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Acetamiprid

Proposed Interim Registration Review Decision
Case Number 7617

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Approved by: _____
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Table of Contents

I. INTRODUCTION 4
A. Summary of Acetamiprid Registration Review 5
B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses . 6
II. USE AND USAGE 8
III. SCIENTIFIC ASSESSMENTS 9
A. Human Health Risks 9
1. Risk Summary and Characterization 10
2. Human Incidents and Epidemiology 11
3. Tolerances 11
4. Human Health Data Needs 12
B. Ecological Risks 12
1. Risk Summary and Characterization 13
2. Ecological Incidents 16
3. Ecological and Environmental Fate Data Needs 17
C. Benefits Assessment 17
IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION 18
A. Proposed Risk Mitigation and Regulatory Rationale 18
1. Proposed Addition of PPE for Basal Bark Treatments in Landscape Uses 18
2. Updated Gloves Statement 19
3. Proposed Addition of Best Management Practices Language for Handling and Adding Water-Soluble Packets to Spray Tanks 19
4. Advisory Statements for Acetamiprid Seed Treatment Uses 19
5. Environmental Hazard Statement for Pollinators 20
6. Spray Drift Management 20
7. Proposed Spray Drift Buffers 22
8. Pesticide Resistance Management 23
B. Tolerance Actions 23
C. Proposed Interim Registration Review Decision 24
D. Data Requirements 24
V. NEXT STEPS AND TIMELINE 24
A. Proposed Interim Registration Review Decision 24
B. Implementation of Mitigation Measures 24
Appendix A: Summary of Proposed Actions for Acetamiprid 26

Appendix B: Proposed Labeling Changes for Acetamiprid Products 27
Appendix C: Endangered Species Assessment..... 33
Appendix D: Endocrine Disruptor Screening Program 34

ED_006569K_00002215-00003

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the agency) Proposed Interim Registration Review Decision (PID) for acetamiprid (PC Code 099050, case 7617), 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 acetamiprid, can be found in EPA's public docket (EPA-HQ-OPP-2012-0329) 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.

EPA is issuing a PID for acetamiprid 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. Therefore, although 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 acetamiprid prior to completing the acetamiprid registration review. Likewise, the agency will complete endocrine screening for acetamiprid, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the acetamiprid registration review.

Acetamiprid is a neonicotinoid insecticide with products registered for use to control a variety of sucking and chewing insect pests. It is a chloropyridinyl neonicotinoid, distinct from the nitroguanidine neonicotinoids (imidacloprid, clothianidin, dinotefuran, and thiamethoxam),

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which are subjects of separate PIDs. All neonicotinoids function by binding to nicotinic acetylcholine receptors in the post-synaptic neurons of an insect's central nervous system.

The first product containing acetamiprid was registered in 2002. Acetamiprid did not undergo reregistration, as the first product containing acetamiprid was registered after November 1984. Formulations include liquid, wettable powder (WP), wettable powder in soluble packets (WSP), soluble granule (SG) or dry flowable (DF) products, baits and sticky traps, impregnated materials, and ready-to-use products. Products containing acetamiprid are registered for use on a variety of agricultural crops and crop seeds, and in livestock premises. Acetamiprid products may also be used in residential, institutional, public, commercial, and industrial settings.

This document is organized in five sections: *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why acetamiprid is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for EPA's proposed interim registration review decision; and, lastly, *Next Steps and Timeline* for completion of this registration review.

A. Summary of Acetamiprid Registration Review

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

- September 2012 - The *Acetamiprid Preliminary Work Plan* (PWP), *Acetamiprid. Human Health Assessment Scoping Document in Support of the Registration Review*, and *Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Acetamiprid* were posted to the docket for a 60-day public comment period.

- March 2013 - The *Final Work Plan* (FWP) for acetamiprid was issued. Stakeholders submitted five public comments on the PWP, none of which changed the schedule, risk assessment needs, or anticipated data needs for acetamiprid.

- May 2013 - A Generic Data Call-In (GDCI) for acetamiprid was issued for data needed to conduct the registration review risk assessments. All the requested data were submitted, and the GDCI is satisfied.

- February 2018 - The agency announced the availability of the *Acetamiprid. Draft Human Health Risk Assessment for Registration Review* and the *Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment for Acetamiprid* for a 60-day public comment period. This comment period was later extended by an additional 30 days based on comments from technical registrants (see the Summary of Public

Comments on the Draft Risk Assessments and Agency Responses section, below, for more information). The EPA received ten public comments from nine sources, including the technical registrants, a crop council, public agencies, researchers, and environmental interest groups. These comments and the agency's responses are summarized below. Comments submitted by one of the technical registrants, Nippon Soda Co, Ltd, and supported by the other technical registrant, GeneraTec LLC, provided the agency with data to refine its human health risk assessment. These data changed the Margin of Exposure (MOE) for two application scenarios. See section III of this document for details.

- January 2020 - The agency is now announcing the availability of the PID in the docket for acetamiprid, for a 60-day public comment period. Along with the PID the following documents are also posted to the acetamiprid docket:
    - *Response to Public Comments on the Acetamiprid Draft Risk Assessment for Registration Review* (dated 12/4/19);
    - *Response to Public Comments and Update to the Preliminary Environmental Fate and Ecological Risk Assessment (PRA) for Acetamiprid* (dated 10/30/19); and
    - *Acetamiprid: BEAD Benefit Assessment and Response to Public Comments in Support of Registration Review* (dated 1/15/20)

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

The public comment period for the *Acetamiprid. Draft Human Health Risk Assessment for Registration Review* and the *Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment for Acetamiprid* was extended from the standard 60 days by an additional 30 days, to a total of 90 days after the agency received public comment from the technical registrants requesting the extension so that they might prepare additional data to support the acetamiprid registration review. During the public comment period, which opened on February 27, 2018 and closed on June 29, 2018, the agency received public comments from nine sources. Comments were submitted by the two technical registrants of acetamiprid, Nippon Soda Co., Ltd. and GeneraTec, LLC. The agency also received comments from The Northwest Horticultural Council, the California Specialty Crops Council, the National Cotton Council, the Central Valley Regional Water Quality Control Board, the US Department of Agriculture's (USDA) Office of Pest Management Policy, a researcher of the Michigan State University, and the Center for Biological Diversity (CBD). Substantive comments, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below. The agency thanks all commenters for their comments and has considered them in developing this PID.

