reports in the Incident Database System (IDS) as of March 2019. The sources of information for incidents include, registrant reports submitted under the FIFRA § 6(a)(2) reporting requirement, as well as reports from local, state, national and international level government reports on bee kills, news articles, and correspondence made to the EPA by phone or via email (through beekill@epa.gov) generally reported by homeowners and beekeepers.

All reported incidents were associated with dinotefuran use on ornamentals, and their relevance to agricultural uses are unknown. Four major incidents dated between June of 2013 and August 2015 on the west coast were noted, all involving large numbers of bumblebees and other insects found dead around the treated ornamental trees (*Myoporum* and linden). Three of the four incidents were associated with spray applications and one from basal trunk application. One incident was associated with a June 2013 basal trunk application to linden trees resulting in a number of bee deaths months was later found to be made by the Oregon Department of Agriculture (ODA) in accordance with the label. During a similar timeframe, ODA also deduced that another dinotefuran incident which resulted in 25,000 to 50,000 bumblebees killed as a result of a misuse application not in accordance with label requirements. The remaining two major incidents listed are still of unknown legality. More detail can be found in EPA's *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran*.

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

7. Ecological and Environmental Fate Data Needs

There are no data deficiencies for the registered uses of dinotefuran with regards to ecological and environmental fate and effects. The agency does not anticipate any further ecological and environmental fate and effects data needs for the dinotefuran registration review at this time.

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 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;

Alternatives to dinotefuran, 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 imidacloprid, thiamethoxam, and acetamiprid, respectively.

<u>The following are summaries of the benefits assessments available in the public docket[13].</u>

Cotton
Although registered for cotton, surveys of insecticide use in an available cotton report showed little or no usage of dinotefuran as of 2015. More recent data[14], through 2017, show an increase in usage. There are anecdotal reports of dinotefuran used against Silverleaf whitefly in the Southeast. The Silverleaf whitefly is a pest that only sporadically reaches damaging levels.

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

Citrus
Dinotefuran is only registered for non-bearing ornamental citrus trees. Its primary benefit is likely as part of an overall strategy to control the Asian citrus psyllid (ACP) and other citrus pests in residential and nursery setting to ultimately protect commercial production from Huanglongbing bacterial disease (HLB), also known as citrus greening disease (UC IPM, 2019)[15]. ACP vectors HLB, which negatively affects both the quantity and quality of fruit and may kill trees within a few years. There may be limited options for insecticides to control the ACP in residential areas; dinotefuran and other neonicotinoids may provide both immediate

[13] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2011-0920
[14] *Dinotefuran (044312) Screening Level Usage Analysis (SLUA), July 8, 2019*
[15] UC IPM, 2019. "Floriculture and Ornamental Nurseries: Citrus Pests." University of California Agricultural Extension

contact and residual control, reducing the need for frequent applications of contact insecticides like pyrethroids.

Grape

Usage of dinotefuran on grapes is relatively low compared to imidacloprid and clothianidin; however, in terms of agricultural crops to which dinotefuran is applied, grapes are one of the top three in average pounds of dinotefuran applied. Applications of nitroguanidine neonicotinoids to table, raisin, and wine grapes are often made post-bloom, with imidacloprid being the leading insecticide prior to and during bloom. Neonicotinoids, like dinotefuran, provide rapid control via contact activity and residual control through systemic activity, as well as an important rotation partner for resistance management and in providing disease control and prevention.

Dinotefuran is used to target primarily leafhoppers, including sharpshooter, and mealybugs. 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.

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

Rice

Dinotefuran is a foliar-applied insecticide to control rice stink bugs late season. Dinotefuran is applied to 92,300 acres annually. The national PCT for rice is only 3%, but rice is a top agricultural use site with 3,000 lbs. AI applied per year. Use in Texas accounts for nearly 90% of dinotefuran applied to rice nationally and the average PCT for rice grown in Texas is 43%. The average application rate used in Texas is 0.095 pounds active ingredient per acre compared to the maximum labeled rate of 0.131 pounds active ingredient per acre. In Texas, an average of 1.2 applications are made per year.

