OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
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MEMORANDUM

Date: **April 10, 2024**

SUBJECT: **Registration Review Draft Risk Assessment for Formaldehyde and Paraformaldehyde**

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Decision No.: NA	Docket No: EPA-HQ-OPP-2015-0739
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This document provides the draft human health and ecological risk assessment conducted in support of the pesticide active ingredients (a.i.) formaldehyde (PC Code 043001) and paraformaldehyde (PC Code 043002) for Registration Review.

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Docket
Supporting information can be found in public docket, Docket ID (EPA-HQ-OPP-2015-0739).

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EXECUTIVE SUMMARY

The Registration Review Case 0556 contains formaldehyde and paraformaldehyde as pesticide active ingredients (a.i.). Formaldehyde is used to disinfect various agricultural premises and equipment such as citrus, egg hatchery, poultry and swine confinement, and mushroom houses; as an in-can materials preservative in industrial and household consumer products such as laundry detergents, automotive cleaning products, fabric softeners, household cleaners, hand cleaners and dish detergents; and as a microbiocide/microbiostat in industrial oil and gas injection water. There is also a special local needs (SLN) registration for the use of formaldehyde in Washington State to control nematodes, insects such as greater bulb flies, mites, and certain plant pathogenic fungi on daffodil and bulbous iris. Paraformaldehyde, the polymerized product of formaldehyde that exists as a solid crystallization form, is used to sterilize laboratory facilities and equipment and to disinfect leaf cutting bee nest materials. Paraformaldehyde is also a mildewcide used to fumigate unoccupied vacation homes and trailers during the off season and clothing and linen storage bins, dresser drawers, bedding, golf bags, suitcases and trunks in closets of occupied homes.

Formaldehyde is undergoing review by the Office of Pesticide Programs (OPP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as part of the Registration Review process while concurrently undergoing review by the Office of Pollution Prevention and Toxics (OPPT) under the Toxic Substances Control Act (TSCA) risk evaluation process. OPP and OPPT have worked jointly on three formaldehyde assessments that support this draft risk assessment (DRA), including the Environmental Hazard Assessment (U.S. EPA, 2024a), the Chemistry, Fate, and Transport Assessment (U.S. EPA, 2024b), and the Human Health Hazard Assessment (U.S. EPA, 2024c). These supporting documents are published separately and are referenced throughout this DRA where appropriate to provide additional detailed information and support data analysis or risk conclusions. These documents, in addition to the draft TSCA Risk Evaluation for Formaldehyde, were posted to the docket (EPA-HQ-OPPT-2023-0613) on March 15, 2024, for public comment and peer review by the Science Advisory Committee on Chemicals (SACC). Although the SACC will not review the FIFRA risk assessment, OPP will use feedback received from public comments and the SACC to inform the final FIFRA assessment.

Formaldehyde is a highly reactive gas that is ubiquitous in indoor and outdoor environments. It is widely used in a range of industrial applications, consumer products, and building materials (e.g., composite wood products, plastics, rubber, various adhesives and sealants). It naturally occurs as a product of combustion, a product of normal metabolism in the human body, and is formed through the decomposition of organic matter (i.e., biogenic sources).

This DRA focuses on the pesticidal uses of formaldehyde and paraformaldehyde registered under FIFRA.

Human Health Risk Summary

OPP conducted assessments for incidental oral, dietary, dermal, and inhalation exposures to products that contain formaldehyde and paraformaldehyde as a pesticide active ingredient for use in residential and occupational settings. The available toxicity data for formaldehyde are adequate for evaluation of human health hazard and risk assessment. The toxicity endpoints and points of departure (PODs) for formaldehyde have been reviewed jointly by OPP and OPPT and revised for Registration Review since the publication of the Reregistration Eligibility Decision (RED) document (U.S. EPA, 2008). This risk assessment includes the updated toxicity PODs for all potential routes of exposure.

Dermal exposure was assessed for formaldehyde based on the anticipated exposure to formaldehyde in liquid form and the dermal toxicity endpoints associated with a similar exposure scenario. Given its use as a fumigant and its volatility, along with the available human toxicity effects data, inhalation exposure was assessed as formaldehyde gas. Lastly, oral exposures are assessed qualitatively due to the chemical properties of formaldehyde and the characteristics of uses.

Table ES-1 provides a summary of the human health risks assessed for the registered uses of formaldehyde and paraformaldehyde. Specific discussions of the exposures and risks are provided in the sections below.

Table ES-1. Human Health Risks from Registered Uses of Formaldehyde/Paraformaldehyde

Scenario	Type of Assessment[2]	Risk of Concern Indicated?			Comments
		Acute	Chronic	Cancer[3]	
Inhalation Exposure					
Residential Handler -preserved materials[1]	Quantitative	**Yes**	No	$2x10^{-5}$	Formaldehyde in household cleaners (surrogate in-can uses)
Residential Bystander - preserved materials[1]	Quantitative	**Yes**	No	$2x10^{-5}$	Formaldehyde in household cleaners (surrogate in-can uses)
Residential Post-Application	Quantitative	**Yes**	**Yes**	$1x10^{-3}$	Paraformaldehyde use in vacation homes, closets, bedding, cabinets, golf bags, etc.
Residential Bystander – Formaldehyde fumigant uses	Quantitative	**Yes**	NA	NA	Agricultural spaces; Risks extend ~430 m for small buildings and >1,500 m for large buildings, which are beyond current buffer distances on labels

Scenario	Type of Assessment[2]	Risk of Concern Indicated?			Comments
		Acute	Chronic	Cancer[3]	
Residential Bystander – paraformaldehyde fumigant uses	Quantitative	**Yes**	NA	NA	Laboratory facilities, equipment; Risks extend ~450 m for small buildings and ~1,500 m for large buildings, no buffers on labels
Residential Bystander – formaldehyde bulb treatment SLN	Qualitative	**Yes**	NA	NA	Cannot preclude risk.
Occupational Handler formaldehyde uses	Qualitative	**Yes**	**Yes**	**Yes**	Open pour for fumigation, materials preservation; bulb treatment SLN); Use of preserved cleaning products.
Occupational Post-Application	Quantitative	**Yes**	NA	NA	Formaldehyde - fumigation in agricultural spaces (with passive aeration) Paraformaldehyde - fumigation in laboratory facilities, equipment
Dermal Exposure					
Residential Handler – preserved materials	Quantitative	**Yes**		ND	Formaldehyde in laundry detergents and household cleaners (surrogate in-can uses)
Occupational Handler Formaldehyde	Qualitative	**Yes**			Open pour for fumigation; materials preservation; bulb treatment SLN
Oral Exposure					
Incidental Oral	Qualitative	No			Formaldehyde in household cleaners.
Dietary (food)	Qualitative	No			Formaldehyde in dish detergents and general-purpose cleaners.
Dietary (drinking water)	Qualitative	**Yes**			Formaldehyde bulb treatment SLN (cannot preclude risk)

NA – not applicable, ND – not determined.

[1] Table 2-2 lists representative scenarios for indoor modeling for labeled uses.

[2] Quantitative assessments were done by calculating exposures using models. Qualitative assessments were done using label instructions, chemical fate properties and usage information.

[3] The cancer risk target of 1×10^{-6} is normally used by OPP as a risk management goal for residential exposures.

Dietary (Food and Drinking Water) Exposures to Formaldehyde and Paraformaldehyde

Fumigation uses are classified as nonfood because the labels require the removal of all food commodities prior to and during treatment (i.e., poultry and swine spaces, citrus packing houses, and mushroom houses, and tools and equipment of mushroom spaces) or because the commodity is not for consumption (i.e., egg hatcheries). There is no expectancy of residues from fumigation uses. Since current labeled fumigation uses are considered nonfood, they do not require a dietary risk assessment.

There is a potential for indirect dietary exposure of formaldehyde from in-can preservative uses in dish detergents and consumer household cleaners. However, due to chemical breakdown, formaldehyde or its transformation products are not expected to remain on food surfaces or persist for oral consumption. Therefore, OPP has determined that there is a low potential for risk from oral exposure from antimicrobial materials preservative dish detergent and cleaning products uses.

Pulp and paper, and coating uses were not assessed as end use dietary exposure since the label identifies these use sites for formulation or manufacture and states that EPA Reg No. 8743-17 may not be used in products coming in direct contact with food and/or drinking water until FDA clearances for the formulation use sites (i.e., pulp and paper and coating) have been obtained. Based on the label's note and lack of use directions, these uses were not considered as indirect dietary exposure, but merely a notification that the uses are prohibited as food uses on end use labels until appropriate FDA food contact clearances are granted.

There are no labeled dietary uses from products containing paraformaldehyde; therefore, dietary exposure from its use is not anticipated or assessed at this time.

Drinking water exposure and risks from residential and industrial wastewater discharge are expected to be low due to the chemical breakdown of formaldehyde and its transformation products as they move through the wastewater treatment system. However, there is the potential for exposure to formaldehyde and its transformation products in drinking water in Washington State from the SLN use after spent dip water is applied to the field. Given the uncertainties around its use, the drinking water assessment is qualitative, and risk cannot be precluded. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

Residential Exposures to Formaldehyde as a Preservative in Consumer Products

There is one product containing formaldehyde that is labeled for use as an in-can preservative of consumer products. Dermal and inhalation exposures are anticipated during the use of formaldehyde-preserved consumer products, but post-application dermal, inhalation, and incidental oral exposures are not anticipated because formaldehyde quickly volatilizes out of the preserved consumer products as they are applied.

Residential dermal exposures for the use of consumer products were assessed at the maximum application rate of 370 ppm. The dermal Margin of Exposure (MOE) of 26 for induction of skin sensitization is of concern because it is less than the LOC of 100 and the dermal MOE of 2.8 for elicitation of skin sensitization is of concern because is it less than the LOC of 10. These MOEs would be increased to their LOCs if the application rate were reduced to 97 ppm.

Residential handler and bystander inhalation exposures were assessed for laundry detergent, general purpose cleaners, and automotive interior cleaners at the maximum rate of 370 ppm as representative scenarios for the in-can material preservative uses. The MOEs and cancer risks are listed in Table ES-2. The MOEs highlighted in bold font are of concern because they are less than the LOC.

Table ES-2 – Preserved Products Residential Inhalation Risk Summary

Use Scenario	Person Exposed	Acute MOE (LOC = 10)	Chronic MOE (LOC = 3)	Cancer Risk[1]
Automotive Interior Cleaner	Adult Handler	13	3,900	3×10^{-8}
	Child Bystander	18	4,100	3×10^{-8}
General Purpose Cleaner	Adult Handler	**6.3**	7.8	2×10^{-5}
	Child Bystander	**8.1**	7.1	2×10^{-5}
Laundry Detergent	Adult Handler	25	N/A	N/A
	Child Bystander	N/A	N/A	N/A

[1] The cancer risk target of 1×10^{-6} is normally used by OPP as a risk management goal for residential exposures.

Residential Exposures to Paraformaldehyde Used in Homes

There is one product containing paraformaldehyde that is labeled for treatment of clothing and linen storage bins, dresser drawers, bedding, golf bags, suitcases, and trunks in closets of occupied homes. This product is packaged as a 3- or 4-ounce pouch that is placed in the area to be treated. No exposures are anticipated during the application of the product; however, post-application inhalation exposures are anticipated as formaldehyde is released into the closet and diffuses to the rest of the house. The MOE of 0.0066 for acute peak exposure for someone who enters the closet is of concern because it is less than the LOC of 10. The MOE of 0.18 for long-term exposure is of concern because it is less than the LOC of 3. The estimated cancer risk assuming 78 years of use is 1×10^{-3}.

Residential Bystander Exposures to Fumigation Applications of Formaldehyde and Paraformaldehyde

There is the potential for residential bystander inhalation exposures, for people who live nearby, when formaldehyde is used to fumigate facilities such as rooms, feed trucks, and railway cars; hatching eggs; poultry and swine confinement houses; mushroom houses; and citrus packing houses. Buffer zones of 150 ft for buildings less than 100,000 ft^3 and 1,100 ft for buildings up to 1,000,000 ft^3 are currently required on the label during aeration. There is also the potential for inhalation exposure to formaldehyde when paraformaldehyde is used in disinfection and fumigation of leaf-cutting bee cells

and nesting materials, and microbiological laboratory settings, including human and animal research facilities and equipment. Buffer zones are not currently required on the label for paraformaldehyde uses.

The one-hour maximum air concentrations, representing exposure concentrations to the bystander outside the treated buildings and considering buffer distances as indicated on the label, were used to estimate acute exposure. When passive aeration is used in buildings and areas that do not have mechanical ventilation systems, the acute MOEs for these air concentrations range from 0.1 to 31,000. When active aeration is used in buildings and areas that have mechanical ventilation systems, the MOEs range from 0.12 to 120 for formaldehyde applications and 0.014 to 3.3 for paraformaldehyde applications. Most of these MOEs are of concern because they are less than the LOC of 10. Required distances from the fumigation buildings for MOEs to no longer be of concern for all registered uses range from 46 to 438 m for smaller building sizes and 280 to > 1,500 m for larger buildings. Some of these distances are larger than buffer zones required on the current labels for formaldehyde.

Residential Exposure to Formaldehyde (Bulb SLN)

There is potential for outdoor inhalation exposure from formaldehyde transformation products to nearby residential bystanders from direct applications of dip-tank water to soil; however, there is uncertainty in this exposure given the slow volatilization of methylene glycol from moist soil. As a result, inhalation exposure cannot be precluded. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion for this use.

Aggregate Exposure

The toxicological effects of oral, dermal and inhalation exposures to formaldehyde are route specific and therefore cannot be aggregated. In addition, the dermal exposures cannot be aggregated for the use of different consumer products because they are based on the concentration of the product and would not increase if multiple products were handled on the same day.

Aggregate exposure to formaldehyde via the inhalation route could occur from residential use of formaldehyde-containing detergent, general purpose cleaner, car interior cleaner and air freshener as well as bystander exposures from the fumigation uses. Some of these exposure scenarios individually have both non-cancer and cancer risks of concern from inhalation. Measures to reduce exposure from each of these sources would be necessary for aggregate risks not to present risks of concern based on the Agency's identified levels of concern. However, pesticidal uses of formaldehyde and paraformaldehyde are relatively minor contributors to the overall formaldehyde exposures.

Occupational Handler Exposure to Formaldehyde (Mixing, Loading, and Fumigation Uses)

There are six occupational handler exposure scenarios that involve formaldehyde pesticidal products: 1. Mechanical Fumigation, 2. Evaporative Fumigation, 3. Catalyzed Evaporative Fumigation, 4. Material Preservation, 5. Oil Production Injection Water Treatment, and 6. Daffodil and Iris Bulb Dipping (SLN). Exposures to occupational handlers are expected to be short-term and intermittent in nature.

Although there are many studies of formaldehyde occupational inhalation exposures reported in the literature, these studies involved the non-pesticidal uses, and there is very little information concerning inhalation exposures from the pesticidal uses. Because of this, formaldehyde specific inhalation exposure data were recommended to be required in the Final Work Plan. These data requirements were included in the 2017 Generic Data-Call-Ins (GDCIs) for formaldehyde and paraformaldehyde; however, relevant data[1] were not submitted to the Agency and the inhalation exposure data remain gaps. More information on the GDCIs and the impact of these data gaps is provided in the Case Overview (Section 1.1) and Data Deficiencies (Section 2.1).

Since it not possible to quantitatively assess the formaldehyde inhalation exposures that result from the pesticidal uses of formaldehyde, these scenarios were assessed qualitatively based upon work practices listed on the labels. These practices include closed loading to prevent exposure when transferring formaldehyde products into mixing vessels for material preservation or oil production injection water treatment and conducting mechanical fumigation applications using equipment that is activated from outside the enclosure or building being treated. Exposures are expected to be of low risk for these uses. For the evaporative fumigation of eggs, applicator exposures are also expected to be of low risk because the product labels require that incubators be ventilated to the outside and that the incubator rooms also have adequate ventilation.

For catalyzed fumigation, which is used to treat room and railcars by pouring the formaldehyde solution into a small pan containing potassium permanganate ($KMnO_4$) and leaving the room immediately, the handler exposures for this application have the potential to be of concern because it is likely that formaldehyde levels will rise quickly due to the catalytic reaction and the risk would depend on how quickly the handler exits the area. The inhalation exposures for the bulb dipping SLN are also potentially of concern because the formaldehyde air concentrations above the dip tank could be quite high if the bulb treatment is done in a poorly ventilated room. Use of personal protective equipment as required by the label, including a full-face respirator with formaldehyde cartridge, will reduce exposures from these uses but may not be sufficient to eliminate concerns. These risk conclusions could be refined if the indoor inhalation exposure data or small chamber emissions data, similar to the studies required as part of the GDCI, were submitted.

[1] MRID 46875901 is a study of formaldehyde air concentrations measured near a dairy barn footbath. It was cited in response to the GDCI; however, it is not relevant to the registered uses of formaldehyde. It was submitted in 2004 to support EPA registration of a footbath use. This use was not registered because it is regulated by FDA.

Dermal exposures are also of potential concern for the occupational handler exposure scenarios. While dermal exposures could not be modeled for occupational handlers, the concentration in the product (370,000 ppm a.i.) is orders of magnitude higher than the concentration (97 ppm a.i.) below which effects would not be expected for unprotected hands based on the residential assessment. The required chemical resistant gloves will reduce hand exposures by a factor of ten, but it is not known if this reduction is sufficient to prevent dermal sensitization which can be caused by localized contact.

Occupational Exposure to Formaldehyde (Use of Preserved Products)

There is the potential for occupational dermal and inhalation exposure to cleaning products that are preserved with formaldehyde. The exposure scenarios include housekeepers using general purpose spray cleaners, commercial or institutional laundry workers using laundry detergent and automotive detailing workers. The occupational dermal exposures are the same as those assessed for residential consumers and do not consider frequency or duration of use because dermal sensitization is a localized skin reaction that can occur after one exposure. Instead, the assessment is conservatively based on the maximum concentration of formaldehyde in the product being used and the assumption that handlers completely immerse their hands in the product during use (i.e., once the hand is wet, it cannot get any wetter).

Since it is not possible to estimate occupational exposures using current models, the estimated exposures modeled for residential uses are used to characterize potential occupational exposures. This characterization is summarized below:

- **Housecleaner Exposure Using General Purpose Cleaners** –The acute MOE for each house or room would likely be equal to or less than the acute MOE that was calculated for consumers. The long-term MOE would be lower and cancer risks would be greater based on the larger number of rooms that would be cleaned per day.
- **Laundry Worker Exposure Using Laundry Detergent** – The acute screening level MOE would be the same as for consumers presented in Table ES-2 because it is based on the same Henry's Law Constant and wash water concentration.
  Automotive Detailing Workers – The acute MOE would likely be lower than the acute MOE that was calculated for consumers due to the more intensive cleaning that is done. The long-term MOE would be lower, and the cancer risks would be greater because more cars are cleaned per day.

Occupational Post-Application Exposures to Formaldehyde from Fumigation Applications

Formaldehyde is used for fumigating buildings used for poultry and swine confinement, mushroom houses, and as citrus facilities. Paraformaldehyde is used for fumigating laboratories and laboratory equipment in sealed enclosures. Post-application inhalation exposures are expected to be acute and intermittent based on the use pattern and application instructions. The acute MOEs are listed in Table ES-3 and range from 0.67 to 12,000 depending upon how the building is aerated. The MOEs highlighted in bold font are of concern because they are less than the LOC of 10. The acute MOE is 0.67 when the building is passively aerated to reach the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 0.75 ppm as required by the formaldehyde label (EPA Reg. No. 8743-17). The acute MOE is 5.0 when the enclosure is aerated to 0.1 ppm as required by the paraformaldehyde label (EPA Reg. No. 4972-43). This level is based on the risk assessment that was done for the Section 3 registration of paraformaldehyde for leaf cutting bee nesting material and laboratory fumigation (US EPA, 2012a).

Table ES-3 – Occupational Post-Application Inhalation Risk Summary

Use Scenario	Initial Air Concentration (ppm)	Aeration Type	Aeration Time (minutes)	Post Aeration Air Concentration (ppm)	Acute MOE (LOC = 10)
Formaldehyde Building Fumigation	20,300[A]	Active	465	0.05[D]	10
			720	0.000041[D]	12,000
		Passive	1,440	0.75[E]	**0.67**
Formaldehyde Room and Railcar Fumigation	6780[B]	Passive	As needed	0.75[E]	**0.67**
Paraformaldehyde Enclosure Fumigation	17,300[C]	As needed	As needed	0.1[F]	**5.0**

A. Based on 60 fluid ounces of EPA Reg No. 8743-17 per 1000 ft^3.

B. Based on 20 fluid ounces of EPA Reg No. 8743-17 per 1000 ft^3.

C. Based on 0.6 grams of EPA Reg. No. 4972-43 per cubic foot. Product contains 91% a.i.

D. Based on ventilation at a rate of 1.67 air changes per hour.

E. Based on passive ventilation until the air concentrations declines to 0.75 ppm (the OSHA PEL) as required by the label.

F. Based on active or passive ventilation until the air concentration declines to 0.1 ppm as required by the label.

Occupational Bystander Exposures to Formaldehyde for the Bulb Dip SLN

There is potential for outdoor inhalation exposure from formaldehyde transformation products to nearby occupational bystanders when the spent dip-tank water from the bulb dip treatment is applied to the soil as directed on the SLN label. However, there is uncertainty in the levels of exposure given the slow volatilization of methylene glycol from moist soil. As a result, inhalation exposure cannot be precluded. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

Ecological Risk Summary

Table ES-4 provides a summary of the ecological risks assessed for the registered uses of formaldehyde and paraformaldehyde. Specific discussions of the risks are provided in the sections below.

Table ES-4. Summary of Ecological Risks from Registered Uses of Formaldehyde and Paraformaldehyde

Scenario	Type of Assessment	Residue(s) of concern	Risks of Concern	Comments
			Acute	
Aquatic	Qualitative	Formaldehyde + transformation products	Cannot preclude risk	Potential risk associated with formaldehyde SLN use
Terrestrial	Quantitative	Formaldehyde gas	Yes	Formaldehyde - fumigation in agricultural spaces and cannot preclude risk from SLN Paraformaldehyde - fumigation in laboratory facilities, equipment Risks extend up to 780 m for plants and 450 m for mammals Cannot preclude risks for birds and terrestrial invertebrates based on lack of ecotoxicity data

OPP evaluated the potential for risks to terrestrial and aquatic organisms from registered pesticidal uses of formaldehyde and paraformaldehyde.

While several pesticidal uses of formaldehyde (i.e., materials preservatives in residential and industrial cleaning products, laundry uses, and in industrial oil and gas injection water) have the potential to go down-the-drain, exposures to aquatic habitats are not anticipated. Based on the rapid transformation in water of formaldehyde to methylene glycol and formaldehyde oligomers in the collection and treatment systems, the potential for additional dilution of these discharges with water not containing formaldehyde and its transformation products, and a > 92% removal of these chemicals via wastewater treatment, potential releases from residential and industrial uses that go down the drain and undergo wastewater treatment are expected to be low. Additionally, any residences not connected to a centralized wastewater treatment system will use their own septic system, which will allow degradation of formaldehyde and its transformation products prior to a discharge to a drainfield. The potential for releases to surface water from these sources are considered low. Therefore, there is low potential for risk to aquatic organisms from these uses. However, there is potential for exposure to

aquatic organisms via runoff from the SLN use of formaldehyde when the spent bulb dip water is applied to fields planted with treated ornamental flower bulbs. Given uncertainties associated with the use pattern, application methods, and application rate, risk to aquatic organisms cannot be precluded at this time. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

There is potential for exposures to terrestrial organisms to formaldehyde from fumigant uses in citrus packing houses, mushroom houses, egg hatcheries, poultry and swine confinement buildings, and feed trucks and rail cars. The residue of concern for terrestrial taxa from fumigant uses is vapor-phase formaldehyde. Ecotoxicity data relevant for assessing vapor-phase exposures are only available for terrestrial plants and mammals. Based on modeled air exposure concentrations and ecotoxicity data, there is potential for risk to terrestrial plants and mammals from registered formaldehyde and paraformaldehyde fumigant uses released through active and passive aeration.

There are uncertainties associated with the modeling (e.g., amount of formaldehyde released, the timing of the release, the number of facilities being treated in a day, etc.), the proximity of the ecological receptor to the building, the duration of the available mammalian and terrestrial plant toxicity studies, and the use of an endpoint for terrestrial plants from a study where no effects were observed. However, estimated exposures exceed the concentration at which effects were observed by more than an order of magnitude and extend 450 m away from the treated building for mammals and 780 m for plants, supporting the potential for risks.

No ecotoxicity data are available to estimate formaldehyde risks to terrestrial invertebrates or avian species via air exposure from fumigant uses. Due to the increased respiration rate of avian species compared to mammals, it is likely that avian species may be exposed to higher doses of available formaldehyde in the air than mammals, potentially resulting in increased sensitivity. Risks to these taxa cannot be precluded at this time.

Bees (and other terrestrial invertebrates) may also be exposed to formaldehyde from the use of paraformaldehyde as a fumigant for leaf-cutting bee nesting materials and leaf-cutting bee cells. Given the current lack of relevant toxicity data for formaldehyde and potential exposure from fumigant uses to bee nesting materials, risk cannot be precluded to bees or other terrestrial invertebrates from this use.

There is also the potential for exposure to terrestrial organisms from the SLN use of formaldehyde transformation products when the spent bulb dip water is applied to fields planted with treated ornamental flower bulbs. Given uncertainties associated with the use pattern, application methods, and application rate, risk to terrestrial organisms cannot be precluded at this time. More information

on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

In conclusion, there is low potential for risks to aquatic organisms from the registered antimicrobial uses of formaldehyde and paraformaldehyde that may go down-the-drain. However, risks to aquatic organisms cannot be precluded for the SLN use of formaldehyde to treat ornamental bulbs given uncertainties in application methods. There is also potential for risk to terrestrial plants and mammals from the registered pesticidal uses of formaldehyde and paraformaldehyde to fumigate various agricultural, commercial, industrial, and residential sites when released through active and passive aeration. Due to lack of data, risks to terrestrial invertebrates and birds cannot be precluded from fumigant uses. Also, given uncertainties in the potential for formaldehyde transformation products to volatilize out of the soil, and the direct application to soil, risks to aquatic and terrestrial organisms cannot be precluded for the SLN use.

1 INTRODUCTION

1.1 Case Overview

The Registration Review Case 0556 contains formaldehyde and paraformaldehyde as active ingredients in pesticidal products. The documents for this case can be viewed at www.regulations.gov in docket EPA-HQ-OPP-2015-0739. The first products containing formaldehyde (PC Code 043001) were registered in the United States in 1967 and paraformaldehyde (PC Code 043002) in 1964. Formaldehyde and paraformaldehyde are registered for use as disinfectants, sanitizers, microbiocides/microbiostats, fungicides, nematicides, and material preservatives.

As part of the reregistration program for which EPA reviewed older pesticides – those initially registered before November 1, 1984 – to ensure that they met current scientific and regulatory standards, the Reregistration Eligibility Decision (RED) was published in June 2008 (U.S. EPA, 2008). For the current Registration Review program, a Final Work Plan (FWP) was completed in March 2017, in which data requirements were identified. Generic Data Call-ins (GDCIs) were issued in September 2017 (formaldehyde: GDCI-043001-1694 and paraformaldehyde: GDCI-043002-1696). The guideline studies that were required as part of the GDCIs for formaldehyde and paraformaldehyde, and the status of the data requirements, are listed below. These data were due to the Agency in 2019. Where data requirements remain unsatisfied, OPP relied on information identified in the open literature (which included data reviewed as part of the collaborative work with OPPT as described in Section 2.3 below), from predictive tools, or made conservative assumptions in order to complete this DRA.

- 870.3100 – 90-Day Oral Toxicity (formaldehyde) – Unsatisfied
- 870.3700 – Prenatal Toxicity (formaldehyde) – Unsatisfied
- 870.3800 – Reproductive and Fertility Effects (formaldehyde) – Unsatisfied
- 870.4100 – Chronic Oral Toxicity (formaldehyde) – Unsatisfied
- 870.4200 – Carcinogenicity (formaldehyde) – Unsatisfied
- 870.4300 – Chronic Toxicity/Carcinogenicity (formaldehyde) – Unsatisfied
- 870.6200 – Neurotoxicity (formaldehyde) – Unsatisfied
- 870.7800 – Immunotoxicity (formaldehyde) – Unsatisfied
- 875.1400 – Inhalation Exposure – Indoor (formaldehyde) – Unsatisfied
- 875.2500 – Inhalation Exposure - Post Application (paraformaldehyde) – Unsatisfied
- SF-1218 – Nature of Residue Study (formaldehyde) – Unsatisfied
- 850.4500 – Algal Toxicity (formaldehyde and paraformaldehyde) – Unsatisfied

As noted in footnote 1 of the formaldehyde GDCI, the requirement for the Inhalation Exposure – Indoor study (GLN 875.1400) can be met either be measuring the exposure directly or by modeling the exposure using data from small chamber emission studies (GLN 875.2500) for the following scenarios:

open pour liquids, spray, mop, sponge, and trigger spray and wipe applications. As noted in footnote 2 of the paraformaldehyde GDCI, the requirement for the Inhalation Exposure – Post Application study (GLN 875.2500) can be met either be measuring the exposure directly or by modeling the exposure using data from small chamber emission studies (GLN 875.2500).

Formaldehyde is undergoing review by the Office of Pesticide Programs (OPP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as part of the Registration Review process while concurrently undergoing review by the Office of Pollution Prevention and Toxics (OPPT) under the Toxic Substances Control Act (TSCA) risk evaluation process. OPP and OPPT have worked jointly on three formaldehyde assessments that support this draft risk assessment (DRA), including the Environmental Hazard Assessment (U.S. EPA, 2024a), the Chemistry, Fate, and Transport Assessment (U.S. EPA, 2024b), and the Human Health Hazard Assessment (U.S. EPA, 2024c). These supporting documents are published separately and are referenced throughout this DRA where appropriate to provide additional detailed information and support data analysis or risk conclusions. These documents, in addition to the draft TSCA Risk Evaluation for Formaldehyde, were posted to the docket (EPA-HQ-OPPT-2023-0613) on March 15, 2024, for public comment and peer review by the Science Advisory Committee on Chemicals (SACC). Although the SACC will not review the FIFRA risk assessment, OPP will use feedback received from public comments and the SACC to inform the final FIFRA assessment.

This DRA focuses on the pesticidal uses of formaldehyde and paraformaldehyde registered under FIFRA. The conclusions conveyed in this assessment were developed in full compliance with *EPA Scientific Integrity Policy for Transparent and Objective Science*, and EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions.* The full text of *EPA Scientific Integrity Policy for Transparent and Objective Science*, as updated and approved by the Scientific Integrity Committee and EPA Science Advisor can be found here: https://www.epa.gov/sites/default/files/2014-02/documents/scientific_integrity_policy_2012.pdf. The full text of the EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions* can be found here: https://www.epa.gov/scientific-integrity/approaches-expressing-and-resolving-differing-scientific-opinions.

1.2 Recent Regulatory Actions

After the FWP was published, some products were cancelled which resulted in the termination of certain uses for formaldehyde. These include EPA Reg. No. 61282-59, which was applied in animal care and housing facilities by handheld spray, mop, or sponge; EPA Reg. No. 90924-6, which was used in drilling muds; and EPA Reg. No. 397-6, which was used in barber and beauty shops.

1.3 Ingredient Profile and Chemical Identity

Formaldehyde is a colorless gas (vapor pressure (VP) of 3890 mm Hg at 25°C) with a pungent odor (NIOSH, 2007). It is a highly reactive chemical substance that is flammable and readily undergoes polymerization in various media. Formaldehyde is miscible in water, alcohols, and other polar solvents. At low temperatures, liquid formaldehyde is miscible in a wide variety of non-polar organic solvents such as toluene, ether, chloroform, and ethyl acetate.

Paraformaldehyde is a white crystalline solid that is the polymerized aldehyde with chain lengths ranging from 8 to 100 units. The number of repeating units affects the physical and chemical properties of the resulting oligomer/polymer. For example, paraformaldehyde molecules with longer chain lengths will have lower vapor pressures and higher melting points.

Chemical characteristics for formaldehyde and paraformaldehyde are available and discussed in greater detail in a joint Chemistry, Fate, and Transport Assessment created by both OPP and OPPT (U.S. EPA, 2024b) and are summarized here.

All registered end use products of formaldehyde contain 37 percent formaldehyde as a liquid, often referred to as “formalin”, or the solid crystalline polymerized form (paraformaldehyde). In the public literature “formaldehyde” and “formalin” are sometimes used interchangeably to describe formaldehyde in water with or without a stabilizer. Stabilizers are used to prevent polymerization of formaldehyde to paraformaldehyde, with methanol being the most commonly used formaldehyde stabilizer.

The chemical reaction and fate of formaldehyde is complex and dependent on multiple environmental factors which must be considered in determining the residues of concern for both ecological and human exposure, as well as how this relates to the toxicity of potential transformation and degradation products. In aqueous solutions, formaldehyde hydrates to form methylene glycol and can polymerize in the absence of stabilizers such as methanol, as shown in Figure 1-1. The equilibrium formation of these oligomers or poly(oxy)methylene glycol depends on formaldehyde concentrations, and higher molecular weight oligomers are most prevalent at high concentrations of formaldehyde. Higher temperature conditions may favor formation of formaldehyde gas.

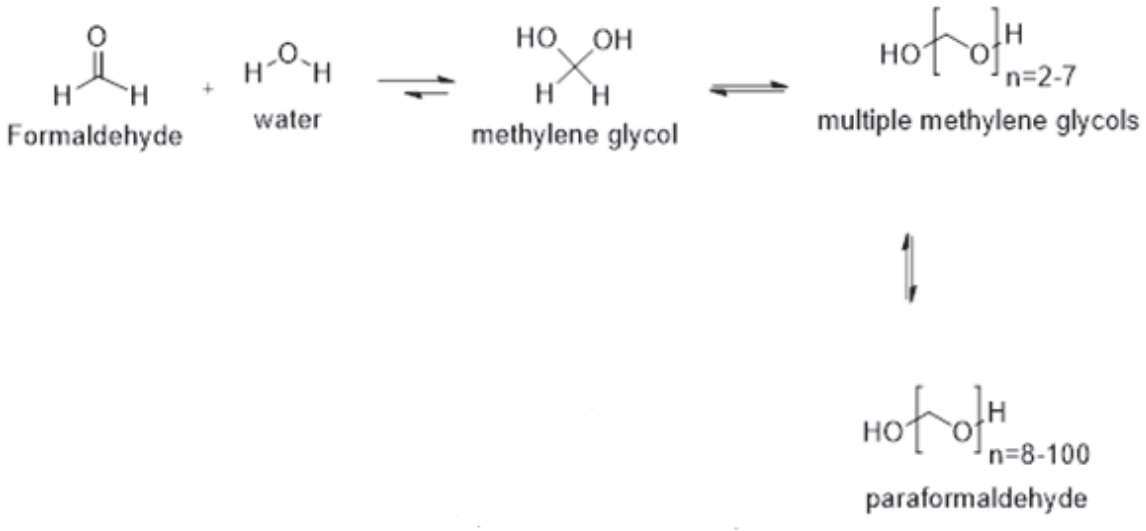

Figure 1-1: Chemical equilibria for formaldehyde in aqueous solutions.

Adapted from (Boyer, et al., 2013).

Due to the reactive nature of formaldehyde (and its associated transformation products), physical and chemical properties can be difficult to isolate, resulting in uncertainty as to how the chemical will behave under various conditions. Thus, it is most appropriate to present the physical and chemical properties of formaldehyde in the gaseous phase as well as in the hydrated forms. The various physical and chemical properties for these compounds as well as formalin (i.e., aqueous formaldehyde in the presence of a stabilizer) are summarized in Table 1-1. These properties are considered best available estimates. Because the chemical substances often exist in a mixture at varying concentrations, these properties can vary based on the equilibration with other chemical substances present.

Table 1-1: Physical/Chemical Properties of Formaldehyde and Associated Chemical Species

Chemical Name	**Formaldehyde**	**Methylene glycol**	**Formalin**	**Paraformaldehyde**
Molecular formula	CH_2O	$CH_2(OH)_2$	$CH_2O + HO(CH_2O)_nH + H_2O$ (n=2 – 7)	$HO(CH_2O)_nH$ (n = 8 – 100)
CAS RN	50-00-0	463-57-0	Not Applicable	30525-89-4
Molecular weight (g/mol)	30.026	48.02	Varies	$18 + (30.03)_n$ [1] (n = 8 – 100)
Physical form	Colorless gas	Colorless liquid	Colorless liquid	White crystalline solid

Chemical Name	Formaldehyde	Methylene glycol	Formalin	Paraformaldehyde
Melting point (ºC)	-92.0 to -118.3	-43.8	-15	120 to 170
Boiling point (ºC)	-19.5	131.6	96	None identified
Density (g/cm^3)	0.815 at 20°C	1.2	1.083	1.46 at 15°C
Vapor pressure (mm Hg)	3890 at 25°C	3.11 at 25°C	1.3 at 20°C	1.45 at 25°C
Vapor density	1.067 (air =1)	None Identified	None Identified	1.03 (air = 1)
Water solubility	400-550 g/L	Miscible	Miscible	Insoluble
Octanol/water partition coefficient (K_{ow})	0.35 (Log K_{ow})	-0.79 (Log K_{ow})	None Identified	Not Applicable
Henry's Law constant (atm/m^3·mol)	3.37×10^{-7} at 25°C	1.65×10^{-7} at 25°C	None Identified	Not Applicable
Flash point (ºC)	N/A	None Identified	50 to 85	71.1
Autoflammability (ºC)	300	None Identified	None Identified	Not Applicable
Viscosity (Pa S)	1.4×10^{-4}	None Identified	None Identified	None Identified
Refractive index	1.3746	None Identified	1.3616	Not Applicable

1. n denotes the number of oligomers (CH_2O) that are part of paraformaldehyde (n=8-100).

1.4 Environmental Fate

EPA considered all reasonably available information identified by the Agency through its systematic review process under TSCA and submissions under FIFRA to characterize the environmental fate and transport of formaldehyde. These data are available and discussed in greater detail in the joint chemistry, fate, and transport characterization assessment created by both OPP and OPPT (U.S. EPA, 2024b). The transport and partitioning of formaldehyde is presented in Figure 1-2 and a summary of the fate properties are presented in Table 1-2. These data were used to determine exposure and risk to human health and nontarget organisms from formaldehyde and paraformaldehyde uses. During the evaluation of formaldehyde, EPA considered both measured and estimated data/information presented in Table 1-2, as applicable.

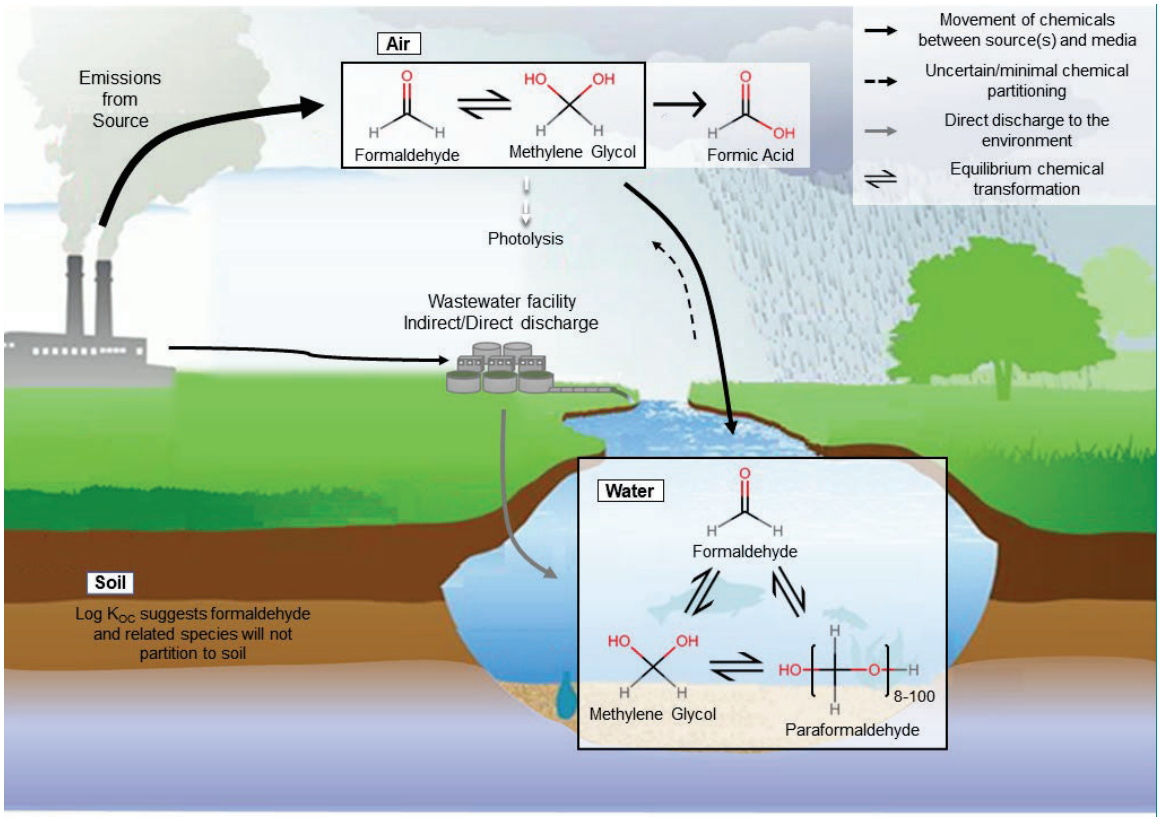

Figure 1-2: Transport and Partitioning of Formaldehyde and its Abiotic Transformations in the Environment[a]

[a] The diagram depicts the distribution (grey arrows), transport and partitioning (black arrows) of formaldehyde in the environment. The width of the arrow is a qualitative indication of the likelihood that the indicated partitioning will occur (i.e., wider arrows indicate more likely partitioning).

Table 1-2: Environmental Fate Properties of Formaldehyde

Property or Endpoint	Value[A B]	Reference(s)
Indirect photodegradation	45 hours (based on ¯OH reaction rate constant 8.5E−12 cm^3/molecule-second at 25 °C) 57 days (based on nitrate radicals reaction rate constant 5.6E−16 cm^3/molecule-second at 25 °C)	NLM, 2019
Direct photodegradation	$t_{1/2}$ = 1.4 to 4 hours in sunlight	NLM, 2019
Hydrolysis half-life	Not expected; however, in an aqueous environment formaldehyde will be fully hydrated to methylene glycol	OECD, 2002
Aerobic Aquatic biodegradation	In water from stagnant lake, formaldehyde completely decomposed in ~30 hours under aerobic conditions, 20 °C	NLM, 2019
	In surface water, estimated half-lives of 24 to 168 hours (1–7 days)	USEPA, 2008

Property or Endpoint	Value[A B]	Reference(s)
Anaerobic Aquatic biodegradation	In water from stagnant lake, formaldehyde completely decomposed in ~48 hours under anaerobic conditions, 20 °C	NLM, 2019
Aerobic Soil biodegradation	In soil, estimated half-lives of 24 to 168 hours (1–7 days)	Howard et al., 1991
Bioconcentration factor (BCF)	Based on log K_{OW} <3, potential for bioconcentration in aquatic organisms is considered low	NLM, 2019 USEPA, 2012c
	Experiments performed on a variety of fish and shrimp show no bioconcentration of formaldehyde	Canada, 2001
Bioaccumulation factor (BAF)	None identified	NA
Organic carbon: water partition coefficient (log K_{OC})	1.57 (K_{OC} of 37 L/kg) Formaldehyde not expected to sorb to suspended solids and sediment	USEPA, 2008
Wastewater treatment	Removal/secondary treatment: 57 to 99% removal percentages based upon data from a semi-continuous sewage and continuous activated sludge biological treatment simulator	Howard et al., 1991
	94% total removal (93% by biodegradation)[B]	USEPA, 2012c
[A] Measured unless otherwise noted. [B] Information estimated using EPISuite™		

Under direct sunlight, formaldehyde vapor undergoes photolysis with a half-life up to 4 hours (NLM, 2019). In the absence of sunlight, formaldehyde vapor can persist with a half-life value up to 114 days, assuming 12 hours of daylight per day (NLM, 2019). In addition, formaldehyde vapor may hydrate in moist air to form methylene glycol and eventually formic acid (NLM, 2019). In indoor environments, the persistence of formaldehyde is driven by dissipation (e.g., mechanical removal via ventilation systems) and adsorption to household materials (e.g., cushions and permeable materials).

