Propylene Oxide (PPO)

Interim Registration Review Decision
Case Number 2560

June 2021

Approved by: _____

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Date: 06/29/2021

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for propylene oxide (PPO; PC Code 042501, case 2560). In a registration review decision under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out 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.[3] For more information on PPO, see EPA's public docket (EPA-HQ-OPP-2013-0156) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by 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. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing an ID for PPO 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). EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) to improve the consultation process for national threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[5] The Agency has not yet fully evaluated PPO's risks to federally listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the PPO registration review. Before completing registration review, EPA will also complete endocrine screening for PPO under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6]

PPO is a fumigant pesticide that is stored as a liquid in pressurized containers and applied as a volatilized gas. The mode of action for PPO has not been determined. PPO products are registered for use to prevent damage to commodities from insects, fungi/mold, and microbial

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[6] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

spoilage. Products containing PPO are registered for use as sterilants during processing and packaging of dried fruits, nuts, and spices, as well as at several non-agricultural use sites (*e.g.*, in shipping containers, boxcars, air-tight chambers, tents, and on pharmaceuticals). There are three product registrations of PPO: a 100% active ingredient (a.i.) technical product (EPA registration 47870-2); a 100% a.i. product registered for use on nuts, herbs, spices, cocoa beans and powder, and dried fruits (dried figs, raisins, and prunes; EPA registration 47870-1); and an 8% a.i. product registered for use on dried fruits and nuts, herbs, and spices (EPA registration 47870-3). As an antimicrobial, PPO also aids in the control of microbial spoilage by acting as a sterilant on food and non-food products for the same use sites described for conventional uses. Antimicrobial uses of PPO are registered under the same product labels as the registered conventional uses. All PPO products are Restricted Use Products (RUP) intended for manufacturing use or use by certified applicators only. There are no PPO products registered for homeowner use or at residential use sites. The first product containing PPO was registered in 1982. PPO underwent Reregistration and a Reregistration Eligibility Decision (RED) was issued in July 2006, amended in September 2008, and amended again in June 2009.

This document is organized in five sections:

- *Introduction* (summarizing the PPO registration review timeline and responding to public comments on the draft risk assessments and the Proposed Interim Decision (PID));
- *Use and Usage* (discussing how and why PPO is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Interim Registration Review Decision* (presenting EPA's interim decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete this registration review).

A. Updates to the Proposed Interim Decision

In October 2020, EPA published the PID for PPO. The Agency has made several changes to the PID in this ID. The changes are summarized in the bulleted list below.

- The Agency has updated the label language for emission reduction technology (scrubbers) to provide mitigation alternatives to scrubbers when fumigations occur in smaller (5,000 ft^3 or less) vacuum-sealed chambers.

- EPA has finalized the label language describing buffer zone specifications in Appendix B. The finalized language provides specific circumstances under which buffer zones are needed to mitigate potential bystander exposure to PPO. The finalized language also includes alternative mitigation measures to buffer zones. These involve ventilation stack height and aeration rate combinations or emissions reduction technology.

- In additional to revoking tolerances for the PPO reaction product propylene chlorohydrin (PCH), as was proposed in the PID, EPA will also amend the tolerance expression for PPO to include PCH.

- For applications above a rate of 1.5 oz PPO/ft^3, the Agency has increased the post-fumigation interval (PFI) for tree nuts (crop group 14-12) to 31 days, or to when measured residues are below tolerance levels.

- EPA has made other adjustments to the label language proposed in the PID to ensure consistency and clarity.

For details on how public comments influenced these changes, see Section I.C. For more information about the changes, see Section IV. and Appendix B.

EPA has also updated the draft Human Health Risk Assessment. The buffer zone tables used to assess potential risks to bystanders were updated to more accurately reflect real-world scenarios, based on public comments. Additional tables were also added to capture more potential use scenarios. The Agency also updated its tolerance recommendations for PPO. These changes are included in the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*, available in the public docket (EPA-HQ-OPP-2013-0156).

This ID finalizes the Agency's interim decision and draft supporting documents (*Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review* and *Propylene Oxide: Draft Ecological Risk Assessment [DRA] for Registration Review*), which are available in EPA's public docket.

B. Summary of Propylene Oxide Registration Review

On September 25, 2013, the Agency formally initiated registration review for PPO with the opening of the registration review docket for the case.[7] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of PPO:

- September 2013 – EPA posted the *Propylene Oxide (PPO) Preliminary Work Plan* (PWP) (September 19, 2013), the *Propylene Oxide Human-Health Assessment Scoping Document in Support of Registration Review* (September 5, 2013), and *Registration Review: Preliminary Problem Formulation for Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments for Propylene Oxide (PPO)* (August 8, 2013) to the public docket for a 60-day public comment period.

- March 2014 – EPA posted the *Propylene Oxide (PPO) Final Work Plan* (FWP) (March 18, 2014) to the public docket. The Agency received seven comments on the PWP. These comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP. In the FWP, EPA noted that data were needed to assess the potential toxicity of and exposure to PPO for humans and the environment. Data were also anticipated for tolerance enforcement.

[7] 40 C.F.R. § 155.50

- August 2014 – EPA issued a generic data call-in (GDCI) for PPO to obtain data needed to conduct the registration review risk assessments (GDCI-042501-1389). The registrants submitted all required data except as described below in Sections III.A.4. and III.B.4.

- October 2020 – EPA posted the *Propylene Oxide Human Health Draft Risk Assessment to Support Registration Review* (September 17, 2020 HHRA) and the *Propylene Oxide: Draft Ecological Risk Assessment (DRA) for Registration Review* (April 29, 2019 DRA) and the *Propylene Oxide (PPO) Proposed Interim Registration Review Decision* (PID) for a 60-day public comment period, which was extended for an additional 30 days. The Agency received 9 comments from 8 commenters. The Agency has summarized and responded to these comments in Section I.B., below. The comments changed the risk assessments and proposed mitigation for PPO. The overall conclusions of the risk assessments did not change; however, some modeling parameters used in the HHRA were adjusted based on the comments received. As a result, refinements were made to the mitigation proposed in the PID. Changes include defining the minimum post-fumigation interval (PFI) for tree nut commodities, narrowing of the requirements for buffer zones, and provision of alternative mitigation measures to buffer zones. For details of refinements to the HHRA see the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review* (available in the public docket). For mitigation refinements see Section IV. and Appendices B and C of this document.

- June 2021 – EPA is completing an ID for PPO and will post the ID to the public docket. Along with the ID, EPA will post the following document to the public docket:

    - *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*

C. Summary of Public Comments on the Draft Risk Assessments and Proposed Interim Decision and Agency Responses

On October 23, 2020, EPA posted the PID and draft risk assessments to the public docket for a 60-day public comment period. The comment period was later extended by an additional 30 days and closed on January 22, 2021. During the public comment period, the Agency received 9 public comments. Comments were submitted by ABERCO, Inc (the registrant of PPO products), several commenters representing the interests of users of PPO products (Elite Spice, Inc, California Walnut Commission, California Citrus Quality Council, Western Agricultural Processors, Cardinal Professional Products, and Almond Board of California), the U.S. Department of Agriculture's Office of Pest Management Policy, and an anonymous public commenter. The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

Comments Submitted by Elite Spice, Inc (Docket ID: EPA-HQ-OPP-2013-0156-0040); California Walnut Commission (Docket ID: EPA-HQ-OPP-2013-0156-0041); Western

Agricultural Processors (Docket ID: EPA-HQ-OPP-2013-0156-0044); Cardinal Professional Products (Docket ID: EPA-HQ-OPP-2013-0156-0046); and Almond Board of California (Docket ID: EPA-HQ-OPP-2013-0156-0047)

Comment: Comments on the benefits of PPO and the proposed risk mitigation were submitted by producers of dried commodities (including fruits, nuts, and spices), and distributors of PPO products or their representatives. These comments highlight the uses and benefits of registered PPO products in the commenters' respective industries. They also describe some of the potential impacts that would result from the loss of these products either by registration cancelation or through an inability to comply with regulation. Finally, these commenters express support for the comment submitted by the registrant, ABERCO, Inc. (see Docket ID: EPA-HQ-OPP-2013-0156-0045 and its associated summary and EPA response, below).

Commenters took issue with EPA's modeling in the HHRA to assess potential exposure to various populations. They state that the modeling parameters and the conclusions drawn from the modeling are inappropriate and do not reflect industry practices or actual conditions of fumigations. The commenters also express concern that the proposed changes to PPO product labels based on the HHRA may interfere with their ability to access and/or apply PPO products. Specifically, they are concerned that it may not be possible to comply with the proposed buffer zone language, creating an effective cancellation of PPO products. They also describe the difficulty of complying with existing federal and state regulations, including existing buffer zone language, and suggest changes to regulations to ease the burden of compliance. In addition to describing existing regulations, the commenters also highlight the safety record of PPO products as evidence that additional regulation is not needed. Finally, commenters also request that EPA not revoke tolerance for propylene chlorohydrin (PCH; a reaction product of PPO), as proposed in the PID.

EPA Response: EPA thanks the commenters for their submissions. In developing the label changes for PPO products proposed in the PID and finalized in this ID, the Agency considered the uses and benefits of these products. The Agency's considerations of the use and benefits are summarized in sections II. Uses and Usage and III.C. Benefits Assessment of this document. For more details, see the Agency's *Overview of Application Methods and Factors, Use, Usage, and Benefits of Commodity and Structural Fumigants* available in the public docket (docket ID: EPA-HQ-OPP-2013-0156-0023).

In conducting it's HHRA, EPA worked with the registrant to develop appropriate modeling parameters. This dialog continued during the public comment period, and in response, the Agency adjusted its modeling. For details, see the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*. In crafting the buffer zone language for product labels, EPA strove to achieve two important goals: (1) to protect bystanders from unsafe levels of exposure, and (2) to avoid disruptions to users. The Agency recognizes the importance of PPO for preventing food spoilage, controlling the spread of invasive pests, and in protecting food security.

Currently, buffer zones are required around fumigation sites in some situations. The buffer zone language in Appendix B is intended to strengthen existing buffer zones and allow flexibility for

fumigant applicators. Buffer zone size is tailored to the specific circumstances of a given fumigation with alternative options for users who do not wish to implement buffer zones. Factors affecting the size of the buffer zone for a given fumigation include type and volume of the fumigation chamber, the application rate, and the ventilation exhaust equipment in place. For more details on the necessary buffer zone label language, see section IV.C. Interim Registration Review Decision and Appendices A and B of this document. Finally, EPA has updated its proposal to revoke tolerances for PCH to include a change to the tolerance expression for PPO. This updated expression will cover residues for PCH. For details, see the Agency's response to USDA's comments below and Sections III.3. and IV.B. of this document.