Comments Submitted by the Northwest Horticultural Council in EPA-HQ-OPP-2012-0329-0048, Michigan State University in EPA-HQ-OPP-2012-0329-0045, the California Specialty Crops Council in EPA-HQ-OPP-0329-0046, the USDA's Office of Pest Management Policy in EPA-HQ-OPP-2012-0329-0047, and the National Cotton Council in EPA-HQ-OPP-2010-0329-0049

Comment: These commenters highlighted the uses and benefits of acetamiprid and of all neonicotinoid pesticides. They stressed that acetamiprid is effective against a diversity of insect pests, including species which have been particularly damaging to crops. They also underscored the use of acetamiprid to control pests of specialty and high value crops. Commenters also stressed the relative safety of acetamiprid to workers and to beneficial insects and pollinator species, as compared to other pesticides, including in comparison to other neonicotinoid pesticides.

EPA Response: The agency thanks these groups and individuals for submitting comments. The agency considered these comments in the development of this PID. See *Acetamiprid: BEAD Benefit Assessment and Response to Public Comments in Support of Registration Review* for more information.

Comments Submitted by the Center for Biological Diversity in EPA-HQ-OPP-2012-0329-0031

Comment: CBD's comments focus on the EPA's duty to consult with the Services on the registration review of acetamiprid in accordance with the Endangered Species Act (ESA). The CBD comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the agency's preliminary determinations regarding the effects of acetamiprid on listed species and their designated critical habitat for the acetamiprid registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

EPA Response: The EPA has reviewed CBD's comments and plans to address many of the concerns regarding listed species as part of the implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. See *Endangered Species Assessment* in Appendix C of this document for more information. The EPA will address concerns specific to acetamiprid, particularly with regard to pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See *Endocrine Disruptor Screening Program* in Appendix D of this document for more information regarding endocrine disruption. The EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, the EPA released an interim process for public comment, available at regulations.gov in docket EPA-HQ-OPP-2017-0433. The comment period closed on October 24, 2019. After the agency has considered the public comments received on the proposed policy, and once the policy has been finalized, the EPA will consider its implications on the EPA's final decision for acetamiprid.

Comment Submitted by Nippon Soda Co., Ltd./Nisso America, Supported by GeneraTec LLC in EPA-HQ-OPP-2012-0329-0051

Comment: The two technical registrants of acetamiprid, Nippon Soda Co., Ltd. (or Nisso America) and GeneraTec LLC, submitted comments refuting assumptions and resulting conclusions in the agency's human health and ecological risks assessments for acetamiprid.

The registrants requested that the agency use data previously submitted to assess the risk to occupational handlers in greenhouses and revise the assessed risks to occupational handlers in landscape settings. The registrants stated that these data approximate landscape application scenarios better than the agency's default assumptions. The registrants also highlighted an error in a data summary table that appears in *Acetamiprid. Draft Human Health Risk Assessment for Registration Review*.

Additionally, the registrants questioned values presented in *Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment for Acetamiprid*, such as biotic metabolism half-life values and others. Nisso America also presented new data from studies assessing acute toxicity to larval honey bees (*Apis mellifera*). While the registrants recognized that the larval bee toxicity data result in risks of concern for bees where before there were none, the registrants believe that typical use patterns of acetamiprid are unlikely to adversely impact bees.

EPA Response: After using the submitted data to revise its assumptions, the agency in turn revised its risk estimates for occupational handlers of acetamiprid using backpacks to make basal bark drench applications with liquids and wettable powders. Although the agency's baseline assumptions of this scenario yielded worker risks of concern, the submitted data yielded acceptable risk estimates. See *Response to Public Comments on the Acetamiprid Draft Risk Assessment for Registration Review*, available in the public docket, and Section III. Scientific Assessments below for more details. EPA also acknowledges there was a typographical error in Table 9.1.1 of the *Acetamiprid. Draft Human Health Risk Assessment for Registration Review* but concludes that the correct values were used in its calculations, even if the data summary was recorded incorrectly.

The agency also responded to each of the registrant's comments on the values and assumptions underlying its environmental fate and ecological risk conclusions in the *Response to Public Comments and Update to the Preliminary Environmental Fate and Ecological Risk Assessment (PRA) for Acetamiprid*, available in the public docket. The agency corrected an error in the calculation of one aerobic soil metabolism half-life reported in the PRA. In this same document, the agency presented new risk conclusions for larval honey bees, based on the new toxicity data. As noted by the registrant, in some cases, the new data produced risks of concern that were not identified in the original document. See the aforementioned response to public comments document for more details.

II. USE AND USAGE

Acetamiprid is a neonicotinoid insecticide that has contact and systemic activity used to control a variety of insects, primarily piercing sucking pests, but also select lepidopteran and coleopteran species. Acetamiprid is registered for use on many crops, including grapes, apples, cotton, beans, soybeans, corn, berries, nuts, stone fruits, and potatoes. Seed treatment uses of acetamiprid

include canola, mustard, and potato seed pieces. Registered non-agricultural sites include indoor and outdoor residential settings. It is also registered for use in institutional, public, commercial (including food handling establishments), industrial, and animal/livestock settings. In agricultural settings, acetamiprid products are applied to leaves, seeds, and soils, as well as directly to insect nests, such as ant nests. In the home they may be applied to surfaces or used in bait traps or dispensed as an aerosol, for treatment of household pests, such as bedbugs, for control of ticks and fleas on dogs, and in landscaping. Formulations include liquid, wettable powder, wettable powder in soluble packets, soluble granule or dry flowable products, baits and sticky traps, impregnated materials, and ready-to-use products. Acetamiprid may be applied by aircraft, groundboom, airblast equipment, backpack, and pressurized handwand.