In the presence of water, formaldehyde transforms rapidly to methylene glycol, with a 50% conversion rate in 65 milliseconds and a 90% conversion rate in 215 milliseconds at 298K (25°C, based on rate constants) (Winkelman, 2002). In the absence of methanol, methylene glycol then forms oligomers [$(CH_2O)_n$] in the presence of low concentrations of formaldehyde and polymerizes to paraformaldehyde when concentrated solutions of formaldehyde are present. Equilibria are attained between monomeric formaldehyde and oligomers within minutes, whereas the formation and polymerization of paraformaldehyde takes hours to days (SCCS EC, 2012). Paraformaldehyde is insoluble in water; therefore, any paraformaldehyde that is present in water or has formed due to polymerization of formaldehyde will precipitate and no longer be present in the water column.

Formaldehyde and methylene glycol are slightly volatile from water, given their Henry's Law Constants of 3.37×10^{-7} atm-m^3/mol (NLM, 2019) and 1.65×10^{-7} atm-m^3/mol (Meylan and Howard, 1991) at 25 °C, respectively.

In aerobic soil, half-lives have been estimated at between 1 and 7 days based on aqueous aerobic biodegradation (Howard et al., 1991). Rapid hydration of formaldehyde to methylene glycol in moist soil is expected. Based on empirical Henry's Law Constants of 3.37×10^{-7} atm-m^3/mol (NLM, 2019) and 1.65×10^{-7} atm-m^3/mol (Meylan and Howard, 1991) at 25 °C for formaldehyde and methylene glycol, respectively, both compounds will volatilize slowly from moist soil. In dry soil, both formaldehyde and methylene glycol are expected to volatilize more rapidly, based on their vapor pressures (3890 and 3.11 mmHg at 25 °C, respectively). Formaldehyde and methylene glycol are considered mobile and highly mobile, respectively (K_{oc} of 37 and ≤1 L/kg_{oc}, respectively) (U.S. EPA, 2008 and Appendix A).

Formaldehyde and methylene glycol have low potential to bioconcentrate, based on a log K_{OW} of 0.35 (NLM, 2019) and an estimated log K_{OW} of -0.79 (), respectively.

Based on data from a semi-continuous sewage and continuous activated sludge biological treatment simulator, a removal efficiency of formaldehyde between 57% to 99% has been reported (Howard et al., 1991). Estimates from EPI Suite™ indicate that 93% and 92% of formaldehyde and methylene glycol, respectively, may be removed through biodegradation (U.S. EPA, 2012c and Appendix A).

Key sources of uncertainty for this assessment are related to formaldehyde's equilibrium in various media. In aqueous media, formaldehyde rapidly forms methylene glycol and formaldehyde oligomers, and their transport is difficult to characterize based on available data. Similarly, the natural formation and abundance of formaldehyde may suggest that the chemical substance persists for longer than expected given its reactivity. In cases where there is little fate and transport data, OPP relied on physical and chemical properties to describe the expected fate and transport of the respective chemical.

1.5 Pesticidal Use Patterns

As of January 5, 2024, there are three Section 3 registered products that contain formaldehyde and one Section 3 product that contains paraformaldehyde. One of the formaldehyde products (EPA Reg. No. 8743-16) is a Manufacturing Use Product (MUP) that is used to formulate end use products. The other two products (EPA Reg. No. 8743-17 and EPA Reg. No. 10707-43) are end use products that are formulated as liquid concentrates. The paraformaldehyde product (EPA Reg. No. 4972-43) is an end use product that is formulated as a solid. There is also a special local needs (SLN) registration (WA20003) for the use of EPA Reg No. 8743-17 in Washington State to control nematodes, insects such as greater bulb flies, mites, and certain plant pathogenic fungi on bulbs of daffodil and bulbous iris. A

summary of the registered uses of formaldehyde is included in Table 1-3, and a summary of the registered uses of paraformaldehyde is included in Table 1-4.

Table 1-3: Summary of Registered Pesticidal Uses of Formaldehyde

Use description from Label	Application Method	Maximum Application Rate[1]	EPA Reg No.
Agricultural Premises and Equipment			
Citrus Packing House (Fruit removed)[2]	Fogging Spray	5,500 ppm a.i. (in air)	8743-17
Rooms, feed trucks, railway cars	Pan Evaporation with Potassium Permanganate	6,800 ppm a.i. (in air)	8743-17
Hatching eggs (nonfood)	Pan Evaporation	0.010 lb a.i. /1000 eggs	8743-17
Mushroom House Disinfection[2] (Small house up to 37 ft x 48 ft x 15 ft high)	Steam Injection	6,600 ppm a.i. (in air)	8743-17
Mushroom House Disinfection[2] (Regular house up to 37 ft x 60 ft x 15 ft)	Steam Injection	6,600 ppm a.i. (in air)	8743-17
Mushroom House Disinfection[2] (Large House up to 37 ft x 80 ft x 15 ft)	Steam Injection	7,900 ppm a.i. (in air)	8743-17
Mushroom House Tools and Equipment[2]	Dip	3,700 ppm a.i. (in water)	8743-17
Poultry and swine confinement buildings[2]	Fixed Sprinkler or Spray Sled	21,000 ppm a.i. (in air)	8743-17
Industrial processes and water systems			
Injection water immediately ahead of de-oiling equipment	Closed Loading	5,000 ppm a.i.	10707-43
Materials Preservative (In-can)			
Air fresheners, automotive products, waxes and automotive polishes, car washes[3]	Open Pour Liquid	370 ppm a.i.	8743-17
Polishes for floors and furniture, shoe polishes, carpet cleaners and spot removers[3]	Open Pour Liquid	370 ppm a.i.	8743-17
Fabric softeners, spray starch, hand and automatic dish detergents, liquid laundry detergents[3]	Open Pour Liquid	370 ppm a.i.	8743-17
Hand cleaners, moist sponges and towelettes, household cleaners, industrial cleaners, liquid hand soaps, oil and grease removers, waterless hand cleaners, raw materials for cleaning products, surfactants and silicone emulsions[3]	Open Pour Liquid	370 ppm a.i.	8743-17
Special Local Need (Washington State) Bulb Dip			
Dip for daffodil and bulbous iris bulbs, Spent dip-tank treatment of fields	Bulb Dip, Field treatment	0.5% a.i. in water dip; field application up to 21,000 gal/acre/year [4]	EPA SLN No. WA-200003 (EPA Reg. 8743-17)

1. Application rates are rounded to two significant figures.
2. Animals, commodity, bedding, food, feed and portable equipment are removed. As a result, the use sites are identified as nonfood.

3. May not be used in products coming in direct contact with food and/or drinking water.
4. Product is mixed at a rate of 2 fluid ounces per gallon to yield a solution containing 0.5% formaldehyde. The bulbs are dipped and soaked for three to four hours in a tank that is maintained at a temperature of 110 to 111°F. Spent dip-tank treatment water may be applied to bulb fields at a concentration not to exceed 1.5% of the Formaldehyde Solution 37 (0.5% formaldehyde) and at a rate of no more than 21,000 gallons of dip-tank solutions per acre per year. Only to be applied to bulb fields when rainfall is not expected for at least 24 hours after application.

Table 1-4: Summary of Registered Pesticidal Uses of Paraformaldehyde

Use	Application Method	Maximum Application Rate	EPA Reg. No.
Agricultural Premises and Equipment			
Leaf-cutting Bee Nesting Material of Bee Cells	Fumigation	5 grams ai/ft^3	4972-43
Commercial/Institutional/Industrial Premises and Equipment			
Microbiological laboratory settings, including human and animal research facilities and areas, animal isolation rooms, animal cages, necropsy suites, ancillary equipment, and biological safety cabinet	Fumigation	0.6 gram a.i./ft^3	4972-43
Residential and Public Access Premises and Equipment			
When closing home for vacation or season[1]	Fumigation	0.23 lb a.i. /700 ft^3	4972-43
Bedding in sealed closet space[2]	Fumigation	0.17 lb a.i. /100 ft^3	4972-43
Clothing and linen storage bins, cupboards, bathroom and kitchen cabinets, dresser drawers, trunks, suitcases, lockers, trailers[3].	Fumigation	0.23 lb a.i. /700 ft^3	4972-43

1. The application rate is based on using one 4-ounce pouch per 700 ft^3.-
2. The application rate is based on using one 3-ounce pouch per 100 ft^3.
3. The label states: "Hang cloth bag in closet or lay on shelf or in drawer. Contents of this bag with treat up 700 cu. ft."

Based on the RED (U.S. EPA, 2008), EPA determined that formaldehyde and paraformaldehyde would be eligible for reregistration as long as certain risk mitigation measures were adopted and certain label amendments were made. The mitigation measures included addition of environmental hazard statements, rate reductions, and various application restrictions to reduce exposures in residential and occupational settings. While many of the mitigation measures were implemented, either through label amendments or voluntary use/product cancellations, Table 1-5 summarizes the modifications that have not yet been adopted. Since these mitigation measures have not been adopted, these uses are still registered, included in Table 1-3 and Table 1-4, and assessed in this document.

Table 1-5: Mitigation Measures Identified in the RED but Not Adopted on Labels

Description	Specified Label Language	Implementation Status
End Use Products Intended for Laundry Detergent	Product application rate to be reduced to 40 ppm[a]	Not implemented – the application rate is 1000 ppm product.
End Use Products Intended for General Purpose Cleaner	Product application rate to be reduced to 72 ppm	Not implemented - the application rate is 1000 ppm product.

Description	Specified Label Language	Implementation Status
End Use Products Intended for Occupational use	In order to reduce potential occupational handler exposures, the following mitigation is specified: • For industrial uses of formaldehyde close systems with dry couplers (or equivalent) are required • All fumigated uses must be done in such a way that the operator is outside the structure undergoing fumigation when applying the fog.	Not implemented - the label allows for open pouring for material preservation. Not implemented - pan fumigation using potassium permangate is still on the label.
End-Use Products for Vacation Homes	ALL labels to limit the use to an UNOCCUPIED structure that can be thoroughly ventilated six (6) hours prior to re-occupancy.	Not implemented - the product allows use in closets of occupied homes.

*Source - Table 9 Labeling Changes Summary Table, Formaldehyde/Paraformaldehyde RED (U.S. EPA, 2008).
[a]While this use is eligible for reregistration at a reduced rate of 40 ppm, the RED stated a use termination was pending for the affected product. This use is still present on labels and so was included in this assessment.

1.6 Label Recommendations to Clarify Existing Uses

On the paraformaldehyde label (EPA Reg. No. 4972-43), it is not clear if the statement "Use only in an unoccupied structure that can be ventilated (6) hours prior to re-occupancy" applies to all of the use sites listed under the heading of "Household Mildewcide" or if it applies only "when closing home for vacation or season". It is also not clear if the use sites of "clothing and linen storage bins, cupboards, bathrooms and kitchen cabinets" are in unoccupied structures or if they are in occupied structures. For the purposes of this risk assessment, it is assumed that paraformaldehyde could be used in closets of occupied homes; however, it is recommended that the label be clarified to allow this use only in unoccupied homes.

On the formaldehyde label (EPA Reg. No. 4972-43) under the heading of "In Container Preservative" air freshener is listed. It is requested that the type of air freshener (i.e., solid, liquid plug-in or aerosol spray) be clarified because the formulation type has an impact on the potential for inhalation exposure and risk. For example, an aerosol spray could generate formaldehyde concentrations of concern depending on how it is applied (e.g., size of room that can be treated and duration of spray time).

The formaldehyde label (EPA Reg. No. 4972-43) lists a use rate range of 0.1 to 1000 ppm product (0.037 to 370 ppm a.i.) and a list of uses under the heading of "In-Container Preservative". It is recommended that the uses be grouped into categories that have narrower use rate ranges.

With regards to the SLN registration in Washington State to control pests on bulbs of daffodil and bulbous iris and the subsequent application of spent dip-tank water to the ground, there is a high degree of uncertainty regarding this use pattern based on the information provided on the label. The following information would be helpful in reducing uncertainties with how the product is used and the

potential for exposure/risk: the maximum and typical batch size, in gallons, of dip-tank water that can be used at one time; the minimum acreage that can be treated with dip-tank water; the maximum number of dip-tank water applications that can occur per year; when applications typically occur; and any minimum ventilation requirements for dip tanks during bulb applications.

1.7 Formaldehyde Pesticidal Uses that are Exempt from FIFRA

Formaldehyde is used in embalming fluids, products to preserve animals or animal organ specimens and in body fluids for laboratory analysis. EPA's regulation at 40 CFR 152.25(c) exempts from all FIFRA requirements certain "preservatives for biological specimens", explaining that "[t]he pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified" (40 CFR 152.25). The following preservatives for biological specimens are listed under this exemption:

(1) Embalming fluids.

(2) Products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning.

(3) Products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis.

Pesticides that meet these criteria are exempt from all provisions of FIFRA, including registration review, and thus these products and uses are not included in this registration review assessment.

1.8 Other Sources of Formaldehyde

Formaldehyde is a chemical with numerous industrial and commercial uses. Annual U.S. industrial production in the early to mid-2000s averaged nearly 5 million tons. In addition to intentional industrial production, formaldehyde is produced from human activities and from natural sources through the breakdown of hydrocarbons and other organic precursors (NTP, 2010).

As previously discussed, formaldehyde is concurrently undergoing review by OPPT, which has authority over a wide variety of industrial, commercial and consumer products. Sources of formaldehyde from TSCA conditions of use (COUs), include textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants. OPPT and OPP have worked jointly on the review of fate, transport, and toxicity data on formaldehyde, but have prepared separate risk assessments in accordance with their office's regulatory statutes. As such this assessment only assesses risk associated with registered pesticide uses, and OPPT has published separate risk assessment documents to address their COUs (U.S. EPA, 2024d).

Formaldehyde is also regulated by EPA under the Resource Conservation and Recovery Act as a byproduct of hazardous waste material, the Clean Water Act as a hazardous substance in surface water, and the Clean Air Act as a hazardous air pollutant[2]. In addition to EPA regulated uses, formaldehyde is regulated by the U.S. Food and Drug Administration (FDA) as a material preservative in cosmetic and personal care products, as an animal drug to treat bacterial and fungal infections in fisheries and hatcheries, and as a food additive.

Other sources of formaldehyde include industrial and consumer chemicals that degrade to or release formaldehyde, including products that incorporate EPA-registered material preservative pesticides. A comprehensive listing of these EPA-registered pesticides is included in Table 1-6.

Table 1-6: Material Preservative Pesticides that Release or Degrade to Formaldehyde

Chemical Name and Registration Review Case Number	PC Code(s)	Number of End Use Products
Azadioxabicyclooctane Case: 3023	107001 107002 107003	1
Bronopol Case: 2770	216400	60
Glycine, N-(hydroxymethyl)-monosodium salt (SHMG) Case: 5030	128972	1
HHT (Grotan) Case: 3074	083301	16
Hydroxymethydimethylhydantoins Case: 5020	115501 115502	18
Methyloxazolidines (DMO) Case: 3095	114801	3
Tris ($HOCH_2$-) Nitro-methane (Tris-Nitro) Case: 3149	083902	5
Bioban P-1487 Case: 3028	100801 100802	3
Morpholine, 4,4'-methylene di- (Contram ST-1) Case: N/A	054702	1
Oxazolidine,3,3'-methylene bis [5-methyl- (Stabicide 71) Case: N/A	114804	1

Finally, formaldehyde can also be generated through natural processes, commonly referred to as biogenic sources. Formaldehyde is a naturally occurring aldehyde produced during combustion, decomposition of organic matter, and is emitted from trees, plants, and soil microbes. It is also generated in the human body as a normal part of metabolism (IPCS, 2002).

[2] Laws and Regulations Concerning Formaldehyde | US EPA

The role of these other sources of formaldehyde in relation to the contribution of OPP's registered pesticide uses to indoor and outdoor air exposure to formaldehyde is further discussed in Section 2.8, Aggregate Exposure/Risk Characterization.

1.9 Usage Information

There is very little information regarding the pesticidal usage of formaldehyde. According to the Kline report (Kline, 2021), formaldehyde is not among the frequently used biocides in the household industrial and institutional (HII) cleaning market or in the oil and gas market. The Kline report further suggests that users are transitioning away from formaldehyde releasing chemistries due to awareness of health and safety concerns for workers.

According to the FracFocus registry (www.fracfocus.org), 4,000, 4,300, 7,600, and 3,700 pounds of formaldehyde were used as a biocide in oil and gas for the years 2019, 2020, 2021 and 2022, respectively.

2 HUMAN HEALTH RISK ASSESSMENT

2.1 Data Deficiencies

2.1.1 Occupational and Residential Exposure Data Deficiencies

As discussed in the Formaldehyde and Paraformaldehyde FWP (U.S. EPA, 2017) in accordance with 40 CFR subpart 158W (Occupational and Residential Data Requirements for Antimicrobial Pesticides), an indoor inhalation exposure study (GLN 875.1400) or an indoor inhalation post application chamber emissions study (GLN 875.2500) along with exposure modeling was recommended to be required for the following formaldehyde exposure scenarios and uses:

- Open pour application (evaporative fumigation, catalyzed fumigation, oil production)
- Trigger spray and wipe cleaning (household cleaner preservation)
- Laundry detergent (laundry detergent preservation)
- Spray, mop, and sponge application (hard surface disinfection)

Additionally, an indoor inhalation post application small chamber emissions study (GLN 875.1400) was recommended to be required to assess the post application inhalation exposures that were associated with the paraformaldehyde closet use.

Although GDCIs were issued for these studies (formaldehyde: GDCI-043001-1694 and paraformaldehyde: GDCI-043002-1696), they were never addressed by submission of indoor exposure data, submission of small chamber emission studies or granted waiver requests. Because the product that was applied using spray, mop or sponge for hard surface disinfection was cancelled, the exposure

data for this scenario are no longer needed. The remaining data requirements remain unsatisfied. In the absence of data, OPP made conservative assumptions for the purposes of this registration review case.

2.1.2 Toxicology Data Deficiencies

As discussed in the Formaldehyde and Paraformaldehyde FWP (U.S. EPA, 2017) in accordance with 40 CFR subpart 158W (Toxicology Data Requirements for Antimicrobial Pesticides), a 90-day oral toxicity study (GLN 870.3100), an immunotoxicity study (GLN 870.7800), acute and subchronic neurotoxicity screening batteries (GLN 870.6200), a prenatal developmental toxicity study (GLN 870.3700), and a reproductive toxicity study (GLN 870.3800) are required for all antimicrobial use patterns that result in oral exposures. These requirements are considered data gaps in the formaldehyde and paraformaldehyde databases. However, the primary route of expected exposure for most pesticidal uses of formaldehyde is through inhalation, and to a lesser extent, dermal exposure. Inhalation studies are available that evaluated immunotoxicological, neurotoxicological, developmental and reproductive effects of formaldehyde via this exposure pathway. Additionally, oral exposure studies for formaldehyde in the open literature were reviewed (Til et al, 1988, 1989) and found to be acceptable for risk assessment purposes. Therefore, these data are not required for the pesticidal use patterns at this time.

As discussed below, OPP collaborated with OPPT on the evaluation of hazard data for formaldehyde and leveraged elements of the standard processes of both OPP and OPPT in the analysis. The toxicological database to support the human health risk assessment for formaldehyde is considered adequate for the purpose of this registration review case.

2.2 Anticipated Exposure Pathways and Residues of Concern

Exposures from the registered pesticide uses of formaldehyde can occur via the dermal and inhalation routes. As discussed in Section 1.3, formaldehyde is volatile and is expected to be released as a gas from consumer and commercial products that contain formaldehyde as a material preservative. Residential, bystander, and occupational handler exposures are anticipated from these uses. Formaldehyde is also used as a fumigant in various agricultural, commercial, and industrial settings where exposures to the gaseous form may occur. Occupational handler, post-application, and bystander exposures are anticipated from these uses. There is also the potential for occupational handler and bystander inhalation exposures from use as a dip-tank treatment for ornamental bulbs. In addition, paraformaldehyde is a polymeric form of formaldehyde designed to release gaseous formaldehyde when used as a fumigant in various agricultural, commercial, industrial, and as a mildewcide in residential settings. Occupational handler and post-application exposure, as well as residential handler and bystander exposure, to formaldehyde vapors are expected from these uses.

Inhalation toxicity studies are based on the volatile gaseous form of formaldehyde, matching the potential exposure which would be present in air. Indoor and outdoor inhalation risk was assessed assuming the chemical properties of liquid formaldehyde (represented as formalin in Table 1-1 above) for exposure modeling and was compared to relevant inhalation endpoints for formaldehyde. Dermal exposures are expected from use of consumer and commercial products that contain formaldehyde as a material preservative and from various occupational handler uses that may involve handling the liquid formaldehyde product. Dermal toxicity data used for establishing endpoints are conducted with formaldehyde (with or without methanol) and are representative of the anticipated actual product exposure, so therefore would be protective or capture the toxicity of methylene glycol, oligomers, and paraformaldehyde (see Section 2.3 and U.S. EPA 2024c). Dermal exposure was assessed as formaldehyde in liquid form and compared to dermal toxicity endpoints associated with a similar exposure scenario.

Oral dietary, oral non-dietary (i.e., incidental oral exposures) and drinking water exposures are assessed qualitatively due to the chemical properties of formaldehyde and the characteristics of use as discussed in Sections 2.5 and 2.6. While oral exposures are assessed qualitatively, PODs for acute, intermediate, and chronic exposures are established for completeness.

2.3 Hazard Characterization and Dose-Response Assessment

2.3.1 Summary of Toxicological Effects

Formaldehyde exposure may occur through inhalation, dermal or oral exposure. Inhaled formaldehyde has been associated with several types of cancer in people, including nasopharyngeal cancer and myeloid leukemia. Formaldehyde is also associated with a range of respiratory and non-respiratory health effects in people, including reduced pulmonary function, increased asthma prevalence, reduced asthma control, allergy-related conditions, sensory irritation, male and female reproductive toxicity, and developmental effects. Formaldehyde is a dermal sensitizer, meaning that skin contact can result in an allergic response. Evidence in animals indicates that oral exposure to formaldehyde may result in damage to the gastrointestinal tract.

OPP and OPPT collaborated to develop a joint human health hazard assessment for formaldehyde (U.S. EPA, 2024c). This joint assessment evaluated available human health hazard and dose-response information for formaldehyde and identified hazard values to support risk assessments in both offices. Below is a summary of that review and the PODs selected for human health risk assessment. The toxicological profile for formaldehyde and paraformaldehyde is further discussed in Appendix B.

For cancer and non-cancer hazards associated with chronic inhalation exposures, OPP and OPPT relied on the analysis already completed in the draft Integrated Risk Information System (IRIS) assessment on

formaldehyde inhalation and recently peer reviewed by the National Academy of Science (NAS) (U.S. EPA, 2022). The systematic review literature searches, data quality review, evidence integration, dose-response analyses, and peer review performed in support of the draft IRIS assessment reflect the best available science on formaldehyde hazards from chronic inhalation exposures and are consistent with the needs of both OPP and OPPT. Numerous health effects from inhalation of formaldehyde were assessed in the IRIS assessment including sensory irritation, reduced pulmonary function, immune system effects, respiratory tract pathology, nervous system effects, reproductive and developmental toxicity, and cancer [including cancers of the upper respiratory tract (i.e., nasopharyngeal cancer, sinonasal cancer, cancers of the oropharynx/hypopharynx, and laryngeal cancer) and of the lymphohematopoietic system (i.e., Hodgkin lymphoma, multiple myeloma, myeloid leukemia, and lymphatic leukemia)]. The chronic reference concentration (RfC) derived by IRIS was based on multiple studies of respiratory system effects (pulmonary function, allergy-related conditions and asthma control in people) and are protective of other potential adverse effects. Discussion of the IRIS chronic inhalation cancer classification is provided in Section 2.3.3. below. Additional information is available in the draft IRIS assessment (U.S. EPA, 2022).

To identify additional available hazard and dose-response information for acute inhalation, dermal, and oral formaldehyde exposures, EPA used a fit-for-purpose systematic review protocol, integrating the needs of both OPP and OPPT. Details of the fit-for-purpose systematic review protocol used in this assessment are described in the Systematic Review Protocol for the Draft Risk Evaluation for Formaldehyde (U.S. EPA, 2023). For acute inhalation exposures, EPA identified sensory irritation as the most sensitive endpoint and included four controlled human exposure studies as part of the weight of evidence (WOE) for POD determination. For dermal exposure, skin sensitization was determined to be the most sensitive effect and was based on consideration of human, animal and *in vitro* data. For oral exposure, gastrointestinal effects were found to be the most sensitive endpoint evaluated based on data available from studies in animals. Consistent with EPA's obligations under its Human Studies Rule, specifically 40 CFR subpart P, EPA reviewed 4 human studies involving inhalation exposure (Kulle et al., 1987; Andersen and Mølhave, 1983; Lang et al., 2008 and Mueller et al., 2013) and 2 studies involving dermal exposure (Flyholm et al., 1997 and Fischer et al., 1995) and determined they were scientifically valid and ethically conducted. EPA consulted with the Human Study Review Board on these study reviews in October 2022, May 2023 and October 2023. Additional information on the review of acute inhalation, dermal, and oral formaldehyde toxicity data is available in the Human Health Hazard Assessment (U.S. EPA, 2024c).

Paraformaldehyde is a polymeric form of formaldehyde and is designed to release formaldehyde. Thus, exposure from the use of paraformaldehyde is to formaldehyde, and studies that examine formaldehyde toxicity can also be applied to paraformaldehyde.

2.3.2 Consideration of Toxicity to Children

The Food Quality Protection Act (FQPA) considerations do not apply to registered pesticide uses of formaldehyde. There are no tolerances established for formaldehyde. Formaldehyde is not intended for direct or indirect food uses and there are no food-use registrations for this chemical; however, there are potential drinking water exposures based on the SLN bulb treatment use which were assessed qualitatively, and risk could not be precluded.

2.3.3 Classification of Carcinogenic Potential

For inhalation exposures, OPP and OPPT relied on the inhalation unit risk (IUR) derived in the draft IRIS assessment on formaldehyde and peer reviewed by the NAS. IRIS concluded that formaldehyde is carcinogenic to humans by the inhalation route of exposure based on several lines of evidence. Specifically, IRIS concluded that "evidence demonstrates that formaldehyde inhalation causes nasopharyngeal cancer, sinonasal cancer and myeloid leukemia in exposed humans, given appropriate exposure circumstances." Based on available human and animal data, the draft IRIS assessment evaluated the WOE and performed dose-response analysis for a range of cancer effects to derive an IUR. IRIS derived IUR estimates based on nasopharyngeal cancer in humans and squamous cell carcinoma in the respiratory tract in animals (U.S. EPA, 2022). IRIS also explored derivation of the IUR based on myeloid leukemia in humans. Although there is strong evidence that formaldehyde exposure causes myeloid leukemia in humans, uncertainties in the available dose-response data reduced IRIS's confidence in the quantitative IUR estimate derived for myeloid leukemia. IRIS therefore identified the IUR derived based on nasopharyngeal cancer in humans as the preferred IUR for quantitatively evaluating cancer risk from inhaled formaldehyde.

EPA has not made a determination regarding the carcinogenic potential of formaldehyde through dermal or oral exposure. However, there is little direct evidence of the carcinogenicity of formaldehyde following oral exposure and no direct evidence of the carcinogenicity of formaldehyde following dermal exposure. Additional information is available in the Human Health Hazard Assessment (U.S. EPA, 2024c).

2.3.4 Toxicity Endpoint and Point of Departure Selections

Toxicity endpoints and PODs for dietary, residential, and occupational exposure scenarios for pesticidal uses of formaldehyde are summarized below and in Table 2-3.

Subchronic oral (incidental oral, short-term (1-30 days)/intermediate-term (1-6 months): OPP and OPPT selected a subchronic oral POD of 25 mg/kg-day based on the no observed adverse effect level (NOAEL) for gastrointestinal histopathology in rats reported in a 28-day drinking water study (Til et al,

1988). This POD is appropriate for these exposure durations and is based on dose-response information in a high-quality study with a relevant exposure duration.

Consistent with EPA guidance on deriving an oral human equivalent dose (HED) for portal-of-entry effects (U.S. EPA, 2011), EPA applied a dosimetric adjustment factor (DAF) to convert the POD identified in rats to an HED using body weight ¾ allometric scaling. Specifically, EPA used the following equation:

HED (mg/kg-day) = POD (mg/kg-day) x DAF

where DAF = 0.24 (using bodyweight ¾ scaling from rats to humans reported in Appendix B of U.S. EPA, 2011). This results in a subchronic HED of 6 mg/kg-day. An uncertainty factor of 30x was applied to this POD (3x interspecies extrapolation, 10x intraspecies variation). The interspecies uncertainty factor is reduced to 3x based on the application of the DAF which accounts for the pharmacokinetic differences between rats and humans (U.S. EPA, 2011).

Chronic oral: OPP and OPPT selected a chronic POD of 15 mg/kg-day based on the NOAEL for gastrointestinal histopathology in rats following 2 years of formaldehyde exposure through drinking water (Civo Inst.,1986; Til et al., 1989). The selected POD is appropriate for the anticipated exposure scenarios and is based on a WOE from several drinking water studies.

Similar to the subchronic oral POD above, EPA applied a DAF to convert the POD identified in rats to an HED using bodyweight ¾ scaling, resulting in a chronic HED = 3.6 mg/kg-day. An uncertainty factor of 30 was applied to this POD (3x interspecies extrapolation, 10x intraspecies variation). As above, the interspecies uncertainty factor is reduced to 3x based on the use of the DAF.

Short-/Intermediate-/Long-term dermal: Dermal endpoints were based on skin sensitization and were established for both induction and elicitation. The use of induction threshold values is protective of persons not yet exposed to formaldehyde, while the use of elicitation threshold values is protective of those persons already sensitized to formaldehyde. Based on available data, EPA selected an elicitation threshold for skin sensitization of 10.5 µg/cm^2 based on benchmark dose (BMD) analyses (benchmark response (BMR) = 10%) conducted using data from Flyholm, et al. (1997 as supported by data from Fischer, et al.,1995). EPA selected an induction threshold for skin sensitization of 100 µg/cm^2 based on the local lymph node assay (LLNA) study in mice by Basketter, et al., (2003) and as supported by *in vitro* analyses conducted in Hirota, et al., (2015). The elicitation threshold was based on human studies; therefore, an uncertainty factor of 10x was applied (1x interspecies extrapolation, reduced due to use of human studies, 10x intraspecies variation). For the induction threshold, based on animal studies and *in vitro* data, an uncertainty factor of 100x was applied (10x interspecies extrapolation, 10x intraspecies variation).

Acute inhalation: EPA identified four controlled human exposure studies (Kulle, 1987; Andersen and Mølhave, 1983; Lang, 2008; Mueller, 2013) to inform selection of an acute peak exposure level. For each of the four key studies for acute POD derivation, EPA considered dose-response information to identify concentrations associated with sensory irritation over relatively short exposure durations. Based on the combined dose-response information for each of the four studies, EPA selected an acute POD based on the 0.5 ppm NOAEL identified for a 3-hour exposure in Kulle, et al., (1987, 1993). The selected POD is supported by the other three inhalation studies and is further described in the Human Health Hazard Assessment (U.S. EPA, 2024c). An uncertainty factor of 10x was applied based on intraspecies variation to this POD (1x interspecies extrapolation, reduced due to use of human studies, 10x intraspecies variation).

This acute POD focuses on defining peak exposure concentrations rather than average 8- or 24-hour exposure concentrations. The sensory irritation effects of formaldehyde appear to be more responsive to the exposure concentration than to exposure duration and may not adhere to Haber's law (Shusterman, 2006; HSRB, 2023). Based on review of the WOE analysis presented to the HSRB in May 2023, the HSRB did not recommend duration adjustments for the 8- or 24-hour PODs for the sensory endpoint, based on the lack of support for this adjustment in the 4 studies presented in the WOE and the existing literature. Therefore, this analysis focuses on identifying peak concentration levels that may result in sensory irritation, rather than deriving duration-adjusted acute PODs for 8- and 24-hour average concentrations.

Chronic Non-Cancer Inhalation: OPP and OPPT rely on the chronic inhalation hazard endpoints and PODs derived in the draft IRIS assessment on formaldehyde. Most commonly when deriving an RfC, IRIS selects a critical effect for the endpoint used to derive the POD. In the case of formaldehyde, IRIS chose the suite of impacts to the respiratory system (pulmonary function, allergy related conditions, and current asthma prevalence or degree of control). As described in the draft IRIS assessment, the overall RfC was "…chosen to reflect an estimate of continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." (pg .89, U.S. EPA, 2022). They estimated individual RfCs for each organ- or system-specific effect and applied the appropriate uncertainty factors to those individual values. This resulted in a range of 0.006-0.009 mg/m^3 for respiratory system related RfCs. IRIS selected the overall RfC of 0.007 mg/m^3 from the midpoint of the range (See Section 2.1.4 of the IRIS assessment). Uncertainty factors are embedded in the composite RfC value. Because OPP and OPPT estimate inhalation risk by calculating margins of exposure (MOE) with a POD that are compared to levels of concern derived from uncertainty factors (UFs) in order to identify any risks of concern, OPP and OPPT will rely on the conclusions in the draft IRIS assessment and use the POD cited in the IRIS Table 2-3, i.e., 0.017 ppm or 0.021 mg/m^3 from Krzyzanowski, et al., 1990 and its attendant total UF of 3. This is quantitatively equivalent for risk assessment purposes as using the IRIS RfC value of 0.007 mg/m^3.

Cancer (chronic inhalation): As discussed above, OPP and OPPT rely on the IUR derived in the draft IRIS assessment on formaldehyde. IRIS derived IUR estimates based on nasopharyngeal cancer in humans and squamous cell carcinoma in the respiratory tract in animals. Based on the mode of action analysis presented in the draft IRIS assessment, EPA concluded that a mutagenic mode of action contributes to cancer risk from inhaled formaldehyde. When a mutagenic mode of action contributes to cancer risk, EPA cancer guidelines (U.S. EPA, 2005) recommend that cancer risk estimates incorporate age-dependent adjustment factors (ADAFs) to account for the potential for greater susceptibility associated with early life exposure. The IUR for lifetime cancer risk is 1.1×10^{-5} per $\mu g/m^3$ (full lifetime exposure, includes ADAF adjustment). For less-than-lifetime exposure scenarios with a very large fraction of exposure during adulthood (e.g., occupational exposure), an ADAF adjustment may not be warranted, and the unadjusted unit risk estimate is 6.4×10^{-6} per $\mu g/m^3$.

Table 2-1 summarizes the selected exposure scenarios and relevant PODs and LOCs for formaldehyde exposure.

Table 2-1: Toxicological Doses and Endpoints for Formaldehyde Exposures

Exposure/ Scenario	Point of Departure (POD)	Uncertainty Factors (UF)	Level of Concern for the MOE	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days)/ Intermediate-Term (1- 6 months)	NOAEL = 25 mg/kg-day HED = 6 mg/kg-day	$UF_A = 3$ $UF_H = 10$	LOC = 30	MRID 52279003 (Til et al., 1988) LOAEL = 125 mg/kg-day based on clinical chemistry and gross and microscopic pathology of the GI tract (lesions, hyperkeratosis, moderate papillomatous hyperplasia, and slight focal atrophic gastritis in forestomach).
Dietary - Chronic	NOAEL = 15 mg/kg-day HED = 3.6 mg/kg-day	$UF_A = 3$ $UF_H = 10$ FQPA= 1	cRfD = cPAD = 0.12 mg/kg/day	MRID 52300501 (Til et al., 1989) LOAEL = 82 mg/kg-day based on gross and microscopic pathology of the GI tract consistent with chronic irritation, and increased incidences of renal papillary necrosis in males and females
Dermal All Durations	Induction: EC_3 = 0.4% (100 $\mu g/cm^2$)	$UF_A = 10$ $UF_H = 10$	LOC = 100 (Occupational and Residential)	MRID 52346401 (Basketter, et al.,2003) based on induction of dermal sensitization in mice treated with formaldehyde in 4:1 acetone: olive oil
	Elicitation: $BMDL_{10}$ = 0.035% (10.5 $\mu g/cm^2$)	$UF_A = 1$ $UF_H = 10$	LOC = 10 (Occupational and Residential)	MRID 52346002 (Flyvholm, et al., 1997); based on threshold for elicitation of dermal sensitization in people

Exposure/ Scenario	Point of Departure (POD)	Uncertainty Factors (UF)	Level of Concern for the MOE	Study and Toxicological Effects
Inhalation – Acute[A]	NOAEC = 0.50 ppm (0.62 mg/m^3)	UF_A = 1 UF_H = 10	LOC = 10 (Occupational and Residential)	MRID 52345905 (Kulle, et al., 1987). Mild to moderate eye irritation at the LOAEC of 1.0 ppm. Supported by Lang et al., 2008 (MRID 52345901), Mueller et al., 2013 (MRID 52345903), and Andersen and Mølhave, 1983 (MRID 52345902).
Inhalation Long-term (>6 months)	$BMCL_{10}$ = 0.017 ppm (0.021 mg/m^3)	UF_A = 1 UF_H = 3	LOC = 3 (Occupational and Residential)	$BMCL_{10}$ is based on the draft IRIS assessment (US EPA, 2022a).
Cancer (inhalation)	Inhalation Unit Risk per µg/m^3 = 6.4 x 10^{-6} (Adult exposure, does not include ADAF adjustments) = 1.1 x 10^{-5} (Full lifetime exposure, includes ADAF adjustments) (U.S. EPA, 2022a)			

A. Acute exposures are assessed as a 15-minute time-weighted average.

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEC = no observed adverse effect concentration. LOAEC = lowest observed adverse effect concentration. EC_3 = concentration required to induce a stimulation of 3 relative to the concurrent vehicle control. BMD/BMC = Benchmark dose/concentration. $BMDL_{10}$/$BMCL_{10}$ = Benchmark dose/concentration level associated with a 10% extra risk of adverse effect. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

Endocrine Disruptor Screening Program

Please see Appendix C for a discussion of the endocrine disruptor screening program as it relates to formaldehyde.

2.4 Dietary Exposure and Risk Assessment

2.4.1 FFDCA Considerations

As of April 2, 2024, the U.S. EPA has not established tolerances or exemptions from the requirement of a tolerance for formaldehyde or paraformaldehyde under the Federal Food, Drug and Cosmetic Act (FFDCA) Section 408.

Under FFDCA Section 409, the U.S. FDA has established clearances for indirect and secondary food additive uses of formaldehyde and paraformaldehyde in food contact substances. There is one food contact notification for paraformaldehyde. See Appendix D for clearance details.

2.4.2 Food Exposure Profile and Risk Assessment

Formaldehyde is registered for use in agricultural settings for fumigation of poultry and swine confinement buildings; citrus packing houses; and mushroom houses, tools and equipment within mushroom treatment areas (EPA Reg. No. 8743-17). However, the label contains instructions to remove all food commodities, feed, mushrooms, citrus fruits etc. prior to and during treatment. Thus, the uses with commodity removal are classified as nonfood according to the antimicrobials pesticide use site index (USI), (U.S. EPA, 2017). Formaldehyde is also registered for fumigation of hatching eggs (EPA Reg. No. 8743-17). Egg hatchery sanitization uses are classified as nonfood per the antimicrobial pesticides USI (U.S. EPA, 2017) because they are intended for fertilization and not consumption. In addition, while the eggs are the treated article and not removed prior to fumigation, the label indicates that sufficient time should be given to allow for complete evaporation of the formaldehyde. Dietary exposure from the SLN for the use of formaldehyde on ornamental bulbs is not expected, as the bulbs are not food items or listed as harvesting crops or commodities. Nonfood uses do not require dietary risk assessments.

Formaldehyde is also registered for use as an in-container preservative in automatic dish detergents, consumer household cleaners, and raw materials for cleaning products (EPA Reg. No. 8743-17). Given that dish detergents are used on dishes and food surfaces, OPP considers dish detergent preservatives an indirect dietary use. And, since the label does not contain nonfood language for household cleaning products or materials, OPP assumes in-container preservatives in household cleaners may contact food surfaces. As a result, in-can preservative uses in dish detergents and consumer household products are assessed for potential indirect food exposure.

In addition to the uses listed above, formaldehyde may also be used to formulate pulp and paper products and coatings. The product label (Reg. No. 8743-17) instructs formulators to obtain the appropriate FDA clearances for their end use products. It should be noted that the formulator instructions do not contain use directions or application rates for pulp and paper products or coatings. Given that the paper and coating uses are intended for formulated products and not for end use of Reg. No. 8743-17, the uses were not considered as potential food contact sites or as potential indirect dietary exposure, and thus are not assessed in this DRA. Future risk assessments may be required for food contact paper or coating use sites of end use labels for formaldehyde.

There are no labeled dietary uses from products containing paraformaldehyde (solid polymeric form of formaldehyde); therefore, dietary exposure and risks are not anticipated, and no quantitative risk assessment was conducted at this time.

There is potential for indirect exposure to formaldehyde from use as an in-can preservative in automatic dish detergents and consumer household cleaners (EPA Reg. No 8743-17). However, due to

chemical characteristics (i.e., dissipation or volatilization), formaldehyde is not expected to be present or remain on surfaces following cleaning product application in food contact spaces or on dishes. This product is a saturated formaldehyde solution stabilized with methanol (to prevent polymerization) and known as formalin. In solution, formalin exists in equilibrium with formaldehyde and various methylene glycol oligomers that quickly change forms under different conditions. Further, heat favors increased formation of formaldehyde gas (Winkelman, 2002; section 1.3). Given its high volatility, it is possible that some of the formaldehyde in solution will volatilize from the dish detergents and containers in gaseous form prior to use. The high solubility and low octanol/water portioning coefficient (K_{ow}) of formaldehyde and its associated transformation products suggest that most residues will be removed by washing and rinsing. Any remaining residues are expected to volatilize from surfaces upon drying. See Section 1.3 for full details on chemical characteristics for formaldehyde in all forms. OPP assessed the in-container preservative use in dish detergents and household cleaners and based on the low potential for dietary exposure or chemical transfer to food for consumption, a qualitative assessment was determined to be appropriate. Due to low exposure potential, dietary risks are not anticipated.

Formaldehyde is produced naturally in a variety of foods (e.g., selective fruits, vegetables, meats, fish, and mushrooms) and present as a food additive. See Appendix E for examples of foods with natural formaldehyde production. See Appendix D for additive clearances approved by U.S. FDA. It should be noted that dietary assessments of natural occurring formaldehyde levels will not be conducted at this time.

2.4.3 Drinking Water Exposure Profile and Risk Assessment

While several pesticidal uses of formaldehyde have the potential to go down-the-drain, including use as a material preservative in consumer (e.g., cleaning and laundry products) and commercial (e.g., oil and gas uses, oil and grease removers and industrial cleaners) products, there is a low potential for drinking water exposures from these releases due to: (1) the rapid conversion (seconds to minutes) of formaldehyde to its transformation products in the wastewater collection system, as well as the wastewater treatment system, compared to the typical hydraulic retention times for activated sludge processes in wastewater treatment plants (4-8 hours) (Tchobanoglous, 2013); (2) the dilution with water from sources that do not contain formaldehyde or its transformation products; (3) the high levels of removal of formaldehyde and its transformation products (>92%) during wastewater treatment; and (4) the likelihood that any paraformaldehyde formed would precipitate out of the water column. For residences that are not connected to collection systems that send wastewater to a treatment plant, wastewater is treated via a septic system which will allow degradation of formaldehyde and its transformation products prior to a discharge to a drainfield, so releases to potential surface water and groundwater drinking sources from these residences should also be minimal.

There is also a low potential for releases of formaldehyde and its transformation products from fumigant uses in citrus packing houses, mushroom houses, egg hatcheries, bee-nesting materials, poultry and swine confinement buildings, microbiology laboratories and research facilities, and feed truck and rail cars, to surface waters that serve as drinking water sources, given the rapid photodegradation in sunlight and degradation in moist air.

