



## Simazine

### Proposed Interim Registration Review Decision Case Number 0070

December 2019

Approved by: \_\_\_\_\_

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Date: \_\_\_\_\_ 12-18-2019 \_\_\_\_\_

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## I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Proposed Interim Registration Review Decision (PID) for simazine (PC Code 080807, case 0070), 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 simazine, can be found in the EPA's public docket (EPA-HQ-OPP-2013-0251) at [www.regulations.gov](http://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 simazine 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 (collectively referred to as, "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 federally-listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for simazine prior to completing the simazine registration review. Likewise, the agency will complete endocrine screening for simazine, 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 simazine registration review.

Simazine is an herbicide with products registered for use to control broadleaf and grassy weeds. Simazine is a member of the triazine chemical class (Class 5), which includes atrazine and propazine and the three major chloro metabolites: desethyl-s-atrazine (DEA), desisopropyl-s-atrazine (DIA), and diaminochlorotriazine (DACT). The EPA has determined that the triazines

and their three chlorinated metabolites share a common mechanism of toxicity, and as such, human health risks were assessed together through a triazine cumulative risk assessment. Pesticide products containing simazine are registered for use on several agricultural crops, most common of which are corn and citrus. Simazine products are also registered for several non-agricultural use sites, including residential and recreational settings. Common non-agricultural uses include turf, nurseries, greenhouse and ornamentals. The first product containing simazine was registered in 1958, and therefore simazine was subject to reregistration. There are three technical product registrants for simazine: Drexel Chemical Company, Oxon Italia, and Syngenta Crop Protection, LLC.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why simazine 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.

#### **A. Summary of Simazine Registration Review**

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

- June 2013- The following documents were posted to the docket for a 60-day public comment period
  - *Simazine Preliminary Work Plan (PWP)*
  - *Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment for Atrazine, Propazine, and Simazine*
  - *Human Health Risk Scoping Document in Support of Registration Review*
  - *Atrazine, Propazine, and Simazine: Review of Human Incidents*
  - *BEAD Chemical Profile for Registration Review: Simazine (080807) Screening Level Usage Analysis (SLUA)*
  - *PRD Label Data Report: Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning*
- January 2014 - The *Final Work Plan (FWP)*, for simazine was issued, 14 sets of public comments were received concerning the PWP. The comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.
- May 2014 - A Generic Data Call-In (GDCI) 080807-1384 for simazine was issued for data needed to conduct the registration review risk assessments. All data have been submitted and accepted.

- June 2016 - The agency announced the availability of the *Preliminary Ecological Risk Assessment for Simazine* for a 60-day public comment period. 119 comments were received as well as another 88 that were posted on the shared atrazine docket. These comments and the agency's responses are summarized below. The comments resulted in the correction of some minor errors, which are discussed in the *Simazine—Environmental Fate and Effects Division's Response to Public Comments* but did not impact the overall conclusions of the risk assessment.
- July 2018 – The agency announced the availability of the *Chlorotriazines: Cumulative Risk Assessment - Atrazine, Propazine, and Simazine* and *Simazine Human Health Risk Assessment for Registration Review to Support the Registration of Proposed Uses on Citrus Fruit (Crop Group 10-10), Pome Fruit (Crop Group 11-10), Stone Fruit (Crop Group 12/12), Tree Nuts (Crop Group 14-12), and tolerance Amendment for Almond Hulls* along with the supporting documents specified below. The comment period opened on July 23, 2018 and was extended until November 23, 2018. During that time sixteen public comments were received related to simazine.
  - *Chlorotriazines: Cumulative Risk Assessment - Atrazine, Propazine, and Simazine*
  - *Cumulative Triazine (Atrazine, Simazine, Propazine) Drinking Water Assessment*
  - *Chlorotriazines. Toxicology Systematic Literature Review- Atrazine, Simazine and Propazine.*
  - *Simazine Human Health Risk Assessment for Registration Review to Support the Registration of Proposed Uses on Citrus Fruit (Crop Group 10-10), Pome Fruit (Crop Group 11-10), Stone Fruit (Crop Group 12/12), Tree Nuts (Crop Group 14-12), and tolerance Amendment for Almond Hulls*
  - *Simazine Occupational and Residential Exposure and Risk Assessment for Registration Review and to Support the Registration of Proposed Uses Citrus Fruit (Crop Group 10-10), Pome Fruit (Crop Group 11-10), Stone Fruit (Crop Group 12-12), Tree Nuts (Crop Group 14-12), and Tolerance Amendment for Almond Hulls*
  - *Simazine. Acute 4-Day, Background, and Chronic Dietary (Food Only) Exposure and Risk Assessments for Registration Review*
- December 2018 - A Generic Data Call-In (GDCI) for simazine was issued for multiresidue data that was identified as a deficiency in the human health risk assessments. The required data are currently under development and due to be submitted to EPA by December 20, 2020. These data are not expected to impact the agency's ability to make a risk management finding.
- December 2019 - The agency has completed the PID for simazine. Soon EPA will announce the availability of the PID in the simazine docket and open a 60-day public comment period. Along with the PID, the following documents are also posted to the simazine docket: <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2013-0251>

- *Simazine—Environmental Fate and Effects Division's Response to Public Comments*. November 25, 2019.
- *Atrazine, Simazine, Propazine: Response to Public Comments on Registration Review Human Health Risk Assessments*. November 25, 2019.
- *Atrazine and Simazine Use on Sweet Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)*. November 25, 2019.
- *Atrazine and Simazine Use on Field Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)*. November 25, 2019.
- *Atrazine and Simazine Use in Forestry, Rights of Way, Turfgrass, and Nursery: Response to Comments, Usage, and Benefits*. November 25, 2019.
- *Simazine Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation on Orchards, Vineyards, Caneberries, Strawberries, and Christmas Trees*. November 25, 2019

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

During the 120-day public comment period for the *Preliminary Ecological Risk Assessment for Simazine*, which opened on June 6, 2016 and closed on October 5, 2016, the agency received public comments from 207 sources. The majority of these comments were part of a mass mailer campaign in support of continued registration of simazine, including 52 post cards sent by individual growers describing their use of simazine products. Other comments expressing support of continued registration of simazine came from industry, various non-government agencies and crop and agricultural associations. In addition, some individual comments supported discontinuing registration of the triazines collectively, including simazine.

During the public comment period for the *Simazine. Draft Human Health Risk Assessment for Registration Review* and the *Chlorotriazines: Cumulative Human Health Risk Assessment - Atrazine, Propazine, and Simazine*, which opened on July 26, 2018 and closed on November 23, 2018, the agency received public comments from sixteen sources. These sources included industry, various non-government agencies, and crop and agricultural associations, along with a few individual citizens. Most of the comments were in support of continued simazine registration but some, including the City of Sacramento Department of Utilities, were concerned about simazine detections in public drinking supplies.

Comments that were technical in nature and specific to the *Ecological Risk Assessment for Simazine* are addressed in the *Simazine—Environmental Fate and Effects Division's Response to Public Comments*.

Technical comments related to the *Simazine. Draft Human Health Risk Assessment for Registration Review* and the *Chlorotriazines: Cumulative Human Health Risk Assessment - Atrazine, Propazine, and Simazine* are addressed in the *Atrazine, Simazine, Propazine: Response to Public Comments on Registration Review Human Health Risk Assessments*.

Comments related to simazine use and usage, benefits, and potential impacts of mitigation are discussed in the following agency documents: (1) *Atrazine and Simazine Use on Sweet Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)*, (2) *Atrazine and Simazine Use on Field Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)*, (3) *Atrazine and Simazine Use in Forestry, Rights of Way, Turfgrass, and Nursery: Response to Comments, Usage, and Benefits*, and (4) *Simazine Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation on Orchards, Vineyards, Caneberries, Strawberries, and Christmas Trees*. These documents are available in the simazine registration review docket through [www.regulations.gov](http://www.regulations.gov) at docket identification number EPA-HQ-OPP-2013-0251. The agency thanks all commenters for their comments and has considered them in developing this PID.

**Comments Submitted by Center for Biological Diversity (CBD) (Docket ID: EPA-HQ-OPP-2013-0251-0103)**

**Comment:** CBD's comments focus on the EPA's duty to consult with the Services on the registration review of atrazine 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 the triazines (atrazine, simazine and propazine) on listed species and their designated critical habitat for the triazines 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 simazine 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. The EPA intends to release this policy for public comment. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's final decision for simazine.

## **II. USE AND USAGE**

Simazine is a selective herbicide that prevents grass and broadleaf weeds from emerging. Simazine products are registered for agricultural use sites such as caneberries, grapes, strawberries, citrus fruits, nut crops, pome fruits, stone fruits, artichokes, corn, asparagus, uncultivated agricultural areas, kale, cabbage, kohlrabi, Brussel sprouts, blueberries, alfalfa, avocado, and olives. Products containing simazine are also registered for use on non-agricultural sites such as forest trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental woody shrubs and vines, ornamental trees, Christmas tree farms, nursery stock, farm buildings, golf course turf, and shelterbelt plantings. Simazine is registered in liquid, dry flowable (DF), and water dispersible granule (WDG) formulations. Simazine can be applied via ground, chemigation, and handheld application equipment; aerial application is prohibited.

