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Propazine

Proposed Interim Registration Review Decision
Case Number 0230

December 2019

Approved by: _____

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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 propazine (PC Code 080808, case 0230), 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 propazine can be found in the EPA's public docket (EPA-HQ-OPP-2013-0250) at www.regulations.gov.

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

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

Propazine is an herbicide with products registered for use to control broadleaf and grass weeds. It is a member of the triazine chemical class, which includes atrazine and simazine and the three major chloro-metabolites: desethyl-s-atrazine (DEA), desisopropyl-s-atrazine (DIA), and diaminochlorotriazine (DACT). Of the three major triazine chloro metabolites, only DEA and DACT are metabolites of propazine. The EPA has determined that the triazines and their degradates share a common mechanism of toxicity, and as such, human health risks were assessed together through a triazine cumulative risk assessment. Each of the triazines produces a hydroxy degradate (i.e. hydroxypropazine) that has a different mode of action from the parent and major chloro-metabolites. Pesticide products containing propazine are registered for use on grain sorghum and containerized ornamental plants grown in greenhouses. There are no registered residential uses of propazine. The first product containing propazine was registered in 1998, and therefore propazine was not subject to reregistration which was the process to re-evaluate pesticides registered prior to November 1, 1984. There is one technical and end-use registrant for propazine: Albaugh, 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 propazine 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 case.

A. Summary of Propazine Registration Review

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

- June 2013 - The *Propazine Preliminary Work Plan* (PWP) (June 2013)*; Atrazine, Propazine, and Simazine. Human Health Risk Scoping Document in Support of Registration Review* (June 2013), and *Registration Review: Problem Formulation for Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments for Propazine* (May 2013) were posted to the docket for a 60-day public comment period.

- January 2014 - The *Propazine Final Work Plan* (FWP) was issued. The agency received two sets of public comments concerning the PWP from the technical registrant for propazine, Albaugh, Inc., and the FIFRA Endangered Species Task Force (FESTF). The comments did not result in a change to the schedule, risk assessment needs, or anticipated data requirements in the FWP. In the PWP, the EPA also solicited comments about the specific topics of environmental justice, water quality concerns, and trade irritants, but no comments or information were received concerning those issues.

- May 2014 – A Generic Data Call-In (GDCI) for propazine was issued for data needed to conduct the registration review risk assessments (GDCI-080808-1371). All data were submitted, and the GDCI is satisfied. A subsequent GDCI was issued on December 2018 requiring multiresidue testing (OSCPP 860.1360) for propazine and its chloro metabolites: G-30033 (DEA) and G-28273 (DACT). This study was determined to be acceptable, and the GDCI is satisfied.

- June 2016 and July 2018 - The agency announced the availability of *Preliminary Ecological Risk Assessment for Registration Review of Propazine* and *Propazine. Draft Human Health Risk Assessment for Registration Review,* respectively for public comment periods. 1,225 comments specific to propazine were received during the comment periods. These comments and the agency's responses are summarized below. The comments did not change the risk assessments or registration review timeline for propazine.

- December 2019 - The agency has completed the PID for propazine. The EPA will announce the availability of the PID in the propazine docket and open a 60-day public comment period. Along with the PID, the following documents will also be posted to the propazine docket:

    - *Atrazine, Simazine, Propazine: Response to Public Comments on Registration Review Human Health Risk Assessments*, November 21, 2019
    - *Propazine – EFED Response to Public Comments Received on the Preliminary Risk Assessment for Registration Review*, November 21, 2019
    - *Atrazine and Propazine Use on Grain Sorghum and Fallow Areas: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation*, November 25, 2019

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

During the public comment periods for the *Preliminary Ecological Risk Assessment for Registration Review of Propazine*, which opened on June 6, 2016 and closed on October 5, 2016 and for the *Propazine. Draft Human Health Risk Assessment for Registration Review*, which opened on July 26, 2018 and closed on November 23, 2018, the agency received comments specific to propazine from approximately 1,225 sources. Most comments (approximately 1,220) were submitted as part of a mass mailing campaign in support of propazine use on sorghum. In addition to the mass mailing campaign, comments were submitted by the propazine technical registrant (Albaugh, LLC), the U.S. Department of Agriculture (USDA), sorghum and agricultural farmers, and citizens. Albaugh, LLC provided comments of a technical nature about the draft risk assessments and the benefits of propazine. The USDA and sorghum/agricultural farmers provided comments in support of propazine use and information about its use and usage, and benefits for sorghum. Other public comments submitted to the propazine docket included comments for or against triazine use (some of which mention propazine; others were specific to simazine and atrazine only), and generic comments about pesticides not related to the triazines or propazine.