While there is potential for yield losses associated with rice stink bug feeding, the major concern with their feeding is reduction in quality of grain, because the discoloration reduces the price farmers are paid for their crop and reduces the ability to export. Rice stink bug is only considered a pest in the Mid-South and Gulf Coast. Dinotefuran is a critical tool to combat pyrethroid-resistant rice stink bugs in Texas. Dinotefuran provides growers with the greatest flexibility in rice stink bug control over alternatives, such as pyrethroids or carbaryl, due to its greater residual control, short pre-harvest interval (PHI), and no water-holding period requirements.

For more information, see *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments*.

Stone Fruit

Among the stone fruits, dinotefuran is only registered for use on peaches and nectarines. The nitroguanidine neonicotinoids as a group are used to control a variety of pests in stone fruits. Important pests targeted by dinotefuran in these crops include the plum curculio, plant bugs, and stinkbugs. Approximately 2% of the peach and nectarine crops are treated with dinotefuran, and about 200 pounds of active ingredient are applied to 1,800 acres of peaches and nectarines annually. The average single application rate of dinotefuran use on peaches and nectarines is

0.123 pounds of active ingredient per acre. On average, one treatment is made annually. Given the low usage of dinotefuran in peaches and nectarines, the agency did not assess rate reduction impacts.

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).*

Pome Fruit
Neonicotinoid target pests for pome fruit (apple and pear) include several economically significant pests that can reduce pome fruit yield. The major use of the nitroguanidine neonicotinoids is during the post-bloom to harvest periods of the pome fruit production cycle. However, 20-30% of neonicotinoid usage occurs during the pre-bloom and bloom period. Early season control can be important to manage early season pests that can build up to high population densities if not controlled early season.

Dinotefuran use on apples is small, and negligible in pears as it is currently only available in that crop as a FIFRA Section-18 emergency exception use. There are relatively few instances of dinotefuran use in the market research database in recent years and thus the agency did not assess the impact of a potential application rate reduction on users. Dinotefuran use on pome fruit accounts for an average of 1,700 total acres treated and 200 pounds applied at 1% PCT. The average application rate for dinotefuran use on pome fruit is 0.122 pounds active ingredient per acre.

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)*

Berries
Berries refer to strawberry, caneberry (*e.g.*, blackberry and raspberry), cranberry, and blueberry, as well as multiple other small soft fruit grown on very small acreage. Dinotefuran is only registered for use on cranberry and blueberry.

Berry pests, targeted by the neonicotinoids, cause direct feeding damage which can cause reductions in the aesthetic quality of harvested fruit (*e.g.*, tarnished plant bug, cranberry root weevil, blueberry maggot), transmit diseases which can result in plant death and/or crop loss (*e.g.*, aphids, leafhoppers). The detection of a single individual of some of these pests (e.g., blueberry maggot) in harvested fruit can result in processors or buyers rejecting all of the harvest from an entire field.

To date, imidacloprid and thiamethoxam are the most frequently used and/or recommended neonicotinoids. Dinotefuran was registered for cranberry and blueberry in 2016; current usage data and recommendations do not provide much information. It is recommended in crop manuals for control of cranberry root weevil[16] in cranberry. Dinotefuran can be utilized as both a foliar

[16] Murray *et al.*, 2017; Rodriguez-Saona, 2013b; Guédot *et al*., 2018; DeLange *et al*., 2015

application (for immediate contact control) and soil application (for residual control) for some berry crops.

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

Cucurbits

The cucurbits benefits assessment 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 primarily aphids, whitefly, and cucumber beetle. Although imidacloprid is the most utilized neonicotinoid active ingredient on cucurbits, there is considerable usage of dinotefuran. Dinotefuran usage however is relatively low, except for usage on cantaloupe (4,200 average lbs. applied per year; 23 PCT) and squash (1,000; 9 PCT).

