UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** **17-DEC-2018**

**SUBJECT:** **Methyl Bromide.** Draft Human Health Risk Assessment for Registration Review.

**PC Code:** 053201
**Decision No.:** 545033
**Petition No.:** NA
**Risk Assessment Type:** Single Chemical Aggregate
**MRID No.:** NA

**DP Barcode:** D449330
**Regulatory Action:** Registration Review
**Case No.:** 0335
**CAS No.:** 74-83-9
**40 CFR:** §180.124

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As part of Registration Review, the Pesticide Reevaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that the Health Effects Division (HED) evaluate the hazard and exposure data and conduct dietary, occupational and residential exposure, and aggregate assessments, as needed, to estimate the risk to human health that will result from the currently registered uses of pesticides. This memorandum serves as HED's draft human health risk assessment of the dietary, occupational, and residential exposure, and aggregate risk from the registered uses of methyl bromide.

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## 1.0 Executive Summary

The Health Effects Division (HED) has conducted a human health draft risk assessment (DRA) to evaluate all existing registrations of the active ingredient (ai) methyl bromide, a broad-spectrum fumigant that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent. This assessment was conducted as part of Registration Review.

*Use Profile*
Methyl bromide is currently registered for both agricultural soil uses and for a variety of non-agricultural uses such as commodity fumigations. The soil uses are considered non-food uses, while the commodity fumigations are food uses with established tolerances. All established methyl bromide tolerances are currently time-limited except for "cotton, undelinted seed", which is permanent.

*Exposure Profile*
Humans may be exposed to methyl bromide in food and drinking water since methyl bromide is approved for postharvest use on most crops, and soil applications may result in methyl bromide reaching ground sources of drinking water. In an occupational setting, applicators may be exposed while handling the pesticide prior to application as well as during application. There is also potential for post-application exposure for workers re-entering fumigation chambers or cold storage areas. There are no uses of methyl bromide resulting in residential exposures; however, non-occupational bystander inhalation exposures are expected.

*Hazard Characterization & Dose Response Assessment*
The toxicity database for methyl bromide is adequate for registration review and there are no toxicology data deficiencies. Data are available for both oral and inhalation routes. The critical effects of methyl bromide exposure via the inhalation route are agenesis of the gall bladder and fused sternebrae observed in the developmental toxicity study in rabbits, neurotoxicity effects (acute, sub-chronic and chronic studies), and nasal histopathology observed in the chronic toxicity/carcinogenicity study in rats. Four studies conducted via the oral route in rats and dogs are also available. The primary effects of methyl bromide exposure via the oral route are decreased body weight, body weight gain and food consumption. The default 10X interspecies and 10X intraspecies factors were applied to all scenarios, except inhalation where the interspecies factor was reduced to 3X since human equivalent concentrations (HECs) were calculated that account for pharmacodynamic differences between animals and humans. The risk assessment team concluded that the 10X Food Quality Protection Act Safety Factor (FQPA SF) can be reduced to 1X for all scenarios except long-term inhalation exposures. For long-term inhalation exposures, a 3X FQPA SF has been applied because a NOAEL was not identified in the study used for the endpoint, and the POD is based on a LOAEL instead of a NOAEL. Methyl bromide is classified as "Not Likely to be Carcinogenic to Humans" based on a weight of evidence evaluation of the toxicity database including no indications of carcinogenesis observed in the chronic rodent bioassays.

*Dietary Exposure Assessment*
Partially refined acute and chronic dietary exposure risk estimates were conducted, making use of anticipated residue levels considering residue dissipation during transit and storage of the commodity, and assuming no methyl bromide residues are present in cooked commodities or in processed commodities subjected to heat. Drinking water estimates were based on the highest residue available from ground water monitoring studies. Overall, both the acute and chronic dietary assessments are likely to overestimate risks since they include no adjustments for percent crop treated (*i.e.,* 100% CT is assumed). Nevertheless, dietary risk estimates were below HED's level of concern (LOC).

*Residential Exposure and Risk Assessment*
There are no residential uses of methyl bromide; therefore, residential exposures were not assessed.

*Aggregate Risk Assessment*
There are no residential uses of methyl bromide; therefore, aggregate assessments are equivalent to the dietary risk assessments.

*Non-Occupational Spray Drift Assessment*
Based on the chemical/physical properties of methyl bromide, as well as the application parameters, potential for spray drift to occur in accordance with HED's standard operating procedures is negligible and has not been quantitatively assessed.

*Non-Occupational Bystander Volatilization Assessment*
Chemical-specific and application-specific studies have been submitted and reviewed to address exposures from volatilization from the soil and non-soil/commodity uses of methyl bromide. These reviews and resulting risk estimates have been presented in previous assessments. Because both the inhalation points of departure (PODs) and the expected exposures have not changed since the previous assessments, the non-occupational bystander volatilization assessment has not been revisited as part of Registration Review. The previous bystander assessments conducted in conjunction with re-registration identified risks of concern from the soil and commodity uses of methyl bromide. As a result, OPP implemented a series of label changes and mitigation measures (administrative controls like buffer zones and rate reductions) that addressed and mitigated bystander exposure concerns.

*Non-Occupational Ambient Inhalation Exposure Assessment*
Inhalation exposures from volatilization from non-point sources (i.e., ambient exposures in high use areas) have been assessed for acute, short-/intermediate-term, and long-term exposure durations for methyl bromide. The current assessment relies on data reported by the California Department of Pesticide Regulation (CDPR) Air Resources Board (ARB) Toxic Air Contaminant (TAC) Program and the California DPR Air Monitoring Network (AMN). For each assessment, acute air concentrations (represented as 24-hour measurements), short- and intermediate-term air concentrations (represented as either 4-week rolling averages or $90^{th}$ percentile air concentrations) and long-term air concentrations (either 1-year averages or means) were used as reported by California DPR (an analysis of the raw data was not conducted; values as reported were used). The monitoring conducted by the TAC and the AMN programs in

agricultural environments throughout California is expected to be representative of ambient concentrations from the soil uses of methyl bromide. In the absence of more targeted data closer to commodity fumigation facilities, the monitoring data collected in non-agricultural/urban areas have been used to represent ambient exposures in California from non-soil/commodity fumigations; however, there is some uncertainty regarding the representativeness of these data for areas around commodity fumigation facilities. Therefore, ambient monitoring data from the Delaware Maritime Exchange Region was required previously to address this data gap, and once these data are submitted, an updated ambient air exposure and risk assessment will be conducted. These required data will be representative of ambient air concentrations corresponding to commodity fumigations in a high-use area. The available ambient air concentrations did not result in risk estimates of concern for acute, short-or intermediate-term, or long-term exposures. The Agency has also re-presented the risk estimates from the EPA National Air Toxics Assessment (NATA).

*Occupational Handler Exposure and Risk Assessment*

There is potential for occupational handler inhalation exposure from both the soil and non-soil/commodity uses of methyl bromide. Dermal exposures are not expected given the high vapor pressure of methyl bromide and based on the delivery systems/application methods, packaging (i.e., pressurized cylinders), and emission reduction techniques (e.g., commodity aeration and tarping) used. Therefore, dermal exposures have not been quantitatively assessed. Because HED has previously conducted occupational exposure and risk assessments using chemical-specific monitoring data and inputs for the soil and non-soil/commodity uses of methyl bromide in the past at comparable application regimes to those currently registered, and because the use pattern, application parameters, and toxicity profile have not changed for methyl bromide, the occupational handler risks associated with the soil uses of methyl bromide have not been re-assessed here. In the previous assessments, occupational risks of concern were identified for soil and commodity fumigation activities. As a result, OPP implemented a series of label changes and mitigation measures that addressed and mitigated worker exposure concerns. These measures included: worker personal protective equipment (PPE; i.e., respirators and self-contained breathing apparatus (SCBA)); administrative controls like rate reductions, active monitoring during the operation, and "Stop Work Triggers". Those risk mitigation measures are now included on the methyl bromide product labels.

*Occupational Post-Application Exposure and Risk Assessment*

Occupational dermal post-application exposures are not expected given the high vapor pressure of methyl bromide. In addition, emission reduction techniques (e.g., commodity aeration and tarping) decrease potential exposures. Therefore, dermal exposures have not been quantitatively assessed. There is potential for inhalation exposure following a soil application of methyl bromide; however, activities like tarp cutting, supervising, loading, driving the tractor, cross-ditching, etc. are all associated directly with the application and are considered handler activities and are therefore mitigated by the measures implemented to address worker exposure concerns. Current labels also prohibit entry to a treated area by anyone other than individuals appropriately trained and equipped as handlers in accordance with the Worker Protection Standard (40 CFR Part 170) until the entry restricted period ends.

For the non-soil/commodity uses of methyl bromide, occupational post-application inhalation exposures may occur from activities that typically happen once the commodity is released from the fumigation facility (e.g. released to a warehouse or cold storage facility). The available incident and monitoring data indicate occupational post-application air concentrations of concern. Since these monitoring data were developed, the industry has implemented "Best Management Practices" (BMPs) to mitigate the exposures received in cold storage facilities. EPA is aware of monitoring data collected in cold storage facilities since the BMPs were implemented, as indicated in status updates from the Maritime Exchange for the Delaware River and Bay, Delaware River Region Cold Storage Facility Task Force and from CDPR. These updates have indicated that data are available demonstrating that the mitigation outlined in the BMPs has significantly reduced worker exposure over time, but these data have not been submitted to the EPA. In absence of these data, EPA cannot quantitatively evaluate the impact the BMPs have on reducing risks from methyl bromide exposure for cold storage workers. Therefore, the 875.2500 monitoring data requirement remains outstanding.

*Environmental Justice*
Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.[1]" HED has used updated available air monitoring data collected from 2011 to 2017 by CDPR to evaluate ambient bystander exposures and found no risk estimates of concern for the currently registered uses of methyl bromide.

*Human Studies*
This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their exposure. Appendix E provides additional information on the review of human research used to complete the risk assessment. There is no regulatory barrier to continued reliance on these studies, and all applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied.

## 2.0 Risk Assessment Conclusions

## 2.1 Data Deficiencies

- 875.2500 [post-application; inhalation exposure] – (off-gassing of previously fumigated commodities)[2]
- Special Study– ambient air monitoring (M. Lloyd, D410208, 09/13/2013)
  - To address unique agricultural conditions (e.g., Siskiyou County, CA) and bystander exposure near active commodity fumigation sites

## 2.2 Tolerance Considerations

### 2.2.1 Enforcement Analytical Method

[1] https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice
[2] GDCI-053201-26629; The Agency required protocol and consultation before the initiation of this study requirement.

The modified head-space procedure of King *et al.* (J. Agric. Food Chem. 29 (5), 1003 (1981)) for determining methyl bromide has been forwarded to FDA for inclusion in PAM Vol. II. This method is adequate for data collection and tolerance enforcement for plant and processed food commodities. The limit of detection (LOD) is 0.01 ppm. Analytical methods for secondary residues of methyl bromide in livestock commodities are not required.

Adequate multiresidue method testing data indicate that the FDA multiresidue methods are not suitable for determining residues of methyl bromide.

### 2.2.2 Recommended & Established Tolerances

Tolerances are established for residues of the fumigant methyl bromide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only methyl bromide.

**Table 2.2.2. Summary of Tolerance Revisions for Methyl Bromide (40 CFR §180.124(a)).**

| Commodity/ **Correct Commodity Definition** | Established Tolerance (ppm) | Recommended Tolerance (ppm) | Comments |
|---|---|---|---|
| Cotton, undelinted seed | 150 | remove | Included in Oilseed group 20 |
| **Berry and small fruit, group 13-07** | | 5.0 | New tolerance |
| **Cocoa bean** | | 5.0 | New tolerance |
| **Coffee, green bean** | | 150 | New tolerance |
| **Cola, seed** | | 150 | New tolerance |
| **Cucurbit, seed** | | 150 | New tolerance |
| **Fruit, citrus, group 10-10** | | 2.0 | New tolerance |
| **Fruit, pome, group 11-10** | | 8.0 | New tolerance |
| **Fruit, stone, group 12-12** | | 5.0 | New tolerance |
| **Grain, cereal, group 15** | | 8.0 | New tolerance |
| **Herb and spice, group 19** | | 35 | New tolerance |
| **Hibiscus, seed** | | 150 | New tolerance |
| **Ivy gourd** | | 5.0 | New tolerance |
| **Kaffir lime, leaves** | | 0.50 | New tolerance |
| **Kenaf, seed** | | 150 | New tolerance |
| **Nut, tree, group 14-12** | | 150 | New tolerance |
| **Oilseed group 20** | | 150 | New tolerance |
| **Peppermint, fresh leaves** | | 35 | New tolerance |
| **Pointed gourd** | | 5.0 | New tolerance |
| **Spearmint, fresh leaves** | | 35 | New tolerance |
| **Tropical and subtropical fruits, edible peel, group 23** | | 10 | New tolerance |
| **Tropical and subtropical fruits, inedible peel, group 24** | | 5.0 | New tolerance |
| **Vegetable, brassica, head and stem, group 5-16** | | 1.0 | New tolerance |
| **Vegetable, bulb, group 3-07** | | 2.0 | New tolerance |
| **Vegetable, cucurbit, group 9** | | 5.0 | New tolerance |
| **Vegetable, foliage of legume, group 7** | | 0.50 | New tolerance |
| **Vegetable, fruiting, group 8-10** | | 7.0 | New tolerance |
| **Vegetable, leafy, group 4-16** | | 0.50 | New tolerance |

| Table 2.2.2. Summary of Tolerance Revisions for Methyl Bromide (40 CFR §180.124(a)). | | | |
|---|---|---|---|
| Commodity/ **Correct Commodity Definition** | Established Tolerance (ppm) | Recommended Tolerance (ppm) | Comments |
| **Vegetable, leaves of root and tuber, group 2** | | 0.50 | New tolerance |
| **Vegetable, legume, group 6** | | 3.0 | New tolerance |
| **Vegetable, root and tuber, group 1** | | 3.0 | New tolerance |
| **Vegetable, stalk, stem and leaf petiole, group 22** | | 0.50 | New tolerance |

### 2.2.3 International Harmonization

Codex has established maximum residue limits (MRLs) for methyl bromide for several raw agricultural and processed commodities as listed in Appendix C. For most of these listings, two MRLs are provided: one for residues measured at point of entry into a country following air exposure for at least 24 hours after fumigation, and one for residues at the point of retail sale or when offered for consumption (all of which are set at the limit of determination of 0.01 ppm). For comparison to U.S. tolerances, the MRL at the point of country entry is the more applicable level. For commodities with both a Codex MRL and a U.S. tolerance, the U.S. tolerance is the same or higher than the Codex MRL. For commodities with higher tolerances, including cereal grains and tree nuts, harmonization with the Codex MRL is not possible.

Codex has also established MRLs for bromide ion from any source. HED recommends retention of the current tolerances for bromide ion to maintain harmonization with international organizations that regulate methyl bromide use based on inorganic bromide levels. avoid creating international trade issues.

## 2.3 Label Recommendations

### 2.3.1 Recommendations from Residue Reviews

None

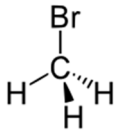
### 2.3.2 Recommendations from Occupational Assessment

There are no risk reduction recommendations based on the occupational assessment. HED notes that a summary of the risk estimates for cold storage workers using data collected prior to 2012 shows that there are risk estimates of concern for registered uses of methyl bromide, however, between 2012 and 2016, the industry implemented BMPs to mitigate the exposures received in cold storage facilities. EPA is aware of monitoring data collected in cold storage facilities that demonstrate that the mitigation outlined in the BMPs has significantly reduced worker exposure over time. These data have not been submitted to the EPA. In absence of these data, EPA cannot quantitatively evaluate the impact the BMPs have on reducing risks from methyl bromide exposure for cold storage workers. Therefore, the 875.2500 monitoring data requirement remains outstanding. EPA will evaluate these data once submitted and incorporate these data in future risk assessment as appropriate.

## 3.0 Introduction

### 3.1 Chemical Identity

Table 3.1 provides the structure and relevant nomenclature for methyl bromide.

| Table 3.1. Test Compound Nomenclature. | |
|---|---|
| **Properties** | **Methyl Bromide** |
| Chemical Structure |  |
| Chemical Group | Alkyl Bromide |
| Common Name | Methyl Bromide |
| Molecular formula | $CH_3Br$ |
| Molecular Weight | 94.94 |
| CAS No. | 74-83-9 |
| PC Code | 053201 |

### 3.2 Physical/Chemical Characteristics

A listing of the physical and chemical properties of methyl bromide are provided in Table 3.2.

| Table 3.2: Physical and Chemical Properties of Methyl Bromide | |
|---|---|
| **Parameter** | **Methyl Bromide** |
| Appearance | colorless, odorless gas at normal temperatures and pressures and a liquified gas under moderate pressure |
| Boiling Point | 3.6°C |
| Vapor Pressure | 1400 mm Hg at 20 °C |
| Partition Coefficient | (log $P_{ow}$) 1.19 |
| Solubility in Water | 1.75 g/100 mL at 20 °C |

Methyl bromide has a high vapor pressure (1400 mm Hg at 20 C); thus, inhalation is the primary route of exposure. Its octanol/water partition coefficient suggests that it may permeate oily, fatty matrices more readily than more watery matrices.

### 3.3 Pesticide Use Pattern

Methyl bromide is a broad-spectrum fumigant chemical that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent for soil

fumigation uses and for fumigation of imported and domestic commodities[3]. The use categories have been categorized in this document as "soil uses" and "non-soil/commodity uses" (which for the purposes of this assessment also includes treatments of non-food durable goods). The non-quarantine soil uses, the residential (structural) uses, and the Critical Use Exemptions (CUEs)[4] (including tree hole and greenhouse hot gas applications) of methyl bromide ended in 2017. Country ham has met the criteria for a CUE but because there are adequate supplies of methyl bromide available, a CUE has not been requested by the U.S. since 2017. However, country ham is still fumigated in the U.S. with existing stocks of methyl bromide.

There are 31 active Section 3 registrations for the soil and non-soil/commodity uses of methyl bromide. There are also four active 24c registrations for non-soil/commodity application of methyl bromide[5]: 1) CA170002 to control Western Flower Thrips on Broccoli prior to export to Taiwan; 2) CA170012 to control navel orangeworm and Oblique banded Leafroller on pomegranates prior to export to Australia; 3) MO000002 to control navel orangeworm and Oblique banded Leafroller on pomegranates prior to export to Australia; and 4) CA160001 to control Western Flower Thrips on blackberries and raspberries prior to export to Panama. Additionally, there is a current Section 18 registration for quarantine (post-harvest/non-soil/commodity) treatment of various food commodities by the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine (PPQ).

*Soil Uses*

The soil uses of methyl bromide are restricted to quarantine applications only. Quarantine applications of methyl bromide are "treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control, where: (i) Official control is that performed by, or authorized by, a national (including state, tribal, or local) plant, animal or environmental protection or health authority; (ii) quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. This definition excludes treatments of commodities not entering or leaving the United States or any State (or political subdivision thereof)." Methyl bromide products may be used as a "soil fumigant at any crop or non-crop site as part of a quarantine program established by the United States Department of Agriculture-Animal Plant Health Inspection Service (USDA-APHIS) under the Plant Protection Act (7 U.S.C. 7701 et seq.). Limitations including, but not limited to, application rates and methods and

[3] Some methyl bromide product labels include antimicrobial claims; *"…and some bacteria (e.g., Salmonella spp.)…*" However, the antimicrobial applications are not separate treatments, and the antimicrobial action occurs during the conventional methyl bromide treatment. Therefore, the methyl bromide commodity treatments relevant to the antimicrobial claims (e.g., railroad cars, trucks, poultry houses) are covered under the Health Effects Division review and do not require separate review by OPP's Antimicrobials Division. *[Registrations 8622-55 (Metabrom Q) and 8536-29 (Methyl Bromide Quarantine Fumigant)]*

[4] In the United States, "Class 1" ozone-depleting substances (ODS) were subject to the first round of phaseout targets under the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol). The amount of methyl bromide produced or imported was reduced incrementally until it was phased out on January 1, 2005. Certain uses of methyl bromide were/are exempt from the phaseout, including critical (critical use exemptions), quarantine, and pre-shipment uses. All of the critical use exemptions ended in 2017.

[5] Two additional Special Local Need (SLN) labels are listed as active in the OPPIN database (CA120004 and CA130008); however, CA120004 expired on 06/30/2017 and CA130008 expired on 07/31/2014.

crops and cropping practices must be in accordance with those established by the USDA APHIS quarantine program."

The use of methyl bromide may also be in non-USDA-APHIS quarantine programs. Use of methyl bromide under non-USDA-APHIS programs is restricted to "fields used for the production of plant propagative material listed below and unplanted areas immediately adjacent thereto, where all production from the treated fields will be shipped to areas where a plant regulatory authority requires the source of the incoming material to be free of quarantine pests or be accompanied by a certificate issued by a plant regulatory official."

- **Forest Seedlings:** Conifer and hardwood seedlings for reforestation, Christmas tree seedlings
- **Nursery Stock:** Roses, strawberry transplants, sweet potato slips, caneberry and blueberry nursery stock, fruit and nut trees, garlic transplants, onion transplants, vineyard stock, seed potato, tobacco seed beds, food crop transplants, and other wild or cultivated trees, shrubs, vines and forbs.
- **Ornamental Plants:** Caladiums, chrysanthemums, flower bulbs, flowering plants, ornamental grasses, rhizomes, shrubs, trees, and other perennials and annuals.
- **Turf or Sod:** For interstate and intrastate shipments to areas that require fumigation with methyl bromide to meet quarantine/phytosanitary requirements

The maximum application rate for all quarantine soil uses is 400 lbs ai/A.

As a soil fumigant, methyl bromide can be injected into soil (e.g., via shanks) or while forming raised beds using tractors equipped with shanks. Use restrictions require that all applications to soil use tarps, except for deep shank orchard replant [California only]. Based on a review of the registered labels, the required clothing and PPE for methyl bromide varies based on the occupational activity. Occupational handlers with no potential contact with the liquid fumigant (including applicators) must wear baseline attire (long-sleeved shirt, long pants, shoes, and socks); shovelers (those who shovel soil onto the edge of a tarp to hold it in place after the fumigant has been applied under the tarp) may also wear cotton, leather, or other porous, non-chemical resistant gloves. When performing tasks with potential for liquid contact with the fumigant, all handlers must wear baseline attire, chemical resistant gloves, chemical resistant apron, protective eyewear (not goggles), and chemical resistant footwear with socks. When respirators are required on the label, a National Institute for Occupational Safety and Health (NIOSH)-certified full facepiece air purifying respirator with cartridges certified by the manufacturer for protection from exposure to methyl bromide at concentrations up to 5 ppm is required (anytime a methyl bromide air sample is greater than 5 ppm, all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone).

*Non-Soil/Commodity Uses*

Methyl bromide is registered for fumigation in structures (e.g., flour mills, rice mills), for post-harvest treatment of food commodities (e.g., tree fruit, tree nuts, berries, grains, vegetables, cocoa, dried fruits, cheese, processed grains, and processed herbs and spices), and for post-harvest treatment of non-food commodities (e.g., logs, tobacco, cotton machinery). Methyl bromide is also used for structural and industrial fumigation treatments of large food handling

and non-food handling establishments (e.g., warehouses, grain elevators, ships, food processing plants, etc.).

Additionally, the PPQ division of USDA-APHIS holds a Section 18 registration to fumigate *non-labeled* imported and some domestic commodities with methyl bromide. These fumigations are conducted as directed by USDA's APHIS PPQ treatment manual[6], and target invasive, non-indigenous quarantine plant pests.

As a commodity fumigant, methyl bromide gas can be injected into an enclosure, a chamber, a structure (e.g., mills, warehouses), or under a tarp. The methods of applications vary and include: chamber and vault fumigation; vacuum chamber fumigation; railroad car, truck, van, trailer, or air and sea container fumigation; tarpaulin fumigation; warehouse; grain elevator, food processing plant, and other structures containing listed commodities and material fumigation; and shipboard, in-transit, or shiphold fumigation. Maximum application rates range from 1 to 15 lb ai/1000 $ft^3$ with commodity exposure (treatment) times ranging from 2 to 72 hours, depending on the commodity. Tolerances for food crops range from 0.5 to 150 ppm. The required clothing and PPE for fumigators varies based on activity. In general, occupational handlers (including applicators) must wear baseline attire (long-sleeved shirt, long pants, shoes, and socks), and protective eyewear when handling liquid fumigant. When respirators are required on the label, a supplied air respirator (i.e., self-contained breathing apparatus (SCBA)), or a half-mask or full-face piece air purifying respirator (if methyl bromide concentrations are less than 5 ppm) with a cartridge certified by the manufacturer for protection from exposure to methyl bromide at concentrations up to 5 ppm is required (anytime a methyl bromide air sample is greater than 5 ppm, all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone).

### 3.3.1 Anticipated Exposure Pathways

Humans may be exposed to methyl bromide in food, since methyl bromide may be applied directly to food crops after harvest. There are no residential uses of methyl bromide; however, non-occupational bystander inhalation exposures are expected from fumigation treatments that occur nearby residential areas, and potential exposures have been evaluated. Because of the potential for fumigants to move off-site following field applications, exposures to bystanders both near treated areas and farther away from treated areas (ambient air) have been quantified based on application-specific data and area-wide monitoring measurements. Acute bystander inhalation exposures for near field/near commodity fumigation and short- and intermediate-term, and chronic ambient bystander exposures have been evaluated.

For the soil uses of methyl bromide, occupational acute, short-, and intermediate-term inhalation exposures are expected and have been evaluated. For the soil uses of methyl bromide, occupational handlers may be exposed while handling the pesticide prior to application, as well as during application; however, there is little potential for post-application exposure for workers re-entering treated fields. Dermal exposures are not expected given the high vapor pressure of methyl bromide, and based on the delivery systems, packaging (i.e., pressurized cylinders), and emission reduction techniques (e.g., tarping) used. Therefore, occupational handler dermal

[6] Available: http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf

exposures have not been quantitatively assessed. Soil fumigant applications with methyl bromide are directed to bare soil; therefore, contact with foliage during or after application is not expected. Therefore, there is no expectation of soil or foliar dermal exposure to methyl bromide following an application. There is potential for inhalation exposure following an application; however; activities like tarp cutting, supervising, loading, driving the tractor, and cross-ditching, are all associated directly with the application and are considered handler activities. Current labels prohibit entry to a treated area by anyone other than individuals appropriately trained and equipped as handlers in accordance with the Worker Protection Standard (40 CFR Part 170) until the entry restriction period ends. For soil applications of methyl bromide, the minimum entry restriction periods are:

- 5 days (120 hours) after application is complete for untarped applications, or
- 5 days (120 hours) after application is complete if tarps are not perforated and removed[7] for at least 14 days after application is complete, or
- 48 hours after tarp perforation is complete if tarps will be perforated within 14 days after the application is complete and will not be removed for at least 14 days after the application is complete.

For the non-soil/commodity uses of methyl bromide, occupational handlers may be exposed while handling the pesticide prior to application and immediately after application and clearance (e.g., forklift drivers). Occupational handler dermal exposures are not expected given the high vapor pressure of methyl bromide, and based on the delivery systems, packaging (i.e., pressurized cylinders), and emission reduction techniques (e.g., commodity aeration and tarping) used. Therefore, dermal exposures have not been quantitatively assessed. Occupational acute, short-, and intermediate-term inhalation exposures are expected and have been evaluated for the non-soil/commodity uses of methyl bromide. Occupational post-application inhalation exposures may also occur from activities associated with storage (e.g., cold storage) of commodities treated with methyl bromide. This risk assessment considers all the aforementioned exposure pathways based on the uses of methyl bromide.

### 3.4 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf). As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age and ethnic group. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and

[7] Tarp removal is completed if tarps are both perforated and removed less than 14 days after application is complete.

exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are also currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

Additionally, methyl bromide played a role in an important civil rights complaint addressed by the Agency. The civil rights complaint *Angelita C. v. California Department of Pesticide Regulation* alleged that California's Department of Pesticide Regulation (CDPR) discriminated against Latino school children by allowing unhealthy levels of methyl bromide to be applied to agricultural fields near schools populated by mostly Latino children. The complaint alleged that this pattern and practice of allowing methyl bromide to be applied to agricultural fields near schools, caused an unhealthy and racially discriminatory condition for Latino school children and their parents. U.S. EPA entered into an Agreement with the California Department of Pesticide Regulation (CDPR) to resolve a civil rights complaint filed under Title VI of the Civil Rights Act of 1964 (Title VI). CDPR has volunteered through this Agreement to expand on-going monitoring of methyl bromide air concentrations by adding a monitor at or near one of the schools named in the original complaint. The purpose of the additional monitor is to confirm that there will be no recurrence of earlier conditions. CDPR also has agreed to share the monitoring results with EPA and the public and will also increase its community outreach and education efforts to schools that are in high methyl bromide usage areas. HED has used updated available air monitoring data collected from 2011 to 2017 by CDPR to evaluate ambient bystander exposures and found no risk estimates of concern for the currently registered uses of methyl bromide.

## 4.0 Hazard Characterization and Dose-Response Assessment

No new toxicity and/or metabolism data have been received since the last risk assessment.

### 4.1 Toxicology Studies Available for Analysis

Methyl bromide is a broad-spectrum fumigant that may be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent. The toxicological database for methyl bromide is complete for characterizing the hazard for human health risk assessment purposes.