Between 2014 and 2018, approximately 80,000 pounds (lbs) of acetamiprid were used to treat over 850,000 acres (A), with average annual application rates ranging from 0.04 lbs to 0.16 pounds active ingredient per acre (lbs a.i./A). During this period, crops with the highest usage in terms of average pounds applied were apple (25,000 lbs), walnut (15,000 lbs), and cotton (10,000 lbs). The greatest percent crop treated (PCT) values were reported for apple (40%), celery (40%), and strawberries (40%).

The agency has limited usage data on non-agricultural use sites. In 2016, over 10,000 lbs of acetamiprid were reported to have been used by pest management professionals (*i.e.*, applicators who typically apply pesticides to turf and ornamental plants, including in residential areas)[1]. Nursery and floriculture data from 2009 suggest that acetamiprid was used in 20% or more of businesses in this sector among surveyed states; the median application rate was 0.131 lb a.i./A. More recent data for this sector are unavailable. At the state-level, California reported that from 2013 to 2017, on average, less than 1,000 lbs. of acetamiprid were applied in nursery and greenhouse sites[1].

More details are available in *Acetamiprid: BEAD Benefit Assessment and Response to Public Comments in Support of Registration Review* and *Acetamiprid (099050) Screening Level Usage Analysis (SLUA), July 15, 2019.*

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 acetamiprid. For additional details on the human health assessment for acetamiprid, see the *Acetamiprid. Draft Human Health Risk Assessment for Registration Review* (or DRA), which is available in the public docket.

[1] *Non-agricultural Market Research Data (NMRD), 2017. Data on consumer and professional pest control markets collected and sold by a private market research firm.*

1. Risk Summary and Characterization

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

No risks of concern were identified for dietary, residential, aggregate, bystander, or occupational post-application exposures. Both acute and chronic estimated dietary risks were below 100% of the population adjusted dose and thus not of concern. Acetamiprid is classified as "not likely to be carcinogenic in humans."

In all residential handler exposure scenarios, the combined estimates of the exposure and toxicity, or margin of exposure (MOE), was greater than the level of concern (LOC), so there are no residential handler exposure risks of concern. The same is true of all residential post-application exposure scenarios. An assessment of the exposure to acetamiprid via spray drift also did not identify any risks of concern. In accordance with the FQPA, the agency aggregated pesticide exposure and risk from three major categories (*i.e.*, food, drinking water, and residential exposure), and there are no aggregate risks of concern. Finally, there are no occupational post-application risks of concern. Based on the acute toxicity of acetamiprid, the restricted entry interval (REI) of 12 hours is adequate to protect agricultural workers from post-application risks.

Occupational Handler Risks

Nearly all the exposure scenarios for those working with acetamiprid yield risk estimates that are not of concern. Assuming baseline clothing (single layer of clothing, including long sleeves and pants, without chemical resistant gloves), the MOEs for combined dermal and inhalation exposure scenarios for occupational handlers ranged from 170 to 700,000. Occupational handlers applying pet spot-on treatments do not have dermal risks of concern (MOEs=120 to 1,200). In all scenarios, the LOC is 100.

In the human health DRA, there were two occupational exposure scenarios that resulted in risks of concern, assuming baseline attire (single layer clothing; *i.e.,* long pants, long sleeves, and socks and shoes):

- Mixing, loading, and applying liquid and wettable powder formulations to the basal bark of landscaping, trees/shrubs/bushes using backpacks, where the MOE was 20 (LOC=100); and,
- Mixing, loading, and applying liquid and wettable powder formulations to the basal bark of landscaping, trees/shrubs/bushes using manually-pressurized handwands. For this scenario, the MOE is 11 (LOC=100); however, with the addition of gloves, the MOE is 1,600.

Even with the addition of double layer and gloves, there were still risks of concern with the backpack scenarios (MOE=65; LOC=100). During the public comment period for *Acetamiprid. Draft Human Health Risk Assessment for Registration Review,* the registrant requested review of a monograph (MRID# 436232) produced by the Agricultural Handlers Exposure Task Force (AHETF) for backpack sprayer exposure from liquid formulation applications (BP-L) to foliage.

This monograph had previously been used to better model exposure to occupational handlers in greenhouse setting; however, the registrant argued that it is also applicable to modeling exposure to occupational handlers in landscape settings. The agency reviewed and incorporated the data into its assessment of landscape handler risks (see *Response to Public Comments on the Acetamiprid Draft Risk Assessment for Registration Review* for details). As a result, the MOE was updated to 150 (LOC=100) for occupational handlers making basal bark treatments with acetamiprid using backpacks, with double layer clothing and chemical resistant gloves.

While potential risks of concern were identified for the handwand scenarios, these risks are mitigated by gloves (MOE=1,600; LOC=100). All acetamiprid products registered for use on ornamental trees/shrubs/bushes, including in landscape settings, currently require the use of gloves; therefore, potential for risk is considered mitigated and these scenarios will not be explored further in this document.

2. Human Incidents and Epidemiology

The current Incident Data System (IDS) analysis from January 1, 2012 to April 28, 2017, shows 24 incidents reported in the Main IDS involving acetamiprid as a single active ingredient and 35 cases involving multiple active ingredients and 117 incidents reported to Aggregate IDS. A query of the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides Database over the period 1998-2013 showed that acetamiprid was involved in 43 cases, primarily agricultural in nature.