Extension publications recommend up to three applications of neonicotinoids on cucurbits, primarily dinotefuran, to control whiteflies and prevent cucurbit yellow stunting disorder virus (CYSDV) across the season (Palumbo 2017). Dinotefuran is also recommended at-plant with two subsequent applications during emergence-to-vining (Palumbo 2017). According to pesticide market research data (2013-2017), imidacloprid is most commonly used in cucurbits prior to crop emergence while dinotefuran may be more commonly applied in the emergence-to-vining period.

Dinotefuran is mostly applied to cucurbits foliarly, accounting for two-thirds of all dinotefuran-treated acres, and soil applications make up the other third. Growers applied dinotefuran at or near the foliar labeled maximum application rate on 46% of foliarly-treated acres and applied dinotefuran at or near 0.267 lbs. AI/A on 97% of soil-treated acres. Thus, a 10% rate reduction would have a significant impact on growers using dinotefuran via foliar application. A 20% rate reduction to 0.262 lbs. AI/A, would impact more than 90% of soil-treated acres of dinotefuran.

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

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

In general, neonicotinoids, including dinotefuran, are widely used and provide high benefits to the producers of fruiting vegetables, leafy vegetables, and *Brassica* vegetables. Dinotefuran provides 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 it is systemic, both soil and foliar applications can be used, permitting growers flexibility in terms of application timing and method. Dinotefuran is less widely used in production of root and tuber crops, bulb vegetables, 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, which may include other neonicotinoids such as imidacloprid. Proposed restrictions on the use of imidacloprid may increase the use of, and the benefits of, dinotefuran.

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

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 dinotefuran 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

EPA's risk management approach for the neonicotinoids aims to preserve a key tool for growers while maximizing targeted risk reduction. Mitigation is being proposed for the potential ecological risks of concern noted for pollinators and 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[17]. Although the focus of the pollinator risk assessments is on honeybees, the agency recognizes that numerous other species of bees occur in North America and that these non-*Apis* bees have ecological importance in addition to commercial importance in some cases. For example, it is important to note that several species of non-*Apis* bees are commercially managed for their pollination services, including bumble bees (*Bombus spp.)*, leaf cutting bees (*Megachile rotundata*), alkali bees (*Nomia melanderi*), blue orchard bees (*Osmia lignaria)*, and the Japanese horn-faced bee (*Osmia cornifrons*). Importantly, a growing body of information indicates native bees play an important role in crop and native plant pollination, in addition to their overall ecological importance via maintaining biological diversity. EPA is therefore proposing mitigation that reduces impact to honeybees that are also expected to benefit other

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

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 dinotefuran uses through the following risk mitigation measures:

- Cancel use on bulb vegetables;
- 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 dinotefuran 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 dinotefuran, 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 dinotefuran. The EPA is also proposing label changes to address general labeling improvements for all dinotefuran products.

1. Cancellation of Uses

The agency is proposing cancellation of dinotefuran use on bulb vegetable crops in order to mitigate potential exceedances to aquatic invertebrates. In a review of available comparative data, dinotefuran was found to have similar chronic LOC exceedances to the other neonicotinoids which calculated potential risk to aquatic invertebrates from bulb use reached

RQs over 500 for aquatic invertebrates. Dinotefuran is rarely used on bulb vegetables; between 2013 and 2017, less than one percent of the acres grown was treated with dinotefuran. Although there are some particular benefits of neonicotinoids in general for the control of thrips, effective alternatives to the neonicotinoids, including dinotefuran, remain available for use on bulbs. In consideration of the high potential risk and the relatively low expected impacts to bulb growers, EPA is proposing cancellation of this use.