Comments Submitted by the U.S. Department of Agriculture (USDA) Office of Pest Management Policy (OPMP) (Docket ID: EPA-HQ-OPP-2013-0156-0042)

Comment: OPMP provided detailed comments on the use, usage, and benefits of registered PPO products and on EPA's draft risk assessments and mitigation proposal. OPMP also offered to reach out to stakeholders on behalf of EPA for any information that could resolve uncertainties in the Agency's draft risk assessments or mitigation proposal. Included with OPMP's comments were responses from the California Walnut Commission (CWC) to a questionnaire conducted by OPMP about the impacts of EPA's proposed changes to product labels.

Generally, OPMP agrees with EPA's approach to risk assessment and agrees with the conclusions of the draft ecological and human health risk assessments. OPMP notes the data deficiencies that present challenges in assessing potential human health risks, particularly the unfulfilled requirements for ambient air monitoring. OPMP encourages the Agency to use actual monitoring data whenever possible to assess potential risks and that, in the absence of these data, EPA use modeling to assess potential exposure and risk. OPMP acknowledges the toxicity of PPO, but also notes that by EPA's own admission, current label language is expected to protect occupational handlers and that EPA identified only one incident involving PPO in the years reviewed (1998 to 2019).

The bulk of OPMP's comments were devoted to EPA's proposed changes to PPO product label language developed in response to the draft risk assessments. OPMP notes that the buffer zone proposal in the PID was vague and made it difficult to assess the impacts to users, but that, in general, buffer zone implementation would be very disruptive to fumigation activities. OPMP asserts that the proposed buffer zone language in the PID may even render fumigation activities impossible at facilities where buffer zones would extend off the property. To mitigate these impacts to users, OPMP suggests several alternatives to buffer zones, including tightness of fit tests for treatment chambers and structures.

OPMP also commented on the Agency's proposed scrubber technology language, fumigant management plans (FMPs), application rates, and tolerance actions. OPMP notes that use of emissions capture technology (*i.e.*, scrubbers) is the norm for fumigations occuring in vacuum-sealed chambers, and that the proposed scrubber mitigation may only impact small facilities where such technology may not be in place. For these, the cost of compliance could be high. OPMP notes that, while development of an FMP can be time-consuming, applicators may already be familiar with their development as they are required in the application of other

fumigants. OPMP's conversations with stakeholders indicate that the total volume of PPO usage on dried fruit is currently low; thus, OPMP expects only minimal impact from the proposal to lower the application rate on these commodities. OPMP has offered to work with stakeholders to produce data to support higher application rates in the future. Finally, USDA's Agricultural Research Service (ARS) is in a multi-year project to establish additional tolerances for PPO and PCH and requests more information around the proposed changes, including specific buffer zone sizes and background on the proposed revocation of PCH tolerances.

EPA Response:
EPA thanks OPMP for these comments. The Agency's considerations of the use, usage, and benefits of PPO are summarized in sections II. Uses and Usage and III.C. Benefits Assessment of this document. For more details, see the Agency's *Overview of Application Methods and Factors, Use, Usage, and Benefits of Commodity and Structural Fumigants* available in the public docket (docket ID: EPA-HQ-OPP-2013-0156-0023).

The Agency sought, when possible, to estimate risk using real world data, including monitoring data. As OPMP notes, this was not always possible as gaps in the data persist. In instances of outstanding and unfulfilled data requirements or when data were otherwise unavailable, EPA utilized modeling to assess exposure and risk.

EPA notes OPMP's concern that compliance with the proposed buffer zone language may not be feasible at some facilities. In the PID, the Agency solicited comment from stakeholders on how best to implement and present the finalized language and on the potential impacts of the proposed buffer zones. In developing the final buffer zone language, EPA sought to protect bystanders from exposure to PPO without substantially affecting its ease of use or availability as a pest management solution. Based on feedback from stakeholders, EPA has provided alternatives to buffer zones, such as minimum release heights and ventilation rates.

EPA thanks OPMP for its input on the potential impacts of the proposed mitigation measures, including scrubber technology, FMPs, and application rates to dried fruit. Regarding the revocation of tolerances for PCH, the Agency directs OPMP to its *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*. PPO residues alone are sufficient for enforcement. Moreover, the residue of concern for compliance with Codex maximum residue limits (MRLs) is the parent, PPO, only. Given these factors, EPA recommended the removal of all PCH tolerances in its 2020 HHRA. In response to comments by both USDA and the product registrant, ABERCO, EPA anticipates removing PCH tolerances and revising the PPO tolerance expression to include reaction products; hence, covering PCH residues due to the use of PPO. For details see Section III.A.3. Tolerances, below.

Comments Submitted by ABERCO, Inc., a Balchem Company (Docket ID: EPA-HQ-OPP-2013-0156-0045)

Comment: ABERCO, Inc. is the sole registrant of registered PPO products, including the technical grade product. The registrant's comments include information on the use and usage of its product, and comments on the human health risk assessment, anticipated tolerance changes,

and changes to label language proposed in the PID. The comments also objected to the Agency's decision to release the draft risk assessments and PID for a joint comment period and reserved ABERCO's right to supplement their comments with additional information.

The registrant asked the Agency to amend its documents to properly distinguish between the uses of the 100% a.i. and 8% a.i. products (EPA Regs. 47870-1 and 47870-3, respectively). The registrant includes examples of EPA language that it contends conflate the two products and their intended uses. They then provide descriptions of the use of the two products, noting instances in which these differ and instances in which they overlap.

The comments on the Agency's human health risk assessment suggested changes to how EPA modeled the potential exposure and resulting risks to bystanders. The comments provided refinements to EPA modeling and evidence to support this reasoning. The registrant also disputed how EPA modeled ambient air concentrations of PPO and EPA's decision not to use data submitted by the registrant in lieu of the data required by the DCI.

In response to EPA's previous request that it provide a new PFI for tree nuts, the registrant proposed 31 days and provided supporting evidence. In response to the anticipated revocation of tolerances for PCH, the registrant stated that it does not support revocation. The registrant contends that revocation could create difficulties for international trade, as it is working to obtain Codex MRLs for PCH. Finally, the registrant contended that EPA overestimated dietary exposure to PCH because EPA assessed residues on all onion commodities, even though PPO is applied only to dried onions. Though the Agency's assessment concludes that there are no dietary risks of concern associated with PCH, the registrant expressed concern that the dietary assessment misleads the public about the dietary risks of PCH.

The registrant made several comments on the label language proposed in the PID. The registrant's comments on the proposed buffer zone language argued that EPA improperly justified the need for a minimum buffer zone on labels, pointing out that modeling suggests no buffer zones are needed in many scenarios. The registrant expressed support for EPA's decision not to propose buffer zone language in many instances and warned that compliance with even limited buffer zone regulations would be burdensome for users. The registrant also asked that buffer zone language be simplified to the greatest extent possible.

The registrant noted that use of emission capture technology for applications occuring in vacuum-sealed chambers is already an industry norm. The registrant urged EPA to expressly permit applicators to produce standardized FMPs that can be used for treatments that are performed repeatedly, routinely, and consistently or otherwise in accordance with standard protocols. The registrant stated that it plans to amend its labels to comply with EPA's proposed changes to the permitted application rates for tree nuts and dried fruits. The registrant further asserted that with the change to the application rate to dried fruit, the Agency will be able confirm that the existing tolerances for dried fruit commodities are adequate and appropriate. The comments stated that the label for EPA Reg. 47870-3 should allow users to ship commodities if residues of PPO are below the tolerance for the commodity (*i.e.*, that the language, "Commodity may be shipped if residues of propylene oxide are determined to be below the tolerance specified for the commodity in 40 CFR 180.491." be retained).

EPA Response:

EPA thanks ABERCO for its comments. The Agency's responses here are limited to comments of a regulatory nature that have affected the Agency's risk mitigation measures. For EPA's responses to comments about the HHRA, see *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*, available in the public docket. This document considers the registrant's comments on the Agency's modeling of potential risks and includes revisions to this modeling. Based on these changes, the Agency has provided specific details of when buffer zones are needed and reduced the scope of the buffer zone mitigation proposed in the PID. EPA has also provided alternative risk mitigation measures to buffer zones. For updated mitigation measures see section IV.A. and Appendix B, below. The aforementioned response to comments document also considers the registrant's comments on EPA's dietary assessment. The Agency's dietary risk conclusions did not change after consideration of the registrant's comments. Based on the registrant's comments, EPA will revoke tolerances for PCH and update the tolerance expression for PPO to cover PCH residues. (see section. III.A. and IV.B., below). Additionally, EPA will increase the PFI for tree nuts (see section III.A., below).

ABERCO sought clarification on how the need for buffer zones was determined and asked how the buffer zone sizes will ultimately be determined. The registrant supports a simplified approach to conveying buffer language on labels. EPA has determined that buffer zones are needed to mitigate risks in some instances, particularly during aeration of commodities treated in non-vacuum-sealed chambers. The factors that determine the size of the necessary buffer zones include treatment chamber volume, release height, and ventilation rates. After consideration of the registrant's comments, EPA has provided alternative mitigation methods to buffer zones, such as minimum ventilation stack heights and aeration rates. For further details, see section IV.C. of this document. The Agency agrees that a simplified approach to labeling for buffer zones is best. For details of the necessary buffer zone label language, see Appendix B of this document.

The FMP language developed in the PID already states that FMPs can be standardized, provided the specific details of a fumigation are included in the FMP for a particular treatment. The language in question is as follows in Appendix B of both the PID and this document:

> For situations where an initial FMP is developed and certain elements do not change for the fumigation, only elements that have changed need to be updated in the site-specific FMP provided that the certified applicator supervising the application has verified that those elements are current and applicable to the fumigation site before the fumigation begins, and record-keeping requirements are followed for the entire FMP (including elements that do not change).

EPA will retain language on the product label for EPA registration 47870-3 allowing shipment of treated commodities prior to the PFI if the measured residues are below tolerance levels.

II. USE AND USAGE

PPO is a fumigant pesticide with both conventional and antimicrobial uses. PPO products are registered for use on both structures and commodities and both agricultural and non-agricultural uses. The first product containing PPO was registered in 1982. The chemical's antimicrobial property of microbial spoilage control is imparted during use of conventional products; there are no separately registered antimicrobial products. Fumigants are pesticides that can exist in a gaseous state and are lethal to target organisms in sufficient concentrations. Products containing PPO are stored in pressurized cylinders and applied in vacuum-sealed chambers, in shipping containers (such as boxcars), and under sealed tarps in warehouses or port facilities.