On September 19, 2019, an incident was reported that alleges that a bus traveling on a highway at 10:30 p.m. was exposed to drift from a nighttime airblast application of acetamiprid (product registration 8033-23-70506) to a citrus orchard. Twenty-nine persons were potentially exposed, with eight reporting itchy and watery eyes. This incident was reported after the search of the incident databases described above and so was not returned in the results of that search, nor was it reported in the *Acetamiprid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment* available in the public docket.

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

3. Tolerances

The tolerances for residues of acetamiprid are listed in 40 CFR §180.578(a), 180.436 (b) and (c), including its metabolites and degradates, for plants and livestock commodities, and for residues resulting from applications made in food handling establishments. EPA is proposing tolerance actions to reflect changes to crop groups, as summarized in Table 1: Summary of Proposed Tolerance Actions below. The acetamiprid human health risk assessment recommended changes to various tolerance levels to conform with the agency's rounding practice (*i.e.*, adding a trailing zero) at that time. Since the risk assessment was issued, the agency has decided to follow the Organization for Economic Cooperation and Development (OECD) rounding class practice, which does not recommend adding a trailing zero. The agency anticipates the following changes

to the tolerances for acetamiprid. The agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Table 1: Summary of Proposed Tolerance Actions

Acetamiprid 40 CFR § 180.578: Summary of Proposed Tolerance Actions			
Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Brassica, head and stem, group 5-16	None	1.2	Update crop group tolerance
Brassica, leafy greens, subgroup 4-16B	None	15	Update crop group tolerance
Fruit, stone, group 12-12, except plum, prune	None	1.2	Update crop group tolerance
Leafy greens, subgroup 4-16A	None	3	Update crop group tolerance
Stalk, stem, and leaf petiole vegetable subgroup 22B	None	3	New crop subgroup tolerance
Nut, tree, group 14-12	None	0.1	Updated crop group tolerance
Celtuce	None	3	Now in subgroup 22A (no subgroup tolerance)
Fennel, Florence	None	3	Now in subgroup 22A (no subgroup tolerance)
Kohlrabi	None	1.2	Now in subgroup 22A (no subgroup tolerance)
Brassica head and stem, subgroup 5A	1.2	None	Revoke tolerance with update to crop group
Brassica, leafy greens, subgroup 5B	15	None	Revoke tolerance with update to crop group
Fruit, stone, group 12-12, except plum, prune	1.20	None	Revoke tolerance with update to crop group
Vegetable, leafy, except Brassica, group 4	3.00	None	Revoke tolerance with update to crop group
Nut, tree, group 14	0.10	None	Revoke tolerance with update to crop group
Pistachio	0.10	None	Revoke tolerance with update to crop group

4. Human Health Data Needs

The agency does not anticipate any further human health data needs for the acetamiprid 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 acetamiprid. For additional details on the ecological assessment for acetamiprid, see the *Preliminary Environmental Fate and Ecological Risk Assessment in Support of the Registration Review of Acetamiprid* (or RDA), which can be found in EPA's public docket (EPA-HQ-OPP-2012-0329) at www.regulations.gov.

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 acetamiprid. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

Terrestrial Risks

Mammals

Acetamiprid is highly toxic to mammals on an acute oral exposure basis, based on a 14-day LD_{50} (lethal dose to 50% of the test subjects) of 149 mg a.i./kg bw (where bw=bodyweight) in rats. The chronic toxicity endpoint (the no observed adverse effect concentration, or NOAEC=160 mg a.i./kg diet) is based on reduced body weight and reduced body weight gains.

While there are no acute (Level of Concern or LOC=0.5) or chronic (LOC=1.0) risks of concern from foliar applications of acetamiprid, there are both acute and chronic risks of concern from consumption of acetamiprid-treated seeds. The maximum acute seed treatment risk quotient (RQ) is 2.65 and the maximum chronic RQ is 48.31. (RQs greater than the established LOC represent potential risks of concern for a given exposure scenario). For context, a small mammal (weighing approximately 15 g) would receive an acutely lethal dose of acetamiprid after ingesting 214 treated canola seeds, or 30% of its diet over a foraging area of 2.53% of its home range. Similarly, a small mammal would reach the chronic LOC after consuming 107 acetamiprid-treated canola seeds, representing 15% of its diet.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Acetamiprid is very highly toxic to passerine species—*e.g.*, zebra finch (*Taeniopygia guttata*)—and moderately toxic to larger birds—*e.g.*, mallard duck (*Anas platyrhynchos*)—on an acute oral exposure basis. The 14-day LD_{50} is 5.68 mg a.i./kg bw in zebra finches and 84.4 mg a.i./kg bw in mallard ducks. The chronic toxicity endpoint (NOEAC=99 mg a.i./kg diet) is based on reduced number of eggs laid and hatched.

There are both acute (LOC=0.5) and chronic (LOC=1.0) risks of concerns to birds from both foliar applications and seed treatments with acetamiprid. From foliar applications, the maximum acute RQ is 23.51 and the maximum chronic RQ is 1.26. For seed treatments, the maximum acute RQ is 167.83 and the maximum chronic RQ is 40.49. For context, a passerine bird would receive an acutely lethal dose of acetamiprid after ingesting as few as 5.4 acetamiprid-treated seeds, or 0.5% of its diet over a foraging area of 0.06% of its home range. Similarly, a passerine bird would reach the chronic LOC after consuming 88 acetamiprid-treated canola seeds, representing 7.8% of its diet and approximately 1% of its home range.

Terrestrial Invertebrates (honey bees)

Since the publication of the PRA, the agency has revised the toxicity estimates and resulting RQs for larval bees upwards by approximately an order of magnitude. For more information on revisions to the PRA, see the *Response to Public Comments and Update to the Preliminary*

Environmental Fate and Ecological Risk Assessment (PRA) for Acetamiprid available in the public docket. The information presented below reflects these updated estimates. The toxicity and resulting RQs for adult bees remain unchanged since the PRA.