Data are available for both oral and inhalation routes and have been used accordingly in the risk assessments. Many of the toxicity studies were performed via the inhalation route since it is the main exposure route expected for methyl bromide. The database is adequate for hazard characterization, endpoint selection and FQPA SF consideration, and contains the following studies:

1) Acute neurotoxicity screening battery in rats (inhalation)
2) Subchronic neurotoxicity screening battery in rats (inhalation)

3) Subchronic oral toxicity studies in rats (oral)
4) Subchronic oral toxicity studies in dogs (oral)
5) Prenatal developmental toxicity study in rats (inhalation)
6) Prenatal developmental toxicity study in rabbits (inhalation)
7) Developmental neurotoxicity study in rats (inhalation)
8) Reproduction and fertility effects in rats (inhalation)
9) Chronic oral toxicity in rats (oral)
10) Chronic oral toxicity in dogs (oral)
11) Chronic toxicity and carcinogenicity study in rats (inhalation)
12) Chronic toxicity and carcinogenicity study in mice (inhalation)
13) Metabolism and pharmacokinetics study (inhalation and oral)
14) Immunotoxicity study in rats (inhalation)
15) Genotoxicity study (rat testicular DNA alkaline elution assay)
16) Cytogenetic micro nucleus assay in mice and rats

No additional studies were submitted since the previous risk assessment. A methyl bromide literature search was performed on August 3, 2018. No studies contained information that would impact the draft human health risk assessment (see Appendix A). Thus, no modifications to the endpoint selections and safety factors are required.

## 4.2 Absorption, Distribution, Metabolism, & Elimination (ADME)

Information on metabolism and pharmacokinetics comes from the International Agency for Research on Cancer (IARC) Monographs, Volume 41, page 198. Approximately 27-50% of the compound inhaled was absorbed, based on a 6-hour exposure to rats to 4.75-9874 mg/m$^3$ $^{14}CH_3Br$ vapor. In a metabolism study, rats received a single gavage dose (preparation of test solution was unspecified) of 24 mg/kg/bw $^{14}CH_3Br$. Over a 3-day period, the radioactivity recovered was as follows: carcass (14-17%), expired carbon dioxide (32%), urine (43%), and feces (less than 3%).

### 4.2.1 Dermal Absorption

No dermal absorption studies are available for methyl bromide. Under proper use practices, dermal exposure to methyl bromide is not expected based on the delivery systems used (e.g., soil injection or drip irrigation), packaging (i.e., pressurized cylinders), and emission reduction technologies (e.g., tarping). The high vapor pressure of methyl bromide also makes significant dermal exposure unlikely and quantifying any potential low-level exposures very difficult. Although incidents resulting in skin burns have been reported, these are typically associated with faulty containers or application equipment and are not expected to occur in the course of a typical methyl bromide application.

Therefore, a dermal absorption factor (DAF) was not necessary and no dermal endpoints were selected.

## 4.3 Toxicological Effects

The critical effects of methyl bromide exposure via the inhalation route are agenesis of the gall bladder and fused sternebrae observed in the developmental toxicity study in rabbits following sub-chronic exposure durations; neurotoxicity effects (acute, sub-chronic and chronic studies); and nasal histopathology observed in the chronic toxicity/carcinogenicity study in rats.

Both acute and sub-chronic inhalation neurotoxicity studies in rats showed evidence of neurotoxic effects of methyl bromide characterized by decreased activity, tremors, ataxia and paralysis. Two sub-chronic studies demonstrated dogs to be the most sensitive species to the neurotoxic effects of methyl bromide, which included decreased responsiveness in females. Neurotoxic effects were also seen in the chronic/carcinogenicity inhalation study in mice (ataxia, limb paralysis, degenerative changes in the cerebellum), the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia), and the developmental neurotoxicity (DNT) study in rats (decrease in motor activity).

Four studies conducted via the oral route (subchronic oral toxicity [rat and dog]; chronic oral toxicity [rat and dog]) are available in the methyl bromide database. Effects noted after oral exposure were primarily decreases in body weight and food consumption. Evidence of stomach lesions were seen in the 90-day oral toxicity study in rats.

The inhalation developmental neurotoxicity study in rats demonstrated increased quantitative susceptibility in the young, where decreased motor activity in females on postnatal day 21 was observed in the absence of maternal effects. In the rat inhalation reproduction study decreased body weights in parental animals were seen at a dose higher than those that elicited decreased pup body weights and reduced pregnancy rates. In the rat prenatal developmental inhalation study, the maternal and developmental NOAEL/LOAEL were 70 ppm, the highest dose tested. The rabbit prenatal developmental inhalation study also did not indicate susceptibility to the young, with the maternal (decreased appetite, lethargy, right side head tilt, ataxia and lateral recumbency), and developmental (agenesis of the gall bladder, increased incidence of fused sternebrae and decreased fetal body weight) effects observed at the same dose (80 ppm).

The inhalation immunotoxicity study did not indicate immunotoxicity at doses up to 120 ppm.

Acutely, methyl bromide is a low to moderate toxicant via the oral and inhalation routes of exposure (Toxicity Categories II and IV, respectively). In contrast, methyl bromide is highly irritating via ocular routes of exposure (Toxicity Category I).

As discussed in Section 4.2.1, studies involving dermal toxicity were not required due to the fact that dermal exposures to methyl bromide are unlikely due to use patterns and high volatility.

## 4.4 Safety Factor for Infants and Children (FQPA Safety Factor)[8]

The methyl bromide risk assessment team recommends that the 10X FQPA SF be reduced to 1X for all exposure scenarios, except for long-term inhalation, where an FQPA SF (due to lack of a

[8] HED's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children)

NOAEL) of 3X was applied. The toxicology database is considered complete and exposure analyses are unlikely to underestimate risk of exposure from methyl bromide. Although there is evidence of increased fetal and offspring susceptibility, the effects are well-characterized with clearly established NOAEL values and selected endpoints are protective for the observed effects.

### 4.4.1 Completeness of the Toxicology Database

The toxicology database is considered complete for evaluating and characterizing toxicity, assessing children's susceptibility under FQPA and selecting endpoints for pertinent exposure pathways. The database contains acceptable prenatal developmental studies in two species, a developmental neurotoxicity study, as well as a multi-generation reproduction study.

### 4.4.2 Evidence of Neurotoxicity

There was evidence of potential neurotoxicity in the methyl bromide database. Both acute and subchronic inhalation neurotoxicity studies in rats showed evidence of neurotoxic effects of methyl bromide characterized by decreased activity, tremors, ataxia and paralysis. Two sub-chronic studies demonstrated dogs to be the most sensitive species to the neurotoxic effects of methyl bromide. Neurotoxic effects were also seen in the chronic/carcinogenicity inhalation study in mice (ataxia, limb paralysis, degenerative changes in the cerebellum), the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia), and the developmental neurotoxicity study in rats (decrease in motor activity). However, concern is low for neurotoxicity since the effects are well-characterized and the selected endpoints are protective of the observed effects.

### 4.4.3 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

There was evidence of increased susceptibility in the inhalation developmental neurotoxicity study and rat inhalation reproduction toxicity study (see Section 4.3). However, concern is low since the effects are well-characterized and the selected endpoints are protective of the observed effects. Therefore, it is concluded that there are no concerns for residual uncertainties. HED has confidence that the risk assessment conducted with no additional safety factor will provide a reasonable certainty of no harm to the safety of infants and children.

### 4.4.4 Residual Uncertainty in the Exposure Database

There are no residual uncertainties in the exposure database: 1) the dietary assessment is based on partially-refined assumptions including 100% crop treated, anticipated residues in foods taking into account residue dissipation, and drinking water values from groundwater monitoring studies; 2) the non-occupational bystander and ambient assessments are based on monitoring data and conservative models; and 3) there are no residential uses of methyl bromide.

## 4.5 Toxicity Endpoint and Point of Departure Selections

Certain NOAEL/LOAELs within the toxicity profile tables contain results that are no longer considered adverse based upon current practices (*e.g.* less than 10% change in absolute body

weight); however, these studies do not impact endpoint selection because updates would result in higher NOAEL/LOAEL values for these studies and the currently PODs used in the risk assessment are protective of these values. Therefore, revised DERs were not completed for these studies.

Toxicity endpoints and PODs for dietary, non-occupational and occupational exposure scenarios are summarized below in Table 4.5.3.1 – Table 4.5.3.2. In the absence of having adequate oral toxicity studies that measure acute endpoints (e.g., developmental studies), values were derived from inhalation toxicity studies (ACN and developmental toxicity via inhalation route). No endpoints have been changed for the current assessment.

*Acute dietary (Females 13-49 years of age):* The prenatal developmental study in rabbits via the inhalation route was considered appropriate for the acute dietary endpoint to protect pregnant females and those of reproductive age. An acute reference dose (aRfD) and acute population adjusted dose (aPAD) of 0.14 mg/kg/day (NOAEL = 14 mg/kg/day) was based on agenesis of the gall bladder and increased incidence of fused sternebrae, observed at the LOAEL of 28 mg/kg/day. An uncertainty factor of 100X (10X to account for interspecies extrapolation, 10X to account for intra-species variation, and 1X FQPA safety factor) was applied to obtain the aRfD and aPAD. In addition, this endpoint is protective of the developmental effects seen in the rat prenatal developmental study.

*Acute dietary (General population, including infants and children):* The POD and endpoint of concern is selected from the acute neurotoxicity study in rats via inhalation exposure. An aRfD and aPAD of 0.9 mg/kg/day (NOAEL 90 mg/kg/day) was based on results of functional observation battery (FOB) tests, including decreased activity, increase in number of animals with drooping/half-closed eyelids and alertness, decreased rears, decreased motor activity, increased piloerection and decreased body temperature. An uncertainty factor of 100X (10X to account for interspecies extrapolation, 10X to account for intra-species variation, and 1X FQPA safety factor) was applied to obtain the aRfD and aPAD.

*Chronic dietary exposure (All populations):* A chronic reference dose (cRfD) and chronic population-adjusted dose (cPAD) of 0.022 mg/kg/day (NOAEL = 2.2 mg/kg/day) was selected from the chronic/carcinogenicity study in rats based on decreased body weight, body weight gain and food consumption following oral dosing. An uncertainty factor of 100X (10X to account for interspecies extrapolation, 10X for intra-species variation, and 1X FQPA safety factor) was applied to obtain the cRfD and cPAD. This is the lowest NOAEL in the database and is protective of all other chronic, developmental, and reproductive effects observed.

*Dermal exposure (Short- and Intermediate-term):* A dermal endpoint was not selected. There are no *in vivo* or *in vitro* dermal absorption studies available for methyl bromide, and acute dermal toxicity and dermal sensitization studies were not required because there is clear evidence that severe irritation to skin occurs after acute dermal exposure to methyl bromide. However, dermal exposure to methyl bromide is not expected due to its high volatility and use pattern.

*Inhalation exposure (Acute):* Acute inhalation endpoints for risk assessment were selected from the route-specific prenatal developmental study in rabbits with a LOAEL of 80 ppm (NOAEL =

40 ppm). In this study, animals were exposed 6 hours/day on Days 6-16 of gestation. At the study LOAEL of 80 ppm, agenesis of the gall bladder and fused sternebrae were observed. To apply the reference concentration (RfC) methodology, a regional gas dose ratio (RGDR) of 1 was applied since the observed effects are systemic. The human equivalent concentrations (HECs) for the agricultural bystander and ambient exposure scenarios, structural & commodity bystander exposure scenarios, and occupational inhalation scenarios are 10 ppm, 40 ppm, and 30 ppm, respectively (Table 4.5.3.2 and Appendix F). Because HECs have been calculated, the interspecies UF is reduced to 3X (to account for pharmacodynamic differences between animals and humans). A 10X UF for intraspecies is applied for extrapolation within species. The FQPA SF is was reduced to 1X. The total uncertainty factor (UF) or LOC for acute inhalation exposure is 30.

*Inhalation exposure (Short- and Intermediate-term):* Short- and intermediate-term inhalation endpoints were selected from the route-specific subchronic toxicity study in dogs with a LOAEL of 10 ppm based on decreased responsiveness in females, and fecal effects and eye irritation (NOAEL = 5 ppm). In this study, animals were exposed 7 hours/day and 5 days/ week. To apply the RfC methodology, a RGDR of 1 was applied since the observed effects are systemic. HECs for the ambient and occupational inhalation scenarios are 1.0 ppm and 4.4 ppm, respectively (Table 4.5.3.2 and Appendix F). Because HECs have been calculated, the interspecies UF is reduced to 3X (to account for pharmacodynamic differences between animals and humans). A 10X UF for intraspecies is applied for extrapolation within species. The FQPA SF is was reduced to 1X. The total uncertainty factor (UF) or LOC for short- and intermediate-term inhalation exposure is 30.

*Inhalation exposure (Long- term):* Long-term inhalation endpoints were selected from the route-specific chronic toxicity and carcinogenicity study in rats with a LOAEL of 3 ppm based on nasal lesions (no NOAEL identified). In this study, animals were exposed 6 hours/day and 5 days/week. To apply the RfC methodology, a RGDR of 0.244 was calculated based on the extrathoracic effects (nasal lesions). HECs for the ambient and occupational inhalation scenarios are 0.13 ppm and 0.55 ppm, respectively (Table 4.5.3.2 and Appendix F). Because HECs have been calculated, the interspecies UF is reduced to 3X (to account for pharmacodynamic differences between animals and humans). A 10X UF for intraspecies is applied for extrapolation within species. Because a NOAEL was not identified in the study, and the POD is based on a LOAEL an uncertainty factor to extrapolate from a LOAEL to a NOAEL ($UF_L$) was applied and incorporated into the FQPA safety factor, when applicable. Due to the limited severity of the effect, HED considered that a 3X UF would be sufficient to extrapolate from the LOAEL to the NOAEL. The total UF or LOC for long-term inhalation exposure is 100.

HED's approach to estimating risks due to inhalation exposure is based on the guidance methodology developed by EPA's Office of Research and Development (ORD) for the derivation of inhalation reference concentrations (RfCs) and human equivalent concentrations (HECs) for use in MOE calculations. Endpoint selection is based on the endpoints occurring at the lowest HECs (which may or may not be the lowest animal NOAEL) derived using the RfC methodology. In this methodology, different HECs may be calculated for the same experimental NOAEL due to: 1) the different algorithms used to derive HECs for systemic *versus* portal of entry effects; or 2) the time adjustments conducted for non-occupational (commodity treatment

facility bystander or agricultural setting bystander) *versus* occupational exposure scenarios. The HECs calculated for methyl bromide are consistent with the RfC methodology guidance and took the most sensitive population for each subgroup into account.

### 4.5.1 Recommendation for Combining Routes of Exposures for Risk Assessment

Based on the exposure profile and available toxicological data, a quantitative dermal assessment was not completed. Because there are no residential uses of methyl bromide and no non-occupational exposures resulting from spray drift, there are no incidental oral exposures expected. Therefore, there are no additional routes of exposure to combine with the expected inhalation exposures. Non-occupational and ambient exposures are not typically aggregated with dietary exposures because the former are isolated and sporadic in nature, and the likelihood of having a significant food exposure occurring concurrently with a significant non-occupational exposure is negligible.

### 4.5.2 Cancer Classification and Risk Assessment Recommendation

Positive findings were reported in micronucleus tests in the rat and mouse at doses that resulted in mortality and in an alkaline elution assay using rat testicular DNA. However, the mutagenic concern regarding carcinogenesis is lessened since no treatment-related tumors were observed by oral route in the rat or by the inhalation route in the mouse or rat. Methyl bromide is classified as "Not Likely to be Carcinogenic to Humans" (P. Chin, TXR 0051439, 01/06/2003).

### 4.5.3 Summary of Points of Departure and Toxicity Endpoints Used in Human Risk Assessment

A summary of the hazard endpoints selected may be found in Tables 4.5.3.1 and 4.5.3.2.

**Table 4.5.3.1. Summary of Toxicological Doses and Endpoints for Methyl Bromide for Use in Dietary Human Health Risk Assessments.**

| Exposure/ Scenario | POD | Uncertainty/FQPA Safety Factors | RfD, PAD, Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Acute Dietary (General Population, including Infants and Children) | NOAEL = 90 mg/kg/day | $UF_A$ = 10X<br>$UF_H$ = 10X<br><br>FQPA SF = 1X | Acute RfD = 0.9 mg/kg/day<br><br>aPAD = 0.9 mg/kg/day | Acute neurotoxicity study - -rat (Inhalation) LOAEL = 314 mg/kg/day based on decreased activity, increase in number of animals with drooping/half-closed eyelids and alertness as measured in the FOB, decreased rears, decreased motor activity, increased piloerection and decreased body temperature |

**Table 4.5.3.1. Summary of Toxicological Doses and Endpoints for Methyl Bromide for Use in Dietary Human Health Risk Assessments.**

| Exposure/ Scenario | POD | Uncertainty/FQPA Safety Factors | RfD, PAD, Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Acute Dietary (Females 13-49 years of age) | NOAEL = 14 mg/kg/day | $UF_A$ = 10X<br>$UF_H$ = 10X<br><br>FQPA SF = 1X | Acute RfD = 0.14 mg/kg/day<br><br>aPAD = 0.14 mg/kg/day | Prenatal developmental Toxicity - Rabbit (Inhalation) LOAEL = 28 mg/kg/day based on agenesis of the gall bladder and increased incidence of fused sternebrae. |
| Chronic Dietary (All Populations) | NOAEL = 2.2 mg/kg/day | $UF_A$ = 10X<br>$UF_H$ = 10X<br><br>FQPA SF = 1X | Chronic RfD = 0.022 mg/kg/day<br><br>cPAD = 0.022 mg/kg/day | Chronic/carcinogenicity study – rats (Oral) (Microencapsulated methyl bromide)<br>LOAEL = 11.1 mg/kg/day based on decreased body weight, body weight gain and food consumption |
| Cancer (oral, dermal, inhalation) | Classification: Not likely to be carcinogenic to humans. | | | |

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. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). $UF_L$ = use of a LOAEL to extrapolate a NOAEL. $UF_S$ = use of a short-term study for long-term risk assessment. $UF_{DB}$ = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

**Table 4.5.3.2. Summary of Toxicological Doses and Endpoints for Use in Methyl Bromide Non-Occupational and Occupational Human Health Inhalation Risk Assessment**

| Risk Assessment* | | POD | Uncertainty Factors | Study/ Toxicological Effects | Human Equivalent Concentrations (HECs) |
|---|---|---|---|---|---|
| Acute | Agricultural Bystander and Ambient (24 hr exposure) | NOAEL = 40 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Developmental Study in Rabbits (Inhalation)<br><br>LOAEL = 80 ppm based on agenesis of gallbladder, fused sternebrae | 10 ppm<br>UF = 30 |
| | Structural & Commodity Bystander (6 hr exposure) | NOAEL = 40 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Developmental Study in Rabbits (Inhalation)<br><br>LOAEL = 80 ppm based on agenesis of gallbladder, fused sternebrae | 40 ppm<br>UF = 30 |

**Table 4.5.3.2. Summary of Toxicological Doses and Endpoints for Use in Methyl Bromide Non-Occupational and Occupational Human Health Inhalation Risk Assessment**

| Risk Assessment* | | POD | Uncertainty Factors | Study/ Toxicological Effects | Human Equivalent Concentrations (HECs) |
|---|---|---|---|---|---|
| | Occupational (8 hr exposure) | NOAEL = 40 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X | Developmental Study in Rabbits (Inhalation)<br>LOAEL = 80 ppm based on agenesis of gallbladder, fused sternebrae | 30 ppm<br>UF = 30 |
| Short- and Intermediate -Term Inhalation (1 day to 6 months) | Ambient | NOAEL = 5 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Subchronic (5 to 7 week) inhalation toxicity study – dogs<br>LOAEL = 10 ppm based on decreased responsiveness in females | 1.0 ppm<br>UF = 30 |
| | Occupational | NOAEL = 5 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X | Subchronic (5 to 7 week) inhalation toxicity study – dogs<br>LOAEL = 10 ppm based on decreased responsiveness in females | 4.4 ppm<br>UF = 30 |
| Long-Term Inhalation (>6 months) | Ambient | No NOAEL identified. LOAEL = 3 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X<br>FQPA SF/$UF_L$ =3X<br>$UF_L$ due to LOAEL to NOAEL extrapolation.<br>$UF_L$ due to LOAEL | Chronic/carcinogenicity study – rats<br>LOAEL = 3 ppm based on nasal lesions | 0.13 ppm<br>UF = 100 |
| | Occupational | No NOAEL identified. LOAEL = 3 ppm | $UF_A$ = 3X<br>$UF_H$ = 10X<br>$UF_L$=3X<br>$UF_L$ due to LOAEL to NOAEL extrapolation | Chronic/carcinogenicity study – rats<br>LOAEL = 3 ppm based on nasal lesions | 0.55 ppm<br>UF = 100 |
| **Cancer** | | Classification: Not likely to be carcinogenic to humans | | | |

***** Agricultural bystander HECs have also been applied to 24-hour Time-Weighted-Average exposure concentrations measured from ambient air. All bystander assessments are non-occupational. Structural and commodity bystander assessments are based on 6-hour exposure durations.

## 4.6 Endocrine Disruptor Screening Program

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ

histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision for methyl bromide, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), methyl bromide is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

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

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[9] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[10]

## 5.0 Dietary Exposure and Risk Assessment

### 5.1 Residues of Concern Summary and Rationale

HED previously recommended that methyl bromide is the residue to be regulated (R. Perfetti, D168913, 09/24/1991), and this recommendation was reiterated in the residue chemistry chapter to the Reregistration Eligibility Decision (RED) (C. Olinger, D271583, 02/22/2002). Prior to these decisions, tolerances were established on inorganic bromide.

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

## 5.2 Food Residue Profile

The Agency has determined that soil fumigation uses of methyl bromide are classified as non-food uses (T. Goodlow, D304618, 02/08/2006). However, commodity fumigation uses are considered food uses that require tolerances, as residues of methyl bromide and inorganic bromide may be present. HED has decided not to separately assess the risks resulting from bromide ion in foods for the following reasons. First, parent methyl bromide is expected to be more toxic than bromide ion. Second, since methyl bromide is metabolized to bromide ion in mammals, it is likely that any toxic effects specific to the ion would have been observed in the available animal toxicity studies. Finally, bromide is ubiquitous in the environment. Distinguishing ubiquitous levels of bromide from those resulting from methyl bromide use may be problematic.

Adequate residue data are available to support registration review of methyl bromide. Residue decline data for methyl bromide following post-harvest fumigation has been submitted and reviewed for numerous crops. Thus, post-harvest fumigation is supported for many crops, and tolerances are recommended for most crop groups. Residues are primarily surface residues and quantifiable residues are likely, although they diminish rapidly in high water content raw agricultural commodities (RACs) and more slowly in high oil content RACs. Established tolerance for residues of inorganic bromide are established under 40 CFR 180.123, while those for methyl bromide are listed under 40 CFR 180.124. Codex currently has MRLs for both inorganic bromide and methyl bromide. To avoid potential harmonization issues, HED recommends retention of tolerances in 40 CFR 180.123 and updates to tolerances in 40 CFR 180.124 as indicated in Section 2.2.2.

## 5.3 Water Residue Profile

The Environmental Fate and Effects Division (EFED) confirmed that the previously derived estimated drinking water concentrations (EDWCs; F. Khan, D311406, 06/06/2005) for methyl bromide remain appropriate (email message from J. Herrick to W. Donovan, 10/11/2018; and M. Ruhman, D449333, 12/06/2018). Due to the rapid dissipation of methyl bromide from water to the air (half-life of 73 minutes), concentrations of methyl bromide in surface water are considered *de minimis* (*i.e.,* negligible). Hence, the methyl bromide EDWC was from ground water estimates. Based on the data base of pesticides in groundwater (U.S. EPA, 1992), 2 wells in California (out of 20,429 wells monitored in Florida, California, and Hawaii) had methyl bromide levels of 2.5 and 6.4 µg/L. Thus, the highest groundwater monitoring value of 6.4 ppb was used in both the acute and chronic assessments (F. Khan, D311406, 06/06/2005).

## 5.4 Dietary Risk Assessment

### 5.4.1 Description of Residue Data Used in Dietary Assessment

Acute and chronic dietary [food and drinking water] exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption

data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

Identical assumptions were used for the acute and chronic dietary assessments: anticipated residues (ARs) based on dissipation rates and time intervals between fumigation and market availability, 100% crop treated assumptions, and use of zero-level residues for food forms involving heating in recognition of the volatility of methyl bromide.

### 5.4.2 Percent Crop Treated Used in Dietary Assessment

No adjustment factors to account for the percent of crop treated with methyl bromide were utilized in the present dietary assessment.

### 5.4.3 Acute Dietary Risk Assessment

The results of the acute dietary exposure analysis are reported in Table 5.4.6. The acute dietary (food + drinking water) exposure assessment used ARs and 100% CT for all crops. Drinking water was incorporated directly in the dietary assessment using the maximum concentration detected from ground water monitoring reports. This assessment indicated that the acute dietary exposure estimates (at the 95$^{th}$ percentile) are not of concern (<100% of the aPAD) for the general U.S. population (1.4% of the aPAD) and all population subgroups. Exposure was equivalent to 3.3% of the aPAD for the most highly exposed population subgroup (Children 1-2 years old). Exposure was equivalent to 6.7% of the aPAD for females 13-49 years old, reflecting the lower point of departure applicable to this population subgroup.

### 5.4.4 Chronic Dietary Risk Assessment

The results of the chronic dietary exposure analysis are reported in Table 5.4.6. The chronic dietary exposure assessment used ARs and 100% CT for all crops. The chronic dietary (food + drinking water) risk assessment was conducted for the general U.S. population and various population subgroups. Drinking water was incorporated directly into the dietary assessment using the maximum concentration detected from ground water monitoring reports. This assessment concludes that the chronic dietary exposure estimates are not of concern (<100% of the cPAD) for the general U.S. population (14% of the cPAD) and all population subgroups. The most highly exposed population subgroup is Children 1-2 years old at 38% of the cPAD.

### 5.4.5 Cancer Dietary Risk Assessment

No quantification needed; "Not likely to be carcinogenic to humans" - No evidence of carcinogenicity in rats and mice.

### 5.4.6 Summary Table

**Table 5.4.6. Results of Methyl Bromide Acute and Chronic Dietary (Food and Water) Exposure Analysis Using DEEM-FCID™**

| Population | Acute Analysis[1] 95th Percentile of Exposure | | | Chronic Analysis[1] | |
|---|---|---|---|---|---|
| | aPAD (mg/kg-day) | Exposure (mg/kg-day) | %aPAD | Exposure (mg/kg-day) | %cPAD[2] |
| General U.S. Population | 0.9 | 0.012367 | 1.4 | 0.003016 | 14 |
| All Infants | 0.9 | 0.016427 | 1.8 | 0.002696 | 12 |
| **Children 1-2 years old[3]** | **0.9** | **0.029595** | **3.3** | **0.008408** | **38** |
| Children 3-5 years old | 0.9 | 0.021185 | 2.4 | 0.005350 | 24 |
| Children 6-12 years old | 0.9 | 0.012014 | 1.3 | 0.002859 | 13 |
| Youth 13-19 years old | 0.9 | 0.007224 | <1 | 0.001895 | 8.6 |
| Adults 20-49 years old | 0.9 | 0.012665 | 1.4 | 0.003056 | 14 |
| Adults 50-99 years old | 0.9 | 0.008799 | <1 | 0.002579 | 12 |
| **Females 13-49 years old** | **0.14** | **0.009364** | **6.7** | 0.002293 | 10 |

[1] The EDWC used in the acute and chronic analyses was 6.4 ppb, based on ground water monitoring data.
[2] The cPAD for all populations is 0.022 mg/kg/day
[3] The populations with the highest risk and exposure estimates are highlighted.

## 6.0 Residential Exposure/Risk Characterization

There are no uses of methyl bromide resulting in residential exposures. The residential (structural) uses of methyl bromide ended in 2017. Therefore, residential handler and post-application exposures are not expected and have not been quantitatively assessed.

## 7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure. There are no residential uses of methyl bromide; therefore, the aggregate assessments are equivalent to the dietary risk assessments. Non-occupational and ambient exposures are not typically aggregated with dietary exposures because the former are isolated and sporadic in nature, and the likelihood of having a significant food exposure occurring concurrently with a significant non-occupational exposure is negligible.

## 8.0 Non-Occupational Spray Drift Exposure and Risk Estimates

A spray drift assessment was not completed for methyl bromide. The application practices for methyl bromide are not reflected in the standard spray drift assessment as outlined in the

Residential SOP Addenda 1: *Consideration of Spray Drift*[11]. Due to the high vapor pressure and physical state of methyl bromide, as well as the requirement for shank injection, tarps, and/or soil incorporation for the soil uses of methyl bromide, the residues (i.e., sprays) available to drift onto nearby or adjacent areas would be negligible. The non-soil/commodity uses of methyl bromide are not expected to result in spray drift because applications typically occur inside or under tarps. Therefore, spray drift exposures have not been quantitatively assessed. However, non-occupational bystander inhalation exposures are expected, and an assessment was completed using the most appropriate methodology to assess the off-site and off-field transport of methyl bromide application related exposures. See Sections 9.0 and 10.0 below for additional information.

## 9.0 Non-Occupational Ambient Inhalation Exposure and Risk Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency has developed a Volatilization Screening Tool and a Volatilization Screening Analysis[12] for conventional pesticides. However, unlike most conventional pesticides, the Screening Analysis is not applicable to methyl bromide because of the extensive information available on its volatility, vapor pressure, and physiochemical properties. Bystanders who live or work near fumigated fields or commodity fumigation sites are potentially exposed to fumigant emissions that travel off-site. There is the potential for inhalation exposure to methyl bromide via ambient air resulting from multiple agricultural soil or commodity applications across large regions. Therefore, the non-occupational ambient inhalation exposure and risk estimates are not meant to represent exposures associated with a single application event.

The Agency previously issued a Generic Data Call-In (GDCI) for ambient air monitoring of methyl bromide (GDCI-053201-836), discussed in Section 9.1.