An average of 3 million pounds of simazine are applied to 2.6 million acres of agricultural cropland per year. Although simazine is not used extensively on major row crops (e.g., corn), these type of use sites do account for the majority of agricultural use in terms of pounds applied and acres treated. Approximately 3% of corn acres in the U.S. are treated with simazine each year and this accounts for 76% of simazine use. Less than 1% of sweet corn acres are treated with simazine, or about 3,600 acres annually.

Simazine is used extensively in orchard, vineyard, and berry crop sites. On average, over 650,000 pounds, or approximately 20%, of simazine is applied in agricultural settings to these sites. The crops with the highest percent crop treated (PCT) with simazine are caneberries (32%), blueberries (20%), raisin grapes (17%), hazelnuts (16%), oranges (12%), and peaches (10%). All the orchard, vineyard, and berry crops surveyed typically received one to two applications of simazine per year on average. Citrus fruit (i.e. oranges, lemons, and grapefruit) typically have the highest reported average simazine application rates, around 2.2 lbs a.i./acre or higher.

In the most recent year with data available (2013-2016), thousands of pounds of simazine were applied to various non-agricultural use sites: nursery/ornamental (400,000 lbs), turf-sod farms (26,000 lbs), non-residential turfgrass [e.g., golf courses] (237,000 lbs) and forestry (less than 5,000 lbs).

## **III. SCIENTIFIC ASSESSMENTS**

### **A. Human Health Risks**

A summary of the agency's human health risk assessments 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 simazine. In addition, EPA has made a determination of a common mechanism of toxicity for atrazine, simazine, propazine, and their chlorinated metabolites. Therefore, in addition to assessing potential risk from simazine, EPA evaluated the potential cumulative risk from combined exposure to the triazines and their three major chlorinated metabolites, desethyl-s-atrazine (DEA), desisopropyl-s-atrazine (DIA), and

diaminochlorotriazine (DACT). For additional details on the human health assessments, see the *Simazine. Human Health Risk Assessment for Registration Review and to Support Registration of Proposed Uses on Citrus Fruit, Pome Fruit, Stone Fruit, Tree Nuts, and Tolerance Amendment for Almond Hulls*, the *Chlorotriazines: Cumulative Human Health Risk Assessment - Atrazine, Propazine, and Simazine*, and *Cumulative Triazine (Atrazine, Simazine, Propazine) Drinking Water Assessment*, which are available in the public docket.

For registration review, the predominant adverse health effect of concern for triazines is suppression of the luteinizing hormone (LH) surge leading to neuroendocrine effects. This effect was observed in rat studies after four days of exposure, therefore potential risk was assessed using a 4-day duration of exposure rather than EPA's typical short- or intermediate-term duration of exposure. Disruptive hormonal effects related to the LH surge are different for different age groups and sexes, and the downstream adverse effects vary considerably. Exposures during early life may lead to effects later in life including delays in sexual maturation, inflammation of the prostate, effects related to development of the genitalia, and/or irregular menstrual cycles. Therefore, this endpoint is relevant for males and females, and all life-stages.

For the acute assessment for simazine and its chlorinated metabolites, the toxicological endpoint is increased incidence of unossified teeth, head, centra vertebrae, and sternbrae, and also rudimentary ribs, which is only applicable to females 13-49 years old. For the 4-day assessment for simazine and its chlorinated metabolites, the toxicological endpoint is attenuation of LH surge, which is applicable to all life-stages. The hydroxy metabolites of simazine are major metabolites in plants but not in livestock. Dermal and inhalation exposures are not expected for the hydroxy metabolites of simazine; however, chronic dietary exposures are expected. The chronic endpoint (kidney effects) is applicable to all life-stages.

## 1. Risk Summary and Characterization

### *Dietary (Food + Water) Risks*

EPA's dietary risk assessments did not identify any potential acute, 4-day, chronic, or cancer risks of concern associated with dietary exposure to simazine and its chlorinated metabolites or to the hydroxy metabolites of simazine. Simazine has been classified as "Not likely to be carcinogenic to humans"; therefore, a quantitative cancer dietary risk assessment was not conducted.

### *Residential Handler Risks*

Simazine products are registered for use in residential areas (e.g., residential lawns and playgrounds). Although all simazine labels require that handlers wear specific clothing (e.g., long sleeved shirt, long pants) and/or use personal protective equipment (PPE), one label is specifically labeled "for residential use" of simazine on residential turf. Therefore, a residential handler assessment was conducted for simazine application to residential turf. There were no residential handler combined (dermal + inhalation) risks of concern; combined (dermal + inhalation) Margins of Exposure (MOEs) ranged from 44 to 180 (Level of Concern (LOC)=30).

### *Residential Post-Application Risks*

Residential post-application exposure is expected via the dermal route for adults, children 11 to 16 years old, children 6 to 11 years old, and children 1 to < 2 years old; and via incidental oral exposure (i.e., hand-to-mouth or object to mouth) for children 1 to < 2 years old as a result of being in an environment that was previously treated with simazine (e.g., lawns, golf courses, playgrounds, recreational areas, etc).

Since dermal and incidental oral exposure routes share a common toxicological endpoint, risk estimates have been combined for those routes for children 1 to < 2 years old. Chemical-specific predicted day zero turf transferrable residues were adjusted in the post-application assessment for any differences between the study application rate and the registered application rates for simazine. Then, a 4-day average residue was used to estimate risk from contact with treated turf because the point of departure (POD) is based on decreased LH surge and available toxicity data indicate that the decrease occurs after a 4-day exposure. EPA's assessment of these exposure pathways demonstrated potential post-application risks of concern (i.e., Margins of Exposure (MOEs) < the level of concern (LOC) of 30) from the currently labeled maximum application rates for spray applications for adults from dermal exposure and for children 1 to < 2 years old from combined dermal and incidental oral exposure to residential turf.

For adults, the dermal MOE resulting from contacting treated turf is 26 at the currently labeled maximum application rate of 2.0 lb ai/A. For children 1 to < 2 years old, the combined dermal and incidental oral MOE resulting from contacting treated turf is 17 at the currently labeled maximum application rate of 2.0 lb ai/A. If the maximum rate is reduced to 1.0 lb ai/A, there are no risk estimates of concern for adults or children 1 to < 2 years old (adult dermal MOE = 52 and combined dermal + incidental oral MOE for children 1 to < 2 years old = 33) from simazine alone. However, in the cumulative assessment (results summarized below), cumulative risks of concern were identified from the use of simazine on residential turf even at 1.0 lb ai/A. Cumulative risks of concern are present unless the rate for simazine use on turf is reduced to 0.65 lb ai/A or lower.

### *Non-Occupational Bystander Risks*

In addition to potential exposure from application directly to residential turf treated with simazine, EPA assessed potential human exposure from off-target movement and deposition (i.e., spray drift) of simazine. Applications to grapefruit and oranges at the maximum application rate of 8.0 pounds per acre (lb/A) resulted in combined dermal + incidental oral risks of concern for children 1 to < 2 years old at the field edge. However, with existing spray drift mitigation on labels, along with the fact that applications to citrus orchards are made at least 10 feet from the edge of the field, there are no bystander risks of concern.

In addition, a non-occupational bystander exposure and risk assessment was conducted using the available application site and ambient volatilization monitoring data available for simazine. There are no risk estimates of concern for adults and children (MOEs  $\geq$  30) using either the maximum air concentration data from application site monitoring or using the average air concentration from all ambient air monitoring.

### *Aggregate Risks*

There is the potential for aggregate risks of concern following exposure to simazine and its chlorinated metabolites (DEA, DIA, and DACT). EPA evaluated acute and 4-day aggregate exposure to simazine (dietary and residential), and chronic aggregate exposure to the hydroxy metabolites of simazine. The acute and chronic aggregate assessments include dietary (food-only) and drinking water. The 4-day aggregate assessment includes dietary (food-only), drinking water, and residential exposures.

EPA used a drinking water level of comparison (DWLOC) approach to evaluate aggregate risk. This approach determines acceptable levels of exposure in the total “risk cup” for drinking water, after accounting for exposures from food/residential uses. DWLOCs are then compared to estimated drinking water concentrations (EDWC) to determine whether there are aggregate risk concerns once exposure from drinking water is added in. The DWLOC approach is useful when there are multiple EDWCs, as is the case for simazine or when there are potential aggregate risk estimates of concern.