For the pesticidal SLN use, there is the potential for releases to surface water and groundwater sources of drinking water to formaldehyde transformation products through runoff and leaching from the application of dip-tank water to a field. However, there is uncertainty in where and how the use is applied to a field, as well as how much of the product is applied to a field at a given time. Additionally, as the label requires that the dip-tank solution only be applied to bulb fields when rainfall is not expected for at least 24 hours after application, it is uncertain how much of the formaldehyde transformation products will still be present when runoff and leaching occurs. Given uncertainties associated with the use pattern, application methods, and application rate, risk from drinking water cannot be precluded at this time. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

2.5 Residential (Non-Dietary) Exposure and Risk Characterization

Formaldehyde – There is one product (EPA Reg. No. 8743-17) containing formaldehyde that is labeled for use as an in-can preservative of the following consumer products: *"industrial and household consumer products such as air fresheners, automotive products, fabric softeners, hand cleaners, polishes for floors and furniture, shoe polishes, moist sponges and towelettes, spray starch, waxes and automotive polishes, hand and automatic dish detergents, liquid laundry detergents and car washes, household cleaners, industrial cleaners, liquid hand soaps, oil and grease removers, carpet cleaners and spot removers, waterless hand cleaners, raw materials for cleaning products, surfactants and silicone emulsions".*

Dermal and inhalation exposures for the handler and inhalation exposures for the bystanders are anticipated during the day of use of formaldehyde-preserved consumer products. Post-application dermal and inhalation exposures beyond the day of use are not anticipated because formaldehyde is expected to quickly volatilize out of the preserved consumer products as they are applied based on the vapor pressure of 1.3 mm Hg at 20 ℃ (Table 1-1). Post-application incidental oral exposures are also not anticipated for the same reason. Uses were grouped into the representative uses of laundry detergent, general purpose spray cleaner and automotive interior cleaner as shown in Table 2-2. These representative scenarios were determined to be protective of the other uses represented.

Table 2-2: Formaldehyde Residential Exposure Scenarios

Representative Use – Uses represented	**Exposure Scenario –** routes	**Application Rate**
Laundry detergents – laundry detergent, fabric softeners, and dish detergents	**Handler** - inhalation and dermal **Bystander** - inhalation	1000 ppm product[A] (370 ppm a.i.)
General purpose spray cleaner – household cleaners, oil and grease removers, moist sponges and towelettes, carpet cleaners and spot removers, polishes for floors and furniture and raw materials for cleaning products.	**Handler** - inhalation and dermal **Bystander** - inhalation	1000 ppm product[B] (370 ppm a.i.)
Automotive interior cleaners – automotive products	**Handler** -inhalation and dermal **Bystander** - inhalation	1000 ppm product (370 ppm a.i.)
Hand cleaners – hand cleaners, waterless hand cleaners, liquid hand soaps	**Hander –** dermal **Handler** – inhalation not assessed separately due to the small amounts used (10 grams per Isaacs, 2014). Is covered by the general-purpose cleaner scenario.	
Automotive exterior cleaners – waxes and automotive polishes, car washes	**Handler** - dermal **Handler** - inhalation not assessed because of the small amounts used and because the use occurs outside.	

A. According to the RED (U.S. EPA, 2008), the EPA determined that this household cleaner use would only be eligible for reregistration if the application rate was reduced to 40 ppm; however, this change was not made on the label.
B. According to the RED (U.S. EPA, 2008), the EPA determined that this household cleaner use would only be eligible for reregistration if the application rate was reduced to 72 ppm; however, this change was not made on the label.

The air freshener use is not included in Table 2-2 because the type (solid, liquid plug-in or aerosol spray) is not specified on the label. As discussed in Section 1-6 Label Recommendations to Clarify Existing Uses, it is requested that the label be clarified to include the formulation type because this has an impact on the potential for inhalation exposure and risk.

Paraformaldehyde – There is one product (EPA Reg. No. 4972-43) containing paraformaldehyde. This product is labeled for the treatment of unoccupied structures such as homes and trailers or for the treatment of items such as bedding, golf bags, suitcase, and trunks either by themselves or in a closet. No exposures are anticipated during the application of the product because it is in a cloth pouch that is placed in the area being treated; however, post-application inhalation exposures are anticipated as the formaldehyde monomer is released from the paraformaldehyde polymer. Given the large number of uses, it is not feasible to assess each one individually; therefore, the uses were grouped into the representative uses of closet and vacation home as shown in Table 2-3.

Table 2-3: Paraformaldehyde Residential Exposure Scenarios

Representative Use – Uses Represented	**Exposure Scenario**	**Application Rate**
Closet – clothing and linen storage bins, dresser drawers, bedding, golf bags, suitcases and trunks in a closet	Post-application inhalation	3 ounces product / 100 ft^3
Vacation home – unoccupied homes or trailers, cupboards, bathroom and kitchen cabinets in unoccupied homes or trailers.	Post-application inhalation	4 ounces product / 700 ft^3

2.5.1 Residential Handler Dermal Exposures and Risks for Formaldehyde

Residential handler dermal exposures could occur while using any of the preserved products, such as general-purpose spray cleaners, laundry detergents, automotive interior cleaners, and automotive exterior cleaners but the highest exposure would occur while using preserved hand cleaners because they are applied directly to the hands. This exposure was assessed using the thin film model as outlined in Table 2-4. At the maximum application rate of 370 ppm, the dermal MOE of 26 for induction of skin sensitization is of concern because it is less than the LOC of 100 and the dermal MOE of 2.8 for elicitation of skin sensitization is of concern because is it less than the LOC of 10. At the application rate of 97 ppm, the dermal MOEs of 100 for induction and 10 for elicitation are equal to the respective LOCs of 100 and 10 and are not of concern.

Table 2-4: Residential Handler Dermal MOEs

Application Rate	**Qu (mg/cm^2)**	**Dermal Loading[D] ($\mu g/cm^2$)**	**Dermal MOE**	
			Induction[E] (LOC = 100)	**Elicitation[F] (LOC = 10)**
370 ppm[A]	10.3[C]	3.8	**26**	**2.8**
97 ppm[B]	10.3[C]	1.0	100	10

A. Based on the maximum product application rate of 1000 ppm. The product contains 37% formaldehyde.
B. Back calculated application rate at which the dermal MOEs are equal to the LOCs.
C. Qu=Quantity of liquid remaining on skin as a film. Standard value used by AD based on hand immersion and wiping experiments reported in Cinalli, 1992.
D. Dermal Loading = [Application Rate (ppm) /1,000,000 ppm] x Qu x 1000 µg/mg
E. Dermal MOE for Induction = Dermal Induction POD (EC_3 = 100 $\mu g/cm^2$) / Dermal Loading ($\mu g/cm^2$).
F. Dermal MOE for Elicitation = Dermal Elicitation POD ($BMDL_{10}$ = 10.5 $\mu g/cm^2$) / Dermal Loading ($\mu g/cm^2$).

2.5.2 Residential Handler Inhalation Exposures and Risks for Formaldehyde

Formaldehyde has a high vapor pressure. Pure formaldehyde is a gas at room temperature and 37% formaldehyde in formalin has a vapor pressure of 1.3 mm Hg at 20°C. As a result, the unit exposure data from the Antimicrobial Exposure Assessment Task Force II (AEATF II) are not applicable because these data are generally based upon chemicals that have a much lower vapor pressure (less than 1.0 x 10^{-4} mm Hg). When the vapor pressure is less than 1.0 x 10^{-4} mm Hg, chemicals are airborne primarily as aerosols, while at a vapor pressure greater than 1.0 x10^{-4} mm Hg, chemicals are airborne primarily

as vapors or gases. In addition, the toxicology endpoints were derived from observational human studies where formaldehyde was in the gas or vapor form.

Because of these considerations, and because using aerosol exposure data to evaluate formaldehyde exposures would underestimate formaldehyde exposures, the AEATF II unit exposure data are not used to assess handler exposures. This was discussed in the FWP and was the basis for recommending that formaldehyde specific inhalation exposure data be required. Although GDCIs were issued, data were not submitted, therefore, generic exposure models were used to estimate formaldehyde air concentrations and assess handler exposures. The EPA's Consumer Exposure Model (CEM) Version 3.2 (U.S. EPA, 2023) was used for the spray cleaner and automotive interior cleaner uses and the Swimming Pool Exposure Model (SWIMODEL) Version 3.0 (U.S. EPA, 2003) was used for the laundry detergent use.

2.5.2.1 General Purpose Cleaner Residential Handler Inhalation Exposures and Risks

CEM Version 3.2 (U.S. EPA, 2023) was used to estimate air concentrations resulting from the use of household cleaning products treated with formaldehyde. The default scenario for the general-purpose cleaner was used for this exposure assessment because it most closely represents the use pattern of the treated products. This scenario assumes that the homeowner uses the general-purpose cleaner in the kitchen of a house. The following general inputs were used in the model:

- The molecular weight of formaldehyde is 30 amu (Table 1-1).
- The vapor pressure is 1.3 mm Hg for formaldehyde as a liquid in formalin (Table 1-1).
- The log of the octonal-water partition coefficient is 0.35 (Table 1-1).
- The weight fraction of 0.00037 is based upon the application rate of 1,000 ppm for EPA Reg No. 8743-17 which contains 37% formaldehyde.
- The product dilution is 1.0.
- The product density is 1.0.
- The air exchange rate is 0.45 air exchanges per hour.
- The kitchen volume is 24 m^3 and the whole house volume is 492 m^3.
- The interzone ventilation rate is 109 m^3/hr. This value is based on the formula for open rooms that is on page 31 of the CEM 3.2 User Guide (U.S. EPA, 2023). This value is also listed as a default in the "Environment Inputs" entry screen.
- The near-field/far-field (NF/FF) modeling option was selected. The near-field volume was set to 1.0 m^3 which is the medium value in CEM.
- The background air concentration inside the house is 0.0 mg/m^3.
- The background air concentration outside the house or in an automobile is 0.0 mg/m^3.

To assess acute exposures, the following inputs were used to calculate a maximum 15-minute peak concentration.

- The amount of general-purpose cleaner used is 60 grams which is the high-end value from CEM.
- The duration of exposure is 30 minutes which is the high-end value from CEM.
- The number of events per day is one because there is a programming error in CEM. Although the default value is three, it is not used by CEM when selected because of the error. To evaluate the effect of three events, the output was downloaded into a spreadsheet and copied and summed in a staggered fashion to yield three cleaning events. The events were set at 9am, 1 pm and 6 pm. The resulting peak concentration of 120 µg/m^3 is greater than the peak exposure of 99 µg/m^3 that occurs after one event as shown in Figure F-1 of Appendix F. This peak exposure is an overestimate of the actual peak exposure; however, because it is more likely that a person would clean three rooms in a day (i.e., a kitchen and two bathrooms) instead of cleaning the same room three times. This would cause the initial air concentration in each room to be lower. Because of this consideration, the acute peak exposure that is based on three events is not used for risk assessment.

To assess annual average exposures, the following inputs were used to calculate air concentrations in each zone on the day of application.

- The amount of product used per event is 30 grams which is a medium value in CEM.
- The event duration is 15 minutes which is a medium value in CEM.

The peak concentration of **99 µg/m^3** for acute exposures was calculated as the maximum 15-minute TWA in the near-field of the kitchen as shown in Figure 2-1.

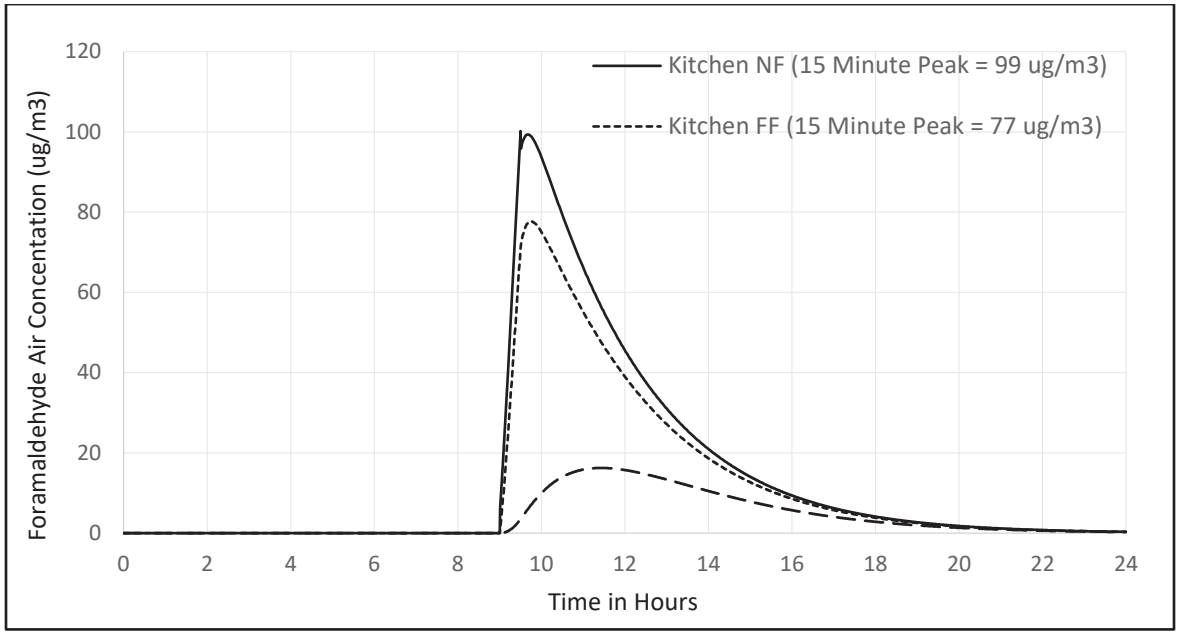

Figure 2-11: General Purpose Cleaner Handlers Acute Peak Exposures

The 24-hour TWA for long-term and lifetime exposures was based on the standard activity pattern in CEM which includes the following:

- 12 am to 8 am – The handler is the bedroom of the house (Zone 2).
- 8 am to 9 am – The handler is in an automobile (zero exposure assumed).
- 9 am to 9:15 am – The handler is in the near-field of the kitchen (Zone 1) while using the cleaning product.
- 9:15 to 10 am – The handler is in the far-field of Zone 1 after using the product.
- 10 am to 12 pm – The handler is in other parts of the house (Zone 2).
- 12pm to 1 pm – The handler is in the far-field of Zone 1.
- 1 pm to 2 pm – The handler is outside (zero exposure assumed).
- 2 pm to 5 pm – The handler is in the other parts of the house (Zone 2).
- 5 pm to 6 pm – The handler is outside (zero exposure assumed).
- 6 pm to 7 pm – The handler is in the far-field of Zone 1.
- 7 pm to 12 am – The handler is in other parts of the house (Zone 2).

The 24-hour TWA for the handler is **3.3 µg/m^3** based on the air concentrations calculated by CEM and the above activity schedule as illustrated in Figure 2-2.

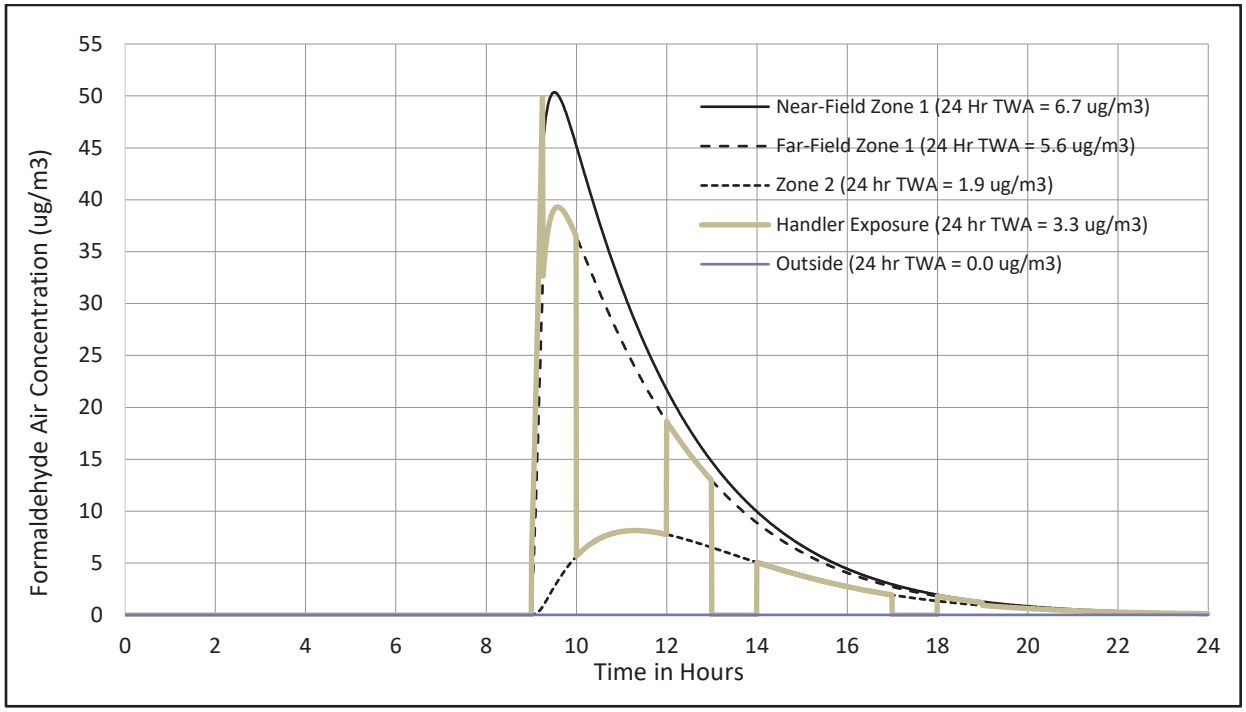

Figure 2-2: General Purpose Cleaner Handler Daily Average Exposures

General Purpose Cleaner Inhalation Risk Summary

The risks for the general-purpose cleaner scenario are included in Table 2-5. The MOE of 6.3 for acute exposures is of concern because it is less than the LOC of 10. The MOE of 7.8 for annual average daily

concentrations (AADC) is not of concern because it is greater than the LOC of 3. The cancer risk for the adult lifetime average daily concentration (ALADC) is 2 x 10^{-5}. These risks are likely overestimates because the CEM emission source models do not account for the unique chemical fate properties of formaldehyde.

Because the exposure in CEM is proportional to the amount of chemical used, the acute MOE would increase from 6.3 to the LOC of 10 if the application rate was reduced to 233 ppm. This application rate is greater than the rate of 72 ppm that was required to mitigate risks identified in the RED because of differences in the underlying assumptions used to evaluate risk at that time, including: 1) the application rate assessed (56 ppm a.i vs. 370 ppm a.i), 2) the POD selected to assess non-cancer risks (1 ppm vs. 0.5 ppm for acute exposures), and 3) the default model assumptions for the amount of product used (123 grams vs. 60 grams).

Table 2-5: Inhalation Risks for General Purpose Cleaner Handlers

Non-Cancer Risks from Acute Exposures Averaged over 15 Minutes					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	15 Minute TWA Peak Concentration	MOE[C] (LOC = 10)
0.00037	60 grams[A]	30 minutes[A]	1x day	99 µg/m^3	**6.3**
Non-Cancer Risks from Long-term Exposures Averaged over a Year					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Annual Average Daily Concentration (AADC)[D]	MOE[E] (LOC =3)
0.00037	30 grams[B]	15 minutes[B]	300 days/year[B]	2.7 µg/m^3	7.8
Cancer Risks from Lifetime Exposures Averaged Over an Adult Lifetime (60 years)					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Adult Lifetime Average Daily Concentration (ALADC)[F]	Cancer Risk[G]
0.00037	30 grams [B]	15 minutes[B]	57 years	2.6 µg/m^3	2 x 10^{-5}

A. High level assumptions as listed in Appendix B of the CEM 3.2 User Guide. (U.S. EPA, 2023)
B. Central level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).
C. MOE = POD/Peak Concentration where the POD = 620 µg/m^3 (0.62 mg/m^3)
D. AADC = 24 hr TWA for the day of use (3.3 µg/m^3) * 300 days of use per year / 365 days per year.
E. MOE = POD/AADC where the POD = 21 µg/m^3 (0.021 mg/m^3).
F. ALADC = AADC * 57 years of use / 60 adult years of a 78-year lifetime
G. Cancer Risk = ALADC (µg/m^3) * Unit Risk, where the Unit Risk = 6.4 x 10^{-6} per µg/m^3 for adults
Bold values indicate MOE less than LOC

2.5.2.2 Automotive Interior Cleaner Residential Handler Inhalation Exposures and Risks

CEM Version 3.2 (U.S. EPA, 2023) was used to estimate air concentrations resulting from the use of automotive interior cleaning products treated with formaldehyde. The default scenario for the automotive interior cleaner was used for this exposure assessment because it most closely represents the use pattern of the treated products. This scenario assumes that the homeowner uses the

automotive interior cleaner in the interior of a car parked in a garage. The following general inputs were used in the model:

- The molecular weight of formaldehyde is 30 amu (Table 1-1).
- The vapor pressure is 1.3 mm Hg for formaldehyde as a liquid in formalin (Table 1-1).
- The log of the octonal-water partition coefficient is 0.35 (Table 1-1).
- The weight fraction of 0.00037 is based upon the application rate of 1,000 ppm for EPA Reg No. 8743-17 which contains 37% formaldehyde.
- The product dilution was set to 1.0.
- The product density was set to 1.0.
- The room of use (Zone 1) is a garage that is attached to a house (Zone 2).
- The garage has a volume of 90 m^3 and the house has a volume of 492 m^3.
- The air exchange rate for each zone is 0.45 ACH.
- The interzone ventilation rate between the garage and the rest of the house is 88.6 m^3/hr.
- The near-field/far-field (NF/FF) modeling option was selected given the large volume of the garage relative to the small volume of the car interior.
- The near-field volume is 1.0 m^3.
- The air exchange rate at the near-field boundary is 402 m^3/hr.
- The background air concentration inside the house is 0.0 mg/m^3.
- The background air concentration outside the house or in an automobile on the road is 0.0 mg/m^3.

To assess acute exposures, the following inputs were used to calculate a 15-minute peak concentration.

- The amount of automotive interior cleaner used is 40 grams which is the high-end value from CEM.
- The duration of exposure is 30 minutes which is the high-end value from CEM.
- The frequency of use per day is one which is the default value from CEM.

To assess annual average exposures, the following inputs were used to calculate air concentrations in each zone on the day of application.

- The amount of product used per event is 10 grams which is a medium value in CEM.
- The event duration is 20 minutes which is a medium value in CEM.

The peak concentration of **46 µg/m^3** for acute exposures was calculated as the maximum 15-minute TWA in the near-field of Zone 1 as shown in Figure 2-3.

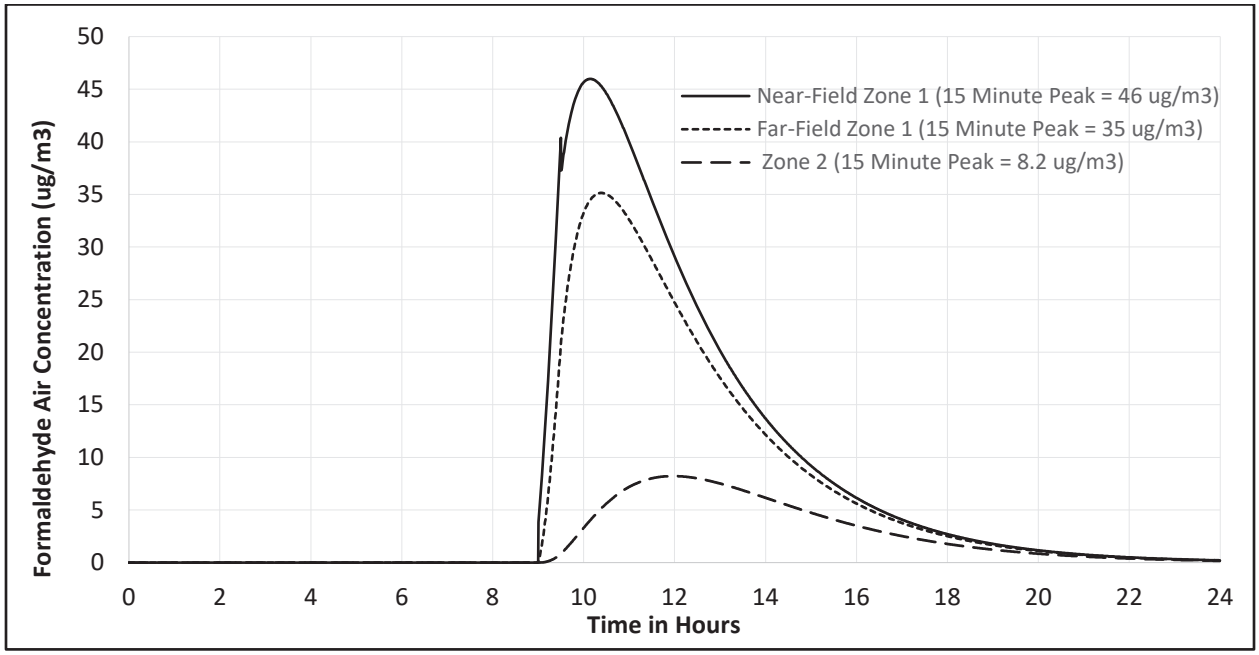

Figure 2-3: Automotive Interior Cleaner Handler Acute Exposures

The 24-hour TWA for long-term and lifetime exposures was based on the standard activity pattern in CEM which includes the following:

- 12 am to 8 am – The handler is the bedroom of the house (Zone 2).
- 8 am to 9 am – The handler is an automobile on the road (zero exposure assumed).
- 9 am to 9:20 am – The handler is in the near-field of Zone 1 while cleaning the automotive interior.
- 9:20 am to 10 am – The handler is in the far-field of Zone 1 while in the garage after using the product.
- 10 am to 1 pm – The handler is in other parts of the house (Zone 2).
- 1 pm to 2 pm – The handler is outside (zero exposure assumed).
- 2 pm to 5 pm – The handler is in other parts of the house (Zone 2).
- 5 pm to 6 pm – The handler is outside (zero exposure assumed).
- 6 pm to 12 am – The handler is in other parts of the house (Zone 2).

The 24-hour TWA for the handler is **0.66 µg/m^3** based on the air concentrations calculated by CEM and the above activity schedule as illustrated in Figure 2-4.

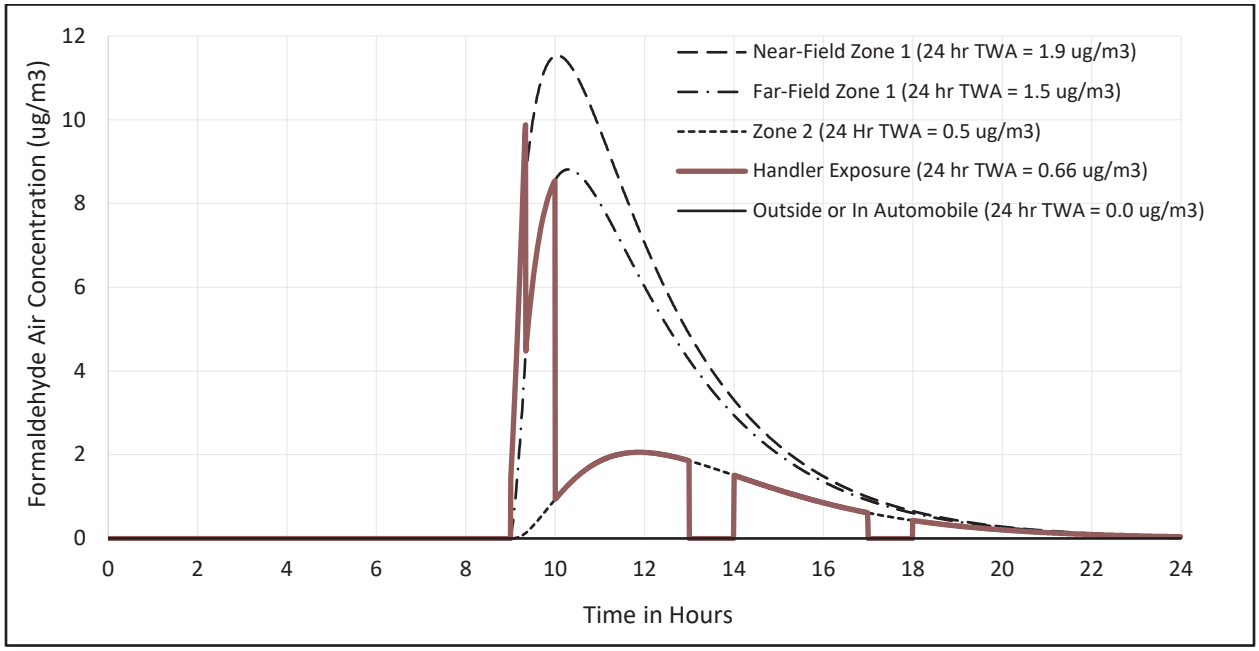

Figure 2-4: Automotive Interior Cleaner Handler Daily Average Exposures

Automotive Interior Cleaner Risk Summary

The exposures and risks for the automotive interior cleaner scenario are included in Table 2-6. The MOE of 13 for acute exposures is not of concern because it is greater than the LOC of 10. The MOE of 3,900 for long-term exposure is not of concern because it is greater than the LOC of 3. The cancer risk is 3 x 10^{-8}. These risks are likely overestimates because the CEM emission source models do not account for the unique chemical fate properties of formaldehyde.

Table 2-6: Inhalation Risks for Automotive Interior Cleaner Handlers

Non-Cancer Risks from Acute Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	15 Minute Peak Concentration	MOE[C] (LOC = 10)
0.00037	40 grams[A]	30 minutes[A]	1x day	46 µg/m^3	13
Non-Cancer Risks from Long-term Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Annual Average Daily Concentration (AADC)[D]	MOE[E] (LOC =3)
0.00037	10 grams[B]	20 minutes[B]	3 days/year[B]	0.0054 µg/m^3	3,900
Cancer Risks from Lifetime Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Adult Lifetime Average Daily Concentration (ALADC)[F]	Cancer Risk[G]
0.00037	10 grams[B]	20 minutes[B]	3 days/year[B]	0.0051 µg/m^3	3 x 10^{-8}

A. High level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).
B. Medium level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).

C. MOE = POD/Peak Concentration where the POD = 620 µg/m^3 (0.62 mg/m^3)
D. AADC = 24 hr TWA for the day of use (**0.66 µg/m^3**) * 3 days of use per year / 365 days per year.
E. MOE = POD/AADC where the POD = 21 µg/m^3 (0.021 mg/m^3).
F. ALADC = AADC * 57 years of use / 60 adult years of a 78-year lifetime
G. Cancer Risk = LADC (µg/m^3) * Unit Risk, where the Unit Risk = 6.4 x 10^{-6} per µg/m^3 for adults

2.5.2.3 Laundry Detergent Residential Handler Inhalation Exposures and Risks

The Henry Law Constant for formaldehyde is very low which means that formaldehyde has a very low rate of volatility from water especially when it is diluted. Although CEM has a modeling scenario for the use of liquid laundry detergent, this scenario was not used for this assessment because the source model in CEM does not use the Henry's Law constant (HLC). Instead, the inhalation exposure model from the SWIMODEL Version 3.0 (U.S. EPA, 2003) which uses the HLC was used to estimate a screening level estimate of the formaldehyde air concentration that could occur above the surface of the wash water in the washing machine. This exposure model is based upon the partitioning of a chemical above and below the water line in a sealed vessel that is partially full of liquid. The following inputs were used:

- The formaldehyde concentration in the detergent is 370 ppm based upon the maximum product application rate of 1,000 ppm for EPA Reg. No. 8743-17 which contains 37% formaldehyde.
- The amount of laundry detergent used is 230 grams. This is the maximum value for regular liquid laundry liquid detergent (A.I.S.E, 2017) that would be used in a standard washing machine. It is understood that less detergent would be used in High Efficiency (HE) machines; however, the label does not specify which type of detergent can be preserved with formaldehyde.
- The wash water volume is 90 liters for a high-volume washer from US EPA (2000b) as cited in McCready (2012). It is understood that HE washers use less water than the standard washer that was studied in US EPA (2000b), however, the amount of detergent used would also be lower to prevent foaming.
- The wash water temperature is 35ºC (95ºF).
- The Henry's Law Constant at 35ºC is 6.67 x 10^{-7} atm/m^3/mol. This was derived from Betterman and Hoffman (1988).
- The HLC in units of atm/m^3/mole was converted to a unitless HLC of 2.64 x 10^{-5} using the Henry's Law Conversion Tool at the EPA On-Line Tools for Site Assessment Website at: https://www3.epa.gov/ceampubl/learn2model/part-two/onsite/henryslaw.html

<u>Laundry Detergent Inhalation Risk Summary</u>

The exposures and risks for the laundry detergent scenario are included in Table 2-7. The acute MOE of 25 is not of concern because it is greater than the LOC. The MOE is a high-end screening level overestimate of risk because it represents the exposure that would occur at equilibrium conditions in a sealed vessel containing the wash water. The actual air concentrations that would occur in a laundry room would be lower due to dispersion and ventilation. Because of this, and because the emissions end when the wash water is discharged from the machine at the end of the wash cycle, it is not appropriate to use the calculated air concentration to represent long term exposures either in the

laundry room or other parts of the house. Therefore, the chronic MOE and the cancer risks were not calculated.

Table 2-7: Inhalation Risks for Laundry Detergent Handlers

Laundry Detergent Formaldehyde Concentration	Wash Water Volume[A]	Wash Water Formaldehyde Concentration (Cw)	Henry's Law Constant Unitless (H')	Air Concentration (Cvp)[D]	Acute MOE[E] (LOC = 10)
370 ppm	90 liters	946 ug/liter[B]	2.64 e-05[C]	25.0 ug/m^3	25

A. High volume washer from US EPA (2000b) as cited in McCready (2012).

B. If 230 grams of laundry detergent (0.085 gm or 85,000 ug formaldehyde) is added to 90 liters of wash water.

C. Converted from the Henry's Law constant of 6.67 x 10^{-7} atm/m^3/mol using the Henry's Law Conversion Tool.

D. Cvp = H' x Cw x 1000 liters/m^3 from page 21 of the SWIMODEL Users Guide (U.S. EPA, 2003) where Cvp is air concentration above the water surface (ug/m^3), H' is Henry's Law Constant (unitless) and Cw is concentration in water (ug/liter).

E. MOE = POD/Peak Concentration where the POD = 620 µg/m^3 (0.62 mg/m^3).

2.5.3 Residential Bystander Inhalation Exposures and Risks from Consumer Products

Residential bystander exposures can occur when persons, such as children, are present in the house while the handler is applying general purpose cleaner, automotive interior cleaner or preserved laundry detergent.

2.5.3.1 Bystander Inhalation Exposures and Risks from General Purpose Cleaners

The CEM scenario for the handler exposure was used to assess the bystander exposures. It is assumed that a bystander in the Zone 1 far-field of the kitchen is exposed to formaldehyde in the general-purpose cleaner when the handler is using the cleaner in the Zone 1 near-field of the kitchen. The peak 15-minute TWA for acute exposures was based on Zone 1 far-field air concentrations that were calculated by CEM for the handler exposure scenario as shown in Figure 2-3.

The 24-hour TWA for long-term exposures was based on the standard activity pattern for child bystanders in CEM which includes the following:

- 12 am to 9 am – The bystander is the bedroom of the house (Zone 2).
- 9 am to 10 am – The bystander is in the far-field of the kitchen (Zone 1) while the handler is using the cleaning product in the near-field of Zone 1.
- 10 am to 12 pm – The bystander is in other parts of the house (Zone 2).
- 12 pm to 1 pm – The bystander is in the far-field of Zone 1.
- 1 pm to 5 pm – The bystander is in the other parts of the house (Zone 2).
- 5 pm to 6 pm – The bystander is in the far-field of Zone 1.
- 6 pm to 12 am – The handler is in other parts of the house (Zone 2).

The 24-hour TWA for the bystander is **3.5 µg/m^3** based on the air concentrations calculated by CEM and the above activity schedule as illustrated in Figure 2-5.

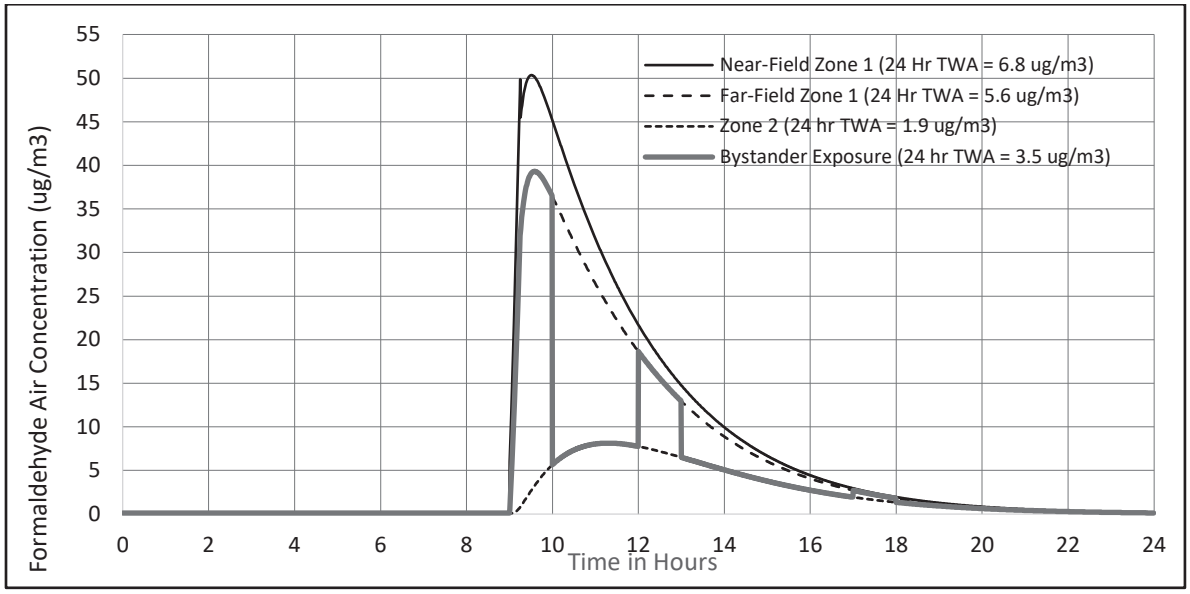

Figure 2-5: General Purpose Cleaner Bystander Exposures

General Purpose Cleaner Bystander Non-Cancer Risk Summary

The inhalation exposures and non-cancer risks are included in Table 2-8. The MOE of 8.1 for acute exposures is of concern because it is less than the LOC of 10. The MOE of 7.1 for average daily exposures is not of concern because it is greater than the LOC of 3.

Table 2-8: General Purpose Cleaner Bystander Exposures and Non-Cancer Risks

Non-Cancer Risks from Acute Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Peak Concentration[B]	MOE[C] (LOC = 10)
0.00037	60 grams[A]	30 minutes[A]	1x day	77 µg/m^3	**8.1**
Non-Cancer Risks from Average Daily Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Annual Average Daily Concentration (AADC)[E]	MOE[F] (LOC =3)
0.00037	30 grams[D]	15 minutes[D]	300 days/year[D]	2.9 µg/m^3	7.1

A. High level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).
B. This is the 15-minute peak air concentration for kitchen 1 far-field (Figure 2-3).
C. MOE = POD/Peak Concentration where the POD = 620 µg/m^3 (0.62 mg/m^3)
D. Medium level assumptions as listed Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023)
E. AADC = 24 hr TWA for the day of use (**3.5 µg/m^3**) * 300 days of use per year / 365 days per year.
F. MOE = POD/AADC where the POD = 21 µg/m^3 (0.021 mg/m^3).

General Purpose Cleaner Bystander Cancer Risk Summary

The inhalation exposures and cancer risks are included in Table 2-9. The total cancer risk for the age period of 0 to 18 is 1.5×10^{-5}.

Table 2-9: General Purpose Cleaner Bystander Exposures and Cancer Risks

Annual Average Daily Concentration (AADC)[A]	Age Period	Years per Age Period	Lifetime Average Daily Concentration (LADC)[B]	ADAF[C]	Unit Risk[D]	Cancer Risk[E]
2.9 ug/m^3	0 to 2	2	0.074	10	6.4×10^{-6} per µg/m^3	4.7×10^{-6}
	3 to 16	14	0.52	3		9.9×10^{-6}
	17 to 18	2	0.074	1		4.7×10^{-7}
	0 to 18	18	N/A	N/A		1.5×10^{-5}

A. From Table 2-8 above.
B. LADC = AADC * years of exposure per age period / 78-year lifetime
C. ADAF = Age Dependent Adjustment Factor
D. Adult Unit Risk for Use with ADAF.
E. Cancer Risk = LADC * ADAF * Unit Risk

2.5.3.2 Bystander Inhalation Exposures and Risks from Automotive Interior Cleaners

The CEM scenario for the handler exposure was used to assess the bystander exposures. It is assumed that a bystander in the far-field of Zone 1 (the garage) is exposed to formaldehyde in the automotive interior cleaner when the handler is using the cleaner in the near-field of Zone 1 (the automobile in the garage). The peak 15-minute TWA of **35 µg/m^3** for acute exposures was based on the Zone 1 far-field air concentrations that were calculated by CEM for the handler exposure scenario as shown in Figure 2-5.

The 24-hour TWA for long-term exposures was based on the standard activity pattern for child bystanders in CEM which includes the following:

- 12 am to 9 am – The bystander is the bedroom of the house (Zone 2).
- 9 am to 10 am – The bystander is in the garage (far-field of Zone 1) while the handler is using the cleaning product in the car in the garage (near-field of Zone 1).
- 10 am to 12 pm – The bystander is in other parts of the house (Zone 2).
- 12 pm to 1 pm – The bystander is in other parts of the house (Zone 2).
- 1 pm to 2 pm – The bystander is outside (zero exposure assumed).
- 2 pm to 5 pm – The bystander is in other parts of the house (Zone 2).
- 5 pm to 6 pm – The bystander is outside (zero exposure assumed).
- 6 pm to 12 am – The bystander is in other parts of the house (Zone 2).

The 24-hour TWA for the bystander is **0.62 µg/m³** based on the air concentrations calculated by CEM and the above activity schedule as illustrated in Figure 2-6.

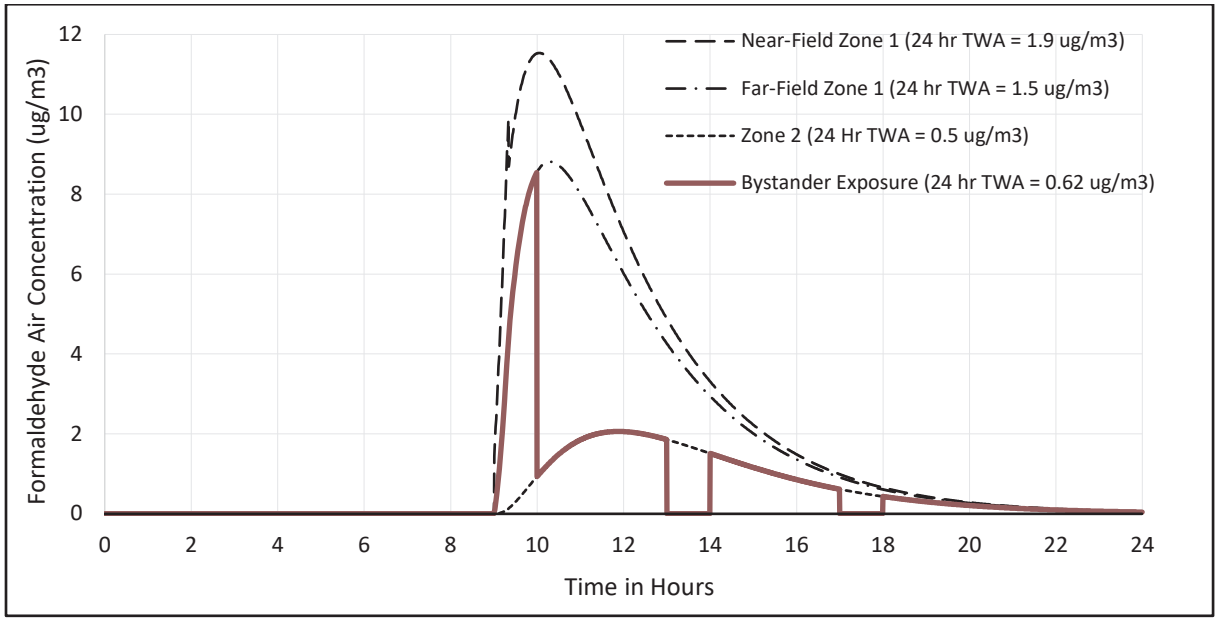

Figure 2-6: Automotive Interior Cleaner Bystander Exposure

Automotive Interior Cleaner Bystander Exposures and Non-Cancer Risks

The bystander exposure estimates, and non-cancer risks are included in Table 2-10. The MOE of 18 for acute exposures is not of concern because it is greater than the LOC of 10. The MOE of 4,100 for average daily exposures is not of concern because it is greater than the LOC of 3.