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

2. Application Rate Reductions

As noted in section III.B. of this PID, EPA has identified several categories of ecological risks of concern as a result of dinotefuran uses, including pollinators and aquatic invertebrates. To help mitigate these risks, EPA is proposing the following reductions in the maximum allowable annual application rates for foliar and soil applications of dinotefuran products:

Table 1. Proposed Maximum Annual Application Rates for Dinotefuran

Crop/Crop Group	Current Rate (Max. Annual)	Proposed Mitigation (Max. Annual)
Leafy Vegetables	Foliar: 0.268 lbs. AI/A/yr	Foliar: 0.23 lbs. AI/A/yr
Brassica/Cole	Foliar: 0.266 lbs. AI/A/yr	Foliar: 0.23 lbs. AI/A/yr
Fruiting Vegetables	Foliar: 0.268 lbs. AI/A/yr	Foliar: 0.23 lbs. AI/A/yr
Cotton	Maximum combined annual application rate regardless of formulation type: 0.263 lbs. AI/A/yr	Maximum combined annual application rate regardless of formulation type: 0.19 lbs. AI/A/yr
Production/Commercial Ornamentals	Foliar and soil: 0.54 lbs. AI/A/yr	Foliar and soil: 0.40 lbs. AI/A/yr

Application rate reductions are being proposed for several uses in order to reduce potential risk exceedances to both pollinators and aquatic invertebrates. For pollinators, these proposed rate reductions focus on certain crops where pollinator/bee exposure and where the highest potential reduction of risks to pollinators is possible. For pollinators and aquatic invertebrates, measured rate reductions are a part of a multi-faceted approach to reducing overall exposure. The goal of these proposed maximum annual application rate reductions is to reduce the total environmental loading of neonicotinoids resulting from the various uses specified, while still providing growers with the ability to use these tools as an effective means of pest control. Additional measures to reduce risk to pollinators and aquatic invertebrates include spray drift and runoff reduction language discussed in Section IV.A.5 of this document.

As part of the assessments of the benefits of neonicotinoids, EPA also analyzed 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 reductions in risk while minimizing the impacts on users of dinotefuran. Although these proposed rate reductions do not eliminate all risks, they are expected to contribute to reducing risk overall. The benefits of these uses outweighs the remaining reduced risks of concern.

Leafy vegetables
For the leafy vegetables crop group, EPA is proposing reducing the current maximum annual foliar application rate from 0.268 lbs. AI/A to 0.23. This rate reduction is targeted at reducing potential risk to aquatic invertebrates.

Potential risk to aquatic invertebrates was noted for foliar applications of dinotefuran from leafy vegetable use, with comparative neonicotinoid foliar RQs up to 989. Benefits of the use of neonicotinoids are high, in general, but dinotefuran use on leafy vegetables is low, with PCTs around 1%. Proposed restrictions on the use of imidacloprid, however, may result in growers shifting to dinotefuran. Average annual application rate is 0.222 lbs. AI/A/year, lower than the proposed mitigation. Around 40% of the acres treated with dinotefuran are treated at rates of 0.210 lbs AI/A/year or more although soil applications are included in this estimate. This mitigation could preclude a grower from making a second application of dinotefuran; the applicator would have to use an alternative insecticide. However, the number of acres affected may be small.

Brassica/Cole
For the brassica/cole crop group which includes broccoli, cabbage, cauliflower, and similar crops, EPA is proposing reducing the current maximum annual application rate from 0.266 lbs. AI/A to not exceed a rate of 0.23 lbs. AI/A annually for foliar applications only. This rate reduction is targeted at reducing potential risk to aquatic invertebrates and to align more with average annual rates.

Potential risk to aquatic invertebrates was noted for both foliar and soil applications of neonicotinoids from brassica/cole crop use, with comparative neonicotinoid RQs ranging up to 680 with the highest exceedances identified for foliar uses. In general, there are high benefits from the use of neonicotinoids in brassica. Dinotefuran's use on brassica/cole crops averages less than 10% of the crop treated, considerably less than imidacloprid and thiamethoxam. Average annual application rates of dinotefuran applied nationally to brassica/cole is approximately 0.222 lbs. AI/A/year, below the proposed new rate, but around 40% of the acres treated with dinotefuran are treated at rates of 0.210 lbs AI/A/year or more. This mitigation could preclude a grower from making a second application of dinotefuran; the applicator would have to use an alternative insecticide.