Honey bees may be exposed to acetamiprid through ingestion of residues in nectar and pollen foraged from treated plants, contact with pesticide residues on plants treated with foliar applications, and direct contact via spray drift. Acetamiprid is classified as moderately toxic to adult bees and highly toxic to larvae on an acute exposure basis. For adult bees, the acute contact LD_{50} is 10.53 µg a.i./bee and the acute oral LD_{50} is 8.96 µg a.i./bee. For larvae, the acute oral LD_{50} was 1.16 µg a.i./larva. The chronic endpoint for bees (the no observed adverse effects level, or NOAEL=0.12 µg a.i./bee/day) is based on a decrease in larval survival.

There are acute (LOC=0.4) and chronic (LOC=1.0) risks of concern to adults and larvae from registered uses of acetamiprid. For adult bees, the maximum acute RQ is 1.86 and the maximum chronic RQ is 6.90. For larvae, the maximum acute RQ is 6.59 and the maximum chronic RQ is 63.7.

Measured residue data suggest that the actual residues of acetamiprid on treated plants may be up to 99% lower than the estimated environmental concentrations (EECs) used to generate RQs. Moreover, though there are risks of concern to individual honey bees, which serve as a surrogate for non-*Apis* bees, colony-level studies show that these risks are not likely to translate into long-term adverse effects on the colony. These studies indicate that adverse effects of acetamiprid are likely transitory and so will probably not pose long-term risks to colony health. However, there are 37 reported incidents associated with the use of acetamiprid involving honey bees, with the numbers of colonies affected per incident ranging from 9 to 12,000. The majority (76%) of the bee-related incidents occurred in Canada. Of the eight incidents that occurred inside of the U.S., six were classified as either "unlikely" or were the result of illegal use of acetamiprid.

Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although the EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for acetamiprid, the problem formulation and registration review DCI for acetamiprid were both issued prior to the EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[2]. This 2014 guidance lists additional pollinator studies that were not included in the acetamiprid registration review DCI. Therefore, the EPA is currently determining whether additional pollinator data are needed for acetamiprid. If the agency determines that additional pollinator exposure and effects data are necessary, then the EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 1: Potential Pollinator Data Requirements below.

Table 1: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees

[2] Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Guideline #	Study
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline	Honey bee adult chronic oral toxicity
Non-Guideline	Honey bee larvae chronic oral toxicity
Tier 2[†]	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3[†]	
850.3040	Full-Field testing for pollinators

[†] The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

Terrestrial Plants

Non-target terrestrial plants may be exposed to acetamiprid via runoff and drift from foliar application sites. Terrestrial plant toxicity studies with acetamiprid resulted in reductions in shoot length in both monocotyledonous (monocots) and dicotyledonous (dicots) plants and reductions in plant weight in monocots. The EC_{25} (the dose at which 25% of the test subjects show adverse effects) for monocot seedling emergence was 0.23 lb a.i./A. The EC_{25} for dicot seedling emergence was 0.16 lb a.i./A. The EC_{25} for monocot vegetative vigor was 0.46 lb a.i./A. The EC_{25} for dicot vegetative vigor was 0.0056 lb a.i./A. There are risks of concern (LOC=1.0) for monocots for both aerial (RQ values up to 1.24) and for ground applications (RQ values up to 1.15). For dicot, there are risks of concern following aerial (RQ values up to 4.64) and ground applications (RQ values up to 1.66).

Aquatic Risks

Freshwater and Estuarine/Marine Fish

Acetamiprid is practically non-toxic to freshwater (96-hr LC_{50}>100 mg a.i./L; 96-hr LC_{50} is the concentration of a.i. in which half of the test subject are immobilized after 96 hours) and slightly toxic to estuarine/marine fish (96-hr LC_{50}=100 mg a.i./L) on an acute exposure basis. The chronic toxicity endpoint for freshwater fish (NOAEC=19.2 mg a.i./L) is based on reduced growth. Chronic toxicity data are not available for estuarine/marine fish.

There are no acute risks of concern (LOC=0.5) for freshwater or estuarine/marine fish. Since freshwater fish serve as surrogates for aquatic-phase amphibians, there are no risks of concern for this taxon as well. There are no chronic risks (LOC=1.0) of concern for freshwater fish; however, chronic risks to estuarine/marine fish were not calculated due to the absence of data. Overall, the likelihood of adverse effects to aquatic vertebrates is considered low, given the available data; therefore, the agency is not requiring chronic toxicity data for estuarine/marine fish at this time.

Freshwater and Estuarine/Marine Invertebrates

Since the publication of the PRA, the agency has revised the toxicity estimates and resulting RQs for freshwater invertebrates upwards by approximately an order of magnitude. For more information on revisions to the PRA, see the *Response to Public Comments and Update to the Preliminary Environmental Fate and Ecological Risk Assessment (PRA) for Acetamiprid* available in the public docket. The information presented below reflects these updated estimates. The toxicity and resulting RQs for estuarine/marine invertebrates remain unchanged since the PRA.

Aquatic invertebrates may become exposed to acetamiprid through residues in runoff, flooding of treatment sites, and spray drift. Acetamiprid is very highly toxic to both freshwater and estuarine/marine invertebrates on an acute exposure basis. The 96-hr LC_{50} for freshwater invertebrates is 3.31 µg a.i./L. The 96-hr LC_{50} for estuarine/marine invertebrates is 66 µg a.i./L. The freshwater invertebrate chronic toxicity endpoint (NOAEC=0.36 µg a.i./L) is based on adult emergence and on the average number of days to emergence. The estuarine/marine invertebrate chronic toxicity endpoint (NOAEC=2.5 µg a.i./L) is based on reduced body weight in males.