Table 2-10: Automotive Interior Cleaner Bystander Exposures and Non-Cancer Risks

Non-Cancer Risks from Acute Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	15 Minute Peak Concentration[B]	MOE[C] (LOC = 10)
0.00037	40 grams[A]	30 minutes[A]	1x day	35 µg/m³	18
Non-Cancer Risks from Long-term Exposures					
Weight Fraction	Amount Used per Day	Duration of Use per Day	Frequency of Use	Annual Average Daily Concentration (AADC)[E]	MOE[F] (LOC =3)
0.00037	10 grams[D]	20 minutes[D]	3 days/year[D]	0.0051 µg/m³	4,100

A. High level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).
B. This is the acute value for the far-field of Zone 1 (Figure 2-5).
C. MOE = POD/Peak Concentration where the POD = 620 µg/m³ (0.62 mg/m³)
D. Medium level assumptions as listed in Appendix B of the CEM 3.2 User Guide (U.S. EPA, 2023).
E. AADC = 24 hr TWA in Zone 2 for the day of use (**0.62 µg/m³**) * 3 days of use per year / 365 days per year.
F. MOE = POD/AADC where the POD = 21 µg/m³ (0.021 mg/m³).

Automotive Interior Cleaner Bystander Exposures and Cancer Risks

The bystander exposures and cancer risks are included in Table 2-11. The total cancer risk for the age period of 0 to 18 is 2.7×10^{-8}.

Table 2-11: Automotive Interior Cleaner Bystander Exposures and Cancer Risks

Annual Average Daily Concentration (AADC)[A]	Age Period	Years per Age Period	Lifetime Average Daily Concentration (LADC)[B]	ADAF[C]	Unit Risk[D]	Cancer Risk[E]
0.0051 ug/m^3	0 to 2	2	0.00013	10	6.4×10^{-6} per µg/m^3	8.3×10^{-9}
	3 to 16	14	0.00092	3		1.8×10^{-8}
	17 to 18	2	0.00013	1		8.3×10^{-10}
	0 to 18	18	N/A	N/A		2.7×10^{-8}

A. From Table 2-12 above.
B. LADC = AADC * years of exposure per age period / 78-year lifetime
C. ADAF = Age Dependent Adjustment Factor
D. Adult Unit Risk for Use with ADAF.
E. Cancer Risk = LADC * ADAF * Unit Risk

2.5.3.3 Bystander Inhalation Exposure and Risks from Laundry Detergent

The screening level risk assessment that was done for laundry detergent handlers is protective for bystanders. This is because the handler risk assessment was based on the exposure that would occur at equilibrium conditions in a sealed vessel containing the wash water. Therefore, a separate assessment is not needed for bystanders.

2.5.4 Residential Post-Application Exposure from Paraformaldehyde

Representative post-application scenarios assessed include inhalation exposures from the paraformaldehyde product (EPA Reg. No. 4972-43) used as a mildewcide in closets and vacation homes.

2.5.4.1 Paraformaldehyde Closet Treatment Inhalation Exposures and Risk

Because the post-application inhalation small chamber emissions study (GLN 875.2500) required by the GDCI for paraformaldehyde was not submitted, the CEM model version 3.2 was used to estimate air concentrations resulting from the use of the paraformaldehyde product (EPA Reg. No. 4972-43) in a closet of an occupied home. The default scenario for the continuous air freshener was used for this exposure assessment. This scenario assumes that the homeowner places the air freshener in the laundry room of a house. Because a laundry room is much larger and has more ventilation than a

closet, the scenario was modified to account for the use in a closet. The following general inputs were used in the model:

- The molecular weight of formaldehyde is 30 amu (Table 1-1).
- The vapor pressure is 1.45 mm Hg for paraformaldehyde (Table 1-1).
- The weight fraction of 0.91 (*i.e.,* 91 percent) is from the product label.
- The outdoor air exchange rate is 0.45 for the house.
- The outdoor air exchange rate is 0.10 air exchanges per hour for the closet.
- The closet (Zone 1) has a volume of 2.83 m^3 based on the label instructions that the 3-ounce product will treat a 100 cubic foot (ft^3) closet.
- The house (Zone 2) has a volume of 492 m^3.
- The interzone ventilation between Zone 1 and Zone 2 is 0.283 m^3/hour. It is assumed that the closet is not directly connected to an HVAC system.

To assess exposures, the following inputs were used to calculate air concentrations:

- The weight of the air freshener is 85.1 grams (i.e., 3 ounces) based on the product label.
- The event duration is 1440 minutes which is the longest duration that is allowed in CEM.
- The product is placed in the closet at 12:00 am to allow for 1440 minutes of emission.
- The emission rate is 0.897 mg/min based on the amount of a.i. in the 3 ounces of product (77.5 grams) and the assumption that the product will last for two months based on the label claim that the product "lasts for months". The emission rate calculator in CEM was not used because it does not account for the release of formaldehyde monomers from the paraformaldehyde polymer. The CEM emission rate calculator is based on the molecular weight and vapor pressure of the chemical.
- The emission rate was entered as 0.897 mg/min into the "User-defined Emission Rt. Mg/hr" box of the "Product/Article Properties" tab of CEM. There is a typo in the CEM interface. The user defined emission rate is listed as mg/hour while the program itself calculates emissions using mg/minute and lists the emission rate as mg/minute in the output.
- The event frequency is one per day. This is lowest frequency allowed in CEM.

The air concentrations from CEM were post processed in Excel to estimate formaldehyde air concentrations over time. The air concentrations increase rapidly for the first few hours and then level off to a near steady concentration of 94,000 µg/m^3 in Zone 1 and a steady state concentration of 120 µg/m^3 in Zone 2 as shown in Figure 2-7.

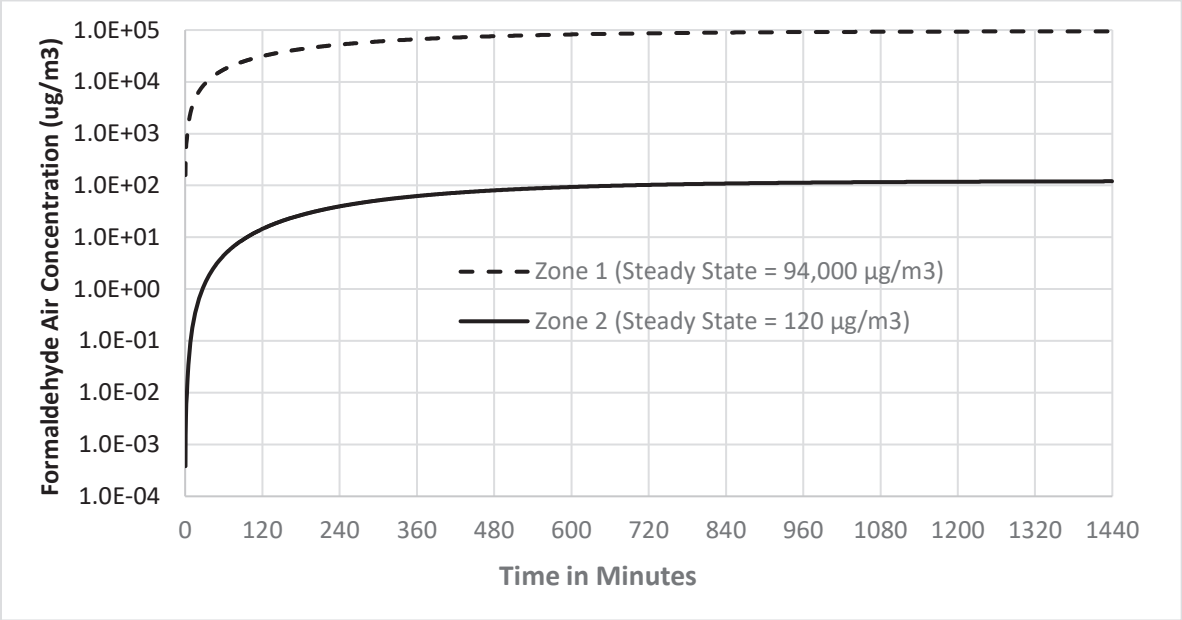

Figure 2-7: Paraformaldehyde Closet Treatment Exposure

The steady state air concentrations were used to assess both acute and long-term inhalation exposures because the emission would occur continuously if the product were replaced at 2-month intervals.

Paraformaldehyde Closet Treatment Risk Summary

The inhalation exposures and risks of the paraformaldehyde closet treatment scenario are included in Table 2-12. The MOE of 0.0066 for acute peak exposures is of concern because it is less than the LOC of 10. The MOE of 0.18 for long-term exposure is of concern because it is less than the LOC of 3. The estimated cancer risk is 1×10^{-3} assuming 78 years of use. It is not known if these risk estimates are conservative because the emission rate of paraformaldehyde is not known. This emission rate is typically measured in a small chamber emission study (GLN 875.2500) that was required in the GDCI; however, the study was not submitted.

Table 2-12: Inhalation Risks for Paraformaldehyde Closet Treatment

Non-Cancer Risks from Acute Peak Exposures					
Weight Fraction	Amount of Product Used[A]	Duration of Use	Duration of Exposure	Peak Concentration[C]	MOE[D] (LOC = 10)
0.91	85.1 grams	1440 Minutes[B]	15 minutes	94,000 µg/m^3	**0.0066**
Non-Cancer Risks from Long-term Exposures					
Weight Fraction	Amount of Product Used	Frequency of Use	Duration of Exposure	Annual Average Daily Concentration (AADC)[E]	MOE[F] (LOC = 3)
0.91	85.1 grams	6 times/year	1 year	120 µg/m^3	**0.18**
Cancer Risks from Lifetime Exposures					
Weight Fraction	Amount of Product Used	Frequency of Use	Duration of Exposure	Lifetime Average Daily Concentration (LADC)[G]	Cancer Risk per Year of Use[H]
0.91	85.1 grams	6 times/year	1 year	120 µg/m^3	1 x 10^{-3}

A. Based on the product weight of 3 ounces listed on the label (EPA Reg. No. 4972-43).
B. This is longest duration of use that is allowed in CEM. The actual duration of use is two months.
C. Peak Concentration = Steady State Air Concentration in Zone 1 (35,000)
D. MOE = POD/Peak Concentration where the POD = 620 µg/m^3
E. AADC = Steady State Air Concentration in Zone 2 (180 µg/m^3)
F. MOE = POD/AADC where the POD = 21 µg/m^3 (0.021 mg/m^3).
G. LADC = AADC * (78 years exposure / 78-year lifetime)
H. Cancer Risk = LADC * Unit Risk (1.1 x 10^{-5} per µg/m^3 for full lifetime exposures).
Bold values indicate MOE less than LOC

2.5.4.2 Paraformaldehyde Vacation Home Treatment Exposures and Risks

The Sun Pac™ product label (EPA Reg. No. 4972-43) indicates that: "When closing home for vacation or season, place one bag for each 700 cubic feet of space. Home will be sunshine fresh, no mildew or musty odor". The label also indicates that: "Use only in unoccupied structures that can be ventilated (6) hours prior to re-occupancy". Depending on how long the house is unoccupied, the emission rate of the Sun Pac™ product and the ventilation rate, the acute formaldehyde air concentrations at re-occupancy might be greater than 62 µg/m^3 which corresponds to an acute MOE that is less than the LOC of 10. If the house is unoccupied for several months during the off season, it is likely that most of the formaldehyde will have been emitted and diffused out of the house by the time it is re-occupied and any remaining formaldehyde will be removed during the 6 hour ventilation period. In this case, it is likely that the air concentrations will be less than 62 µg/m^3 and the corresponding acute MOE would greater than the LOC of 10. If the house is unoccupied for a few weeks during a vacation, only a portion of the formaldehyde will have been emitted and diffused by the time of re-occupancy. In this case, the six-hour ventilation period might not be sufficient to reduce formaldehyde exposures to 62 µg/m^3 and the MOE would be less than 10. The small chamber emissions data that were required for the closet use could also be used to estimate the emission rate for this scenario.

2.6 Residential Bystander Inhalation Exposure from Fumigation Treatments

There is the potential for residential bystander (i.e., individuals outside the treated buildings and beyond any specified buffer zone) inhalation exposures when the formaldehyde product (EPA Reg. No. 8743-17) is used to fumigate facilities such as rooms, feed trucks, and railway cars; hatching eggs; poultry and swine confinement houses; mushroom houses; and citrus packing houses. This product has a buffer zone requirement of 150 ft for buildings less than 100,000 ft^3 and 1,100 ft for buildings up to 1,000,000 ft^3 during aeration. Exposures are expected to be short-term and intermittent based on the labeled uses and application instructions. Continuous exposures are not anticipated.

There is also the potential for inhalation exposure to formaldehyde when the paraformaldehyde product (EPA Reg. No. 4972-43) is used to fumigate: leafcutting bee cells and nesting materials; and government, industrial, commercial, and institutional microbiological laboratory settings, including human and animal research facilities and areas, animal isolation rooms, animal cages, necropsy suites, ancillary equipment, and biological safety cabinets. This product does not have a buffer zone requirement. Exposures are expected to be short-term and intermittent based on the labeled uses and application instructions. Continuous exposures are not anticipated.

A Tier 1 analysis, using EPA's AERSCREEN version 21112 model[3], was conducted to determine if risks were present and if further air modeling refinements were needed. For those uses that were still identified as a risk, a refined outdoor air exposure analysis was conducted using the Probabilistic Exposure and Risk Model for Fumigants (PERFUM v. 3.1[4]). The uses and application rates that were modeled are listed in Table 2-13.

Table 2-13: Fumigation Treatment Uses and Application Rates

EPA Reg. No	Use	% a.i.	Product Density	Product Application Rate (oz /1000 ft^3)	Formaldehyde Application Rate	
					lb a.i. /1000 ft^3	mg/m^3
8743-17	Rooms, Rail cars	37	9.1 lbs/gal	20	0.52	8,300
8743-17	Hatching eggs	37	9.1 lbs/gal	351[A]	9.1	150,000
8743-17	Poultry / swine houses	37	9.1 lbs/gal	60	1.6	26,000
8743-17	Mushroom houses	37	9.1 lbs/gal	19-23[B]	0.49 to 0.60	7,900 to 9,600
8743-17	Citrus packing house	37	9.1 lbs/gal	16	0.42	6,700
4972-43	Bee cells	91	1.0 gm/cm^3	1.1	1.0	16,000
4972-43	Laboratories, equipment, animal areas	91	1.0 gm/cm^3	1.3[C]	1.2	19,000

A. Rate is 2 oz product per 1000 eggs. Assumes eggs are on 34 flats, 1 ft x 1 ft x 2 in (0.17 ft^3), or 5.7 ft^3.
B. Rate ranges from 4 gallons product per 37 ft x 48 ft x 15 ft to 8 gallons product per 37 ft x 80 ft x 15 ft.
C. Rate is 0.6 grams product per cubic foot.

[3] https://www.epa.gov/scram/air-quality-dispersion-modeling-screening-models#aerscreen
[4] https://www.exponent.com/capabilities/probabilistic-exposure-risk-model-fumigants

Uses were modeled as area and/or point sources, as depicted in Table 2-14. Uses were modeled as area sources when the use was typically contained in a room or building, and passive aeration (e.g., no mechanical ventilation) was being used. Uses were modeled as point sources when an aeration rate was specified on the label, and it was likely that mechanical ventilation via a vent (stack) would be used to remove the formaldehyde during aeration. For the paraformaldehyde use for laboratories, equipment, and animal areas, an aeration rate was not specified on the label; as such, the rate provided on the formaldehyde label was used as a surrogate, as 1 air exchange every 2.5 hours was considered a protective estimate.

Table 2-14: Fumigation Treatment Building Sizes Modeled by Use

EPA Reg No	Use	Volumes (ft^3)	Area/Point Source
8743-17	Rooms, feed trucks, rail cars	1,000 – 10,000	Area
8743-17	Hatching eggs	1,000, 2,000	Area
8743-17	Poultry and swine confinement housing	1,000 – 1,000,000	Both
8743-17	Mushroom houses	1,000 – 50,000	Both
8743-17	Citrus packing house	1,000 – 1,000,000	Both
4972-43	Bee cells	1,000, 2,000	Area
4972-43	Laboratories, equipment, animal areas	1,000 – 1,000,000	Both

For area sources, emissions during aeration were modeled as occurring in 1 hour, as a catastrophic release, and over 24 hours, per label instructions. For aeration emissions occurring over a 24-hour period, it was assumed that emissions would occur in an exponential decay fashion (i.e., more mass being released initially, with less mass being released over time), with an air exchange rate of 1 air exchange per 2.5 hours. The air exchange rate was estimated based on an aeration time of 24 hours with the air exchange rate reduced to the initial air concentration to 0.75 ppm (0.92 mg/m^3), according to the label. Hourly emission rates are provided for the various uses in **Appendix G**. For the Tier 1 analysis, the highest hourly flux rate, highest 8-hour average flux rate, and highest 24-hour average flux rate were used to evaluate occupational and residential bystander exposures.

For point sources, emissions during aeration were modeled as occurring in 1 hour, as a catastrophic release, and over 24 hours, per label instructions. It was assumed building downwash would occur (standard assumption) and that emissions would occur in an exponential decay fashion (i.e., more mass being released initially, with less mass being released over time), using an air exchange rate of 20 air exchanges per 12 hours, per the label. Hourly emission rates are provided for the various uses in **Appendix H**. For the Tier 1 analysis, the highest hourly flux rate, highest 8-hour average flux rate, and highest 24-hour average flux rate were used to evaluate occupational and residential bystander exposures. It was assumed that flagpole receptors using a height of 1.5 m were representative of average human height. A rural environment was assumed, where grassland was the dominant surface profile, as it provided the most protective estimates, and employed average moisture and AERMET seasonal parameters for surface roughness length, albedo, and bowen ratio. Minimum and maximum temperatures were set to 250.0 and 310.0 Kelvin (K), respectively, the minimum wind speed was set to

0.5 m/s, and the anemometer height was set to 10 m (all standard model assumptions). The surface friction velocity of the model was adjusted and receptors were modeled out to 5,000 m (all standard model assumptions).

Table 2-15 depicts the building and ventilation dimensions used in the area and point source modeling.

Table 2-15: Building and Stack Dimensions Used in Air Modeling

Building Volume (ft^3)	Building Height (m)	Building Area[1] (m^2)	Side[2] (m)	Vent rate[3] (m^3/sec)	Stack Diameter (m)	Stack Cross Section (m^2)	Stack Exit Velocity[4] (m/s)	Stack Height[5] (m)	Szinit[6] (m)
1,000	3.05	9.3	3.05	0.013	0.3	0.071	0.185	4.0	1.42
2,000	3.66	15.5	3.93	0.027	0.4	0.13	0.209	4.7	1.70
5,000	5.18	27.3	5.23	0.067	0.5	0.20	0.334	6.2	2.41
10,000	7.62	37.2	6.10	0.13	1.0	0.79	0.167	8.6	3.54
25,000	7.62	92.9	9.64	0.33	1.0	0.79	0.417	8.6	3.54
50,000	7.62	186	13.6	0.66	2.0	3.1	0.209	8.6	3.54
100,000	7.62	372	19.3	1.31	2.0	3.1	0.417	8.6	3.54
250,000	15.2	465	21.6	3.28	2.0	3.1	1.04	16.2	7.09
500,000	15.2	929	30.5	6.55	5	19.6	0.334	16.2	7.09
750,000	15.2	1390	37.3	9.82	5	19.6	0.501	16.2	7.09
1,000,000	15.2	1860	43.1	13.1	5	19.6	0.668	16.2	7.09
m^3/sec = cubic meters per second, m/s = meters per second									

1. Area = building volume divided by height
2. Side = square root of building area
3. Ventilation rate = 20 air exchanges in 12 hours (*i.e.,* 1.67 air changes per hour) times building volume
4. Stack exit velocity = vent rate divided by stack cross sectional area, assumed to be a circle
5. Stack height = building height plus 1 m
6. Initial vertical dimension (Szinit) = building height divided by 2.15, for area sources

The results from the AERSCREEN modeling indicated that the 1-hour air concentrations for both area and point source scenarios exceed 62 µg/m^3 and the corresponding acute MOEs were less than 10. Because these MOEs are less than the LOC of 10, the scenarios were further refined using the PERFUM model.

2.7 Modeling Refinements using PERFUM

For the PERFUM modeling, the same building and application rate information from the Tier 1 assessment was used, although hourly emission rates (**Appendix G and Appendix H**) were estimated instead of the highest emission rate. A start time for the aeration of 8 am (Hour 9) was assumed, given that a fumigation event would likely start in the morning, last 24 hours, and the building would be aerated the following morning. Daily meteorological data for Ventura, CA from 2012-2016 was used because this meteorological file has been supplied with the PERFUM model. Prior modeling efforts

conducted by OPP's Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) have indicated that this site is representative of rural areas where a fumigant might be used and results in conservative air exposure estimates.

The acute inhalation MOEs, which are based on the maximum one-hour air concentrations, are provided in Table 2-16 for uses that incorporate passive aeration and in Table 2-17 for uses that incorporate active aeration. The results depicted in the tables reflect the incorporation of a 150 ft buffer zone for buildings less than 100,000 ft^3 and a 1,100 ft buffer zone for buildings greater than 100,000 ft^3 for all uses except for uses of paraformaldehyde in beehives and the laboratory and research facility sites, which do not require buffer zones on the product label. The acute MOEs when passive aeration is used range from 0.1 to 31,000. The acute MOEs when active ventilation is used range from 0.014 to 120. Many of these MOEs are less than the LOC of 10 and are of concern.

Table 2-16. Acute Inhalation MOEs for Uses with Passive Aeration*

Use	Beehive		Egg fumigation		Rooms and Railcars			
Building size (ft^3)	1000	2000	1000	2000	1000	2000	5000	10,000
Percentile	Acute Inhalation MOEs (based on the maximum 1-hour air concentrations)							
75	620	310	78	41	1200	770	310	310
90	21	11	**2**	**1**	41	21	**9**	**6**
95	15	**8**	**2**	**1**	28	15	**7**	**4**
Use	Citrus Packing Houses				Poultry and Swine Confinement Houses			
Building size (ft^3)	1000	10,000	100,000	1 million	1000	10,000	100,000	1 million
Percentile	Acute Inhalation MOEs (based on the maximum 1-hour air concentrations)							
75	1600	600	31000	780	620	120	6900	210
90	52	**7**	28	**3**	13	**2**	**7**	**1**
95	36	**5**	16	**2**	10	**1**	**4**	**1**
Use	Mushroom Houses				Laboratories, equipment, and animal areas			
Building size (ft^3)	1000	5000	10,000	50,000	1000	10,000	100,000	1 million
Percentile	Acute Inhalation MOEs (based on the maximum 1-hour air concentrations)							
75	1200	310	310	48	23	160	4	2
90	34	**8**	**5**	**1**	**1**	**2**	**0.2**	**0.1**
95	25	**6**	**3**	**1**	**1**	**1**	**0.1**	**0.1**

*MOEs reflect a 150 ft buffer zone for buildings less than 100,000 ft^3 and a 1,100 ft buffer zone for buildings greater than 100,000 ft^3 for all uses except for the paraformaldehyde uses to beehives and laboratories and equipment, and animal areas, which has no buffer requirements on the label. The MOEs highlighted in **bold** are less than the LOC of 10.

Table 2-17: Acute Inhalation MOEs for Uses with Active Aeration*

Use	Citrus Packing Houses				Poultry and Swine Confinement Housing			
Building size (ft^3)	1000	10,000	100,000	1 million	1000	10,000	100,000	1 million
Percentile	Acute Inhalation MOEs (based on the maximum 1-hour air concentrations)							
75	120	18	100	13	34	**5**	28	**3**
90	28	**4**	14	**2**	**7**	**1**	**4**	**0.48**
95	15	**2**	**7**	**0.98**	**4**	**0.52**	**2**	**0.26**
Use	Mushroom Houses				Laboratories, equipment, and animal areas			
Building size (ft^3)	1000	5000	10,000	50,000	1000	10,000	100,000	1 million
Percentile	Acute Inhalation MOEs (based on the maximum 1-hour air concentrations)							
75	89	22	12	**3**	**3**	**0.28**	**0.068**	**0.052**
90	20	**4**	**3**	**0.70**	**0.77**	**0.11**	**0.031**	**0.020**
95	11	**2**	**1**	**0.31**	**0.56**	**0.091**	**0.024**	**0.014**

* MOEs reflect a 150 ft buffer zone for buildings less than 100,000 ft^3 and a 1,100 ft buffer zone for buildings greater than 100,000 ft^3 for all uses except for the paraformaldehyde uses to laboratories and equipment, and animal areas, which has no buffer requirements on the label. The MOEs highlighted in **bold** are less than the LOC of 10.

Use of paraformaldehyde for beehives and laboratory and research facility sites requires that after treatment, the formaldehyde gas needs to be neutralized by heating ammonium carbonate or bicarbonate to generate ammonia gas. However, it is unclear how much formaldehyde remains after neutralization and is subsequently released into the atmosphere during aeration. As such, the MOEs reported above reflect no neutralization and should be considered upper bound estimates.

MOEs presented in Table 2-16 and Table 2-17 above reflect the concentrations at the relevant buffer distance (150 or 1100 ft) for the building size, or no buffer for paraformaldehyde use (laboratories). Formaldehyde concentrations decline with increased distance from the treated facility. Figure 2-8 and Figure 2-9 below reflect 95th percentile concentrations from poultry/swine confinement building fumigation employing active aeration for building sizes from 1000 to 50,000 ft^3 (Figure 2-8) and 100,000 to 1 million ft^3 (Figure 2-9) with the appropriate buffer zone and the concentration where the acute MOE is equal to the LOC (62 $\mu g/m^3$) reflected on the graph. Required distances from the fumigation buildings for exposure concentrations to drop below 62 $\mu g/m^3$ for all registered uses range from 46 to 438 m for smaller building sizes and 280 to > 1,500 m for larger buildings. Tabulated results for all building size PERFUM runs and figures for additional uses are provided in Appendix I.

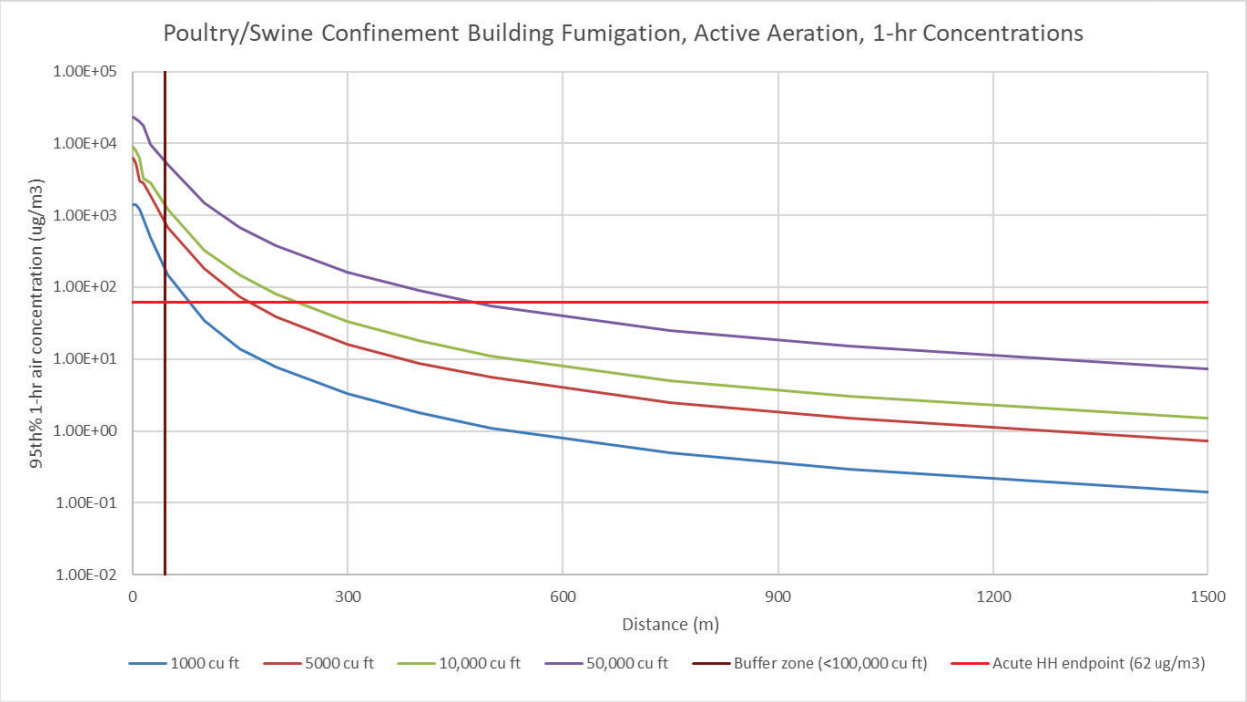

Figure 2-8: One hour air concentrations of formaldehyde with increasing distance after fumigation of poultry and swine confinement buildings (1,000 to 50,000 cu ft).

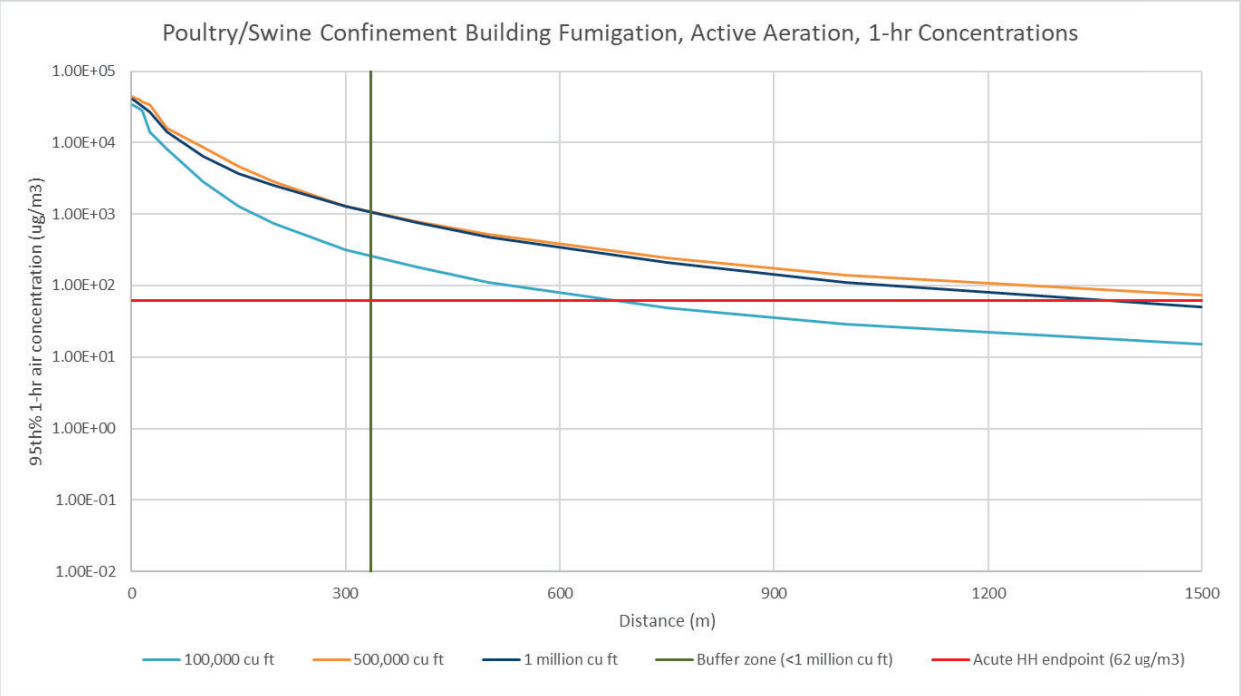

Figure 2-9: One hour air concentrations of formaldehyde with increasing distance after fumigation of poultry and swine confinement buildings (100,000 to 1 million cu ft).

Modeling Assumptions and Uncertainties

The assessment presented above for the fumigation uses is based on numerous assumptions, which may or may not be representative of application scenarios and conditions commonly found in the environment. The major assumptions and uncertainties include the following:

- Modeling was conducted assuming there was no leakage of formaldehyde during treatment, such that the concentration in the treated room at the start of aeration, and the release of formaldehyde, was the same as the initial application of formaldehyde. As most building have natural leakage, the emissions during aeration are considered overestimates.
- Modeling was conducted assuming there were no pollution control devices attached to the ventilation units, such that there was no reduction of emissions during aeration. Ventilation units at laboratories may contain filters and scrubbers to ensure harmful emissions do not occur. In these cases, the emissions during aeration are considered overestimates.
- Generic building dimensions (e.g., height, width, and length) were assumed during the modeling and may not represent actual building parameters. It is uncertain how this impacts the air concentrations.
- OPP evaluated a single application occurring to a facility. If multiple facilities at the same location are being treated simultaneously, modeled air concentrations may be underestimated.
- Formaldehyde has a photodegradation half-life of 1.4 to 4 hours in sunlight. While 1-hour concentrations were evaluated, the estimated concentrations may be 16-40% higher than expected.
- PERFUM modeling for facilities employing mechanical ventilation only permits the use of a single stack release. While this may be true for small buildings, larger buildings will probably employ multiple stacks. It is uncertain how this impacts the air concentrations.
- The highest aeration release was modeled to occur early in the morning when turbulence and mixing are low. If aeration were to begin later in the day, turbulence and mixing are expected to be higher, resulting in lower ground level air concentrations.
- Stacks were modeled approximately 1 m above the building height. Larger stack heights will result in greater release heights, increased mixing, and lower ground level air concentrations.

2.8 Aggregate Exposure/Risk Characterization

The toxicological effects of oral, dermal, and inhalation formaldehyde exposures are route-specific and therefore cannot be aggregated. In addition, the dermal exposures cannot be aggregated for the use of different consumer products, because they are based on the concentration of the product and would not increase if multiple products were handled on the same day. Aggregate exposure to formaldehyde via the inhalation route, however, could potentially occur from residential use of formaldehyde-containing detergent, general purpose cleaner, car interior cleaner and air freshener as well as bystander exposures from the fumigation uses. As noted from the residential risk assessment in this document, some of these exposure scenarios individually have non-cancer risks of concern from

inhalation. Measures to reduce exposure from each of these sources to meet acceptable MOEs is required in order that an aggregate risk be considered acceptable. In addition, aggregate inhalation exposure may occur from the use of consumer products that are preserved with EPA registered material preservative pesticides that degrade to or release formaldehyde. These pesticides are listed in Table 2-18.

Table 2-18: Pesticides that Release or Degrade to Formaldehyde that Have Residential Uses

Chemical Name	Number of End Use Products	Residential Uses
Azadioxabicyclooctane	1	Paints
Bronopol	60	Paints Cleaners Laundry Detergents
Glycine, N-(hydroxymethyl)-monosodium salt (SHMG)	1	Paints Cleaners Laundry Detergents
HHT (Grotan)	16	Paints Cleaners Laundry Detergents
Hydroxymethydimethylhydantoins	18	Paints Cleaners Laundry Detergents
Methyloxazolidines (DMO)	3	Paints Cleaners Laundry Detergents

The general population may be also exposed to formaldehyde from sources that are unrelated to the EPA-registered pesticide uses (see Section 1.8). As listed in Table 3-2 of the Draft Indoor Air Exposure Assessment for Formaldehyde (US EPA, 2024f), there are a variety of studies of formaldehyde air concentrations measured in homes, travel trailers and mobile homes. The American Healthy Home Survey II (AHHS II), which is a formaldehyde residential indoor air monitoring survey, represents the most recent and relevant high-quality American residential indoor dataset for formaldehyde. The AHHS II was the first nationally representative study of formaldehyde concentrations in indoor air from U.S. homes and was sponsored by the U.S. Department of Housing and Urban Development (HUD) along with EPA (QuanTech, 2021).

The AHHS II was conducted from March 2018 through June 2019 and measured household levels of lead, lead-based paint hazards, pesticides, formaldehyde, and mold in American homes. The survey was conducted in 78 cities and counties across 37 states. Approximately 800 homes were randomly selected in these areas to participate in the survey. The final sample size for formaldehyde-specific

indoor air sampling was 688 homes. These represent homes that were lived in permanently, rather than temporary dwellings (QuanTech, 2021).

Indoor air concentrations of formaldehyde were measured as 3-to-4-hour samples and the air concentrations generally ranged from 12 to 40 µg/m^3 with a maximum of 124 µg/m^3. This sample represents the indoor air concentration of formaldehyde in the most used room in the home. Statistical weights reported in the AHHS II data were applied, which reduce sampling bias to produce a more nationally representative distribution of concentration values. A summary of the AHHS II monitoring data is included in Table 2-19.

Table 2-19: Summary of the AHHS II Formaldehyde Monitoring Data (µg/m^3)

Number of Homes	Minimum	10th Percentile	Median	90th Percentile	Maximum
688	0.27	7.54	19.8	41.8	124

If the adult lifetime average daily concentration (ALADC) of 2.6 µg/m^3 for the general-purpose cleaner use is added to the ALADC of 0.010 µg/m^3 for the car cleaning use in a garage, the combined ALADC is 2.61 µg/m^3. This is less than the 10th percentile value of 7.54 ug/m^3 measured in the AHHS study. This suggests that the material preservative uses are a minor contributor to the overall aggregate exposure and associated risks.

2.9 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to formaldehyde and paraformaldehyde and any other substances. For the purposes of this action, therefore, EPA has not assumed that formaldehyde and paraformaldehyde have a common mechanism of toxicity with other substances. In 2016, OPP released a guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* [https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs)[5] and conducting cumulative risk assessments (CRA)[6]. Formaldehyde and paraformaldehyde have not been classified in a group for screening. At this time, EPA does not expect any exposures from other pesticides or substances that would warrant screening

[5] *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (EPA, 1999)
[6] *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (EPA, 2002)

with the framework. As a result, EPA concludes that formaldehyde and paraformaldehyde do not have a common mechanism of toxicity with other substances that contribute to the risk assessment. If other pesticides are registered that have the potential to be screened with formaldehyde and paraformaldehyde, EPA will use the framework to examine the potential for a common mechanism of toxicity and the potential for cumulative risk as part of the ongoing registration review process.

2.10 Occupational Hander Exposure/Risk Characterization

2.10.1 Occupational Handler Exposures for Mixing, Loading, and Fumigation Uses

The term "handler" applies to individuals who mix, load, and apply pesticide products. There are six occupational handler exposure scenarios that involve formaldehyde products. These scenarios are listed below:

1. Mechanical and Steam Fumigation
2. Evaporative Fumigation
3. Catalyzed Evaporative Fumigation
4. Material Preservation
5. Oil Production Injection Water Treatment
6. Daffodil and Iris Bulb Dipping

Occupational Handler Exposure Assessment Rationale

Similar to the residential handler exposure assessment above, because formaldehyde has a high vapor pressure and exists as a vapor or gas, the unit exposure data from the AEATF II are not applicable.

Although there are many studies of formaldehyde occupational exposures reported in the literature, these studies involved the non-pesticidal uses and there is very little information concerning exposures from the pesticidal uses. Because of this, formaldehyde specific inhalation exposure data were recommended to be required in the Final Work Plan. As discussed previously, these data requirements were included in the GDCI; however, no relevant data[7] were submitted to the Agency and the inhalation exposure data remain gaps. Since it is not possible to quantitatively assess the formaldehyde exposures that result from the pesticidal uses covered by Scenarios 1 through 6, these scenarios were assessed qualitatively based upon work practices listed on the labels.

Occupational Inhalation Exposure Risk Target for Non-Cancer Effects

[7] MRID 46875901 is a study of formaldehyde air concentrations measured near a dairy barn footbath. It was cited in response the GDCI; however, it is not relevant to the currently registered uses of formaldehyde. It was submitted in 2004 to support EPA registration of a foot bath use. The use was not registered because it is regulated by the FDA.

The formaldehyde concentrations at which the non-cancer inhalation risk equals the LOC for the MOE (i.e., the RfCs) were calculated as shown in Table 2-20. The RfCs are 0.050 ppm for acute exposures and 0.024 ppm for lifetime exposures. If the formaldehyde exposures do not exceed these RfCs, the risks are not of concern.

Table 2-20: Occupational Inhalation RfCs Associated with Non-Cancer Risks

Exposure Duration	Point of Departure[A]	LOC for the MOE[A]	RfC[B]
Acute (15-minute Peak Exposure)	0.50 ppm (0.62 mg/m^3)	10	0.050 ppm (0.062 mg/m^3)
Long-term (8-hour Average Exposure)	0.071 ppm (0.088 mg/m^3)	3	0.024 ppm (0.029 mg/m^3)

A. From Table 2-3.

B. RfC = POD / LOC for the MOE

Occupational Inhalation Exposure Risk Targets for Cancer

The cancer risk target of 1 x 10^{-4} is normally used by OPP as a risk management goal for occupational exposures. The formaldehyde concentration at which the cancer risk equals 1 x 10^{-4} was calculated from the inhalation unit risk for adults as shown in Table 2-21. This calculation indicates that if the formaldehyde exposure does not exceed 98 ppb (120 µg/m^3) as an 8-hour TWA, the lifetime cancer risk from occupational inhalation exposure will not exceed 1 x 10^{-4}.

Table 2-21: Occupational Exposures Associated with a Cancer Risk of 1 x 10^{-4}

Cancer Risk Target	8-hr TWA (ppb)	8-hr TWA[A] (µg/m^3)	Hours per Day	Days per Year	Years per Lifetime	ALADC[B,C] (µg/m^3)	Cancer Risk[D]
1 x 10^{-4}	98	120	8.0	240	35	16	1 x 10^{-4}

A. 8-hr TWA (µg/m^3) = 8-hr TWA (ppm) * 1.23 mg/m^3 per ppm * 1000 µg/m^3 per mg/m^3.

B. ALADC = Adult Lifetime Average Daily Concentration based on 60 years of adulthood in a 78-year lifespan.

C. ALADC = 8-hr TWA (µg/m^3) * (8 hrs exposure per day/24 hrs) * (240 days exposure per year/365 days) * (35 years/60 years)

D. Cancer Risk = ALADC (µg/m^3) * Inhalation Unit Risk for Adult Lifetime Exposure (6.4 x 10^{-6} per µg/m^3)

2.10.1.1 Occupational Handler Risk Assessment for Mixing, Loading, and Fumigation Uses

Mechanical and Steam Fumigation

The formaldehyde product (EPA Reg. No. 8743-17) has instructions for mechanical and steam fumigation of large areas including Poultry and Swine Confinement Buildings, Mushroom Houses, and Citrus Packing Houses. This fumigation is accomplished by mechanical methods such as sprinkler application, spray sled application, steam injection or spray manifold application. Mixer/Loader dermal and inhalation exposures are expected to be of low risk because the label requires that formaldehyde solutions be transferred to the mixing tank through a closed system.

Applicator inhalation and dermal exposures are also expected to be of low risk because the product labels require that all applications should be carried out and controlled from outside the area being fumigated.

Evaporative Fumigation of Hatching Eggs

The formaldehyde product (EPA Reg. 8743-17) has instructions for evaporative fumigation of incubators and hatchers. This fumigation is accomplished by pouring the formaldehyde solution into a pan at a rate of 2 fluid ounces per 1,000 eggs and allowing it to evaporate. Handler dermal and inhalation exposures only occur during the brief period that the solution is poured into the pan.

Handler inhalation exposures during application are expected to be of low risk because the product labels require that incubators be ventilated to the outside and that the incubator room also have adequate ventilation. If this ventilation is designed correctly, the incubator will be under slight negative pressure such that the formaldehyde vapors will not migrate into occupied areas. The label also states that the last application should be conducted at least 12 hours prior to chick pulling so that the pan contents will be completely evaporated before the incubator is opened to remove the chicks. In addition, the label requires handlers wear a full-face respirator with a formaldehyde cartridge, which will further reduce potential exposures.

Although the label requires PPE such as chemical resistant gloves, handler dermal exposures could be of concern because this PPE does not eliminate the potential for exposures as the product is poured into the pan. While dermal exposures could not be modeled for occupational handlers, the concentration in the formaldehyde product is 370,000 ppm a.i. (i.e., 37%) which is orders of magnitude higher than the concentration (97 ppm a.i.) below which effects would not be expected for unprotected hands. The required chemical resistant gloves will reduce hand exposures by a factor of ten, but it is not known if this reduction is sufficient to prevent dermal sensitization which can be caused by localized contact.

Catalyzed Fumigation of Fumigating Rooms and Railcars

The formaldehyde product (EPA Reg. 8743-17) has instructions for catalyzed fumigation which is similar to evaporative fumigation with the exception that potassium permanganate ($KMnO_4$) is added to catalyze the release of formaldehyde gas. The application rate is 16.6 ounces of $KMnO_4$ and 20 ounces of formaldehyde per 1,000 cubic feet which yields a formaldehyde air concentration of 6,780 ppm. The label indicates that the application is made by pouring the formaldehyde solution into a small pan containing $KMnO_4$ and leaving the area immediately. The handler inhalation exposures for this application may be significant depending upon how long it takes the handler to exit the treatment

area and how quickly the formaldehyde gas is released; therefore, risks of concern cannot be precluded. Additional data on potential inhalation exposure from this use, as required in the GDCI, would help refine this risk conclusion.