Comments of a technical nature concerning the draft propazine risk assessments, use and usage, or benefits of propazine are summarized and addressed in the *Atrazine, Simazine, Propazine: Response to Public Comments on Registration Review Human Health Risk Assessments*; *Propazine – EFED Response to Public Comments Received on the Preliminary Risk Assessment for Registration Review*; and *Atrazine and Propazine Use on Grain Sorghum and Fallow Areas: Response to Comments, Usage, Benefits, and Impacts of Potential Mitigation*. For additional details please refer to these documents which will be posted on the propazine registration review docket (www.regulations.gov). The agency thanks all commenters for their comments and has considered them in developing this PID.

II. USE AND USAGE

Propazine is a selective herbicide that is grouped by the Weed Science Society of America with other triazines in Class 5. Propazine has residual activity and can prevent weeds from emerging for several weeks. The primary target pests based on pesticide Market Research Data and extension literature are pigweed species.

Sorghum is the only crop that has recorded propazine use. Based on the available pesticide usage data, growers apply propazine to 4% of the sorghum crop and treat a total of 308,800 acres. The average number of applications per year is slightly over one application and the average single application rate is 0.707 pounds of active ingredient per acre.

Most sorghum growers apply propazine before crop emergence (80% of acres treated). Propazine can be applied by ground equipment or by air. Propazine was annually applied by air to an average of 1,200 acres over the years 2013-2017, all in Texas and Kansas. All aerial applications were done with liquid formulations.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of propazine. The EPA has made a determination of a common mechanism of toxicity for propazine, atrazine, and simazine (the triazines) and their chlorinated metabolites. Therefore, in addition to assessing potential risk from propazine, the EPA evaluated the potential cumulative risk from combined exposure to the triazines and their metabolites. For additional details on the human health assessments, see the *Propazine Draft Human Health Risk Assessment for Registration Review* and the *Chlorotriazines: Cumulative Risk Assessment: Atrazine, Propazine, and Simazine*, which are available in the public docket.

1. Risk Summary and Characterization

There are no dietary, residential (handler and post-application), non-occupational bystander, or occupational post-application risk estimates of concern for the registered uses of propazine. Occupational handler (combined dermal and inhalation exposure) risk estimates of concern with baseline attire and label-specified PPE (chemical resistant gloves) were identified for some worker scenarios for the greenhouse ornamental use. See below for details.

Dietary (Food + Water) Risks

There are no anticipated food exposures to propazine. Based on available food consumption survey data and pesticide field trial residue studies, human exposure to propazine residues from sorghum use is considered negligible[1]. With insignificant exposure to propazine in food expected from the current uses, the total dietary exposure to propazine and its metabolites is through drinking water. A drinking water level of comparison (DWLOC) approach was used to calculate potential drinking water exposure and risk to propazine and its major chloro metabolites, as well as hydroxypropazine residues of concern. No dietary (drinking water) risks of concern were identified. For propazine and its major chloro metabolites, the acute and 4-day DWLOCs are greater than estimated drinking water concentrations (EDWCs). For hydroxypropazine, the chronic DWLOCs are greater than the EDWCs. Therefore, there are no dietary (drinking water) risks of concern for propazine and its major chloro metabolites or hydroxypropazine.

Residential Handler and Post-Application Risks

There are no registered residential uses of propazine. Consequently, no risk assessment was performed for these scenarios. Therefore, there are no residential risks of concern.

Non-Occupational Spray Drift Risks

A quantitative non-occupational spray drift assessment was conducted for propazine use on sorghum (1.2 lb ai/A) to assess potential exposure from off-target movement and deposition of propazine (i.e., spray drift); spray drift is not expected from the registered use on greenhouse ornamentals. Adult dermal and children's (1 to < 2 years old) dermal and incidental oral risk estimates from spray drift exposure to propazine were not of concern at the edge of field assuming screening-level nozzle types and droplet sizes (MOEs > the level of concern (LOC) of 30).