There are both acute (LOC=0.5) and chronic (LOC=1.0) risks of concern to both freshwater and estuarine/marine invertebrates from registered uses of acetamiprid. For freshwater invertebrates, the maximum acute RQ is 10.2 and the maximum chronic RQ is 91.7. For estuarine/marine invertebrates, the maximum acute RQ is 0.57 and the maximum chronic RQ is 14.56.

Aquatic Vascular and Non-Vascular Plants

Toxicity studies showed no effects to the growth of both vascular and non-vascular aquatic plants up to the highest concentrations tested (1.1 mg a.i./L). The RQs for both vascular and non-vascular plants were lower than the LOC of 1.0; therefore, there are no risks of concern for aquatic plants from the currently registered uses of acetamiprid.

2. Ecological Incidents

A review of the Incident Data System (IDS) in October 2017 indicated 55 incidents involving adverse effects to terrestrial plants between 2004 and 2015. All 55 plant incidents were associated with the use of just two formulations of acetamiprid. The certainty code for all but two incidents was "possible", while the certainty code for the remaining two was "unlikely". These incidents suggest that there is potential for effects to occur to terrestrial plants from the current uses of acetamiprid.

Thirty-seven reported incidents in the IDS involved bees. Of these, six were assigned the "unlikely" certainty level, one was assigned "highly probable", and the remaining majority were characterized as "probable". Four incidents were not assigned a certainty level. Although bee kill incidents have been associated with the use of acetamiprid on cotton and apples, the incidents were listed as misuses.

One aquatic incident was reported after water used to extinguish a fire at an agrochemical warehouse later contaminated a river, killing 700 to 1,000 fish. A complete list of the chemicals present in the runoff is not known, but acetamiprid was present and the certainty level assigned was "possible".

The October 2017 IDS analysis of aggregated incident reports identified 78 aggregate incidents reported between October 1, 2004 and June 30, 2016. Seventy-four involved damage to plants, while four involved wildlife; however, the wildlife affected were not specified.

EPA will continue to monitor the incident information, and additional analysis will be conducted if ongoing ecological incident monitoring indicates a concern.

3. Ecological and Environmental Fate Data Needs

There are no data gaps related to the environmental fate database for the acetamiprid registration review at this time. The agency will consider calling in pollinator data as a separate action.

C. Benefits Assessment

Acetamiprid controls piercing/sucking insects, an assortment of lepidopterans, and some coleopterans pests in numerous agricultural crops. Such pests include aphids, whiteflies, oriental fruit moth, apple maggot, pear psylla, adelgid, borer and scale insects, flea beetle, certain flies, and wireworm. Acetamiprid reduces not only direct damage incurred by insect pests but also the spread of plant diseases by insect vectors. There are also applications of acetamiprid in residential pest control, such as for cockroaches and bedbugs.

Acetamiprid seed treatments in mustard and canola are primarily used to target flea beetles and wireworms. Flea beetle is a major economic concern in canola plantings with more than half of all canola acreage treated for this pest. Acetamiprid is a viable control method for these pests, but it is not the top option since most canola seed is preferentially treated with thiamethoxam.

In many crop systems (e.g., vegetables, fruits, and tree nuts), aphids, thrips, whiteflies, codling moth, and other insects targeted by acetamiprid not only cause direct yield loss but also vector important crop diseases (e.g., cucurbit yellow stunting disorder, mosaic viruses, yellow spot virus) that can result in high yield losses. Specifically, for vegetable crops like celery or leafy greens, insecticidal control is important because any visible scarring from insect feeding can result in downgrading or rejection of harvested crops.

In pome and stone fruits, acetamiprid functions as a broad-spectrum spray to control numerous pests simultaneously including codling moth, oriental fruit moth, apple maggot, pear psylla, aphids, and mealybugs. These insects can also cause yield loss via direct feeding or vectoring diseases, which may impact the quantity or quality of marketable fruit.

In strawberry production, acetamiprid is primarily used to target aphids, lygus bug, and thrips. These are some of the top insect pests targeted generally in strawberries because of the damage

they cause (e.g., direct feeding, vectoring diseases, etc.). Acetamiprid is one of the top two insecticide options, by acres treated, for aphids and thrips within strawberry production.

In walnut production, acetamiprid is primarily used to target walnut husk fly and codling moth, both of which attack the developing fruit on walnut trees which contains the nut within. These are the top two insect pests targeted in walnuts. In California (i.e., where almost all walnuts are produced), acetamiprid is the top recommended insecticide for control of walnut husk fly and the top choice for control of moderate populations of codling moth in walnut production. Based on usage data, acetamiprid is the second most used control option for walnut husk fly and a generally used option for codling moth.

For more information on the benefits of acetamiprid, see the *Acetamiprid: BEAD Benefit Assessment and Response to Public Comments in Support of Registration Review* available in the public docket.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

EPA has identified risks of concern to occupational handlers applying liquids and wettable powders as basal bark treatments using backpacks. EPA has also identified risks to mammals and birds that consume treated seeds, to birds from foliar applications, to terrestrial invertebrates from foliar applications, to aquatic invertebrates from foliar applications, and to terrestrial plants. To mitigate the risks to occupational handlers, EPA proposes updating personnel protective equipment (PPE) standards for certain applications of acetamiprid. To mitigate risks to birds, invertebrates and terrestrial plants, EPA proposes spray drift mitigation and buffer zones to limit the movement of acetamiprid. To mitigate risks to birds and mammals, EPA proposes standards for handling acetamiprid-treated seeds. The agency is also proposing updated gloves statements, insecticide resistance management language, an environmental hazard statement for pollinators, and best practices language for water soluble packaging.

1. Proposed Addition of PPE for Basal Bark Treatments in Landscape Uses

As discussed in Section III of this document, EPA found risks of concern for occupational mixer/loader/applicators of liquid and wettable powder formulations as basal bark treatments using backpacks in landscaping. Requiring these occupational handlers to wear double layer clothing and chemical-resistant gloves mitigates these risks of concern to acceptable levels. Therefore, EPA proposes PPE standards of gloves and double layer clothing for occupational handlers using backpacks in landscaping (trees, shrubs, and bushes).