Previously, the Agency conducted several assessments to quantify the potential volatilization of methyl bromide from various sources, using available ambient air concentration data from the California DPR ARB TAC Program and the California DPR AMN. These assessments have been updated to reflect the available monitoring data from more recent years, which more accurately reflect the current use of methyl bromide (Section 9.2 and Section 9.3). For each assessment, acute air concentrations (represented as 24-hour measurements), short- and intermediate-term air concentrations (represented as either 4-week rolling averages or 90$^{th}$ percentile air concentrations) and long-term air concentrations (either 1-year averages or means) were used as reported by California DPR (an analysis of the raw data was not conducted; values as reported were used). The Agency has also re-presented the risk estimates from the EPA NATA (Section 9.3).

Additional ambient data generated by the Alliance of the Methyl Bromide Industry (AMBI) were previously considered. Review of the AMBI data identified quality control issues in some

[11] https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0676-0003
[12] https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2014-0219-0003&disposition=attachment&contentType=pdf

sample collection procedures (J. Dawson, D337288, 04/10/2007); therefore, the results using these data are not re-presented here.

### 9.1 Data Requirement for Ambient Monitoring of Methyl Bromide in High Use Areas

The 2009 Amended Reregistration Eligibility Decision (RED) required one methyl bromide exposure study relating to non-occupational ambient exposures (GDCI-053201-836):
An ambient monitoring study for methyl bromide (non-guideline) that addresses ambient exposures to both agricultural and commodity fumigations from high use areas.

To fulfill the GDCI, ambient monitoring data from three separate areas of high methyl bromide use were required: Georgia, Siskiyou County (California), and the Delaware Maritime Exchange Region.

HED recently evaluated a waiver request for ambient air monitoring in Georgia for forest seedling nursery applications and recommended that the requirement for ambient monitoring in Georgia be waived (K. Rickard, D439182, 05/16/2017). The waiver was granted because the soil uses of methyl bromide in nurseries is declining. Based on the relatively small number of acres treated in soil nursery applications compared to the quantity of commodities fumigated at quarantine sites, it is unlikely that ambient air monitoring in Georgia would provide useful estimates of ambient air concentrations for risk assessment and risk mitigation. The Agency also recently provided comments on the protocol for the ambient air monitoring study in the Delaware Maritime Exchange Region (K. Rickard, D441334, 08/08/2017 and K. Rickard, D435567, 12/21/2016); comments included requests for clarification on the sampling site distances, sampling intervals, and limits of detection; and reiterated the need for sampling to be conducted under normal operations and normal fumigation calendar, not during the time when stacks may be converted from horizontal stacks to vertical stacks. HED reiterates that the results at the two remaining sites (Siskiyou County and the Delaware Maritime Exchange Region) will be applied nationwide as representative of all other use types and sites (quarantine fumigations, and/or soil fumigations). The Agency notes that a query of the California Pesticide Information Portal (CALPIP) Pesticide Use Reporting (PUR)[13] database for 2016 (most recent year reported) showed approximately ~730,000 lbs of methyl bromide applied in Siskiyou County. Therefore, Siskiyou County is still considered an area of high methyl bromide use.

### 9.2 Ambient Air Inhalation Exposure Assessment Using California Department of Pesticide Regulation (DPR) Air Monitoring Data

HED has used available monitoring data from the Western U.S. (i.e., California) to evaluate ambient exposures to methyl bromide. Data from the California DPR ARB TAC Program were used to calculate ambient bystander exposure in both agricultural[14] (Section 9.2.1) and non-

[13] https://calpip.cdpr.ca.gov/main.cfm Applications reported in Siskiyou County included only soil application, preplant, outdoor applications (seedbeds, etc) only. This type of application would be reflective of the application of interest in the required ambient monitoring study (soil application in strawberry fields) in Siskiyou County.
[14] https://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_reports.htm

agricultural/urban environments[15] (Section 9.2.2). For the monitoring conducted in agricultural environments, the samples were collected by the ARB near an application site and in ambient air of nearby communities. Because most large-scale pesticide applications are seasonal and occur in agricultural areas, ARB conducts monitoring in areas of high use, and at times when use is at its peak[16]. For the monitoring conducted in non-agricultural/urban environments[17], a variety of toxic air contaminants are monitored at each site, including volatile organic compounds, polycyclic aromatic hydrocarbons, and metals; the majority of monitored contaminants are not pesticides. The sampling conducted in non-agricultural/urban areas was designed to produce a statewide annual average and the site locations were not necessarily selected near known pesticide application sites or near areas of high pesticide use. HED also used data from the California DPR AMN (Section 9.2.3) to calculate ambient bystander exposure in agricultural environments[18]. For the AMN in agricultural environments, DPR evaluated and prioritized 226 communities in California as candidates for inclusion in the network. The 226 communities were prioritized based on pesticide use (both local and regional), demographic data (including: communities with higher populations of children, persons over 65, and number of persons living in close proximity to farms and agricultural areas with high pesticide use), and availability of other exposure and health data. DPR also considered other factors, including air sampling feasibility, weather patterns, and the potential for collaboration with other projects focused on environmental health. Over 36 pesticides, including four fumigants (methyl bromide, 1,3-dichloropropene, chloropicrin, and MITC generators) were monitored.

HED has queried the recent years of CDPR monitoring for methyl bromide. A query of the CALPIP PUR database[19] for 2016 (most recent year reported) shows that approximately 3.4 million pounds of methyl bromide were applied as "soil application, pre-plant-outdoor" applications in the State of California across nine counties. Therefore, the monitoring conducted by the TAC and the AMN programs in agricultural environments throughout California is expected to be representative of ambient concentrations from the soil uses of methyl bromide.

In absence of more targeted data closer to commodity fumigation facilities, the monitoring data collected in non-agricultural/urban areas has been used to represent ambient exposures in California from non-soil/commodity fumigations; there is some uncertainty regarding the representativeness of these data for areas around commodity fumigation facilities. Therefore, once the required (GDCI-053201-836) data from the Delaware Maritime Exchange Region (a high use methyl bromide commodity fumigation region) are submitted, an updated ambient air exposure and risk assessment will be conducted. These required data will be representative of ambient air concentrations corresponding to commodity fumigations in a high-use area.

[15] https://www.arb.ca.gov/adam/toxics/sitelists/mbrsites.html
[16] https://www.cdpr.ca.gov/docs/emon/pubs/tac/tac_prog.htm
[17] https://www.arb.ca.gov/adam/toxics/sitelists/mbrsites.html
[18] https://www.cdpr.ca.gov/docs/emon/airinit/air_network_results.htm.
[19] https://calpip.cdpr.ca.gov/main.cfm

### 9.2.1 Ambient Air Inhalation Exposure Assessment Using California DPR Air Resources Board (ARB) Toxic Air Contaminant (TAC) Program Monitoring Data in Agricultural Environments

In September 2010, as part of the California TAC program, DPR submitted a request to the California ARB for monitoring of two pesticide fumigants, methyl bromide and 1,2-dichloropropene. Because most large-scale pesticide applications are seasonal and occur in agricultural areas, ARB conducts monitoring in areas of high use, and at times when use is at its peak. This worst-case information can help determine the ambient exposures of people living in all areas where the pesticide is used. Methyl bromide was monitored from 2010 to 2017 in three sites in central and southern California [Oxnard (Ventura County), Santa Maria (Santa Barbara County), and Watsonville (Santa Cruz County)]. ARB originally established a site in Camarillo in August of 2010, and continued sampling at this location only until October 17, 2011. The air sampler was then moved to Rio Mesa High School in Oxnard (Ventura County) on October 24, 2011 and monitoring continued until the end of 2016.

HED evaluated different durations of exposure including single day (acute) exposures, short- and intermediate-term exposures, and long-term exposures. Acute risks were calculated using the highest 1-day air concentrations (24-hour samples taken once every 6 days) for all sampling years for each location and the acute ambient 24-hour human equivalent concentration (HEC) for the inhalation POD (10,000 ppb). Short- and intermediate-term risks were calculated using the highest 4-week rolling average air concentration for all sampling years for each location and the short- and intermediate-term ambient HEC for the inhalation POD (1,000 ppb). Long-term risks were calculated using the highest 1-year average air concentration for all sampling years by location and the long-term ambient HEC for the inhalation POD (130 ppb).

The available ambient air concentrations did not result in risk estimates of concern for acute, short- or intermediate-term, or long-term exposures. The acute ambient MOEs range from 2,600 to 100,000 (LOC = 30) (Table 9.2.1.1). The short- and intermediate-term ambient MOEs range from 630 to 50,000 (LOC = 30) (Table 9.2.1.2). The long-term ambient MOEs range from 680 to 6,500 (LOC = 100) (Table 9.2.1.3).

Since monitoring began in 2010, none of the detected concentrations for all three fumigants exceeded DPR's screening levels or regulatory targets for acute exposure (1-day), subchronic exposure (4-week), or chronic exposure (1-year). DPR explains the results for methyl bromide in 2017 as being "non-detects" as: "Overall, methyl bromide concentrations have generally decreased over time at all three sampling locations. On December 31, 2016, most uses of methyl bromide were discontinued and this was reflected in monitoring results as no detections occurred at any TAC monitoring location in 2017[20]."

[20] https://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_reports/2010-2017_results.pdf

**Table 9.2.1.1. Acute (Single Day) Ambient Inhalation Exposure and Risk Assessment for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program and California Air Resources Board (ARB) Monitoring Data.**

| Location | Highest 1-day Concentration (ppb)[1] | | | | | | | | Acute (24 Hour) MOE[6] (LOC = 30) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[7] | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[8] |
| Santa Maria[2] | 3.7 | 3.8 | 0.8 | 0.8 | 0.6 | 1.7 | 1.7 | ND | 2,700 | 2,600 | 13,000 | 13,000 | 17,000 | 5,900 | 5,900 | N/A |
| Camarillo[3] | 0.5 | 1.4 | - | - | - | - | - | - | 20,000 | 7,100 | - | - | - | - | - | - |
| Oxnard[4] | - | 0.5 | 3.4 | 0.2 | 8.7 | 0.5 | 0.6 | ND | - | 20,000 | 2,900 | 50,000 | 1,100 | 20,000 | 17,000 | N/A |
| Watsonville[5] | - | 0.1 | 1.5 | 1.8 | 0.1 | 0.2 | 0.7 | ND | - | 100,000 | 6,700 | 5,600 | 100,000 | 50,000 | 14,000 | N/A |

1. Air monitoring reports available at https://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_reports.htm.
2. Sampling started on 8/11/10.
3. Sampling occurred between 8/11/10 and 10/17/11.
4. Sampling started on 10/24/11.
5. Sampling started on 11/05/11.
6. Acute MOE = Acute ambient (24-hour exposure) human equivalent concentration (HEC) for the inhalation POD (10,000 ppb)/highest 1-day concentration (ppb). LOC = 30.
7. ND = Non-Detect.
8. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted.

**Table 9.2.1.2 Short- and Intermediate-Term Ambient Inhalation Exposure and Risk Assessment for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program and California Air Resources Board (ARB) Monitoring Data.**

| Location | Highest 28-day Rolling Average Concentration (ppb)[1] | | | | | | | | Short- and Intermediate-Term MOE[6] (LOC = 30) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[7] | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[8] |
| Santa Maria[2] | 1.52 | 1.6 | 0.56 | 0.26 | 0.3 | 1.15 | 0.75 | ND | 660 | 630 | 1,800 | 3,800 | 3,300 | 870 | 1,300 | N/A |
| Camarillo[3] | 0.28 | 0.87 | - | - | - | - | - | - | 4,000 | 1,100 | - | - | - | - | - | - |
| Oxnard[4] | - | 0.15 | 0.90 | 0.05 | 1.97 | 0.27 | 0.18 | ND | - | 6,700 | 1,100 | 20,000 | 510 | 3,700 | 5,600 | N/A |
| Watsonville[5] | - | 0.02 | 0.75 | 0.77 | 0.07 | 0.13 | 0.25 | ND | - | 50,000 | 1,300 | 1,300 | 14,000 | 7,700 | 4,000 | N/A |

1. Air monitoring reports available at https://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_reports.htm.
2. Sampling started on 8/11/10.
3. Sampling occurred between 8/11/10 and 10/17/11.
4. Sampling started on 10/24/11.
5. Sampling started on 11/05/11.
6. Short- and Intermediate-Term MOE = Short- and Intermediate-term ambient human equivalent concentration (HEC) for the inhalation POD (1,000 ppb)/highest 4-week rolling average concentration (ppb). LOC = 30.
7. ND = Non-Detect.
8. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted.

**Table 9.2.1.3. Long-Term Ambient Inhalation Exposure and Risk Assessment for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program and California Air Resources Board (ARB) Monitoring Data.**

| Location | 1-Year Average Concentration (ppb)[1] | | | | | | | | Long-Term MOE[6] (LOC = 100) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[7] | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017[8] |
| Santa Maria[2] | - | 0.18 | 0.09 | 0.06 | 0.05 | 0.14 | 0.09 | ND | - | 720 | 1,400 | 2,200 | 2,600 | 930 | 1,400 | N/A |
| Camarillo[3] | * | * | - | - | - | - | - | - | * | - | - | - | - | - | - | - |
| Oxnard[4] | - | * | 0.1 | 0.02 | 0.19 | 0.05 | 0.03 | ND | - | * | 1,300 | 6,500 | 680 | 2,600 | 4,300 | N/A |
| Watsonville[5] | - | - | 0.12 | 0.15 | 0.02 | 0.04 | 0.04 | ND | - | - | 1,100 | 870 | 6,500 | 3,300 | 3,300 | N/A |

1. Air monitoring reports available at https://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_reports.htm.
2. Sampling started on 8/11/10.
3. Sampling occurred between 8/11/10 and 10/17/11.
4. Sampling started on 10/24/11.
5. Sampling started on 11/05/11.
6. MOE = Long-term ambient human equivalent concentration (HEC) for the inhalation POD (130 ppb)/average concentration or highest 1-year average concentration (ppb). LOC = 100.
7. ND = Non-Detect.
8. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted.

* 12 months of monitoring data at the sampling location were not available; therefore, no 1-year average air concentration was determined.

### 9.2.2 Ambient Air Inhalation Exposure Assessment Using California DPR Air Resources Board (ARB) Toxic Air Contaminant (TAC) Program Monitoring Data in Non-Agricultural/Urban Environments

In addition to the agricultural area monitoring sites described above, TAC monitoring sites are also located throughout urban areas in California, such as Long Beach, Burbank, Los Angeles, and San Francisco[21]. Air concentrations collected from these urban sites have been used to represent ambient concentrations near commodity port fumigations. There is some uncertainty regarding the representativeness of these data for areas around commodity fumigation facilities because of the distances from the monitoring sites to ports. Therefore, once the required (GDCI-053201-836) data from the Delaware Maritime Exchange Region (a high use methyl bromide commodity fumigation region) are submitted, an updated ambient air exposure and risk assessment will be conducted. These required data will be representative of ambient air concentrations corresponding to commodity fumigations in a high-use area.

Additionally, in the future, monitoring sites proposed in California Assembly Bill 617[22] may be located less than a mile from the Port of Long Beach facilities[23], providing better information on ambient air concentrations closer to the fumigating facilities from the non-soil/commodity uses of methyl bromide.

For the ambient bystander exposure assessment in urban environments, HED evaluated different durations of exposure including single day (acute) exposures, short- and intermediate-term exposures, and long-term exposures. Acute risks were calculated using the maximum air concentration[24] at each station for each year and the acute ambient (24-hour exposure) HEC for the inhalation POD (10,000 ppb). Short- and intermediate-term risks were calculated using the 90$^{th}$ percentile air concentration for each year for each station and the short-term ambient HEC for the inhalation POD (1,000 ppb). Long-term risks were calculated using the mean air concentrations for all sampling years by location and the long-term ambient HEC for the inhalation POD (130 ppb). Means shown on ARB's toxics pages are means of monthly means. Using the mean of monthly means compensates for the uneven distribution of samples over the 12 months of the year.

The available ambient air concentrations did not result in risk estimates of concern for acute, short- or intermediate-term, or long-term exposures. The acute ambient MOEs range from 6,300 to 670,000 (LOC = 30), the short- and intermediate-term ambient MOEs range from 1,900 to 670,000 (LOC = 30), and the long-term ambient MOEs range from 710 to 8,700 (LOC = 100) (Table 9.2.2.1).

[21] https://www.arb.ca.gov/adam/toxics/sitelists/mbrsites.html
[22] http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180AB134
[23] http://www.aqmd.gov/nav/about/initiatives/environmental-justice/ab617-134
[24] Samples were collected over a 24-hour period (midnight to midnight) every 12 days.

**Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2].**

| Site | Year | Mean | 90th Percentile | Max | # of Observations | Acute MOE (LOC = 30)[3] | Short- and Intermediate-Term MOE (LOC = 30)[4] | Long-Term MOE (LOC = 100)[5] |
|---|---|---|---|---|---|---|---|---|
| Azusa | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.023 | 0.05 | 0.08 | 30 | 130,000 | 20,000 | 5,700 |
| | 2015 | 0.017 | 0.03 | 0.04 | 30 | 250,000 | 33,000 | 7,600 |
| | 2014 | 0.02 | 0.04 | 0.05 | 29 | 200,000 | 25,000 | 6,500 |
| | 2013 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2012 | 0.02 | 0.05 | 0.06 | 30 | 170,000 | 20,000 | 6,500 |
| | 2011 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2010 | 0.018 | 0.015 | 0.04 | 24 | 250,000 | 67,000 | 7,200 |
| | 2009 | 0.018 | 0.015 | 0.06 | 31 | 170,000 | 67,000 | 7,200 |
| | 2008 | *[6] | 0.015 | 0.07 | 28 | 140,000 | 67,000 | * |
| | 2007 | 0.019 | 0.03 | 0.05 | 27 | 200,000 | 33,000 | 6,800 |
| | 2006 | 0.022 | 0.04 | 0.06 | 29 | 170,000 | 25,000 | 5,900 |
| | 2005 | 0.026 | 0.05 | 0.07 | 29 | 140,000 | 20,000 | 5,000 |
| | 2004 | 0.036 | 0.07 | 0.21 | 29 | 48,000 | 14,000 | 3,600 |
| | 2003 | 0.036 | 0.08 | 0.16 | 28 | 63,000 | 13,000 | 3,600 |
| | 2002 | 0.041 | 0.1 | 0.14 | 27 | 71,000 | 10,000 | 3,200 |
| Burbank | 2014 | * | * | 0.06 | 15 | 170,000 | 33,000 | * |
| | 2013 | 0.017 | * | 0.04 | 29 | 250,000 | 67,000 | 7,600 |
| | 2012 | 0.019 | * | 0.06 | 29 | 170,000 | 67,000 | 6,800 |
| | 2011 | 0.017 | 0.03 | 0.04 | 27 | 250,000 | 67,000 | 7,600 |
| | 2010 | 0.018 | 0.015 | 0.07 | 29 | 140,000 | 67,000 | 7,200 |
| | 2009 | 0.015 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,700 |
| | 2008 | 0.02 | 0.015 | 0.09 | 30 | 110,000 | 33,000 | 6,500 |
| | 2007 | 0.017 | 0.015 | 0.05 | 29 | 200,000 | 67,000 | 7,600 |
| | 2006 | 0.022 | 0.015 | 0.06 | 31 | 170,000 | 25,000 | 5,900 |
| | 2005 | 0.023 | 0.03 | 0.06 | 29 | 170,000 | 25,000 | 5,700 |
| | 2004 | 0.024 | 0.015 | 0.06 | 31 | 170,000 | 20,000 | 5,400 |
| | 2003 | * | 0.04 | 0.1 | 26 | 100,000 | 20,000 | * |
| | 2002 | 0.031 | 0.04 | 0.14 | 30 | 71,000 | 20,000 | 4,200 |
| Calexico-Ethyl Street | 2017 | 0.015 | 0.015 | 0.015 | 29 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.016 | 0.015 | 0.04 | 29 | 250,000 | 67,000 | 8,100 |
| | 2015 | 0.022 | 0.03 | 0.11 | 30 | 91,000 | 33,000 | 5,900 |
| | 2014 | 0.019 | 0.04 | 0.05 | 30 | 200,000 | 25,000 | 6,800 |
| | 2013 | 0.015 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,700 |
| | 2012 | 0.022 | 0.05 | 0.1 | 29 | 100,000 | 20,000 | 5,900 |
| | 2011 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2010 | * | 0.015 | 0.015 | 19 | 670,000 | 67,000 | * |
| | 2009 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2008 | 0.015 | 0.015 | 0.015 | 29 | 670,000 | 67,000 | 8,700 |
| | 2007 | 0.015 | 0.015 | 0.015 | 28 | 670,000 | 67,000 | 8,700 |
| | 2006 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2005 | 0.018 | 0.03 | 0.04 | 30 | 250,000 | 33,000 | 7,200 |
| | 2004 | 0.032 | 0.06 | 0.31 | 31 | 32,000 | 17,000 | 4,100 |
| | 2003 | 0.036 | 0.05 | 0.33 | 30 | 30,000 | 20,000 | 3,600 |
| | 2002 | 0.02 | 0.015 | 0.11 | 29 | 91,000 | 67,000 | 6,500 |
| Chula Vista | 2017 | 0.015 | 0.015 | 0.015 | 28 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.017 | 0.015 | 0.05 | 29 | 200,000 | 67,000 | 7,600 |

**Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2].**

| Site | Year | Mean | 90th Percentile | Max | # of Observations | Acute MOE (LOC = 30)[3] | Short- and Intermediate-Term MOE (LOC = 30)[4] | Long-Term MOE (LOC = 100)[5] |
|---|---|---|---|---|---|---|---|---|
| | 2015 | 0.019 | 0.04 | 0.05 | 31 | 200,000 | 25,000 | 6,800 |
| | 2014 | 0.018 | 0.015 | 0.05 | 28 | 200,000 | 67,000 | 7,200 |
| | 2013 | 0.016 | 0.015 | 0.03 | 30 | 330,000 | 67,000 | 8,100 |
| | 2012 | 0.019 | 0.04 | 0.06 | 30 | 170,000 | 25,000 | 6,800 |
| | 2011 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2010 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2009 | 0.016 | 0.015 | 0.05 | 32 | 200,000 | 67,000 | 8,100 |
| | 2008 | 0.017 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 7,600 |
| | 2007 | 0.016 | 0.015 | 0.04 | 31 | 250,000 | 67,000 | 8,100 |
| | 2006 | * | 0.015 | 0.015 | 26 | 670,000 | 67,000 | * |
| | 2005 | 0.019 | 0.04 | 0.06 | 29 | 170,000 | 25,000 | 6,800 |
| | 2004 | 0.021 | 0.03 | 0.09 | 31 | 110,000 | 33,000 | 6,200 |
| | 2003 | * | 0.04 | 0.05 | 28 | 200,000 | 25,000 | * |
| | 2002 | 0.021 | 0.05 | 0.06 | 29 | 170,000 | 20,000 | 6,200 |
| El Cajon-Floyd Smith Drive | 2016 | * | 0.015 | 0.06 | 16 | 170,000 | 67,000 | * |
| | 2015 | * | 0.015 | 0.08 | 32 | 130,000 | 67,000 | * |
| | 2014 | * | * | 0.015 | 6 | 670,000 | * | * |
| El Cajon-Redwood Avenue | 2013 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2012 | 0.021 | 0.05 | 0.07 | 30 | 140,000 | 20,000 | 6,200 |
| | 2011 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2010 | 0.016 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 8,100 |
| | 2009 | 0.015 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,700 |
| | 2008 | 0.016 | 0.015 | 0.03 | 30 | 330,000 | 67,000 | 8,100 |
| | 2007 | 0.016 | 0.015 | 0.04 | 28 | 250,000 | 67,000 | 8,100 |
| | 2006 | 0.018 | 0.015 | 0.05 | 32 | 200,000 | 67,000 | 7,200 |
| | 2005 | 0.016 | 0.015 | 0.03 | 28 | 330,000 | 67,000 | 8,100 |
| | 2004 | 0.02 | 0.04 | 0.09 | 30 | 110,000 | 25,000 | 6,500 |
| | 2003 | 0.021 | 0.04 | 0.05 | 30 | 200,000 | 25,000 | 6,200 |
| | 2002 | 0.02 | 0.04 | 0.06 | 28 | 170,000 | 25,000 | 6,500 |
| Los Angeles – North Main Street | 2017 | 0.015 | 0.015 | 0.015 | 29 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.016 | 0.015 | 0.06 | 30 | 170,000 | 67,000 | 8,100 |
| | 2015 | 0.018 | 0.015 | 0.04 | 26 | 250,000 | 67,000 | 7,200 |
| | 2014 | * | 0.015 | 0.05 | 23 | 200,000 | 67,000 | * |
| | 2013 | 0.016 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,100 |
| | 2012 | 0.018 | 0.04 | 0.06 | 29 | 170,000 | 25,000 | 7,200 |
| | 2011 | 0.016 | 0.015 | 0.04 | 31 | 250,000 | 67,000 | 8,100 |
| | 2010 | 0.018 | 0.015 | 0.06 | 29 | 170,000 | 67,000 | 7,200 |
| | 2009 | 0.017 | 0.015 | 0.04 | 29 | 250,000 | 67,000 | 7,600 |
| | 2008 | 0.021 | 0.04 | 0.08 | 29 | 130,000 | 25,000 | 6,200 |
| | 2007 | 0.018 | 0.015 | 0.05 | 23 | 200,000 | 67,000 | 7,200 |
| | 2006 | * | 0.04 | 0.07 | 25 | 140,000 | 25,000 | * |
| | 2005 | 0.029 | 0.05 | 0.15 | 30 | 67,000 | 20,000 | 4,500 |
| | 2004 | 0.023 | 0.05 | 0.07 | 24 | 140,000 | 20,000 | 5,700 |
| | 2003 | 0.032 | 0.06 | 0.1 | 29 | 100,000 | 17,000 | 4,100 |
| | 2002 | * | 0.07 | 0.14 | 21 | 71,000 | 14,000 | * |
| | 2013 | * | 0.015 | 0.05 | 22 | 200,000 | 67,000 | * |

**Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2].**

| Site | Year | Mean | 90th Percentile | Max | # of Observations | Acute MOE (LOC = 30)[3] | Short- and Intermediate-Term MOE (LOC = 30)[4] | Long-Term MOE (LOC = 100)[5] |
|---|---|---|---|---|---|---|---|---|
| North Long Beach | 2012 | 0.023 | 0.04 | 0.07 | 29 | 140,000 | 25,000 | 5,700 |
| | 2011 | 0.02 | 0.03 | 0.06 | 30 | 170,000 | 33,000 | 6,500 |
| | 2010 | 0.03 | 0.04 | 0.18 | 26 | 56,000 | 25,000 | 4,300 |
| | 2009 | 0.023 | 0.04 | 0.15 | 30 | 67,000 | 25,000 | 5,700 |
| | 2008 | 0.021 | 0.04 | 0.06 | 30 | 170,000 | 25,000 | 6,200 |
| | 2007 | 0.017 | 0.015 | 0.05 | 29 | 200,000 | 67,000 | 7,600 |
| | 2006 | 0.028 | 0.06 | 0.08 | 30 | 130,000 | 17,000 | 4,600 |
| | 2005 | * | 0.07 | 0.12 | 26 | 83,000 | 14,000 | * |
| | 2004 | 0.034 | 0.07 | 0.09 | 31 | 110,000 | 14,000 | 3,800 |
| | 2003 | 0.035 | 0.09 | 0.13 | 27 | 77,000 | 11,000 | 3,700 |
| | 2002 | 0.035 | 0.07 | 0.11 | 25 | 91,000 | 14,000 | 3,700 |
| Riverside-Rubidoux | 2017 | 0.015 | 0.015 | 0.015 | 27 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.017 | 0.015 | 0.07 | 30 | 140,000 | 67,000 | 7,600 |
| | 2015 | * | 0.015 | 0.04 | 25 | 250,000 | 67,000 | * |
| | 2014 | 0.019 | 0.04 | 0.05 | 28 | 200,000 | 25,000 | 6,800 |
| | 2013 | 0.016 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,100 |
| | 2012 | 0.02 | 0.04 | 0.06 | 30 | 170,000 | 25,000 | 6,500 |
| | 2011 | 0.016 | 0.015 | 0.05 | 31 | 200,000 | 67,000 | 8,100 |
| | 2010 | 0.016 | 0.015 | 0.04 | 31 | 250,000 | 67,000 | 8,100 |
| | 2009 | * | 0.015 | 0.04 | 27 | 250,000 | 67,000 | * |
| | 2008 | 0.016 | 0.015 | 0.03 | 30 | 330,000 | 67,000 | 8,100 |
| | 2007 | 0.017 | 0.03 | 0.05 | 30 | 200,000 | 33,000 | 7,600 |
| | 2006 | 0.022 | 0.05 | 0.06 | 29 | 170,000 | 20,000 | 5,900 |
| | 2005 | 0.02 | 0.04 | 0.06 | 31 | 170,000 | 25,000 | 6,500 |
| | 2004 | 0.023 | 0.06 | 0.09 | 30 | 110,000 | 17,000 | 5,700 |
| | 2003 | 0.028 | 0.06 | 0.1 | 30 | 100,000 | 17,000 | 4,600 |
| | 2002 | * | 0.05 | 0.13 | 25 | 77,000 | 20,000 | * |
| Simi Valley-Cochran Street | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.02 | 0.015 | 0.06 | 30 | 170,000 | 67,000 | 6,500 |
| | 2015 | 0.024 | 0.04 | 0.17 | 28 | 59,000 | 25,000 | 5,400 |
| | 2014 | 0.018 | 0.015 | 0.05 | 27 | 200,000 | 67,000 | 7,200 |
| | 2013 | * | 0.015 | 0.04 | 26 | 250,000 | 67,000 | * |
| | 2012 | * | 0.07 | 0.18 | 20 | 56,000 | 14,000 | * |
| | 2011 | 0.056 | 0.14 | 0.54 | 31 | 19,000 | 7,100 | 2,300 |
| | 2010 | 0.039 | 0.07 | 0.3 | 30 | 33,000 | 14,000 | 3,300 |
| | 2009 | 0.039 | 0.08 | 0.34 | 31 | 29,000 | 13,000 | 3,300 |
| | 2008 | 0.051 | 0.15 | 0.33 | 32 | 30,000 | 6,700 | 2,500 |
| | 2007 | 0.058 | 0.2 | 0.41 | 31 | 24,000 | 5,000 | 2,200 |
| | 2006 | 0.073 | 0.17 | 0.26 | 31 | 38,000 | 5,900 | 1,800 |
| | 2005 | 0.075 | 0.2 | 0.57 | 30 | 18,000 | 5,000 | 1,700 |
| | 2004 | 0.062 | 0.13 | 0.54 | 31 | 19,000 | 7,700 | 2,100 |
| | 2003 | 0.12 | 0.53 | 0.9 | 31 | 11,000 | 1,900 | 1,100 |
| | 2002 | 0.101 | 0.33 | 0.91 | 26 | 11,000 | 3,000 | 1,300 |
| Bakersfield | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.038 | 0.015 | 0.46 | 30 | 22,000 | 67,000 | 3,400 |
| | 2015 | 0.021 | 0.03 | 0.08 | 30 | 130,000 | 33,000 | 6,200 |

| Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2]. | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Site** | **Year** | **Mean** | **90th Percentile** | **Max** | **# of Observations** | **Acute MOE (LOC = 30)[3]** | **Short- and Intermediate-Term MOE (LOC = 30)[4]** | **Long-Term MOE (LOC = 100)[5]** |
| | 2014 | * | 0.015 | 0.015 | 16 | 670,000 | 67,000 | * |
| | 2013 | * | 0.015 | 0.03 | 23 | 330,000 | 67,000 | * |
| | 2012 | 0.023 | 0.05 | 0.06 | 33 | 170,000 | 20,000 | 5,700 |
| | 2011 | 0.038 | 0.08 | 0.3 | 32 | 33,000 | 13,000 | 3,400 |
| | 2010 | 0.026 | 0.05 | 0.14 | 30 | 71,000 | 20,000 | 5,000 |
| | 2009 | 0.046 | 0.12 | 0.33 | 34 | 30,000 | 8,300 | 2,800 |
| | 2008 | 0.029 | 0.05 | 0.11 | 33 | 91,000 | 20,000 | 4,500 |
| | 2007 | 0.036 | 0.06 | 0.28 | 32 | 36,000 | 17,000 | 3,600 |
| | 2006 | 0.073 | 0.17 | 0.34 | 30 | 29,000 | 5,900 | 1,800 |
| | 2005 | 0.059 | 0.14 | 0.25 | 31 | 40,000 | 7,100 | 2,200 |
| | 2004 | * | 0.17 | 0.38 | 25 | 26,000 | 5,900 | * |
| | 2003 | 0.08 | 0.18 | 0.88 | 29 | 11,000 | 5,600 | 1,600 |
| | 2002 | 0.058 | 0.12 | 0.22 | 29 | 45,000 | 8,300 | 2,200 |
| Chico-East Avenue | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.017 | 0.015 | 0.04 | 29 | 250,000 | 67,000 | 7,600 |
| | 2015 | 0.019 | 0.03 | 0.08 | 30 | 130,000 | 33,000 | 6,800 |
| | 2014 | 0.02 | 0.03 | 0.08 | 29 | 130,000 | 33,000 | 6,500 |
| | 2013 | 0.026 | 0.03 | 0.21 | 31 | 48,000 | 33,000 | 5,000 |
| | 2012 | * | 0.04 | 0.05 | 18 | 200,000 | 25,000 | * |
| Chico-Manzanita Avenue | 2012 | * | 0.04 | 0.04 | 12 | 250,000 | 25,000 | * |
| | 2011 | 0.015 | 0.015 | 0.03 | 29 | 330,000 | 67,000 | 8,700 |
| | 2010 | 0.018 | 0.015 | 0.05 | 30 | 200,000 | 67,000 | 7,200 |
| | 2009 | 0.024 | 0.06 | 0.11 | 31 | 91,000 | 17,000 | 5,400 |
| | 2008 | 0.027 | 0.04 | 0.28 | 31 | 36,000 | 25,000 | 4,800 |
| | 2007 | 0.043 | 0.03 | 0.59 | 29 | 17,000 | 33,000 | 3,000 |
| | 2006 | 0.02 | 0.04 | 0.05 | 30 | 200,000 | 25,000 | 6,500 |
| | 2005 | 0.044 | 0.06 | 0.51 | 31 | 20,000 | 17,000 | 3,000 |
| | 2004 | 0.022 | 0.04 | 0.08 | 30 | 130,000 | 25,000 | 5,900 |
| | 2003 | 0.022 | 0.03 | 0.15 | 31 | 67,000 | 33,000 | 5,900 |
| | 2002 | 0.026 | 0.04 | 0.14 | 29 | 71,000 | 25,000 | 5,000 |
| Freemont-Chapel Way | 2010 | * | 0.015 | 0.015 | 17 | 670,000 | 67,000 | * |
| | 2009 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2008 | 0.018 | 0.015 | 0.05 | 31 | 200,000 | 67,000 | 7,200 |
| | 2007 | 0.016 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 8,100 |
| | 2006 | 0.018 | 0.015 | 0.05 | 29 | 200,000 | 67,000 | 7,200 |
| | 2005 | * | 0.015 | 0.04 | 28 | 250,000 | 67,000 | * |
| | 2004 | 0.02 | 0.03 | 0.08 | 30 | 130,000 | 33,000 | 6,500 |
| | 2003 | 0.019 | 0.015 | 0.11 | 30 | 91,000 | 67,000 | 6,800 |
| | 2002 | 0.018 | 0.015 | 0.05 | 27 | 200,000 | 67,000 | 7,200 |
| Fresno-1st Street | 2012 | * | * | 0.015 | 1 | 670,000 | * | * |
| | 2011 | 0.022 | 0.05 | 0.08 | 30 | 130,000 | 20,000 | 5,900 |
| | 2010 | 0.026 | 0.05 | 0.13 | 30 | 77,000 | 20,000 | 5,000 |
| | 2009 | 0.027 | 0.05 | 0.08 | 32 | 130,000 | 20,000 | 4,800 |
| | 2008 | 0.026 | 0.05 | 0.08 | 31 | 130,000 | 20,000 | 5,000 |
| | 2007 | 0.032 | 0.06 | 0.1 | 29 | 100,000 | 17,000 | 4,100 |
| | 2006 | 0.042 | 0.07 | 0.11 | 31 | 91,000 | 14,000 | 3,100 |

**Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2].**

| Site | Year | Mean | 90th Percentile | Max | # of Observations | Acute MOE (LOC = 30)[3] | Short- and Intermediate-Term MOE (LOC = 30)[4] | Long-Term MOE (LOC = 100)[5] |
|---|---|---|---|---|---|---|---|---|
| | 2005 | 0.044 | 0.09 | 0.18 | 34 | 56,000 | 11,000 | 3,000 |
| | 2004 | 0.051 | 0.1 | 0.14 | 30 | 71,000 | 10,000 | 2,500 |
| | 2003 | 0.055 | 0.11 | 0.19 | 31 | 53,000 | 9,100 | 2,400 |
| | 2002 | 0.049 | 0.12 | 0.19 | 30 | 53,000 | 8,300 | 2,700 |
| Fresno-Garland | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.024 | 0.05 | 0.07 | 31 | 140,000 | 20,000 | 5,400 |
| | 2015 | 0.019 | 0.04 | 0.07 | 30 | 140,000 | 25,000 | 6,800 |
| | 2014 | 0.031 | 0.05 | 0.15 | 29 | 67,000 | 20,000 | 4,200 |
| | 2013 | 0.023 | 0.03 | 0.09 | 31 | 110,000 | 33,000 | 5,700 |
| | 2012 | 0.024 | 0.05 | 0.07 | 29 | 140,000 | 20,000 | 5,400 |
| Roseville-N Sunrise Blvd | 2017 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.017 | 0.015 | 0.05 | 30 | 200,000 | 67,000 | 7,600 |
| | 2015 | 0.016 | 0.015 | 0.05 | 30 | 200,000 | 67,000 | 8,100 |
| | 2014 | 0.017 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 7,600 |
| | 2013 | 0.02 | 0.015 | 0.16 | 31 | 63,000 | 67,000 | 6,500 |
| | 2012 | 0.018 | 0.03 | 0.04 | 30 | 250,000 | 33,000 | 7,200 |
| | 2011 | 0.016 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,100 |
| | 2010 | 0.021 | 0.015 | 0.14 | 29 | 71,000 | 67,000 | 6,200 |
| | 2009 | 0.017 | 0.015 | 0.04 | 31 | 250,000 | 67,000 | 7,600 |
| | 2008 | 0.017 | 0.03 | 0.04 | 31 | 250,000 | 33,000 | 7,600 |
| | 2007 | 0.017 | 0.015 | 0.05 | 30 | 200,000 | 67,000 | 7,600 |
| | 2006 | 0.016 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 8,100 |
| | 2005 | 0.016 | 0.015 | 0.05 | 31 | 200,000 | 67,000 | 8,100 |
| | 2004 | 0.018 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 7,200 |
| | 2003 | 0.016 | 0.015 | 0.03 | 31 | 330,000 | 67,000 | 8,100 |
| | 2002 | 0.021 | 0.04 | 0.11 | 29 | 91,000 | 25,000 | 6,200 |
| San Francisco-Arkansas St | 2017 | 0.015 | 0.015 | 0.015 | 29 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.017 | 0.015 | 0.08 | 30 | 130,000 | 67,000 | 7,600 |
| | 2015 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2014 | 0.017 | 0.015 | 0.04 | 30 | 250,000 | 67,000 | 7,600 |
| | 2013 | 0.016 | 0.015 | 0.05 | 31 | 200,000 | 67,000 | 8,100 |
| | 2012 | 0.019 | 0.03 | 0.06 | 29 | 170,000 | 33,000 | 6,800 |
| | 2011 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2010 | 0.016 | 0.015 | 0.04 | 29 | 250,000 | 67,000 | 8,100 |
| | 2009 | 0.015 | 0.015 | 0.015 | 28 | 670,000 | 67,000 | 8,700 |
| | 2008 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2007 | 0.015 | 0.015 | 0.015 | 29 | 670,000 | 67,000 | 8,700 |
| | 2006 | 0.018 | 0.015 | 0.05 | 30 | 200,000 | 67,000 | 7,200 |
| | 2005 | 0.017 | 0.015 | 0.07 | 31 | 140,000 | 67,000 | 7,600 |
| | 2004 | 0.015 | 0.015 | 0.03 | 30 | 330,000 | 67,000 | 8,700 |
| | 2003 | 0.015 | 0.015 | 0.015 | 31 | 670,000 | 67,000 | 8,700 |
| | 2002 | * | 0.03 | 0.08 | 15 | 130,000 | 33,000 | * |
| San Jose-4th St | 2002 | * | * | 0.09 | 8 | 110,000 | * | * |
| San Jose-Jackson St | 2017 | 0.015 | 0.015 | 0.015 | 28 | 670,000 | 67,000 | 8,700 |
| | 2016 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |
| | 2015 | 0.015 | 0.015 | 0.015 | 30 | 670,000 | 67,000 | 8,700 |

| Table 9.2.2.1. Results of Urban Ambient Monitoring for Methyl Bromide using California Department of Pesticide Regulation (DPR) Toxic Air Contaminant (TAC) Program[1,2]. | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Site** | **Year** | **Mean** | **90th Percentile** | **Max** | **# of Observations** | **Acute MOE (LOC = 30)[3]** | **Short- and Intermediate-Term MOE (LOC = 30)[4]** | **Long-Term MOE (LOC = 100)[5]** |
| | 2014 | * | 0.03 | 0.05 | 27 | 200,000 | 33,000 | * |
| | 2013 | 0.016 | 0.015 | 0.04 | 31 | 250,000 | 67,000 | 8,100 |
| | 2012 | 0.02 | 0.04 | 0.06 | 29 | 170,000 | 25,000 | 6,500 |
| | 2011 | 0.02 | 0.015 | 0.08 | 32 | 130,000 | 67,000 | 6,500 |
| | 2010 | 0.019 | 0.015 | 0.07 | 30 | 140,000 | 67,000 | 6,800 |
| | 2009 | 0.02 | 0.03 | 0.09 | 31 | 110,000 | 33,000 | 6,500 |
| | 2008 | 0.02 | 0.04 | 0.07 | 31 | 140,000 | 25,000 | 6,500 |
| | 2007 | 0.027 | 0.05 | 0.18 | 30 | 56,000 | 20,000 | 4,800 |
| | 2006 | 0.025 | 0.05 | 0.1 | 30 | 100,000 | 20,000 | 5,200 |
| | 2005 | 0.03 | 0.05 | 0.34 | 31 | 29,000 | 20,000 | 4,300 |
| | 2004 | 0.023 | 0.05 | 0.12 | 30 | 83,000 | 20,000 | 5,700 |
| | 2003 | 0.031 | 0.05 | 0.23 | 31 | 43,000 | 20,000 | 4,200 |
| | 2002 | * | * | 0.05 | 6 | 200,000 | * | * |
| Stockton-Hazelton St | 2017 | 0.019 | 0.015 | 0.07 | 28 | 140,000 | 67,000 | 6,800 |
| | 2016 | 0.019 | 0.015 | 0.11 | 29 | 91,000 | 67,000 | 6,800 |
| | 2015 | 0.024 | 0.06 | 0.07 | 30 | 140,000 | 17,000 | 5,400 |
| | 2014 | 0.035 | 0.06 | 0.23 | 31 | 43,000 | 17,000 | 3,700 |
| | 2013 | 0.021 | 0.03 | 0.1 | 30 | 100,000 | 33,000 | 6,200 |
| | 2012 | 0.022 | 0.05 | 0.07 | 30 | 140,000 | 20,000 | 5,900 |
| | 2011 | 0.045 | 0.14 | 0.18 | 29 | 56,000 | 7,100 | 2,900 |
| | 2010 | 0.031 | 0.08 | 0.11 | 30 | 91,000 | 13,000 | 4,200 |
| | 2009 | 0.068 | 0.16 | 0.41 | 31 | 24,000 | 6,300 | 1,900 |
| | 2008 | 0.078 | 0.18 | 0.61 | 31 | 16,000 | 5,600 | 1,700 |
| | 2007 | 0.182 | 0.53 | 1.6 | 30 | 6,300 | 1,900 | 710 |
| | 2006 | 0.183 | 0.46 | 1.4 | 30 | 7,100 | 2,200 | 710 |
| | 2005 | 0.134 | 0.39 | 0.69 | 31 | 14,000 | 2,600 | 970 |
| | 2004 | 0.131 | 0.24 | 1.1 | 30 | 9,100 | 4,200 | 990 |
| | 2003 | 0.088 | 0.29 | 0.48 | 30 | 21,000 | 3,400 | 1,500 |
| | 2002 | 0.144 | 0.41 | 0.9 | 27 | 11,000 | 2,400 | 900 |

1. Air concentrations available at https://www.arb.ca.gov/adam/toxics/sitelists/mbrsites.html.
2. Values below the LOD are assumed to be ½ the LOD 0.03 ppb).
3. Acute MOE = Acute ambient (24-hour exposure) HEC for the inhalation POD (10,000 ppb)/maximum concentration (ppb). LOC = 30.
4. Short- and Intermediate-Term MOE = Short- and Intermediate-term ambient HEC for the inhalation POD (1,000 ppb)/mean concentration (ppb). LOC = 30.
5. Long-Term MOE = Long-term ambient HEC for the inhalation POD (130 ppb)/median concentration (ppb). LOC = 100.
6. "*" indicates insufficient data or no data to determine the value.

### 9.2.3 Ambient Air Inhalation Exposure Assessment Using California DPR Air Monitoring Network (AMN) Program Data

In February 2011, DPR implemented a multi-year statewide air monitoring program, the AMN, to measure pesticides in various agricultural communities. The AMN originally provided monitoring for three communities, but with the passing of the Budget Act of 2016, it was expanded to include a total of eight sites for a two-year period. Four sites were operational in 2017, while the other four were added to the AMN in 2018. The four operational AMN

monitoring sites were in the communities of Shafter (Kern County), Santa Maria (Santa Barbara County), Watsonville (Monterey County), and Chualar (Monterey County). At each sampling site location, one 24-hour (h) air sample set was collected on a weekly basis. Monitoring data on methyl bromide are available for 2011 – 2017[25].

For the ambient bystander exposure assessment using the available AMN data, HED evaluated different durations of exposure including single day (acute) exposures, short- and intermediate-term exposures, and long-term exposures. Risks from acute exposures were calculated using the highest 24-hour air concentrations for each location and the acute ambient (24-hour exposure) HEC for the inhalation POD (10,000 ppb). Risks from short- and intermediate-term exposures were calculated using the highest 4-week rolling average concentration for each location and the short-term ambient HEC for the inhalation POD (1,000 ppb). Risks from long-term exposures were calculated using the 1-year average air concentration for each location and the long-term ambient HEC for the inhalation POD (130 ppb).

The available ambient air concentrations did not result in risk estimates of concern for acute, short- or intermediate-term, or long-term exposures. The acute ambient MOEs range from 6,400 to 340,000 (LOC = 30) (Table 9.2.3.1). The short- and intermediate-term ambient MOEs range from 940 to 48,000 (LOC = 30) (Table 9.2.3.2). The long-term ambient MOEs range from 490 to 19,000 (LOC = 100) (Table 9.2.3.3).

[25] https://www.cdpr.ca.gov/docs/emon/airinit/air_network_results.htm. 2017 report is draft.

| Table 9.2.3.1. Acute (Single Day) Ambient Inhalation Exposure and Risk Assessment for Methyl Bromide using California Air Monitoring Network (AMN) Data. | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Site** | **Highest 24-Hour Concentration (ppb)[1,2]** | | | | | | | **Acute MOE (LOC = 30)[3]** | | | | | | |
| | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** |
| Shafter | 0.76 | 0.55 | 0.054 | 0.25 | 0.073 | 0.029 | ND | 13,000 | 18,000 | 190,000 | 40,000 | 140,000 | 340,000 | N/A |
| Salinas | 1.56 | 0.65 | 1.14 | 0.79 | 0.046 | 0.11 | - | 6,400 | 15,000 | 8,800 | 13,000 | 220,000 | 89,000 | - |
| Ripon | 0.76 | 0.69 | 0.30 | 0.60 | 0.768 | 0.30 | - | 13,000 | 5,000 | 34,000 | 7,000 | 13,000 | 33,000 | - |
| Santa Maria | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Watsonville | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Chualar | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| **All Sites** | 1.56 | 0.69 | 1.14 | 0.79 | 0.77 | 0.30 | ND | 6,400 | 15,000 | 8,800 | 13,000 | 13,000 | 33,000 | N/A |

1. Air concentrations available at https://www.cdpr.ca.gov/docs/emon/airinit/air_network_results.htm. Concentrations were converted from mg/m$^3$ to ppb using the following: [((air concentration in mg/m$^3$ ÷ 10,000,00) × 24.45 conversion factor) ÷ 94.94 (molecular weight of methyl bromide)] × 1000. https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.files/fileID/14285
2. Not all sites were sampled from 2011 – 2017.
3. Acute MOE = Acute ambient (24-hour exposure) HEC for the inhalation POD (10,000 ppb)/highest 24-hour concentration (ppb). LOC = 30.
4. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted.

| Table 9.2.3.2. Short- and Intermediate-Term Ambient Inhalation Exposure Assessment for Methyl Bromide using California Air Monitoring Network (AMN) Data. | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Site** | **Highest 4-Week Rolling Concentration (ppb)[1,2]** | | | | | | | **Short- and Intermediate-Term MOE (LOC = 30)[3]** | | | | | | |
| | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** |
| Shafter | 0.36 | 0.18 | 0.051 | 0.10 | 0.048 | 0.021 | ND | 2,800 | 5,700 | 20,000 | 10,000 | 21,000 | 48,000 | N/A |
| Salinas | 1.06 | 0.28 | 0.48 | 0.32 | 0.031 | 0.066 | - | 940 | 3,500 | 21,000 | 3,100 | 32,000 | 15,000 | - |
| Ripon | 0.43 | 0.29 | 0.11 | 0.22 | 0.42 | 0.15 | - | 2,300 | 3,500 | 8,900 | 4,500 | 2,400 | 6,500 | - |
| Santa Maria | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Watsonville | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Chualar | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| **All Sites** | 1.06 | 0.29 | 0.11 | 0.22 | 0.42 | 0.15 | ND | 940 | 3,500 | 2,100 | 3,100 | 2,400 | 6,500 | N/A |

1. Air concentrations available at https://www.cdpr.ca.gov/docs/emon/airinit/air_network_results.htm. Concentrations were converted from mg/m$^3$ to ppb using the following: [((air concentration in mg/m$^3$ ÷ 10,000,00) × 24.45 conversion factor) ÷ 94.94 (molecular weight of methyl bromide)] × 1000. https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.files/fileID/14285
2. Not all sites were sampled from 2011 – 2017.
3. Short- and Intermediate-Term MOE = Short- and intermediate-term ambient HEC for the inhalation POD (1,000 ppb)/highest 4-week rolling average concentration (ppb). LOC = 30.
4. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted

| Table 9.2.3.3. Long-Term Ambient Inhalation Exposure and Risk Assessment for Methyl Bromide using California Air Monitoring Network (AMN) Data. | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Site** | **1-Year Average Concentration (ppb)[1,2]** | | | | | | | **Long-Term MOE (LOC = 100)[3]** | | | | | | |
| | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017[4]** |
| Shafter | 0.11 | 0.064 | 0.042 | 0.018 | 0.0103 | 0.0067 | ND | 1,200 | 2,000 | 3,100 | 7,200 | 13,000 | 19,000 | N/A |
| Salinas | 0.26 | 0.091 | 0.077 | 0.048 | 0.0091 | 0.0105 | - | 490 | 1,400 | 1,700 | 2,700 | 14,000 | 12,000 | - |
| Ripon | 0.17 | 0.081 | 0.050 | 0.044 | 0.044 | 0.021 | - | 770 | 1,600 | 2,600 | 2,900 | 3,000 | 6,300 | - |
| Santa Maria | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Watsonville | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| Chualar | - | - | - | - | - | - | ND | - | - | - | - | - | - | N/A |
| **All Sites** | 0.18 | 0.079 | 0.056 | 0.037 | 0.021 | 0.013 | ND | 730 | 1,700 | 2,300 | 3,500 | 6,200 | 10,000 | N/A |

1. Air concentrations available at https://www.cdpr.ca.gov/docs/emon/airinit/air_network_results.htm. Concentrations were converted from mg/m$^3$ to ppb using the following: [((air concentration in mg/m$^3$ ÷ 10,000,00) × 24.45 conversion factor) ÷ 94.94 (molecular weight of methyl bromide)] × 1000. https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.files/fileID/14285
2. Not all sites were sampled from 2011 – 2017.
3. Long-Term MOE = Long-term ambient HEC for the inhalation POD (130 ppb)/1-year average concentration (ppb). LOC = 100.
4. All samples in 2017 were reported as "ND"; therefore, a quantitative assessment has not been conducted.

### 9.3 EPA 2018 National Air Toxics Assessment (NATA)[26]

In August 2018, EPA released the most recent update to the National Air Toxics Assessment (NATA). NATA is EPA's ongoing review of air toxics in the United States, and was developed as a screening tool for state, local, and tribal air agencies. NATA's results help these agencies identify which pollutants, emissions sources, and places they may wish to study further to better understand any possible risks to public health from air toxics. These data aren't intended to provide precise exposures and risks for a specific person, and are best applied to larger areas (counties, states, and the nation as a whole).

The most recent NATA[27] uses emissions data from 2014 to estimate health risks from toxic air pollutants. In an air toxics risk assessment, the potential for non-cancer effects in humans is typically quantified by calculating a ratio of the inhalation exposure concentration to the toxicity reference concentration (RfC); the methyl bromide chronic RfC used in the NATA assessment was 0.005 mg/m$^3$ (equivalent to 0.13 ppm used by OPP for long-term risk assessment[28]). This ratio is referred to as the hazard quotient (HQ). For a given air toxicant, HQs of 1 or less are not likely to be associated with adverse health effects. Using the data collected for all sites, the respiratory hazard quotients (HQs) (the route of concern for methyl bromide) for methyl bromide are all < 0.46 (equivalent to a MOE of approximately 220 with a LOC of 100)[29] and are not of concern.

## 10.0 Non-Occupational Bystander Exposure and Risk Estimates

There are no residential uses of methyl bromide, but bystanders who live or work near fields where soil fumigation occurs or sites where commodity fumigation occurs may potentially be exposed to fumigant emissions that travel off-site. When considering the potential risks to bystanders from single applications from known sources (e.g., a farm field or a fumigated structure/commodity), HED previously used distributional modeling[30] to calculate distances at which target concentrations are achieved at varied percentiles of exposure. The distances determined based on a target concentration defined by the inhalation HEC adjusted by an uncertainty factor may be used as a basis for determining "buffer zones" to establish for reducing potential risk.

For site-specific bystander assessments, the Agency considered only acute methyl bromide inhalation exposures because peak air concentrations typically occur in the first 24 to 48 hours after application and dissipate quickly. As they represent peak air concentrations for someone working or living near a field or building following a single fumigation treatment, the air concentrations estimated from the fumigant air models are most appropriately compared with acute toxicological endpoints. Due to infrequency of soil fumigation applications and rapid air dissipation, these modeled concentrations are not expected to persist for multiple days and would

[26] https://www.epa.gov/national-air-toxics-assessment
[27] https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results#about
[28] Long-term Bystander HEC = 0.13 ppm = 0.5 mg/m$^3$ = 0.005 mg/m$^3$ RfC (HEC ÷ 100 UF)
[29] HQ = Exposure ÷ (POD÷UF). MOE = NOAEL ÷ Exposure.
[30] *Probabilistic Exposure and Risk Model For Fumigants* (PERFUM)

be inappropriate to compare with longer-term toxicity profiles. For commodity bystanders, although there may be multiple applications made per week, the dissipation is expected to be quicker than that for field applications because of ventilation/aeration requirements, resulting in a higher peak air concentration. EPA believes that any persistent exposure over many days to concentrations in air via fumigant applications are better represented by ambient/background air concentrations which were appropriately compared with longer-term toxicity profiles covered in Section 8 and once the required (GDCI-053201-836) data from the Delaware Maritime Exchange Region (a high use methyl bromide commodity fumigation region) are submitted, an updated ambient air exposure and risk assessment will be conducted. These required data will be representative of ambient air concentrations corresponding to commodity fumigations in a high-use area.

*Soil Uses*

There are three human health risk assessments that evaluated acute residential bystander inhalation exposure to methyl bromide for agricultural field (soil) applications: D337288 (J. Dawson, 04/10/2007); D350818 (J. Dawson, 06/02/2008); and D375752 (J. Dawson, 01/06/2011). These assessments were based on numerous field volatility studies and Probabilistic Exposure and Risk model for Fumigants (PERFUM) air modeling.

In the human health risk assessments listed above, PERFUM results (i.e., buffer zone distances) were presented based on a range of inputs for each modeled parameter, including: historical weather data, field sizes, application rates and percentile of exposure for risk management purposes. A complete review of the modeling inputs is available in the Phase 5 risk assessment (J. Dawson, D337288, 04/10/2007) and its associated addendum (J. Dawson, D350818, 06/02/2008).

The results of the previous assessments show that bystander inhalation exposure to methyl bromide after a soil fumigation application can vary depending on a variety of factors such as application method, agricultural tarps, water seals, and soil parameters like moisture and organic content. For many application scenarios, the PERFUM air modeling results showed that concentrations protective of residential bystanders were not achieved at the edge of the field.

In 2011, HED reviewed data from the MBIP to evaluate soil emission reduction potential of various application techniques and sealing methods (J. Dawson, D375752, 01/06/2011). The assessment used PERFUM buffer outputs in a similar manner to the previous assessments evaluating pre-plant soil treatments, and the results of the assessment indicated that overall emissions were reduced when the control measures (e.g., Totally Impermeable Film (TIF) films) were used compared to current common agricultural practices.

The maximum currently registered application rate for the soil (quarantine) uses of methyl bromide is 400 lbs ai/A. An application rate of 430 lb ai/A was used in the previous residential bystander exposure PERFUM modeling analyses. The application parameters and control measures used in the previous assessments are still representative of the currently registered uses of methyl bromide. Therefore, the previous analyses are representative of the currently registered use pattern of methyl bromide.

*Non-Soil/Commodity Uses*

There are five human health risk assessments that evaluated acute residential bystander inhalation exposure from the commodity applications of methyl bromide: D304623 (J. Dawson, 03/10/2006); D304619 (J. Dawson, 07/12/2006); D304632 (J. Dawson, 08/30/2007); D304612 (J. Dawson, 11/26/2008); and D362979 (J. Dawson, 04/03/2009).

In commodity fumigation, a fumigant gas is introduced and held in the building/chamber for a prescribed amount of time, in order to penetrate any packaging and containers that might harbor a pest. After treatment, the building/chamber is aerated, normally using fans, to release the fumigant into the atmosphere. Stacks can also be employed to increase the point of release of the fumigant.

In the human health risk assessments listed above, PERFUM results (i.e., distances to reach the LOC) were presented based on a range of inputs for each modeled parameter, including: historical weather data, stack diameters, treatment frequencies, emission profiles, and chamber/structure volumes and heights. A complete review of the modeling inputs is available in the risk assessments noted above.