Aggregate Risks

There are no residential uses of propazine, and exposures from food are not expected. Exposures are only expected from drinking water, and there are no risks estimates of concern for this pathway. There are no aggregate risks of concern for propazine.
Cumulative Risks

[1] *What We Eat in America* (WWEIA/NHANES). 2003-2010. USDA and DHHS surveys report no human consumption for sorghum grain. In addition, field trial studies have demonstrated that residues of propazine and its metabolites are less than the limit of quantification (LOQ) of the analytical test method in sorghum grain.

The EPA has determined that propazine shares a common mechanism of toxicity (neuroendocrine effects in rats that can cause developmental and reproductive toxicity) with the other triazine herbicides, atrazine and simazine, and their chlorinated metabolites (DEA, DIA, and DACT). The EPA assessed cumulative risk from the triazines and their chlorinated metabolites in the July 10, 2018 document titled *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.

There were some 4-day cumulative aggregate (food + drinking water + residential) exposures; however, these risks of concern were driven by residential uses of simazine and atrazine. Propazine did not contribute to the aforementioned 4-day cumulative aggregate (food + drinking water + residential) exposures as there are no registered residential uses of propazine. Further information regarding these cumulative aggregate risks of concern can be found in *Chlorotriazines: Cumulative Risk Assessment - Atrazine, Propazine, and Simazine.*

Occupational Handler Risks

Occupational handler dermal and inhalation exposure and risk estimates were calculated for the registered uses of propazine. The occupational handler exposure and risk estimates indicate that some of the combined dermal and inhalation risk estimates are not of concern (MOEs > 30) with baseline attire + label specified PPE (chemical resistant gloves) for greenhouse ornamental use. Mixing/loading/applying liquids via backpack spray equipment to greenhouse ornamentals is not of concern with the addition of a double layer of clothing. Mixing/loading/applying liquids with a mechanically pressurized handgun to greenhouse ornamentals remains of concern when assuming label-specified PPE, a double layer of clothing, and a particulate-filtering facepiece respirator (PF10) respirator. Dermal exposures are the highest contributors to the combined dermal + inhalation risk estimates.

The propazine registrant has requested to voluntarily cancel the greenhouse use which will nullify these risks.

Occupational Post-Application Risks

Occupational post-application dermal exposure and risk estimates were assessed for registered uses of propazine (sorghum and greenhouse-grown ornamentals). Although there are no chemical-specific dislodgeable foliar residue (DFR) data available for propazine, DFR data are available on field corn treated with liquid and dry flowable formulations of atrazine. Using atrazine-specific DFR data, the occupational post-application MOEs (range from 120 to 2,500) are not of concern for the registered uses of propazine on the day of application (LOC = 30).

2. Human Incidents and Epidemiology

The agency performed an updated Tier I review of human incidents from 2010-2017 for the triazine herbicides (atrazine, propazine and simazine) using the following sources: OPP Incident Data System (IDS); the National Pesticide Information Center (NPIC); the California Pesticide Illness Surveillance Program (CA PISP); and the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) databases (S. Recore *et. al*., D444041, 11/01/2017). The Agricultural Health Study (AHS) findings and epidemiological investigations for the triazines are reviewed in separate documents (A. Aldridge, D447696, 7/09/2018 and A. Aldridge, D447697, 07/09/2018).

No propazine incidents were reported to IDS, NPIC, CA PISP, or SENSOR-Pesticides and there does not appear to be a concern at this time. The agency will continue to monitor the incident information and additional analyses will be conducted if ongoing incident monitoring indicates a concern.

The agency recently conducted an updated epidemiology systematic literature review to investigate evidence about the human health effects associated with exposure to atrazine, simazine, and/or propazine. Ninety-three publications from 1990 – 2017 were identified for inclusion in the epidemiology literature review. Of these 93 publications, 90% reported an estimate of effect for atrazine and 14% reported an estimate of effect for simazine (not mutually exclusive). No epidemiology studies were found for propazine. However, since atrazine, simazine and propazine share a common mechanism of toxicity, refer to the risk assessments for atrazine (K. Rickard *et al.*, D418316, 07/10/2018) and simazine (K. Rickard *et al.*, D402163, D428603, 07/10/2018) for additional information regarding the human health effects associated with certain triazines.