There were no acute risks of concern for simazine and its chlorinated metabolites, and no chronic aggregate risks of concern for the hydroxy metabolites of simazine. For the 4-day aggregate assessment, the maximum application rate on residential turf (2.0 lb ai/A) would need to be reduced to 0.65 lb ai/A to be not of concern for all subpopulations.

### *Cumulative Risks*

EPA has determined that simazine shares a common mechanism of toxicity (neuroendocrine effects in rats that can cause developmental and reproductive toxicity) with the other triazine herbicides, atrazine and propazine, and their chlorinated metabolites. EPA assessed cumulative risk from the triazines and their chlorinated metabolites in the July 10, 2018 *Chlorotriazines: Cumulative Risk Assessment - Atrazine, Propazine, and Simazine*, which is available in the public docket.

There were no risks of concern identified for the chlorotriazine 4-day cumulative dietary (food only) exposure and risk assessment, or for the 4-day dietary cumulative aggregate (food + drinking water) exposure and risk assessment. There were also no cumulative risks of concern for the chronic dietary (food only) or screening-level aggregate (food + drinking water) assessment for the hydroxytriazines.

However, there were some 4-day cumulative aggregate (food + drinking water + residential) exposures that resulted in risks of concern at the maximum labeled rates for simazine spray application to residential turf at the maximum application rate (2.0 lb ai/A). However, if the application rate is reduced to 0.65 lb ai/A for turf, there are no cumulative aggregate risks of concern.

### *Occupational Handler Risks*

There is potential for occupational handler risk from combined dermal and inhalation exposure to simazine, with dermal exposure driving the risk estimates. EPA calculated risk estimates based on combined dermal and inhalation exposure for various levels of PPE; label-specified PPE (i.e., long sleeves, pants and socks and chemical resistant gloves), and any additional PPE or engineering controls required to result in risk estimates that are not of concern. The occupational handler scenarios evaluated resulted in potential risks of concern with MOEs ranging from 2.7 to 1,400 (LOC = 30) assuming label-specified PPE. Uses with potential occupational risks of concern are:

- Mixing/loading/applying dry flowable/water dispersible granule (DF/WDG) and liquid formulations for backpack application to grapefruit, oranges and landscape turf.
- Mixing/loading/applying DF/WDG and liquid for mechanically pressurized handgun application to:
  - Citrus (Grapefruit, Oranges, Lemons)
  - Pome Fruits (Apples, Pears)
  - Stone Fruits (Cherries [sweet and tart], peaches, Plums, Nectarines)
  - Tree Nuts (Pecans, Walnuts, Filberts, Almonds, Macadamia Nuts)
  - Berry and Small Fruit (Blueberries, Blackberries, Loganberries, Raspberries, Grapes, Lowbush Blueberries, Cranberries)
  - Tropical and Sub-tropical Fruits (Avocado, Olive)
  - Nursery/Ornamentals
  - Sweet corn
  - Strawberries

Based on EPA's risk assessment, a requirement of additional PPE could eliminate potential risk for some but not all scenarios.

The scenarios for which potential occupational risks of concern remain (*i.e.*, MOEs remain below the LOC of 30) assuming the highest possible level of PPE and/or engineering controls include:

- Mixing/loading/applying DF/WDG and liquid formulations for broadcast backpack sprayer applications to landscape turf (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 27).
- Mixing/loading/applying DF/WDG and liquid formulations for mechanically pressurized handgun applications to:
  - grapefruit and oranges (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 4.4);
  - lemons, apples, pears, tart cherries, avocados, filberts, grapes, olives, peaches, plums, sweet cherries, pecans, walnuts (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 8.7);
  - almonds, peaches, nectarines, macadamia nuts, blueberries, blackberries, loganberries, raspberries (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 18);
  - nursery ornamentals (MOE assuming a double layer of clothing, gloves, and a

- particulate filtering facepiece or elastomeric particulate respirator = 12);
- lowbush blueberries (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 18);
- cranberries (MOE assuming a double layer of clothing, gloves, and a PF 10 respirator = 8.7); and,
- sweet corn (MOE assuming a double layer of clothing, gloves, and a particulate filtering facepiece or elastomeric particulate respirator = 14).

The occupational handler exposure assessment relied on maximum registered application rates, generic handler data in absence of chemical-specific unit exposure data, standard area/amount treated assumptions. Registered simazine labels vary with respect to required attire and PPE. The DF/WDG labels require mixer/loaders for groundboom applications; and/or mixer/loaders, cleaners of equipment or spills, or other handlers otherwise exposed to the concentrate to wear baseline attire (long sleeved shirts, long pants, shoes, and socks), chemical resistant gloves, and a dust/mist respirator. Some labels also require mixer/loaders to wear a double layer of clothing or coveralls. All other handlers of DF/WDG products must wear baseline attire and chemical resistant gloves. All of the registered liquid labels require handlers to wear baseline attire and waterproof or chemical resistant gloves. Therefore, results were presented for “baseline attire,” (long sleeved shirt, long pants, shoes plus socks), protective gloves, and no respirator; as well as baseline, gloves, and various levels of PPE as necessary (e.g., double layer of clothing, respirator, etc.).

### *Occupational Post-Application Risks*

Using atrazine dislodgeable foliar residue (DFR) and simazine turf transferrable residue (TTR) data, there are no occupational post-application MOEs of concern for the registered and proposed uses of simazine on the day of application, except for hand-set irrigation for highbush and lowbush blueberries (MOE = 24; LOC=30). One day after application there are no risks of concern (MOE = 43). The agency does not consider this a risk of concern because there is an existing restricted entry interval (REI) of 12 hours and the risk calculated at the maximum label rate of 4 lb ai/A is much lower than the typical use rate of 1.6 lb ai/A. All other registered uses had MOEs above the LOC.

## **2. Human Incidents and Epidemiology**

Four minor severity incidents were reported in the OPP Incident Data System (IDS) between January 1, 2012 and January 12, 2017 involving simazine. A National Pesticide Information Center (NPIC) query from 2012 to 2017 found one minor severity incident involving simazine. A query of California Pesticide Illness Surveillance Program incidents from 2010 to 2014 found one incident involving simazine. Lastly, a query of Sentinel Event Notification System for Occupational Risk-Pesticides from 2010 to 2013 identified three cases involving simazine. Two cases were moderate in severity and one case was low in severity. All three cases were occupational exposures.

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

The agency recently conducted an updated epidemiology systematic literature review to investigate evidence about the human health effects potentially associated with exposure to atrazine, simazine, and/or propazine. Ninety-three publications from 1990 to 2017 were identified for inclusion in the epidemiology literature review. These publications investigated carcinogenic and noncarcinogenic effects (43% and 58%, respectively; not mutually exclusive). Most (88%) reported an effect estimate for atrazine, 14% reported an effect estimate for simazine (not mutually exclusive: some articles reported estimates for both chemicals, while other articles reported estimates for only one). No publications reported an effect estimate for propazine. Additional details can be found in *Chlorotriazines. Toxicology Systematic Literature Review- Atrazine, Simazine and Propazine*.

### 3. Tolerances

Tolerances are established under 40 CFR §180.213 for the combined residues of simazine and its two chlorinated metabolites in/on a variety of crops and livestock commodities. The agency intends to propose that the residue definition for the tolerance expression for simazine be modified in accordance with current policy to read:

*“Tolerances are established for residues of the herbicide simazine, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of simazine, 6-chloro-N,N’-diethyl-1,3,5-triazine-2,4-diamine, its desethyl metabolite 2-amino-4-chloro-6-ethylamino-s-triazine (G-28279) (DIA), and its diamino metabolite 2,4-diamino-6-chloro-s-triazine (G-28273) (DACT), calculated as the stoichiometric equivalent of simazine, in or on the commodity.*

A summary of the tolerance revisions and revocations that the agency intends to propose for simazine is listed below.