The results of the previous assessments show that bystander inhalation exposure to methyl bromide after a commodity fumigation application can vary depending on a variety of factors such as treatment volumes, application rates, and the weather data used. For many application scenarios, the PERFUM air modeling results showed that concentrations protective of residential bystanders were not achieved at the edge of the field.

The currently registered maximum application rates for the commodity uses of methyl bromide range from 1 to 15 lb ai/1000 $ft^3$ with commodity exposure (treatment) times ranging from 2 to 72 hours, depending on the commodity. The bystander analyses completed in the risk assessments noted above were extensive and evaluated application rates ranging from 1 to 15 lb ai/1000 $ft^3$. The application parameters and control measures used in the previous assessments are still representative of the currently registered uses of methyl bromide. Therefore, the previous analyses are representative of the currently registered use pattern of methyl bromide.

*Conclusions*

As noted above, in previous human health risk assessments for methyl bromide, bystander risks of concern were identified from the soil and commodity uses of methyl bromide. As a result, OPP implemented a series of label changes and mitigation measures (administrative controls like buffer zones and rate reductions) that addressed bystander exposure concerns. For methyl bromide, because the toxicity PODs and uncertainty factors have not changed since the previous assessment, and no new uses have been added, the previous bystander risk estimates, buffer zone estimates, and current labels/mitigation remain relevant for methyl bromide.

## 11.0 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 methyl bromide and any other substances and methyl bromide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that methyl bromide has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs 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)[31] and conducting cumulative risk assessments (CRA)[32]. During Registration Review, the agency will utilize this framework to determine if the available toxicological data for methyl bromide suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

## 12.0 Occupational Exposure/Risk Characterization

### 12.1 Acute and Short-/Intermediate-Term Occupational Handler Exposure and Risk Estimates

There is potential for occupational handler inhalation exposure from both the soil and non-soil/commodity uses of methyl bromide. Dermal exposures are not expected given the high vapor pressure of methyl bromide, and based on the delivery systems, packaging (i.e., pressurized cylinders), and emission reduction techniques (e.g., commodity aeration and tarping) used. Therefore, dermal exposures have not been quantitatively assessed.

Because methyl bromide is classified as a Restricted Use Pesticide, it may only be applied under the direct supervision of a trained, certified applicator. Occupational acute, short-, and intermediate-term inhalation exposures are expected from the registered uses of methyl bromide; long-term exposures, or continuous exposures for more than 6 months per year, are not expected based on the seasonal nature of methyl bromide use.

*Soil Uses*

For the soil uses of methyl bromide, occupational handlers may be exposed while handling the pesticide prior to application, as well as during application. For soil fumigation, the activities considered under "occupational handlers" include: first tractor driver, co-pilot, second tractor driver, shovelman, irrigation worker, tarp cutter, and tarp remover.

[31] *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999)

[32] *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA, 2002)

Two previous human health risk assessments quantitatively assessed occupational handler inhalation risks from pre-plant soil fumigation with methyl bromide (J. Dawson, D337288, 04/10/2007 and J. Dawson, D350818, 06/02/2008). In these assessments, many chemical-specific air monitoring studies were available to evaluate occupational handler exposures, including those exposures of applicators and others involved after the application, such as tarp cutters and tarp removers.

In the assessments noted above and in the 2009 amended RED[33], occupational risks of concern were identified for soil fumigation activities. As a result, OPP implemented a series of label changes and mitigation measures that addressed worker exposure concerns. These measures included: worker personal protective equipment (PPE) (i.e., respirators and SCBA); administrative controls like rate reductions, active monitoring during the operation, and "Stop Work Triggers" (e.g., "if at any time (1) a handler experiences sensory irritation (tearing, burning of the eyes or nose) while wearing a half-mask or full-facepiece air-purifying respirator, or (2) any air sample is greater than 5 ppm for methyl bromide, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone). Those risk mitigation measures are now included on the methyl bromide product labels.

Because HED has conducted an occupational exposure and risk assessment for the soil uses of methyl bromide in the past at comparable application regimes to those currently registered, the use pattern and application parameters have not changed, and the toxicity profile for methyl bromide has not changed, the occupational handler risks associated with the soil uses of methyl bromide have not been re-assessed here (See Appendix D for a summary of the recent occupational handler risk estimates).

*Non-Soil/Commodity Uses*

For the non-soil/commodity uses of methyl bromide, occupational handlers include those individuals who handle the pesticide prior to application and immediately after application and clearance (e.g., forklift drivers). Typically, in pesticide human health risk assessment, activities happening after the application are considered "post-application" activities and are assessed differently. However, for commodity fumigants, those activities performed immediately after application are still considered occupational handlers because the fumigation job site is under the purview of the fumigator until the fumigation and aeration has been completed and the commodity released.

The previous HED human health risk assessments quantitatively assessing or characterizing occupational handler inhalation risks from the commodity uses of methyl bromide were performed in 2013 (M. Lloyd, D412377, 09/13/2013); 2009 (J. Dawson, D362979, 04/03/2009); 2008 (J. Dawson, D304612, 11/26/2008); and 2006 (J. Dawson, D304623, 03/10/2006 and J. Dawson, D304619, 07/12/2006). In these assessments, many chemical-specific air monitoring studies were available to evaluate occupational handler exposures, including those exposures of applicators and others involved after the application, such as venters, forklift drivers, and line workers.

[33] Available: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0123-0716;oldLink=false

These HED risk assessments identified risks of concern for all scenarios associated with commodity fumigation activities for all exposure durations if no respiratory protection is used. Risks for the majority of commodity fumigation workers who use a PF10 respirator were of concern. Because of these risks, OPP has designated risk mitigation measures to ensure that air concentrations do not exceed specific levels that would result in exposures of concern for workers (e.g., occupational handlers and potentially exposed workers involved after the application) as described in the 2006 TRED and in subsequent Agency analyses. For example, the mitigation measures include respiratory requirements and work time restrictions throughout the fumigation process. The Agency is also requiring that fumigators ensure that site-specific management plans are in place before initiating fumigation to protect on-site workers. More extensive information on the mitigation measures required for methyl bromide commodity fumigations can be found in docket EPA-HQ-OPP-2005-0123.

Because HED has conducted an occupational exposure and risk assessment for fumigated commodities in the past at comparable application regimes to those currently registered, the use pattern and application parameters have not changed, and the toxicity profile for methyl bromide has not changed, the occupational handler risks associated with commodity fumigations of methyl bromide have not been re-assessed here.

### 12.2 Acute and Short-/Intermediate-Term Occupational Post-Application Exposure and Risk Estimates

Occupational dermal post-application exposures are not expected given the high vapor pressure of methyl bromide. In addition, emission reduction techniques (e.g., commodity aeration and tarping) used reduce potential exposures. Therefore, dermal exposures have not been quantitatively assessed. Occupational acute, short-, and intermediate-term inhalation post-application exposures are expected from the registered uses of methyl bromide; long-term exposures, or continuous exposures for more than 6 months per year, are not expected based on the seasonal nature of methyl bromide use.

*Soil Uses*

Soil fumigant applications with methyl bromide are directed to bare soil and contact with treated foliage is not expected. Therefore, there is no expectation of soil or foliar dermal exposure to methyl bromide following an application. There is potential for inhalation exposure following an application; however; activities like tarp cutting, supervising, loading, driving the tractor, cross-ditching, etc. are all associated directly with the application are considered handler activities and are assessed/discussed Section 12.1 and Appendix D. Current labels prohibit entry to a treated area by anyone other than individuals appropriately trained and equipped as handlers in accordance with the Worker Protection Standard (40 CFR Part 170) until the entry restricted period ends. For soil applications of methyl bromide, the minimum entry restricted periods are:

- 5 days (120 hours) after application is complete for untarped applications, or

- 5 days (120 hours) after application is complete if tarps are not perforated and removed[34] for at least 14 days after application is complete, or
- 48 hours after tarp perforation is complete if tarps will be perforated within 14 days after the application is complete and will not be removed for at least 14 days after the application is complete.

*Non-Soil/Commodity Uses*

For the non-soil/commodity uses of methyl bromide, occupational post-application inhalation exposures may occur from activities that typically happen once the commodity is released from the fumigation facility (e.g. released to a warehouse or cold storage facility). The movement of grapes through port and cold storage facilities occurs in a seasonal manner, consistent with the import of Chilean grapes into the United States typically occurring from late fall through spring. Ports receiving Chilean grapes will accept many ships over a season, with each ship typically containing thousands of pallets of grapes. The associated warehouse and cold storage facilities would then also handle thousands of pallets of fumigated grapes over a season. Because of this seasonal use pattern, it is reasonable to expect that exposures would be consistent with the Agency definition of short- and intermediate-term exposures. If the exposure pattern was such that shipments only occurred on a single day per season and were widely separated by times of no exposure, or if individuals only worked a few days per season, the exposures would be considered acute. As noted in Section 2.1, EPA has required additional inhalation monitoring data for methyl bromide to evaluate post-application inhalation exposures from off-gassing of treated commodities. A summary of the historical events involving methyl bromide exposures in cold storage facilities is provided below.

*April 2010 – Cold Storage Worker Exposure Incidents Reported in California[35]*

In April of 2010, California DPR was informed of an incident involving two possibly ill workers exposed to methyl bromide. The incident was submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 6(a)(2m) adverse effects disclosure. The affected workers were employed in cold storage facilities as produce quality inspectors and had blood bromide levels of 15 and 44 ppm. Because of these reported incidents, California DPR subsequently conducted an industrial hygiene (IH) investigation.

As part of the IH investigation, a DPR industrial hygienist traveled to the Port of Los Angeles, Long Beach, three times to conduct colorimetric air sampling at the harbor/dockside fumigation facility, at the cold storage facility, and on the trailers used to haul fruit from the dockside fumigation facility to cold storage. Samples[36] at the dockside fumigation facility showed

[34] Tarp removal is completed if tarps are both perforated and removed less than 14 days after application is complete.

[35] https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf

[36] Air sampling was conducted using a Sensidyne® aspirating pump connected to Sensidyne® methyl bromide sampling colorimetric tubes (product 157SB). Air is drawn through the colorimetric tube by pulling the piston stroke-handle until it locks. Depending on the air concentration, more than one stroke of the piston may be necessary to register a color change in the tube. If the initial stroke resulted in non-detect, a second stroke would be performed. If the result was non-detectable or very low, two more strokes would be done and the final reading made, taking into account the required adjustments specified in the directions. Samples were drawn from the alleys, pathways and

concentrations of methyl bromide as high as 8 and 5 ppm (Table 12.2.2.1) (although the 8 ppm could not be replicated). Samples were also taken from the trailers used to haul fruit from the fumigation facility to the storage facilities once loaded. Samples from the loaded trailers showed concentrations of methyl bromide as high as 5.5 ppm (Table 12.2.2.2). Samples were also taken from the trailers once they had arrived at the cold storage facility and showed concentrations of methyl bromide as high as 20 ppm (Table 12.2.2.3). Samples were also taken from within the cold storage facility and showed methyl bromide concentrations as high as 7 ppm (Table 12.2.2.4). Since the trailers and the cold storage facility appeared to be the sites with the highest concentration of methyl bromide, sampling was also conducted on shipments being sent to a cold storage facility that was further away from the dockside fumigation facility [San Joaquin Valley cold storage facility in Tulare County (Table 12.2.5)]. The trailer samples showed methyl bromide concentrations as high as 20 ppm, and the air sample drawn directly from the Tulare cold storage facility was 7 ppm (Table 12.2.2.4).

The American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) is 1 ppm (8-hour time weighted average). The Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA) also cites a TWA of 1 ppm as the Permissible Exposure Limit (PEL), with a ceiling (do not exceed) level of 20 ppm. The present Federal/OSHA exposure standard is a 20-ppm ceiling value for methyl bromide. All samples collected were of concern and exceeded the short- and intermediate-term LOC (i.e., 0.15 ppm or HEC of 4.4 ppm ÷ UF of 30). All MOEs (if calculated) would be < LOC of 30 [MOE = HEC ÷ methyl bromide air concentration (ppm)], and of concern. Some samples collected at the cold storage facility also exceeded the acute LOC (i.e., 1 ppm or HEC of 30 ppm ÷ UF of 30).

**Table 12.2.2.1. Methyl Bromide Air Concentrations after Aeration of Commodity Fumigated at the Dockside Fumigation Facility Reported[1,2]**

| Location | Date | Time | Grid ID | Aeration time (hrs) | Methyl Bromide Air Concentration (ppm) | Notes |
|---|---|---|---|---|---|---|
| Alley[3] | April 13 | 0715 | ---[4] | 9 | 2.5 | One fan at end of alley |
| | | 0728 | ---[4] | 9 | 2 | One fan at end of alley |
| | | 0735 | ---[4] | 9 | 2 | One fan at end of alley |
| | | 0830 | ---[4] | 9 | 5 | Fans removed |
| | April 19 | 1700 | 1 | 9 | 1 | Fans moved into alley 10 m |
| | | 1700 | 6 | 9 | 2 | Fans moved into alley 10 m, kiwi |
| | | 1710 | 2 | 9 | 1 | Fans moved into alley 10 m |
| | | 1710 | 5 | 9 | <0.4 | Fans moved, partial grid |
| | | 1725 | 2 | 9 | 0.6 | Between end and fan intake (5m in) |
| | | 1745 | 4 | 4 | 1.4 | |
| | | 1805 | 4 | 4 | 8 | Fans removed |
| | | 1815 | 1 | 9 | 0.4 | Fans removed, worked stack |
| | | 1820 | 4 | 4 | 1.2 | Between end and center |
| | | 1825 | 4 | 4 | 3.5 | Fan returned |
| | | 1830 | 4 | 4 | 2.5 | |

working faces (where forklifts were removing pallets) of the grids. Air was also sampled in the center of an empty grid as a control (https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf).

| Table 12.2.2.1. Methyl Bromide Air Concentrations after Aeration of Commodity Fumigated at the Dockside Fumigation Facility Reported[1,2] | | | | | | |
|---|---|---|---|---|---|---|
| **Location** | **Date** | **Time** | **Grid ID** | **Aeration time (hrs)** | **Methyl Bromide Air Concentration (ppm)** | **Notes** |
| | | 1855 | 4 | 4 | 2 | Fan removed |
| | | 1900 | 4 | 4 | 1.8 | Wind speed measured 3 to 13 mph |
| | April 21 | 0805 | 3 | 9 | 0.5 | |
| | | 0815 | 6 | 9 | 1 | |
| | | 0815 | 1 | 9 | 0.6 | No fans/kiwis and grapes |
| | | 0850 | 6 | 9 | 5 | |
| | | 0850 | 1 | 9 | 1.4 | No fans |
| | | 0900 | 3 | 9 | 3 | |
| Pathway | April 13 | 0750 | ---[4] | 9 | 5 | No discernable air movement |
| Pathway 1-2 | April 19 | 1725 | ---[4] | 9 | <0.4 | Breezy |
| Pathway 4-5 | | 1730 | ---[4] | 4 | <0.4 | Breezy |
| Pathway 5-6 | | 1747 | ---[4] | 9 | <0.4 | Grid 5 partially removed, breezy |
| Control Sample | April 13 | 0755 | 3 | NA | <0.4 | Empty grid |
| Control Sample | April 19 | 0755 | 3 | NA | <0.4 | Empty grid |
| Working Face | April 13 | 0758 | ---[4] | 9 | 2 | Indentation (pallet removed from grid) |
| | | 0825 | ---[4] | 9 | 1 | Pallets just prior to sample collection |
| | April 19 | 1755 | 1 | 9 | 0.8 | |
| | | 1755 | 4 | 4 | 0.6 | |
| | April 21 | 0820 | 3 | 9 | <0.4 | |
| | | 0855 | 3 | 9 | <0.4 | |

1. https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf
2. All results are from using Sensydine detector tubes with a minimum level of detection of 0.4 ppm and a variability of ± 15%.
3. Alley sampling, unless noted otherwise, was from center of alley, underneath aeration tubing.
4. Grid identification not reported.

| Table 12.2.2.2. Methyl Bromide Air Concentrations in Loaded Trailers From Truck Monitoring at Dockside Fumigation Facility[1,2] | | | | | |
|---|---|---|---|---|---|
| **Trailer #/Sampling Location** | **Date** | **Time** | **Aeration (hrs)** | **Methyl Bromide Air Concentration (ppm)** | **Notes** |
| W / Inside, side of load | April 13 | 0845 | 9 | 1 | Loaded 22 pallets |
| 1 / Inside, side of load | April 19 | 1820 | 4 | 2.5 | Loaded 20 pallets |
| 2 / Inside, side of load | April 19 | 1840 | 4 | 5.5 | Loaded 18 pallets |
| 3 / Inside, side of load | April 19 | 1920 | 4 | 2 | Loaded 17 pallets |
| A / Inside, side of load | April 19 | 1840 | 9 | <0.4 | Loaded, no count available |
| B /Inside, side of load | April 19 | 1850 | 9 | 0.5 | Loaded, no count available |
| C /Inside, side of load | April 19 | 1700 | 9 | <0.4 | Loaded, no count available |

1. https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf
2. All results are from using Sensydine detector tubes with a minimum level of detection of 0.4 ppm and a variability of ± 15%.

| Table 10.2.2.3. Methyl Bromide Air Concentrations In Loaded Trailers from Truck Monitoring at Carson Cold Storage Facility[1,2] | | | | | | |
|---|---|---|---|---|---|---|
| **Trailer #/Sampling Location** | **Date** | **Time** | **Trailer Location** | **Aeration (hrs)** | **Methyl Bromide Air Concentration (ppm)** | **Notes** |
| X / Rear aeration door | April 13 | 0940 | Outside cold storage | 9 | 13 | 21 pallets in truck |
| Y / Rear aeration door | April 13 | 1000 | Outside cold storage | 9 | 14 | 21 pallets in truck |
| Z / Rear aeration door | April 13 | 1020 | Outside cold storage | 9 | 20 | 21 pallets in truck |
| 1 / Rear aeration door | April 19 | 1955 | Outside cold storage | 4 | 15 | 20 pallets in truck |
| 2 / Rear aeration door | April 19 | 2000 | Outside cold storage | 4 | 10 | 18 pallets in truck |
| 3 / Rear aeration door | April 19 | 2005 | Outside cold storage | 4/9 | 11 | 12 pallets grapes, 5 kiwi in truck. Grapes 4 hours and kiwis 9 hours aeration. |
| | | | | | | |
| X / Rear trailer door open, sample at open face | April 13 | 0950 | Outside cold storage | 9 | 2.5 | 21 pallets in truck, door open 5 minutes |
| 1 / Inside, side of load[3] | April 19 | 2015 | Outside cold storage | 4 | 2.5 | 20 pallets in truck |
| 2 / Inside, side of load | April 19 | 2025 | Outside cold storage | 4 | <0.4 | 18 pallets in truck |
| 3 / Inside, side of load | April 19 | 2030 | Outside cold storage | 4/9 | 4 | 12 pallets grapes, 5 kiwi in truck. Grapes 4 hours and kiwis 9 hours aeration. |
| 3 / Inside, side of load | April 19 | 2050 | Outside cold storage | 4/9 | 2.5 | 12 pallets grapes, 5 kiwi in truck. Grapes 4 hours and kiwis 9 hours aeration. |
| | | | | | | |
| X Inside, side of load | April 13 | 1030 | Inside cold storage | 9 | 1.4 | 90% unloaded |
| Y Inside, side of load | April 13 | 1055 | Inside cold storage | 9 | 2.5 | 0% unloaded |
| Y Inside, side of load | April 13 | 1115 | Inside cold storage | 9 | 2.5 | 50% unloaded |

1. https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf
2. All results are from using Sensydine detector tubes with a minimum level of detection of 0.4 ppm and a variability of ± 15%.
3. All sampling "inside, side of load" done with all rear trailer doors open.

| Table 12.2.2.4. Methyl Bromide Air Concentrations from Sampling Inside Cold Storage Facilities[1,2] | | | | | |
|---|---|---|---|---|---|
| **Facility/Sampling Location** | **Date** | **Time** | **Aeration (hrs)** | **Methyl Bromide Air Concentration (ppm)** | **Notes** |
| Carson area/loading dock | April 13 | 1040 | 9 | 2 | |
| Carson area/loading dock | April 19 | 2055 | 9 | <0.4 | 4-hour aeration loads not included |
| Carson area/chiller C1 | April 13 | 1110 | NA | 4 | |
| Carson area/chiller C1 | April 19 | 2055 | 9 | 2 | 4-hour aeration loads not included |
| Tulare Co./loading dock | April 21 | 1710 | NA | 7 | Heavily loaded with fruit |

1. https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf
2. All results are from using Sensydine detector tubes with a minimum level of detection of 0.4 ppm and a variability of ± 15%.

**Table 12.2.2.5. Methyl Bromide Air Concentrations from Sampling of Long Haul Trailers Following Commodity Fumigation[1,2]**

| Trailer #/Sampling Location | Trailer Location | Aeration Doors During Transit | Date | Time | Aeration Time (hrs) | Methyl Bromide Air Concentration (ppm) |
|---|---|---|---|---|---|---|
| F1 / Inside, side of load | Harbor | NA | April 21 | 1015 | 9 | <0.4 |
| F1 / At aeration door[3] | Storage | Closed | | 1536 | 9 | 10 |
| F1 / Inside, side of load[3] | Storage | Closed | | 1555 | 9 | 4 |
| F2 / Inside, side of load | Harbor | NA | April 21 | 1035 | 9 | 1 |
| F2 / At aeration door | Storage | Closed | | 1620 | 9 | 20 |
| F2 / Inside, side of load | Storage | Closed | | 1640 | 9 | 4 |
| F3 / Inside, side of load | Harbor | NA | April 21 | 1100 | 9 | <0.4 |
| F3 / At aeration door | Storage | Open | | 1605 | 9 | <0.4 |
| F3 / Inside, side of load | Storage | Open | | 1615 | 9 | 4 |

1. https://www.cdpr.ca.gov/docs/whs/memo/hsm10009.pdf
2. All results are from using Sensydine detector tubes with a minimum level of detection of 0.4 ppm and a variability of ± 15%.
3. Sampling at "aeration door" was done with arm inserted into trailer through rear aeration door; sampling "inside, side of load" was done with all rear trailer doors open; after 10 to 20 minutes of open trailer door aeration.

*April 2011 – EPA Reviews Cold Storage Worker Monitoring Protocol*

In April 2011, HED reviewed a revised port and cold storage facility worker monitoring protocol submitted by the methyl bromide industry panel (MBIP) to address the post-application inhalation monitoring data requirement (J. Dawson, D387451, 04/05/2011). The design of the study was informed by the incidents involving cold storage workers reported in California in 2010. The protocol included monitoring workers handling Chilean grapes and Peruvian asparagus to determine whether the workers were being exposed to more than the ACGIH TLV of 1 ppm. The study was to be conducted in three locations: California, Florida, and the mid-Atlantic; and would evaluate exposures from different tasks throughout the commodity fumigation process. The protocol specified monitoring forklift drivers, clerks, expediters (those who direct traffic flow and placement of pallets), quality assurance (QA) inspectors (typically independent employees of companies hired to advise buyers and sellers on the quality of the product), general laborers (those that carry loose boxes of fumigated commodities to delivery trucks and/or stack pallets of fumigated commodities for movement by forklift), and coopers (coopers re-stack and repair damaged pallets) at the port fumigation facilities; and forklift drivers, clerks, and QA inspectors at the cold storage facilities.

*March 2012 – Cold Storage Worker Monitoring Begins in California, Port of Long Beach*

*May 2012 – Initial Monitoring Data from California Submitted to EPA under FIFRA 6(a)(2)*

In May 2012, the data from the completed California phase of the monitoring study were submitted to the Agency. Because the measured values shown in California indicated exposure levels of concern, the results were submitted under FIFRA 6(a)(2) adverse effects reporting. EPA subsequently required that the sampling be suspended in the other required sampling areas

(Pennsylvania, Delaware, New Jersey). The Agency required that the remainder of the study be completed only after risk management measures were implemented to reduce exposures. An updated research plan was developed and a progress report was submitted in June of 2012 (see below; *June 2012 – Review of Progress Report on Research Plan for Evaluating Worker Exposure Associated with Commodity Fumigation*).

The submitted results from the CA site were reviewed by HED (J. Dawson, D395248, 05/30/2012) and a summary of the data and HED's review is provided below:

Prior to exposure monitoring, grapes were treated with Meth-O-Gas Q between March 21, 2011 and April 2, 2011. Typically, grapes are received into the Long Beach, California area and are quarantined until fumigated in a dockside warehouse. Once inside the warehouse, curtain-like tarps are lowered over the pallets and sealed. Methyl bromide gas is then introduced into the sealed containments, held, and then dispersed through active aeration. Once aeration is complete, the treated fruit is transferred to one of three cold storage facilities. Each facility had some measures in place to manage worker exposure levels. These measures vary by facility and include engineered changes to the facility (e.g., exhaust fans and sources of make-up air), informal measures to manage air flow through the structure, and managing the location of the treated grapes while in storage.

The exposures of one expediter (those who direct traffic flow and placement of pallets) as well as one forklift driver were measured at the dockside warehouse; and the exposures of one clerk, one forklift driver, and one fruit inspector were measured at each of the three cold storage facilities.

Stationary (fixed location) samples were also collected at each of the five sites where monitoring occurred.

Port and cold storage worker monitoring results, reported by the investigators and verified by HED (J. Dawson, D395248, 05/30/2012), are summarized in Table 12.2.2.6. All samples collected were of concern and exceeded the short- and intermediate-term LOC (i.e., 0.15 ppm or HEC of 4.4 ppm ÷ UF of 30). All samples collected at the cold storage facility also exceeded the acute LOC (i.e., 1 ppm or HEC of 30 ppm ÷ UF of 30). All MOEs (if calculated) would be < LOC of 30 [MOE = HEC ÷ methyl bromide air concentration (ppm)], and of concern. Workers in 3 of the 4 port monitoring units also had levels that exceeded 1 ppm exposure limits established by other organizations (i.e., ACGIH TLV = 1 ppm).

**Table 12.2.2.6. Worker Exposure Sampling Results from Observational Study of Port and Cold Storage Workers Handling Treated Chilean Grapes in Long Beach California (from D395248).**

| Date & Location | MU[1] | Activity | Sample Duration (minutes) | Methyl Bromide Air Concentrations (ppm)[2] |
|---|---|---|---|---|
| **Port Workers** | | | | |
| Berth 54 Warehouse 3/22/11 | 1 | Expediter | 167 | 1.21 |
| | 2 | Forklift Operator | 159 | 0.923 |
| Berth 55 Warehouse 3/23/11 | 3 | Expediter | 210 | 0.821 |
| | 4 | Forklift Operator | 207 | 0.531 |
| | | | Mean | 0.871 |

| Table 12.2.2.6. Worker Exposure Sampling Results from Observational Study of Port and Cold Storage Workers Handling Treated Chilean Grapes in Long Beach California (from D395248). | | | | |
|---|---|---|---|---|
| **Date & Location** | **MU[1]** | **Activity** | **Sample Duration (minutes)** | **Methyl Bromide Air Concentrations (ppm)[2]** |
| | | | Std. Dev. | 0.28 |
| **Cold Storage Workers** | | | | |
| Cold Storage Facility 1 3/24/11 | 5 | Clerk | 490 | 2.60 |
| | 6 | Forklift Operator | 489 | 4.25 |
| | 7[3] | QC Inspector | 384 | 3.00 |
| Cold Storage Facility 2 3/25/11 | 8 | Clerk | 825 | 2.91 |
| | 9 | Forklift Operator | 816 | 3.44 |
| | 10 | QC Inspector | 632 | 3.38 |
| Cold Storage Facility 3 4/3/11 | 11 | Clerk | 265 | 3.91 |
| | 12 | Forklift Operator | 265 | 8.33 |
| | 13 | QC Inspector | 294 | 3.87 |
| | | | Mean | 3.97 |
| | | | Std. Dev. | 1.72 |

1. MU = monitoring unit.
2. The monitoring event for MU 7 was split into 2 sample collection periods. The combined results are presented in this table. Methyl bromide concentrations are displayed as time-weighted averages (TWAs). The TWAs range from approximately 2.5 hrs to 14 hrs.