Fruiting Vegetables
For the fruiting vegetables crop group, EPA is proposing reducing the current maximum annual foliar application rate from 0.268 to 0.23 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 dinotefuran from fruiting vegetable use, with comparative neonicotinoid RQs up to 768. Benefits of neonicotinoid use are high, but dinotefuran's use on fruiting vegetables, with PCTs around 5 – 10%, is much lower than that of imidacloprid and thiamethoxam. The average annual rate for dinotefuran to fruiting vegetables is 0.25 lbs. AI/A, above the proposed new rate, and annual rates above 0.210 lbs. AI/A are observed on about 75% of the treated acreage. However, soil applications are used on some of these acres. This mitigation could preclude a grower from making a second application of dinotefuran; the applicator would have to use an alternative insecticide, but the number of acres affected, given the PCT, may be low.

Cotton
For cotton, EPA is proposing reducing the current maximum combined rate of 0.263 lbs. AI/A regardless of formulation type and reducing it to 0.19 lbs. AI/A applied annually. This mitigation is being proposed to address pollinator exceedances.

Potential risks from dinotefuran cotton foliar use was considered under the strongest category of evidence for pollinator exceedances. Foliar adult honeybee RQs reached 56 on an acute basis and 2900 on a chronic basis. Cotton is considered to be one of the major drivers of potential pollinator risk. To date, usage of dinotefuran on cotton has been sporadic; multiple applications in a year appear rare. With consideration of current usage, the reduction in the annual rate is unlikely to impact users.

Production/Commercial Ornamentals
For production/commercial ornamentals, EPA is proposing reducing the current maximum annual foliar and soil application rate from 0.54 lbs. AI/A to 0.40. 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 mitigation does not include indoor commercial nursery, greenhouse uses, Christmas trees, or forestry use on public land and quarantine application by USDA.

Potential risks from dinotefuran use on ornamentals was included under the strongest category of evidence for pollinator exceedances. Residues exceeded the colony-level endpoint for periods of time ranging from 22 days (foliar applications) to 617 days (soil applications). In addition, multiple ecological incidents have been associated with dinotefuran applications to ornamental plants that span foliar and soil applications methods. Ornamentals are considered to be one of the major drivers of potential pollinator and aquatic invertebrate risk. Benefits are considered to be high for this use of dinotefuran as data showed that an average of 139,000 lbs. are applied annually. Other than the available 2014 AgInfomatics report and review, usage data was limited. This rate reduction is considered to potentially have moderate impacts on usage.

3. Crop Stage Restrictions

As noted in section III.B.1., 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 showing residues of neonicotinoids in pollen and nectar over time. Through this analysis the agency calculated pre-bloom intervals to determine at what stage in the growing season risk exceedances went above the level of concern. By selecting application restrictions based on crop stage, the agency expects potential exposure can be significantly reduced. These proposed restrictions were preferable only in crops with distinct phenological stages which were easily identifiable by growers.

Table 2. Proposed Crop Stage Restrictions for Dinotefuran

Crop/Crop Group	Proposed Mitigation
Fruiting Vegetables	The agency 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. Additionally, for tomatoes, peppers, chili peppers and okra only, EPA is also proposing to not apply after 5 days after planting or transplanting regardless of application method.
Stone Fruit	The agency is proposing a crop stage restriction to prohibit application from bud break until after petal fall is complete and all petals have fallen off

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

Potential risk to pollinators was noted under the strongest evidence of risk for foliar uses of fruiting vegetables, and soil uses were listed under weakest evidence of risk. LOC exceedances for pollinators were identified with RQs up to 3800. Benefits of neonicotinoid use are high, but dinotefuran's use on fruiting vegetables, with PCTs about 5 – 7%, is much lower than that of imidacloprid and thiamethoxam.

Applications of neonicotinoids after crop emergence or transplanting account for around two-thirds of the treated acres of peppers and tomato acres. Dinotefuran targets season-long pests, particularly aphids and whitefly that vector viral diseases, which can seriously impact the development, quality and/or yield of the harvested fruit. The proposed restriction will preclude most of these applications and is likely to result in impacts on growers.