<b>Commodity/ Correct Commodity Definition</b>	<b>Established Tolerance (ppm)</b>	<b>Proposed Tolerance (ppm)</b>	<b>Comments</b>
Almond, hulls	0.25	3	Based on field trial data (D409212, W. Donovan, 26-JUN-2013)
Avocado	0.20	0.2	OECD rounding class consistency
Blackberry	0.20	0.2	
Blueberry	0.20	0.2	
Cattle, meat	0.03	remove	40 CFR §180.6(a)(3)
Cattle, meat byproducts	0.03	remove	D442822, W. Donovan, 12-JUN-2018
Corn, field, forage	0.20	0.2	OECD rounding class consistency
Corn, field, grain	0.20	0.2	
Corn, pop, grain	0.20	0.2	
Corn, sweet, forage	0.20	0.2	
Corn, sweet, kernel plus cob with husks removed	0.25	0.2	D442825, W. Donovan, 10-JUL-2018 OECD rounding class consistency
Egg	0.03	remove	40 CFR §180.6(a)(3)

<b>Table 1: Summary of Proposed Tolerance Revisions for Simazine (40 CFR §180.213)</b>			
<b>Commodity/ Correct Commodity Definition</b>	<b>Established Tolerance (ppm)</b>	<b>Proposed Tolerance (ppm)</b>	<b>Comments</b>
Goat, meat	0.03	remove	D442822, W. Donovan, 12-JUN-2018
Goat, meat byproducts	0.03	remove	
Fruit, citrus, group 10-10	-	0.04	Establishment of crop group tolerance
Grapefruit	0.25	remove	
Lemon	0.25	remove	
Orange	0.25	remove	
Fruit, pome, group 11-10	-	0.03	Establishment of crop group tolerance
Apple	0.20	remove	
Pear	0.25	remove	
Fruit, stone, group 12-12	-	0.1	Establishment of crop group tolerance
Cherry	0.25	remove	
Peach	0.20	remove	
Plum	0.25	remove	
Grape	0.20	0.2	OECD rounding class consistency
Horse, meat	0.03	remove	40 CFR §180.6(a)(3)
Horse, meat byproducts	0.03	remove	D442822, W. Donovan, 12-JUN-2018
Loganberry	0.20	0.2	OECD rounding class consistency
Milk	0.03	remove	40 CFR §180.6(a)(3) D442822, W. Donovan, 12-JUN-2018
Nut, tree, group 14-12	-	0.05	Establishment of crop group tolerance
Almond	0.25	remove	
Hazelnut	0.20	remove	
Nut, macadamia	0.20	remove	
Pecan	0.20	remove	
Walnut	0.2	remove	
Olive	0.20	0.2	OECD rounding class consistency
Raspberry	0.20	0.2	
Sheep, meat	0.03	remove	40 CFR §180.6(a)(3)
Sheep, meat byproducts	0.03	remove	D442822, W. Donovan, 12-JUN-2018
Strawberry	0.25	0.03	D442825, W. Donovan, 10-JUL-2018

The agency will use its Federal Food, Drug, and Cosmetic (FFDCA) rulemaking authority to undertake any needed tolerance changes.

#### 4. Human Health Data Needs

The human health risk assessment identified multiresidue method testing results (OCSPP 860.1360) for the chlorinated metabolites of atrazine, propazine, and simazine (desethylatrazine (DEA), desisopropylatrazine (DIA), and diaminochloroatrazine (DACT)) as a data deficiency. These data are needed to determine the suitability of multiresidue methodology for quantification of simazine and its regulated metabolites. The agency issued a GDCI to require these data on December 12, 2018. These data are under development and due to be submitted to the agency by December 20, 2020. Pending review and acceptability of this study, the agency does not anticipate any further human health data needs for the simazine registration review.

## **B. Ecological Risks**

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of simazine. For additional details on the ecological assessment for simazine, see the *Preliminary Ecological Risk Assessment for Simazine*, which is available in the public docket.

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

### **1. Risk Summary and Characterization**

EPA estimated risks associated with simazine use to non-target birds, mammals, reptiles, freshwater fish, amphibians, and aquatic invertebrates; terrestrial invertebrates, including honeybees and other insect pollinators; and plants. Risk estimates (risk quotients, or RQs) were compared with EPA's LOCs. For ecological risk, RQs below the LOC are not of concern to the agency. For all taxa in the terrestrial assessment, except for plants, the LOC for acute exposure is 0.5 and the LOC for chronic exposure is 1.0. The LOC for plants is 1.0. In the draft risk assessment, the agency identified potential chronic risk concerns for mammals, birds, freshwater fish, amphibians, reptiles, and aquatic invertebrates. In addition, available information suggests potential risk to terrestrial invertebrates. The draft risk assessment assessed the maximum-labelled and typical application rates.

#### *Terrestrial Risks*

##### Mammals

The ecological risk assessment did not identify acute risks of concern for mammals; however, chronic risk estimates exceed the agency's LOC of 1 for all uses. At maximum application rates, chronic risk quotients (RQs) range from 1 - 869. The toxicity endpoint is based on decreased body weight and body weight gains. In addition, chronic LOCs for mammals are exceeded up to distances of 1,000 feet off field depending on the method of application and application rate.

##### Birds, Reptiles, and Terrestrial-Phase Amphibians

The ecological risk assessment did not identify acute risks of concern for birds; however, chronic levels of concern (LOC = 1) are exceeded for birds for all simazine uses. Birds serve as surrogates for reptiles and terrestrial-phase amphibians in the absence of taxa-specific data. Chronic RQs range from 0.2 to 11.2. The chronic endpoint is based on reproduction impacts observed in the most sensitive species, bobwhite quail.

### Terrestrial Invertebrates (honeybees)

Available toxicity data indicate that simazine is practically non-toxic to bees on an acute oral exposure basis. Based on these data, the agency calculated an RQ of 0.11, which is below the agency's LOC of 0.4 for acute exposure. However, there is uncertainty about potential risks to terrestrial invertebrates because a full Tier 1 suite of terrestrial invertebrate toxicity studies is not available at this time.

Given the uncertainty surrounding potential risks to terrestrial invertebrates due to lack of data, the EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. The EPA is currently determining whether additional pollinator data are needed for simazine. If the agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for simazine, then the EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 2 below and based on the EPA's June 2014 *Guidance for Assessing Pesticide Risks to Bees*<sup>1</sup>.

<b>Table 1: Potential Pollinator Data Requirements</b>	
<b>Guideline #</b>	<b>Study</b>
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
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 <sup>†</sup>	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3 <sup>†</sup>	
850.3040	Full-Field testing for pollinators

<sup>†</sup> 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

Consistent with its herbicidal mode of action, simazine is highly toxic to monocot and dicot terrestrial plant species. As such, non-target terrestrial plant species in areas adjacent to treated fields are likely to be impacted by exposure to simazine. At the maximum single application rate, RQs associated with exposure via spray drift, as well as the combination of runoff and spray drift exposure to dry areas and semi-aquatic habitats exceed the LOC of 1. RQs for spray drift-only exposure range from 0.5 to 8.9, RQs for runoff and spray drift deposition to dry areas range from 1.0 to 10.7, and RQs for runoff and spray drift deposition to semi-aquatic areas range from 5.5 to 48.9. The adverse effect endpoint is based on impacts to seedling emergence.

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<sup>1</sup> Available at [https://www.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf)

For characterization, EPA evaluated potential risks to terrestrial plants at reduced application rates and developed species vegetative vigor and seedling emergence sensitivity distributions (SSDs); however, risks to terrestrial plants remain of concern.

### *Aquatic Risks*

#### Freshwater Fish and Aquatic-Phase Amphibians

EPA's chronic LOC of 1 is exceeded for freshwater fish and aquatic-phase amphibians through runoff and spray drift deposition into waterways following labeled applications for many simazine uses (including corn, orchard, and berries), with RQs ranging from 0.1 to 5.7. The chronic fish endpoint is based on decreased egg production in the freshwater Japanese medaka fish; this endpoint is from a study conducted with atrazine, as no such study is available for simazine. With aquatic-phase amphibian data unavailable, freshwater fish data is considered as surrogate data for aquatic phase amphibians, and therefore chronic risks to aquatic-phase amphibians are the same as freshwater fish. While there are amphibian-specific data for atrazine which indicate potential sublethal effects at low exposure concentrations, it is unclear to what degree those data represent simazine.

#### Estuarine/Marine Fish

Acute and chronic RQs did not exceed the LOC for estuarine/marine fish.

#### Freshwater Invertebrates

The ecological risk assessment did not identify acute risks of concern for freshwater invertebrates; however, chronic risk estimates exceed the agency's LOC of 1, with RQs ranging from 0.2 to 9.

#### Estuarine/Marine Invertebrates

The ecological risk assessment did not identify acute risks of concern for estuarine/marine invertebrates; however, chronic risk estimates exceed the agency's LOC of 1 for estuarine/marine invertebrates, with RQs ranging from 0.1 to 5.7.

#### Aquatic Vascular and Non-Vascular Plants

Risk estimates exceed the Agency's LOC for aquatic vascular and non-vascular plants for nearly all uses. RQs range from 0.8 – 46.4 for vascular plants, and 0.1 – 5.5 for non-vascular plants.

#### Aquatic Plant Communities

Simazine does not have an extensive body of research on micro and mesocosms like atrazine does. However, because atrazine and simazine share a common mechanism of action and similar potency in plants and coupled with their propensity to move into aquatic ecosystems and their persistence in water, these chemicals both pose a potential risk to aquatic plant communities. Based on the toxicity data, there are risks to non-vascular plants for all simazine uses and risks to vascular plants for many uses.

## **2. Ecological Incidents**

A review of the Ecological Incident Information Systems (EIIS) database for ecological incidents involving simazine was completed on January 25, 2015. The Avian Monitoring System (AIMS) is a database administered by the American Bird Conservancy and are included in the EIIS summary. The EIIS search resulted in three incidents involving terrestrial animals, four for plants, and ten freshwater incidents involving fish kills.