3. Tolerances

Tolerances are established under 40 CFR §180.243 for residues of propazine in/on sorghum commodities. In a separate action, the EPA will use its Federal Food, Drug, and Cosmetic Act (FFDCA) rulemaking authority to propose changes which will have a public comment period. The agency intends to propose that the residue definition for the tolerance expression for propazine be modified in accordance with current policy on tolerance definitions, to read:

"Tolerances are established for residues of the herbicide propazine, 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 propazine, 6-chloro-N,N'-bis(1-methylethyl)-1,3,5-triazine-2,4-diamine, its desisopropyl metabolite 2-amino-4-chloro-6-isopropylamino-s-triazine (G-30033) (DEA), and its diamino metabolite 2,4-diamino-6-chloro-s-triazine (G-28273) (DACT), calculated as the stoichiometric equivalent of propazine, in or on the commodity."

The recommended tolerances are lower than the established tolerances and are based on limit of quantification (LOQ) considerations. There were no detects in sorghum grain or stover; therefore, the proposed tolerance is 0.15 ppm (LOQ = 0.05 ppm; 0.05+0.05+0.05=0.15 ppm). There were no detects in trials with sorghum forage for propazine or G-30033, but a maximum level of 0.078 ppm was found for DACT, so the EPA intends to propose the tolerance be set at 0.2 ppm.

No Codex or Canada Pest Management Regulatory Agency (PMRA) maximum residue levels (MRLs) have been established for propazine. There are no harmonization issues at this time.

Table 1: Summary of Proposed Tolerance Revisions for Propazine (40 CFR §180.243)

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Sorghum, grain, forage	0.25	0.2	Sum of LOQs for propazine and DEA plus maximum level of DACT in forage
Sorghum, grain, grain	0.25	0.15	Sum of LOQs: no detects in grain
Sorghum, grain, stover	0.25	0.15	Sum of LOQs: no detects in stover

4. Human Health Data Needs

The *Propazine Draft Human Health Risk Assessment for Registration Review* stated that there were no multiresidue method testing results (OCSPP 860.1360) for the regulated chloro metabolites of propazine: G-30033 (DEA) and G-28273 (DACT); however, this study (MRID 50917201) was recently submitted to the EPA and found to be acceptable. The agency does not anticipate any further human health data needs for the propazine 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 propazine. For additional details on the ecological assessment for propazine, see the *Preliminary Risk Assessment for Registration Review of Propazine* and *Propazine: Addendum to "Preliminary Risk Assessment for Registration Review of Propazine" for Update on ECOTOX Database Query* which are 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 propazine. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

The EPA calculated risk estimates associated with propazine use to non-target mammals; birds, reptiles and terrestrial-phase amphibians; terrestrial invertebrates; terrestrial plants; fish, amphibians, and aquatic invertebrates; and aquatic vascular and nonvascular plants. Risk estimates (risk quotients, or RQs) were compared with the EPA's LOC. For ecological risk, RQ's 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, reptiles, and terrestrial-phase amphibians. Risks from spray drift were identified for terrestrial and aquatic nonvascular plants. In addition, available information suggests potential risk to terrestrial invertebrates. The draft risk assessment assessed the maximum label number of applications and maximum application rate (1.2 lb. a.i./A/application).

Terrestrial Risks

Mammals
Propazine is classified as practically nontoxic to mammals on an acute exposure basis, but effects from chronic exposure (adult toxicity and reproduction effects) were observed as low as 50 mg ai/kg-body weight/day. 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 most scenarios modeled for all uses. Chronic RQs range from 0.16 – 25, compared to the LOC of 1.0, based on on-field exposure estimates.

Birds, Reptiles, and Terrestrial-Phase Amphibians
Propazine is classified as practically nontoxic to terrestrial birds from acute dose-based or dietary-based exposure. Chronic risk estimates minimally exceed the agency's LOC of 1 (chronic RQ = 1.1, LOC = 1). The adverse effect upon which the chronic endpoint is based is adult female body weight gain.

Terrestrial Invertebrates (honeybees)
Available toxicity data indicate that propazine is practically non-toxic to honeybees on an acute contact basis.

Given the uncertainty surrounding potential risks to terrestrial invertebrates due to lack of data, 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 propazine. If the agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for propazine, 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*[2].