Stone Fruit
For stone fruit, EPA is proposing a crop stage restriction to prohibit application from bud break until after petal fall is complete and all petals have fallen off. Potential risk to pollinators was noted under the strongest evidence of risk for foliar pre-bloom uses on stone fruit crops, while soil uses were listed under weakest evidence of risk pre-bloom. There was low risk deemed to pollinators from post-bloom uses. Exceedances to pollinators were identified with RQs ranging up to 3900. EPA is targeting a 12-day pre-bloom interval to reduce potential exposure. Dinotefuran has limited overall usage on stone fruit, and the majority of this use applied post-bloom, therefore the proposed changes are not expected to significantly impact growers.

4. 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. Benefits were considered high for this use, 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.

5. Label Language Improvements

EPA is proposing several advisory label language changes intended to better inform applicators of pollinator risks and reduce pollinator exposures. 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.

6. 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 dinotefuran 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 dinotefuran.

The agency is proposing the following spray drift mitigation language be included on all dinotefuran 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 dinotefuran registrants to standardize all advisory language on dinotefuran 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 dinotefuran that can enter waterbodies from runoff, EPA is proposing a vegetative filter strip (VFS) requirement for all dinotefuran agricultural products of 10 feet. Currently some dinotefuran product labels have a 25 feet VFS requirement on labels, the proposed mitigation would reduce this requirement to 10 feet across all relevant 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 dinotefuran 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 dinotefuran. 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 Reduction Mitigation
Applications are currently prohibited during temperature inversions, therefore the requirement listed above does not represent a change in use directions. Requirements listed above for airblast applications are also consistent with current requirements.

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

- Do not apply when wind speeds exceed 10 mph at the application site. The boom length must be 75% or less of the wingspan or rotor diameter.
- 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.

There are no proposed changes for release height. Proposed changes will allow applications at higher wind speed, which will provide growers with greater flexibility to make applications in a timely manner. Further, at wind speeds of 10 mph or less, the boom length for helicopter is increased to 90 percent of the rotor diameter, which may necessitate fewer passes to complete an application, likely decreasing application costs. Currently, there are no requirements for swath displacement. The agency has not assessed the impacts of a ½ or ¾ swath displacement upwind at the downwind edge of the field. The agency invites comments if this mitigation would impact growers.

Current requirements for ground applications are:

- Do not apply when wind speeds exceed 10 mph at the application site.
- The release height must be no higher than 10 feet from the top of the crop canopy or ground

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

Droplet Size
The agency is considering establishing a mandatory droplet size of medium or coarser. 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. Systemic insecticides, like dinotefuran, control some insects regardless of droplet size due to the systemic movement within the plant. However, neonicotinoids, including dinotefuran, are valuable because they have immediate, contact activity, especially when applied to the foliage.

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

Buffers and Vegetative Filter Strips
Currently, a 25-foot VFS is required between the field edge and down gradient aquatic habitat to prevent runoff. The proposed requirement for would reduce the size of the VFS to 10 feet and require a 25-foot buffer from aquatic habitats for ground applications. Reducing the size of the VFS could reduce the costs growers incur to maintain the VFS and potentially increase the cultivated area of their fields, although they could not apply dinotefuran within the area previously part of the VFS due to the proposed buffer.

However, the new 150-foot buffer from aquatic habitats for aerial applications represents a substantial change that could impact usage of dinotefuran. Currently, aerial applications are used for nearly two-thirds of the area treated with dinotefuran and is particularly common in rice, lettuce, and *brassica* vegetables (MRD, 2013-2017).