The Aggregate Incident Summary report in the IDS shows six simazine related incidents, including two involving plant damage and the others were single reports involving moderate property damage, minor to moderate effects on domestic animals, fatal domestic animal event and one unspecified human event.

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

## **3. Ecological and Environmental Fate Data Needs**

Except for the potential pollinator data requirements described previously, the ecological and environmental fate database for simazine is complete.

### **C. Benefits Assessment**

Simazine is a chlorinated triazine herbicide and is classified as a Weed Science Society of America (WSSA) Group 5 herbicide. Simazine is applied before the weed emerges to control broadleaf and grass weeds, and it can be applied in the fall for winter weed control. Simazine is a commonly used preemergence, soil residual herbicide in orchards, vineyard, berry crops, nurseries/ornamentals, and Christmas tree farms. There is also usage of simazine in non-agricultural sites, including turfgrass and forestry sites. It is an important herbicide for these use sites because it is economical, has a flexible use pattern, has a long residual period, has good crop safety, and is highly effective against a broad spectrum of weeds.

#### *Field Corn*

In field corn, simazine provides residual control and offers control of a broad-spectrum of broadleaf weeds and grasses. It has a flexible use pattern in that it can be applied before planting, before crop emergence, or as a fall application after harvest. The Corn Belt states (Illinois, Indiana, Iowa, Missouri, Ohio) account for approximately 76% of simazine's total acre treatments, followed by the Southern/Seaboard states (Kentucky, Maryland, North Carolina, Virginia) with about 18% of total area treatments and Northeast/Lakes states (Delaware, Michigan, Pennsylvania, Wisconsin) with about 7% of total acre treatments. Application timing varies by region, but nationally about 48% of simazine is applied during the previous fall (after the harvest primarily in the Corn Belt for winter weed control), and the remaining 52% is applied before corn emerges. In the absence of simazine, in the Corn Belt and Northeast/Lakes states, the EPA estimates a loss of approximately 4% in net revenue (\$7 per acre) for applications made

prior to crop emergence using the next best alternative herbicide. For the Southern/Seaboard states, the EPA estimates that growers may choose to use atrazine in the absence of simazine, which is slightly cheaper than simazine per acre, so no net revenue losses are expected.

For more information refer to *Atrazine and Simazine Use on Field Corn: Response to comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)* in the docket.

#### *Orchards, Vineyards, Berries and Christmas Trees*

In perennial crop settings such as orchards, vineyards, and berries, simazine is used for residual control of grasses and broadleaf weeds that occur in row middles and around the base of crops or trees. Simazine is typically applied in the late fall or early spring months to provide weed control in perennial cropping systems. It is the top pre-emergent option used in caneberry production. In strawberries, simazine may be important for operations that do not use fumigation or for residual control after harvest, especially in the Pacific Northwest strawberry production areas. In Christmas tree production, simazine is a preemergence herbicide that can provide residual control with winter applications.

For more information refer to *Simazine Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation on Orchards, Vineyards, Caneberries, Strawberries, and Christmas Trees; PC Code (080807)* in the docket.

#### *Sweet Corn*

Simazine provides residual control and offers control of a broad-spectrum of broadleaf weeds and grasses in sweet corn. It has a flexible use pattern in that it can be applied before planting, at plant, before crop emergence or as a fall application after harvest. Growers in the North Central / Northeastern (Indiana, Illinois, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, Wisconsin) region account for nearly all of the simazine usage in sweet corn, even though simazine is recommended by university extension in other regions. Without simazine, the agency estimates an increase in production costs of \$11 per acre in the North Central / Northeastern region using the next best alternative herbicide. Simazine is more expensive than atrazine and used less frequently; however, it is still less expensive than many other herbicides that can be used to target the similar suite of broadleaf weeds and grasses.

For more information refer to *Atrazine and Simazine Use on Sweet Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)* in the docket.

#### *Turfgrass and Nursery/Ornamental*

Simazine is a top preemergence herbicide for a few non-agricultural use sites (i.e., certain types of turfgrass and nursery/ornamental sites). Herbicides are applied to turfgrass at golf courses, homes, parks, and professionally maintained turfgrass sites to control annual broadleaf and grass weeds which may impact yield and/or seed/turf quality, playability, or it may be primarily driven by aesthetics. According to the most recent data (2013) available to the agency, simazine was the

third most used preemergence herbicide on turf-sod farms, and the second most used preemergence herbicide on golf courses in terms of pounds applied. Simazine can be used on many ornamental species without causing damage to the species. Simazine was the second-most used herbicide overall in nursery/ornamental sites in 2013.

For more information refer to *Atrazine and Simazine Use in Forestry, Rights of Way, Turfgrass, and Nursery: Response to Comments, Usage, and Benefits; PC Codes (080803 and 080807)* in the docket.

## **IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION**

### **A. Proposed Risk Mitigation and Regulatory Rationale**

The currently registered uses of simazine pose potential human health risks of concern, including residential post application, aggregate, and cumulative risk associated with simazine use on residential turf and potential occupational risk to handlers from mixing, loading, and applying simazine. In addition, simazine use poses potential ecological risks to mammals, birds, reptiles, amphibians, fish, aquatic invertebrates, terrestrial plants and aquatic plant communities.

The EPA is describing the proposed mitigation based on the risks to be addressed and subsequently discusses the expected impacts by use site (unless otherwise noted). By describing the mitigation in this way, the agency seeks to clarify the specific mitigation proposed, that may impact each specific simazine user group.

To address the potential residential post-application aggregate, and cumulative risk concerns, the EPA is proposing to cancel simazine use on residential turf. In addition, EPA is proposing to require additional PPE or engineering controls to address potential occupational handler risk concerns associated with various simazine uses, as discussed in more detail below. EPA is also proposing to update spray drift reduction language, herbicide resistance management language, and require some additional label updates for consistency with generic labeling requirements.

In evaluating potential risk mitigation for simazine, the EPA considered the risks, the benefits, and the use pattern of this compound. Although there are potential risks of concern associated with the use of simazine, with the adoption of the mitigation measures discussed in this section, the potential risks are outweighed by the benefits associated with the use of this compound.

#### **1. Proposing Cancellation of Simazine Residential Turf Use**

As discussed in the Risk Summary and Characterization section of this document (Section III. A.1.), the human health risk assessment indicates potential post-application, aggregate, and cumulative triazine risks of concern for adults from dermal exposures to treated residential turf and children 1 to <2 years old from combined dermal and incidental oral exposures to treated residential turf. Acceptable MOEs could be reached if the application rate was reduced from 2.0 lb ai/A to 0.65 lb ai/A, but that rate is below an efficacious level. As a result, EPA is proposing cancellation of the residential and recreational turf use, which would mean that simazine could

not be used to treat turf around homes, daycare facilities, schools, playgrounds, parks, recreational areas, or sports fields. Use on golf courses and sod-production fields, however, would not be affected.

For information about the impacts of the proposed mitigation, please refer to Section IV.A.7, Impacts of Mitigation.

## 2. Risk Mitigation for Occupational Handlers

The human health risk assessment identifies several scenarios that result in potential risks of concern to occupational handlers who mix, load, and apply simazine. Additional PPE is necessary to address these potential risks. Therefore, EPA is proposing to require the following additional PPE to include a respirator in some cases and, for pesticides covered by the Worker Protection Standard<sup>2</sup> (WPS), the associated fit test, training, and medical evaluation:

- The agency is proposing to require that occupational handlers wear a double layer of clothing for the uses listed below. A double layer of clothing will bring the MOEs to above the LOC and remove any potential risks of concern.
  - Dry flowable and Water Dispersible Granule (DF/WDG) – backpack application – grapefruit, oranges
  - Liquid – backpack application– grapefruit, oranges
- The agency is proposing to require that occupational handlers wear a double layer of clothing or to apply via spot treatment only for the uses listed below. Either action will bring the MOEs to above the LOC and remove any potential risks of concern.
  - DF/WDG – mechanically pressurized handgun – strawberries
  - Liquid – mechanically pressurized handgun – strawberries
- The agency is proposing to restrict mechanically pressurized handgun applications of DF, WDG, and liquid formulations of simazine to spot treatment only for the following uses because these uses do not reach acceptable MOEs with additional PPE.
  - Citrus (Grapefruit, Oranges, Lemons)
  - Pome Fruits (Apples, Pears)
  - Stone Fruits (Cherries [sweet and tart], peaches, Plums, Nectarines)
  - Tree Nuts (Pecans, Walnuts, Filberts, Almonds, Macadamia Nuts)
  - Berry and Small Fruit (Blueberries, Blackberries, Loganberries, Raspberries, Grapes, Lowbush Blueberries, Cranberries)
  - Tropical and Sub-tropical Fruits (Avocado, Olive)
  - Nursery/Ornamentals
  - Sweet corn

For information about the impacts of the proposed mitigation, please refer to Section IV.A.7, Impacts of Mitigation.