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

Table 1: Potential Pollinator Data Requirements	
Guideline #	**Study**
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†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators (tunnel or colony feeding study)
Tier 3†	
850.3040	Full-Field testing for pollinators

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

Terrestrial Plants

There were risks of concern for terrestrial plants. Effects were seen in both seedling emergence and vegetative vigor studies in both monocots and dicots, more so for dicots. The plants used in the guideline testing were crop species. The EPA used a 25% inhibition of growth endpoint focusing on either biomass or emergence. For aerial applications of propazine, monocot RQs were 2.06 (dry), 5.14 (semi-aquatic), and 1.71 (spray drift) and dicot RQs were 4.50 (dry), 11.25 (semi-aquatic), and 3.75 (spray drift) which all exceeded the LOC of 1. For ground applications of propazine, monocot RQs were 0.69 (dry), 3.77 (semi-aquatic), and 0.34 (spray drift) and dicot RQs were 1.50 (dry) and 8.25 (semi-aquatic), and 0.75 (spray drift) with an LOC of 1. RQ numbers exceeding the LOC indicate a potential for risk to that plant group.

Aquatic Risks

Fish, Amphibians, and Aquatic Invertebrates

There are no risks of concern for fish, amphibians, and aquatic invertebrates.

Aquatic Vascular and Nonvascular Plants

There is no risk of concern for aquatic vascular plants from the propazine use on sorghum (RQ = 0.32 – 0.43; LOC = 1). There is a risk of concern for aquatic nonvascular plants from the propazine use on sorghum via aerial and ground spray drift with RQs (1.3 – 1.7) exceeding the LOC of 1.

2. Ecological Incidents

The ecological incident information system (EIIS) is an OPP database that houses ecological incidents that have been reported to the Agency. When available, EIIS includes data and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. IIS incidents are categorized

according to the certainty that the incident resulted from pesticide exposure. The Avian Monitoring System (AIMS) is a database administered by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. Many of the incidents listed in this database are also in the EIIS.

As of October 2019, there are no reported incidents for propazine in the Ecological Incidents database or in the Aggregate Summaries database.

The absence of reported incidents should not be interpreted as an absence of incidents. Incident reports for non-target organisms typically provide information only on mortality events and plant damage. Sublethal effects in organisms such as abnormal behavior, reduced growth and/or impaired reproduction are rarely reported, except for phytotoxic effects in terrestrial plants.

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 propazine is complete.

C. Benefits Assessment

General Benefits of Propazine

Flexible Use Pattern
Propazine can be applied either before or after the crop emerges. Additionally, propazine has residual activity and can prevent weeds from emerging for several weeks.

Crop Safety
Propazine is one of three herbicides registered for use on sorghum that do not require a seed safener to prevent injury to the emerging crop. Saflufenacil and atrazine are the other sorghum use herbicides that do not require a safener. Generally, propazine offers better crop safety against grain sorghum than atrazine.

Inexpensive
Propazine is a relatively inexpensive herbicide, at approximately $4/acre to apply, on average; as compared to a commonly used preemergence active ingredient, metolachlor-S, at $10/acre. Propazine is mostly used before crop emergence when control of weed pests is paramount to establishing a crop which significantly reduces the probability of incurring some yield and financial loss.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The agency has reviewed the risks, benefits, and uses of propazine in formulating its proposed risk mitigation. The EPA has identified potential human health risks of concern for occupational handlers from dermal and inhalation exposure scenarios, such as mixing/loading/applying using backpack sprayers and mechanically pressurized handgun application equipment for greenhouse ornamental use. The EPA also identified cumulative risks for the triazines which stem from atrazine and simazine, but not propazine. The EPA has also identified potential ecological risks of concern for mammals, birds, terrestrial plants, and non-vascular aquatic plants. The agency weighed the benefits against the potential ecological risks and, as a result, is proposing mandatory spray drift language which will reduce ecological exposure of propazine in the environment. Besides mandatory spray drift management language, the EPA is proposing to update the herbicide resistance management language and personal protective equipment (gloves) on the propazine label. The registrant has agreed to all of the proposed label changes for propazine.

1. Cancellation of Greenhouse Use

The registrant has requested cancellation of the greenhouse use. This will nullify the occupational handler risks of concern for dermal and inhalation exposures that are present for greenhouse uses. This cancellation will be published in the federal register as a separate action.

2. Mandatory Spray Drift Reduction

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

The agency is proposing the following spray drift mitigation language to be included on all propazine 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 providing recommendations which allow propazine registrants to standardize all advisory language on propazine 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 aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters.

Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.

- For aerial applications, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- For groundboom applications, do not apply when wind speeds exceed 15 mph at the application site.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground and/or aerial applications, select nozzle and pressure that deliver medium or courser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1).