Port and cold storage stationary air monitoring results, reported by the investigators and verified by HED, are summarized in Table 10.2.2.7. All but two samples collected were of concern and exceeded the Agency's short- and intermediate-term LOC (i.e., 0.15 ppm or HEC of 4.4 ppm ÷ UF of 30) and the acute LOC (i.e., 1 ppm or HEC of 30 ÷ UF of 30). All but two MOEs (if calculated) would be < LOC of 30 [MOE = HEC ÷ methyl bromide air concentration (ppm)], and of concern. Exposure limits established by regulatory agencies and other organizations were also exceeded (i.e., California OSHA and ACGIH TLV are both = 1 ppm for 8-hour TWA).

| Table 12.2.2.7. Stationary Air Sampling Results from Observational Study of Port and Cold Storage Workers Handling Treated Chilean Grapes in Long Beach California (from D395248). | | | | |
|---|---|---|---|---|
| **Date & Location** | **Corresponding MUs[1]** | **Sample** | **Sample Duration (minutes)** | **Methyl Bromide Air Concentrations (ppm)[2]** |
| **Port Facilities** | | | | |
| Berth 54 Warehouse 3/22/11 | 1, 2 | Warehouse | 192 | 1.81 |
| | | | 197 | 1.66 |
| | | | 201 | 0.042 |
| Berth 55 Warehouse 3/23/11 | 3, 4 | Warehouse | 235 | 1.34 |
| | | | 232 | 1.42 |
| | | | 228 | 0.031 |
| | | | Mean | 1.05 |
| | | | Std. Dev. | 0.80 |
| **Cold Storage Facilities** | | | | |
| Cold Storage Facility 1 3/24/11 | 5, 6, 7 | QC Area | 398 | 4.83 |
| | | | 400 | 4.71 |
| | | | 404 | 4.98 |
| | | Loading Dock | 473 | 1.66 |
| | | | 476 | 1.97 |

| Table 12.2.2.7. Stationary Air Sampling Results from Observational Study of Port and Cold Storage Workers Handling Treated Chilean Grapes in Long Beach California (from D395248). | | | | |
|---|---|---|---|---|
| **Date & Location** | **Corresponding MUs[1]** | **Sample** | **Sample Duration (minutes)** | **Methyl Bromide Air Concentrations (ppm)[2]** |
| | | | 479 | 19.9 |
| | | Cooler | 488 | 10.8 |
| | | | 455 | 9.90 |
| | | | 482 | 2.96 |
| Cold Storage Facility 2 3/25/11 | 8, 9, 10 | QC Area | 610 | 4.56 |
| | | | 625 | 4.83 |
| | | | 559 | 4.21 |
| | | Loading Dock | 726 | 4.35 |
| | | | 805 | 4.08 |
| | | | 731 | 2.47 |
| | | Cooler | 596 | 5.67 |
| | | | 799 | 5.75 |
| | | | 783 | 8.95 |
| Cold Storage Facility 3 4/3/11 | 11, 12, 13 | QC Area | 284 | 3.54 |
| | | | 284 | 4.54 |
| | | | 284 | 5.39 |
| | | Loading Dock | 288 | 3.09 |
| | | | 288 | 3.07 |
| | | | 288 | 2.01 |
| | | Cooler | 270 | 8.45 |
| | | | 270 | 8.84 |
| | | | 270 | 8.79 |
| | | | Mean | 5.71 |
| | | | Std. Dev. | 3.80 |

1. MU = monitoring unit.

To enhance the potential utility of the collected data, an analysis was completed to evaluate how the worker monitoring results (Table 12.2.2.6) and stationary air monitoring results (Table 12.2.2.7) agree with one another. This is important because stationary air monitoring represents a possible approach, which is less complex to implement, for facility operators who want to more actively manage exposures of their employees in real-time (e.g., fixed stationary monitors could trigger cease work alarms or automated ventilation systems). See Appendix E for the analysis.

*June 2012 – Review of Progress Report on Research Plan for Evaluating Worker Exposure Associated with Commodity Fumigation*

As noted above, the EPA required that sampling be suspended in other required sampling areas until modifications to the study design were made to reflect risk management measures that were implemented to reduce exposures. In 2011, HED reviewed the draft progress report (Steps 1 to 4) submitted by the MBIP pursuant to Steps 1-4 of the research plan for the other required sampling areas (J. Dawson, D396565, 06/07/2012). The draft progress report is the first step in determining how to proceed with the remainder of the study. Steps 1 to 4 of the research plan included: (1) characterization of the use pattern as it pertained to worker exposure, (2) categorization of the use pattern as it applied to exposure potential (e.g., off gassing potential), (3) creation of exposure profiles, and (4) identification of use patterns for mitigation. The

progress report characterized the use patterns for the commodity/post-harvest uses of methyl bromide, and created exposure profiles to identify commodity uses, outside of Chilean grapes and Peruvian asparagus, which may require further evaluation and risk mitigation. A ranking scheme was proposed in the document and several other factors were discussed (e.g., desorption/adsorption properties, storage practices). The presented information provided a framework for how the completed analysis could be reported and it also detailed the types of information which would be considered. Much of the information included in the document was consistent with previous discussions that have occurred with MBIP, but there were some noticeable differences that should be reconciled. In general, the exposure ranking criteria proposed by MBIP appear reasonable, but refinements are needed as noted in the review. No additional worker monitoring data in cold storage facilities located in the other required sampling areas have been submitted.

*November 2012 – Present*
Between 2012 and 2016, the industry implemented BMPs in California to mitigate the exposures received in cold storage facilities. Since then, Delaware, Pennsylvania, and New Jersey have implemented California's model of BMPs in some capacity. Only templates of the BMPs have been provided to OPP, not individual facility BMPs. The templates include the following core elements: (1) notification that potentially hazardous levels of methyl bromide may be present, (2) monitoring of methyl bromide to inform and evaluate the mitigation measures of the BMP, (3) recordkeeping, (4) agreement to participate in regulatory monitoring (including inspections, audits, and spot sampling by regulatory authorities), and (5) implementation of mitigation measures (e.g., worker time and location management, shift management, ventilation, and filtration) to provide compliance with the regulatory exposure limits.

Therefore, as part of the BMPs, cold storage facilities have likely implemented quantitative monitoring/sampling of methyl bromide levels to inform and evaluate mitigation measures. EPA is aware of monitoring data collected in cold storage facilities as indicated in status updates from the Maritime Exchange for the Delaware River and Bay, Delaware River Region Cold Storage Facility Task Force and from CDPR. These updates have indicated that data are available demonstrating that the mitigation outlined in the BMPs has significantly reduced worker exposure over time, but these data have not been submitted to the EPA. In absence of these data, EPA cannot quantitatively evaluate the impact the BMPs have on reducing risks from methyl bromide exposure for cold storage workers. Therefore, the 875.2500 monitoring data requirement remains outstanding.

## 13.0 Incident and Epidemiological Data Review

In the current five-year IDS analysis, from January 1, 2013, to September 14, 2018, in Main IDS there were seven incidents reported that involved the active ingredient methyl bromide. One incident was a death involving an equipment failure that released methyl bromide resulting in the death of a worker in Illinois in 2017. Two of the incidents were classified as major severity and four of the incidents were classified as moderate severity. Six of these incidents occurred in an occupational setting and two of these occupational incidents involved multiple people. The non-occupational incident occurred in 2015 and involved a family of four who were exposed to

methyl bromide while vacationing in the Virgin Islands. They experienced seizures and inability to breathe[37]. In Aggregate IDS, four minor severity incidents were reported.

In SENSOR-Pesticides from 2010-2015, 34 cases involving methyl bromide were identified. One case was high in severity, nine cases were moderate in severity, and 24 cases were low in severity. All cases were work-related exposures. The high severity case was a fieldworker who was harvesting broccoli and got sick after a tarp in the adjacent field ruptured and caused the off-target movement of methyl bromide. The high severity case went to the hospital with burning, teary and painful eyes, dizziness, sore throat, shortness of breath, coughing, headache, chest pain, chills, fever and weakness. This case was one of six workers harvesting broccoli when made ill from this event. Eleven of the 34 methyl bromide cases involved exposure related to tarp rip/tears or tarp handling activities.

Overall, while there were some severe incidents and one fatality reported involving methyl bromide, the frequency of methyl bromide incidents reported to both datasets has remained low over time.

A total of 46 published epidemiologic studies on the association between methyl bromide exposure and adverse health outcomes were reviewed for this updated Tier I Review. This includes 41 studies from the AHS, three additional studies that were identified for EPA's previous 2013 scoping assessment, and two studies identified in support of the current risk assessment. Based on review of these studies, there is insufficient evidence to suggest a clear associative or causal relationship between exposure to methyl bromide and carcinogenic and non-carcinogenic health outcomes evaluated in the AHS and other study populations identified. The Agency will continue to monitor the epidemiology data, and – if a concern is triggered – additional analysis will be conducted.

## 14.0 References

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# Appendix A. Toxicology Profile and Executive Summaries

## A.1 Toxicology Data Requirements

The requirements (40 CFR 158.500) for methyl bromide are in Table 1. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

| Study | | Technical | |
|---|---|---|---|
| | | Required | Satisfied |
| 870.1100 | Acute Oral Toxicity | yes | yes |
| 870.1200 | Acute Dermal Toxicity | NA | NA |
| 870.1300 | Acute Inhalation Toxicity | yes | yes |
| 870.2400 | Acute Eye Irritation | yes | yes* |
| 870.2500 | Acute Dermal Irritation | yes | yes* |
| 870.2600 | Skin Sensitization | yes | yes* |
| 870.3100 | 90-Day Oral Toxicity in Rodents | yes | yes |
| 870.3150 | 90-Day Oral Toxicity in Nonrodents | yes | + |
| 870.3200 | 21/28-Day Dermal Toxicity | yes | NA |
| 870.3250 | 90-Day Dermal Toxicity | no | -- |
| 870.3465 | 90-Day Inhalation Toxicity | no | yes |
| 870.3700a | Prenatal Developmental Toxicity (rodent) | yes | yes |
| 870.3700b | Prenatal Developmental Toxicity (nonrodent) | yes | yes |
| 870.3800 | Reproduction and Fertility Effects | yes | yes |
| 870.4100a | Chronic Toxicity (rodent) | yes | yes |
| 870.4100b | Chronic Toxicity (nonrodent) | yes | yes |
| 870.4200a | Carcinogenicity (rat) | yes | yes |
| 870.4200b | Carcinogenicity (mouse) | yes | yes |
| 870.4300 | Combined Chronic Toxicity/Carcinogenicity | yes | yes |
| 870.5100 | Mutagenicity—Bacterial Reverse Mutation Test | yes | NA |
| 870.5300 | Mutagenicity—Mammalian Cell Gene Mutation Test | yes | NA |
| 870.5395 | Mutagenicity—Micronucleus Assay | yes | yes |
| 870.5xxx | Mutagenicity—DNA Alkaline Elution Assay | yes | yes |
| 870.6200a | Acute Neurotoxicity Screening Battery (rat) | yes | yes |
| 870.6200b | 90-Day Neurotoxicity Screening Battery (rat) | yes | yes |
| 870.6300 | Developmental Neurotoxicity | no | yes |
| 870.7485 | Metabolism and Pharmacokinetics | yes | yes |
| 870.7600 | Dermal Penetration | no | -- |
| 870.7800 | Immunotoxicity | yes | yes |

* Acute dermal toxicity and dermal sensitization potential studies were not required because there is already clear evidence that severe irritation to skin occurs after acute dermal exposure to methyl bromide. Data are available for both oral and inhalation routes and have been used accordingly in the risk assessments. Many of the toxicity studies were performed via the inhalation route since it is the main exposure route expected for methyl bromide.

## A.2 Toxicity Profiles

### Table A.2.1 Acute Toxicity Profile- Methyl Bromide

| Table A.2.1. Acute Toxicity Data on Methyl Bromide Technical. | | | | |
|---|---|---|---|---|
| **Guideline No.** | **Study Type** | **MRID No.(s)** | **Res** | **Toxicity** |
| 870.1100 | **Acute oral (methyl bromide in vegetable oil)** | 43510301 | $LD_{50}$ = 120-160 mg/kg (males) $LD_{50}$ = 86 mg/kg (females) | I I |
| 870.1200 | **Acute dermal** | N/A[d] | N/A[d] | N/ |
| 870.1300 | **Acute inhalation** | Kato et al (1986)[a] | $LC_{50}$ = 3.03 mg/L, 4 hr exposure | I |
| 870.2400 | **Primary eye irritation** | Alexeef, G.; Kilgore, W. (1983)[b] and Hezemans-Boer et al (1988)[c] | Severe irritation following accidental exposure to humans | I |
| 870.2500 | **Primary skin irritation** | Alexeef, G.; Kilgore, W. (1983) and Hezemans-Boer et al (1988) | Severe irritation following accidental exposure to humans | I |
| 870.2600 | **Skin sensitization** | N/A[d] | N/A[d] | N/ |

a: Kato, N.; Morinobu, S.; Ishizu, S. (1986) Subacute inhalation Experiment for methyl bromide in Rats. Industr. Health. 24: 87-103.
b: Alexeef, G.; Kilgore, W. (1983) MeBr. In: Gunther, F.; Gunther, J., ed. Residue Reviews. Residues of Pesticides and Other Contaminants in the Total Environment, Vol. 88, p. 102-153. New York, Springer Verlag.
c: Hezemans-Boer, M; Toonstra, J.; Meulenbelt, J.; et al. (1988) Skin Lesions Due to Exposure to methyl bromide. Arch. Derm. 124:917-921.
d: N/A (Not Available): Acute dermal toxicity and dermal sensitization potential studies were not required because there is already clear

### Table A.2.2 Subchronic, Chronic, and Other Toxicity Profile

| Table A.2.2: Methyl Bromide Sub-chronic, Chronic and Other Toxicity. | | |
|---|---|---|
| **Guideline No./ Study Type** | **MRID No. (year)/ Classification /Doses** | **Resul ts** |
| 870.3100 **90-Day oral toxicity in rats** (peanut oil) | 00154564 (1984) classification: **no DER available.** | NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on slight hyperplasia of the stratified squamous epithelium of the fore stomach. HDT was 50 mg/kg/day. |
| 870.3150 **4-week oral toxicity in rats** (capsule) | 43776401 (1995) acceptable/non-guideline | NOAEL = 0.835 mg/kg/day. LOAEL = 7.99 mg/kg/day (HDT), based on slightly decreased body weight gain and food consumption. |

**Table A.2.2: Methyl Bromide Sub-chronic, Chronic and Other Toxicity.**

| Guideline No./ Study Type | MRID No. (year)/ Classification /Doses | Results |
|---|---|---|
| 870.3465<br><br>**Sub-chronic Inhalation Toxicity in dogs** | 43386802 (1994)<br>acceptable/guideline<br>0, 5, 10/150, 25, 50 or 100 ppm (actual mean concentrations 0, 5.3, 11.0/158.0, 26.0, 53.1 or 102.7 ppm; equivalent to 1.43, 2.97/42.7, 7.02, 14.3, 27.7 mg/kg/day). 7 hours/day | **Systemic toxicity** (7 weeks, 34 exposures)<br>NOAEL (threshold) = <5 ppm.<br>LOAEL (threshold)= 5 ppm (0.021 mg/L), based on decreased responsiveness in females. |
| 870.3700a<br><br>**Prenatal developmental in Wistar rats** (via inhalation) | 00102990 (1981)<br>acceptable/guideline<br>0, 20 or 70 ppm (equivalent to 0, 20, or 71 mg/kg/day)–7 hrs/day; 5 days/wk | **Maternal**<br>NOAEL/ LOAEL > 70 ppm (HDT).<br><br>**Developmental**<br>NOAEL /LOAEL > 70 ppm (HDT) |
| 870.3700b<br><br>**Prenatal developmental in rabbits** (via inhalation) | 41580401 (1990)<br>acceptable/guideline<br>0, 20, 40, or 80 ppm (equivalent to 0, 7.1, 14 or 28 mg/kg/day) - 6 hrs/day for 17 days | **Maternal**<br>NOAEL = 40 ppm;<br>LOAEL = 80 ppm based on decreased appetite, lethargy, right side head tilt, ataxia and lateral recumbency.<br><br>**Developmental**<br>NOAEL = 40 ppm<br>LOAEL = 80 ppm based on agenesis of the gall bladder, increased incidence of fused sternebrae and decreased fetal body weight |
| 870.3800<br><br>**Reproduction and fertility effects in CD rats** (via inhalation) | 00160477 (1986)<br>acceptable/guideline<br>0, 3, 30, or 90 ppm for 6 hours/day (equivalent to males: 0, 2.4, 24 or 73 mg/kg/day; females: 0, 2.8, 28 or 85 mg/kg/day) | **Parental/Systemic**<br>NOAEL = 30 ppm<br>LOAEL = 90 ppm based on reduced body weight<br>**Reproductive**<br>NOAEL = 3 ppm<br>LOAEL = 30 ppm based on reduced pregnancy rates (23%, F2b)<br>**Offspring**<br>NOAEL = 3 ppm<br>LOAEL = 30 ppm based on reduced pup weight on post-natal day 21 (F1a, F2a, F2b generations) ranging from 10-20%. |
| 870.4100b<br><br>**Chronic toxicity dogs** (fumigated feed) | 43885201 (1996)<br>acceptable/guideline<br>0, 0.5, 1.5 or 5 ppm (M: 0, 0.06, 0.13 or 0.27; F: 0, 0.07, 0.12 or 0.27 mg/kg/day for 12 months. | NOAEL/LOAEL > 5 ppm (HDT) (equivalent to 0.27 mg/kg/day)<br>It is noted that this study was conducted to establish a margin of safety for human dietary exposure **rather than to determine a LOAEL**. |

**Table A.2.2: Methyl Bromide Sub-chronic, Chronic and Other Toxicity.**

| Guideline No./ Study Type | MRID No. (year)/ Classification /Doses | Results |
|---|---|---|
| 870.4300<br><br>**Chronic toxicity and carcinogenicity in rats** (micro-encapsulated) | 44462501 (1997)<br>acceptable/guideline<br>0, 0.5, 2.5, 50, or 250 ppm (M: 0, 0.02, 0.11, 2.2, or 11.1; F: 0, 0.03, 0.15, 2.92, and 15.12 mg/kg/day for 24 months | NOAEL = 50 ppm (2.2 mg/kg/day for males and 2.92 mg/kg/day for females). LOAEL = 250 ppm (11.1 mg/kg/day for males and 15.12mg/kg/day for females), based on decreased body weight, body weight gain, and food consumption in males and females during the first<br>18 months of the study.<br>**No evidence of carcinogenicity** |
| 870.4300<br><br>**Chronic toxicity and carcinogenicity (29-month) in rats** (via inhalation)– Wistar rats | 41213301 (1987); 42418301; 44359101<br>acceptable/guideline<br>0, 3, 30 or 90 ppm (0, 0.0117, 0.117 or 0.335 mg/L)<br>(equivalent to males: 0, 1.9, 19 or 58 mg/kg/day; females: 0, 2.2, 22 or 65 mg/kg/day) | **Local irritation**<br>NOAEL < 3 ppm (0.0117 mg/L);<br>LOAEL = 3 ppm (0.0117 mg/L), based on increased incidence of basal cell hyperplasia of the nasal cavity in both sexes.<br>**Systemic toxicity**<br>NOAEL = 30 ppm (0.117 mg/L)<br>LOAEL = 90 ppm (0.335 mg/L), based on increased mortality, decreased body weight and relative brain weight, hemothorax, increased incidence of thrombus, cartilaginous metaplasia, myocardial degeneration and irritation of the esophagus and fore stomach. |
| 870.4300<br><br>**Chronic toxicity and carcinogenicity in mice – B6C3F$_1$** (via inhalation)–2 years<br>National Toxicology Program Study TR 385 | 42504101 (1992)<br><br>acceptable/guideline for carcinogenicity study.<br>0, 10, 33 or 100 ppm–6 hrs/day; 5 days/week (0, 11.8, 38.9 or 118 mg/kg/day) | **Local irritation**<br>NOAEL/LOAEL = not reported<br>**Systemic toxicity**<br>NOAEL = 33 ppm (0.1279 mg/l)<br>LOAEL = 100 ppm<br>(0.3876 mg/l), based on mortality (males), neurological signs (abnormal posture, tremors, ataxia, limb paralysis and emaciation) decreased body weight/weight gain and microscopic lesions in the brain, heart, sternum and olfactory epithelium.<br>**No evidence of** |
| Other Genotoxicity Study<br><br>**Genotoxicity: Rat testicular DNA alkaline elution assay** | 43180201 (1994)<br>Acceptable/non-guideline<br>Dose range: 0, 75, 150 or 250 ppm (0, 291, 581 or 969 mg/m$^3$) for 6 hr/day over 5 consecutive days | The test was **positive.** |
| 870.5395<br><br>**Cytogenetic Micro nucleus assay in mice and rats** | 43786501 (1986?)<br>Acceptable/guideline<br>Dose range: 0, 154, 200, 260, 338 or 440 ppm (equivalent to 0, 0.597, 0.776, 1.008, 1.311 or 1.706 mg/L) for 6 hrs/day, 5 days/week for 14 days, or 10 exposures. | The test was **positive.**<br><br>Micro nucleus (MN) induction was evaluated in bone marrow of rats and mice and in peripheral blood of mice. Positive results were at doses which also caused deaths. |
| 870.6200a<br><br>**Acute neurotoxicity screening battery in CD rats** (via inhalation) | 42793601 (1993)<br>acceptable/guideline<br>0, 30, 100 or 350 ppm, for 6 hrs<br>(M: 27, 90 or 314; F: 30, 101, or 354 mg/kg/day). | NOAEL = 100 ppm<br>LOAEL = 350 ppm based on decreased activity and alertness as measured in a functional observation battery examination, decreased motor activity and decreased body temperature in males and females<br>were observed. A slight decrease in hind-limb grip strength in males may have been treatment-related. Effects were transient, and all animals were |

| Table A.2.2: Methyl Bromide Sub-chronic, Chronic and Other Toxicity. | | |
|---|---|---|
| **Guideline No./ Study Type** | **MRID No. (year)/ Classification /Doses** | **Results** |
| 870.6200b<br><br>**Sub-chronic neurotoxicity screening battery in rats** (via inhalation) | 42964301; 43077401 (1993)<br>acceptable/guideline<br>0, 30, 70 or 140 ppm 6 hr/day, 5 days/week –13 weeks (equivalent to males: 0, 19, 45, or 90 mg/kg/day; females: 0, 22, 51, 101 mg/kg/day) | NOAEL = 30 ppm (F)<br>LOAEL = 70 ppm (F) based on decreased body weight and motor activity.<br>NOAEL = 70 ppm (M)<br>LOAEL = 140 ppm (M) based on decreased body weight, increased mortality (2 animals), convulsions (2 animals affected), effects on several FOB parameters and brain histopathology in males. |
| 870.6300<br><br>**Developmental Neurotoxicity Study** | 46665001 (2004)<br>No DER available.<br>Acceptable/non-guideline<br>Doses: 0, 5, 25, or 50 ppm | **Maternal**<br>NOAEL = 50 ppm (HDT)<br>LOAEL = not identified<br><br>**Developmental**<br>NOAEL =5 ppm<br>LOAEL = 25 ppm based on decreased motor activity on PND21 females |
| 870.7485<br><br>**Metabolism and pharmacokinetics** | International Agency for Research on Cancer (IARC) Monographs Vol 41, p198 | Rats received a single gavage dose (preparation of test solution was unspecified) of 24 mg/kg/b.w. $^{14}$C-MeBr. Over a 3-day period, the radioactivity recovered were as follows: carcass (14-17%), expired carbon dioxide (32%), urine (43%), and feces (less than 3%).<br><br>During a 6-hour exposure of rats to 4.75-9874 mg/cu.m $^{14}$C-MeBr vapor, approximately 27-50% of the compound inhaled was absorbed. |
| 870.7800<br><br>**Immunotoxicity Rats** | 48510101<br><br>0, 20, 60 or 120 ppm, via inhalation 6 hours per day for 28 consecutive days<br>Acceptable/Guideline | **Immunotoxicity**<br>**NOAEL:** 120 ppm (the highest dose tested)<br>**LOAEL** not established (>120 ppm)<br><br>**Systemic Toxicity**<br>**NOAEL:** 60 ppm<br>**LOAEL:** 120 ppm, based on treatment related decreases in body weights and body weight gains. |

## A.3 Hazard Identification and Endpoint Selection

## A.4 Executive Summaries

### A.4.1 Subchronic Toxicity

**870.3100 90-Day Oral Toxicity – Rat**
No DER available for study, (MRID 00154564). NOAEL = 2 mg/kg/day based on effects seen at the LOAEL = 10 mg/kg/day, including: slight hyperplasia of the stratified squamous epithelium of the fore stomach. Highest dose tested was 50 mg/kg/day.

**870.3150 4-week oral toxicity – rat**
In a 4-week dietary range finding toxicity study (MRID 43776401), methyl bromide (0.48% a.i. in microencapsulated form) was administered to 15 Crl:CD(BR)SD rats/sex/dose in the diet at dose levels of 0 (negative controls), 0 (untreated microcapsules in diet), 0.1, 10 or 100.0 ppm. Dietary levels were equivalent to 0, 0.009, 0.085, 0.835 or 7.99 mg methyl bromide/kg/day.

At 100 ppm. slightly decreased body weight gain was observed in males (-7% of controls) and females (-13% of controls) due to decreased gain in weeks 1 or 2, along with slightly decreased food consumption. There were no compound related effects on mortality, clinical signs, hematology, clinical chemistry, organ weights or gross/histologic pathology. **The threshold LOEL is 100 ppm (7.99 mg/kg/day), based on slightly decreased body weight gain and food consumption. The NOEL is 10 ppm (0.835 mg/kg/day).**

This range finding study is classified **Supplementary (not upgradable)** because it is additional information submitted to support Guideline 83-l(a) and is not in itself a guideline requirement.

**870.3150 90-Day Oral Toxicity – Dog**
In a subchronic (5- to 7-week) inhalation toxicity study (MRID 43386802), MeBr (tech., 100% a.i.) was administered 7 hours/day, 5 days/week to 4 beagle dogs/sex/dose by whole body exposure at target concentrations of 0, 5, 10/150, 25, 50 or 100 ppm (actual mean concentrations 0, 5.3, 11.0/158.0, 26.0, 53.1 or 102.7 ppm; equivalent to 0, 0.021, 0.043/0.614, 0.101, 0.206 or 0.399 mg/L), as follows:

5 Week Sacrifice: 2 dogs/sex, 0 ppm group and all dogs, 25, 50 and 100 ppm groups, for 5 weeks (total 24 exposures).

7 Week sacrifice - 2 dogs/sex, 0 ppm group and all dogs, 5 ppm group for 7 weeks (total 34 exposures); and all dogs, 10/150 ppm group for 5 weeks at 10 ppm (24 exposures), then at 150 ppm for 6 additional exposures and terminated. In addition to standard evaluations performed in a guideline subchronic study, a neurological examination was performed by a veterinarian after termination of exposures and serum bromide levels were measured weekly.

5 Week sacrifice:
At 5.3, 11, or 26 ppm, there were no treatment-related effects on food consumption,

ophthalmological findings, hematology parameters, organ weights or gross findings (Table 2). However, at 53.1 ppm, 2/8 dogs showed decreased activity during exposure beginning day 14. And, at 102.7 ppm, 3/8 dogs showed decreased activity beginning exposure day 9, and by exposure day 12 and continued until sacrifice all dogs showed decreased activity. One male developed tremors on day 10. In addition, these dogs at 102.7 ppm lost body weight (9% less than controls). Cumulative weight loss of males and females were 0.6 kg and 1.0 kg, respectively. **The systemic toxicity NOAEL for 5 weeks (24 exposures) is 26 ppm. The LOAEL is 53.1 ppm based on decreased activity.**

7 Week sacrifice:
In this study, MeBr at 5 ppm dose demonstrated an unresponsiveness in 1 female dog and unresponsiveness and depressed appearance in another female at the end of 34 exposures. However, these effects are not considered as treatment-related because these effects did not show clear dose-response relationship (similar effects of unresponsiveness and depressed appearance were not observed at higher exposure levels of shorter duration) and were not corroborated with other findings.

No clinical signs of toxicity were observed at 26 ppm. At 53 ppm, decreased activity (lack of interest when approached) was first observed in 2 dogs on day 14. Thereafter, 1 to 4 of the dogs in that group showed decreased activity on most exposure days. At 103 ppm, 3 dogs showed decreased activity on day 9; by day 12, all animals had decreased activity during most of the remainder of the exposure period. One animal (sex not indicated) had tremors on day 10. When exposure of Group III animals (11 ppm) was increased to 158 ppm on exposure day 25, decreased activity was observed in all animals beginning on day 27. All dogs were in poor condition by day 30, including one male that was prostrate and had tremors.

This subchronic toxicity study is classified Acceptable/Non-Guideline (§82-4) and fulfills the intent of the study. A subchronic inhalation study in the dog was not required by the U.S. EPA for reregistration of MeBr; this study was conducted as a range-finding study for a chronic inhalation study in dogs to satisfy CDPR's data requirements.

### A.4.2 Prenatal Developmental Toxicity

**870.3700a Prenatal Developmental Toxicity Study – Rat**
In a developmental toxicity study (MRID 00102990), methyl bromide vapor (99.5%) was administered to female Wistar rats by whole body exposure at concentrations of 0, 20 and 70 ppm:
(1) During entire gestation period (Days 1-19) only,
(2) For 3 weeks prior to insemination, and
(3) For 3 weeks prior to insemination through gestation period; exposure for 7 hrs/day, 5 days/week.

Dams treated at high dose during gestation showed a non-statistically significant decrease in body weight at day 14 of gestation and at termination. Among dams treated at high dose both before and during gestation, statistically significant but small (3.5%) decreases in body weight

were observed between days 1-14 of gestation. These body weights were primarily low because of decreased weight gain that occurred between days 17-21 of pre-gestational treatment. Weight gain as a percent of gestation day 1 weight was similar to that of controls during gestation. In addition, slightly increased incidence of interstitial nephritis at 70 ppm during gestation is not considered significant enough to determine a LOAEL but is considered a possible threshold effect.

NOTE: A preliminary range-finding developmental toxicity study was not performed for this study. However, the rationale for dosing was based on the previous testing of methyl bromide at 66 or 100 ppm (7 hours/day, 5 days/week) in rats. This study showed that 6 months of exposure to 66 ppm was tolerated and that exposure to 100 ppm produced severe pneumonia in some rats but no effects in others. In addition, decreased body weight was observed at 70 and 90 ppm with methyl bromide in a subchronic neurotoxicity study (MRID 43077401; 42964301) and a 2-generation reproduction study in rats (MRID 00160477), respectively.

It is also noted in the previous DER (TXR No. 0014593), the NOAEL for maternal toxicity is 20 ppm and the LOAEL for maternal toxicity is 70 ppm (HDT) based on an increase in the incidence/severity of interstitial nephritis. However, the HIARC determined that slightly increased incidence of interstitial nephritis at 70 ppm during gestation is not considered significant enough to determine a LOAEL but is considered a possible threshold effect (IDARC Report, June 20, 2001).

The NOAEL for maternal toxicity is 70 ppm (HDT). Slightly increased incidence of interstitial nephritis at 70 ppm during gestation is not considered significant enough to determine a LOAEL but is considered a possible threshold effect.