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

Removing land from production can decrease revenue from lost crop area. EPA previously estimated impacts of lost productive lands from increasing vegetative filter strips for pyrethroids, which also restrict application near water bodies. Buffers do not need to be maintained like vegetative filter strips, but the value of lost cropped area is likely to be similar. For the earlier BEAD analysis, lost crop areas were presented for increases in lost area of 15 and 25 feet. However, the proposed buffer for aerial applications is 150 feet, an increase of 125 feet over the existing vegetative filter strip. Using the same method that was used for pyrethroids, the value of the potential lost crop area from the increased buffer can also be estimated. The estimated impacts disproportionally affect growers producing crops from small acreage fields, as a greater portion of the total field is lost to a buffer. For example, dinotefuran is widely used on various vegetable crops such as tomato. The median size tomato field is 5.4 acres, and if that field is assumed to be rectangular with a waterbody along the long side, the lost crop value is estimated to be $1,748 per acre for the increase in lost cropped area of 125 feet. The impacts are greater for smaller fields. Ten percent of tomato fields are 0.2 acres or smaller and a 150-foot buffer would preclude use of dinotefuran if the field were adjacent to a water body. Aerial applications are particularly common on brassica crops. For broccoli, the median field size is 7.4 acres, and if the aerial buffer meant production would be lost, the estimated revenue loss would be equivalent to $1,985 per acre. For crops with lower revenue per acre or grown on larger fields, the estimated loss per acre is lower, however impacts as a proportion of grower income may be similar or even greater. The crop with the highest area treated with dinotefuran is rice, and the median field size is 38.4 acres. The estimated cost, in terms of foregone production, of a 125-foot increase in the buffer over the existing VFS in that field is equivalent to $112 per acre.

Instead of taking land out of production, a grower could switch to a different chemical that does not have a buffer requirement, accept pest damage in the buffered areas, or apply an alternative to only those areas of the field that is within the buffer.

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 dinotefuran 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 dinotefuran 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 for residential and commercial use sites, in particular the definition of ‘spot treatment’. In general, however, the agency considers these measures consistent with application practices. The agency invites comments if this mitigation would impact applicators.

In addition to including the following spray drift restrictions on dinotefuran labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all dinotefuran 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.

7. 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 dinotefuran, 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 updating product labels to ensure pesticides continue to meet the safety standard, EPA's registration review for the N-nitroguanidine neonicotinoids 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[18].

As highlighted by several of the proposed mandatory and advisory label statements outlined in section IV.A.1, users should not apply neonicotinoids when bees and other pollinators are actively foraging on pollinator-attractive plants during bloom; 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[19].

As highlighted in section III.B.1, treated seed is most likely to become available to birds and mammals through accidental spills, excess unplanted seed on the edges of the field, shallow planted seed, and the improper disposal of treated seed. An effective method to reduce exposure would be encouraging growers to take additional care when planting treated seed to ensure any exposed seed is retrieved. While the EPA is proposing advisory language for covering seeds and cleaning up spillage, the American Seed Trade Organization has also published a guide[20] 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.

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

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 conversion to updated crop groups for several crop groups, updates for consistency with the EPA's policy on trailing zeros, and harmonization of certain tolerances with Codex Maximum Residue Limits (MRLs); there are no MRLs established in Canada and Mexico for dinotefuran. Tolerances are proposed to be revoked for vegetable leafy (except *Brassica*) group 4, *Brassica* leafy greens subgroup 5B, *Brassica* head and stem subgroup 5A, and vegetable fruiting group 8. Tolerances are proposed to be established for leafy greens subgroup 4-16A, leaf petiole vegetable subgroup 22B, *Brassica* leafy greens subgroup 4-16B, vegetable head and stem *Brassica* group 5-16, and vegetable fruiting group 8-10. For more details, all proposed tolerance revisions for dinotefuran are listed in Section III.A.3. The agency will use its FFDCA rulemaking authority to undertake needed tolerance 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 or their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of dinotefuran, 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 dinotefuran. The agency's final registration review decision for dinotefuran 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 dinotefuran 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 dinotefuran 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 dinotefuran. However, a final decision for dinotefuran may be issued without the agency having previously issued an interim decision. A final decision on the dinotefuran 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 dinotefuran registrants must submit amended labels that include the label changes described in Appendices A – D. 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 Dinotefuran