3. Non-target 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 propazine is uncertain. It is possible that pollinators may be exposed to propazine 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 non-target organism advisory language to be placed on propazine labels to address this potential concern. The proposed statement is below.

> "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."

4. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.[3] 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.

[3] 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 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.

5. Label Cleanup

The agency is proposing two items for label cleanup as stated below.

- The agency is proposing to update the glove statement currently on labels to be consistent with the Label Review Manual[4]. The proposed new glove language does not fundamentally change the personal protective equipment that workers need to use, and therefore should impose no impacts on users.
- The agency is proposing to add the following information on product labels near rate tables: "Do not apply propazine if atrazine has been or will be applied to the same acreage in the same growing season."

6. Expected Impacts of Proposed Mitigation

Spray drift reduction language is being proposed. The impact of each component to sorghum growers is discussed below.

<u>Impacts of Inversion Restriction</u>
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.

[4] See https://www.epa.gov/sites/production/files/2016-02/documents/chap-10-feb-2016.pdf

Impacts of the Percent of Usable Boom Length and Wind Speed Restrictions

If this mitigation is adopted, there will be no impact on propazine applications when boom length is 75% or less for fixed wing aircraft. However, flexibility will be increased by allowing applications to occur at a reduced percentage of the useable boom length (65% or less) except when wind speeds are greater than 10 mph and less than 15 mph. Given that applications with fixed wing aircraft were previously prohibited at wind speeds greater than 10 mph, this change would increase flexibility.

For rotary aircraft, there would be a 15% increase in boom length when wind speeds are less than 10 mph allowingmore area to be covered in less time. Additionally, there would be no reduction in boom length for applications made with helicopters when the wind speed is between 10 and 15 mph which would provide greater flexibility for applicators given that aerial applications are not allowed above 10 mph.

The agency has not assessed the impacts of windspeed restrictions for aerial applications and the requirement of a ½ swath displacement upwind at the downwind edge of the field.

Impacts of Establishing a Mandatory Maximum Spray Release Height Requirement for Ground Applications

Spray release height is important to minimize overlap of spray from nozzles while maintaining proper coverage. The agency has determined that a maximum release height of 4-feet allows adequate coverage for the majority of nozzles[5]. Therefore, the EPA does not anticipate any negative impact to growers.

Impacts of Windspeed Restrictions for Ground Applications

Wind conditions vary across the U.S., and wind speed restrictions could prevent timely applications of propazine. Survey data indicate that most applicators consider wind speed when making applications and typically apply at wind speeds of 15 mph or lower[6]. However, there are situations when applicators will spray at wind speeds greater than 15 mph (less than 10 percent of survey respondents). Mandatory wind speed restrictions complicate weed and crop management by reducing the available time to make applications and make it more likely that a grower may need to alter weed control plans. Once the window of application passes for either the crop or weeds, the weeds may be too large to be adequately controlled by propazine which could accelerate the development of resistance or there may be phytotoxicity issues at the later crop stage, either of which could reduce yields. Alternatively, a grower may develop another weed control strategy. However, changing plans could become more costly given that a different, more expensive herbicide(s) may be used or multiple applications could be needed to achieve the same level of weed control as propazine. Additionally, growers are likely to incur higher costs if they hire a custom applicator or purchase additional spray equipment and hire additional

[5] Tindall, K. and C. Hanson. 2018. Qualitative Benefits and Usage Assessment of Diflufenzopyr (PC Code 005108) and Diflufenzopyr-Sodium (PC Code 005107). Available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0911-0022.

[6] : Bish, M. and K.W. Bradley. 2017. Survey of Missouri Pesticide Applicator Practices, Knowledge, and Perceptions. Weed Technology 31:165–177. Available at: https://weedscience.missouri.edu/Pesticide%20Applicator%20Knowledge_2017.pdf.

personnel to operate the sprayers to make applications in a timely manner. If applications were not made in a timely manner, weed control could decline necessitating additional herbicide applications and/or resulting in yield losses.

Droplet Size

The agency is proposing a restriction on droplet size, because coarser droplets have been demonstrated to decrease spray drift and therefore reduce potential risks to non-target species. Because chemical-specific data for the performance of droplet sizes is limited, EPA was not able to evaluate the effects of medium or coarser droplet sizes (as defined by ASABE S572.1) specifically for propazine. Therefore, the EPA does not know the effect this requirement will have on the performance of propazine 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, more 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.