Although the label requires PPE such as chemical resistant gloves, handler dermal exposures could be of concern because this PPE does not eliminate the potential for exposures as the product is poured into the pan. As discussed above for evaporative fumigation, the concentration in the formaldehyde product is orders of magnitude higher than the concentration below which effects would not be expected for unprotected hands. The required chemical resistant gloves will reduce hand exposures by a factor of ten, but it is not known if this reduction is sufficient to prevent dermal sensitization which can be caused by localized contact.

Material Preservation

The formaldehyde product (EPA Reg No. 8743-17) includes in-container preservation for industrial and household consumer products. The formaldehyde product is added to the consumer product during the final stage of production to prevent product spoilage during shipping and storage. The label indicates that the use range is 0.037 to 370 ppm a.i. in the material that is being preserved. The label does not specify if closed system transfer is required. Mixer/Loader dermal and inhalation exposures could be of significant risk if the product is open poured into the material that is being preserved. Additional data on potential inhalation exposure from this use, as required in the GDCI, and details on how the product is applied would help refine this risk conclusion.

Oil Production Injection Water Treatment

There is one product (EPA Reg No. 10707-43) that is used to treat injection water. The application rate ranges from 200 to 5,000 ppm a.i. The product label specifies that closed delivery systems must be used and therefore handler dermal and inhalation exposures are expected to be minimal.

Daffodil and Iris Bulb Dipping Special Local Need (SLN) Registration

As mentioned previously, there is a SLN registration (WA20003) for the use of EPA Reg No. 8743-17 to treat ornamental bulbs in Washington State. This product is mixed at the rate of 2 fluid ounces per gallon to yield a solution containing 0.5% formaldehyde (5,000 mg/liter). The bulbs are dipped and soaked for three to four hours in a tank that is maintained at a temperature of 110 to 111°F, which may increase the potential for inhalation exposure since higher temperatures favor release of formaldehyde gas. The size of the tanks is not mentioned in the SLN, but the directions that the spent dip-tank treatment water may be applied to bulb fields at a rate of no more than 21,000 gallons of dip-tank solutions per acre per year suggests that the tank is quite large. Inhalation exposures could be quite high if the bulb dip treatment is done in a poorly ventilated space. Although the label requires

PPE such as chemical resistant gloves and use of a full-face respirator, handler dermal and inhalation exposures could be of concern because this PPE does not eliminate the potential for exposures. More information on how and where this use is applied will be needed to further refine OPP's risk conclusion from this use.

2.10.2 Occupational Exposure to Cleaning Products Preserved with Formaldehyde

There is the potential for occupational dermal and inhalation exposure to cleaning products that are preserved with formaldehyde. The exposure scenarios include housekeepers using general purpose spray cleaners, commercial or institutional laundry workers using laundry detergent and automotive detailing workers.

Dermal Exposures

The dermal exposures are the same as those assessed for consumers in Section 2.6.1 because exposures are based on the concentration of the product being used rather than the frequency and duration of use. At the maximum application rate of 370 ppm, the dermal MOE of 26 for induction of skin sensitization is of concern because it is less than the LOC of 100 and the dermal MOE of 2.8 for elicitation of skin sensitization is of concern because is it less than the LOC of 10. At the application rate of 97 ppm, the dermal MOEs of 100 for induction and 10 for elicitation are equal to the respective LOCs of 100 and 10 and are not of concern.

Inhalation Exposures

The inhalation exposures for consumers were calculated using the Consumer Exposure Model (CEM) Version 3.2. This model is designed to assess consumer exposures and cannot be readily modified to assess occupational exposures because it does not allow for multiple applications per day. Despite this limitation, the model results provide information that can be used to characterize occupational exposures. This characterization is provided below:

- **Housecleaner Exposure Using General Purpose Cleaners** – A housekeeper that cleans houses or hotel rooms would clean multiple houses or rooms per day. The peak 15-minute exposure for each house or room would likely be equal to or greater than the peak 15-minute exposure of 120 $\mu g/m^3$ that was calculated using CEM. The acute MOE for this exposure is 5.2 which is of concern because it is less than the LOC of 10. The actual acute MOE for a housekeeper would likely be lower. The long-term exposure and cancer risks would also be greater for housekeepers based on the larger number of rooms that they would clean per day.

- **Laundry Worker Exposure Using Laundry Detergent** – Although a laundry worker would use more laundry detergent per load and would run more loads per day than a consumer, the peak 15-minute exposure would be the same as for consumers (25 ug/m^3, Table 2-5) because it is based on the same Henry's Law Constant and wash water concentration. As shown in Table 2-5, this peak concentration corresponds to an MOE of 25 which is not of concern.
- **Automotive Detailing Workers** – An automotive detailing worker would clean multiple cars per day and each car would be cleaned using professional grade equipment. The peak 15-minute exposure for each car would likely be equal to or greater than the peak 15-minute exposure of 46 µg/m^3 that was calculated using CEM due to the more intensive cleaning that is done. The acute MOE for consumer exposure is 13 which was not of concern because it is greater than the LOC of 10. The actual MOE for the automotive interior detailer would likely be lower than the LOC of 10. The long-term exposure and cancer risks would also be much greater based on the larger number of automobiles that they would clean per day and year.

2.11 Occupational Post-Application Exposure to Formaldehyde

There is the potential for occupational post-application inhalation exposure to formaldehyde when workers reenter areas that have been treated.

2.11.1 Fumigation of Buildings

Formaldehyde is used for fumigating buildings used for poultry and swine confinement, mushroom houses, and as citrus facilities. The label requires aeration for a certain time interval or number of air changes. The label also requires that reentry not be allowed until formaldehyde levels decrease to 0.75 ppm as determined using an OSHA approved method. Inhalation exposures to these reduced levels can occur after fumigating when the workers re-enter the treated area. Exposures are expected to be short-term and intermittent based on the labeled uses and application instructions. Continuous exposures are not anticipated.

An inhalation exposure assessment was conducted for active aeration using the single chamber decay formula from the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). This assessment was based upon the application parameters listed in the formaldehyde product label (EPA Reg No. 8743-17). The following assumptions were made:

- The application rate is 60 ounces per 1,000 cubic feet (ft^3) based upon the maximum rate listed on the label for Use in Fumigation of Poultry and Swine Confinement Buildings.
- The application rate in terms of a.i. is 1.56 lb ai per 1,000 ft^3 based upon the following: (60 fluid oz applied per 1,000 ft^3 / 128 fluid oz per gallon) x (9.0 lb per gallon * 37% ai)
- The initial concentration is 25,000 mg/m^3 (20,300 ppm) based upon the following: (1.56 lb ai * 454,000 mg per lb) / (1000 ft^3 * 0.0283 m^3 per ft^3)

- All openings such as windows and doors are closed, and the ventilation system is turned off during the application of the fog.
- After the fog has been applied and given time to penetrate, the ventilation system is activated.
- The area is ventilated for a minimum of 20 air changes and 12 hours based on the label. This is equivalent to 1.67 air changes per hour for 12 hours.

An inhalation exposure assessment was conducted for passive aeration using the same initial air concentration (20,300 ppm) as is used for active aeration above and assuming that reentry does not occur until formaldehyde air concentrations have declined to 0.75 ppm.

The formaldehyde exposures and risks for formaldehyde building fumigation are included in Table 2-22. If active aeration is used, the air concentration declines to 0.05 ppm in 465 minutes. The acute MOE at 0.05 ppm is 10, equal to the LOC of 10 which means the risk is not of concern. The acute MOE is 12,000 when the building is actively aerated for 20 air changes and 12 hours as required by the label. If the building is passively aerated until air concentrations reach 0.75 ppm, the acute MOE is 0.67 which is of concern.

Table 2-22: Inhalation Exposures and Risks for Formaldehyde Building Fumigation

Initial Air Concentration (ppm)	Aeration Type and Rate	Aeration Time (minutes)	Air Concentration after Aeration (ppm)	Acute MOE[F] (LOC = 10)
20,300[A]	Active – 1.67 ACH[B]	465[D]	0.05	10
	Active – 1.67 ACH[B]	720[B]	0.000041	12,000
	Passive[C]	1440	0.75[E]	**0.67**

A. Based on 60 fluid ounces of EPA Reg No. 8743-17 per 1000 ft^3. Product contains 37% a.i. and has a density of 9.0 lbs/gal.
B. If mechanical ventilation is used, label requires 20 air changes and 12 hours which equals 1.67 air changes per hour (ACH).
C. If no mechanical ventilation is used, label requires a minimum of 24 hours (1440 minutes) of aeration. Passive aeration was modeled using an air exchange rate of 0.4 air exchanges per hour in order to achieve an air concentration of 0.75 ppm at 24 hours. However, if the air exchange rate is less than 0.4 ACH, then the air concentration will be higher than 0.75 ppm.
D. This is the time needed to get down to 0.05 ppm assuming an air exchange rate of 1.67 air changes per hour.
E. The label requires that reentry not be allowed until the air concentration is 0.75 ppm.
F. MOE = Acute POD (0.5 ppm) / Air Concentration (ppm). MOEs highlighted in **bold** are less than the LOC of 10.

2.11.2 Fumigation of Rooms and Railcars

The formaldehyde product (EPA Reg. No. 8743-17) is used for fumigating rooms and railcars using potassium permanganate ($KMnO_4$) to catalyze the release of formaldehyde gas. The following assumptions were made to assess post application exposures:

- The application rate is 20 ounces of formaldehyde per 1,000 ft^3.
- The application rate in terms of a.i. is 0.52 lb a.i. per 1,000 ft^3 based upon the following: (20 fluid oz applied per 1,000 ft^3 / 128 fluid oz per gallon) x (9.0 lb per gallon * 37% a.i.)
- The initial concentration is 8,340 mg/m^3 (6,780 ppm) based upon the following: (0.52 lb a.i. * 454,000 mg per lb) / (1000 ft^3 * 0.0283 m^3 per ft^3)

- The room is ventilated until the air concentration is 0.75 ppm.

The formaldehyde exposures and risks for rail car and room fumigation are included in Table 2-23. The acute MOE is 0.67 which is less than the LOC of 10 and is of concern.

Table 2-23: Inhalation Exposures and Risks for Formaldehyde Railcar/Room Fumigation

Initial Air Concentration (ppm)	Aeration Time (minutes)	Air Concentration (ppm)	Acute MOE[C] (LOC = 10)
6,780[A]	Unknown[B]	0.75	**0.67**

A. Based on 20 fluid ounces of EPA Reg No. 8743-17 per 1000 ft^3. Product contains 37% a.i. and has a density of 9.0 lbs/gal.

B. The label indicates that the room or railcar should be ventilated until the air concentration drops to 0.75 ppm.

C. MOE = Acute POD (0.5 ppm) / Air Concentration (ppm) The MOEs highlighted in **bold** are less than the LOC of 10.

2.12 Occupational Exposures to Paraformaldehyde

The paraformaldehyde product (EPA Reg. No. 4972-43) can be used to fumigate/sterilize/ decontaminate laboratories and laboratory equipment in sealed enclosures. This is accomplished by heating the product on an electric heating device or generator until it is depolymerized to release formaldehyde gas. The enclosure is then kept sealed for at least 10 hours to allow for the exposed surfaces to be sterilized and/or decontaminated. After the 10-hour contact time, a measured amount of ammonium carbonate or bicarbonate is heated in the enclosure to neutralize the formaldehyde. The enclosure is then aerated until the formaldehyde levels, as measured using a Draeger detection tube with a formaldehyde activation tube or comparable device and method, are less than 0.1 ppm. Exposures are expected to be short-term and intermittent based on the labeled uses and application instructions. Continuous exposures are not anticipated.

The following assumptions were made to assess post application exposures:

- The application rate is 0.6 grams of paraformaldehyde per cubic foot of space to be treated. This is equivalent to 21,200 mg/m^3 (17,300 ppm) of formaldehyde gas.
- The formaldehyde is neutralized, and the enclosure is ventilated until the air concentration is 0.10 ppm.

The formaldehyde exposures and risks for paraformaldehyde enclosure fumigation are included in Table 2-24. The acute MOE is 5.0 which is less than the LOC of 10 which means the risk is of concern.

Table 2-24: Inhalation Exposures and Risks for Paraformaldehyde Enclosure Fumigation

Initial Air Concentration (ppm)	Aeration Time (minutes)	Air Concentration (ppm)	Acute MOE[C] (LOC = 10)
17,300[A]	Unknown[B]	0.10	**5.0**

A. Based on 0.6 grams of product per cubic foot. Product contains 91% a.i.

B. The label indicates that the enclosure should be ventilated until the air concentration drops to 0.10 ppm.
C. MOE = Acute POD (0.5 ppm) / Air Concentration (ppm)

2.13 Human Health Incidents

OPP Incident Data System

There are no individual incidents listed in the OPP Incident Data System for the five-year period from 2/6/2019 to 2/6/2024, when the data system was queried, that relate to the FIFRA registered uses of formaldehyde.

2.14 Risk Characterization

Inhalation of formaldehyde for a short period of time can cause sensory irritation such as eye irritation. Inhaling formaldehyde for longer periods of time can damage the lungs and increase asthma and allergy-related conditions, sensory irritation, reproductive toxicity, and cancer. Skin contact with products containing formaldehyde can also cause allergic reactions. Risks were identified for several exposure scenarios associated with the pesticidal uses of formaldehyde, primarily from acute inhalation and dermal exposure. Acute inhalation and dermal risks were identified for the general-purpose cleaner scenario for residential handlers and bystanders, which represents several uses of formaldehyde as an in-can preservative (see Table 2-2). Only dermal risks were identified for the representative laundry, hand cleaner, and automotive car care uses for residential handlers. Acute and chronic inhalation and dermal risks for occupational handlers from in-can preservative uses were also identified. Paraformaldehyde uses in home closets can result in acute and chronic risks based on inhalation. Risks due to fumigation with formaldehyde and paraformaldehyde for occupational handlers and bystanders from acute inhalation were also identified. Lastly, risks associated with the SLN bulb dip use could not be precluded based on the available data. There are several factors that should be considered when interpreting the results of the human health risk assessment as discussed below.

Inhalation Risks

Acute inhalation risks were identified for both residential and occupational exposures to formaldehyde and paraformaldehyde. These acute effects are based on several controlled exposure studies in humans where sensory irritation (mild to moderate eye irritation) was observed over short exposure periods. This endpoint is expected to be protective of other acute exposure effects (e.g., nasal and throat irritation, reduced nasal mucociliary flow, conjunctival redness, etc.) observed in the toxicity database.

This acute endpoint is treated as a threshold value, where exceedance of the value for any duration will elicit the effect. This is based on review of the sensory irritation effects of formaldehyde, which appear to be more responsive to the exposure concentration than to exposure duration and may not adhere to Haber's law (Shusterman, 2006; HSRB, 2023). For comparison to indoor exposure modeling, the acute endpoint is assessed against a 15-minute peak exposure duration. While there are uncertainties associated with comparing a 15-minute average exposure to a peak/threshold effect, changes in exposure times have relatively minor impacts on exposure concentration. For example, considering the antimicrobial uses of formaldehyde in consumer products such as cleaners, changes in the assumed exposure times from 10 to 30 minutes have minimal impact on risk conclusions due to only minor differences in exposure concentrations over this duration (range from 98 to 99 ug/m^3). This rationale is consistent with the Acute Exposure Guideline Limits (AEGL) for formaldehyde, which are the same for exposures ranging from ten minutes to 8 hours, as well as the World Health Organization (WHO) guideline for exposure based on a 30-minute peak (U.S.EPA, 2024c, Table Apx A-1).

Exposure assumptions made in the models for indoor air exposures can impact risk conclusions, particularly regarding the chemical properties of formaldehyde and model parameterization. Residential handler and bystander inhalation exposures from consumer products were modeled using the CEM or the SWIMODEL inhalation formula. CEM, used for the general-purpose cleaner and automotive interior cleaner handler scenarios, utilizes the vapor pressure of formalin in the model to predict volatilization from the cleaner. However, once formaldehyde interacts with water, the potential for volatilization drops and would be better reflected by the use of Henry's Law Constant, which would predict lower inhalation exposures; CEM does not allow for the incorporation of the Henry's Law Constant. The use of exposure through cleaners may occur with or without product interactions with water, so both of these scenarios are appropriate, and the use of the vapor pressure for modeling is risk protective. The SWIMODEL was used for the laundry detergent scenario as this model uses the Henry's Law Constant for formaldehyde, which is more relevant for laundry detergent based on the short time until the product interacts with water for this use pattern. The SWIMODEL likely overestimates predicted exposure as the equation reflects the concentrations just above the water surface and does not account for ventilation or the rapid conversion of formaldehyde to methylene glycol in water; however, no inhalation risks were predicted even under these conservative assumptions.

Model exposure assumptions were also necessary based on the lack of available exposure data. As discussed in Section 2.1, data was requested to better estimate indoor air exposures, including small chamber emissions studies. In the absence of this data, EPA made conservative health protective assumptions in the analysis. These conservative assumptions can impact risk conclusions for acute and chronic (non-cancer and cancer) risks. In particular, risks associated with the paraformaldehyde closet use are conservative because the emission rate of paraformaldehyde is unknown as well as the duration and frequency with which someone might treat closets in occupied homes. Additionally, for some uses, including some occupational uses and the SLN bulb use, only qualitative analyses could be

completed due to the lack of data to perform a reliable quantitative assessment. In some cases, this resulted in risk assumptions or the inability to preclude risk.

Outdoor air exposure due to fumigant uses were modeled using PERFUM. As these exposures are considered short term and intermittent in nature, exposures were compared to acute exposure endpoints. For each fumigation scenario, a single treatment and aeration event was modeled. As such, there is uncertainty if some of the fumigation uses are used more frequently and present a more chronic exposure scenario. However, given that changes in meteorological conditions (e.g., turbulence, wind direction, etc.) should result in lower exposure concentrations when averaged over a longer period of time, the analysis based on acute risks is expected to be protective of chronic risks. The acute endpoint, which is based on a peak/threshold value, was compared to a one-hour average concentration from PERFUM based on the time step of the model output. While there are uncertainties in comparing the threshold value to a one-hour exposure concentration, it is not possible to compare it to a shorter exposure duration based on model limitations. Uncertainties associated with PERFUM modeling include the amount and timing of the formaldehyde release, the number of facilities being treated in a day, and specific building parameters such as size, as described in Sections 2.7 and 2.8 above.

Dermal Risks

Dermal exposure risks were identified for both residential and occupational exposures to formaldehyde. The established endpoints for dermal risk are based on skin sensitization and are expected to be protective of other potential effects, including irritation. The elicitation endpoint is based on results from occluded (i.e., covered) human patch tests, which may not be representative of exposures from the pesticidal uses of formaldehyde. The non-occluded patch tests and repeated open application test (ROAT) in the same study, which may better represent the pesticidal uses of formaldehyde, did not show definitive reactions for sensitization, although there were some follicular reactions observed that may be an allergic response. However, the dermal endpoint is supported with data from LLNA studies and in vitro data that align with the POD from the human patch tests. Exposures were modeled based on a total immersion in the product and calculated as mass per unit area exposed, without dependence on duration or frequency of exposure. This assumes that sensitization can occur from one exposure event, although there is uncertainty on how repeated exposures can increase the likelihood of sensitization.

Bulb dip use from SLN

The SLN use of formaldehyde to treat daffodil and bulbous iris bulbs and the fields where they are planted, using a 0.5% solution of formaldehyde, may result in inhalation exposure to occupational handlers due to formaldehyde air concentrations above the dip and nearby occupational bystanders

when the spent dip-tank water from the bulb dip treatment is applied to the soil. Oral exposure to residential consumers through drinking water is also possible due to runoff of the formaldehyde solution applied to the field to nearby water bodies. Given the relatively high application rate (876 lbs formaldehyde per acre, assuming all 21,000 gallons per acre of dip tank solution specified on the current label can be applied in a single application), and the uncertainty in application methods, human health risks from the use described by the SLN cannot be precluded. More information on how and where this use is applied will be needed to further refine the risk conclusion from the SLN use.

3 ECOLOGICAL RISK ASSESSMENT

This section evaluates the potential for risks to terrestrial and aquatic organisms from the registered pesticidal uses of formaldehyde. Please refer to Section 1.4 for a discussion of the Environmental Fate of formaldehyde and its transformation products.

3.1 Anticipated Exposure Pathways and Residues of Concern

Exposures to terrestrial organisms are expected when used as an indoor fumigant in citrus packing houses, mushroom houses, egg hatcheries, bee-nesting materials, poultry and swine confinement buildings, microbiology laboratories, and feed truck and rail cars from inhalation of vapor-phase formaldehyde when released during aeration. Toxicity data are available for vapor-phase formaldehyde, which is considered the primary exposure for terrestrial organisms from fumigant uses. The potential for aquatic exposure from deposition of formaldehyde and its transformation products from fumigant uses into surface waters is low as released formaldehyde is expected to interact with moisture in the air and is subject to photodegradation in the sun.

There is also potential for exposures to terrestrial organisms that may consume treated bulbs treated with formaldehyde when they are planted in the field or when the spent dip tank water is applied to the field. However, there is uncertainty in where and how this use is applied. Once in the field, the formaldehyde solution would be expected to rapidly convert to methylene glycol (assuming the spent water is allowed to cool to ambient temperature prior to application) and then to formaldehyde oligomers. While there is uncertainty in the potential for methylene glycol and formaldehyde transformation products to evaporate from treated fields, there is potential for inhalation and oral exposure to terrestrial organisms from breathing formaldehyde that volatilizes off the field or consuming treated bulbs, respectively.

While several pesticidal uses of formaldehyde have the potential to go down-the-drain, including as a material preservative in consumer (e.g., cleaning and laundry products) and commercial uses (e.g., oil and gas uses, oil and grease removers and industrial cleaners), as discussed previously, there is a low potential for exposures to aquatic organisms from these releases to surface water and ground water. However, there is potential for exposures to aquatic habitats from the pesticidal SLN use on ornamental bulbs when the spent dip tank water is applied to the field. As discussed above, there is uncertainty in where and how this use is applied. There is also uncertainty in whether formaldehyde and its transformation products would persist in the field long enough for a runoff or leaching event to occur. As a result, there is potential for aquatic exposure from application of the spent dip tank water.

Given the properties of formaldehyde in water, aquatic organisms are likely exposed to formaldehyde and its transformation products (i.e., methylene glycol, oligomers, and paraformaldehyde). The Agency therefore considered the comparative toxicity of formaldehyde and its transformation products to

aquatic organisms and determined that formaldehyde toxicity data are protective or capture the toxicity of methylene glycol, oligomers, and paraformaldehyde (U.S. EPA, 2024a).

3.2 Water Quality – Total Maximum Daily Load

Based on a search of the Assessment and Total Maximum Daily Load Tracking and Implementation System (ATTAINS) database on 12/18/2023, formaldehyde, methylene glycol, formalin, and paraformaldehyde are not identified as a cause of impairment for any water bodies listed as impaired under Section 303(d) of the Clean Water Act.[8] In addition, no Total Maximum Daily Loads (TMDLs) have been developed for formaldehyde, methylene glycol, formalin, and paraformaldehyde.[9] More information on impaired water bodies and TMDLs can be found at the Agency's website.[10]

3.3 Monitoring Data

The Water Quality Portal[7] was searched on 12/18/2023, for formaldehyde concentrations in water spanning 2008 to 2023. Results were not available for methylene glycol, formalin, or paraformaldehyde, as these chemicals were not listed as monitored chemicals. Groundwater samples were collected at wells in Michigan on 11/2/2015, 12/7/2016, and 2/28/2017, with reported concentrations of formaldehyde ranging from 14 to 23 µg/L (n=11). However, the reported detection limit was 20 µg/L, with only two of the reported monitored values above this limit (21 and 23 µg/L). Sixty-eight surface water samples were collected during 2012 and 2013 in Montana as part of targeted monitoring for oil and gas releases. All were reported as being below the limit of detection (< 250 µg/L).

While ambient air monitoring data have been reported for a number of sources (U.S. EPA, 2024e), none of the sources were identified as antimicrobial in nature. In addition, the registered antimicrobial uses of formaldehyde and paraformaldehyde are anticipated to result in intermittent and short-term exposures that may not be well represented in the available ambient monitoring data. As such, the data were not included in the ecological risk characterization of this assessment.

3.4 Ecological Effects

3.5 Selected Ecotoxicity Endpoints

Available ecotoxicity data for formaldehyde include studies for freshwater fish (acute and chronic); freshwater invertebrates (acute); freshwater vascular plants; estuarine/marine fish (acute);

[8] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

[9] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

[10] http://www.epa.gov/tmdl/

estuarine/marine invertebrates (acute); terrestrial vertebrates (avian: acute and subacute; mammalian: oral and inhalation routes of exposure); and terrestrial vascular plants. These data are available in a joint environmental hazard characterization document created by both OPP and OPPT (U.S. EPA, 2024a). Here we present the most sensitive ecotoxicity results for each surrogate nontarget receptor group (Figure 3-1; Table 3-1). These data were used to determine risk to nontarget organisms from formaldehyde uses. OPP also assumed risk to those formaldehyde or paraformaldehyde uses where exposure is anticipated but toxicity data are lacking (terrestrial invertebrate toxicity data and inhalation toxicity to avian species).

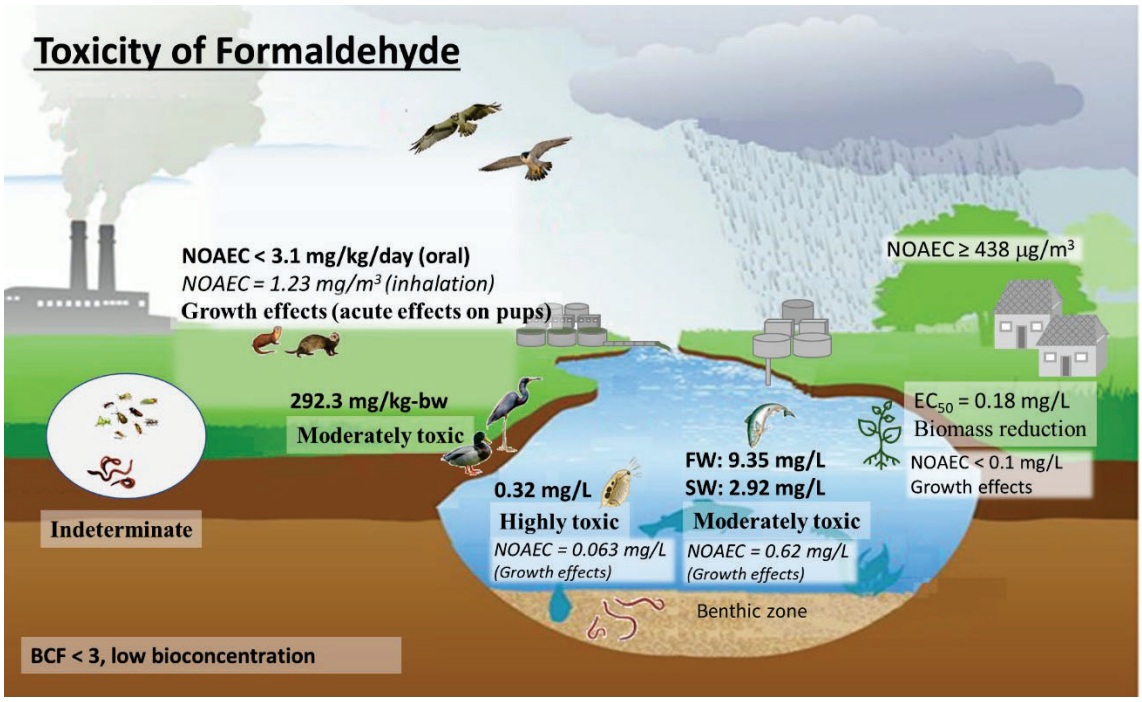

Figure 3-1: Visual summary of ecotoxicity data for formaldehyde.

Values in bold represent acute toxicity endpoints (endpoints are the lethal or adverse effect concentration to 50% of the test population (LC_{50} or EC_{50}), unless otherwise indicated). Values in italics represent chronic toxicity endpoints. NOAEC = no observable adverse effect concentration. Plant ecotoxicity endpoints are neither acute nor chronic and written in plain text.

Most aquatic toxicity data were conducted using formalin (solution of water, 37% formaldehyde, and often 6 to 15% methanol), which is expected to best represent aquatic exposure scenarios for formaldehyde. As stated previously, formaldehyde is known to transform to methylene glycol, various oligomers, and paraformaldehyde in water. Intentional exposure to formaldehyde in aquatic toxicity studies will therefore yield organism exposure to all three compounds due to the presence of water. Thus, the Agency considered the comparative toxicity of these compounds and determined that the formaldehyde toxicity data are protective or capture the toxicity of methylene glycol, oligomers, and paraformaldehyde (U.S. EPA 2024a).

Based on selected ecotoxicity endpoints (Table 3-1), on an acute basis, formaldehyde is moderately toxic to birds, moderately toxic to freshwater fish, highly toxic to freshwater invertebrates, moderately toxic to marine invertebrates and fish, and moderately toxic to mammals via oral routes of exposure (Figure 3-1). Chronic exposure toxicity was approximately an order of magnitude lower (i.e., more toxic) than acute exposure toxicity. Additional details on formaldehyde hazard characterization can be found in the joint environmental hazard characterization document (U.S. EPA, 2024a).

Table 3-1: Ecological Effects Endpoints Selected for Formaldehyde

Receptor Group	Exposure Scenario	Toxicity Endpoint (mg/L, *unless otherwise specified*)[a]	Toxicity Category	Citation or MRID (classification)
Freshwater fish	Acute	LC_{50} = 9.35	Moderately toxic	Fajer-Avila, et al., 2003[b]
	Chronic	NOAEC = 0.62 LOAEC = 1.25 (40% reduction in weight gain)	NA	Omoregie, et al., 1998[b]
Freshwater invertebrates	Acute	LC_{50} = 0.32	Highly toxic	MRID 00132485 (acceptable)
	Chronic	NOAEC = 0.063	NA	ACR[c]
Freshwater vascular plants	NA	EC_{50} = 0.18 (biomass) LOAEC = 0.1 (25% reduction in biomass) NOAEC < 0.1	NA	Singh, et al., 2008[b]
Freshwater non-vascular plants	NA	No data	NA	NA
Estuarine/marine fish	Acute	LC_{50} = 2.92	Moderately toxic	Takayanagi, et al., 2000[b]
	Chronic	No data	NA	NA
Estuarine/marine invertebrates	Acute	LC_{50} = 1.96	Moderately toxic	Fajer-Avila, et al., 2003[b]
	Chronic	No data	NA	NA
Birds	Acute Oral	LD_{50} = 292.3 mg/kg-bw[1]	Moderately toxic	MRID 00148774 (acceptable)
	Subacute dietary	LC_{50} > 1,850 mg/kg-diet	Slightly toxic	MRID 00148775 (acceptable)
Mammals	Acute oral	LOAEC = 3.1 mg/kg/day NOAEC < 3.1 (based on pup weight)	Moderately toxic	MRID 00143291 (acceptable)
	26-wk inhalation	LOAEC = 3.0 ppm (3.68 mg/m^3) NOAEC = 1.0 ppm (1.23 mg/m^3)	NA	MRID 00149755 (acceptable)

Receptor Group	Exposure Scenario	Toxicity Endpoint (mg/L, *unless otherwise specified*)[a]	Toxicity Category	Citation or MRID (classification)
Terrestrial plants	4-week fumigation study	NOAEC ≥ 438 µg/m^3	NA	Mutters, et.al., 1993[b]

[a] mg/L = mg per liter formaldehyde adjusted for chemical purity by multiplying the measured hazard value by the percent chemical purity unless otherwise noted

[b] High-ranking studies from OPPT systematic review (*see* U.S. EPA 2023)

[c] An acute-to-chronic ratio (ACR) was used to estimate the chronic endpoint for the most sensitive freshwater invertebrate, ostracods (*Cypridopsis* sp.). An ACR of 5.29 is derived from the acute and chronic studies of (MRID 00148772 and Institut, 2008) for *Daphnia magna*. ACR = 5.29/1.04 = 5.08. The NOAEC for ostracod was estimated using the following equation: NOAEC = Acute ostracod/ACR = 0.32/5.08 = 0.063.

[1]bw = body weight

3.6 Major Ecotoxicity Uncertainties

Given the registered use of paraformaldehyde as a fumigant for leaf-cutting bee-nesting materials and leaf-cutting bee cells, and the lack of toxicity data for formaldehyde or paraformaldehyde for bees (OCSPP 850.3020, 850.3030), uncertainty exists for formaldehyde risks to bees from this and other fumigant uses. Additionally, given the lack of chronic exposure toxicity data for the most acutely sensitive aquatic invertebrate (i.e., ostracod) to formaldehyde, the Agency used an acute-to-chronic ratio to estimate chronic toxicity to freshwater invertebrates (Table 3-1). Available data suggest that chronic sublethal aquatic invertebrate toxicity to formaldehyde is approximately an order of magnitude below acute exposure values. Further, the terrestrial plant NOAEC is based on a 4-week fumigation study on the common bean (*Phaseolus vulgaris*) where the maximum exposure concentrations of 438 mg/m^3 showed no effects (Mutters et al. 1993). These results may suggest that a higher NOAEC could have been found if a higher concentration was tested. However, the lowest LOAEC for terrestrial plants (lily plants; *Lilium longiflorum*) was similar to this NOAEC at 450 µg/m^3 after 5-hours of exposure (72.5% reduction in pollen-tube length and no germination, a growth effect related to reproduction) and approximately an order of magnitude higher at 1720 µg/m^3 after 1-hour of exposure (13.5% reduction in pollen-tube length). The lack of avian and terrestrial invertebrate inhalation toxicity data for formaldehyde and paraformaldehyde also causes uncertainty in formaldehyde risks to avian and terrestrial invertebrate species given the likelihood of air exposure from fumigant uses and potentially from fields applied with spent dip tank water from the SLN use.

3.7 Ecological Incidents

The Agency's Incident Data System (IDS) was queried on February 13, 2024, for all records over time. There were no reported ecological incidents for PC Codes 043001, 043002, or the terms formaldehyde, formalin, methylene glycol, or paraformaldehyde.

3.8 Aquatic Exposure

As discussed above in Section 3.1, there is minimal potential for aquatic exposure to formaldehyde and its transformation products from consumer and commercial product uses of formaldehyde that are discharged down the drain and used as fumigants. However, there is the potential for exposure to formaldehyde transformation products to aquatic organisms from the SLN use through runoff from bulb treatment and planting, and the application of dip-tank water to a field. This product is mixed at the rate of 2 fluid ounces per gallon to yield a solution containing 0.5% formaldehyde. The bulbs are dipped and soaked for three to four hours in a tank that is maintained at a temperature of 110 to 111°F. Spent dip-tank treatment water may be applied to bulb fields at a concentration not to exceed 1.5% of the Formaldehyde Solution 37 (0.5% formaldehyde) and at a rate of no more than 21,000 gallons of dip-tank solution per acre per year for suppression of *Fusarium spp*. This is equivalent to 876 lbs formaldehyde per acre per year, using the equation below.

$$AR_f = Ff \; x \; AR_{dw} \; x \; CF$$

Where:

- AR_f application rate of formaldehyde (lbs formaldehyde/A/yr)
- Ff concentration of formaldehyde in dip tank water (5,000 mg formaldehyde/liter dip tank water)
- AR_{dw} application rate of dip tank water solution (21,000 gallon [79,500 liters] dip tank water/A/yr)
- CF conversion factor from milligram to pounds ($2.205x10^{-6}$ lb/mg)

However, there is uncertainty in where and how the use is applied to a field, as well as how much of the product is applied to a field or a bulb at a given time. Additionally, as the label requires that the dip-tank solution only be applied to bulb fields when rainfall is not expected for at least 24 hours after application, it is uncertain how much of the formaldehyde transformation products will still be present when runoff occurs. Given these uncertainties, the aquatic exposure for the pesticidal SLN use cannot be quantified and is assumed.

3.9 Terrestrial Exposure

Terrestrial exposure is expected from the pesticidal SLN use of a 0.5% formaldehyde solution applied to bulbs planted in the ground and to soil applied with spent dip-tank solution. Formaldehyde is expected to rapidly transform to methylene glycol and potentially formaldehyde oligomers in the spent dip-tank solution. However, because of the uncertainty in where and how this use would be applied, and how long formaldehyde and its transformation products remain in and on the treated bulbs, exposure to terrestrial organisms from consumption of treated bulbs and direct applications to soil cannot be quantified and is assumed. There is also uncertainty in the potential for methylene glycol and formaldehyde transformation products to evaporate from treated fields, although the potential is

considered low given the slow volatilization of methylene glycol from moist soil, so inhalation exposure to terrestrial organisms cannot be precluded.

Terrestrial exposure was evaluated for air exposure to formaldehyde from disinfection and fumigation of rooms, feed trucks, and railway cars; hatching eggs; poultry and swine confinement houses; mushroom houses; and citrus packing houses. Terrestrial exposure was also evaluated for air exposure to formaldehyde from paraformaldehyde use in disinfection and fumigation of leaf-cutting bee cells and nesting materials; and government, industrial, commercial, and institutional microbiological laboratory settings, including human and animal research facilities and areas, animal isolation rooms, animal cages, necropsy suites, ancillary equipment, and biological safety cabinets. A Tier 1 analysis, using EPA's AERSCREEN version 21112 model[11], was conducted to determine if potential risks were identified and if further air modeling refinements were needed. For those uses that were still identified as a potential risk, a refined outdoor air exposure analysis was conducted using the Probabilistic Exposure and Risk Model for Fumigants (PERFUM v 3.1[12]).

3.10 Tier 1 Modeling Using AERSCREEN

Tier 1 modeling was conducted for the fumigation uses of formaldehyde and paraformaldehyde relying on use rates, building dimensions, and modeling parameters described earlier in Section 2.7. Only 1-hour exposures were modeled as 24-hour exposures were not considered relevant for ecological receptors.

The results from the AERSCREEN modeling indicated that ecological exposure would result in risk exceedances of the only available and most sensitive ecological effects endpoints for terrestrial plants (NOAEC = 438 µg/m^3) and mammals (NOAEC = 1230 µg/m^3), when 1-hour exposures were estimated for formaldehyde and paraformaldehyde fumigated facilities.

3.11 Refined Modeling using PERFUM

The PERFUM model was used to refine its risk estimates developed in the Tier 1 analysis. For the refined modeling, the same building and application rate information as the Tier 1 assessment was used, although hourly (**Appendix G and Appendix H**) rather than the highest emission rate was assumed. A start time for the aeration of 8 am (Hour 9) was assumed, given that a fumigation event would likely start in the morning, last 24 hours, and then the building would be aerated the following morning. Daily meteorological data for Ventura, CA from 2012-2016 was used because this meteorological file was supplied with the PERFUM model. Prior modeling efforts conducted by OPP's Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) have indicated that

[11] https://www.epa.gov/scram/air-quality-dispersion-modeling-screening-models#aerscreen
[12] https://www.exponent.com/capabilities/probabilistic-exposure-risk-model-fumigant s

this site is representative of rural areas where a fumigant might be used and produce conservative air exposure estimates.

Table 3-2 and Table 3-3 depict select building sizes at the 75th, 90th, and 95th percentile maximum 1-hour air concentrations across the distances assessed (e.g., 1 to 2,500 m) derived from the PERFUM runs for the various fumigation releases that did not use mechanical ventilation (passive aeration), and those that employed mechanical ventilation (active aeration). Results for all building sizes are provided in **Appendix I**. For facilities employing active and passive aeration, maximum 1-hr air exposure results using PERFUM showed citrus house fumigation exceeded the most sensitive air exposure ecotoxicity endpoint (i.e., NOAEC for terrestrial plants) for facilities ≥ 2,000 cu ft (95th percentile) and ≥ 25,000 cu ft (95th percentile), respectively. Mushroom house use exceeded the most sensitive ecotoxicity endpoints at the 95th percentile for all modeled facilities when employing active aeration and for buildings ≥ 25,000 cu ft when employing passive aeration. Poultry confinement and laboratory fumigation uses exceed the most sensitive ecotoxicity endpoints for all modeled facilities at the 95th percentile for both active and passive aeration. Beehive and egg fumigation exceeded the most sensitive ecotoxicity endpoints at the 95th percentile for all modeled facilities when employing passive aeration, while fumigation of rooms, feed trucks, and railway cars did not. While the terrestrial plant NOAEC is based on a 4-week fumigation study on the common bean (*Phaseolus vulgaris*) where the maximum exposure concentration of 438 mg/m^3 showed no effects (Mutters, et al. 1993), these exposure values also exceeded the lowest LOAEC for terrestrial plants at 450 µg/m^3 (5-hour exposure) and 1720 µg/m^3 (1-hour exposure). At the 95th percentile, modeled formaldehyde exposure concentrations for active and passive aerated facilities also exceeded the most sensitive NOAEC for mammals for citrus fumigation at facilities ≥ 5,000 cu ft and ≥ 100,000 cu ft, respectively; for mushroom house fumigation at facilities ≥ 2,000 cu ft and ≥ 50,000 cu ft, respectively; for poultry fumigation at all facilities and ≥ 25,000 cu ft, respectively; and laboratory fumigation at facilities ≥ 2,000 cu ft and ≥ 25,000 cu ft, respectively.

Table 3-2: Maximum 1-hour air concentrations using PERFUM across distances for uses without mechanical ventilation (passive aeration).

Use	Beehive		Egg fumigation		Rooms and Railcars			
Building size (ft^3)	1000	2000	1000	2000	1000	2000	5000	10,000
Percentile	Maximum 1-hour air concentration (µg/m^3)							
75	23	25	210	230	12	13	4	2
90	380	380	***3500***	***3500***	210	200	170	140
95	530	520	***5000***	***4800***	280	270	280	240
Use	Citrus Packing Houses				Poultry and Swine Confinement Houses			
Building size (ft^3)	1000	10,000	100,000	1 million	1000	10,000	100,000	1 million
Percentile	Maximum 1-hour air concentration (µg/m^3)							
75	9	1	55	120	35	5	210	450
90	160	110	***1200***	***2600***	**600**	410	***4300***	***9900***

95	230	190	***1700***	***4000***	**850**	**730**	***6500***	***15000***
Use	Mushroom Houses				Laboratories, equipment, and animal areas			
Building size (ft^3)	1000	5000	10,000	50,000	1000	10,000	100,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)							
75	14	4	2	21	27	4	160	340
90	230	200	160	**840**	**460**	310	***3300***	***7700***
95	330	320	270	***1300***	**660**	**560**	***5000***	***12000***

Bold values exceed the plant endpoint (438 $\mu g/m^3$). Bold italics values exceed the mammalian endpoint (1230 $\mu g/m^3$).

Table 3-3: Maximum 1-hour air concentrations using PERFUM across distances for uses with mechanical ventilation (active aeration).

Use	Citrus Packing Houses				Poultry and Swine Confinement Housing			
Building size (ft^3)	1000	10,000	100,000	1 million	1000	10,000	100,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)							
75	67	***770***	***3200***	***4100***	250	***2900***	***12000***	***15000***
90	280	***2000***	***7000***	***11000***	**1100**	***7400***	***26000***	***40000***
95	370	***2400***	***9000***	***16000***	***1400***	***8900***	***34000***	***58000***
Use	Mushroom Houses				Laboratories, equipment, and animal areas			
Building size (ft^3)	1000	5000	10,000	50,000	1000	10,000	100,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)							
75	96	**730**	**1100**	***3600***	190	***2200***	***9100***	***12000***
90	400	***2000***	***2800***	***7300***	**810**	***5700***	***20000***	***31000***
95	**530**	***2400***	***3400***	***8900***	**1100**	***6800***	***26000***	***45000***

Bold values exceed the plant endpoint (438 $\mu g/m^3$). Bold italics values exceed the mammalian endpoint (1230 $\mu g/m^3$).

Formaldehyde concentrations decline with increasing distance from the treated facility. Figure 3-2 below reflects the 95th percentile concentrations from poultry/swine confinement building fumigation with active aeration for building sizes from 1,000 to 100,000 ft^3 and relevant toxicity endpoints reflected on the graph. Exposure concentrations drop below the endpoint for all registered uses at distances from the fumigation buildings of 0 to 780 m for plant endpoints and 0 to 450 m for mammalian endpoints. Tabulated results for all building size PERFUM runs and figures for additional uses are in Appendix H.