Products containing PPO are registered for broad spectrum control of insect, fungal, and bacterial spoilage of dry food commodities and non-food commodities during packing, storage, and shipping. Registered use sites include dried herbs, onions, garlic, spices, fruits, and nuts, as well as shipping containers, airtight chambers, and pharmaceutical materials. There are no PPO products registered for residential use and all registered products are classified as restricted use (*i.e.*, they must be applied by certified applicators or workers under the supervision of a certified applicator). The mode of action has not been determined. Usage data for PPO are limited outside of California. The California Department of Pesticide Regulation (CDPR) reports that an average of 370,000 pounds of PPO active ingredient were applied to nuts and other commodities in California on an annual basis from 2013 to 2017[8]. In terms of pounds applied, over 30% of total usage was applied to various nuts from 2013 to 2017. The remaining usage reported during this period is not associated with specific commodities.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2020 HHRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of PPO. The use of PPO as an antimicrobial pesticide against microbial spoilage is covered as part of the risk assessment for the conventional uses described in this ID. The application rate and methods for antimicrobial uses are the same as for the assessed conventional uses; therefore, risk conclusions for conventional uses are applicable to the antimicrobial uses. For additional details on the 2020 HHRA, see *Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review* in EPA's public docket (EPA-HQ-OPP-2013-0156). For updates to the 2020 HHRA based on public comments, see the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*.

[8] California Department of Pesticide Regulation (CDPR). 2020. Annual Statewide Pesticide Use Report for the periods 2013-2017. Available at: https://calpip.cdpr.ca.gov/main.cfm.

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

No toxicological effects of concern were identified from oral exposure to PPO. While dietary exposure to PPO residues is expected from consumption of treated commodities, toxic effects are not expected as a result. Based on its registered uses, PPO residues are not expected in surface water or groundwater, so exposure to PPO in drinking water is not expected. Given these factors, a dietary assessment was not conducted for PPO.

A quantitative risk assessment was conducted for PCH, a product of reaction between PPO and chloride ions present in treated commodities. Acute and chronic exposure estimates are below 100% of their respective population adjusted doses (PAD); thus, no dietary risks of concern were identified for PCH.

The acute exposure reference dose (aRfD) for PCH is 0.75 mg/kg, based on decreased total ambulatory activity in an acute neurotoxicity study at a no observed adverse effects level. At the 95th percentile of exposure, the estimated risk is 37% of the acute population adjusted dose (aPAD) for the U.S. population. The population subgroup with the highest estimated risk was for children 1-2 years at 63% aPAD. Risk estimates below 100% of the PAD are not considered to be of concern for PCH.

The chronic exposure reference dose (cRfD) for PCH is 0.35 mg/kg/day, based on decreases in pup body weight in a reproductive study. For PCH, the estimated exposure is 20% of the chronic population adjusted dose (cPAD) for the U.S. population. The population subgroup with the highest estimated exposure was for children 3-5 years at 33% cPAD. Given that the chronic exposure estimates are below 100% of the cPAD, there are no identified chronic dietary risks of concern for PCH.

No dietary cancer risks of concern were identified for PPO or PCH. The Agency did not conduct an oral quantitative cancer risk assessment for PPO, based on the available information (*i.e.,* because no effects relevant to humans were identified as a result of oral exposure to PPO). Similarly, no cancer risk of concern was identified for PCH. PCH is classified as "Not Likely to be Carcinogenic to Humans.[9]" Moreover, no cancer effects were observed in a carcinogenicity study at doses of PCH below the cRfD.

Residential Handler and Residential Post-Application Risks

There are no residential uses and PPO is a RUP, limited to use by or under the supervision of certified applicators only; therefore, quantitative residential handler and residential post-application exposure assessments were not conducted.

[9] See *Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review*, p 31, available at https://www.regulations.gov/document/EPA-HQ-OPP-2013-0156-0024

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate exposure to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. Because residential exposure to PPO is not expected nor are dietary toxic effects identified for PPO, an aggregate risk assessment for PPO was not conducted. For PCH, aggregate exposures are equivalent to dietary exposure estimates because there are no residential exposures.

Bystander Risks

The *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review* includes updates to the Agency's modeling of potential risks to bystanders from registered uses of PPO. For details of these updates, see the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*, available in the public docket.

Bystander Risks from Application and Post-Application Exposures

Those living near fumigation facilities may be exposed to PPO emissions that travel offsite. Exposure may occur during the treatment phase of a fumigation, because of leakage from the treatment structure or chamber, or during the aeration phase of a fumigation, when a fumigation structure or chamber is aerated. Bystander exposure may also result from accidents or emergencies. The Agency assessed potential bystander exposure from labelled applications using the Probabilistic Exposure and Risk Model for Fumigants (PERFUM) 3.0. PERFUM is a statistical model that calculates the size of theoretical areas around treatment facilities inside of which potential bystander exposure to fumigant air concentrations exceed toxicological levels of concern. In other words, PERFUM calculates a boundary around a treatment site inside of which bystanders may be exposed to air concentrations of a fumigant above regulatory standards.

PERFUM inputs include local meteorological records, fumigation structure size, frequency of treatments, treatment concentrations, leakage rates, aeration rates and utilization of emissions recapture technology, and the human equivalent concentrations (HECs; a measure of toxicity). The model also incorporated weather data from a weather station near a port facility in California—an area known for commodity fumigation.

Data about treatment facilities and use and usage were submitted by the registrant and generated based on product label instructions. PPO may be used in large, indoor facilities with sophisticated ventilation and emissions recapture technology, or in sites like shipping containers with passive ventilation. Treatments may occur sporadically or continuously at a facility, based on demand. Additionally, treatments may be made at varying concentrations of PPO and carbon dioxide or nitrogen gas and at various application rates (*i.e.*, lbs PPO/1,000 ft^3). Moreover, facilities may experience loss or leakage from treated areas during fumigation. To account for these factors, a variety of theoretical treatment conditions were modeled.

Toxicity data for PPO came from studies reviewed by the Agency. These showed toxic effects—including biochemical changes, nasal lesions, inflammation, and weight loss—in rats exposed to PPO via inhalation. Both acute and chronic effects were observed. The 6-hr exposure HEC used for modeling was 86.527 mg PPO/m^3 and the 24-hr exposure HEC was 21.632 mg PPO/m^3.

Based on these inputs, PERFUM outputs describe fumigant air concentrations as a function of distance from the emission source. PERFUM calculates this data for each day of a 5-year period (or 1,825 days). It then summarizes them as a "Maximum Buffer" distribution and a "Whole Field Buffer" distribution. Each is a distribution of protective buffer distances, but each utilize different underlying statistical assumptions. The Maximum Buffer distribution shows the single maximum distance from a treatment facility needed to protect bystanders, for each of the 1,825 days. The Whole Field Buffer distribution considers the maximum distance needed to protect bystanders not just in one direction from the emission source, but in multiple directions from the emission source. For PPO, PERFUM produced a wide range of buffer outputs, based on the scenario considered. These are discussed in detail in the *Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review* and only an overview is presented here.

Modeling suggests that no minimum buffer is needed to prevent unsafe bystander exposure via leakage during the treatment phase in many scenarios; however, some leakage scenarios did produce buffers greater than zero. In assessing leakage exposure, the Agency considered leakage rates of 1% and 5% and various application rates.

The 5% leakage scenario with the highest permitted application rate (125 lbs PPO/1,000 ft^3) produced the largest buffer zones (up to 85 feet, based on 90th percentile PERFUM outputs for multiple fumigations and the 6-hr exposure HEC). However, applications at a rate greater than 2.8 lbs PPO/1,000 ft^3 must be made in a vacuum-sealed chamber. Given that these chambers are intended to be a vacuum, a loss of 5% is unlikely. The negative pressure differential would result in leakage of the outside atmosphere into the chamber, rather than PPO emission from the chamber into the atmosphere. When a leakage rate of 1% for a vacuum-sealed chamber is considered the resulting buffers were substantially smaller (less than 14 ft, but often zero feet, based on 90th percentile PERFUM outputs for multiple fumigations and the 6-hr exposure HEC).

The maximum labeled application rate in a vacuum-sealed chamber with no emission reduction technology is 75 lbs PPO/1,000 ft^3. At this rate, modeling indicates that, at most, 23-foot buffers are needed to protect bystanders from leakage (assuming a 5% leakage rate, and when considering 90th percentile PERFUM outputs for single applications, comparing to either the 6-hr or 24-hr exposure HEC). As discussed, these chambers are intended to be a vacuum, and so loss of 5% is unlikely. Assuming a 1% loss rate, PERFUM suggests that a 3-foot buffer is necessary (based on 90th percentile outputs and the 24-hr HEC; the corresponding outputs for the 6-hr HEC is zero feet).

Applications in non-vacuum sealed chambers and other structures (such as shipping containers and tents) yielded buffers of zero feet at the 90th percentile of the distribution for all treatment phase scenarios considered. Though such fumigation chambers are not vacuum-sealed, fumigations are conducted at application rates substantially lower than those made in vacuum-sealed chambers, thus accounting for the comparatively small buffer zones.

Bystander exposure to PPO resulting from post-treatment aeration of fumigated commodities was also assessed with PERFUM. Again, the resulting buffer zones were often zero feet, but were larger for some modeling scenarios. Factors affecting the size of buffers included chamber size, aeration equipment and aeration rates, and application rates.

Modeling of small vacuum-sealed chambers (*i.e.*, those 2,000 ft^3 in volume or less) suggests that no buffers are needed to protect bystanders from post-fumigation aeration exposure, regardless of aeration equipment or aeration rates. Modeling of vacuum-sealed chambers of all sizes equipped with scrubber technology (designed to reduce fumigant emissions by at least 95%) likewise suggests that no buffers are needed to protect bystanders. Such scrubber technology is needed when fumigations are conducted in vacuum-sealed chambers at an application rate greater than 75 lbs PPO/1,000 ft^3. Generally, the modeling scenarios that produce the largest buffers for post-treatment aeration are those assessing large treatment facilities (5,000 ft^3) without scrubber technology in place, and when conducting multiple successive fumigations. In such cases, PERFUM outputs suggest that buffers decrease with ventilation stack height.

Assessment of potential bystander exposure due to aeration of non-vacuum-sealed chambers (*e.g.*, treatments in shipping containers or under tarpaulins) suggests that buffer zones are needed only when aeration is conducted with certain combinations of aeration rates and stack heights.