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<sup>2</sup> 40 CFR 170

### **3. Spray Drift Reduction Language**

In the 2006 Reregistration Eligibility Decision for Simazine (RED), mandatory and advisory spray drift language was specified. The agency is proposing to update existing label language to the latest spray drift mitigation language on all simazine product labels for products applied by liquid spray application. The proposed spray drift language is intended to consist of mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is proposing standardized advisory language on simazine 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 PID, once effective.

- Applicators must not spray during temperature inversions.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground applications, do not apply when wind speeds exceed 10 mph at the application site.
- For ground applications, select nozzle and pressure that deliver coarse or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1).

In addition to including the spray drift restrictions on simazine labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all simazine labels where such information currently appears. The proposed new language above, which cites ASABE S572.1, eliminates the need for VMD information.

### **4. Non-target Organism Advisory Statement**

The agency is also proposing the addition of a non-target organism advisory statement. The protection of pollinating organisms is a priority for the agency. Risk to pollinators from the use of simazine is uncertain. It is possible that pollinators may be exposed to simazine from residues in pollen or nectar through spray drift. This may negatively impact forage and habitat of pollinators and other non-target organisms. It is the agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, the EPA is proposing the following non-target organism advisory language to be placed in the Environmental Hazards section of simazine labels to address this potential concern:

“NON-TARGET ORGANISM ADVISORY STATEMENT: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift.”

For information about the impacts of the proposed mitigation, please refer to Section IV.A.7, Impacts of Mitigation.

## 5. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.<sup>3</sup> Consistent with the Notice, the EPA is proposing the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID.

The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide resistant weeds have been known since the 1950s, the number of species and their geographical extent, has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide resistant weeds, both in mitigating established herbicide resistant weeds and in slowing or preventing the development of new herbicide resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

The EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

## 6. Additional Label Changes

In addition to the above-mentioned proposed mitigation, the EPA is also proposing the following label changes to address generic labeling requirements for all simazine products and uses:

- *Updated Glove and Respirator Label Language*: see Appendix B
- *Non-target Organism Advisory Label Statement*: see Appendix B
- *Directions for Mixing/Loading Water Soluble Packages (WPS) Label Language*: see Appendix B

### B. Status of Simazine Water Monitoring Program and Proposed Changes

A drinking water monitoring program was required through a 2008 simazine Generic Data Call-In (GDCI-080807-26466) (2008) and the Simazine RED (2006). The simazine drinking water monitoring program, which is conducted in conjunction with a similar monitoring program for atrazine, monitors community drinking water systems, primarily in the midwest United States in areas of high simazine use, to assess simazine levels in drinking water sources.

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<sup>3</sup> PRN 2017-2, “Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship”. Available at <https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year>

The EPA recognizes that the totality of available triazine monitoring data, including data collected through the simazine drinking water monitoring programs, is robust and comprehensive. The availability of robust triazine monitoring data enabled the EPA to refine and characterize its draft human health risk assessments. While having monitoring data specific to community water systems is useful, given the conclusions of the 2018 draft triazine human health risk assessments, the EPA is proposing to discontinue the requirements for simazine drinking water monitoring. Model-estimated triazine concentrations, as well as measured concentrations for community water systems, are well below the drinking water level of concern (DWLOC). The vast majority of samples from the simazine monitoring program were below 1 ppb, while the highest triazine concentration ever measured was 227 ppb, which is well below the triazine DWLOC of 580 ppb. Therefore, the agency does not see value in continuation of the simazine drinking water monitoring program. For these reasons, EPA will suspend the requirements for the simazine drinking water monitoring program for calendar year 2020, during which time the agency will accept and evaluate comments on the triazine PIDs and any comments specific to the proposal to permanently discontinue the simazine drinking water monitoring program. After comments are evaluated, EPA will make a final decision about the future of the simazine drinking water monitoring requirements.

### **C. Expected Impacts of Proposed Mitigation**

#### Impact of Spray Drift Reduction Language Update

The agency recognizes that the 2006 Reregistration Eligibility Decision for Simazine (RED) specified mandatory spray drift language; however, not all components of that language were incorporated on all product labels, including frequently used products (e.g., EPA Reg# 100-526). Therefore, the agency is evaluating the impacts of each component of the spray drift language update.

#### Impacts of Inversion Restriction

This requirement could reduce the amount of time users have to apply triazines. Users may switch to other products that only have advisory language for this restriction if they encounter temperature inversions when needing to treat a field.

#### Impacts of Mandatory Maximum Spray Release Height Requirement for Ground Applications

For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy. This currently exists as mandatory label language; therefore, there will be no impact.

#### Impacts of Windspeed Restrictions for Ground Applications

The agency is aware that low wind speeds reduce the number of available hours a grower would have to make an application. However, a restriction of 10 miles per hour for ground applications currently exists as mandatory label language; therefore, there will be no impact.

#### Impacts of Droplet Size

The agency is ensuring that a restriction on droplet size is specified as mandatory label language because coarser or coarser droplets have been demonstrated to decrease spray drift, and therefore, reduce potential risks to non-target species. The current droplet size language specified

in the simazine RED is advisory; through registration review, the agency is proposing to adjust the language to clarify the droplet size restrictions are mandatory.

Because chemical-specific data for the performance of droplet sizes is limited, EPA is not able to evaluate the effects of medium or coarser droplet sizes (as defined by ASABE S572.1) specifically for simazine. Therefore, the EPA does not know the effect this requirement will have on the performance of simazine across various use patterns, especially regarding tank mix partners that require a finer droplet size. In general, potential negative impacts to growers from requiring larger droplets could include: reductions in efficacy, increased selection pressure for the evolution of herbicide resistance due to a decrease in lethal dose delivered to target weeds, increased application rates used by growers, increased costs associated with reduced yield, additional herbicide 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.

#### Impacts of Interaction of Individual Components of Spray Drift Mitigation

The agency acknowledges the impacts of multiple mitigation measures could be compounded and further reduce the time in which applicators could apply herbicides. For instance, applicators may deal with wind restrictions by spraying early in the morning/late evenings when winds are calmer; however, temperature inversions are more likely to occur several hours before sunset and can persist until 1-2 hours after sunrise. As the window of application gets smaller, growers may be forced to switch to products without these restriction on short notice. Therefore, the alternative may be based on availability and not cost and/or performance, which could be costly and reduce weed control. Additionally, growers may have situations where a tank is loaded and ready to spray, but they are not able to spray due to prolonged weather conditions that prevent application due mandatory multi-layered restrictions. In rare situations, there could be scenarios where applicators cannot spray what is mixed in the tank for a long period of time and would need to dispose of a large quantity of mixed herbicides in order to switch to an alternative mixture. There may be additional concerns (e.g., tank clean-out when products settle out) when a loaded tank sits hours, and possibly days.

#### **Impacts of Mitigation by Use Site**

##### Turfgrass

##### *Cancellation of Residential and Recreational Turfgrass*

The agency is proposing the cancellation of the residential and recreational turf use, which would mean that simazine could not be used to treat turf around homes, daycare facilities, schools, playgrounds, parks, recreational areas, or sports fields. Current simazine users would have to select another herbicide or a combination of herbicides to control the weeds present in their site (simazine has over 50 weeds on the label). Selecting a different herbicide or combination of herbicides could lead to higher prices for users and/or poorer weed control. Simazine usage has declined in residential and recreational turfgrass use sites, so this potential mitigation may have decreasing impacts over time if current usage trends continue.

### *Spray Drift Management*

Given that this use site is being proposed to be cancelled, the impacts from spray drift mitigation could be minimal. However, golf course and sod-production uses will be retained; these uses could have impacts. For the mandatory spray droplet size of coarse or coarser, a maximum four-foot boom height, and maximum wind speed restrictions, the impacts are as described above.

### Impacts of Inversion Restriction

This component does not appear on all labels. However, the agency assumes that applications to golf course would be made during normal work hours when temperature inversions are unlikely. Therefore, the agency assumes that requiring that applications be made when temperature inversions were not likely to occur would not impact golf course and recreational uses. For sod-production fields, there could be a reduction in hours when applications could be made (impacts of the spray drift mitigation, see above).

For more information refer to *Atrazine and Simazine Use in Forestry, Rights of Way, Turfgrass, and Nursery: Response to Comments, Usage, and Benefits* in the docket.

### Field Corn

#### *Spray Drift Management*

For impacts of the spray drift mitigation, see above.

For more information refer to *Atrazine and Simazine Use on Field Corn: Response to comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)* in the docket.

### Sweet Corn

#### *Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency anticipates that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in sweet corn. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, the impact of limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

#### *Spray Drift Management*

For impacts of the spray drift mitigation, see above.