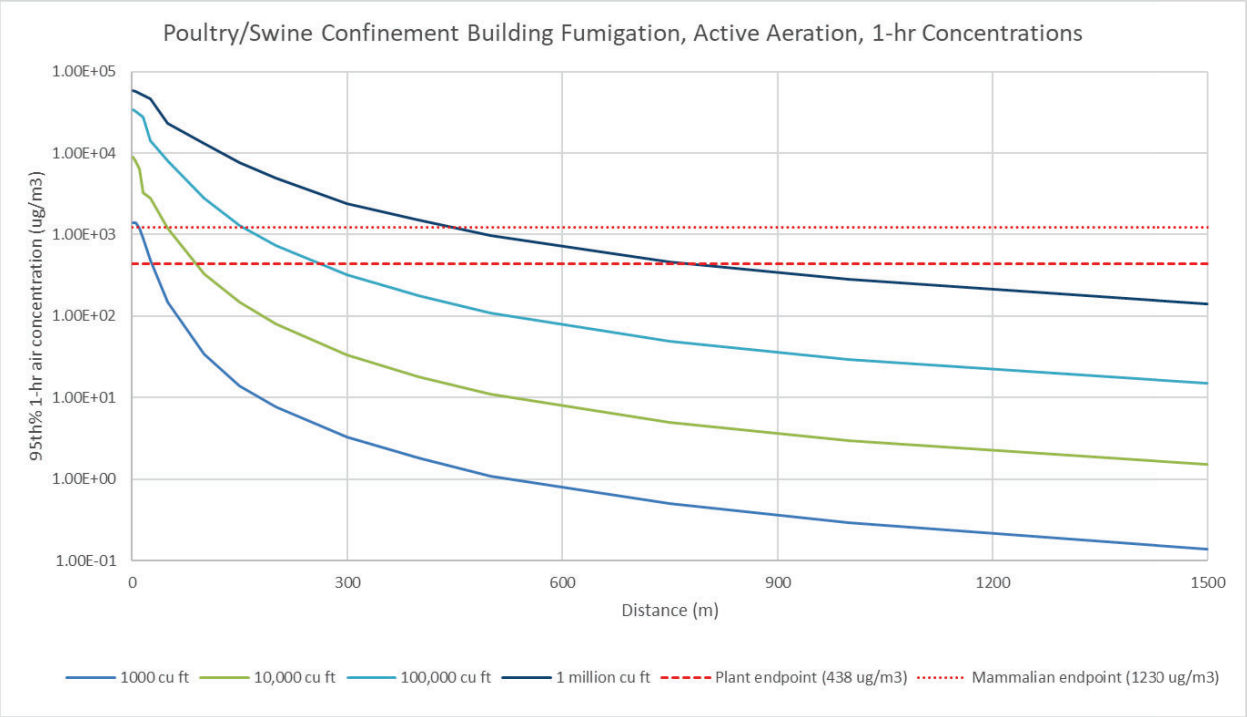

Figure 3-2: 1-hr 95th percentile air concentrations from poultry/swine confinement building fumigation for building sizes of 1,000 to 1 million cubic ft.

Modeling Assumptions and Uncertainties

The assessment presented above for the fumigation uses is based on numerous assumptions, which are discussed in Sections 2.7 and 2.8 above. Additionally, only two terrestrial taxa (plants and mammals) had air exposure ecotoxicity data that could be compared to estimated air exposure concentrations.

3.12 Ecological Risk Characterization

Formaldehyde and paraformaldehyde consumer and commercial product use patterns and fate data indicate low potential for risk of formaldehyde to aquatic organisms via surface water or sediment from down-the-drain exposures. While several antimicrobial uses of formaldehyde (i.e., materials preservatives in residential and industrial cleaning products, laundry uses, and in industrial oil and gas injection water) have the potential to go down-the-drain, exposures to aquatic organisms are not anticipated due to the chemical properties of formaldehyde. As discussed previously, once in water, formaldehyde is rapidly (milliseconds) converted to methylene glycol, in the absence of methanol, then is converted to formaldehyde oligomers in minutes and, if present in sufficient quantities, into paraformaldehyde in hours to days. Formaldehyde and its transformation products are expected to be removed during movement in water from down-the-drain uses to a wastewater treatment plant, during wastewater treatment. Paraformaldehyde is expected to precipitate out through down-the-

drain movement and wastewater treatment as it is insoluble in water. As such, the potential for formaldehyde and its transformation products to be discharged to surface water from a treatment plant receiving wastewater from either residential uses or industrial discharges is low.

There is potential for exposures to terrestrial organisms to formaldehyde from antimicrobial fumigant uses in citrus packing houses, mushroom houses, egg hatcheries, poultry and swine confinement buildings, and feed trucks and rail cars. Ecotoxicity data relevant for assessing vapor-phase exposures are only available for terrestrial plants and mammals. Based on modeled air exposure concentrations and ecotoxicity data, there is potential for risk to terrestrial plants and mammals from registered formaldehyde and paraformaldehyde fumigant uses released through active and passive aeration.

Estimated exposures based on maximum 1-hr air concentrations modeled in PERFUM exceed the endpoints for terrestrial plants and mammals for buildings employing active and passive aeration. While there are uncertainties associated with the exposure modeling, including the amount and timing of the formaldehyde release, the number of facilities being treated in a day, and specific building parameters such as size, the estimated exposures are more than an order of magnitude greater than the concentration at which reductions in body weight were observed in the available mammalian toxicity study and the concentration at which no effects were observed in the available terrestrial plant study. There is some uncertainty associated with using longer duration exposure studies (26-week and 4-week exposures for mammals and plants, respectively) to assess risks from acute exposures; however, it is not possible to determine what exposure timing or duration is necessary to elicit the observed effects based on the study designs. In fact, statistically significant decreases in body weight were observed from week two (9% decrease) onward (10 to 15% decrease), suggesting shorter exposure durations can elicit effects for formaldehyde. For terrestrial plants, there is additional uncertainty in using an endpoint from a study where no effects were observed at the highest concentration tested. However, estimated exposures also exceed concentrations at which reductions in pollen tube lengths and germination of lily plant pollen (*Lilium longiflorum*), which would potentially impact the plant's ability to reproduce, were observed after 5-hours (450 µg/m^3) and 1-hour (1720 µg/m^3).

No ecotoxicity data are available to estimate formaldehyde risks to terrestrial invertebrates or avian species via air exposure from fumigant uses. Due to the increased respiration rate of avian species compared to mammals it is likely that avian species may be exposed to higher doses of available formaldehyde in the air than mammals, potentially resulting in increased sensitivity. Risks to these taxa cannot be precluded at this time.

There is also potential for exposure to bees (and other terrestrial invertebrates) from the antimicrobial use of paraformaldehyde as a fumigant for leaf-cutting bee nesting materials and leaf-cutting bee cells (EPA Reg. No. 4972-43). This labeled use specifies treatment occur in an incubator in the absence of bees and directs that bee nesting materials and bee cells be moved directly to the field after air

concentrations reach 0.1 ppm in the treatment chamber. While there is uncertainty in whether residual formaldehyde from treatment may remain on nesting materials or in bee cells and volatilize in the presence of bees, no acceptable data are available to evaluate formaldehyde toxicity to bees or other terrestrial invertebrates. Given the current lack of relevant toxicity data for formaldehyde and potential exposure from fumigant uses to bee nesting materials, risk cannot be precluded to bees or other terrestrial invertebrates from this use.

The SLN use of formaldehyde to treat daffodil and bulbous iris bulbs and the fields where they are planted, using a 0.5% solution of formaldehyde, may result in direct soil exposures from formaldehyde solution leached from planted bulbs and applied directly to the soil, runoff of the formaldehyde solution applied to the field to local waterbodies, and air exposure to terrestrial organisms from methylene glycol and formaldehyde transformation products vaporizing from the field where bulbs are planted and the spent dip-tank solution is directly applied. Given the relatively high application rate (876 lbs formaldehyde per acre, assuming all 21,000 gallons per acre of dip tank solution specified on the current label can be applied in a single application), and the uncertainty in application methods, OPP cannot preclude risk to the aquatic, soil or terrestrial organisms exposed to formaldehyde and its transformation products from the use described by the SLN. More information on how and where this use is applied will be needed to further refine the risk conclusion from the SLN use.

In conclusion, there is low potential for risks to aquatic organisms from the registered antimicrobial uses of formaldehyde and paraformaldehyde that may go down-the-drain. However, risks to aquatic organisms cannot be precluded for the SLN use of formaldehyde to treat ornamental bulbs given uncertainties in application methods and locations. There is also potential for risk to terrestrial plants and mammals from the registered pesticidal uses of formaldehyde and paraformaldehyde to fumigate various agricultural, commercial, and industrial areas when released through active and passive aeration. Due to lack of data, risks to terrestrial invertebrates and birds cannot be precluded from fumigant uses. Also, given uncertainties in the potential for formaldehyde and methylene glycol to volatilize out of the soil, and the direct application to soil, risks to terrestrial organisms cannot be precluded for the SLN use.

4 LISTED SPECIES OF CONCERN

The EPA is currently working with its federal partners and other stakeholders to improve the consultation process for listed species and their designated critical habitats. The Agency has not yet fully evaluated risks to listed species from formaldehyde and paraformaldehyde. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the registration review for formaldehyde and paraformaldehyde. See Appendix J for more details. As such, the potential risks for non-target species are described in Section 3.7 above.

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Appendix A. EPI Suite Analysis for Methylene Glycol

CAS Number: (null)
SMILES : C(O)O
CHEM :
MOL FOR: C1 H4 O2
MOL WT : 48.04
---------- EPI SUMMARY (v4.11) ----------

KOCWIN Program (v2.00) Results:
==========
SMILES : C(O)O
CHEM :
MOL FOR: C1 H4 O2
MOL WT : 48.04
---------- KOCWIN v2.00 Results ----------

Koc Estimate from MCI:

First Order Molecular Connectivity Index ..... : 1.414
Non-Corrected Log Koc (0.5213 MCI + 0.60) ..... : 1.3370
Fragment Correction(s):
2 Aliphatic Alcohol (-C-OH) ..... : -2.6358
Corrected Log Koc ..... : -1.2988
Over Correction Adjustment to Lower Limit Log Koc ... : 0.0000

Estimated Koc: 1 L/kg <==========

Koc Estimate from Log Kow:

Log Kow (Kowwin estimate) ..... : -0.79
Non-Corrected Log Koc (0.55313 logKow + 0.9251) .... : 0.4881
Fragment Correction(s):
2 Aliphatic Alcohol (-C-OH) ..... : -0.8229
Corrected Log Koc ..... : -0.3348

Estimated Koc: 0.4626 L/kg <==========

STP Fugacity Model: Predicted Fate in a Wastewater Treatment Facility
==========
(using 10000 hr Bio P,A,S)
PROPERTIES OF:

Molecular weight (g/mol) 48.04
Aqueous solubility (mg/l) 0

Vapour pressure (Pa) 0
(atm) 0
(mm Hg) 0
Henry 's law constant (Atm-m3/mol) 9.85E-008
Air-water partition coefficient 4.02836E-006
Octanol-water partition coefficient (Kow) 0.162181
Log Kow -0.79
Biomass to water partition coefficient 0.832436
Temperature [deg C] 25
Biodeg rate constants (h^-1),half life in biomass (h) and in 2000 mg/L MLSS (h):
-Primary tank 0.04 16.62 10000.00
-Aeration tank 0.04 16.62 10000.00
-Settling tank 0.04 16.62 10000.00

STP Overall Chemical Mass Balance:
---
g/h mol/h percent

Influent 1.00E+001 2.1E-001 100.00

Primary sludge 2.50E-002 5.2E-004 0.25
Waste sludge 1.51E-001 3.1E-003 1.51
Primary volatilization 5.37E-005 1.1E-006 0.00
Settling volatilization 1.46E-004 3.0E-006 0.00
Aeration off gas 3.61E-004 7.5E-006 0.00

Primary biodegradation 1.76E-003 3.7E-005 0.02
Settling biodegradation 5.27E-004 1.1E-005 0.01
Aeration biodegradation 6.93E-003 1.4E-004 0.07

Final water effluent 9.81E+000 2.0E-001 98.15

Total removal 1.85E-001 3.9E-003 1.85
Total biodegradation 9.22E-003 1.9E-004 0.09

STP Fugacity Model: Predicted Fate in a Wastewater Treatment Facility
==========
(using Biowin/EPA draft method)
PROPERTIES OF:

Molecular weight (g/mol) 48.04
Aqueous solubility (mg/l) 0
Vapour pressure (Pa) 0
(atm) 0
(mm Hg) 0
Henry 's law constant (Atm-m3/mol) 9.85E-008

Air-water partition coefficient 4.02836E-006
Octanol-water partition coefficient (Kow) 0.162181
Log Kow -0.79
Biomass to water partition coefficient 0.832436
Temperature [deg C] 25
Biodeg rate constants (h^-1),half life in biomass (h) and in 2000 mg/L MLSS (h):
-Primary tank 41.69 0.02 10.00
-Aeration tank 416.94 0.00 1.00
-Settling tank 416.94 0.00 1.00

STP Overall Chemical Mass Balance:

	g/h	mol/h	percent
Influent	1.00E+001	2.1E-001	100.00
Primary sludge	2.13E-002	4.4E-004	0.21
Waste sludge	1.22E-002	2.5E-004	0.12
Primary volatilization	4.57E-005	9.5E-007	0.00
Settling volatilization	1.18E-005	2.5E-007	0.00
Aeration off gas	3.77E-005	7.8E-007	0.00
Primary biodegradation	1.50E+000	3.1E-002	14.95
Settling biodegradation	4.26E-001	8.9E-003	4.26
Aeration biodegradation	7.25E+000	1.5E-001	72.51
Final water effluent	7.94E-001	1.7E-002	7.94
Total removal	9.21E+000	1.9E-001	92.06
Total biodegradation	9.17E+000	1.9E-001	91.72

Appendix B. Toxicology Profile

The toxicology summaries in this section are applicable to both formaldehyde and paraformaldehyde. Paraformaldehyde is a polymeric form of formaldehyde and is designed to release formaldehyde. Therefore, exposure is to formaldehyde and studies that examine formaldehyde toxicity can also be applied to paraformaldehyde. Studies included in this appendix do not necessarily fulfill the current guideline requirements, see Section 2 for data gaps.

Acute Toxicity

As summarized in the 2017 Formaldehyde and Paraformaldehyde Final Work Plan, the acute toxicity database for formaldehyde is considered complete. Technical grade formaldehyde (37% a.i.) has a moderate order of acute toxicity in experimental animals via the oral and dermal routes (Toxicity Categories II and III). Inhalation toxicity studies on formaldehyde are extensive and include both acute exposures and longer-term exposures. Toxicity from acute exposures is characterized by pathology of the respiratory epithelium and has been observed in rats exposed for 4 hours to a concentration of 10 ppm (Bhalla, 1991), while longer term exposures of rats (3 ppm for 6 hours/day for 5 days) also results in respiratory tract lesions (Buckley et al., 1984). Formaldehyde is a severe eye and skin irritant (Toxicity Category I) and is positive for dermal sensitization. There are no acceptable data defining the median lethal concentration (LC_{50}) for formaldehyde from inhalation exposure.

Table B-1. Acute Toxicity Studies for Formaldehyde

Guideline Number	Study Type/ Test substance (% a.i.)	MRID Number	Result	Toxicity Category
870.1100 (§81-1)	Acute Oral – Guinea Pig Formaldehyde (37.3%)	00058054	LD_{50} = 260 mg/kg	II
870.1200 (§81-2)	Acute Dermal – Rat Formaldehyde (37.3%)	00058054	LD_{50} = 300 mg/kg mg/kg	II
870.1200 (§81-2)	Acute Dermal – Rabbit Formaldehyde (37.3%)	00058054	LD_{50} = 240 mg/kg mg/kg	II
870.1200 (§81-2)	Acute Dermal – Dog Formaldehyde (37.3%)	00058054	LD_{50} = 550 mg/kg mg/kg	II
870.1300 (§81-3)	Acute Inhalation –Rat	An acceptable study is not available		
870.2400 (§81-4)	Primary Eye Irritation - Formaldehyde (37.3%)	00058054	Severe eye irritant	I
870.2500 (§81-5)	Primary Dermal Irritation – Formaldehyde (37.3%)	00058054	Formation of vesicles with superficial necrosis or nodules.	I
870.2600 (§81-6)	Dermal Sensitization – Guinea pigs Formaldehyde (40.0%)	40161103	Positive Sensitizer	NA

Overall toxicity database

Additional toxicity data includes data available to the Agency from open scientific literature sources on repeat dose toxicity of formaldehyde, including subchronic, developmental, reproductive, and chronic toxicity as well as carcinogenicity. These data have been previously summarized in the 2008 RED and 2017 FWP (U.S. EPA 2008 and U.S. EPA 2017, respectively) and can be found in the associated appendices of those documents. For this assessment, additional data was considered as discussed in the joint human health hazard assessment for formaldehyde developed by OPP and OPPT (U.S. EPA, 2024c). This included consideration of human toxicity studies as well as the draft IRIS assessment (U.S. EPA 2022), and the analysis of studies identified through the OPPT systematic review process. The reader is referred to these data sources for complete study descriptions and reviews.

Appendix C. Endocrine Disruption Screening Program

The Federal Food Drug and Cosmetic Act (FFDCA) §408(p) requires EPA to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." (21 U.S.C. 346a(p)). In carrying out the Endocrine Disruptor Screening Program (EDSP), FFDCA section 408(p)(3) requires that EPA "provide for the testing of all pesticide chemicals," which includes "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1) and 346a(p)(3)). However, FFDCA section 408(p)(4) authorizes EPA to, by order, exempt a substance from the EDSP if the EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." (21 U.S.C. 346a(p)(4)).

The EDSP initiatives developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. 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 pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any adverse estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an adverse endocrine effect on humans, FFDCA § 408(p)(6) also requires EPA, "… as appropriate, [to] take action under such statutory authority as is available to the Administrator … as is necessary to ensure the protection of public health." (21 U.S.C. 346a(p)(6))[13].

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife.[14]

[13] For additional details of the EDSP, please visit https://www.epa.gov/endocrine-disruption.

[14] Summarized in *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions*; EPA-HQ-OPP-2023-0474-0001; https://www.regulations.gov/document/EPA-HQ-OPP-2023-0474-0001

In addition, for FIFRA registration, registration review, and tolerance-related purposes, EPA collects and reviews numerous studies to assess potential adverse outcomes, including potential outcomes to endocrine systems, from exposure to pesticide active ingredients. Although EPA has been collecting and reviewing such data, EPA has not been explicit about how its review of required and submitted data for these purposes also informs EPA's obligations and commitments under FFDCA section 408(p). Consequently, on October 27, 2023, EPA issued a Federal Register Notice (FRN) providing clarity on the applicability of these data to FFDCA section 408(p) requirements and near-term strategies for EPA to further its compliance with FFDCA section 408(p). This FRN, entitled *Endocrine Disruptor Screening Program (EDSP): Near-Term Strategies for Implementation' Notice of Availability and Request for Comment* (88 FR 73841) is referred to here as EPA's EDSP Strategies Notice. EPA also published three documents supporting the strategies described in the Notice:

- *Use of Existing Mammalian Data to Address Data Needs and Decisions for Endocrine Disruptor Screening Program (EDSP) for Humans under FFDCA Section 408(p)*;
- *List of Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6) Determination is Needed;* and,
- *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions* (referred to here as List 1 Screening Conclusions).

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, considering its current focus on developing a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan[15] and November 2022 ESA Workplan Update[16]). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda[17] indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential adverse effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account additional work being done in concert with researchers within the EPA's Office of Research and Development (ORD).

As discussed in EPA's EDSP Strategies Notice and supporting documents, EPA will be using all available data to determine whether additional data are needed to meet EPA's obligations and

[15] https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf
[16] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf
[17] https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and

discretionary commitments under FFDCA section 408(p). For some conventional pesticide active ingredients, the toxicological databases may already provide sufficient evaluation of endocrine potential for estrogen, androgen, and/or thyroid pathways and EPA will generally not need to obtain any additional data to reevaluate those pathways, if in registration review, or to provide an initial evaluation for new active ingredient applications. For instance, EPA has endocrine-related data for numerous conventional pesticide active ingredients through either a two-generation reproduction toxicity study performed in accordance with the current guideline (referred to here as the updated two-generation reproduction toxicity study; OCSPP 870.3800 - Reproduction and Fertility Effects) or an extended one-generation reproductive toxicity (EOGRT) study (OECD Test Guideline 443 - Extended One-Generation Reproductive Toxicity Study). In these cases, EPA expects to make FFDCA 408(p)(6) decisions for humans without seeking further estrogen or androgen data. However, as also explained in the EPA's EDSP Strategies Notice, where these data do not exist, EPA will reevaluate the available data for the conventional active ingredient during registration review to determine what additional data, if any, might be needed to confirm EPA's assessment of the potential for impacts to estrogen, androgen, and/or thyroid pathways in humans. For more details on EPA's approach for assessing these endpoints, see EPA's EDSP Strategies Notice and related support documents.

Also described in the EPA's EDSP Strategies Notice is a framework that represents an initial approach by EPA to organize and prioritize the large number of conventional pesticides in registration review. For conventional pesticides with a two-generation reproduction toxicity study performed under a previous guideline (i.e., an updated two-generation reproduction toxicity study or an EOGRT is not available), EPA has used data from the Estrogen Receptor Pathway and/or Androgen Receptor Pathway Models to identify a group of chemicals with the highest priority for potential data collection (described in EPA's EDSP Strategies Notice as Group 1 active ingredients). For these cases, although EPA has not reevaluated the existing endocrine-related data, EPA has sought additional data and information in response to the issuance of EPA's EDSP Strategies Notice to better understand the positive findings in the ToxCast™ data for the Pathway Models and committed to issuing DCIs to require additional EDSP Tier 1 data to confirm the sufficiency of data to support EPA's assessment of potential adverse effects to the estrogen, androgen, and/or thyroid pathways in humans and to inform FFDCA 408(p) data decisions. For the remaining conventional pesticides (described in EPA's EDSP Strategies Notice as Group 2 and 3 conventional active ingredients), EPA committed to reevaluating the available data to determine what additional studies, if any, might be needed to confirm EPA's assessment of the potential for impacts to endocrine pathways in humans.

Although EPA has prioritized conventional active ingredients as presented in EPA's EDSP Strategies Notice, EPA is planning to develop similar strategies for biopesticide and

antimicrobial pesticide (*i.e*., nonconventional) active ingredients and will provide public updates on these strategies, when appropriate. At this time, EPA is making no findings associated with the implementation of EDSP screening of formaldehyde. Such issues will be addressed in future updates by EPA on its strategies for implementing FFDCA section 408(p).

Appendix D. FDA Clearances and Food Contact Notifications

Formaldehyde and paraformaldehyde food additive clearance registrations granted by U.S. FDA. Formaldehyde is widely used as a food preservative and is approved as a food additive by U.S. FDA. There is one food contact notification (FCN) for paraformaldehyde when used in additive mixtures or coating solutions of food contact paper and paperboard (FCN No. 1380-Troy Corporation). The U.S. FDA also reports a Cumulative Estimated Daily Intake (micrograms/kilogram body weight/person/day, µg/kg bw/d) of 1.71 µg/kg bw/d (34.2 ppb) for formaldehyde. See Table D-1 for a summary of clearances and use limitations.

Table D-1. **Summary of** FDA Clearances

21 CFR Section	Substance	Clearance type	Use	Limitations
176.105	Formaldehyde	Indirect food additive	Adhesives	None
176.105	Paraformaldehyde	Indirect food additive	Adhesives	None
173.340	Formaldehyde	Secondary direct food additive	Defoaming Agent: As a preservative in defoaming agents containing dimethylpolysiloxane	not to exceed 1.0 percent of the dimethyl-polysiloxane content
173.340	Formaldehyde	Secondary direct food additive	Defoaming Agent: As a preservative in processing beet sugar and yeast	None
175.210	Formaldehyde	Indirect food additive	Acrylate ester copolymer coating	None
175.300	Formaldehyde	Indirect food additive	Resinous and polymeric coatings	
176.170	Formaldehyde	Indirect food additive	Components of paper and paperboard in contact with aqueous and fatty acids	for use only as preservative for coating formulations
176.170	Paraformaldehyde	Indirect food additive	Components of paper and paperboard in contact with aqueous and fatty acids	for use only as setting agent for protein
176.180	Formaldehyde	Indirect food additive	Components of paper and paperboard in contact with dry food	None
176.200	Formaldehyde	Indirect food additive	Defoaming agents used in coatings: preservative of defoamer only	None
177.1200	Melamine Formaldehyde	Indirect food additive	Cellophane: basic polymer	None
177.1210	Paraformaldehyde	Indirect food additive	Polymers: Closures with sealing gaskets for food containers	1.0 percent
178.3120	Formaldehyde	Indirect food additive	Animal glue: as a preservative only	None

21 CFR Section	Substance	Clearance type	Use	Limitations
177.2800	Formaldehyde	Indirect food additive	Polymers: Preservative in Textiles and textile fibers	None

Appendix E. Examples of Foods with Natural Occurring Formaldehyde

Table E-1. Examples of foods with natural occurring formaldehyde

Food Type	Level (mg/kg)
Fruit and Vegetables	
Apple	6.3 - 22.3
Banana	16.3
Beetroot	35
Bulb vegetables (e.g. onion)	11
Green onion	13.3 - 26.3
Cauliflower	27
Cucumber	2.3- 3.7
Pear	39-60
Spinach	3.3 – 7.3
Tomato	5.7- 13.3
Watermelon	9.2
Shiitake mushroom (dry)	100-406
Shiitake mushroom (raw)	6-54.4
Meat and Meat Products	
Beef	4.6
Poultry	5.8 – 20
Processed meat products	≤ 20.7
Dairy Products	
Milk (Cow's Milk)	≤ 3.3
Cheese	≤ 3.3
Seafood	
Cod	4.6 - 34
Shrimp (raw)	1 – 2.4
Crustacean	1-98
Beverages	

Food Type	Level (mg/kg)
Coffee (brewed)	3.4 – 4.5
Soft drinks	8.7

Content sources (WHO, 1989; Masona, 2004; CFS, 2017)

Appendix F. Consumer Exposure Modeling Results Assuming Three Events per Day

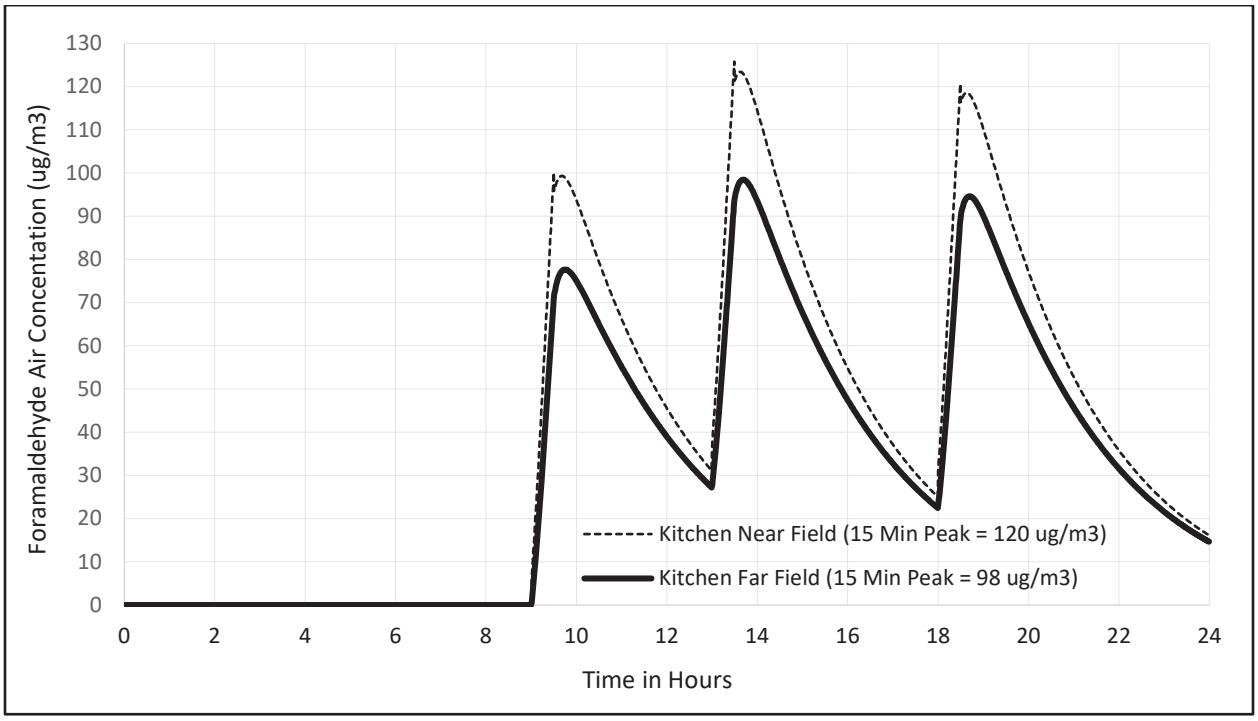


Figure F-1: General Purpose Cleaner Handler Acute Peak Exposures (3 Events per Day)

Appendix G. Emission rates, no mechanical ventilation (passive aeration)

Railcars	0.52	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	8.33				
1	5.58	2327.782	2793.339	3957.230	5819.456
2	3.74	1560.359	1872.431	2652.611	3900.898
3	2.51	1045.940	1255.128	1778.098	2614.850
4	1.68	701.115	841.338	1191.895	1752.786
5	1.13	469.971	563.965	798.951	1174.928
6	0.76	315.031	378.037	535.553	787.578
7	0.51	211.172	253.406	358.992	527.929
8	0.34	141.553	169.863	240.639	353.881
9	0.23	94.886	113.863	161.305	237.214
10	0.15	63.604	76.324	108.126	159.009
11	0.10	42.635	51.162	72.479	106.587
12	0.07	28.579	34.295	48.584	71.447
13	0.05	19.157	22.988	32.567	47.893
14	0.03	12.841	15.410	21.830	32.103
15	0.02	8.608	10.329	14.633	21.520
16	0.01	5.770	6.924	9.809	14.425
17	0.01	3.868	4.641	6.575	9.669
18	0.01	2.593	3.111	4.407	6.482
19	0.00	1.738	2.085	2.954	4.345
20	0.00	1.165	1.398	1.980	2.912
21	0.00	0.781	0.937	1.328	1.952
22	0.00	0.523	0.628	0.890	1.309
23	0.00	0.351	0.421	0.596	0.877
24	0.00	0.235	0.282	0.400	0.588
	1-hr cat	7061	8473	12003	17652
	1-hr exp	2328	2793	3957	5819
	8-hr avg	847	1016	1439	2117
	24-hr avg	294	353	500	735

Eggs	9.13	lb a.i./1000ft^3	
	Volume (ft^3)	1000	2000
		24hr, single release	24hr, single release
		Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	146.25		
1	98.03	40838.288	49005.946
2	65.71	27374.723	32849.668
3	44.05	18349.826	22019.791
4	29.53	12300.256	14760.307
5	19.79	8245.108	9894.130
6	13.27	5526.861	6632.234
7	8.89	3704.766	4445.719
8	5.96	2483.379	2980.055
9	4.00	1664.659	1997.590
10	2.68	1115.854	1339.025
11	1.80	747.979	897.575
12	1.20	501.386	601.663
13	0.81	336.089	403.307
14	0.54	225.287	270.344
15	0.36	151.014	181.217
16	0.24	101.228	121.474
17	0.16	67.855	81.426
18	0.11	45.485	54.582
19	0.07	30.489	36.587
20	0.05	20.438	24.525
21	0.03	13.700	16.440
22	0.02	9.183	11.020
23	0.01	6.156	7.387
24	0.01	4.126	4.952
	1-hr cat	123874	148649
	1-hr exp	40838	49006
	8-hr avg	14853	17823
	24-hr avg	5161	6193

Poultry	1.56	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	24.99				
1	16.75	6983.347	8380.017	11871.69	17458.37
2	11.23	4681.078	5617.293	7957.83	11702.69
3	7.53	3137.820	3765.384	5334.29	7844.55
4	5.05	2103.344	2524.013	3575.68	5258.36
5	3.38	1409.914	1691.896	2396.85	3524.78
6	2.27	945.093	1134.112	1606.66	2362.73
7	1.52	633.515	760.218	1076.98	1583.79
8	1.02	424.658	509.589	721.92	1061.64
9	0.68	284.657	341.588	483.92	711.64
10	0.46	190.811	228.973	324.38	477.03
11	0.31	127.904	153.485	217.44	319.76
12	0.21	85.737	102.884	145.75	214.34
13	0.14	57.471	68.965	97.70	143.68
14	0.09	38.524	46.229	65.49	96.31
15	0.06	25.823	30.988	43.90	64.56
16	0.04	17.310	20.772	29.43	43.27
17	0.03	11.603	13.924	19.73	29.01
18	0.02	7.778	9.333	13.22	19.44
19	0.01	5.214	6.256	8.86	13.03
20	0.01	3.495	4.194	5.94	8.74
21	0.01	2.343	2.811	3.98	5.86
22	0.00	1.570	1.884	2.67	3.93
23	0.00	1.053	1.263	1.79	2.63
24	0.00	0.706	0.847	1.20	1.76
	1-hr cat	21183	25419	36010	52956
	1-hr exp	6983	8380	11872	17458
	8-hr avg	2540	3048	4318	6350
	24-hr avg	883	1059	1500	2206

Poultry	1.56	Lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	24.99				
1	16.75	17458.37	17458.37	17458.37	34916.74
2	11.23	11702.69	11702.69	11702.69	23405.39
3	7.53	7844.55	7844.55	7844.55	15689.10
4	5.05	5258.36	5258.36	5258.36	10516.72
5	3.38	3524.78	3524.78	3524.78	7049.57
6	2.27	2362.73	2362.73	2362.73	4725.47
7	1.52	1583.79	1583.79	1583.79	3167.57
8	1.02	1061.64	1061.64	1061.64	2123.29
9	0.68	711.64	711.64	711.64	1423.28
10	0.46	477.03	477.03	477.03	954.06
11	0.31	319.76	319.76	319.76	639.52
12	0.21	214.34	214.34	214.34	428.68
13	0.14	143.68	143.68	143.68	287.36
14	0.09	96.31	96.31	96.31	192.62
15	0.06	64.56	64.56	64.56	129.12
16	0.04	43.27	43.27	43.27	86.55
17	0.03	29.01	29.01	29.01	58.02
18	0.02	19.44	19.44	19.44	38.89
19	0.01	13.03	13.03	13.03	26.07
20	0.01	8.74	8.74	8.74	17.47
21	0.01	5.86	5.86	5.86	11.71
22	0.00	3.93	3.93	3.93	7.85
23	0.00	2.63	2.63	2.63	5.26
24	0.00	1.76	1.76	1.76	3.53
	1-hr cat	52956	52956	52956	105913
	1-hr exp	17458	17458	17458	34917
	8-hr avg	6350	6350	6350	12699
	24-hr avg	2206	2206	2206	4413

Poultry	1.56	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	24.99			
1	16.75	34916.74	34916.74	34916.74
2	11.23	23405.39	23405.39	23405.39
3	7.53	15689.10	15689.10	15689.10
4	5.05	10516.72	10516.72	10516.72
5	3.38	7049.57	7049.57	7049.57
6	2.27	4725.47	4725.47	4725.47
7	1.52	3167.57	3167.57	3167.57
8	1.02	2123.29	2123.29	2123.29
9	0.68	1423.28	1423.28	1423.28
10	0.46	954.06	954.06	954.06
11	0.31	639.52	639.52	639.52
12	0.21	428.68	428.68	428.68
13	0.14	287.36	287.36	287.36
14	0.09	192.62	192.62	192.62
15	0.06	129.12	129.12	129.12
16	0.04	86.55	86.55	86.55
17	0.03	58.02	58.02	58.02
18	0.02	38.89	38.89	38.89
19	0.01	26.07	26.07	26.07
20	0.01	17.47	17.47	17.47
21	0.01	11.71	11.71	11.71
22	0.00	7.85	7.85	7.85
23	0.00	5.26	5.26	5.26
24	0.00	3.53	3.53	3.53
	1-hr cat	105913	105913	105913
	1-hr exp	34917	34917	34917
	8-hr avg	12699	12699	12699
	24-hr avg	4413	4413	4413

Mushroom	0.6	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	9.61				
1	6.44	2684.290	3221.15	4563.29	6710.72
2	4.32	1799.333	2159.20	3058.87	4498.33
3	2.89	1206.129	1447.35	2050.42	3015.32
4	1.94	808.493	970.19	1374.44	2021.23
5	1.30	541.949	650.34	921.31	1354.87
6	0.87	363.279	435.93	617.57	908.20
7	0.58	243.513	292.22	413.97	608.78
8	0.39	163.232	195.88	277.49	408.08
9	0.26	109.418	131.30	186.01	273.54
10	0.18	73.345	88.01	124.69	183.36
11	0.12	49.164	59.00	83.58	122.91
12	0.08	32.956	39.55	56.03	82.39
13	0.05	22.091	26.51	37.55	55.23
14	0.04	14.808	17.77	25.17	37.02
15	0.02	9.926	11.91	16.87	24.82
16	0.02	6.654	7.98	11.31	16.63
17	0.01	4.460	5.35	7.58	11.15
18	0.01	2.990	3.59	5.08	7.47
19	0.00	2.004	2.40	3.41	5.01
20	0.00	1.343	1.61	2.28	3.36
21	0.00	0.900	1.08	1.53	2.25
22	0.00	0.604	0.72	1.03	1.51
23	0.00	0.405	0.49	0.69	1.01
24	0.00	0.271	0.33	0.46	0.68
	1-hr cat	8142	9771	13842	20356
	1-hr exp	2684	3221	4563	6711
	8-hr avg	976	1172	1660	2441
	24-hr avg	339	407	577	848

Mushroom	0.6	lb a.i./1000ft^3	
	Volume (ft^3)	25000	50000
		24hr, single release	24hr, single release
		Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	9.61		
1	6.44	6710.72	6710.72
2	4.32	4498.33	4498.33
3	2.89	3015.32	3015.32
4	1.94	2021.23	2021.23
5	1.30	1354.87	1354.87
6	0.87	908.20	908.20
7	0.58	608.78	608.78
8	0.39	408.08	408.08
9	0.26	273.54	273.54
10	0.18	183.36	183.36
11	0.12	122.91	122.91
12	0.08	82.39	82.39
13	0.05	55.23	55.23
14	0.04	37.02	37.02
15	0.02	24.82	24.82
16	0.02	16.63	16.63
17	0.01	11.15	11.15
18	0.01	7.47	7.47
19	0.00	5.01	5.01
20	0.00	3.36	3.36
21	0.00	2.25	2.25
22	0.00	1.51	1.51
23	0.00	1.01	1.01
24	0.00	0.68	0.68
	1-hr cat	20356	20356
	1-hr exp	6711	6711
	8-hr avg	2441	2441
	24-hr avg	848	848

Citrus packing	0.416	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	6.66				
1	4.47	1862.226	2234.671	3165.784	4655.565
2	2.99	1248.287	1497.945	2122.089	3120.718
3	2.01	836.752	1004.102	1422.478	2091.880
4	1.35	560.892	673.070	953.516	1402.229
5	0.90	375.977	451.172	639.161	939.942
6	0.60	252.025	302.430	428.442	630.062
7	0.41	168.937	202.725	287.193	422.343
8	0.27	113.242	135.890	192.512	283.105
9	0.18	75.908	91.090	129.044	189.771
10	0.12	50.883	61.060	86.501	127.207
11	0.08	34.108	40.929	57.983	85.270
12	0.05	22.863	27.436	38.867	57.158
13	0.04	15.326	18.391	26.054	38.314
14	0.02	10.273	12.328	17.464	25.683
15	0.02	6.886	8.264	11.707	17.216
16	0.01	4.616	5.539	7.847	11.540
17	0.01	3.094	3.713	5.260	7.735
18	0.00	2.074	2.489	3.526	5.185
19	0.00	1.390	1.668	2.364	3.476
20	0.00	0.932	1.118	1.584	2.330
21	0.00	0.625	0.750	1.062	1.562
22	0.00	0.419	0.503	0.712	1.047
23	0.00	0.281	0.337	0.477	0.702
24	0.00	0.188	0.226	0.320	0.470
	1-hr cat	5649	6778	9603	14122
	1-hr exp	1862	2235	3166	4656
	8-hr avg	677	813	1151	1693
	24-hr avg	235	282	400	588

Citrus packing	0.416	lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	6.66				
1	4.47	4655.565	4655.565	4655.565	9311.130
2	2.99	3120.718	3120.718	3120.718	6241.437
3	2.01	2091.880	2091.880	2091.880	4183.760
4	1.35	1402.229	1402.229	1402.229	2804.458
5	0.90	939.942	939.942	939.942	1879.885
6	0.60	630.062	630.062	630.062	1260.124
7	0.41	422.343	422.343	422.343	844.687
8	0.27	283.105	283.105	283.105	566.210
9	0.18	189.771	189.771	189.771	379.542
10	0.12	127.207	127.207	127.207	254.415
11	0.08	85.270	85.270	85.270	170.539
12	0.05	57.158	57.158	57.158	114.316
13	0.04	38.314	38.314	38.314	76.628
14	0.02	25.683	25.683	25.683	51.365
15	0.02	17.216	17.216	17.216	34.431
16	0.01	11.540	11.540	11.540	23.080
17	0.01	7.735	7.735	7.735	15.471
18	0.00	5.185	5.185	5.185	10.371
19	0.00	3.476	3.476	3.476	6.952
20	0.00	2.330	2.330	2.330	4.660
21	0.00	1.562	1.562	1.562	3.124
22	0.00	1.047	1.047	1.047	2.094
23	0.00	0.702	0.702	0.702	1.403
24	0.00	0.470	0.470	0.470	0.941
	1-hr cat	14122	14122	14122	28243
	1-hr exp	4656	4656	4656	9311
	8-hr avg	1693	1693	1693	3386
	24-hr avg	588	588	588	1177

Citrus packing	0.416	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	6.66			
1	4.47	9311.130	9311.130	9311.130
2	2.99	6241.437	6241.437	6241.437
3	2.01	4183.760	4183.760	4183.760
4	1.35	2804.458	2804.458	2804.458
5	0.90	1879.885	1879.885	1879.885
6	0.60	1260.124	1260.124	1260.124
7	0.41	844.687	844.687	844.687
8	0.27	566.210	566.210	566.210
9	0.18	379.542	379.542	379.542
10	0.12	254.415	254.415	254.415
11	0.08	170.539	170.539	170.539
12	0.05	114.316	114.316	114.316
13	0.04	76.628	76.628	76.628
14	0.02	51.365	51.365	51.365
15	0.02	34.431	34.431	34.431
16	0.01	23.080	23.080	23.080
17	0.01	15.471	15.471	15.471
18	0.00	10.371	10.371	10.371
19	0.00	6.952	6.952	6.952
20	0.00	4.660	4.660	4.660
21	0.00	3.124	3.124	3.124
22	0.00	2.094	2.094	2.094
23	0.00	1.403	1.403	1.403
24	0.00	0.941	0.941	0.941
	1-hr cat	28243	28243	28243
	1-hr exp	9311	9311	9311
	8-hr avg	3386	3386	3386
	24-hr avg	1177	1177	1177

Bee cells	1	lb a.i./1000ft^3	
	Volume (ft^3)	1000	2000
		24hr, single release	24hr, single release
		Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	16.02		
1	10.74	4478.290	5373.948
2	7.20	3001.887	3602.265
3	4.82	2012.225	2414.670
4	3.23	1348.835	1618.602
5	2.17	904.151	1084.981
6	1.45	606.071	727.285
7	0.97	406.261	487.514
8	0.65	272.325	326.790
9	0.44	182.545	219.054
10	0.29	122.364	146.836
11	0.20	82.023	98.427
12	0.13	54.981	65.978
13	0.09	36.855	44.226
14	0.06	24.705	29.646
15	0.04	16.560	19.872
16	0.03	11.101	13.321
17	0.02	7.441	8.929
18	0.01	4.988	5.985
19	0.01	3.343	4.012
20	0.01	2.241	2.689
21	0.00	1.502	1.803
22	0.00	1.007	1.208
23	0.00	0.675	0.810
24	0.00	0.452	0.543
	1-hr cat	13584	16301
	1-hr exp	4478	5374
	8-hr avg	1629	1955
	24-hr avg	566	679