Bystander Ambient Exposure Risks

In addition to exposure resulting directly from fumigation activities (discussed above), bystanders may also be exposed to traces of PPO in ambient air. The registration review DCI (GDCI-042501-1389) required submission of ambient air monitoring data for PPO. The Agency did not receive the required data and no such data are publicly available. In lieu of these data, the registrant submitted ambient air modeling data using EPA's Human Exposure Model (HEM-3). The Agency does not consider HEM-3 data to be an adequate substitute for monitoring data. HEM-3 uses metrological data and data about treatment facilities (such as size and aeration equipment) to predict resulting ambient air concentrations from emission sources. By contrast, monitoring data represent actual measurements of air pollutants in the atmosphere. Moreover, EPA was unable to verify the model input parameters submitted by the registrant. With these limitations in mind, the Agency attempted to use the submitted HEM-3 data as a potential line of evidence to quantify the potential non-cancer and cancer risks to bystanders from ambient exposure. The HEM-3 exposure estimates were all below their respective HECs for non-cancer risks, suggesting that this exposure type would not be expected to produce risks of concern. The HEM-3 ambient exposure cancer risk estimate was $1x10^{-5}$.

The Agency also quantified potential ambient exposure risks using data from EPA's National Air Toxics Assessment (NATA), an ongoing review of air toxins in the U.S. The most recent NATA uses emissions data from 2014. NATA is a tool that helps EPA highlight potential regional and national public health concerns and is not meant to assess risks to individuals from ambient exposure to toxins. The required ambient air monitoring studies would provide the most relevant quantification of ambient PPO concentrations and resulting risk. The NATA-modeled non-cancer risk estimate was below the respective HEC and considered not of concern. The NATA-

modeled cancer risk estimate was $2x10^{-6}$. Moreover, the NATA assessments and HEM-3 modeling indicate that bystanders are not expected to be exposed to ambient levels of PPO greater than the regulatory or recommended exposure level values.

Cumulative Risks

EPA has not made a common-mechanism-of-toxicity-to-humans finding for PPO and any other substance. PPO does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has premised this ID and the underlying risk assessments on the belief that PPO does not have a common mechanism of toxicity with other substances.

Occupational Handler Risks

PPO is an RUP intended only for use by or under the supervision of a certified applicator. As such, the fumigation job site is under the purview of the certified applicator until the fumigation and aeration has been completed and the commodity released. For this reason, those workers engaging in activities imminently following application (but not involved directly in application, *e.g.*, forklift operators) are considered occupational handlers, in addition to those directly engaged in treatment activities.

Occupational dermal exposure to PPO is not expected. PPO readily volatilizes into a gas at room temperature and under standard pressure, and so it is not expected to make dermal contact with workers. For this reason, occupational dermal exposure to PPO was not quantitatively assessed and no dermal risks were identified. However, dermal exposure may occur if volatilized PPO gas becomes trapped against the skin by tight-fitting clothing, particularly during an emergency or "spill" situation, such as a ruptured pressurized storage cylinder.

Occupational handlers may experience inhalation exposure to PPO by inhaling the volatilized gas during treatment operations. Acute, short-, intermediate-, and long-term inhalation exposures are possible based on PPO's registered uses. Workers are protected from potential PPO inhalation by product label language describing personnel protective equipment (PPE) and occupational safety standards (set by various agencies) for monitored air concentrations of PPO at job sites.

The Agency required submission of exposure data for applicators involved in fumigating activities in its registration review DCI for PPO (GDCI-042501-1389). The registrant submitted a waiver request for these data that included area monitoring data from treated product processing, handling, and storage areas. The Almond Board of California and the California Walnut Commission each submitted worker exposure data. The Agency does not consider the data sufficient to satisfy the requirements of the DCI and the monitoring data requirements remain outstanding. The available data indicate that workers will not be exposed to levels of PPO that exceed regulatory and occupational safety standards. The Agency maintains that actual personal exposure monitoring is still required to assess potential occupational exposure and that the submitted data do not replace the required monitoring data.

Occupational Post-Application Risks

As is the case for occupational handlers, occupational post-application dermal exposure to PPO is not expected, due to the volatile nature of the substance. PCH may be present on treated commodities, but dermal exposure is not expected because of sealed packaging around treated commodities that would prevent direct contact.

PPO may continue to off-gas from treated commodities, resulting in potential inhalation exposure to workers handling treated commodities post-application. Acute-, short-, intermediate-, and long-term inhalation exposures are possible. Labels state that entry into treated areas is not allowed unless respiratory protection is worn when PPO air concentrations measured by a direct-read device exceeds 10 ppm at any time, or as measured as an 8-hour time weighted average (TWA) exceeds 2 ppm.

EPA was not able to fully quantify the potential for post-application exposure to PPO as the registrant did not submit the post-application exposure data required by GDCI-042501-1389. The worker exposure data submitted by the Almond Board of California and the California Walnut Commission (discussed above) allow only a limited assessment of potential post-application PPO inhalation exposure. These limited data suggest that post-application handlers of commodities treated with PPO will not be exposed to PPO at levels that exceed regulatory and occupational safety standards.

PCH residues on treated commodities are not expected to volatilize and post-occupational handler inhalation exposure to PCH is not expected.

2. Human Incidents and Epidemiology

EPA reviewed PPO incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on May 8, 2019, IDS showed no incidents reported from January 1, 2014 to March 13, 2019. SENSOR showed one moderate-severity incident reported from 1998 to 2015, involving multiple active ingredients, in which the exposed person suffered an asthma attack and related respiratory symptoms. The Agency intends to conduct ongoing human incident monitoring for PPO and additional analyses if that monitoring indicates risks of concerns.

3. Tolerances

PPO is registered for uses that result in residues in or on food. Generally, a tolerance must cover the residues or the affected food is considered adulterated.[10]

The Agency has established tolerances for PPO under 40 CFR §180.491(a)(1). Separate tolerances for PCH are established in 40 CFR §180.491(a)(2). PPO residues alone are adequate for detection of PPO misuse for enforcement activities. Additionally, there are no established Codex MRLs for PCH. Therefore, the Agency will revoke all PCH tolerances on all commodities for harmonization purposes and amend the tolerance expression for PPO to specify the inclusion

[10] 21 U.S.C. §§ 342, 346(a).

of reaction products; hence, covering PCH residues due to the use of PPO. For more information, see Section IV.B, below.

4. Human Health Data Needs

The human health database for PPO is not considered complete. The Agency previously required the following data (GDCI-042501-1389). The registrant has not fulfilled the data requirements. The Agency will amend the DCI to establish a timeline for submitting the following outstanding data.

Table 1: Summary of Unfulfilled DCI Data Requirements

DCI Guideline	Study	Description
875.1400	Inhalation exposure—indoor	Inhalation Exposure Study for Applicators: Required to assess PPO exposure to workers involved in fumigation activities
875.2500	Inhalation exposure—outdoor	Post-Application Inhalation Exposure Study: Required to assess post-application exposure to workers handling treated commodities and bystanders who live near fumigation facilities
SS-1076	Ambient Air Monitoring	Ambient air monitoring: Required to assess PPO ambient air concentrations for communities near to treated facilities.
SS-1117	Monitoring Data on Fumigated Commodities	Monitoring data on fumigated commodities: Required to evaluate the potential for post-application occupational exposure to PPO emission from treated commodities after fumigation activities are complete (*e.g.*, in transportation).

In addition, data are needed to support tolerance enforcement.

Table 2: Data Needed to Support Tolerance Enforcement

Study Guideline	Study	Description
860.1340	Residue Analytical Method	An adequate confirmatory method for residues of PPO in plant commodities is required for tolerance enforcement.
860.1650	Submittal of Analytical Reference Standard	An analytical reference standard for PPO is not currently available in EPA National Pesticide Standards Repository (NPSR). For more information, see section IV. of this document.

B. Ecological Risks

The Agency has summarized the 2019 Draft Ecological Risk Assessment (DRA) 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 PPO.[11] The use of PPO as an antimicrobial pesticide against microbial spoilage is covered as part of the risk assessment for the conventional uses described in this ID. The application rate and methods for antimicrobial uses are the same as for the assessed conventional uses; therefore, risk conclusions for conventional uses are applicable to the antimicrobial uses. For additional details on the 2019 DRA, see *Propylene Oxide: Draft Ecological Risk Assessment (DRA) for Registration Review* in EPA's public docket (EPA-HQ-OPP-2013-0156).

1. Risk Summary and Characterization

Terrestrial Risks

Terrestrial animals that live downwind of fumigation sites may inhale PPO emissions in the air during and immediately after a treatment occurs. Bystander buffer zones are designed to mitigate human health risks, but terrestrial plants and animals that inhabit or enter buffer zone areas may be exposed to concentrations of PPO above the level of concern. However, the exposure is expected to be short and temporary (*i.e.*, acute), depending on the wind speed and atmospheric conditions. Prolonged (*i.e.*, chronic) inhalation exposure is not expected because of the rapid dissipation of PPO gas in the atmosphere.

Mammals

Potential terrestrial mammal inhalation exposure to PPO was assessed in the registration review DRA, available in the public docket, using a conservative air screen model (AERSCREEN, v11126). A potential acute risk of concern was identified for terrestrial mammals in one of three modeling scenarios assessed. The scenario assumed an application rate of 150 lbs PPO/1,000 ft^3, occuring in a vacuum-sealed chamber equipped with a five-foot exhaust stack and an aeration rate of one air exchange per hour. Other modeled combinations of higher stacks and more frequent air exchanges were not of concern.

Data on chronic toxicity to terrestrial mammals do not show any adverse effects at the highest tested treatment level. However, because modeled estimated environmental concentrations (EECs, or the predicted exposure levels) are higher than the concentrations in the toxicity studies, it is unknown if effects would occur at EEC-relevant doses. Although there are uncertainties in the toxicity database, due to the nature of the chemical and its release/use patterns, chronic exposure is unlikely.

[11] The 2019 ERA only addresses potential risks to species not listed under the Endangered Species Act. EPA is working with its federal partners and other stakeholders to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to listed species and their designated critical habitats. The Agency will complete PPO's listed-species assessment once EPA has fully implemented the scientific methods necessary to complete listed species' risk assessments. For more details, see Appendix C.

In summary, terrestrial mammals downwind and near fumigation exhaust stacks may become exposed to PPO by inhaling exhaust fumes. One modeled scenario produced acute risks of concern to mammals in the vicinity of the application site. EPA understands that the modeled scenario may not accurately reflect the majority of real-world conditions. While the EECs for chronic exposure are higher than the levels tested in the available data, chronic exposure is not expected, given the volatility and quick dissipation of PPO.