Registration Review Case#: 7441 PC Code: 044312 Chemical Type: insecticide Chemical Family: Neonicotinoids [Mode or Mechanism (for herbicides)] of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
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
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

Appendix B: Proposed Labeling Changes for Dinotefuran Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Dinotefuran Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>Technical Products</td><td></td></tr>
<tr><td>Foliar spray and soil drench use on bulb vegetables</td><td>Delete foliar spray and soil drench use on bulb vegetables.</td><td>Directions for Use</td></tr>
<tr><td colspan="3">End Use Products</td></tr>
<tr><td>Mode/Mechanism of Action Group Number</td><td>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.

<table><tr><td>Dinotefuran</td><td>GROUP</td><td>4A</td><td>INSECTICIDE</td></tr></table></td><td>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.</td></tr>
<tr><td>Updated Gloves Statement</td><td>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.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</td></tr>
<tr><td>Resistance-management labeling statements for insecticides and acaricides</td><td>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</td><td>Directions for Use, prior to directions for specific crops</td></tr>
<tr><td>Additional Required Labelling Action
Applies to all products delivered via liquid spray applications</td><td>Remove information about volumetric mean diameter from all labels where such information currently appears.</td><td>Directions for Use</td></tr>
</table>

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

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
	6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as in case of a spill or equipment break-down."	
All outdoor foliar spray uses	Update the bee advisory box according to the following: https://www.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides	Follows directly after the Environmental Hazard statement
All outdoor foliar spray uses	For foliar spray application to crops under contract pollinator services: "Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless the following condition has been met. If an application must be made when managed bees are at the treatment site, the beekeeper providing the pollination services must be notified no less than 48 hours prior	Directions for use

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
	to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying.” For foliar spray application to crops not under contract pollinator services: “Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen off unless the application is made in response to a public health emergency declared by appropriate State or Federal authorities.”	
All outdoor foliar spray uses	“Do not apply by ground within 25 feet, or by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.”	Directions for use
Brassica (cole) leafy vegetables, set maximum annual rate for foliar spray	Foliar spray only: maximum annual application rate is not to exceed 0.23 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 0.23 lbs. AI/A/yr	Directions for use
Fruiting vegetables, set maximum annual rate for foliar spray, and add application timing restriction based on crop stage	Foliar spray only: maximum annual application rate is not to exceed 0.23 lbs. AI/A/yr For all outdoor uses: “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.”	Directions for use
Stone Fruit add application timing restriction based on crop stage	“Do not apply from bud break until after petal fall is complete and all petals have fallen off.”	Directions for use
Cotton set maximum annual rate	Regardless of application method, apply no more than 0.19 lbs. active ingredient per acre per year, including soil drench and foliar sprays.	Directions for use
For 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 Dinotefuran Products	Placement on Label
	Only apply products containing dinotefuran 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
Production/Commercial 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 0.40 lbs. AI/A/yr	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:	Directions for Use

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
	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.”	
For 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
For 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
Spot treatment guidance statement	“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 (2 ft. 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.	Directions for Use, in a box titled “Spray Drift Management” under the heading “Aerial Applications”

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
	• 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."	
Spray Drift Management Application Restrictions for products that allow airblast applications	**"SPRAY DRIFT** **Airblast applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift Management" under the heading "Airblast Applications"
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications	**"SPRAY DRIFT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. Do not apply during temperature inversions."	Directions for Use, in a box titled "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	**"SPRAY DRIFT** **Boomless Ground Applications:** • Applicators are required to use a medium or coarser droplet size (ASABE S572.1) for all applications. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift Management" under the heading "Boomless Applications"

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
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. **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**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Dinotefuran Products	Placement on Label
	Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
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"

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[21]. 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 dinotefuran 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 dinotefuran. 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 dinotefuran as part of completing this registration review.

[21] 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 dinotefuran, 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), dinotefuran 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,[22] 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. Dinotefuran 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.[23]

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

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