Laboratory	1.2	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	19.22				
1	12.89	5386.161	6463.394	9156.474	13465.404
2	8.64	3610.452	4332.542	6137.768	9026.130
3	5.79	2420.158	2904.190	4114.269	6050.396
4	3.88	1622.281	1946.737	2757.877	4055.702
5	2.60	1087.447	1304.937	1848.660	2718.618
6	1.74	728.938	874.725	1239.194	1822.344
7	1.17	488.622	586.346	830.657	1221.554
8	0.78	327.533	393.039	556.806	818.832
9	0.53	219.552	263.462	373.238	548.880
10	0.35	147.170	176.604	250.189	367.925
11	0.24	98.651	118.381	167.707	246.627
12	0.16	66.128	79.353	112.417	165.319
13	0.11	44.327	53.192	75.355	110.817
14	0.07	29.713	35.656	50.512	74.283
15	0.05	19.917	23.901	33.859	49.793
16	0.03	13.351	16.021	22.697	33.377
17	0.02	8.949	10.739	15.214	22.374
18	0.01	5.999	7.199	10.198	14.997
19	0.01	4.021	4.825	6.836	10.053
20	0.01	2.696	3.235	4.582	6.739
21	0.00	1.807	2.168	3.072	4.517
22	0.00	1.211	1.453	2.059	3.028
23	0.00	0.812	0.974	1.380	2.030
24	0.00	0.544	0.653	0.925	1.361
	1-hr cat	16338	19605	27774	40844
	1-hr exp	5386	6463	9156	13465
	8-hr avg	1959	2351	3330	4897
	24-hr avg	681	817	1157	1702

Laboratory	1.2	lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	19.22				
1	12.89	13465.404	13465.404	13465.404	26930.807
2	8.64	9026.130	9026.130	9026.130	18052.260
3	5.79	6050.396	6050.396	6050.396	12100.792
4	3.88	4055.702	4055.702	4055.702	8111.403
5	2.60	2718.618	2718.618	2718.618	5437.236
6	1.74	1822.344	1822.344	1822.344	3644.688
7	1.17	1221.554	1221.554	1221.554	2443.108
8	0.78	818.832	818.832	818.832	1637.664
9	0.53	548.880	548.880	548.880	1097.759
10	0.35	367.925	367.925	367.925	735.850
11	0.24	246.627	246.627	246.627	493.255
12	0.16	165.319	165.319	165.319	330.639
13	0.11	110.817	110.817	110.817	221.634
14	0.07	74.283	74.283	74.283	148.566
15	0.05	49.793	49.793	49.793	99.586
16	0.03	33.377	33.377	33.377	66.755
17	0.02	22.374	22.374	22.374	44.747
18	0.01	14.997	14.997	14.997	29.995
19	0.01	10.053	10.053	10.053	20.106
20	0.01	6.739	6.739	6.739	13.478
21	0.00	4.517	4.517	4.517	9.034
22	0.00	3.028	3.028	3.028	6.056
23	0.00	2.030	2.030	2.030	4.059
24	0.00	1.361	1.361	1.361	2.721
	1-hr cat	40844	40844	40844	81689
	1-hr exp	13465	13465	13465	26931
	8-hr avg	4897	4897	4897	9795
	24-hr avg	1702	1702	1702	3403

Laboratory	1.2	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (µg/m^2-s)	ER (µg/m^2-s)	ER (µg/m^2-s)
0	19.22			
1	12.89	26930.807	26930.807	26930.807
2	8.64	18052.260	18052.260	18052.260
3	5.79	12100.792	12100.792	12100.792
4	3.88	8111.403	8111.403	8111.403
5	2.60	5437.236	5437.236	5437.236
6	1.74	3644.688	3644.688	3644.688
7	1.17	2443.108	2443.108	2443.108
8	0.78	1637.664	1637.664	1637.664
9	0.53	1097.759	1097.759	1097.759
10	0.35	735.850	735.850	735.850
11	0.24	493.255	493.255	493.255
12	0.16	330.639	330.639	330.639
13	0.11	221.634	221.634	221.634
14	0.07	148.566	148.566	148.566
15	0.05	99.586	99.586	99.586
16	0.03	66.755	66.755	66.755
17	0.02	44.747	44.747	44.747
18	0.01	29.995	29.995	29.995
19	0.01	20.106	20.106	20.106
20	0.01	13.478	13.478	13.478
21	0.00	9.034	9.034	9.034
22	0.00	6.056	6.056	6.056
23	0.00	4.059	4.059	4.059
24	0.00	2.721	2.721	2.721
	1-hr cat	81689	81689	81689
	1-hr exp	26931	26931	26931
	8-hr avg	9795	9795	9795
	24-hr avg	3403	3403	3403

Appendix H. Emission rates, mechanical ventilation (active aeration)

Poultry	1.56	lb a.i./1000ft^3			
	Volume (ft^3)	1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	24.99				
1	4.70	0.160	0.319	0.798	1.596
2	0.89	0.030	0.060	0.150	0.300
3	0.17	0.006	0.011	0.028	0.057
4	0.03	0.001	0.002	0.005	0.011
5	0.01	0.000	0.000	0.001	0.002
6	0.00	0.000	0.000	0.000	0.000
7	0.00	0.000	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	0.20	0.39	0.98	1.97
	1-hr exp	0.16	0.32	0.80	1.60
	8-hr avg	0.02	0.05	0.12	0.25
	24-hr avg	0.0082	0.016	0.041	0.082

Poultry	1.56	lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	24.99				
1	4.70	3.989	7.978	15.955	39.889
2	0.89	0.751	1.502	3.004	7.509
3	0.17	0.141	0.283	0.565	1.414
4	0.03	0.027	0.053	0.106	0.266
5	0.01	0.005	0.010	0.020	0.050
6	0.00	0.001	0.002	0.004	0.009
7	0.00	0.000	0.000	0.001	0.002
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	4.92	9.84	19.68	49.20
	1-hr exp	3.99	7.98	15.96	39.89
	8-hr avg	0.61	1.23	2.46	6.15
	24-hr avg	0.21	0.41	0.82	2.05

Poultry	1.56	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)
0	24.99			
1	4.70	79.777	119.666	159.555
2	0.89	15.018	22.527	30.036
3	0.17	2.827	4.241	5.654
4	0.03	0.532	0.798	1.064
5	0.01	0.100	0.150	0.200
6	0.00	0.019	0.028	0.038
7	0.00	0.004	0.005	0.007
8	0.00	0.001	0.001	0.001
9	0.00	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000
	1-hr cat	98.40	147.59	196.79
	1-hr exp	79.78	119.67	159.56
	8-hr avg	12.30	18.45	24.60
	24-hr avg	4.10	6.15	8.20

Mushroom	0.6	lb a.i./1000ft^3		
	Volume (ft^3)	1000	2000	5000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)
0	9.61			
1	1.81	0.061	0.123	0.307
2	0.34	0.012	0.023	0.058
3	0.06	0.002	0.004	0.011
4	0.01	0.000	0.001	0.002
5	0.00	0.000	0.000	0.000
6	0.00	0.000	0.000	0.000
7	0.00	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000
	1-hr cat	0.08	0.15	0.38
	1-hr exp	0.06	0.12	0.31
	8-hr avg	0.01	0.02	0.05
	24-hr avg	0.0032	0.0063	0.016

Mushroom	0.6	lb a.i./1000ft^3		
	Volume (ft^3)	10000	25000	50000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)
0	9.61			
1	1.81	0.614	1.534	3.068
2	0.34	0.116	0.289	0.578
3	0.06	0.022	0.054	0.109
4	0.01	0.004	0.010	0.020
5	0.00	0.001	0.002	0.004
6	0.00	0.000	0.000	0.001
7	0.00	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000
	1-hr cat	0.76	1.89	3.78
	1-hr exp	0.61	1.53	3.07
	8-hr avg	0.09	0.24	0.47
	24-hr avg	0.032	0.079	0.16

Citrus packing	0.416	lb a.i./1000ft^3			
		1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	6.66				
1	1.25	0.043	0.085	0.213	0.425
2	0.24	0.008	0.016	0.040	0.080
3	0.04	0.002	0.003	0.008	0.015
4	0.01	0.000	0.001	0.001	0.003
5	0.00	0.000	0.000	0.000	0.001
6	0.00	0.000	0.000	0.000	0.000
7	0.00	0.000	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	0.05	0.10	0.26	0.52
	1-hr exp	0.04	0.09	0.21	0.43
	8-hr avg	0.007	0.013	0.03	0.07
	24-hr avg	0.0022	0.0044	0.011	0.022

Citrus packing	0.416	lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	6.66				
1	1.25	1.064	2.127	4.255	10.637
2	0.24	0.200	0.400	0.801	2.002
3	0.04	0.038	0.075	0.151	0.377
4	0.01	0.007	0.014	0.028	0.071
5	0.00	0.001	0.003	0.005	0.013
6	0.00	0.000	0.001	0.001	0.003
7	0.00	0.000	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	1.31	2.62	5.25	13.12
	1-hr exp	1.06	2.13	4.26	10.64
	8-hr avg	0.16	0.33	0.66	1.64
	24-hr avg	0.055	0.11	0.22	0.55

Citrus packing	0.416	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)
0	6.66			
1	1.25	21.274	31.911	42.548
2	0.24	4.005	6.007	8.010
3	0.04	0.754	1.131	1.508
4	0.01	0.142	0.213	0.284
5	0.00	0.027	0.040	0.053
6	0.00	0.005	0.008	0.010
7	0.00	0.001	0.001	0.002
8	0.00	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000
	1-hr cat	26.24	39.36	52.48
	1-hr exp	21.27	31.91	42.55
	8-hr avg	3.28	4.92	6.56
	24-hr avg	1.09	1.64	2.19

Laboratory	1.20	lb a.i./1000ft^3			
		1000	2000	5000	10000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	19.30				
1	3.64	0.123	0.246	0.616	1.231
2	0.69	0.023	0.047	0.116	0.233
3	0.13	0.004	0.009	0.022	0.044
4	0.02	0.001	0.002	0.004	0.008
5	0.00	0.000	0.000	0.001	0.002
6	0.00	0.000	0.000	0.000	0.000
7	0.00	0.000	0.000	0.000	0.000
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	0.15	0.30	0.76	1.52
	1-hr exp	0.12	0.25	0.62	1.23
	8-hr avg	0.019	0.038	0.09	0.19
	24-hr avg	0.0063	0.0126	0.032	0.063

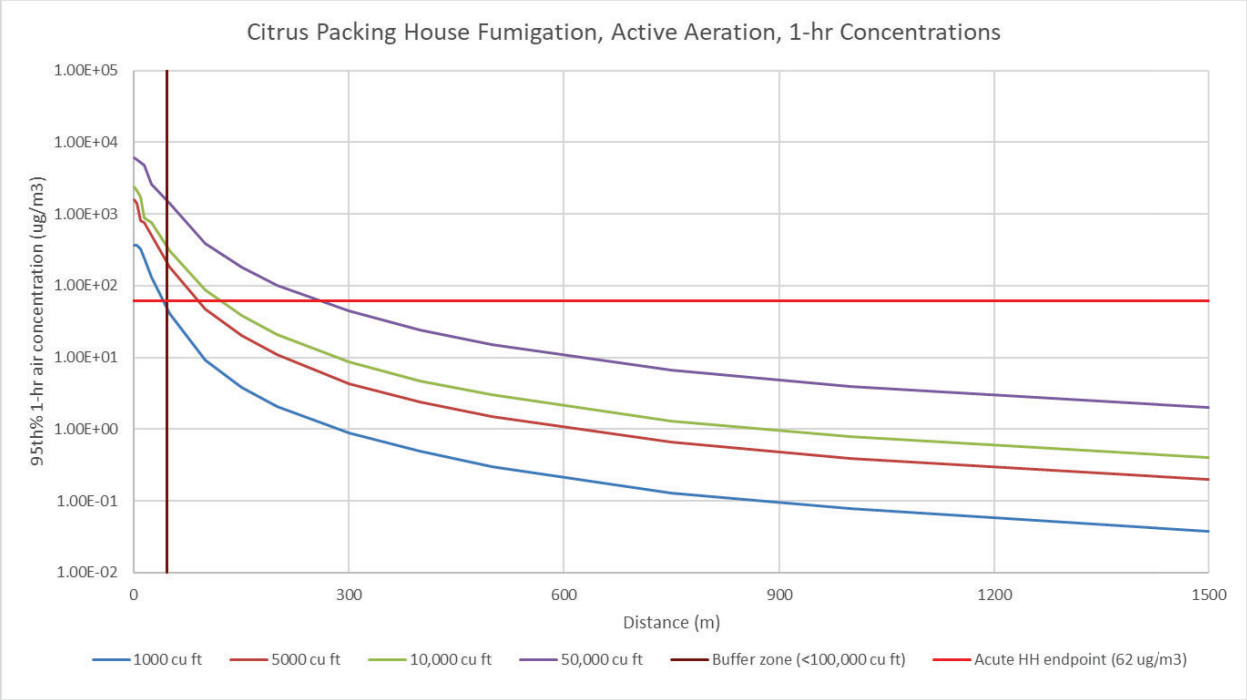
Laboratory	1.20	lb a.i./1000ft^3			
	Volume (ft^3)	25000	50000	100000	250000
		24hr, single release	24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)	ER (g/s)
0	19.30				
1	3.64	3.078	6.156	12.311	30.778
2	0.69	0.581	1.163	2.325	5.813
3	0.13	0.110	0.220	0.439	1.098
4	0.02	0.021	0.041	0.083	0.207
5	0.00	0.004	0.008	0.016	0.039
6	0.00	0.001	0.001	0.003	0.007
7	0.00	0.000	0.000	0.001	0.001
8	0.00	0.000	0.000	0.000	0.000
9	0.00	0.000	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000	0.000
	1-hr cat	3.79	7.59	15.18	37.95
	1-hr exp	3.08	6.16	12.31	30.78
	8-hr avg	0.47	0.95	1.90	4.74
	24-hr avg	0.158	0.316	0.632	1.581

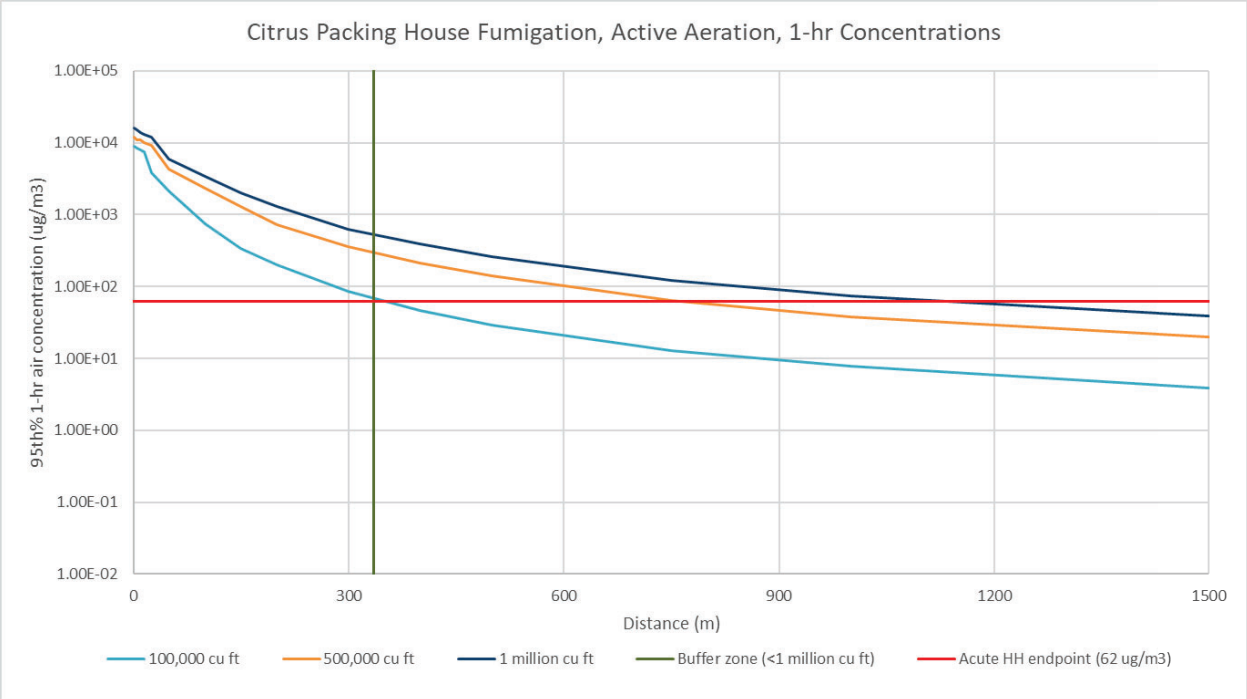
Laboratory	1.20	lb a.i./1000ft^3		
	Volume (ft^3)	500000	750000	1000000
		24hr, single release	24hr, single release	24hr, single release
		Exponential	Exponential	Exponential
Hour	C (g/m^3)	ER (g/s)	ER (g/s)	ER (g/s)
0	19.30			
1	3.64	61.557	92.335	123.113
2	0.69	11.627	17.440	23.253
3	0.13	2.196	3.294	4.392
4	0.02	0.415	0.622	0.830
5	0.00	0.078	0.118	0.157
6	0.00	0.015	0.022	0.030
7	0.00	0.003	0.004	0.006
8	0.00	0.001	0.001	0.001
9	0.00	0.000	0.000	0.000
10	0.00	0.000	0.000	0.000
11	0.00	0.000	0.000	0.000
12	0.00	0.000	0.000	0.000
13	0.00	0.000	0.000	0.000
14	0.00	0.000	0.000	0.000
15	0.00	0.000	0.000	0.000
16	0.00	0.000	0.000	0.000
17	0.00	0.000	0.000	0.000
18	0.00	0.000	0.000	0.000
19	0.00	0.000	0.000	0.000
20	0.00	0.000	0.000	0.000
21	0.00	0.000	0.000	0.000
22	0.00	0.000	0.000	0.000
23	0.00	0.000	0.000	0.000
24	0.00	0.000	0.000	0.000
	1-hr cat	75.89	113.84	151.78
	1-hr exp	61.56	92.34	123.11
	8-hr avg	9.49	14.23	18.97
	24-hr avg	3.16	4.74	6.32

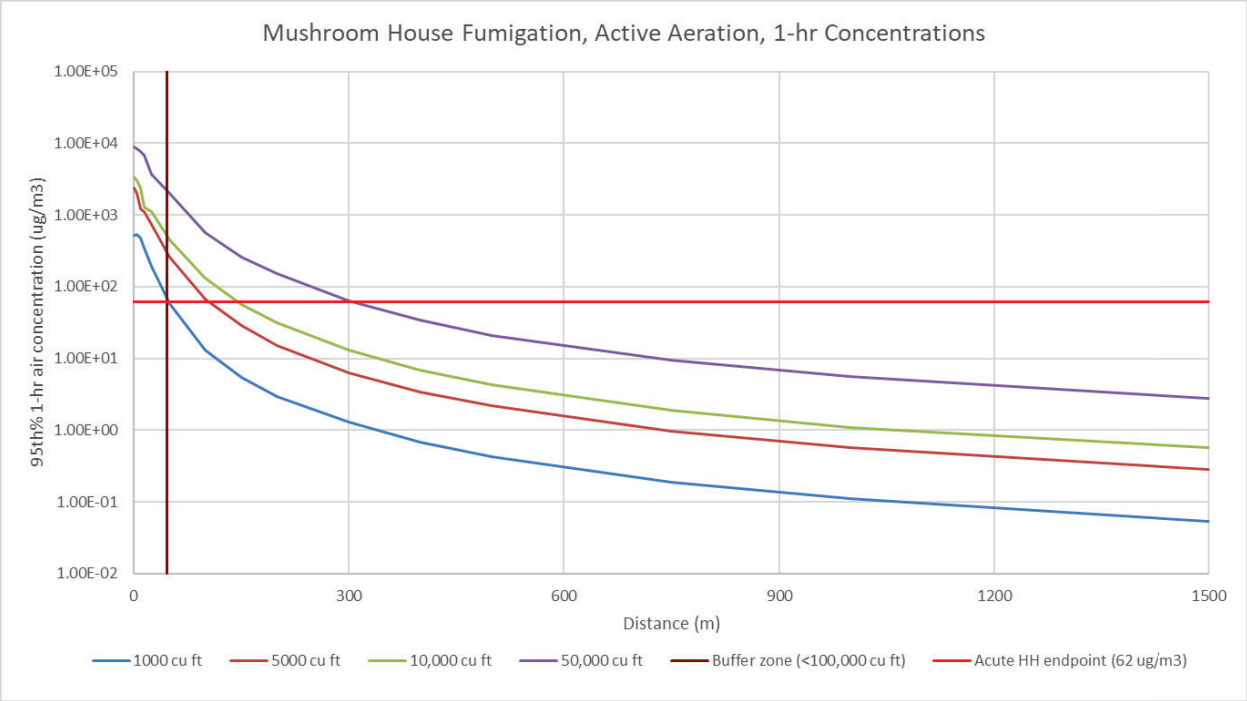
Appendix I. PERFUM Results

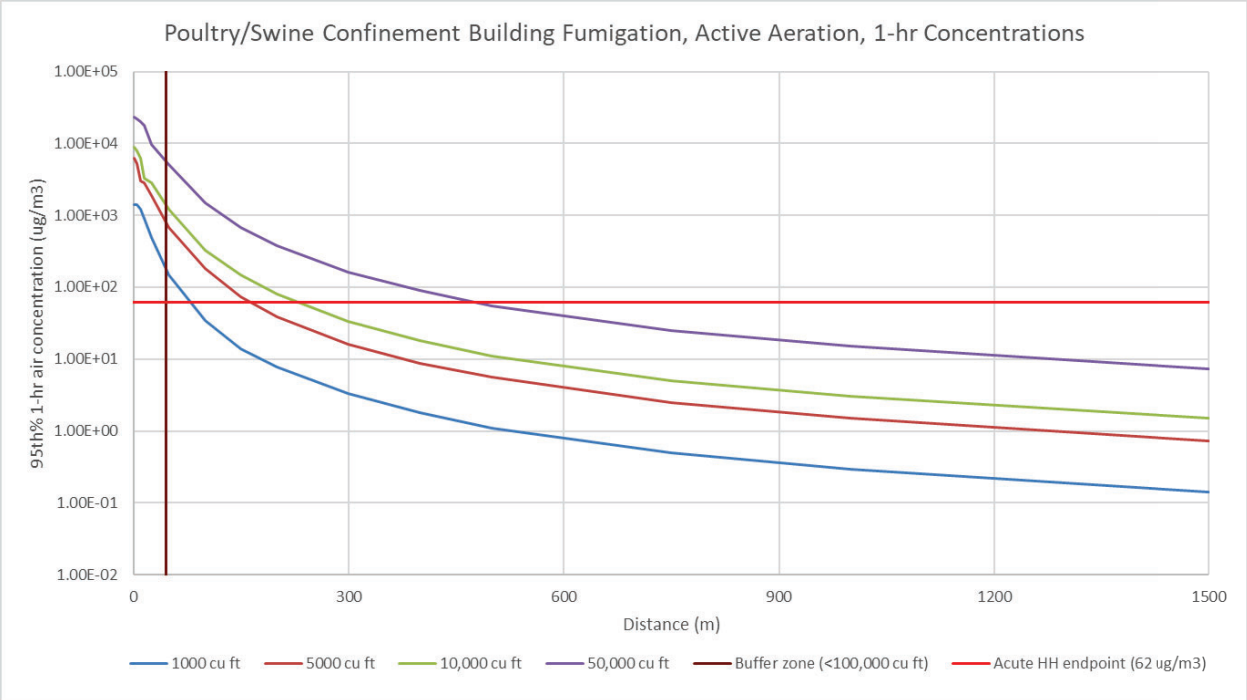
The following appendix contains figures and tables of air concentrations versus distance for PERFUM runs for facilities employing mechanical ventilation (active aeration) and for facilities not employing mechanical ventilation (passive aeration).

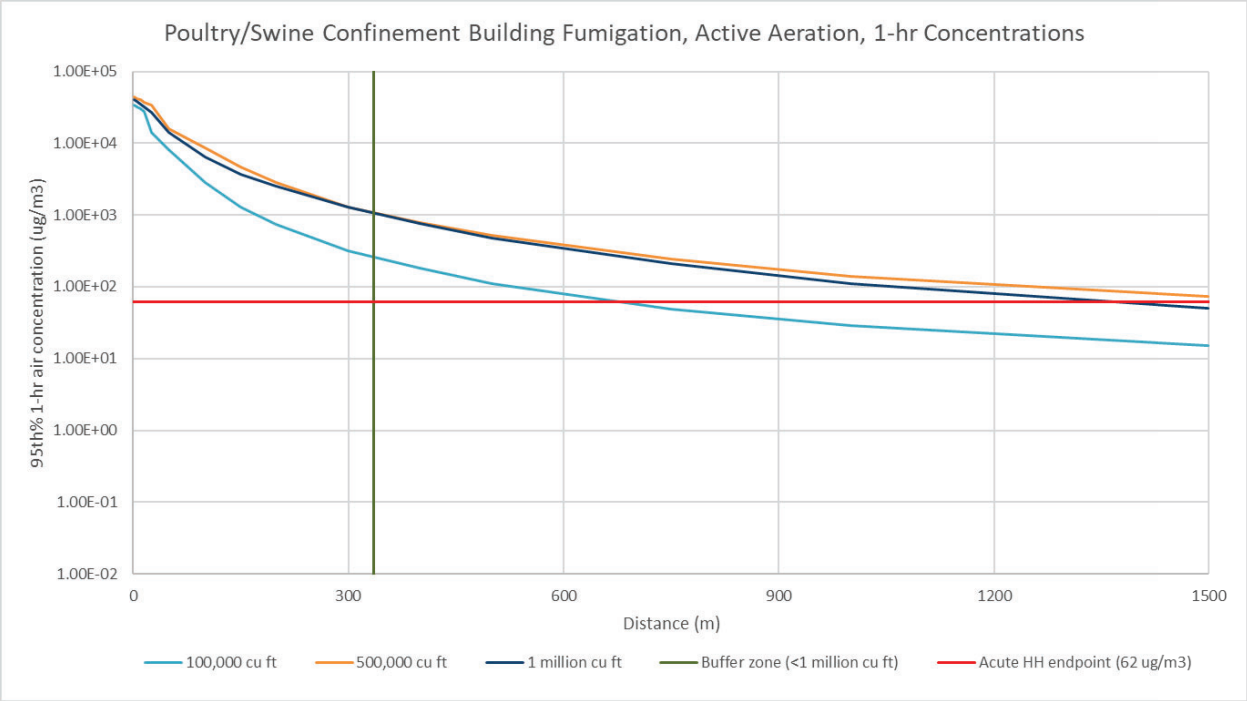
Human health, 1-hour Concentrations

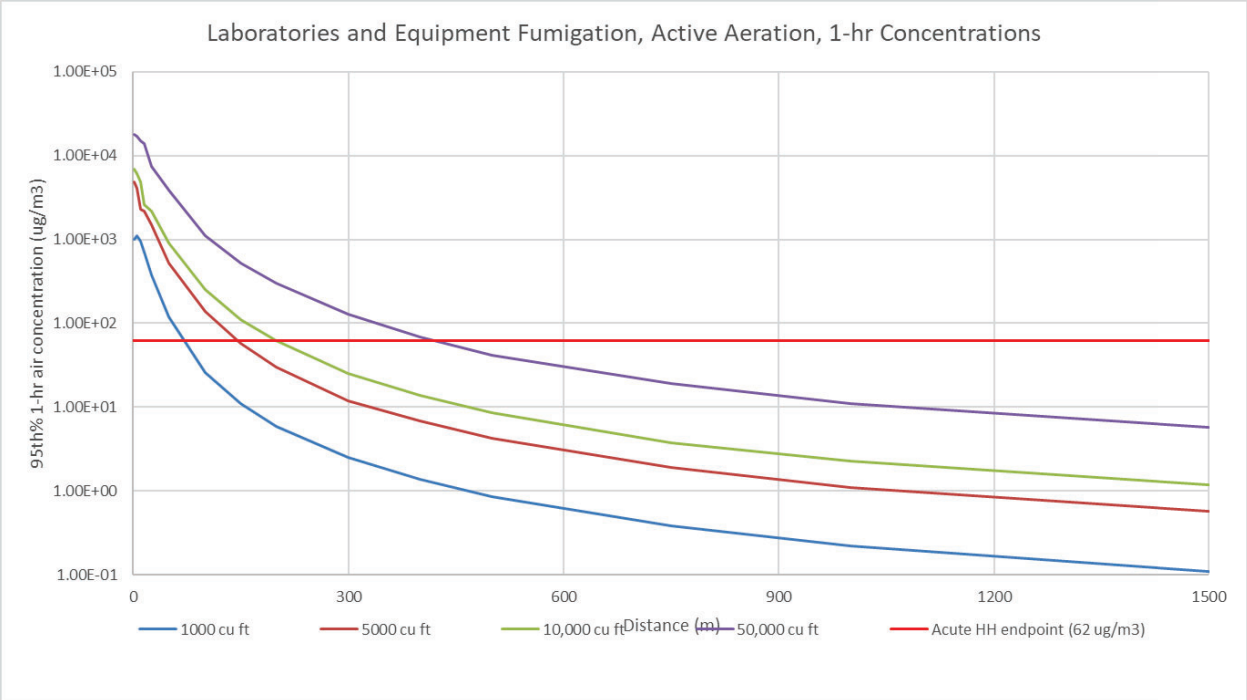


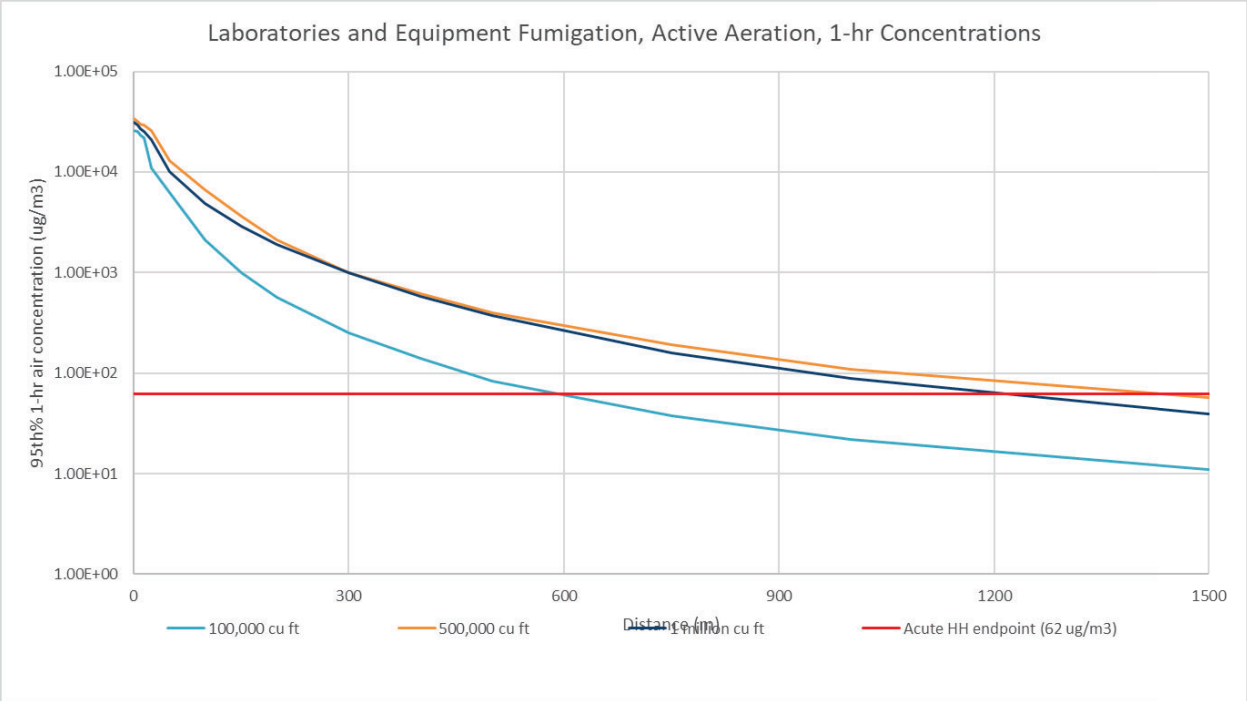


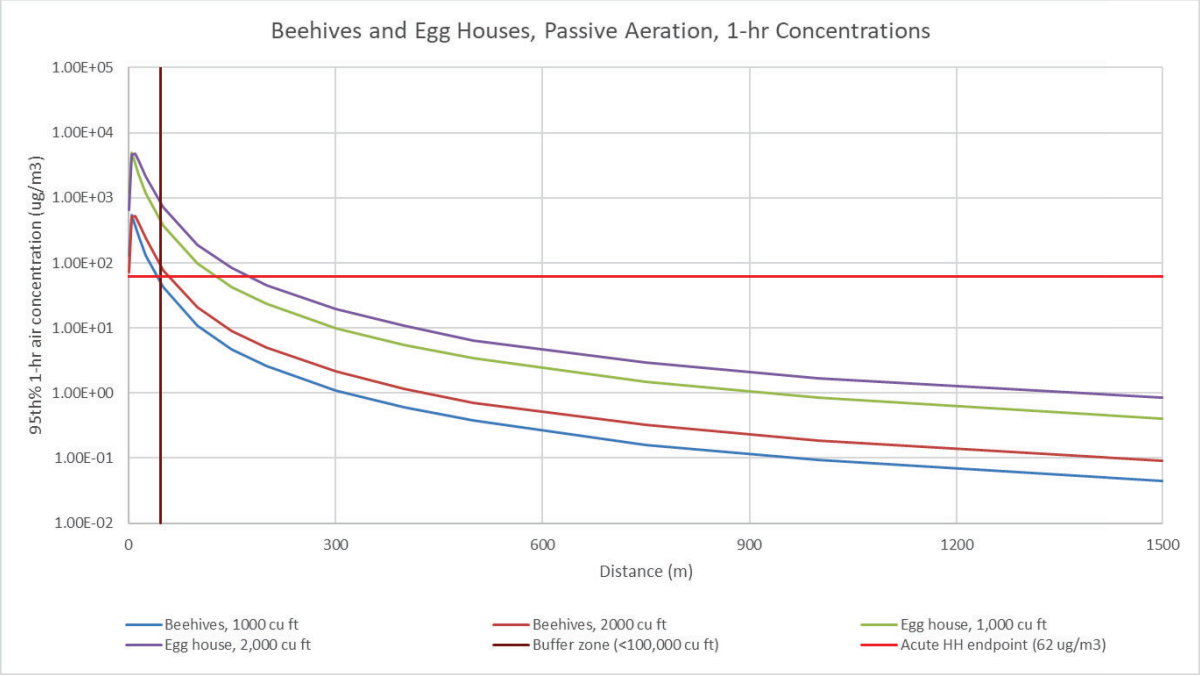

Mushroom House Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)

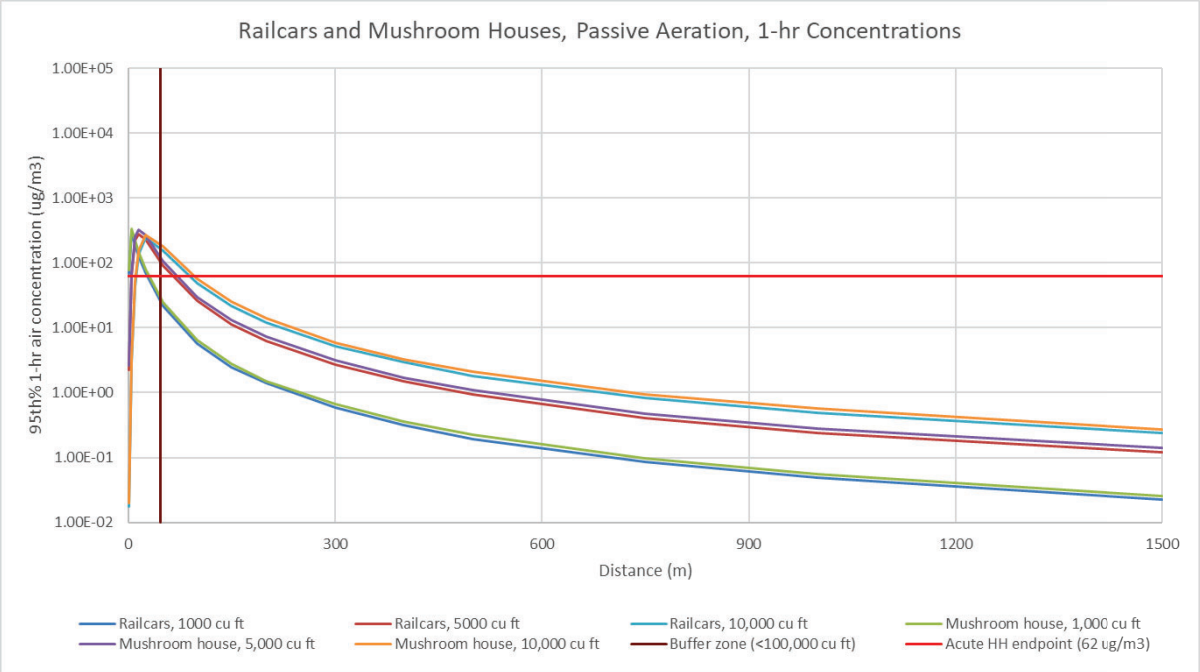

Poultry/Swine Confinement Building Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)

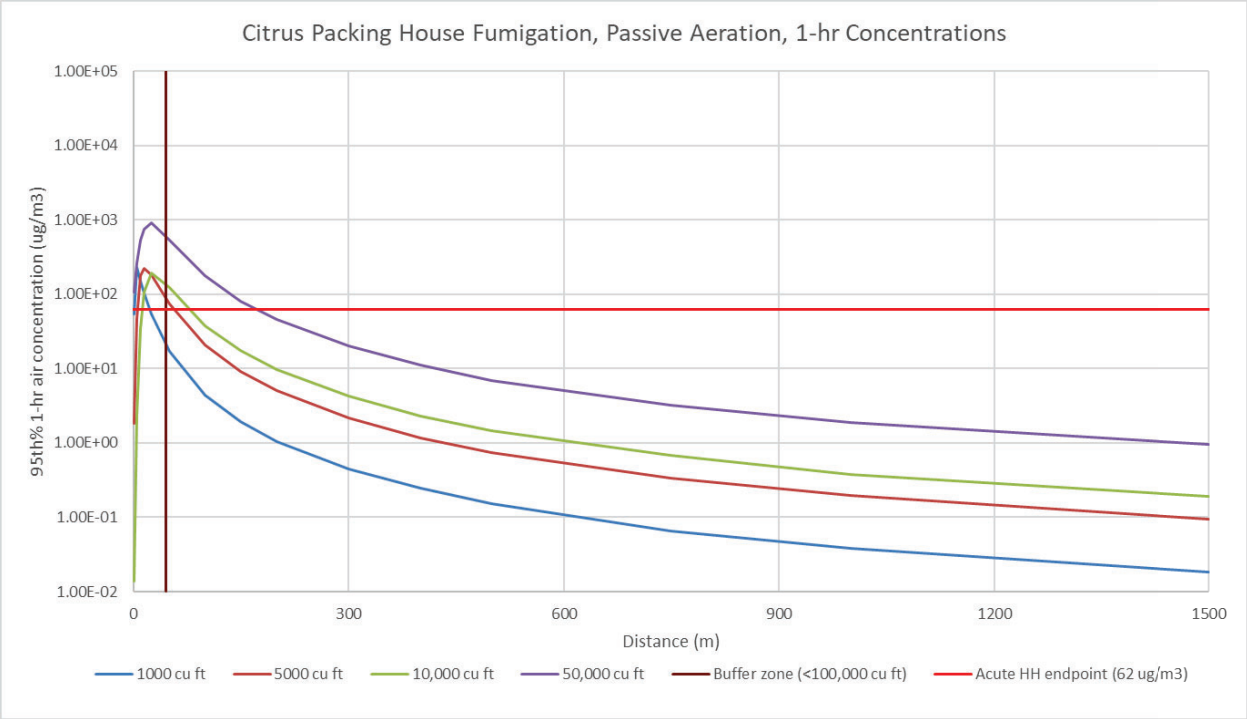

Poultry/Swine Confinement Building Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
100,000 cu ft
500,000 cu ft
1 million cu ft
Buffer zone (<1 million cu ft)
Acute HH endpoint (62 ug/m3)

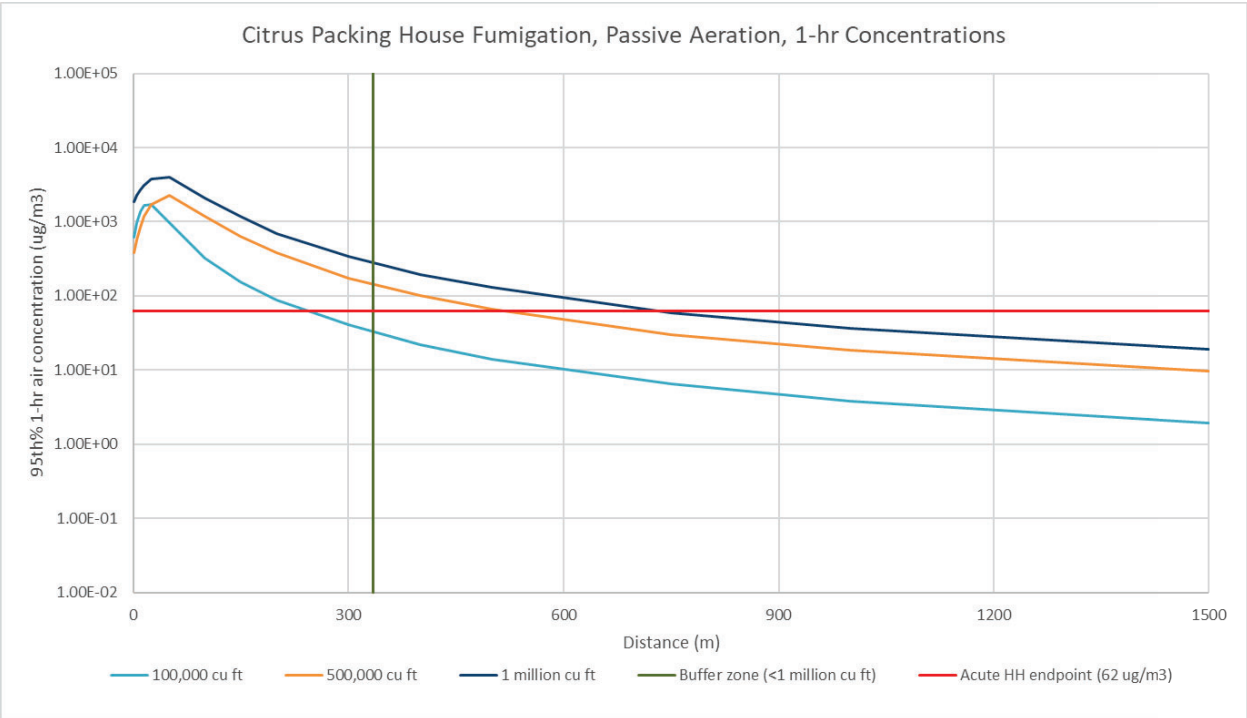

Laboratories and Equipment Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Acute HH endpoint (62 ug/m3)

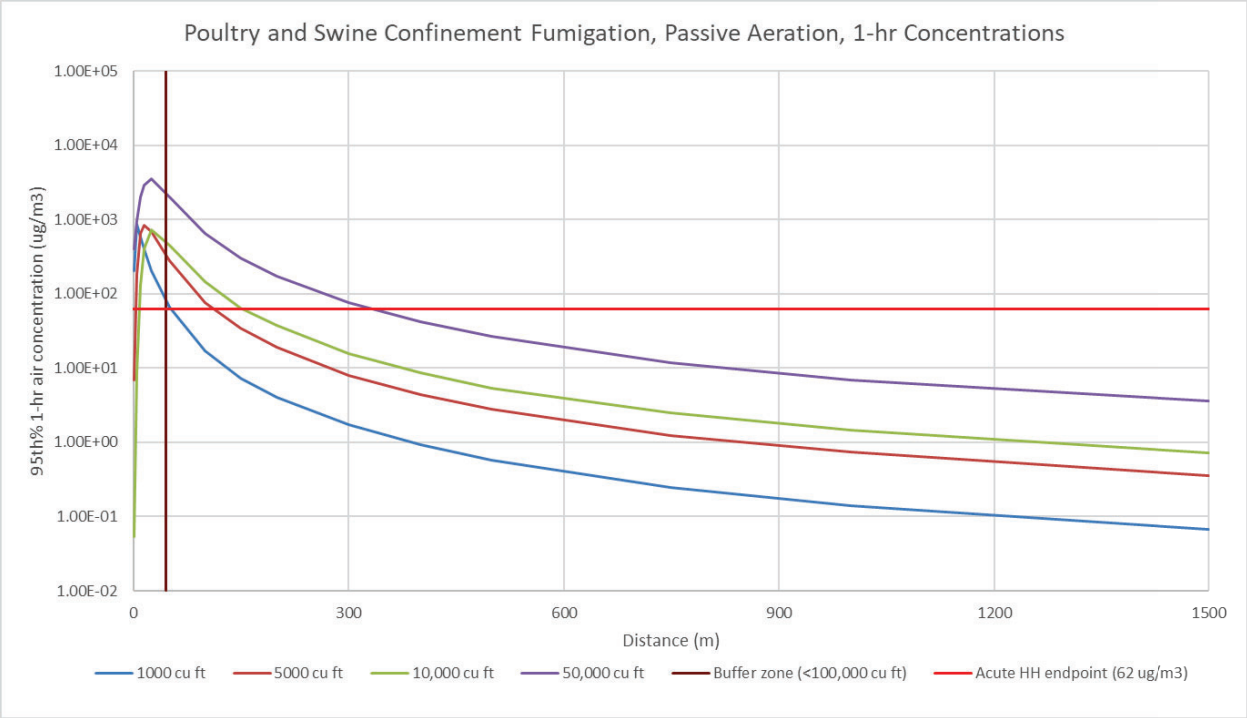

Laboratories and Equipment Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
0
300
600
900
1200
1500
Distance (m)
100,000 cu ft
500,000 cu ft
1 million cu ft
Acute HH endpoint (62 ug/m3)