Birds, Reptiles, and Terrestrial-Phase Amphibians

No potential acute risks of concern were identified for birds (the surrogate for reptiles and terrestrial-phase amphibians) from registered uses of PPO. In the assessed scenarios, the EECs of PPO were all below the acute toxicity endpoint (lethality in 50% of test subjects—LD_{50}). Therefore, no potential risks of concern were identified. As discussed above, potential chronic risks to birds were not assessed as chronic inhalation exposure is not expected for terrestrial organisms. The DRA also notes that no chronic toxicity data are available for birds exposed to PPO.

Terrestrial Invertebrates

EPA relies on data about honey bees as a surrogate for terrestrial invertebrate species. Based on the available data, EPA believes that PPO uses do not present risks of concern to honey bees. In the assessed scenarios, the EECs of PPO were all below the acute toxicity endpoint for adult honey bees (the LD_{50}). Therefore, no potential acute risks of concern were identified. Based on available honey bee vapor study results, it is unlikely that exposure concentrations will be high enough to cause a concern to warrant the need for honey bee toxicity testing at higher tiers. Therefore, the Agency is not proposing requiring additional pollinator studies for PPO. As discussed above, potential chronic risks to terrestrial insects were not assessed as chronic inhalation exposure is not expected for terrestrial organisms.

Terrestrial Plants

The study submitted to fulfill the vegetative vigor guideline requirement of the DCI showed no effects to terrestrial plants at the highest treatment dose; however, modeled EECs were all greater than the highest treatment dose in the study. Moreover, the study did not include enough species to meet EPA's guideline requirements. As a result, the potential for risks of concern to terrestrial plants from registered uses of PPO are uncertain.

Aquatic Risks

Risks to aquatic organisms were not assessed. PPO enters the atmosphere mainly through ventilation as volatilized gas, where it is expected to undergo downwind dilution and subsequent degradation by free radicals in the air. Negligible amounts of PPO gas may reach adjacent water bodies during rainfall events, but the gas will rapidly volatize from the water surface after the rain. Therefore, aquatic exposure is expected to be negligible. As a result, risks of concern to fish, aquatic-phase amphibians, aquatic invertebrates, and aquatic plants are not expected from registered uses of PPO.

2. Ecological Incidents

EPA reviewed PPO incidents reported to the Incident Data System (IDS). As of EPA's latest search on October 4, 2018, IDS showed zero incidents reported since the registration of PPO products. The Agency intends to conduct ongoing ecological incident monitoring for PPO and additional analyses if that monitoring indicates risks of concern to non-target organisms.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for PPO is considered complete. Additional aquatic plant, fish, and aquatic invertebrate toxicity studies are not considered data gaps because PPO is not expected to reach the receptors via surface water run-off or any other exposure pathway. Finally, since publication of the DRA, the Agency received an acceptable terrestrial plant toxicity study and no further data are needed to assess terrestrial plant toxicity.

C. Benefits Assessment

Broadly, fumigants, including PPO, provide several benefits to fumigators: they provide fast-acting, broad-spectrum pest eradication; they have the ability to penetrate and treat commodities and structures where other pesticides cannot; and they leave minimal or no surface residues. Also, because PPO may be used under a variety of conditions (*e.g.*, vacuum chambers, atmospheric chambers, shipping containers and railcars, tarpaulin), it provides flexibility to applicators.

Postharvest fumigations with PPO are conducted widely on and are beneficial for stored commodities and packaged foods because they can be used to protect products from insects or microbes. This is critical to prevent food spoilage and to ensure food safety for human consumption. As an antimicrobial agent, PPO prevents spoilage of non-food commodities as well. Commodities commonly fumigated with PPO include processed nutmeats (except peanuts), dried herbs and spices, dried fruits (*e.g.*, figs, plums, raisins), cocoa (cacao) bean, cocoa powder, and cosmetics. The nut, herb, and spice industries[12, 13] have indicated that PPO is important for reducing the levels of bacteria and fungi, such as *Salmonella*, aflatoxins, and other pathogens, in raw nuts, herbs, and spices intended for human consumption.

When applicable, prevention, sanitation, and insecticides (*e.g.*, pyrethroids, organophosphates, insect growth regulators) are used instead of fumigation to prevent or control pests that may infest commodities. However, few alternative sterilization technologies are available for pest control in commodities. Currently, PPO is the only fumigant approved to reduce the levels of *Salmonella* on raw nutmeats. Fumigators may rotate PPO with sulfuryl fluoride or phosphine or the metal phosphides for insect control in nutmeats or with ethylene oxide for microbial control in herbs and spices. Non-fumigant alternatives for PPO uses include heat/steam and irradiation. However, not all commodities (*e.g.*, nuts, herbs, and spices) are compatible with heat/steam

[12] Almond Board of California (ABC). 2012. The Food Safety Program and Almond Pasteurization. http://www.almondboard.com/Handlers/Food0ualitySafety/Pasteurization/Pages/Default.aspx
[13] Elite Spice. 2012. Food Safety and Quality: Microbial Reduction. http://www.elitespice.com/quality/microbial-reduction/

sterilization as the exposure to heat and moisture can negatively impact the quality of the commodity (*e.g.*, mouthfeel, texture, aromatics, clumping of spices). Further, irradiation sterilization methods do not have market (*i.e.*, consumer) acceptance in the U.S.

For more information on the benefits of fumigations and individual commodity and structural fumigants see *Overview of Use, Usage, and Benefits of Commodity and Structural Fumigants: Phosphine [(066500) including Aluminum Phosphide (066501) and Magnesium Phosphide (066504)], Propylene Oxide (042501), Sulfur Dioxide (077601), Sodium Metabisulfite (111409), Sulfuryl Fluoride, (078003), Ethylene Oxide (042301), and Methyl Bromide (053201)* available in the public docket.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

In the *Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review*, the Agency identified potential risks of concern to non-occupational bystanders from registered conventional and antimicrobial uses of PPO. To mitigate these risks, the Agency has developed language describing the establishment of either minimum release heights and aeration rates or buffer zones around use sites. The purpose of these mitigation measures is to protect bystanders from potentially unsafe levels of PPO in the air around treatment sites. The Agency also determined that the use of scrubber technology designed to reduce PPO emissions by at least 95% during aeration of treated commodities fumigated in vacuum-sealed chambers is needed to mitigate risks. Language indicating that clothing must be loose-fitting is needed to mitigate potential dermal contact. In an emergency or "spill" scenario, tight clothing may trap PPO against the skin, exacerbating potential dermal irritation.

Additionally, to standardize best practices across different types of fumigants, product labels need updated language describing the drafting and use of fumigation management plans (FMPs). FMPs are documents intended to ensure all safety requirements for proper fumigant use are met and that emergency responders have access to information in the event of an accident at a fumigation site.

To address possible tolerance exceedances on dried fruits, the application rate for dried fruit needs to be lowered from 0.2 oz PPO/ft^3 to 0.045 oz PPO/ft^3. To address possible tolerance exceedances on tree nuts, EPA determined that the minimum post-fumigation intervals (PFIs) for tree nuts needs to be increased from 28 to 31 days. To clarify the Directions for Use section of the product label for EPA registration 47870-1, the maximum permitted application rate for this product needs to be lowered from 150 lbs PPO/1,000 ft^3 to 125 lbs PPO/1,000 ft^3.

EPA also identified potential risks of concern for terrestrial mammals in its *Propylene Oxide: Draft Ecological Risk Assessment (DRA) for Registration Review*. Potential risks were identified in one modeling scenario that assumed an application rate of 150 lbs PPO/1,000 ft^3. While the maximum permitted application rate on any PPO product label is 150 lbs PPO/1,000 ft^3 (EPA registration 47870-1), the highest permitted application rate on any specific use site is just 125 lbs PPO/1,000 ft^3. Moreover, this modeling scenario did not consider the use of emission

reduction technology (scrubbers), which is needed at applications rates greater than 75 lbs PPO/ft^3. When the use of scrubbers is considered, the scenario is not of concern. Finally, the model assumed atmospheric conditions that favor exposure (such as a strong downdraft of wind from the release stack to the ground), which are expected to occur only transiently. In addition, the use of ventilation stacks to reduce exposure to human bystanders will also reduce exposure to mammals in the vicinity of treatment sites. Therefore, the Agency has not developed any label changes in response to this potential risk of concern.

1. Label Mitigation: Update to Description of PPE Fit

To mitigate potential dermal exposure, labels should specify that occupational handlers wear loose-fitting, rather than tight-fitting, PPE. In the event of dermal contact, tight-fitting clothing can trap PPO against the skin, worsening potential dermal irritation. Current language on labels may describe PPE that could trap PPO against the skin. Language should be updated to ensure that PPE is loose-fitting.

2. Label Mitigation: Ventilation Stack Height, Aeration Rate, and Buffer Zones

To mitigate risks to non-occupational bystanders, language is needed on labels that describes ventilation stack heights and aeration conditions or buffer zone implementation during aeration of commodities treated with PPO in non-vacuum-sealed chambers.

The Agency developed the release height, aeration conditions, and buffers zone language detailed in Appendix B based on:

- Whole Field Buffer Distances from PERFUM. Because the Whole Field Buffer distribution considers buffers in all directions from the emissions source, it is thought to capture changes in wind patterns and movement of people around the emissions source and to thus reflect the dynamic nature of real-world conditions.

- Single-application PERFUM outputs. For instances in which buffer zones are required and for which the buffer zones for two or more applications overlap, the buffer zones should be determined by the total volume treated.

Additional evidence used to develop the language in Appendix B can be found in Appendix C of this document and in the HHRA and the *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration* Review (available in the public docket). Currently, one PPO product label (EPA product registration 47870-3) describes buffer zones of at least 10 feet up to 200 feet (depending on a variety of factors). In its PID, the Agency proposed additional buffer zones of at least 10 feet during treatment and aeration of all commodities fumigated in non-vacuum-sealed chambers. In the PID, EPA acknowledged that the buffer zones presented in the PID may be burdensome for users to implement and sought comment on the potential impacts and alternative mitigation strategies. Based on the public comments, changes to the Agency's modeling of risks, and further review of PERFUM outputs, EPA has modified the buffer zones proposed in the PID. The Agency has since developed a mitigation strategy that uses minimum release heights, aeration conditions, and buffer zones. The goal of this revised strategy is to mitigate potential bystander risks, while

providing flexibility to users of PPO. Fumigation facilities lacking appropriate ventilation equipment can choose to invest in such equipment or to implement buffer zones. Equipment upgrades may be costly, while buffer zones may interfere with other activities at the facility. For more information about how the Agency determined the minimum release heights, aeration conditions, and buffer zones necessary to protect bystanders, see *Propylene Oxide. Human Health Draft Risk Assessment to Support Registration Review* (available in the public docket) and Appendix C, below. Additionally, the buffer zone label language presented in Appendix B, below, includes exemptions for entry into buffer zones under limited circumstances.