No compound related developmental toxicity was found in this study. The NOAEL is 70 ppm (HDT).

This study is classified as acceptable/non-guideline and satisfies the requirements (§83-3) for a developmental toxicity study in rats.

**870.3700b Prenatal Developmental Toxicity Study – Rabbit**

In a developmental toxicity study (MRID No. 41580401), pregnant New Zealand White rabbits (26 animals/dose) were exposed by whole body inhalation to 0, 20, 40 or 80 ppm MeBr vapor for 6 hr/day on Days 6-16 of gestation. Mating was conducted using artificial insemination. Based on the insemination record the females were inseminated with sperm pooled from several bucks.

Maternal Toxicity

At 80 ppm, clinical signs of maternal toxicity including decreased appetite, lethargy, right side head tilt, slight ataxia and slight lateral recumbency were observed. These signs were mostly observed in three rabbits: #5427, #5428 and #5431. One doe (#5428) in this treatment group delivered on gestation day 27 and it was determined that this early delivery may have been related to the toxicity that this animal was experiencing. In addition, a treatment-related, but not dose-related, decrease in body weight was observed in the maternal animals in the high dose

group. Three animals (# 5427, 5428, and 5431) caused decrease in the mean body weights of the high dose group. The body weight loss of these animals prior to delivering their litters were 604, 464, and 136 g, respectively. No clinical signs of toxicity were present in the lower treatment groups.

Developmental Toxicity

The fetal data indicate an increase in the incidence of agenesis (absence) of the gall bladder in the fetuses of the high dose group (13/159) (8.2%) relative to the control group (2/190) (1.1%). The litter incidences of agenesis of the gall bladder were 5/19 (26.3%) in the high dose group and 1/21 (4.8%) in the control group. The litter incidences of agenesis of the gall bladder in the low- and mid-dose groups were 1/15 (6.7%) and 1/19 (5.3%), respectively. The individual animal data indicate 9 fetuses with missing gall bladder were from 4 does with maternal toxicity in the high dose group. The litter incidences of agenesis was seen in 6 fetuses from one litter (animal # 5427) and 1 fetus each from 3 litters [animal # 5428, 5431 and 5430]. One doe (animal # 5432) with no maternal toxicity had 4 fetuses with missing gall bladder. Two does (animal # 5426 and 5433) with maternal toxicity (lethargy only) had normal fetuses.

In a repeated study, it was confirmed that the observed finding of agenesis of the gall bladder was related to treatment and was not attributed to a particular male used for artificial insemination. The incidence of agenesis of the gall bladder found in this repeat study is similar to the incidence in the main study. The incidence of agenesis of the gall bladder in the fetuses were 4/92 (4.3%) in the high dose group and 1/114 (0.9%) in the control group. The incidence of agenesis of the gall bladder in the litters were 4/14 (28.6%) in the high dose group and 1/16 (6.3%) in the control group. At 80 ppm, the signs of severe maternal toxicity (lethargy, right side head tilt, slight ataxia and slight lateral recumbency) were not observed in this repeat study.

At 80 ppm, the number of fused sternebrae were increased in the high dose group (12.6%) when compared to the control group (0%). In addition, mean fetal body weight was slightly lower (4.4%; non-statistically significant) compared to the control group. Although the nominal fetal weight decrement was not statistically significant, the decrease is consistent with other effects occurring at the high dose.

The data seemed to indicate that the failure of gall bladder development was due to the direct effects of MeBr and it might not be caused by the parental influence.

This study is classified as acceptable/guideline and satisfies the guideline requirement (§83-3) for a developmental toxicity study in rabbits.

### A.4.3 Reproductive Toxicity

#### 8700.3800 Reproduction and Fertility Effects - Rat

In a two-generation reproduction study (MRID 00160477), methyl bromide (purity unspecified) was administered to male and female CD Sprague-Dawley rats (25 rats/sex/dose) by whole body exposure at concentration of 0, 3.0, 30 or 90 ppm as vapor for two successive generations (6 hours/day, 5 days/week). F0 males and females were exposed for 8 weeks prior to mating.

Exposure to F1 and F2 generations was initiated at 29-33 days of age and was continued for 11 weeks. Females were not exposed from Day 21 of gestation to Day 4 of lactation.

At 90 ppm, F0 males showed significantly reduced body weight when compared to controls after the third week of the study. At this dose, significantly reduced absolute brain weights were observed in F0 males and Fl males and females. Significantly increased relative liver weights were evident in high-dose F0 males and females. In addition, decreased pregnancy rate was observed for the F2b generation and decreased pup weights on post-natal day 21 (Fla, F2a, F2b) ranging from 10-20%. Also at 90 ppm, decreased pup survival was observed in the Flb and F2a litters (12-16%).

At 30 ppm, decreased pregnancy rate (23%) was observed for the F2b generation and decreased pup weights on post-natal day 21 (F1a, F2a, F2b) ranging from 10-20%. However, at 30 ppm the reproductive effects were marginal.

The NOAEL for parental/systemic toxicity is 30 ppm and the LOAEL is 90 ppm based on reduced body weight during gestation.

The NOAEL for reproductive toxicity is 3 ppm and the LOAEL is 30 ppm based on reduced pregnancy rates (F2b).

The NOAEL for offspring toxicity is 3 ppm and the LOAEL is 30 ppm based on reduced pup weight on post-natal day 21 (F1a, F2a, F2b) ranging from 10-20%.

This study is classified as Acceptable/Guideline and satisfies the guideline requirements for a multi-generation reproduction study (83-4) in rats.

### A.4.4 Chronic Toxicity/Carcinogenicity

**870.4100b Chronic toxicity dogs (fumigated feed)**

No DER available for study (MRID 43885201). NOAEL/LOAEL > 5 ppm (highest dose tested; equivalent to 0.27 mg/kg/day). This study was conducted to establish a margin of safety for human dietary exposure rather than to determine a LOAEL. This study was Acceptable/Guideline.

**870.4300 Chronic toxicity and carcinogenicity in rats**

In a chronic toxicity/oncogenicity study (MRID 44462501), microencapsulated methyl bromide was administered to 4 groups of male and female Crl:CD®(SD)BR rats for a period of 12 or 24 months (interim and main study, respectively) in the diet at concentrations of 0 (diet control), 0 (placebo control), 0.5, 2.5, 50, or 250 ppm. These concentrations resulted in doses of 0, 0.2, 0.11, 2.20, and 11.10 mg/kg/day in males and 0, 0.03, 0.15, 2.92, and 15.12 mg/kg/day in females for the controls, 0.5, 2.5, 50, 250 ppm groups, respectively. Groups of 50 males and 50 females were designated for the main study and were maintained on the treated food for up to 104 weeks. Groups of 20 males and 20 females were sacrificed at 52 weeks in the diet control, placebo control, 50 ppm group, and the 250 ppm group.

Survival was not affected by the test substance in any of the treated groups compared to either of the control groups. No treatment-related clinical signs or effects on hematology, serum chemistry, urinalysis, or organ weight data were observed. The test article did not produce change in ophthalmoscopic examinations for the treated groups compared to the controls. Macroscopic and microscopic evaluations of organs and tissues at the interim and final sacrifices revealed only normal age-related changes, changes that were observed with equal frequency in the controls, and/or were sporadic and not dose-related. Treatment with methyl bromide did not produce oncogenicity when fed to rats for up to 2 years.

Statistically significant treatment-related effects were observed on body weights, body weight gains, and food consumption in males and females treated with 250 ppm of the test substance during the first 12 to 18 months of the study. Males in the 250 ppm group had decreases of 5.5% in mean body weight compared to the diet control at week 2. by week 14 this decrease was 10% and remained consistently lower through week 70, during the second year of the study these animals gradually regained the weight and were comparable to controls at the end of the study. Females in the 250 ppm group had a decrease of 3.7% in mean body weight compared to the diet control at week 2. by week 14 this decrease was 8.3% and also remained consistently lower through week 57. After week 57 females in the 250 ppm group gained weight gradually and the decreases disappeared by the end of the study (week 104) at which time this group had mean body weight values that were similar to controls. Mean body weight gain was markedly decreased during the first 18-months of the study for animals treated with 250 ppm methyl bromide; decreases of 9-18% and 12-21 % were observed for males. and 7-22% and 11-19% were observed for females when compared to the basal diet and placebo control groups. respectively. Males receiving 250 ppm had decreased food consumption that ranged from 3.7 - 11.5 % for week 71-72, and females at this concentration had decreases of 4.8 - 10.5% for week 54-55 compared to their respective control groups.

**The LOAEL is 250 ppm (11.10 mg/kg/day for males and 15.12mg/kg/day for females), based on decreased body weight, body weight gain, and food consumption in males and females during the first 18 months of the study. The NOAEL is 50 ppm (2.20 mg/kg/day for males and 2.92 mg/kg/day for females).**

**No evidence of carcinogenicity was observed in male or female rats fed Methyl Bromide at dietary concentrations of O.S, 2.SO, SO or 2SO ppm for 104 weeks.** Dosing was adequate based on decreases in body weight, body weight gain, and food consumption in males and females.

This chronic toxicity/carcinogenicity study in the rat is **Acceptable/guideline** and satisfies the guideline requirement for a combined chronic toxicity/carcinogenicity oral study (§83-5) in rats.

**870.4300 Chronic toxicity and carcinogenicity (29-month) in Wistar rats (via inhalation)**

In a chronic toxicity/carcinogenicity study (MRIDs 41213301; 42418301; 44358101) 50 Wistar (Cpb:Wu) rats/sex/dose were exposed to methyl bromide (>98.8% a.i.) by inhalation at 0, 3, 30

or 90 ppm (0, 0.0117, 0.117 or 0.335 mg/L) for 127 weeks (males) or 129 weeks (females). Four additional groups of 10 animals/sex/dose were also included for sacrifice as follows: (a) week 13, clinical chemistry/hematology evaluations; (b) week 53, clinical chemistry/hematology evaluations and gross/microscopic pathology; (c) week 105, gross/microscopic pathology and (d) week 41, behavioral evaluations (males only). A reexamination of nasal cavity microscopic lesions was later conducted by an independent reviewing pathologist and the final diagnosis reached after discussion with the study pathologist (MRID 44359101). (The reexamination was not performed according to
recommended protocol for peer review and therefore the conclusions of this review of the study are based on the results from the original report).

At 3 ppm, statistically significant increases in incidence (but not severity) of basal cell hyperplasia of the nasal cavity were observed at termination (27.0%, males and 31.7%, females, vs. 8.7% and 11.9%, controls, respectively; severity of most lesions very slight). At 30 ppm, severity as well as incidence of nasal lesions were increased at termination (46.9%, males and 40.8%, females; increased percentage of slight or moderate severity lesions). At 90 ppm, decreased survival (at termination, males 30% vs. 16%, controls and females 14% vs. 30%, controls; statistically significant only on a few occasions in each sex), decreased mean body weight (at termination -5% males; significant frequently during study and -12% , females; significant throughout most of study after Week 4), increased incidence of grossly visible hemothorax in animals found dead or sacrificed *in extremis,* and significantly increased incidence of thrombus (43% vs. 10%, controls, males and 33% vs. 8%, females), cartilaginous metaplasia (24% vs. 4%, controls, males) and moderate to severe myocardial degeneration (73% vs. 41%, controls, females; not significant in males - 84% vs. 65%) were observed. Irritation of the esophagus and forestomach may have been related to inadvertent ingestion of test material (e.g., during grooming) - in males, increases in hyperkeratosis of the esophagus (67% vs. 39%, controls; statistically significant) and stomach (52% vs. 30%, controls; not significant) were observed. There were no treatment-related effects on clinical signs, hematology, clinical chemistries, urinalysis parameters or behavioral parameters in males.

**The LOAEL for local respiratory irritation is 3 ppm (0.0117 mg/L), based on increased incidence of basal cell hyperplasia of the nasal cavity in both sexes. The NOAEL for local respiratory irritation is < 3 ppm. The LOAEL for systemic toxicity** is **90 ppm (0.335 mg/L), based on increased mortality, decreased body weight and relative brain weight, hemothorax, increased incidence of thrombus, cartilaginous metaplasia, myocardial degeneration and irritation of the esophagus and forestomach. The systemic toxicity NOAEL is 30 ppm (0.117 mg/L).**

There were no increases in the incidence of neoplastic lesions attributed to exposure to methyl bromide in males or females.

This chronic toxicity/carcinogenicity study is classified **Guideline-Acceptable** for 83-2(a) carcinogenicity study and satisfies the guideline requirement for an inhalation carcinogenicity study in the rodent. This study is classified **Guideline-Acceptable** for 83-l(a), chronic toxicity study in rat, despite several study deficiencies (see "Discussion" section of this review for

rationale). [At this time, a chronic toxicity inhalation study in the rat is not required to support reregistration of methyl bromide (a chronic oral study was required instead). However, this study is the basis for the Agency RfC for methyl bromide].

**870.4300 Chronic toxicity and carcinogenicity in mice – B6C3F1 (2 years, via inhalation)**

No DER available (MRID 42504101). This study was conducted by the National Toxicology Program (Study TR 385).

**The LOAEL is 100 ppm (0.3876 mg/L), based on mortality (males), neurological signs (abnormal posture, tremors, ataxia, limb paralysis and emaciation), decreased body weight/weight gain and microscopic lesions in the brain, heart, sternum and olfactory epithelium.**

No evidence of carcinogenicity.

**A.4.6 Mutagenicity**

**870 – Other Genotoxic Study Genotoxicity: Rat testicular DNA Alkaline Elusion Assay**

In a testicular DNA alkaline elution assay study (MRID 43180201), male Fischer 344 rats were exposed in vivo by inhalation to methyl bromide vapor at concentrations of 0, 75, 150, or 250 ppm (0, 291, 581 or 969 mg/m$^3$) for 6 hours/day over 5 consecutive days. Negative controls were exposed only to air. Positive controls were given intraperitoneal injections of 50 mg/kg methylmethane sulfonate (MMS) in 2 mL PBS/kg; vehicle controls received only saline injections. Animals exposed to methyl bromide or air were sacrificed at 1 hour and at 24 hours post-exposure. Positive and vehicle control animals were sacrificed 2 hours after injection.

At 250 ppm, the elution rate of testicular DNA was statistically significantly increased (about 4X faster than air controls). Significant toxicity was also observed at this dose, including mortality (2), decreased body weight and neurotoxicity (ataxia, lethargy, spasms, salivation). Less severe toxicity was also observed at 150 ppm, but no mortality occurred. **Methyl bromide demonstrated genotoxic potential in germ cell (testicular) DNA following repeated short-term inhalation exposure of male rats at 250 ppm (highest dose tested).**

This study is classified as Acceptable and satisfies the guideline requirement for an in vivo exposure alkaline elution assay of rodent testicular DNA (84-4). The rodent testicular DNA alkaline elution study was required as a "second tier" of mutagenicity tests because methyl bromide is positive in other mutagenicity tests.

**870.5395 Cytogenic micronucleus assay in mice and rats**

In a rodent micronucleus induction study (MRID 43786501); 10/sex/dose BDFl mice and F344 rats were exposed in vivo by inhalation to methyl bromide vapor at concentrations of 0, 154, 200, 260, 338 or 440 ppm (equivalent to 0, 0.597, 0.776, 1.008, 1.311 or 1.706 mg/L) for 6 hours/day, 5 days/week for 14 days, or 10 exposures. Micronucleus (MN) induction was evaluated in bone marrow of rats and mice and in peripheral blood of mice.

In mice, significantly increased incidence of MN in bone marrow polychromatic erythrocytes (PCEs) was observed in males at 154 and 200 ppm (2.6- and 10.5-fold, respectively) and in females at 154 ppm (5.8-fold); smaller increases in MN frequency were observed in normochromatic erythrocytes (NCEs). Peripheral blood showed significant increases at 200 ppm in males (32.6-fold) and 154 ppm in females (2.6-fold); MN in NCE showed small increases. Mice exposed to ≥260 ppm were not assayed due to excessive mortality. In rats, MN in PCEs of bone marrow were increased at 338 ppm in males (13.6-fold; statistically significant) and in females at 260 and 338 ppm (33-fold; not statistically significant). Rats exposed to 440 ppm were not assayed due to excessive mortality.

**This study is classified as Acceptable and fulfills the guideline requirement for mutagenicity testing (chromosomal aberrations; 84-2b) of methyl bromide. Several deficiencies related to reporting of the methods and results (see Discussion section of DER) did not preclude acceptance of the study or the conclusion that a positive effect on the micronucleus frequency was observed in two species.**

Outstanding mutagenicity data: At this time, the only outstanding mutagenicity data requirement is a mouse heritable locus assay. This study requirement was triggered by a positive testicular DNA alkaline elution study in rats following inhalation exposure to methyl bromide (MRID 43180201; reviewed in HED doc. no. 011065). The micronucleus study reviewed in this document satisfies the guideline requirement for 84-2b, chromosomal aberrations.

### A.4.7 Neurotoxicity

#### 870.6200a Acute neurotoxicity screening battery in CD rats

In an acute neurotoxicity screening battery in CD rats (MRID 42793601), methyl bromide vapor was administered by inhalation at 0, 30, 100 or 350 ppm for 6 hours to CD® rats, which resulted in a LEL of 350 ppm (NOEL = 100 ppm), based on decreased activity and alertness as measured by functional observation battery parameters for neurobehavioral effects, decreased motor activity and decreased body temperature in males and females. A slight decrease in hind-limb grip strength in males may have been treatment-related. All animals were assessed to be normal by 1 week post-exposure.

The study was Acceptable/Guideline.

#### 870.6200b Subchronic neurotoxicity screening battery in rats (via inhalation)

In a 13-week neurotoxicity study (MRID No. 42964301; 43077401), CD rats (15 rats/sex/dose) were exposed by whole body inhalation to methyl bromide vapor (>99% a.i.) at levels of 0, 30, 70 or 140 ppm for 6 hours/day, 5 days/week (equivalent to male: 0, 19, 45, or 95 mg/kg/day; females: 0, 22, 51, or 101 mg/kg/day). Functional observation battery (FOB) and motor activity measurements were conducted at pre-test and weeks 4, 8 and 13 of the study.

Males and females showed different responses to methyl bromide in this study. In females at 30 ppm, methyl bromide did not produce treatment-related effects on mortality, body weight, FOB or motor activity. At 70 ppm, females had significantly decreased body weight/body weight gain

(-7%/-23%), decreased total motor activity (-37%) and slightly reduced absolute brain weight (-5%). At 140 ppm, females had further decreases in mean body weight/body weight gain (-13%/-44%) and absolute brain weight (-10%). Motor activity decrease (-34%) was comparable to 70 ppm females. Number of rears was decreased (30% of controls) and ataxia was observed in 1-3 animals during FOB sessions. Increased inactivity was also noted. Slight nasal cavity epithelium dysplasia was observed in 3/6 females at 140 ppm.

In males at 30 and 70 ppm, methyl bromide did not produce treatment-related effects on mortality, body weight, FOB or motor activity. However, at 140 ppm, males had decreased body weight/body weight gain (-13%/-36%), mortality (2 animals), convulsions (2 animals), increased landing foot splay (+48%), increased incidence of uncoordinated air righting (8 vs. 4 control animals), possible slight decrease in fore- and hindlimb grip strength (-20%) were observed. Brain histopathology (2/6 ma1es) was observed in animals that developed convulsions (one survived, one died during study). Slight nasal cavity epithelium dysplasia was also observed in 3/6 males at 140 ppm.

**For females, the NOAEL is 30 ppm (22 mg/kg/day) and the LOAEL is 70 ppm (51 mg/kg/day) based on decreased body weight and motor activity.**

**For males, the NOAEL is 70 ppm (45 mg/kg/day). The LOAEL is 140 ppm (90 mg/kg/day) in males based on decreased body weight, increased mortality (2 animals), convulsions (2 animals affected), effects on several FOB parameters and brain histopathology in males.**

This study is considered as scientifically acceptable for a subchronic neurotoxicity study in rats. However, according to the record the positive control data were not submitted.

**870.6300 Developmental Neurotoxicity Study in rats**

In a developmental neurotoxicity study (MRID 46665001), methyl bromide (99.9% a.i., lot #4010PI136V) was administered by whole-body inhalation to 24 mated female Crl:CD®(SD)IGS BR rats/group at nominal concentrations of 0, 5, 25, or 50 ppm from gestation day (GD) 6-20 and females with selected pups from their litter were exposed on lactation days (LDs) 5-20. A Functional Observational Battery (FOB) was conducted on 12 dams/group on GDs 6 and 13 and LDs 10 and 21. On PND 4, litters were standardized to eight pups; sexes were represented as equally as possible. Pups were weaned from their dam on PND 21 with no further exposure to the test material. Dams were sacrificed after weaning. A subset of 20 pups/sex/group was assigned to FOB, acoustic startle response, locomotor activity and learning and memory testing (PND 62). From this subset, 15 pups/sex/group were selected for neurological, morphometric, and brain weight evaluations on PND 72. A second subset of 20 pups/sex/group was selected for learning and memory (PND 26) and a third subset of 15 pups/sex/group was selected for neuropathological, morphometric, and brain weight evaluations on PND 21. Pup physical development was evaluated by body weight. The age of sexual masturation (vaginal opening in females and preputial separation in males) was assessed.

One control female was sacrificed on GD 23 because of dystocia. All remaining animals survived to scheduled sacrifice. No clinical signs of toxicity were observed during the daily examinations, midway through the exposure, or 1-2 hours post-exposure. No treatment-related changes were noted during the FOB on any testing day. Maternal body weight and food

consumption were not affected by treatment at any time during the study. No treatment-related effects were observed in reproductive parameters and gross necropsy was unremarkable.

No treatment-related effect on the mean number of pups born, mean live litter size, percentage of males per litter, or pup survival was observed. No treatment-related abnormalities were noted post-weaning during weekly physical examination.

Pup body weights were similar between the treated and control groups on PNDs 1-11. On PNDs 13-21, mean body weight was significantly decreased in the high-concentration female offspring (90-92% of control value) and was slightly (n.s.) or significantly decreased in the high-concentration male offspring (92-94% of control value). Mean body weight gain was significantly decreased in the high-concentration males (83% of control value) during the PND 13-17 interval. The mid-concentration males and females also had reduced body weight gain (87-88% of control value) during the PND 13-17 interval. Post-weaning, absolute body weight of the high-concentration group was significantly less than that of controls through PND 56 for males (92-95% of controls) and PND 42 for females (91-95% of controls. Thereafter until study termination on PND72, body weight was comparable between the treated and control groups in both sexes. Weight gain by the high-concentration males and females was significantly less than that of the controls during the PND 28-35 interval. Body weight gain was similar between the treated and control groups for all intervals after PND 35. The average age of onset of preputial separation in males was significantly delayed by 1.4 days in the high-concentration group compared with controls. The average age of onset of vaginal opening for high-concentration females was significantly delayed by 1.6 days compared with controls. Body weight in the treated males and females was similar to that of the control group at the time of acquisition.

No treatment-related FOB changes were observed in males or females on any testing day. Auditory startle response and learning and memory were not affected by treatment. No statistically significant differences in total activity or ambulatory activity was found between the treated and control groups on any testing day. However, on PND 21 total and ambulatory activities of high-concentration males were 60% and 54%, respectively, of the control levels, and for high-concentration females were 64% and 60%, respectively, of the control levels. Mid-concentration females had total and ambulatory activities 76% and 68%, respectively, of the control levels on PND 21. In these treated groups, the level of activity was reduced throughout the testing interval although the pattern of habituation was not affected.

Brain weight, gross necropsy, and microscopic findings were similar between the treated and control groups. On PND 21, high-concentration males had significantly smaller brain width (14.7 mm vs 15.1 mm for controls). No other treatment-related differences in any brain morphometric measurement were noted between treated and control groups for either sex at any time point.

**The maternal systemic and neurotoxicity LOAEL for methyl bromide in rats is not identified and the maternal NOAEL is ≥50 ppm.**

**The offspring systemic and neurotoxicity LOAEL for methyl bromide in rats is 25 ppm based on decreased body weight gain in males and females and decreased motor activity in females. The offspring NOAEL is 5 ppm.**

This study is classified as **Acceptable/Guideline** and satisfies the guideline requirement for a developmental neurotoxicity study in rats (OPPTS 870.6300, §83-6); OECD 426. It is noted that adequate positive control studies have been submitted to demonstrate proficiency of the testing facility only for FOB, motor activity, and auditory startle tests in young adult rats. Adequate positive control data have not been submitted for learning and memory or neuropathology and morphometrics.

### A.4.8 Metabolism

**870.7485 Metabolism and Pharmacokinetics**

No DER available. Information on metabolism and pharmacokinetics comes from the International Agency for Research on Cancer (IARC) Monographs, Volume 41, page 198. Rats received a single gavage dose (preparation of test solution unspecified) of 24 mg/kg/b.w. $^{14}$C-MeBr. Over a 3-day period, the radioactivity recovered were as follows: carcass (14-17%), expired carbon dioxide (32%), urine (43%), and feces (less than 3%). During a 6-hour exposure of rats to 4.75-9874 mg/m$^3$ $^{14}$C-MeBr vapor, approximately 27-50% of the compound inhaled was absorbed.

### A.4.9 Immunotoxicity

**870.7800 Immunotoxicity study in rats**

In an immunotoxicity study (MRID 48510101), methyl bromide (99.9%, Batch numbers 0200PK156 and 0200PL306) was administered to female CD(SD) rats (10/group) via whole-body inhalation at dose levels of 0, 20, 60 or 120 ppm, 6 hours per day for 28 consecutive days. Positive control group consisted of 10 females received cyclophosphamide (CPH) 50 mg/kg/day (dose volume 10 ml/kg) by intraperitoneal injection on Days 24–27. On Day 24, animals in all groups received a single intravenous injection (IV) of the antigen, 2 x$10^8$ sheep red blood cells (SRBC) in 0.5 ml of Earle's Balanced Salt Solution (EBSS) with 15 mM HEPES. On Day 28, all animals were killed by carbon dioxide inhalation; spleens were harvested and used for assessment of immunotoxicity using a splenic antibody-forming cell (AFC) assay.

The animals were monitored for mortality and treatment related symptoms twice daily. Detailed physical examinations were performed weekly. Body weights were recorded twice weekly; food and water consumption were recorded weekly. A complete gross necropsy was done on all animals; spleen and thymus were weighed.

One animal in the 120 ppm group was euthanized on study Day 27 due to treatment related adverse effects (hypoactivity, hyper-reactivity to touch, twitching, continuous convulsions and impaired use of the left and right forelimbs and hindlimbs). There were no differences in food and water consumption. Animals in the 120 ppm group had decreases in body weights and body weight gains throughout the study with statistical significance for the study Day 24 -28 (12.1% lower than the vehicle control group; $p<0.05$). There were no effect on spleen and thymus

(absolute and relative weights) at any dose level. The positive control group showed lower body weight and body weight gain during study Day 24-28 when compared to the vehicle control group ($p<0.05$), and statistically significant decrease in spleen and thymus size and weights when compared to the vehicle control group ($p<0.05$).

**The systemic toxicity NOAEL is 60 ppm; the LOAEL was 120 ppm, based on treatment related decreases in body weights and body weight gains.**

There were no treatment related effects on spleen cell numbers and anti-SRBC antibody response in any of the treated group. A high inter-individual variability was noted in all the treatment groups as well as in the control group. Evaluation of individual animal data of this study did not show any trend or distribution that would demonstrate a significant suppression of anti-SRBC AFC response. Positive control group had statistically significant decrease in mean spleen cell number, mean specific activity, and mean total spleen activity ($p\leq0.01$). This confirmed the ability of the test system to detect immunosuppressive effects and confirmed the validity of the study design.

The Natural Killer (NK) cells activity was not evaluated. The toxicology database for methyl bromide does not reveal any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. Under HED guidance, a NK cells activity assay is not required at this time.

**The immunotoxicity NOAEL by inhalation route is 120 ppm (the highest dose tested). The LOAEL was not established (>120 ppm).**

This immunotoxicity study is classified **acceptable/guideline** and satisfies the guideline requirement for an immunotoxicity study (OPPTS 870.7800) in rats.

## Appendix B. Review of Human Research

The previous quantitative occupational human health risk assessments for methyl bromide relied in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their exposure. Appendices T, V, W, and X of D316326 (S. Kinard, D316326, 06/13/2005) lists the monitoring data used in the occupational handler assessments for methyl bromide. The following MRIDs were incorporated into the occupational post-application assessment: MRID 48602701. Additional information on the review of human research used to complete the risk assessment is provided in the occupational handler assessment. There is no regulatory barrier to continued reliance on these studies, and all applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied.