For more information refer to *Atrazine and Simazine Use on Sweet Corn: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation; PC Codes (080803 and 080807)* in the docket.

Citrus (Grapefruit, Oranges, Lemons)

*Double-layers and Gloves for Grapefruit and Oranges for DF/WDG/L Formulations Applied Via Backpack Sprayers*

Requiring double-layer coveralls and gloves for users applying via backpack will not likely impact the overall use of simazine since it is likely that applications via backpack sprayers are infrequent. However, users who apply with backpack equipment may incur some additional costs or burdens. For example, the use of PPE (e.g., wearing double layers when applying pesticides) can reduce productivity of workers because of the physiological stress when working in high temperatures and/or humid conditions. Workers may need to take more frequent breaks in certain situations than if extra PPE were not required. Individuals will respond differently depending on many factors, such as fitness level, hydration, acclimatization, etc. The requirement of additional PPE when individuals are applying simazine with a backpack applicator could decrease productivity, which will increase the time required for an application to be made, and likely increase costs. Alternatively, applicators may choose to use a different herbicide, which could be more expensive and potentially less effective than simazine.

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only (Grapefruit, Oranges, Lemons)*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in citrus groves. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

*Spray Drift Management*

For impacts of the spray drift mitigation to Grapefruit, Oranges, and Lemons, see above.

Pome Fruits (Apples, Pears)

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in orchards. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our

assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

*Spray Drift Management*

For impacts of the spray drift mitigation for Pome fruit, see above.

Stone Fruits (Cherries [sweet and tart], Peaches, Plums, Nectarines)

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in orchards. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

*Spray Drift Management*

For impacts of the spray drift mitigation to Stone Fruit, see above.

Tree Nuts (Pecans, Walnuts, Filberts, Almonds, Macadamia Nuts)

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in orchards. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment

*Spray Drift Management*

For impacts of the spray drift mitigation to Tree Nuts, see above.

Berry and Small Fruit (Blueberries, Blackberries, Loganberries, Raspberries, Grapes, Lowbush Blueberries, Strawberries, Cranberries)

*Double-layers and Gloves for DF/WDG/L Formulations Applied Via Mechanically Pressurized Handguns (Strawberries)*

Requiring double-layer coveralls and gloves for users applying via mechanically pressurized handguns will not likely impact the overall use of since it is likely that applications via mechanically pressurized handguns are infrequent. However, users who apply with mechanically pressurized handguns, may incur some additional costs or burdens. For example, the use of a PPE (e.g., wearing double layers when applying pesticides) can reduce productivity of workers because of the physiological stress when working in high temperatures and/or humid conditions. Workers may need to take more frequent breaks in certain situations than if extra PPE were not required. Individuals will respond differently depending on many factors, such as fitness level, hydration, acclimatization, etc. Alternatively, applicators may choose to use a different herbicide, which could be more expensive and potentially less effective than simazine.

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only (Blueberries, Blackberries, Loganberries, Raspberries, Grapes, Lowbush Blueberries, Cranberries)*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in orchards. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

*Spray Drift Management*

For impacts of the spray drift mitigation to Berries and Small Fruit, see above.

Tropical and Sub-tropical Fruits (Avocado, Olive)

*Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in orchards. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole) or the perimeter of a field (e.g., fencerows). Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our

assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

#### *Spray Drift Management*

For impacts of the spray drift mitigation to Avocado and Olives, see above.

For more information refer to *Simazine Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation on Orchards, Vineyards, Caneberries, Strawberries, and Christmas Trees* in the docket.

#### Nursery and Ornamentals

##### *Restrict Mechanically Pressurized Handgun Applications of DF/WDG/L Formulations to Spot Treatments Only*

The agency assumes that mechanically pressurized handguns would be used for spot treatments to small areas, not for broadcast treatments over large acreages in nursery and ornamental operations. In some instances, applicators may use a mechanically pressurized handgun attached to small ground boom sprayers to treat around an obstruction (e.g., telephone pole), the perimeter of a field (e.g., fencerows), or for small groups of nursery or ornamental crops in small acreage sites. Therefore, limiting mechanically pressurized applications to spot treatments is likely to be low in terms of acres impacted. However, if there are growers who use mechanically pressurized handguns for broadcast applications of simazine, they would have to make an application using a different herbicide, which may be more expensive and possibly less effective. The agency invites public comments to better inform impacts if their practices differ from our assumption that most applications with mechanically pressurized hand guns are used primarily for spot treatment.

#### *Spray Drift Management*

Nursery and ornamental users generally have mixtures of many plant species and are therefore careful about off-site movement. Therefore, impacts of the spray drift mitigation relevant to maximum droplet size, boom height, and maximum windspeed should be minimal, see above.

For more information refer to *Atrazine and Simazine Use in Forestry, Rights of Way, Turfgrass, and Nursery: Response to Comments, Usage, and Benefits*. in the docket.

### **D. Tolerance Actions**

EPA is proposing the establishment and revocation, as well as amendment of tolerances for several commodities. Refer to Section III.A.3 for details. The agency will use its FFDCa rulemaking authority to make the needed changes to the tolerances.

### **E. Proposed Interim Registration Review Decision**

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

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

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of simazine, nor is it making a complete endangered species finding or a complete assessment of effects to pollinators. 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 simazine. The agency's final registration review decision for simazine 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.

## **F. Data Requirements**

The EPA issued a GDCI requiring multiresidue method testing results (OCSPP 860.1360) for simazine and its chlorinated metabolites (desethylatrazine (DEA), desisopropylatrazine (DIA), and diaminochloroatrazine (DACT)) on December 12, 2018. These data are needed to determine the suitability of multiresidue methodology for quantification of simazine and its regulated metabolites. These data are under development and are required to be submitted to the agency by December 20, 2020.

No additional data are anticipated to be needed to be called-in for this registration review at this time. The EPA will consider requiring submission of pollinator data as a separate action.

The analytical reference standard for desisopropylatrazine (DIA), and diaminochloroatrazine (DACT) have expired and must be submitted to the EPA's National Pesticide Standards Repository (see <https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository>).

## **V. NEXT STEPS AND TIMELINE**

### **A. Proposed Interim Registration Review Decision**

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

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labels and requests for amendment of registrations 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 Simazine

Registration Review Case#: 0070 PC Code: 080807 Chemical Type: Herbicide Chemical Family: Triazine Mechanism of Action: 5						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment (use to briefly clarify or elaborate on risk or mitigation)
Occupational handler (applicator of simazine via mechanically-pressurized handgun on numerous uses)	<ul style="list-style-type: none"> <li>Air (e.g., respirable particles at/on site while mixing/loading)</li> <li>Residues (e.g., at/on site while mixing/loading)</li> </ul>	Combined dermal and inhalation	4-day and longer	LH surge suppression	Limit application to spot treatment only	
Occupational handler (applicator of simazine via backpack sprayer on oranges and grapefruit)	<ul style="list-style-type: none"> <li>Air (e.g., respirable particles at/on site while mixing/loading)</li> <li>Residues (e.g., at/on site while mixing/loading)</li> </ul>	Combined dermal and inhalation	4-day and longer	LH surge suppression	Require additional PPE (double layer)	
Post-Application Residential and Recreational	<ul style="list-style-type: none"> <li>Chlorotriazine cumulative aggregate exposure (food +water+ residential post-application exposure to treated residential turf)</li> </ul>	<ul style="list-style-type: none"> <li>Dietary (food)</li> <li>Combined dermal and incidental oral (residential post-application to treated residential turf)</li> </ul>	4-day and longer	LH surge suppression	Prohibit residential and recreational turf use	
Avian	Dietary and spray drift	Ingestion	Chronic	Growth	Enforceable spray drift management measures	Label clarification
Mammals	Dietary and spray drift	Ingestion	Chronic	Reproductive and Growth	Enforceable spray drift management measures	Label clarification
Terrestrial Plants	Spray drift	Direct contact	Acute Chronic	Growth	Enforceable spray drift management measures	Label clarification
Aquatic plants (nonvascular)	Spray drift and runoff	Direct contact	Acute Chronic	Growth	Enforceable spray drift management measures	Label clarification