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

Impacts of Interaction of Individual Components of Spray Drift Mitigation

The agency acknowledges the impacts of multiple mitigations 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 will 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 to 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 or possibly days.

B. Tolerance Actions

The EPA intends to propose amendment of the tolerance expression and tolerances for several commodities. Refer to Section III.A.3 for details. The agency will use its FFDCA rulemaking authority to propose the needed changes to the tolerances.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP), 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 propazine, 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 propazine. The agency's final registration review decision for propazine will be dependent upon the result of the agency's ESA assessment and any needed § 7 consultation with the Services, and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

The propazine registration review generic data call-in issued in 2014 (GDCI-080808-1371) has been satisfied. The EPA issued a second propazine registration review DCI in 2018 (GDCI-080808-1776) requiring multiresidue testing (OSCPP 860.1360) for propazine and its chloro metabolites: G-30033 (DEA) and G-28273 (DACT). These data were found acceptable, and the data call-in has been satisfied. No additional data are anticipated as being needed at this time for this registration review. The EPA will consider requiring submission of additional pollinator data as a separate action.

The analytical reference standard for propazine's chloro metabolite G-28273 (DACT) has expired and must be submitted to the EPA's National Pesticide Standards Repository (see https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository).

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

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

Registration Review Case#: 0230
PC Code: 080808
Chemical Type: herbicide
Chemical Family: triazine
Mechanism of Action: inhibiting photosynthesis in photosystem II (PSII)

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 (for greenhouse ornamentals)	Dermal and inhalation	Dermal and inhalation	Short and intermediate term	Neurological, reproductive, developmental effects	Cancel greenhouse ornamental use and remove use from labels	Registrant requests voluntary use cancellation
Avian	Dietary and spray drift	Ingestion	Chronic	Growth	Enforceable spray drift management measures	Chronic dietary RQ = 1.1 which marginally exceeds the LOC of 1
Mammals	Dietary and spray drift	Ingestion	Chronic	Reproductive and Growth	Enforceable spray drift management measures	
Terrestrial Plants	Spray drift	Direct contact	Acute Chronic	Growth	Enforceable spray drift management measures	Aerial spray drift modeling showed RQs from 1.71 – 3.75 which exceed the LOC of 1
Aquatic plants (nonvascular)	Spray drift and runoff	Direct contact	Acute Chronic	Growth	Enforceable spray drift management measures	Aerial and ground spray modeling showed RQs from 1.3 – 1.7 which exceed the LOC of 1

Appendix B: Proposed Labeling Changes for Propazine Products

Description	Proposed Label Language for Propazine Products	Placement on Label
	Manufacturing Use Product	
Removal of greenhouse use pattern and use site	Remove "greenhouse weeds" / "in greenhouses" wording	Title/Directions for Use
	End Use Products	
Removal of greenhouse use	Remove wording referring to container grown ornamentals in greenhouses use	Title, Greenhouse Application Instructions
Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP"** in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide (*i.e.*, **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE)** in the fourth column. **PROPAZINE** | **GROUP** | **5** | **HERBICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the glove statements to be consistent with Chapter 10 of the Label Review Manual. The propazine end-use product contains outdated glove statements. All appropriate glove types must be identified on the label (not named as examples). Registrants are no longer allowed to reference solvent categories (A-H) or category charts on the product labels.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable

Description	Proposed Label Language for Propazine Products	Placement on Label
Non-target Organism Advisory Statement	"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
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action **Applies to all products delivered via liquid spray applications**	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	"**SPRAY DRIFT** **Aerial Applications:** • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1). • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Aerial Applications"

Description	Proposed Label Language for Propazine Products	Placement on Label
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications	"**SPRAY DRIFT** **Ground Boom Applications**: • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Ground Boom Applications"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	"**SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** (note to registrants: remove if ground boom is prohibited on product labels) • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** (**note to registrants**: remove if aerial application is prohibited on product labels) • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** (**note to registrants**: remove if ground boom is prohibited on product labels) For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** (**note to registrants**: remove if aerial application is prohibited on product labels)	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

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

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 propazine 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[7]. 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 propazine 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 propazine. 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 propazine as part of completing this registration review.

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

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

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

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[8] 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. Propazine is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[9]

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

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