EPA expects that this mitigation will have low impacts on most current users of acetamiprid. Backpack sprayer basal bark treatments of acetamiprid in forestry or residential settings are likely a minor component of pest control in these sites. Additionally, professional applicators will likely have the required PPE readily available, so cost increases are not likely. Nevertheless,

for the users of acetamiprid as a basal bark treatment, the use of additional PPE (i.e., wearing double layers or respirators when applying pesticides) can reduce their productivity because of the physiological stress when working in high temperatures and/or humid conditions.

2. Updated Gloves Statement

The agency is proposing to update the glove statement currently on labels to be consistent with the Label Review Manual[3]. The proposed new glove language does not fundamentally change the personal protective equipment that workers need to use, and therefore should impose no impacts on users.

Specifically, all statements that refer to the chemical resistance category selection chart are proposed to be removed from acetamiprid labels, as they might cause confusion for users. These statements are proposed to be replaced with specific chemical-resistant glove types.

3. Proposed Addition of Best Management Practices Language for Handling and Adding Water-Soluble Packets to Spray Tanks

For products formulated in water-soluble packaging, the agency proposes to incorporate up-to-date instructions for proper mixing and loading of water-soluble packets to ensure that packets are allowed to dissolve in water via mechanical agitation as intended and to prevent rupturing, as well as an up-to-date engineering controls statement.

4. Advisory Statements for Acetamiprid Seed Treatment Uses

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

To help mitigate these risks, EPA is proposing that all pesticide products that contain acetamiprid and are registered for seed treatment uses include the following advisory statements:

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

The purpose of these required advisory statements is to encourage the adoption of best management practices when handling and planting acetamiprid-treated seeds that will reduce the exposure of birds and mammals to treated seeds. Covering or collecting spilled seed and burying excess seed are all measures that will reduce the likelihood that animals will find and consume treated seeds. Disposing of excess seeds and equipment wash water away from water bodies, which tend to be gathering points for birds and mammals, decreases the chance of contaminating

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

those water bodies with neonicotinoid residues and the chance that animals will discover and consume treated seeds while visiting a body of water.

5. Environmental Hazard Statement for Pollinators

As discussed in Section III of this document, registered uses of acetamiprid poses potential risks to bees. Therefore, the agency proposes the following pollinator advisory language for all products with outdoor uses:

- "This product is moderately toxic to bees and other pollinating insects exposed to direct treatment, or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms."

6. Spray Drift Management

The agency 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 acetamiprid 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 acetamiprid.

The agency is proposing the following spray drift mitigation language be included on all acetamiprid 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 acetamiprid registrants to standardize all advisory language on acetamiprid 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)

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.
- 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.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- Specify spray droplet size of Medium or coarser (ASABE S572.1)

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

Impacts of Spray Drift and Runoff Mitigation

<u>Wind Speed, Boom Length/Swath Displacement, Release Height, and Temperature Inversions</u>

Current requirements for aerial applications are:

- Do not apply acetamiprid 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 of 10 feet from the top of target, unless a greater application height is required for pilot safety is advisory.
- Mandatory language prohibiting applications during temperature inversions.
- There are no requirements for swath displacement on current labels.

For aerial applications, proposed changes will allow applications of acetamiprid 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. There are no proposed changes for applications during inversions. The agency has not assessed the impacts of a ½ or ¾ swath displacement upwind at the downwind edge of the field or a 10-foot release height; however, the agency does not anticipate impacts as a result of a mandatory swath displacement or 10-foot release height as this corresponds to good application practices. The agency invites comments if this mitigation would impact growers.

Currently, there are no mandatory requirements for ground applications. 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

acetamiprid. The agency has been proposing wind speed restrictions and proposing prohibitions against applying during temperature inversions for several years in many decisions. Proposed mandatory windspeed requirements and prohibitions on applications during temperature inversions could result in delays to intended applications and, more generally, could reduce the amount of time users have to apply acetamiprid. Management of production activities may be more complex. Potentially, growers might switch to a different active ingredient that does not have this restriction, but that could be costly and potentially difficult in a short period of time. This could also lead to reduced yield and/or quality. Additionally, temperature inversions are more likely to occur a couple of hours before sunset and after sunrise, which is when applications may be timed to avoid spraying during windy hours of the day or when pollinators are active. This may complicate growers' ability to follow good stewardship programs.

Droplet Size

The agency is proposing a restriction on droplet size because coarser droplets have been demonstrated to decrease spray drift and therefore reduce potential risks to non-target species. Because chemical-specific data for the performance of droplet sizes is limited, the EPA was not able to evaluate the effects of Medium or coarser droplet sizes (as defined by ASABE S572.1) specifically for acetamiprid. Therefore, the EPA does not know the effect this requirement will have on the performance of acetamiprid across various use patterns. In general, the agency expects a droplet size requirement would not likely have a major impact in pest control scenarios where acetamiprid is valued for its systemicity in plants and residual control of target pest(s); however, acetamiprid also offers value to users for its contact activity which may be impacted by a droplet size requirement due to potential reductions in coverage and possibly efficacy in killing the target pest(s). In general, potential negative impacts to growers from requiring larger droplets could include reductions in efficacy, increased selection pressure for the evolution of insecticide resistance due to a decrease in lethal dose delivered to target insects, increased application rates used by growers, increased costs associated with reduced yield, more insecticide applications, purchase of alternative products, or an inability to use tank mix or premix products. The EPA encourages comments on any potential impacts to growers from specifying a mandatory minimum droplet size on product labels.