3. Label Mitigation: Use of Scrubber Technology for Applications in Vacuum-Sealed Chambers

In order to protect bystanders from exposure to PPO resulting from aeration of treated commodities fumigated in vacuum-sealed chambers, and to reduce potential ambient exposures away from treatment facilities, vacuum-sealed chambers need to be equipped with emissions capture technology specifically designed to reduce PPO emission by at least 95%. Data submitted by the registrant indicate that most treatment facilities currently in use utilize such technology; however, EPA acknowledged in the PID that this requirement may be burdensome for some users of PPO, especially smaller facilities. As a result, the Agency has updated the emissions reduction technology proposal in the PID to allow for flexibility for aeration of chambers of less than or equal to 5,000 ft^3. This flexibility is currently present on the product label for EPA Reg 47870-1 and allows aeration without emissions reduction technology for small chambers (less than or equal to 5,000 ft^3 in volume), provided minimum release criteria are met. For details of these criteria, see Appendix B. Public comments and feedback from the product registrant indicate that scrubber technology is already in place at most fumigation facilities. The finalized mitigation is intended to provide alternative mitigation measures for smaller facilities that may not have scrubbers in place and for which investment in scrubbers may not be feasible.

4. Label Mitigation: Site-Specific Fumigation Management Plan (FMP)

Currently only one PPO label requires a site-specific Fumigation Management Plan (FMP). All product labels need to include updated language for developing and implementing an FMP. The site-specific FMP ensures consistent achievement of sound fumigation applications which are the foundation to minimizing the potential for adverse effects to bystanders, handlers, and workers. The purpose of the FMP is to ensure the safety of the fumigators, other on-site employees, the surrounding community, and the environment. It is also designed to ensure an effective fumigation that complies with label requirements. The use of a comprehensive FMP will result in careful planning of all aspects of the fumigation process. In cases where errors may have occurred, a post-application summary may prevent similar problems from occurring during future applications. The Agency expects that the FMPs will ensure directions on product labels have been followed, conditions for the fumigation documented, and aid in the proper response of the applicator and others involved should an incident occur. Comments indicate that users will likely be familiar with FMPs, which are required in the application of other fumigants. FMPs can be expensive and time-consuming to develop. The Agency estimates that a carefully designed FMP could take several days to develop. Subsequent FMPs should require substantially less time

to develop because much of the information can be reused from the initial plan for fumigations, especially for fumigations being conducted in chambers or other structures with known volumes.

5. Label Mitigation: Application Rate for Dried Fruit on Product Label for EPA Registration 47870-1

To resolve tolerance issues, the Agency determined the maximum application rate of PPO for dried fruit (dried fig, grape raisin, and dried plum prune) needs to be lowered from 0.2 oz PPO/ft^3 to 0.045 oz PPO/ft^3.

6. Label Mitigation: Revised Post-Fumigation Interval (PFI) for Tree Nuts (Crop Group 14-12) on Product Label for EPA Registration 47870-1

To resolve tolerance concerns for tree nuts, the Agency requested in its PID that the registrant propose a new PFI for tree nuts (members of Crop Group 14-12). In its public comments on the PID, the registrant proposed a PFI of 31 days (or until PPO residues are determined to be below 300 ppm) and submitted data to support its proposal. After reviewing the data, EPA agrees that the registrant's proposed PFI of 31-days is appropriate for PPO-fumigated shelled nut commodities at the maximum registered fumigation rate for PPO (*i.e.*, 2.0 oz PPO/ft^3 or 125 lbs PPO/1,000 ft^3) and that residues of PPO in/on these commodities will not exceed 300 ppm, the currently established tolerance level for residues of PPO in/on tree nut commodities. In response to public comments, EPA has retained language that allows shipment sooner than the PFI if measured residues of PPO can be determined to be less than tolerance levels. As a result, impacts of this mitigation are expected to be minimal for users.
EPA finds that, based on the available tree nut data, the currently registered 28-day PFI is adequate for PPO-fumigated in-shell tree nut commodities at the maximum registered fumigation rate for PPO (2.0 oz PPO/ft^3) and PPO-fumigated shelled nut commodities at fumigation rates of less than 1.5 oz PPO/ft^3. PPO product label for EPA Registration 47870-1 needs to be updated accordingly. For details of the Agency's review of the registrant's proposal and supporting data, see *Propylene Oxide: Response to Comments on the Draft Human Health Risk Assessment and Proposed Interim Decision for Registration Review*.

7. Label Mitigation: Clarification of Use Site

Labels allowing use on "fig[s]" need to be revised to specify that the use is for "dried fig[s]".

8. Label Mitigation: Maximum Application Rate on Product Label for EPA Registration 47870-1

Currently, the product label for EPA registration 47870-1 permits a maximum application rate of 150 lbs PPO/1,000 ft^3. In contrast, the highest application rate permitted by this label for any single commodity use site is 125 lbs PPO/1,000 ft^3. That is, the maximum rate permitted on labels is 150 lbs PPO/1,000 ft^3, but the maximum rate applied is 125 lbs PPO/1,000 ft^3. Therefore, the maximum permitted application rate for this product needs to be lowered to 125 lbs PPO/1,000 ft^3.

9. Label Mitigation: Standardization of Post-Fumigation Intervals (PFIs) on Product Label for EPA Registration 47870-3

The product label for EPA registration 47870-3 needs to be revised such that the post-fumigation intervals (PFIs) and target residue levels for treated commodities are consistent with those on the product label for EPA registration 47870-1. For example, the direction for use on the product label for EPA registration 47870-1 instructs users to hold PPO-treated dried herb commodities at a minimum of 25°C for at least 48 hours prior to shipment or until residues of PPO in/on the commodity are below 300 ppm (the tolerance for PPO on this commodity). Instructions for holding treated commodities on the product label for EPA registration 47870-3 need to be changed to match those on the product label for EPA registration 47870-1.

B. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has conducted assessments of risks to people who handle PPO and those who may be exposed to PPO when handling treated commodities and has found no risks of concern. EPA has also evaluated the risks to people living adjacent to fumigation facilities and found no risks of concern for PPO. Moreover, EPA has created label language to mitigate potential exposure to bystanders to fumigations with buffer zones or ventilation stack height and aeration rate minimums.

To help address potential environmental justice issues related to registration review decisions, the Agency sought information during the public comment period on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to PPO compared to the general population or who may otherwise be disproportionately affected by the use of PPO as a pesticide. The Agency did not receive any information during the public comment period pertaining to environmental justice concerns. Therefore, this ID assumed that there are no environmental justice concerns for PPO.

C. Tolerance Actions

The Agency plans to exercise its FFDCA authority to update the tolerance expression to appropriately cover the metabolites and degradates of PPO and to specify the residues to be measured for each commodity for enforcement purposes. EPA expects to propose amending the tolerance expression to read as follows:

“Tolerances are established for residues of the fumigant propylene oxide, including its metabolites and its degradates, including the reaction products propylene chlorohydrin and propylene bromohydrin, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only propylene oxide in or on the commodity.”

The Agency plans to remove all PCH tolerances. The Agency also plans to revise the commodity definition from fig to fig, dried. In addition, the Agency plans to revise the nut, tree, group 14 tolerance currently established at 300 ppm to nut, tree, group 14-12 at 300 ppm and remove the

following tolerances: nut, pine (300 ppm), nut, tree, group 14 (300 ppm), nutmeat, processed, except peanut (300 ppm), and pistachio (300 ppm). Finally, the Agency plans to correct tolerance levels as needed to be consistent with OECD rounding class practice.

D. Interim Registration Review Decision

The Agency is issuing this ID in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency has made the following interim decision: (1) EPA reaffirms the requirement of the studies listed in Section IV.E, below, which remain outstanding. These data were required in GDCI-042501-1389; and (2) EPA has determined that PPO does not meet the registration standard without changes to the affected registrations and their labeling. EPA finds that the mitigation specified in Sections IV. A-B and Appendices A and B are sufficient to address certain concerns.

The Agency conducted detailed draft human health and ecological risk assessments for registered uses of PPO. In these assessments, EPA observed some potential risks to human health to continuing to register PPO. Risks were identified to bystanders in the vicinity of fumigation activities. Though registered uses of PPO may result in dietary exposure to residues of PCH, the human health risk assessment did not identify any potential risks of concern from this exposure. Risks were also identified in limited instances to terrestrial mammals that are expected to be transitory in nature, and which will be partially mitigated by scrubber technology in vacuum-sealed chambers and by emissions stacks meant to reduce exposure to bystanders.

The Agency also determined that the continued registration of PPO provides several benefits. PPO is one of only a few a.i.s with products registered to prevent insect spoilage of dried commodities. It also plays an important public health role in its use against microbial agents, including *Salmonella*.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[14] Here, EPA determined that PPO does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A and B. Although there are several benefits to PPO use, the benefits do not outweigh the human health risks identified, and thus these need to be mitigated in order to meet the FIFRA registration standard.

EPA determined that there is no human dietary risk from registered uses of PPO that is inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA assessed PPO's potential aggregate risks, including dietary (food and water) and non-occupational residential exposures, and found no risks exceeding the Agency's levels of concern.

[14] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" FIFRA risk-benefit standard **and** "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the FFDCA safety standard"). In an ID, EPA sets out an interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to PPO, including all anticipated dietary exposures and all other exposures for which there is reliable information. Therefore, the PPO residues are safe.

In this ID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of PPO. Similarly, the Agency is not making a complete endangered species finding. The Agency will complete a listed-species assessment and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services, and make an EDSP determination before issuing a final registration review decision for PPO.

E. Data Requirements

Certain data from GDCI-042501-1389, issued in 2014, are still outstanding. The Agency reaffirms that these data are still required to support the registration review of PPO. The Agency will amend the DCI to establish a timeline for submitting the following outstanding data:

- 875.1400 Inhalation Exposure Study for Applicators: Required to assess PPO exposure to workers involved in fumigation activities.

- 875.2500 Post-Application Inhalation Exposure Study – outdoor: Required to assess post-application exposure to workers handling treated commodities and bystanders who live near fumigation facilities.

- Special Study - Monitoring data on fumigated commodities: Required to evaluate the potential for post-application occupational exposure to PPO emissions from treated commodities after fumigation activities are complete (*e.g.*, in transportation).

- Special Study – Ambient air monitoring: Required to assess PPO ambient air concentrations for communities near treated facilities.

In addition, the following studies are needed for tolerance enforcement:

- 860.1340 Residue Analytical Method: An adequate confirmatory method for residues of PPO in plant commodities is required for tolerance enforcement.