### Appendix B: Proposed Labeling Changes for Simazine Products

Description	Proposed Label Language for Simazine Products	Placement on Label
<p><b>PPE Requirement</b>            For backpack application of DF, WDG, and liquid formulations on Grapefruit and Oranges</p>	<p>Mixer/loader/applicators for backpack application to grapefruit and oranges are required to wear double layer clothing</p>	
<p><b>Use Restrictions</b> for mechanically pressurized handguns of DF, WDG, and liquid formulations</p>	<ul style="list-style-type: none"> <li>• Applications made by mechanically pressurized handguns are restricted to spot treatment only for the following uses               <ul style="list-style-type: none"> <li>○ Citrus (Grapefruit, Oranges, Lemons)</li> <li>○ Pome Fruits (Apples, Pears)</li> <li>○ Stone Fruits (Cherries [sweet and tart], peaches, Plums, Nectarines)</li> <li>○ Tree Nuts (Pecans, Walnuts, Filberts, Almonds, Macadamia Nuts)</li> <li>○ Berry and Small Fruit (Blueberries, Blackberries, Loganberries, Raspberries, Grapes, Lowbush Blueberries, Cranberries)</li> <li>○ Tropical and Sub-tropical Fruits (Avocado, Olive)</li> <li>○ Nursery/Ornamentals</li> <li>○ Sweet Corn</li> </ul> </li> <li>• Applications made by mechanically pressurized handguns to strawberries are restricted to either spot treatment only or mixer/loader/applicators are required to wear double layer of clothing.</li> </ul>	
	<p><b>End Use Products</b></p>	
<p>Mechanism of Action Group Number</p>	<p><b>Note to registrant:</b></p> <ul style="list-style-type: none"> <li>• Include the name of the <b>ACTIVE INGREDIENT</b> in the first column</li> <li>• Include the word “<b>GROUP</b>” in the second column</li> <li>• Include the <b>MODE/MECHANISM OF ACTION CODE</b> 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)</li> <li>• Include the type of pesticide (<i>i.e.</i>, <b>HERBICIDE</b> or <b>FUNGICIDE</b> or <b>INSECTICIDE</b>) in the fourth column.</li> </ul>	<p>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</p>

Description	Proposed Label Language for Simazine Products				Placement on Label
	Simazine	GROUP	5	Herbicide	be surrounded by a black rectangle.
<b>For products registered for use on turf</b>	Use is permitted on golf course turf and sod farms only. Do not use on residential turf or lawns, institutional turf, parks or recreational fields.				Directions for Use
<b>Updated Gloves Statement</b>	Update the glove statements to be consistent with Chapter 10 of the Label Review Manual				In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
<b>Updated Respirator Language</b>	<p>[<b>Note to registrant:</b> If your end-use product only requires protection from particulates only (low volatility), use the following language:]  “Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.”  *Drop the “N” option if there is oil in the product’s formulation and/or the product is labeled for mixing with oil-containing products.</p> <p>[<b>Note to registrant:</b> For respiratory protection from organic vapor <b>and</b> particulates (or aerosols), use the following language:]  “Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor(OV) cartridges and combination N*, R, or P filters; <u>OR</u> a NIOSH-approved gas mask with OV canisters; <u>OR</u> a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters.”</p> <p>[<b>Note to registrant:</b> <u>For products requiring protection for organic vapor only</u>, use the following language:]  “Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor(OV) cartridges; <u>OR</u> a NIOSH-approved full face respirator with OV cartridges; <u>OR</u> a gas mask with OV canisters; <u>OR</u> a powered air purifying respirator with OV cartridges.”</p>				In the Personal Protective Equipment (PPE) within the Precautionary Statements

Description	Proposed Label Language for Simazine Products	Placement on Label
	*Drop the “N” option if there is oil in the product’s formulation and/or the product is labeled for mixing with oil-containing products.	
<b>Non-target Organism Advisory Statement</b>	“NON-TARGET ORGANISM ADVISORY STATEMENT: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift.”	Environmental Hazards
<b>HERBICIDE RESISTANCE MANAGEMENT:</b> Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 ( <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-notice-year">https://www.epa.gov/pesticide-registration/pesticide-registration-notice-year</a> )	Directions for Use, prior to directions for specific crops under the heading “WEED RESISTANCE-MANAGEMENT”
<b>Additional Required Labelling Action</b> <b>Applies to all products delivered via liquid spray applications</b>	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
<b>Directions for mixing/loading products packaged in water soluble bags</b>	<p>Instructions for Introducing Water Soluble Packages Directly into Spray tanks:</p> <p>"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)].</p> <p>Handling Instructions  Follow these steps when handling pesticide products in WSPs.</p> <ol style="list-style-type: none"> <li>1. Mix in spray tank only.</li> <li>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.</li> <li>3. Keep the WSP in outer packaging until just before use.</li> <li>4. Keep the WSP dry prior to adding to the spray tank.</li> <li>5. Handle with dry gloves and according to the label instructions for PPE.</li> </ol>	

Description	Proposed Label Language for Simazine Products	Placement on Label
	<p>6.Keep the WSP intact. Do not cut or puncture the WSP.  7.Reseal the WSP outer packaging to protect any unused WSP(s).</p> <p>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.</p> <ol style="list-style-type: none"> <li>1.If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.</li> <li>2.Fill tank with water to approximately one-third to one-half of the desired final volume of spray.</li> <li>3.Stop adding water and stop any agitation.</li> <li>4.Place intact/unopened WSP into the tank.</li> <li>5.Do not spray water from a hose or fill pipe to break or dissolve the WSP.</li> <li>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.</li> <li>7.Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.</li> <li>8.Stop agitation before tank lid is opened.</li> <li>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.</li> <li>10.Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.</li> <li>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.</li> <li>12.Use the spray solution when mixing is complete.</li> <li>13.Maintain agitation of the diluted pesticide mix during transport and application.</li> <li>14.It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label.</li> </ol> <p>ENGINEERING CONTROLS  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.”</p>	

Description	Proposed Label Language for Simazine Products	Placement on Label
<p><b>Spray Drift Management Application Restrictions</b> for products that are applied as liquids and allow ground boom applications</p>	<p><b>“SPRAY DRIFT Ground Boom Applications:</b></p> <ul style="list-style-type: none"> <li>• User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy.</li> <li>• Applicators are required to use a coarse or coarser droplet size (ASABE S572.1).</li> <li>• Do not apply when wind speeds exceed 10 miles per hour at the application site.</li> <li>• Do not apply during temperature inversions.”</li> </ul>	<p>Directions for Use, in a box titled “Spray Drift” under the heading “Ground Boom Applications”</p>
<p><b>Advisory Spray Drift Management Language</b> for all products delivered via liquid spray application</p>	<p><b>“SPRAY DRIFT ADVISORIES</b>  THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.</p> <p><b>IMPORTANCE OF DROPLET SIZE</b>  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.</p> <p><b>Controlling Droplet Size – Ground Boom</b> <i>(note to registrants: remove if ground boom is prohibited on product labels)</i></p> <ul style="list-style-type: none"> <li>• <b>Volume</b> - 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.</li> <li>• <b>Pressure</b> - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size.</li> <li>• <b>Spray Nozzle</b> - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.</li> </ul> <p><b>BOOM HEIGHT – Ground Boom</b> <i>(note to registrants: remove if ground boom is prohibited on product labels)</i>  For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p><b>SHIELDED SPRAYERS</b>  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.</p> <p><b>TEMPERATURE AND HUMIDITY</b>  When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p> <p><b>TEMPERATURE INVERSIONS</b></p>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Proposed Label Language for Simazine Products	Placement on Label
	<p>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.</p> <p><b>WIND</b>  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.”</p>	
<p><b>Advisory Spray Drift Management Language</b> for all products that allow liquid applications with handheld technologies</p>	<p><b>“SPRAY DRIFT ADVISORIES</b>  <u><b>Handheld Technology Applications:</b></u></p> <ul style="list-style-type: none"> <li>• Take precautions to minimize spray drift.”</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

## Appendix C: Endangered Species Assessment

This Appendix provides general background about the Agency's assessment of risks from pesticides to endangered and threatened (listed) species under the Endangered Species Act. Additional background specific to simazine appears at the conclusion of this Appendix.

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<sup>4</sup>. 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 simazine 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 simazine. 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 simazine as part of completing this registration review.

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<sup>4</sup> <https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process>

Simazine is one of the chemicals in stipulated partial settlement agreement in the case of Center for Biological Diversity et. al., v. United States Environmental Protection Agency et al., No. 3:11 cv 0293 (N.D. Cal.). Among other provisions, this agreement sets an August 14, 2021, deadline for EPA to complete nationwide ESA section 7(a)(2) effects determination for simazine and, as appropriate, request initiation of any ESA section 7(a)(2) consultations with the Services that EPA may determine to be necessary as a result of those effects determinations.

## 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, subchronic 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 review decision for simazine, 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), simazine 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. A second list of chemicals identified for EDSP screening was published on June 14, 2013<sup>5</sup> 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.

Simazine is on List 1 for which EPA has received all of the required Tier 1 assay data. The Agency has reviewed all of the assay data received for the appropriate List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets (see Docket # EPA-HQ-OPP-2013-0251).

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<sup>5</sup> See <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

Docket Number EPA-HQ-OPP-2013-0251  
www.regulations.gov

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<sup>6</sup>.

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<sup>6</sup> <https://www.epa.gov/endocrine-disruption>