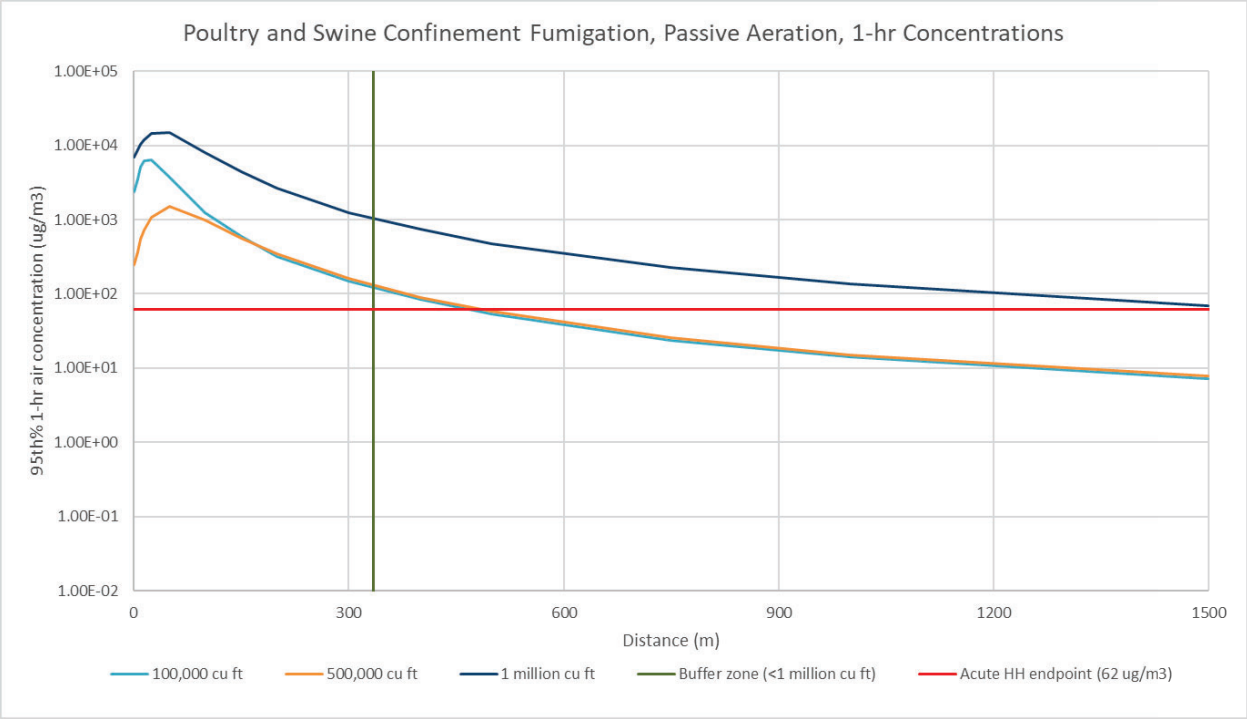

Beehives and Egg Houses, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
Beehives, 1000 cu ft
Beehives, 2000 cu ft
Egg house, 1,000 cu ft
Egg house, 2,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)

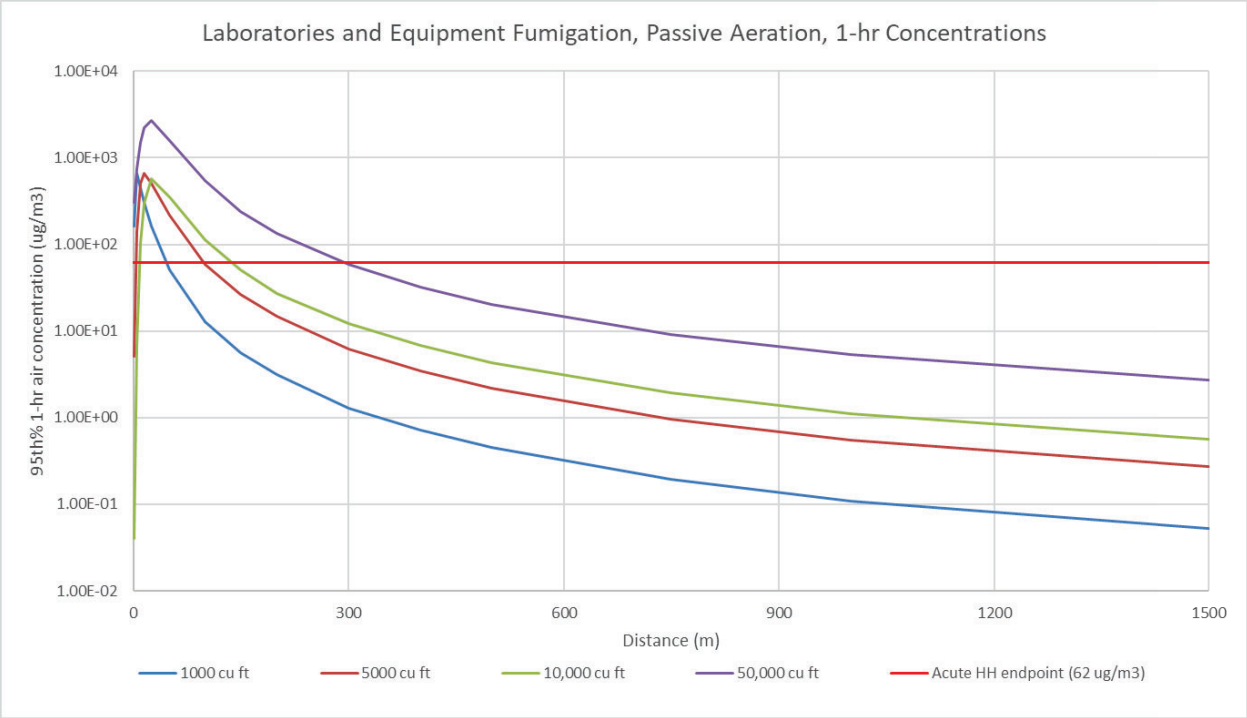

Railcars and Mushroom Houses, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
Railcars, 1000 cu ft
Railcars, 5000 cu ft
Railcars, 10,000 cu ft
Mushroom house, 1,000 cu ft
Mushroom house, 5,000 cu ft
Mushroom house, 10,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)

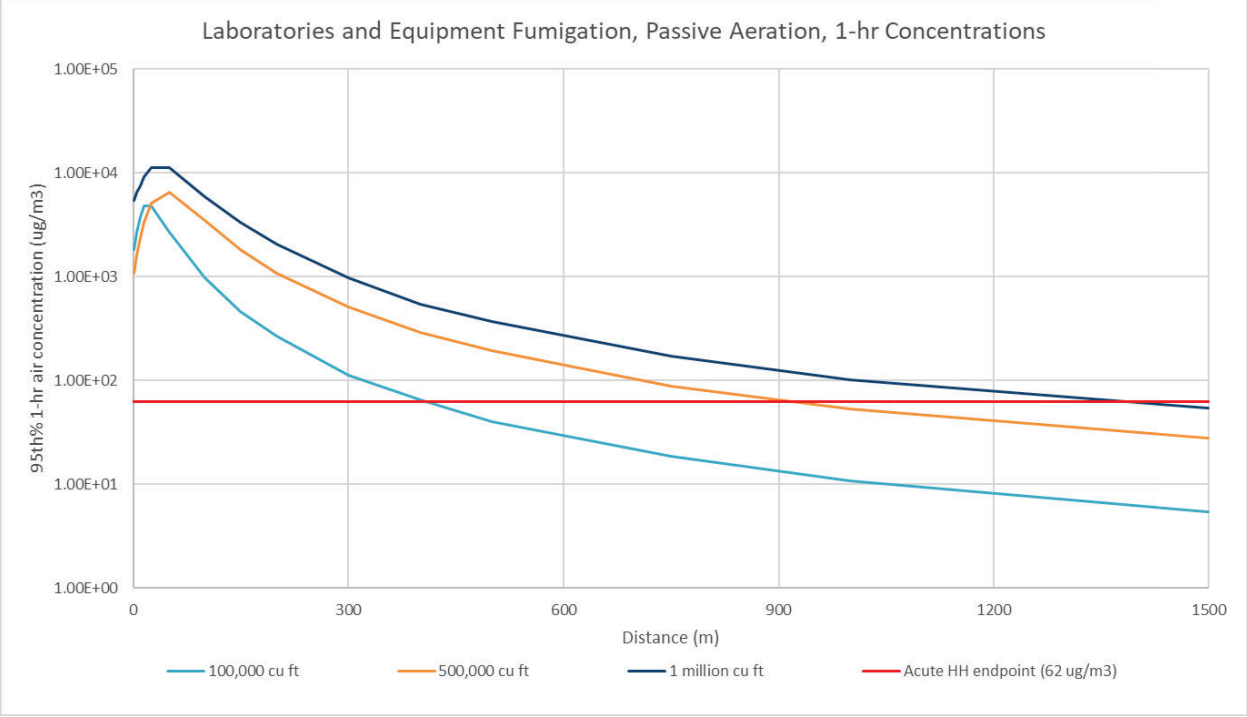

Citrus Packing House Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)


Citrus Packing House Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
100,000 cu ft
500,000 cu ft
1 million cu ft
Buffer zone (<1 million cu ft)
Acute HH endpoint (62 ug/m3)


Poultry and Swine Confinement Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Buffer zone (<100,000 cu ft)
Acute HH endpoint (62 ug/m3)


Poultry and Swine Confinement Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
100,000 cu ft
500,000 cu ft
1 million cu ft
Buffer zone (<1 million cu ft)
Acute HH endpoint (62 ug/m3)


Laboratories and Equipment Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
5000 cu ft
10,000 cu ft
50,000 cu ft
Acute HH endpoint (62 ug/m3)


Laboratories and Equipment Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
0
300
600
900
1200
1500
Distance (m)
100,000 cu ft
500,000 cu ft
1 million cu ft
Acute HH endpoint (62 ug/m3)

Maximum 1-hour air concentrations from facilities using mechanical ventilation (active aeration)

Use	Citrus Packing Houses										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	5	9	20	35	71	150	6	13	27	38	48
90	22	43	97	160	350	620	43	100	200	270	340
95	41	78	180	310	74	1400	86	200	360	500	630
Use	Mushroom Houses										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000					
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	7	13	28	51	100	220					
90	31	62	140	240	510	890					
95	58	110	260	450	1100	2000					
Use	Poultry and Swine Confinement Housing										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	18	34	74	130	270	570	22	50	100	140	180
90	83	160	360	610	1300	2300	160	380	740	1000	1300
95	150	290	670	1200	2800	5100	320	760	1300	1900	2400
Use	Laboratories, equipment, and animal areas										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	190	640	1500	2200	400	7300	9100	8800	12000	12000	12000
90	810	200	4000	5700	9900	15000	20000	18000	25000	27000	31000
95	1100	2500	4800	6800	12000	18000	26000	23000	34000	39000	45000

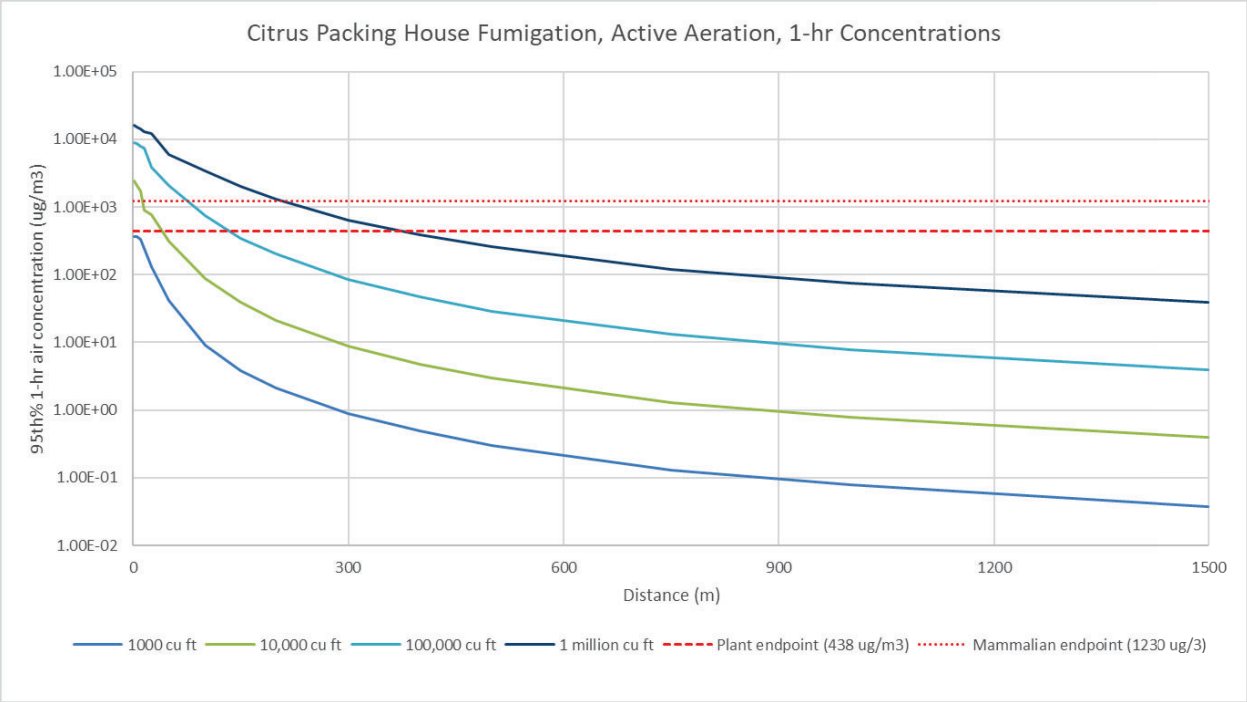
* Concentrations reflect a 150 ft buffer zones for buildings less than 100,000 ft^3 and a 1,100 ft buffer zone for buildings greater than 100,000 ft^3 for all uses except for paraformaldehyde, which has no buffer requirements on the label.

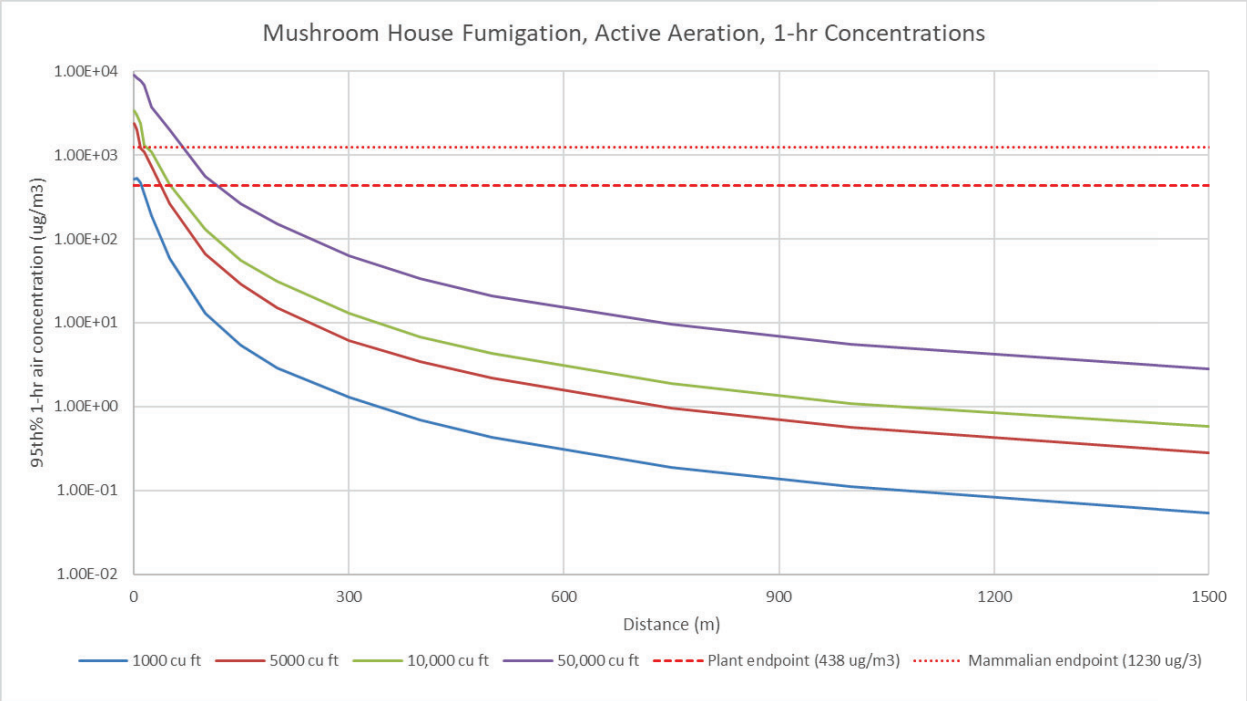
Maximum 1-hour air concentrations from facilities not using mechanical ventilation (passive aeration)

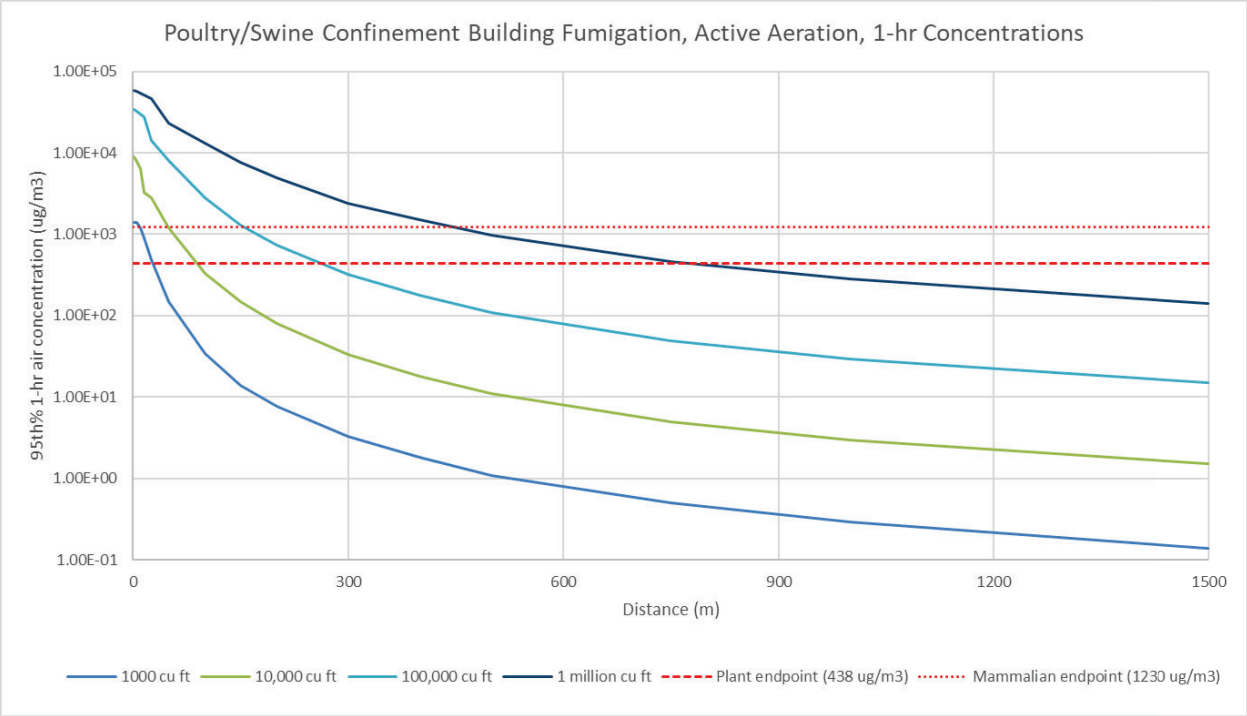
Use	Citrus Packing Houses										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	0.4	0.7	1	1	4	9	0.02	0.2	0.4	0.6	0.8
90	12	24	54	88	210	390	22	56	110	160	200
95	17	33	73	120	290	540	40	92	180	260	340
Use	Mushroom Houses						Beehive		Egg Fumigation		
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	1000	2000	1000	2000	
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	0.5	1	2	2	5	13	1	2	8	15	
90	18	34	79	130	300	570	30	57	270	520	
95	25	48	110	180	420	780	42	79	380	720	
Use	Poultry and Swine Confinement Housing										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	1	3	5	5	14	34	0.09	0.7	1	2	3
90	46	89	210	330	790	1500	84	210	400	590	750
95	65	120	280	460	1100	2000	150	350	670	1000	1200
Use	Laboratories, equipment, and animal areas										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	27	30	9	4	11	43	160	15	67	160	340
90	460	460	400	310	840	1700	3300	2000	4000	5900	7700
95	660	630	650	560	1400	2700	5000	3400	6500	9200	12000
Use	Rooms and Railcars										
Building size (ft^3)	1000	2000	5000	10,000							
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	0.5	0.8	2	2							
90	15	30	68	110							
95	22	41	93	150							

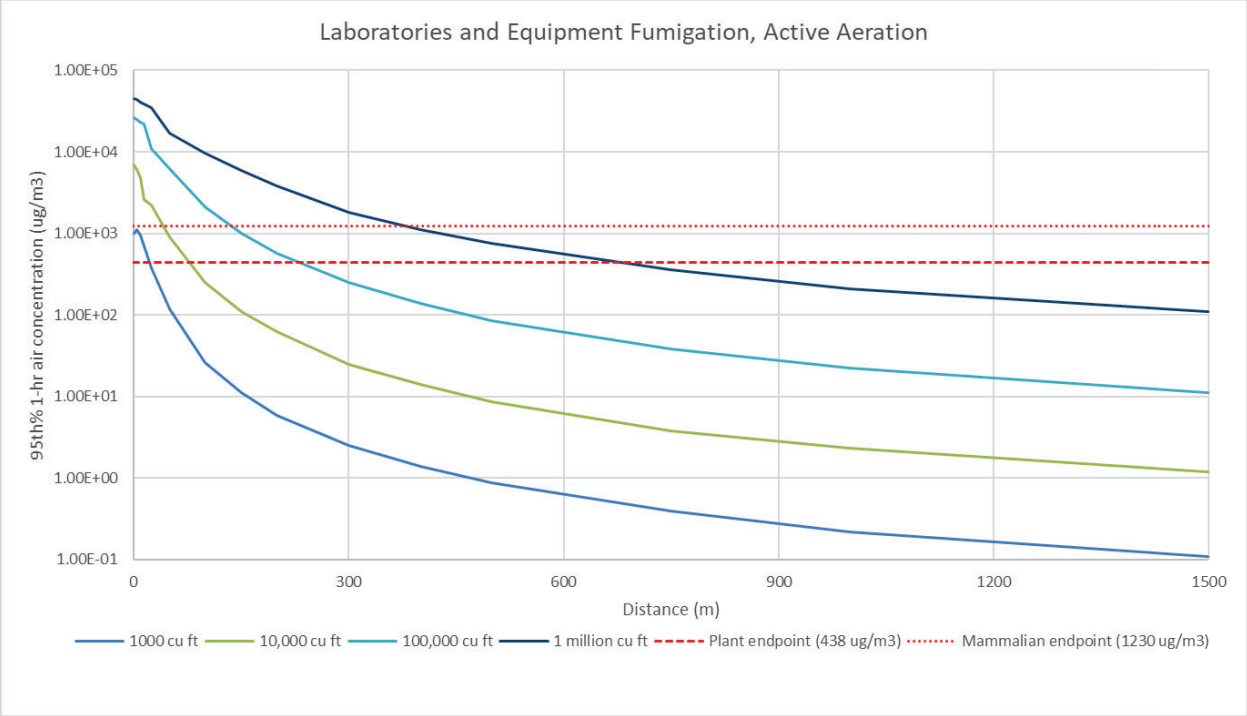
* Concentrations reflect a 150 ft buffer zones for buildings less than 100,000 ft^3 and a 1,100 ft buffer zone for buildings greater than 100,000 ft^3 for all uses except for paraformaldehyde, which has no buffer requirements on the label.

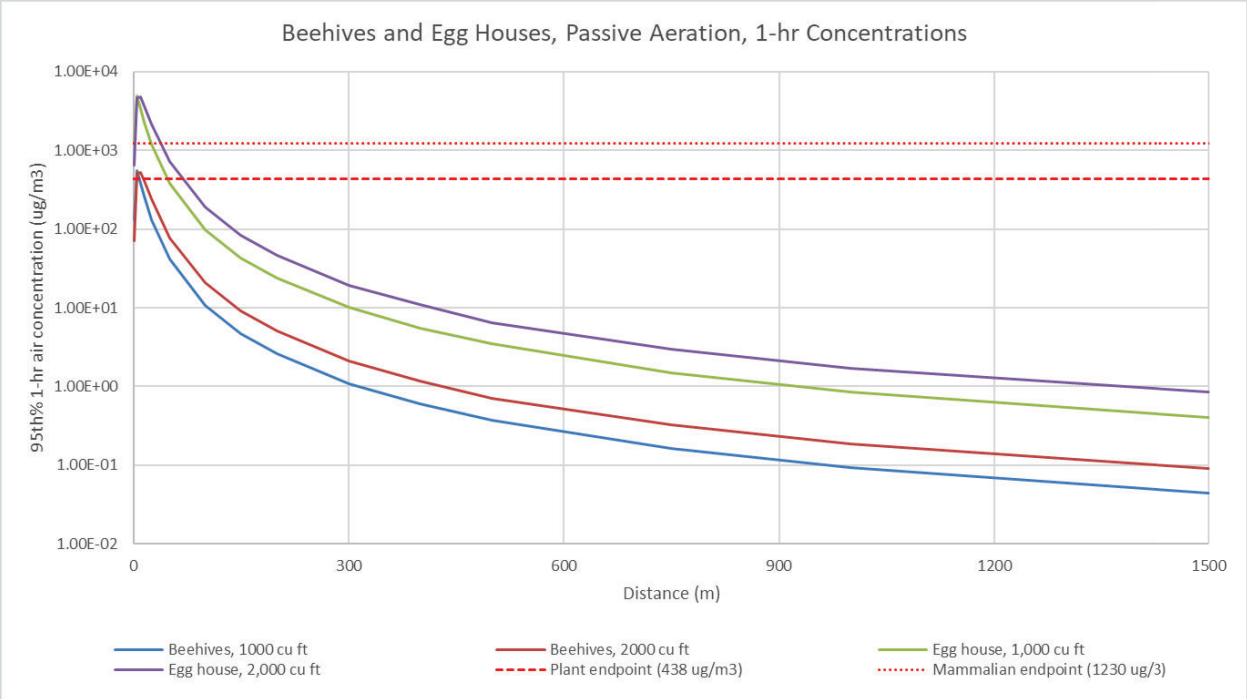
Ecological, 1-hour Concentrations

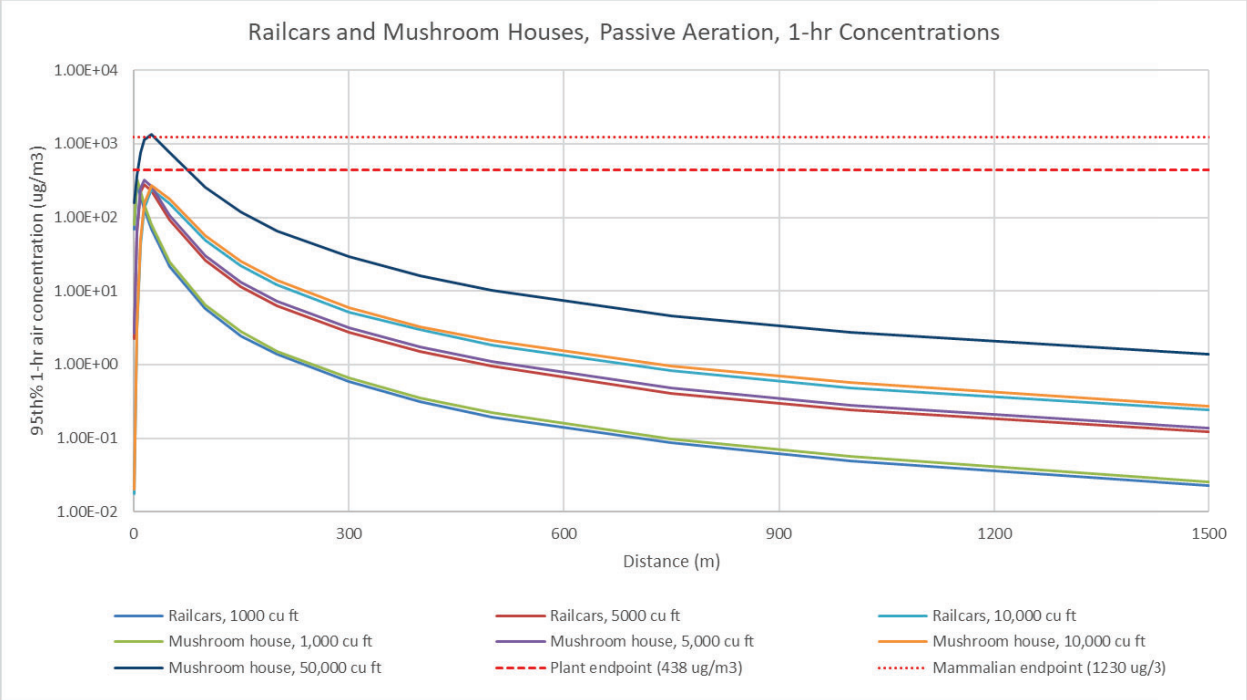


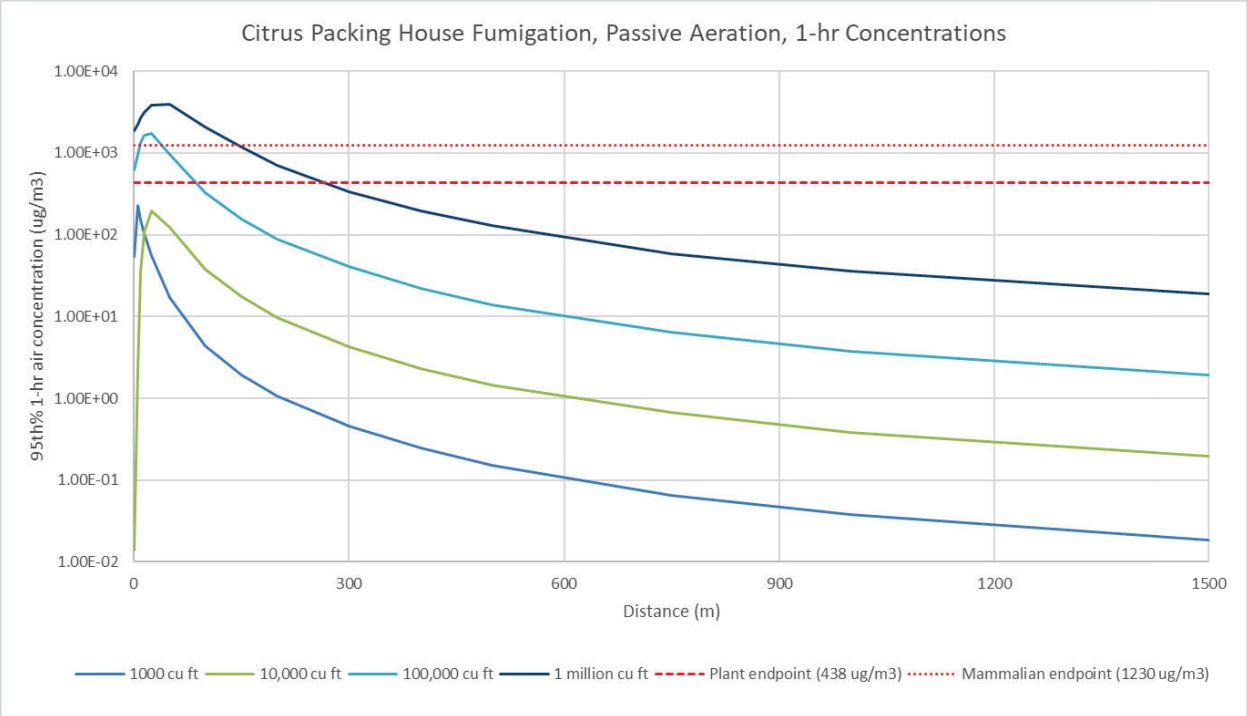


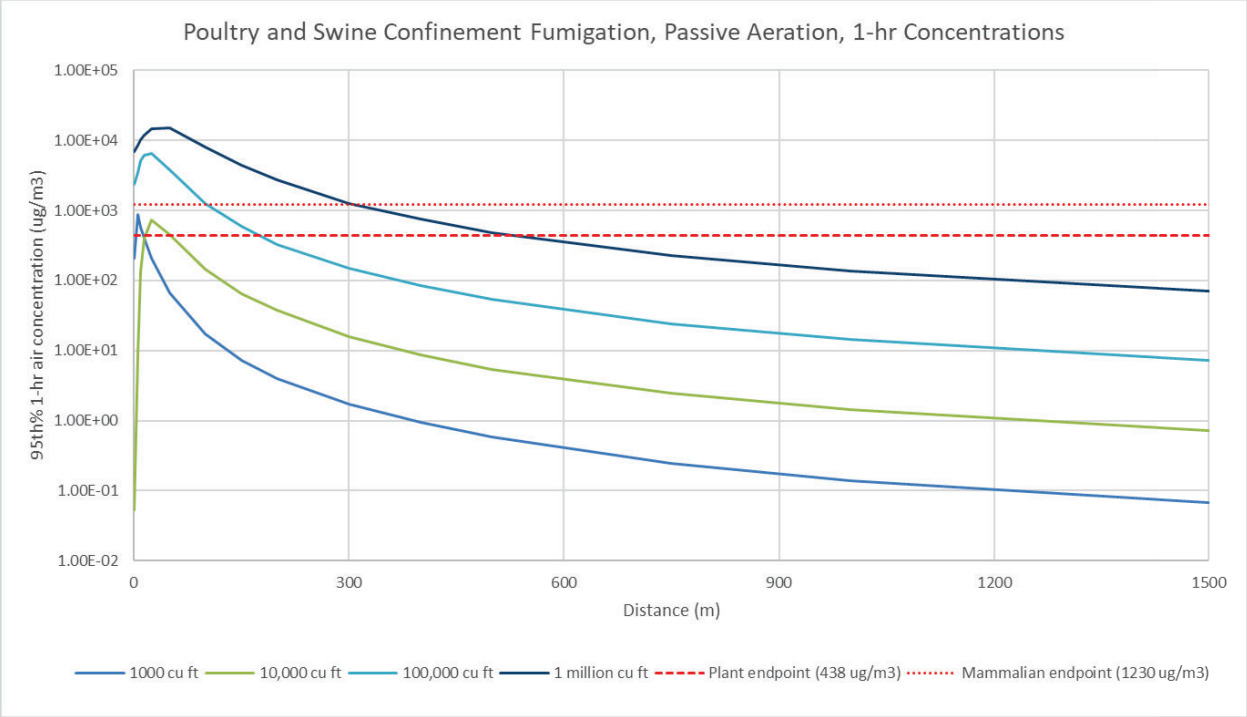

Poultry/Swine Confinement Building Fumigation, Active Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
10,000 cu ft
100,000 cu ft
1 million cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/m3)

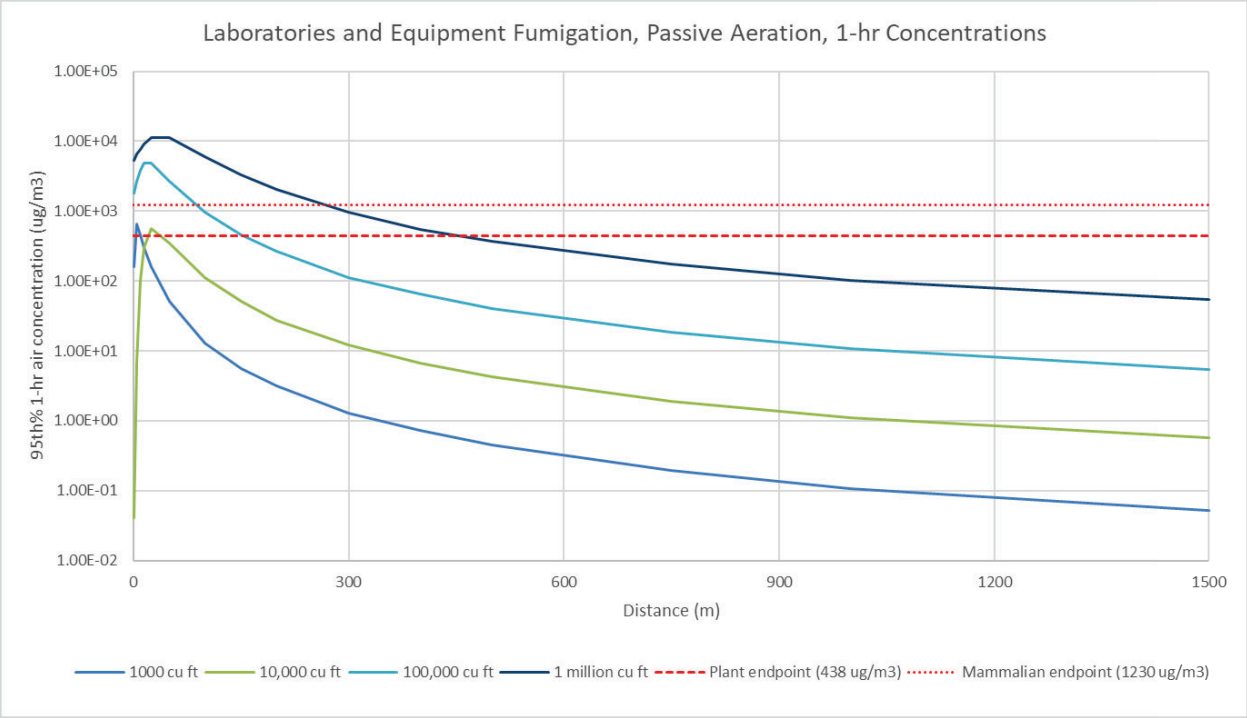

Laboratories and Equipment Fumigation, Active Aeration
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
10,000 cu ft
100,000 cu ft
1 million cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/m3)


Beehives and Egg Houses, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
Beehives, 1000 cu ft
Beehives, 2000 cu ft
Egg house, 1,000 cu ft
Egg house, 2,000 cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/3)


Railcars and Mushroom Houses, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
Railcars, 1000 cu ft
Railcars, 5000 cu ft
Railcars, 10,000 cu ft
Mushroom house, 1,000 cu ft
Mushroom house, 5,000 cu ft
Mushroom house, 10,000 cu ft
Mushroom house, 50,000 cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/3)


Citrus Packing House Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
10,000 cu ft
100,000 cu ft
1 million cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/m3)


Poultry and Swine Confinement Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
10,000 cu ft
100,000 cu ft
1 million cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/m3)


Laboratories and Equipment Fumigation, Passive Aeration, 1-hr Concentrations
95th% 1-hr air concentration (ug/m3)
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
0
300
600
900
1200
1500
Distance (m)
1000 cu ft
10,000 cu ft
100,000 cu ft
1 million cu ft
Plant endpoint (438 ug/m3)
Mammalian endpoint (1230 ug/m3)

Maximum 1-hour air concentrations from facilities using mechanical ventilation (active aeration)

Use	Citrus Packing Houses										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	67	220	510	770	1500	2500	3200	3100	4200	4200	4100
90	280	700	1400	2000	3400	5100	7000	6300	8600	9500	11000
95	370	880	1600	2400	4100	6100	9000	7800	12000	13000	16000
Use	Mushroom Houses										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000					
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	96	320	730	1100	2200	3600					
90	400	1000	2000	2800	5000	7300					
95	530	1300	2400	3400	5800	8900					
Use	Poultry and Swine Confinement Housing										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	250	830	1900	2900	5700	9500	12000	11000	16000	16000	15000
90	1100	2600	5200	7400	13000	19000	26000	24000	32000	36000	40000
95	1400	3300	6200	8900	15000	23000	34000	29000	44000	50000	58000
Use	Laboratories, equipment, and animal areas										
Building size (ft^3)	1000	2000	5000	10,000	25000	50,000	100,000	250000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	190	640	1500	2200	400	7300	9100	8800	12000	12000	12000
90	810	200	4000	5700	9900	15000	20000	18000	25000	27000	31000
95	1100	2500	4800	6800	12000	18000	26000	23000	34000	39000	45000

Maximum 1-hour air concentrations from facilities not using mechanical ventilation (passive aeration)

Use	Citrus Packing Houses										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	9	11	3	1	4	15	55	5	23	57	120
90	160	160	140	110	290	590	1200	680	1400	2000	2600
95	230	220	220	190	480	930	1700	1200	2200	3200	4000
Use	Mushroom Houses						Beehive		Egg Fumigation		
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	1000	2000	1000	2000	
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	14	15	4	2	6	21	23	25	210	230	
90	230	230	200	160	420	840	380	380	3500	3500	
95	330	320	320	270	690	1300	550	530	5000	4800	
Use	Poultry and Swine Confinement Housing										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	35	39	12	5	15	55	210	19	87	210	450
90	600	600	520	410	1100	2200	4300	2600	5200	7700	9900
95	850	820	840	730	1800	3500	6500	4500	8400	12000	15000
Use	Laboratories, equipment, and animal areas										
Building size (ft^3)	1000	2000	5000	10,000	25,000	50,000	100,000	250,000	500,000	750,000	1 million
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	27	30	9	4	11	43	160	15	67	160	340
90	460	460	400	310	840	1700	3300	2000	4000	5900	7700
95	660	630	650	560	1400	2700	5000	3400	6500	9200	12000
Use	Rooms and Railcars										
Building size (ft^3)	1000	2000	5000	10,000							
Percentile	Maximum 1-hour air concentration ($\mu g/m^3$)										
75	12	13	4	2							
90	210	200	170	140							
95	280	270	280	240							

Appendix J. Endangered Species Act

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA).

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[18] for assessing the effects of pesticides to listed species. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of assessments of pesticides' effects to listed species. Since that time, the agencies have been continuing to work to improve the approaches for assessing effects to listed species. After receiving input from the Services and USDA on proposed revisions to the interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* ("Revised Method") in March 2020.[19]

The agencies also continue to work collaboratively through a FIFRA Interagency Working Group (IWG). The IWG was created under the 2018 Farm Bill to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[20]

Consultation on Chemicals in Registration Review

EPA initially conducted biological evaluations (BEs) using the interim method 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 as the start of an iterative process. Later that year, NMFS issued a final biological opinion for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion. EPA received a final

[18] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.
[19] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional.
[20] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.

malathion biological opinion[21] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.[22] In August 2023, the Agency implemented the FWS malathion biological opinion by issuing Endangered Species Protection Bulletins[23] and approving malathion label amendments[24] to incorporate measures to protect listed species. EPA plans to implement the NMFS biological opinion on malathion, chlorpyrifos and diazinon according to the 18-month timeframes specified in the opinion.

In 2020, EPA released draft BEs for the first two chemicals conducted using the 2020 Revised Method—carbaryl and methomyl. Subsequently, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, glyphosate, clothianidin, imidacloprid, and thiamethoxam. EPA is currently in consultation with the Services on these active ingredients.

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[25] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use would not have a likelihood of jeopardizing listed species or adversely modifying their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In April 2022, EPA released a comprehensive, long-term approach to meeting its ESA obligations, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use*.[26] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*.[27] As part of this update, EPA announced its plan to consider and include, as appropriate, a menu of FIFRA Interim Ecological Risk Mitigation intended to reduce off-target movement of pesticides through spray drift and runoff in its

[21] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[22] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[23] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins
[24] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0154
[25] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides.
[26] https://www.epa.gov/endangered-species.
[27] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

registration review and other FIFRA actions. These measures are intended to reduce risks to nontarget organisms efficiently and consistently across pesticides with similar levels of risks and benefits. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.