- 860.1650 Submittal of Analytical Reference Standard: An analytical reference standard for PPO is not currently available in EPA National Pesticide Standards Repository (NPSR). For more information, see section IV. of this document.

V. NEXT STEPS AND TIMELINE

Once the Interim Registration Review Decision is issued, the PPO 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.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the Propylene Oxide (PPO) Interim Registration Review Decision and EPA regulations at 40 C.F.R. Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the Propylene Oxide (PPO) Interim Registration Review Decision and 40 C.F.R. Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Jonathan Williams at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

VIA Courier
Pesticide Re-evaluation Division
c/o Front End Processing
Room S-4910, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Appendix A: Summary of Risk Mitigation for Propylene Oxide

Registration Review Case#: 2560
PC Code: 042501
Chemical Type: Fumigant
Chemical Family: Fumigant
Mode/Mechanism of Action: Not identified

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Non-occupational bystanders	Volatilized PPO present in the atmosphere near treatment sites as a result of leakage during application, aeration of treated commodities, or spills/emergency situations.	Inhalation	Short-, intermediate-, and long-term	Inhalation toxicity	• Establish mandatory buffer zones around fumigation facilities into which bystanders may not enter during treatment or aeration of commodities post-treatment. • Update/add Fumigation Management Plan instructions on labels.

Appendix B: Necessary Labeling Changes for Propylene Oxide Products

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	End Use Products	
Description of PPE (Clothing)	Update the description of PPE clothing to include the following: "Wear loose-fitting or well-ventilated long-sleeved shirt and long pants, and shoes and socks when handling liquid product." Add the following statement: "Do not wear jewelry when handling."	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Description of PPE (Clothing)	Add the following statement: "Do not wear jewelry, tight clothing, rubber protective clothing, or rubber boots when handling. Propylene oxide can be trapped inside clothing or objects and cause skin injury."	In the User Safety Requirements, below the informations about respirators
Emission Reductions Technology (For labels that allow applications in vacuum-sealed chambers at application rates greater than 35 lbs PPO/1,000 ft^3)	Add the following text: "For all propylene oxide applications made in vacuum-sealed chambers less than or equal to 5,000 ft^3 in volume and at a rate of 75 lbs PPO/1,000 ft^3 (1.2 oz/ft^3) or less: • A chamber must have a release height of at least 27 feet and, during the aeration period, there must be a minimum flow rate through the stack equivalent to at least 20 air changes per hour; OR • A chamber must have a release height of at least 40 feet and minimum flow through the stack equivalent to at least 4 air changes per hour; OR • The chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by at least 95 percent.	Directions for Use, Fumigation in Vacuum Sealed Chambers

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	For all propylene oxide applications in vacuum-sealed chambers less than or equal to 5,000 ft^3 in volume at a rate greater than 75 lbs PPO/1,000 ft^3 (1.2 oz/ft^3), the chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by at least 95 percent. For all propylene oxide applications in vacuum-sealed chambers greater than 5,000 ft^3 in volume and at a rate of 75 lbs PPO/1,000 ft^3 (1.2 oz/ft^3) or greater, the chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by at least 95 percent."	
Fumigation management plans (FMP)	Create a "Site-Specific Fumigation Management Plan (FMP)" section and include the following language: "Prior to fumigating, the certified applicator supervising the fumigation must verify that a site-specific fumigation management plan (FMP) exists. The FMP is intended to ensure a safe and effective fumigation. The certified applicator in charge of the fumigation is responsible for working with the owners and/or responsible employees of the site to be fumigated to develop a site-specific FMP. The certified applicator supervising the fumigation must ensure that the FMP is up-to-date and applicable to the fumigation before it takes place. Before the start of any fumigation, the certified applicator supervising the fumigation must verify in writing (sign and date) that the FMP reflects current site conditions and that it addresses all elements identified in this labeling. For situations where an initial FMP is developed and certain elements do not change for the fumigation, only elements that have changed need to be updated in the site-specific FMP provided that the certified applicator supervising the application has verified that those elements are current and applicable to the fumigation site before the fumigation begins, and record-keeping requirements are followed for the entire FMP (including elements that do not change). The FMP must document the characteristics of the site, the aeration buffer zones and appropriate monitoring and notification requirements consistent with, but not limited to, the following:	Directions for Use, Site-Specific Fumigation Management Plan

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	1) The Certified Applicator, or a person under his/her supervision, must inspect the application site to determine its suitability for fumigation. The application site consists of the treatment area and any structure that the treatment area is inside of. 2) Before fumigating, the Certified Applicator, or a person under his/her supervision, must assess the application site for any changes since the last application that could affect the efficacy or safety of the fumigation. This assessment must include a review of the most recent fumigation log from the application site and the most recent monitoring data from adjacent, occupied buildings, where such documents are available. In addition, the Certified Applicator, or a person under his/her supervision, must consult the site manager regarding changes to the application site monthly or, if no fumigation has occurred at the application site for a month or more, upon resumption of fumigation activities. If the Certified Applicator determines, based on this assessment, that modifications to the application site are required to ensure efficacy or safety, the basis for this conclusion, and confirmation that the modifications were made prior to fumigation, shall be recorded. 3) The Certified Applicator, or a person under his/her supervision, prior to each fumigation must review any available existing FMPs, MSDS, propylene oxide label and other relevant safety procedures for the specific location or site, and consult with owners or site manager and appropriate employees, if available. 4) The Certified Applicator, or a person under his/her supervision, must develop an appropriate exterior monitoring plan that will conform with the requirements of the treatment and aeration area buffer zones to ensure that nearby handlers and bystanders are not exposed to levels above the allowed limits during fumigation and aeration and consult with owners or site managers, if available. 5) The Certified Applicator, or a person under his/her supervision, must determine whether Aeration Buffer Zones are needed and, if required, the proper Aeration Buffer Zones according to the propylene oxide product label and record the application rate, fumigated volume, and other parameters used to determine the buffer distances.	

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	6) The Certified Applicator, or a person under his/her supervision, must develop procedures for notification of local emergency responders in the event of an emergency ("Emergency Response Plan") and consult with owners or site managers, if available. The Emergency Response Plan must comply with all requirements established by local emergency responders while remaining consistent with label requirements. If local emergency responders have not established any requirements, or if requirements are minimal or contradict the label, then the plan shall still include, at a minimum, instructions on the persons or entities to contact if: (1) there is a spill, leak, equipment failure, or other emergency at the application site during a fumigation that presents a risk to humans or domestic animals; or (2) anyone at the application site is experiencing symptoms of exposure. The Certified Applicator, or a person under his/her supervision, must consult with local emergency responders at least annually to confirm that the Emergency Response Plan conforms to their requirements, or, in the absence of such requirements, that the Emergency Response Plan contains the correct contact information. 7) The Certified Applicator, or a person under his/her supervision, must confirm the placement of warning placards around the fumigation site as described on the label. 8) The Certified Applicator, or a person under his/her supervision, must document the following: a. Credentials of the Certified Applicator in charge when the fumigant was introduced and when final clearance testing was completed (if different) b. Credentials and/or names and contact information of all personnel members part of the fumigation/aeration prior to the induction of the fumigant and at the time the commodity is aerated (if different) c. The commodity being fumigated	

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	d. The target pest (if known) e. The amount of fumigant introduced into the treatment area f. Date and time of the fumigant introduction g. Date and time final clearance testing completed This information may be documented on a form designated for this purpose or on supplemental documents such as those identified below, provided that each data point is documented in at least one location. 9) The Certified Applicator, or a person under his/her supervision, must confirm the required safety and monitoring/clearance equipment (including equipment required for entry into an area under fumigation) is in place and the necessary, trained fumigation handlers are available to complete a safe, effective fumigation. Elements of the FMP may be fulfilled through the use of supplemental documents such as fumigation logs, service reports, pesticide application records, facility maps, facility emergency plans, state or federally required forms, and other supplemental documents prepared for or used during the actual fumigation."	
Update References to Dried Figs	Replace "fig" with "dried fig" on all labels. Replace "figs" with "dried figs" on all labels.	Directions for Use
	For Labels That Allow Applications in Non-Vacuum Sealed Structures	
Buffer Zones	Create a "Buffer Zones" section and include the following language: "The appropriate aeration buffer zone distances must be used and must be included in the site-specific fumigation management plan. Aeration buffer zones are required to be in place around treatment structures until the aeration of commodities treated with propylene oxide is complete, provided that the following conditions have NOT been meet:	Directions for Use

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	1) The treatment occurs in a vacuum sealed chamber that is equipped with equipment specifically designed to reduce propylene oxide emissions by at least 95 percent; OR 2) The treatment occurs in a vacuum sealed chamber that is 5,000 ft^3 or less in volume and an application rate of 75 lbs PPO/1,000 ft^3 (1.2 lbs PPO/ft^3) or less and with a minimum release height of 27 feet and during the aeration period there is a minimum flow rate through the stack of at least 20 air changes per hour; OR 3) The treatment occurs in a vacuum sealed chamber that is 5,000 ft^3 or less in volume and an application rate of 75 lbs PPO/1,000 ft^3 (1.2 lbs PPO/ft^3) or less and with a minimum release height of 40 feet and during the aeration period there is a minimum flow rate through the stack of at least four air changes per hour; OR 4) The treatment occurs in a non-vacuum sealed structure that is passively aerated; OR 5) The treatment occurs in a non-vacuum sealed structure and aeration occurs through a fixed stack that has a minimum height of 10 ft above the highest point of the structure and there is a minimum flow rate through the stack equivalent to five air changes per hour; OR 6) The treatment occurs in a non-vacuum sealed structure and aeration occurs through a portable stack of at least 10 feet and there is a minimum flow rate through the stack equivalent to 10 air changes per hour.	