Requirements for Air Blast Sprayers

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

7. Proposed Spray Drift Buffers

In addition to the proposed spray drift mitigation measures above, the EPA is proposing buffers from waterbodies of 25 ft for ground application and 150 ft for aerial applications to limit the amount of spray drift that enters waterbodies. These proposed mitigation measures will establish a baseline level of protection for waterbodies against spray drift that is consistent across all

acetamiprid products. Reducing the overall amount of spray drift that reaches waterbodies will reduce the extent of environmental exposure and risk to aquatic organisms.

Currently, labels are silent on buffers to water bodies. Impacts could include yield losses in untreated portions of fields. If growing areas are adjacent to water bodies, buffers may require growers to leave a portion of the land dedicated to crops untreated, remove land from production, or apply another insecticide without this proposed requirement. The impact of this mitigation can be highly localized and may depend on the size and shape of a field. Leaving an area untreated in a field can harbor insects and vectored diseases and serve as a source of re-infestation and inoculum, requiring subsequent applications, thus increasing costs. Alternatively, a grower could switch to a different chemical that does not have a buffer requirement, at least along the edge of the field next to the water body. Potential alternatives are typically more expensive per acre than acetamiprid.

Aerial applications are common in crops such as cantaloupes, squash, lettuce, and cotton. The effect of buffers will be larger for crops that are typically grown in small fields, such as cucurbits, than on crops typically grown in larger fields, such as cotton. See *Acetamiprid: BEAD Benefit Assessment and Response to Public Comments in Support of Registration Review.*

8. 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 acetamiprid, 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. Tolerance Actions

The agency is proposing several crop group conversions/revisions, as well as typographical corrections to be consistent with agency rounding procedures. Refer to Section III.A.3 for

details. The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances.

C. 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), the agency has made the following Proposed Interim Registration Review Decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Sections IV. A and Appendices A and B.

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

D. Data Requirements

The agency does not anticipate calling in data for the acetamiprid registration review at this time. The EPA will consider requiring submission of pollinator data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for acetamiprid 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 acetamiprid. However, a final decision for acetamiprid may be issued without the agency having previously issued an interim decision. A final decision on the acetamiprid 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 acetamiprid registrants must submit amended labels that include the label changes described in Appendices A and B. The revised

labels must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Appendix A: Summary of Proposed Actions for Acetamiprid

Registration Review Case #: 7468
PC Code: 099050
Chemical Type: Insecticide
Chemical Family: Neonicotinoid
Mode of Action: Group 4: Nicotinic Acetylcholine Receptor Competitive Modulators

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Occupational Handlers	Backpacks for basal bark treatments	Dermal exposure	Short- and intermediate-term	Reproductive and neurotoxic effects	Addition of double layer clothing and gloves to PPE
Mammals and Birds, Reptiles, and Terrestrial-Phase Amphibians	Seed treatments	Dietary exposure	Acute and chronic	Acute toxicity and weight loss, behavioral changes, labored breathing, and reproductive effects	Require specific handling and management of treated seeds
Birds, Reptiles, and Terrestrial-Phase Amphibians	Foliar applications	Dietary and dermal exposures	Acute and chronic	Acute toxicity and reproductive effects	Spray drift and runoff mitigation language
Terrestrial Invertebrates (Pollinators)	Foliar treatments	Dietary exposure	Acute and chronic	Acute toxicity and increased mortality in adult and larval workers and drones	Environmental hazard statement on labels Spray drift and runoff mitigation language
Terrestrial Plants	Drift; runoff	Contact	Not applicable	Seedling emergence and vegetative vigor	Spray drift and runoff mitigation language
Aquatic Invertebrates	Foliar treatments; runoff	Dermal exposure	Acute and chronic	Acute toxicity and decreased size and reproductive effects	Spray drift and runoff mitigation language

Appendix B: Proposed Labeling Changes for Acetamiprid Products

Description	Proposed Label Language for Acetamiprid Products	Placement on Label
	End Use Products	
Mode of Action Group 4	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include 4A 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 (*i.e.*, **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE)** in the fourth column. **ACETAMIPRID** | **GROUP** | **4A** | **INSECTICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
For products with liquid or wettable powder formulations that allow basal bark application in landscape settings to trees, bushes, and shrubs by backpack	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. "Coverall worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, and waterproof or chemical-resistant gloves*." *The gloves statement should be consistent with Chapter 10 of the Label Review Manual.	In the Personal Protective Equipment (PPE) within the Precautionary Statements

Description	Proposed Label Language for Acetamiprid Products	Placement on Label
Environmental Hazard Statement for Pollinators	"This product is moderately toxic to bees and other pollinating insects exposed to direct treatment, or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms."	Environmental Hazards
Resistance-management labeling statements for insecticides/acaricides	Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use
Additional Required Labelling Action	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Directions for mixing/loading products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Water 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.	Directions for Use

Description	Proposed Label Language for Acetamiprid Products	Placement on Label
	5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as in case of a spill or equipment break-down.	
The following proposed label language applies to end-use products that have agricultural uses		
Mandatory Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1). • 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 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	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Aerial Applications"

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

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

Description	Proposed Label Language for Acetamiprid Products	Placement on Label
Advisory Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	**"SPRAY DRIFT ADVISORIES** **Boom-less Ground Applications:** Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Buffer zones to Water Bodies	Ground Application • "Do not apply by ground within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)." **Aerial Application** • "Do not apply by air within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."	Directions for use
Seed handling language for products that allow seed treatment	Add the following statements to labels to clean up spills, dispose of excess seed, and to avoid contamination of water bodies: • "Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)." • "Dispose of all excess treated seed by burying seed away from bodies of water." • "Do not contaminate bodies of water when disposing of planting equipment wash water."	Directions for use

Appendix C: Endangered Species Assessment

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

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

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

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for acetamiprid 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 acetamiprid. 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 acetamiprid as part of completing this registration review.

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, 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, 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 acetamiprid, 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 section 408(p), acetamiprid is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

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 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 section 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, 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[4] 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. Acetamiprid 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 our website.[5]

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

[5] http://www.epa.gov/endo/

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