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	OR 7) The treatment occurs in a non-vacuum sealed structure and aeration occurs through a portable stack of at least 25 feet and there is a minimum flow rate through the stack equivalent to 5 air changes per hour. Buffer zones are needed during all aeration activities under conditions other than those described above. The needed buffer zone depends on the volume of the aeration structure: • For non-vacuum sealed structures 10,000 ft^3 in volume or less (volume ≤ 10,000 ft^3), the minimum aeration buffer zone needed is 17 ft; • For non-vacuum sealed structures greater than 10,000 ft^3, but no more than 25,000 ft^3 (10,000 ft^3 < volume ≤ 25,000 ft^3), the minimum aeration buffer zone needed is 40 ft; • For non-vacuum sealed structures greater than 25,000 ft^3, (25,000 ft^3 < volume), the minimum aeration buffer zone needed is 105 ft. *Buffers and Buildings*: If the treatment area is contained within a closed building (exterior windows, doors, ventilation intakes, and other openings are closed), the entire building must follow all buffer zone restrictions, even if the calculated treatment buffer zone distance would not encompass the entire building. If the treatment area is within an opened building (all exterior windows, doors, and other openings are open), then only the area within the buffer zone must follow the buffer zone restrictions. The treatment and aeration buffer zones extend into nearby buildings unless all openings (exterior windows, doors, ventilation intakes, and other openings) inside the buffer zone are closed or sealed. *Buffer Zone Overlap*: If treatment or aeration buffer zones overlap from more than one propylene oxide fumigation, then to determine the treatment and aeration buffer zone the certified applicator must:	

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	• calculate the ***total volume fumigated*** for all the sites, • select the ***highest application rate*** from the multiple fumigations, and • select the ***longest air exchange interval***. Using those inputs, look up the buffer zone size in the Buffer Zones section of the Directions for Use. This buffer zone distance must be used for the aeration buffer zones for each site."	
Buffer Zone Entry Restrictions	Create a "Buffer Zone Entry Restrictions" section and include the following language: "Entry by any person, except the certified applicator supervising the fumigation, or persons under his/her direct supervision, is prohibited in the aeration buffer zone. Authorized persons who enter the treatment or aeration buffer zones must follow the personal protective equipment requirements specified for fumigation handlers on this labeling. If a structure within the aeration buffer zone is not occupied, ensure that persons do not enter the structure until the aeration buffer zone is terminated. For structures that have been vacated, persons may not re-enter until one air sample for propylene oxide, taken in the breathing zone on each floor of the structure after the termination of the aeration buffer zone indicates 10 ppm when measured using a direct read device and the propylene oxide air concentration is below 2 ppm as an 8-hour time weighted average and the level of carbon dioxide is below 5,000 ppm. The sampling requirement does not apply to unoccupied buildings used for storage (*e.g.,* sheds, barns, garages). Local, state, or federal officials performing inspection, sampling, or other similar official duties related to the fumigation are not excluded from the treatment area or aeration buffer zone by this labeling. The certified applicator supervising the application and the owner of the establishment where the application is taking place are not authorized to, or responsible for, excluding those officials from the treatment area or aeration buffer zone. **Transit Exception to Buffer Zone Entry Restrictions:** Limited transit through aeration buffer zones is allowed if brief and unavoidable. Routine or repeated work-related tasks are prohibited in the buffer zones. No person is allowed to transit through a buffer zone for more than 30 cumulative minutes in a 24-hour period. To use this exception, the FMP must state the distance from the treatment area to areas where transit is anticipated, the estimated length of time persons in transit will be in the buffer	Directions for Use, Buffer Zone Entry Restricts

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	zone, and the rationale why transit through the buffer zone will not exceed 30 minutes. No transit exception when horizontal exhaust stacks are used."	
	Changes to Product Label for EPA Registration 47870-1	
Specify Maximum Application Rate	Add the follow statement: "Do not apply more than 125 lbs propylene oxide per 1,000 ft^3 (2.0 oz PPO/ft^3)." Replace any remaining references on the label to a maximum application rate of 150 lbs propylene oxide per 1,000 ft^3 (2.4 oz PPO/1,000 ft^3) with 125 lbs propylene oxide per 1,000 ft^3 (2.0 oz PPO/1,000 ft^3).	Directions for Use
Emission Reduction Technology	Remove existing references to emission reduction technology on labels and replace it with the language described above.	Direction for Use
Reduce Application Rate on Dried Fruit Commodities	Update instructions for application to dried figs; grapes, raisins; and dried plum prunes to restrict application to no more than 0.045 oz propylene oxide per cubic foot.	Directions for Use
Post-Fumigation Intervals (PFIs)	Create a "Post-Fumigation Intervals (PFIs)" section and include the following language: "**Nut tree group 14 Nutmeat processed except peanuts Nut pine and Pistachio**: For applications at a rate of 1.5 oz PPO/ft^3 or below, hold tree nuts at 25°C for 28 days or at 35°C prior to shipment. Alternatively, tree nut commodities can be shipped if residues of propylene oxide are determined to be below 300 PPM. For applications at a rate above 1.5 oz PPO/ft^3, hold in-shell tree nuts at 25°C for 28 days and shelled tree nuts at 25°C for 31 days or at 35°C prior to shipment. Alternatively, tree nuts can be shipped if residues of propylene oxide are determined to be below 300 PPM. **Herbs and spices group 19 Dried garlic dried and Onion dried:** Hold herbs and spices group 19, dried garlic, and dried onion commodities 48 hours at 25°C or higher prior to shipment. Alternatively, herbs and spices group 19, dried garlic, and dried onion commodities can be released for shipment if residues of propylene oxide are determined to be below 300 PPM. **Cacao bean dried bean and Cacao bean cocoa powder:** Hold cacao bean and cacao powder commodities 48 hours a 25°C or higher prior to shipment. Alternatively, cacao commodities can be released for shipment if residues of propylene oxide are determined to be below 200 PPM.	Directions for Use, Post-Fumigation Intervals (PFIs)

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	Dried fig Grape raisin and Plum prune dried: Hold dried fig, grape raisin, and plum prune dried commodities 24 hours a 25°C or higher prior to shipment. Alternatively, dried fig, grape raisin, and plum prune dried commodities can be released for shipment if residues of propylene oxide are determined to be below 3 PPM, 1 PPM, and 2 PPM, respectively."	
Post-Fumigation Intervals (PFIs)	Remove the existing PFI language from the "**Nut tree group 14 Nutmeat processed except peanuts Nut pine and Pistachio**", "**Herbs and spices group 19 dried Garlic dried and Onion dried**", "**Cacao bean dried bean and Cacao bean cocoa powder**", and "**Fig Grape raisin and Plum prune dried**" in the Direction for Use, which will be updated with the language above.	Directions for Use
	Changes to Product Label for EPA Registration 47870-3	
Fumigation management plans (FMP)	Remove existing Site-Specific Fumigant Management Plan (FMP) section from the Direction for Use and replace it with the language described above.	Directions for Use
Buffer Zones	Remove the existing Buffer Zone section from the Directions for Use and replace it with the language described above.	Directions for Use
Post-Fumigation Intervals (PFIs)	Create a "Post-Fumigation Intervals (PFIs)" section and include the following language: "**Nut tree group 14 Nutmeat processed except peanuts Nut pine and Pistachio**: Hold tree nuts at 25°C for 28 days or at 35°C prior to shipment. Alternatively, tree nut commodities can be shipped if residues of propylene oxide are determined to be below 300 PPM. **Herbs and spices group 19 Dried garlic dried and Onion dried:** Hold herbs and spices group 19, dried garlic, and dried onion commodities 48 hours at 25°C or higher prior to shipment. Alternatively, herb and spices group 19, dried garlic, and dried onion commodities can be released for shipment if residues of propylene oxide are determined to be below 300 PPM. **Cacao bean dried bean and Cacao bean cocoa powder:** Hold cacao bean and cacao powder commodities 48 hours a 25°C or higher prior to shipment. Alternatively, cacao commodities can be released for shipment if residues of propylene oxide are determined to be below 200 PPM. **Dried fig Grape raisin and Plum prune dried:** Hold dried fig, grape raisin, and plum prune dried commodities 24 hours a 25°C or higher prior to shipment. Alternatively, dried fig, grape raisin, and plum prune dried commodities can be released for shipment	Directions for Use, Post-Fumigation Intervals (PFIs)

Description	Necessary Label Language for Propylene Oxide Products	Placement on Label
	if residues of propylene oxide are determined to be below 3 PPM, 1 PPM, and 2 PPM, respectively."	

Appendix C: Additional Modeling for Bystander Risks to Inform Updates to Buffer Zones

The following four tables were used to develop the revised mitigation strategy for risks to bystanders, presented in section IV.A. and Appendix B, above. They were created using modeling outputs from PERFUM 3.0, as described in section III.A.1., above. To read the tables, begin with an aeration scenario (*i.e.*, passive aeration, active aeration, no stack, fixed stack, portable stack) and select its corresponding table (*e.g.*, Table C.2: Active Aeration, No Stack). Next identify the structure size (*e.g.*, 25,000 ft^3) and aeration rate (*e.g.*, minimum 10 ACH). The resulting intersection of these variables shows the PERFUM output for the whole field buffer zone at the 90th percentile for a single fumigation given a scenario. *E.g.*, for an active aeration—Table C.2.— of a 25,000 ft^3 structure with no ventilation stack and a minimum aeration rate of 10 air changes per hour (ACH), PERFUM indicates that a buffer zone of 32 m (105 ft) is needed to protect bystanders. The tables presented here demonstrate that bystanders can be protected from unsafe PPO exposure through a variety of release height, aeration rate, and buffer zone combinations, as described in section IV.A. and Appendix B.

Table C.1.: Passive Aeration

Structure volume → **Aeration rate ↓**	5,000 ft^3 or less	5,001 to 10,000 ft^3	10,001 to 50,000 ft^3	50,001 to 100,000 ft^3
Passive aeration	0 m	0 m	0 m	0 m

Table C.2.: Active Aeration, No Stack

Structure volume → **Aeration rate ↓**	5,000 ft^3 or less	5,001 to 10,000 ft^3	10,0001 to 25,000 ft^3	25,001 to 50,000 ft^3	50,001 to 100,000 ft^3
Minimum 10 ACH	5 m	0 m	12 m	32 m	0 m
Minimum 20 ACH	5 m	0 m	12 m	32 m	0 m

Table C.3.: Active, Aeration Minimum Ten-Foot Fixed Stack

Structure volume → **Aeration rate ↓**	5,000 ft^3 or less	5,001 to 10,000 ft^3	10,001 to 50,000 ft^3	50,001 to 100,000 ft^3
Minimum 5 ACH	0 m	0 m	0 m	0 m
Minimum 20 ACH	0 m	0 m	0 m	0 m

Table C.4.: Active Aeration, Minimum Ten-Foot Portable Stack

Structure volume → **Aeration rate ↓**	5,000 ft^3 or less	5,001 to 10,000 ft^3	10,0001 to 25,000 ft^3	25,001 to 50,000 ft^3	50,001 to 100,000 ft^3
Minimum 10 ACH	0 m	0 m	0 m	0 m	0 m
Minimum 20 ACH	0 m	0 m	0 m	14 m	0 m

Appendix D: Endangered Species Assessment

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

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated Revised Method for conducting national level BEs in March 2020.[15]

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 in 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 ID for PPO does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this ID, 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 PPO. This will allow 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 PPO as part of completing this registration review.

[15] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional

Appendix E: 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 PPO, 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), PPO 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,[16] 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. PPO 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.[17]

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

[16] See https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[17] https://www.epa.gov/endocrine-disruption