## Appendix C. International Residue Limit Status Sheet.

| Table C.1. Summary of U.S. and International Tolerances and Maximum Residue Limits. | | | | | |
|---|---|---|---|---|---|
| *Residue Definition*: | | | | | |
| US | Canada | | | Mexico[2] | Codex |
| 40 CFR §180.124: General: methyl bromide | None | | | | Residue definition not listed |
| Commodity[1] | *Tolerance (ppm)/Maximum Residue Limit (mg/kg)* | | | | |
| | US Established | HED-Recommended | Canada | Mexico[2] | Codex[3] |
| | | | | | |
| Bread and other cooked cereal products | | | | | 0.01 (*)[4] |
| Cacao beans | | 5.0 | | | 5 Po[5] |
| **Cereal grains** | | 8.0 | | | 5 Po[5] |
| Cocoa products | | | | | 0.01 (*) Po[4] |
| Dried fruits | | | | | 0.01(*) Po[4]<br>2 Po[5] |
| Milled cereals products | | | | | 0.01 (*) Po[4]<br>1 Po[5] |
| Peanut | | 10 | | | 0.01 (*) Po[4]<br>10 Po[5] |
| **Tree nuts** | | 150 | | | 0.01 (*) Po[4]<br>10 Po[5] |
| Berry and small fruit, group 13-07 | | 5.0 | | | |
| Coffee, green bean | | 150 | | | |
| Cola | | 150 | | | |
| Cucurbit, seed | | 150 | | | |
| Fruit, citrus, group 10-10 | | 2.0 | | | |
| Fruit, pome, group 11-10 | | 8.0 | | | |
| Fruit, stone, group 12-12 | | 5.0 | | | |
| Herb and spice, group 19 | | 35 | | | |
| Hibiscus, seed | | 150 | | | |
| Ivy gourd | | 5.0 | | | |
| Kaffir lime, leaves | | 0.50 | | | |
| Kenaf, seed | | 150 | | | |
| Oilseed group 20 | | 150 | | | |
| Peppermint, fresh leaves | | 35 | | | |
| Pointed gourd | | 5.0 | | | |
| Spearmint, fresh leaves | | 35 | | | |
| Tropical and subtropical fruits, edible peel, group 23 | | 10 | | | |
| Tropical and subtropical fruits, inedible peel, group 24 | | 5.0 | | | |
| Vegetable, brassica, head and stem, group 5-16 | | 1.0 | | | |
| Vegetable, bulb, group 3-07 | | 2.0 | | | |
| Vegetable, cucurbit, group 9 | | 5.0 | | | |

| **Table C.1. Summary of U.S. and International Tolerances and Maximum Residue Limits.** | | | | | |
|---|---|---|---|---|---|
| *Residue Definition*: | | | | | |
| US | Canada | | | Mexico[2] | Codex |
| 40 CFR §180.124: General: methyl bromide | None | | | | Residue definition not listed |
| Commodity[1] | *Tolerance (ppm)/Maximum Residue Limit (mg/kg)* | | | | |
| | US Established | HED-Recommended | Canada | Mexico[2] | Codex[3] |
| Vegetable, foliage of legume, group 7 | | 0.50 | | | |
| Vegetable, fruiting, group 8-10 | | 7.0 | | | |
| Vegetable, leafy, group 4-16 | | 0.50 | | | |
| Vegetable, leaves of root and tuber, group 2 | | 0.50 | | | |
| Vegetable, legume, group 6 | | 3.0 | | | |
| Vegetable, root and tuber, group 1 | | 3.0 | | | |
| Vegetable, stalk, stem and leaf petiole, group 22 | | 0.50 | | | |
| | | | | | |
| | | | | | |
| Completed using Global MRL. 05-NOV-2018 | | | | | |

[1] Commodities with different tolerance levels between the US, Canada, Mexico, and Codex are **bolded**.
[2] Mexico adopts U.S. tolerances and/or Codex MRLs for its export purposes.
[3] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat.
[4] = To apply to commodity at point of retail sale or when offered for consumption.
[5] = To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation.

## Appendix D. Occupational Handler Summary

### Occupational Handler Risk Estimates for Soil Uses of Methyl Bromide:

The summary below has been excerpted from two recently completed human health risk assessments for methyl bromide (J. Dawson, D337288, 04/10/2007 and J. Dawson, D350818, 06/02/2008)

**Table D.1. Methyl Bromide Worker Exposure Associated with Pre-Plant Agricultural Field Fumigation (from D337288)**

| Scenario | N | Acute Risk Summary | | | | Short/Intermediate-term Risk Summary | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Maximum Monitored [MeBr] (ppm) | Acute MOE With No Respiratory Protection | Maximum Monitored [mebr] With Air Purifying Respirator (PF10) (ppm) | Acute MOE With Air Purifying Respirator (PF10) | Average Monitored [mebr] (ppm) | Short-term MOE With No Respiratory Protection | Maximum Monitored [MeBr] With Air Purifying Respirator (PF10) (ppm) | Short-term MOE With Air Purifying Respirator (PF10) |
| 1st Tractor Driver | 82 | 38.1 | <1 | 3.81 | 8 | 2.5 | 2 | 0.25 | 18 |
| Co Pilot | 92 | 47.4 | <1 | 4.74 | 6 | 4.1 | 1 | 0.41 | 11 |
| 2nd Tractor Driver | 3 | 0.02 | 1500.0 | 0.002 | 15000 | 0.015 | 293 | 0.0015 | 2933 |
| Shovelman | 67 | 12.4 | 2 | 1.24 | 24 | 0.95 | 5 | 0.095 | 46 |
| Irrigation | 20 | 20.4 | 2 | 2.04 | 15 | 1.2 | 4 | 0.12 | 37 |
| Tarp Cutter | 7 | 4.8 | 6 | 0.48 | 63 | 0.67 | 7 | 0.067 | 66 |
| Tarp Remover | 22 | 1.3 | 23 | 0.13 | 231 | 0.48 | 9 | 0.048 | 92 |

Total number of monitoring events used for this analysis = 293
MOE = Margin of Exposure, Level of concern is MOE<30
Acute MOE = (30 ppm HEC/maximum [MeBr])
Short/Intermediate-term MOE = (4.4 ppm HEC/mean [MeBr])
As a result of the risk estimates of concern identified, OPP implemented a series of label changes and mitigation measures since 2008 that addressed worker exposure concerns.

### Occupational Risks Updates From 2007 Risk Assessment (D337288)

Table D.2 presents a comparison of the risks calculated using the Agency approach (reported in D337288) compared with risk estimates based on the comments of the Methyl Bromide Industry Panel (MBIP). [Note: For more information refer to: http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPP-2005-0123-0444.1 .]

The MBIP was the key commenter on the values used in the worker exposure and risk assessment. Their comments suggested that the Agency remove certain data because they do not represent more current cultural methods and in some cases MBIP identified double counting of certain data points by the Agency. The major difference between the two datasets is how the data relates to current practices as noted by MBIP. MBIP also suggested that the Agency consider using the 99th percentile of the upper confidence limit and the geometric means instead of maximum and mean values, as used by the Agency, for regulation so these values are presented here as well for comparative purposes (i.e., note target MOE for all scenarios is 30 as in D337288).

As illustrated in Table D.2., similar risks were calculated, and the conclusion is similar between the Agency-based estimates and the MBIP-based comparable values (i.e., using the MBIP proposed maximum and arithmetic mean values). If the MBIP recommended values are used (i.e., based on the different statistics of 99th tile UCL and geometric mean), then respirators are also required for some tasks to alleviate concerns for acute and short-term exposures. However, the use of such statistical methods is circumspect because the data were collected under such a wide variety of conditions and any number of factors could have impacted exposure. Even given that this uncertainty exists in the data, regardless of which statistic that is selected for regulation, exposure levels indicate that inhalation exposures to methyl bromide can occur that exceed the Agency's LOC.

**Table D.2. Methyl Bromide Occupational Risk Summary and Comparison With MBIP Phase 5 Comments (from D350818).**

| | Agency-Based Estimates | | | MBIP-Based Estimates | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Comparable | | Recommended | |
| Task | N | [Max] (ppm) | [Mean] (ppm) | N | [Max] (ppm) | [Mean] (ppm) | [99% UCI] (ppm) | [Geo. Mean] (ppm) |
| 1st Tractor Driver | 82 | 38.10 | 2.50 | 46 | 4.72 | 0.75 | 1.14 | 0.33 |
| Co Pilot | 92 | 47.40 | 4.10 | 49 | 29.17 | 2.70 | 4.62 | 0.72 |
| 2nd Tractor Driver | 3 | 0.02 | 0.02 | 5 | 0.29 | 0.11 | 0.38 | 0.05 |
| Shovelman | 67 | 12.40 | 0.95 | 35 | 2.94 | 0.40 | 0.64 | 0.22 |
| Irrigation | 20 | 20.40 | 1.20 | 21 | 20.40 | 1.12 | 3.87 | 0.12 |
| Tarp Cutter | 7 | 4.80 | 0.67 | 4 | 0.43 | 0.16 | 0.70 | 0.08 |
| Tarp Remover | 22 | 1.30 | 0.48 | 20 | 3.05 | 0.48 | 1.10 | 0.06 |
| MOEs Without Respiratory Protection | | | | | | | | |
| 1st Tractor Driver | N/A | 0.8 | 1.8 | N/A | 6.4 | 5.9 | 26.3 | 13.5 |
| Co Pilot | N/A | 0.6 | 1.1 | N/A | 1.0 | 1.6 | 6.5 | 6.1 |
| 2nd Tractor Driver | N/A | 1500.0 | 293.3 | N/A | 103.4 | 40.0 | 78.1 | 97.8 |
| Shovelman | N/A | 2.4 | 4.6 | N/A | 10.2 | 11.0 | 47.1 | 20.4 |
| Irrigation | N/A | 1.5 | 3.7 | N/A | 1.5 | 3.9 | 7.8 | 36.4 |
| Tarp Cutter | N/A | 6.3 | 6.6 | N/A | 69.8 | 27.5 | 42.7 | 53.7 |
| Tarp Remover | N/A | 23.1 | 9.2 | N/A | 9.8 | 9.2 | 27.2 | 74.6 |
| MOEs With PF 10 Air Purifying Respirators | | | | | | | | |
| 1st Tractor Driver | N/A | 7.9 | 17.6 | N/A | 63.6 | 58.7 | 263.2 | 134.6 |
| Co Pilot | N/A | 6.3 | 10.7 | N/A | 10.3 | 16.3 | 65.0 | 60.8 |
| 2nd Tractor Driver | N/A | 15000.0 | 2933.3 | N/A | 1034.5 | 400.0 | 781.3 | 977.8 |

| Table D.2. Methyl Bromide Occupational Risk Summary and Comparison With MBIP Phase 5 Comments (from D350818). | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Agency-Based Estimates | | | MBIP-Based Estimates | | | | |
| | | | | | Comparable | | Recommended | |
| Task | N | [Max] (ppm) | [Mean] (ppm) | N | [Max] (ppm) | [Mean] (ppm) | [99% UCI] (ppm) | [Geo. Mean] (ppm) |
| Shovelman | N/A | 24.2 | 46.3 | N/A | 102.0 | 110.0 | 471.0 | 203.7 |
| Irrigation | N/A | 14.7 | 36.7 | N/A | 14.7 | 39.3 | 77.6 | 363.6 |
| Tarp Cutter | N/A | 62.5 | 65.7 | N/A | 697.7 | 275.0 | 427.4 | 536.6 |
| Tarp Remover | N/A | 230.8 | 91.7 | N/A | 98.4 | 91.7 | 272.2 | 745.8 |
| PF-10 APR Respirator Use Required To Achieve Target Levels | | | | | | | | |
| 1st Tractor Driver | N/A | Yes | Yes | N/A | Yes | Yes | Yes | Yes |
| Co Pilot | N/A | Yes | Yes | N/A | Yes | Yes | Yes | Yes |
| 2nd Tractor Driver | N/A | No | No | N/A | No | No | No | No |
| Shovelman | N/A | Yes | Yes | N/A | Yes | Yes | No | Yes |
| Irrigation | N/A | Yes | Yes | N/A | Yes | Yes | Yes | No |
| Tarp Cutter | N/A | Yes | Yes | N/A | No | Yes | No | No |
| Tarp Remover | N/A | Yes | Yes | N/A | Yes | Yes | Yes | No |

It should also be noted that the Agency has been involved for the last several years in a project with the Agricultural Handlers Exposure Task Force (AHETF). This project is important to consider in this context because it entails designing a multi-year complex field research program where the goal is to develop of series of exposure estimates for those involved in pesticide applications (See http://www.exposuretf.com/). As part of the evolution of this project, there have been significant discussions related to statistical issues pertaining to how individuals and exposure scenarios are selected for the research and how monitoring events from those individuals can be used to represent the populations as a whole. For more information please refer to the following:

http://www.epa.gov/scipoly/sap/meetings/2007/january/january2007finalmeetingminutes.pdf

http://www.epa.gov/OSA/hsrb/jun-27-29-2007-public-meeting.htm

http://www.epa.gov/OSA/hsrb/apr-18-20-2007-public-meeting.htm

Given the above scientific and statistical considerations related to the interpretation of the current assessment, the fact that application operations are evolving in the industry because of the phase-out of methyl bromide, moves toward other chemistries as possible replacements, and risks that generally indicate respiratory protection is required, a risk mitigation approach that allows for flexibility by users is being considered. This proposal relies on several key elements to ensure workers are not exposed to levels of methyl bromide that could be of concern. Some of the key elements include: the use of chloropicrin as a warning agent, the use of chemical-specific monitoring during actual applications to ensure exposures are not exceeded, fit testing and medical clearance for individuals who use respirators, limited use of respirators only when indicated to alleviate concerns about heat stress issues and to eliminate as much actuarial risks

from equipment dangers (and other factors) because of the limited communication capability afforded by respirators. Another requirement is that a respirator would be available to anyone who wants to wear it at all times rather than only when certain action levels are met. Also, if measured air concentrations are too high, operations would be required to cease until air concentrations subside and fumigators would also be required to verify their equipment is functioning properly.

One issue that has not been scientifically explored previously is how effective chloropicrin is as a potential warning agent. The available emissions data, represented by profiles of intensity over time developed by plotting hourly flux estimates or, in the case of methyl bromide, a flux profile based on several studies worth of hourly flux estimates, indicates that the shape of the emission profiles are essentially similar for chloropicrin and methyl bromide (Figures 1 and 2). Particularly, the timing of the peak emissions after application and the relative decline rates observed in the emission profile are similar. Figures 1 and 2 also indicate that methyl bromide and chloropicrin emissions were within an order of magnitude of each other in most instances when comparable application rates were considered. It should be noted that many factors influence emissions and the data presented in Figures 1 and 2 represent a wide range of field conditions, preparations, application equipment, and application rates. It should be noted that in Figures 1 and 2, the chloropicrin emission curves are not based on "warning agent" levels (i.e., 2% chloropicrin relative to methyl bromide has been used historically), but are based on applications of 100 percent chloropicrin at varied application rates. In summary, these results should be considered an indication that under normal application situations at high levels of chloropicrin relative to methyl bromide, that chloropicrin will be emitted from treated fields in a manner similar to methyl bromide. At lower "warning agent" levels, determining the relative emission rates is more uncertain because no data are available that reflect such situations.

**Fig. 1: Normalized Fumigant Flux Rates (100 lb ai/A Effective Broadcast Rate) Tarped Broadcast (Flat Fume) Applications**

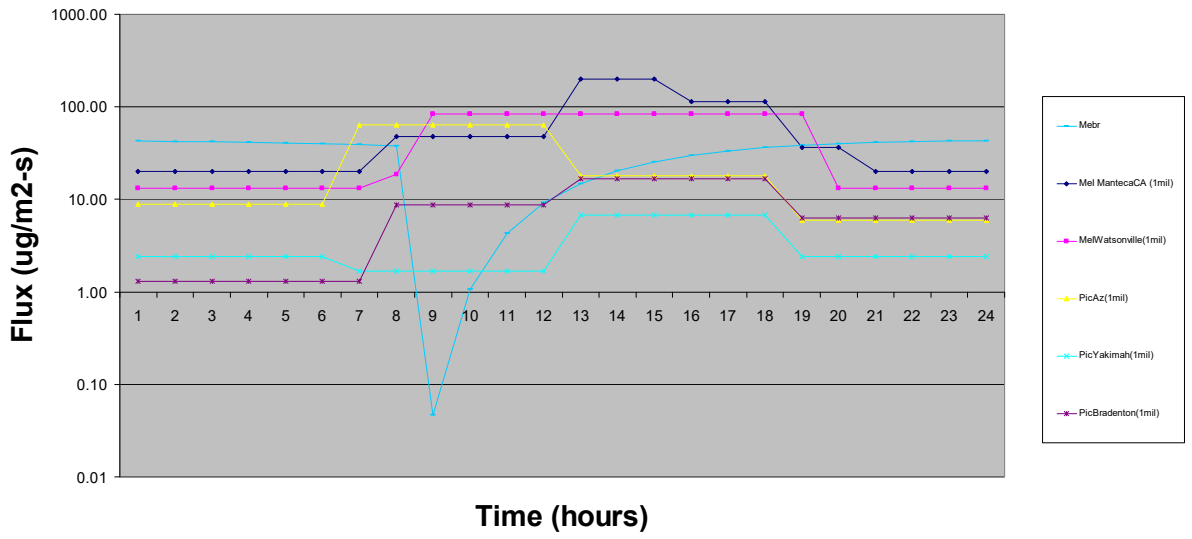
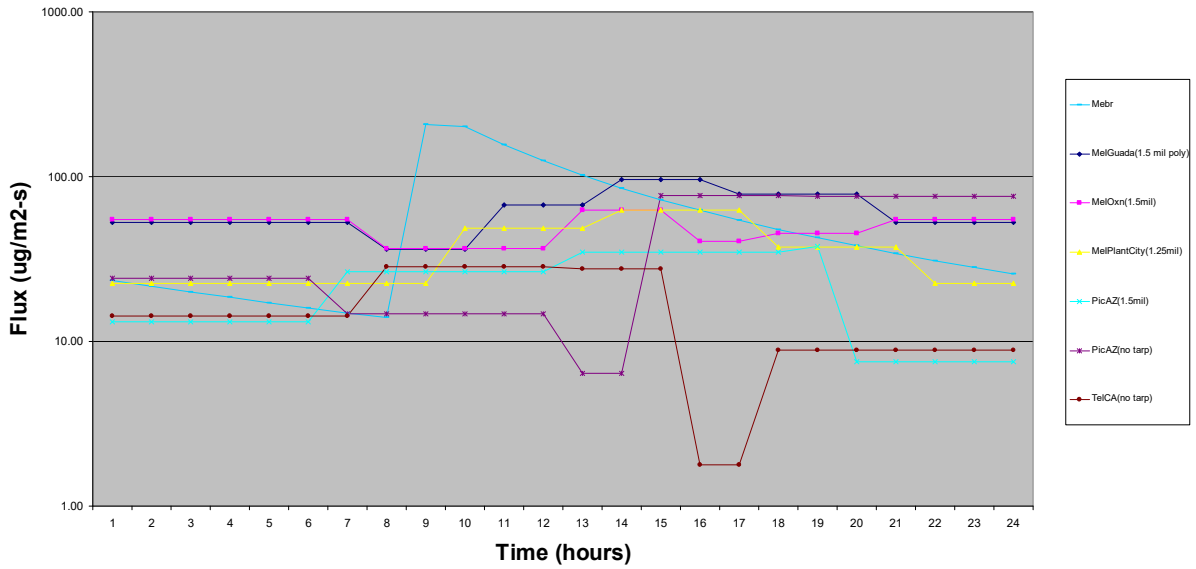


**Fig. 2: Normalized Fumigant Flux Rates (100 lb ai/A Effective Broadcast Rate) Tarped & Untarped Raised Bed Applications**




Available worker exposure data were also evaluated in this analysis to determine whether chloropicrin levels also mirror methyl bromide concentrations as noted above. Specifically, four studies were identified where chloropicrin levels and methyl bromide levels were simultaneously quantified. All of these studies were conducted by the California Department of Pesticide Regulation by Maddy *et al* and are reported, respectively, as HS-1183, HS-1175, HS-1076, and HS-1061. All of these studies were conducted between 1983 and 1984. HS-1183 collected ambient air samples, while HS-1175 collected worker exposure samples for tractor drivers and co-pilots. Applications were made at three sites, but sample breakthrough occurred at the third site so reliable data were only collected from the first two sites. At these sites, the applications were shallow shank at an application rate of 275 lb/acre using products that were 75 percent methyl bromide and 25 percent chloropicrin. In HS-1076, shallow injection was also used but the application rate at site 1 was 300 lb/acre using a 67 percent methyl bromide mixed with 33 percent chloropicrin. Driver, co-pilot, and shoveler exposures were monitored in this study. In HS-1061, both methyl bromide and chloropicrin ambient air levels were quantified around a single field at 3 locations. No information was reported about the application rate, although the method was reported as a shallow shank injection. Since field emissions data were evaluated above in Figures 1 and 2 with information that is more relevant to current methyl bromide application methods, only the worker exposure monitoring data will be further addressed. Table D.3 summarizes these data. In all of the circumstances observed in HS-1076 and HS-1175, chloropicrin exposures increased as methyl bromide exposures increased in a particular location. The acute HEC for methyl bromide is 30 ppm (30,000 ppb) and the corresponding short-term HEC is 4.4 ppm (4400 ppb). In all cases where the short-term HEC for methyl bromide is exceeded, the level of chloropicrin is greater than 150 ppb which is the level where individuals are expected to begin to recognize irritation effects. In no cases were levels near the 300 ppb air concentration for chloropicrin where more severe irritation would be noted. It should be noted, however, that in many current applications, a 50/50 mixture of methyl bromide and chloropicrin

is used, so in circumstances similar to those from these studies, severe irritation from chloropicrin exposure could possibly be observed. This is because twice as much chloropicrin would be used in current applications and the chloropicrin values could possibly double, all factors being relative. [Note: No data were available to evaluate the 2% "warning agent level of chloropicrin and a similar uncertainty exists in this analysis for such mixtures as described above.]

**Table D.3. Summary of Concurrent Methyl Bromide and Chloropicrin Monitoring Data From HS-1076 and HS-1175 (from D350818).**

| DPR Study | Site # (& appl. info.) | Sample Time (min.) | Driver Exposure (ppb) | | Co-Pilot Exposure (ppb) | | Shoveler Exposure (ppb) | | Air Temp (ºF) | Soil Temp (ºF) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Mebr | Pic | Mebr | Pic | Mebr | Pic | | |
| 1076 | 1 (300 lb/A) 67/33 | 45 | 3400 | 106 | 4200 | 96 | No data | No data | 71 | 73 |
| | | 45 | 800 | 47 | 600 | 26 | No data | No data | 74 | 73 |
| | | 45 | 1200 | 43 | 1000 | No data | No data | No data | 74 | 73 |
| | | 45 | 400 | 80 | 700 | No data | No data | No data | 82 | 73 |
| | 2 (275 lb/A) 75/25 | 45 | 2500 | 126 | 6300 | 181 | 700 | 45 | 57 | 73 |
| 1175 | 1 (275 lb/A) 75/25 | 60 | 3100 | 90 | 3800 | 86 | No data | No data | 66 | No data |
| | 2 (275 lb/A) 75/25 | 67 | 3500 | 101 | 8300 | 190 | No data | No data | 68 | No data |
| | | 64 | 5000 | 154 | 5900 | 178 | No data | No data | 72 | No data |

Table D.4 presents another analysis completed using the MBIP synopsis of the available monitoring data for methyl bromide workers that determined how many workers were exposed at levels less than the detection limits for the available real-time monitoring devices (0.5 ppm) yet still exceeded the short-term target concentration of concern (0.15 ppm). This range of exposure concentrations is important because it is below levels where the warning properties of chloropicrin can be relied upon as a trigger for remedial action without higher levels of uncertainty and these air concentrations in this range cannot be adequately monitored using reliable real-time devices in the field to actively manage risks for workers. The last line of this table (% exceeds target yet can be analyzed) describes this factor. To summarize, for those in proximity to the nozzles/injection equipment (applicators, co-pilots) the exposure concentrations that are of concern due to short-term exposures will be identified via monitoring most of the time (~60 to 70% of the time). Shoveler detection rates are less than expected, but relatively still high at 36 percent. The tarp cutters, tarp removers, and irrigators have low rates as expected because they would be exposed after most methyl bromide had dissipated. The results for second tractor driver values are confounding probably because of the low numbers of available samples.

| Table D.4. Summary of Exceedance Levels In Methyl Bromide Worker Exposure Monitoring Data (from D350818). | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Sampling Duration >4hrs** | **[mebr>0.15 ppm]** | **Applicators** | **Co-pilots** | **Irrigators** | **Shovelers** | **2nd Tractor Drivers** | **Tarp Cutters** | **Tarp Removers** |
| no | no | 2 | 0 | 0 | 0 | 0 | 3 | 13 |
| yes | no | 8 | 7 | 6 | 10 | 3 | 0 | 0 |
| no | yes | 15 | 13 | 0 | 3 | 0 | 1 | 7 |
| yes | yes | 21 | 29 | 15 | 22 | 2 | 0 | 0 |
| | total | 46 | 49 | 21 | 35 | 5 | 4 | 20 |
| | # [mebr>0.50 ppm] | 22 | 29 | 1 | 9 | 0 | 0 | 7 |
| | (%) exceeds target yet can be analyzed | 61.1 | 69.0 | 6.7 | 36.0 | 0.0 | 0.0 | 100.0 |
| Notes:<br>Drager tube LOQ ~ 0.5 ppm<br>4 hours min sample time to represent full shift (most were in the 6 to 8 hour range)<br>[mebr>0.15 ppm] = short-intermediate-term target concentration defined by HEC/UF (4.4/30) | | | | | | | | |

In summary, based on the available field emissions and worker exposure monitoring data, it is believed that a flexible approach based on real-time monitoring and the irritating properties of chloropicrin is viable for protecting workers if chloropicrin is used in sufficient quantities relative to methyl bromide. It should be noted that the efficacy of "warning agent" levels (i.e., 2%) of chloropicrin remains uncertain because such use situations could not be directly evaluated due to a lack of monitoring data for these scenarios. It is also believed that the use of a flexible approach provides applicators and anyone under their employment with ample opportunities for protecting themselves without undo burdens of mandated respirator use as indicated in the current risk assessment. In some cases, the flexibility may also eliminate increased actuarial risks (e.g., from inability to adequately communicate around heavy machinery or enhanced cardiopulmonary stress from respirator use in hot, humid environments). It also should be indicated that the risk assessment adequately represents the technologies of the timeframe under which the data were collected, but that many enhancements in fumigant applications such as better controller systems, less permeable tarp materials, and a better understanding of agricultural practices that can achieve efficacy at reduced use rates all lead to the conclusion that the occupational risks in the current assessment could be conservative for many situations.

However, it is also fully anticipated that, even using the most modern practices, respiratory protection will be warranted in many applications, so in many cases, action levels will be met and those involved in applications will be mandated to wear respiratory protection or take other actions such as verifying calibration of the rig or ceasing operations until levels dissipate.

**Occupational Handler Risk Estimates for Non-Soil/Commodity Uses of Methyl Bromide:**

The summary below has been excerpted from the most recently completed quantitative occupational handler human health risk assessments for methyl bromide (J. Dawson, D304623, 03/10/2006 and J. Dawson, D304619, 07/12/2006)

**Occupational Exposure:**

The Agency received several comments requesting additional clarification regarding the tasks which were evaluated in the occupational assessments, and also the types of respiratory protection that should be used. In this assessment data that were classified as either from commodity-specific treatments or industrial treatments (i.e., that involved large grain storage and transfer points akin to large flour mills, etc.) so the exposure values from the studies are appropriate. The tasks that were identified include:

**For commodities:** applicator; aerator; and post-fumigation workers (forklift drivers and line workers)

**For industrial settings:** remote application; canister application; and aeration

The Agency believes that most commodity fumigation tasks that involve direct contact with methyl bromide have been addressed in the scenarios included above. However, the risks calculated based on the available monitoring data should be considered in context because they are mostly a decade or so old and practices have substantively changed over that time with a focus on risk reduction through better training, facilities, and other factors. Through various outreach efforts, the Agency has been attempting to ascertain what, if any, key tasks where methyl bromide exposure may occur have not been addressed in some manner. To date, no significant tasks have been identified. Possible refinements to the current risk estimates could involve the collection of data that represent more modern cultural practices, and also additional outreach activities to better understand tasks associated with current practices, so that the Agency can further ensure addressing risks for methyl bromide users.

There are many possible ways to reduce occupational inhalation exposure, the most preferred of which is through the use of engineering controls (e.g., better sealing for treated chambers or higher stacks) or the use of administrative controls (e.g., lowering application rates). However, in some cases, the use of respirators to reduce exposure levels is a necessary option in order to appropriately manage worker risk levels. In most circumstances, the Agency prefers to use air purifying respirators (APRs) as the type of device that would be worn by affected workers. These devices reduce exposure by 90 percent if worn properly (i.e., the protection factor is 10x). APRs are commonly available, relatively inexpensive, and also relatively easy to use and maintain compared to other available respirator technology. Many fumigation companies and other methyl bromide users also tend to have access to more sophisticated devices, the most common of which are called self-contained breathing apparatus (SCBA) which if worn properly can reduce exposures as much as 10,000 times. The commonly available SCBAs have air tanks that last 30 minutes so the routine use of such devices over entire working days or even periods of a few hours is prohibitive. They are also relatively costly to maintain and refill. Some facilities also use supplied air systems instead of SCBA which can reduce exposure as much as 1000 times, but these systems tend to be relatively difficult to maintain and are not portable. For these reasons, the Agency believes that the use of SCBAs should be a regulatory option only for a limited number of tasks. For this assessment, the only tasks for which the Agency believes that SCBAs would be appropriate are canister users and aerators in industrial settings because of the

size of the facilities and the specialized nature of the tasks. The Agency believes SCBAs are appropriate for these scenarios because the exposure durations are relatively short and there is a potential for exposure to larger amounts of methyl bromide given the anticipated sizes of some industrial facilities. In all other scenarios, the Agency believes that routine risk reduction should be accomplished with APRs and that the requirement for SCBAs on a routine basis would be ineffectual and inappropriate.

Tables D.5 and D.6 below are excerpted from the risk assessment and present the risk estimates for all durations of exposure for commodity uses and industrial applications, respectively. The Agency believes that most applicator exposures are likely to be of a shorter duration (i.e., acute or short-term by agency definition). A much smaller percentage of the overall user population is expected to have longer duration exposures (i.e., intermediate-term or chronic). Risk estimates for workers in this case have been calculated using the margin of exposure (i.e., MOE) approach where the target is 30 for all durations except chronic exposures where the target MOE is 100. The results for each scenario are described below.

**For commodities (refer to Table D.5 below):**

- *Commodity applicators (APR/PF 10 used for respiratory protection, SCBAs are not applicable to this scenario):* risks are of concern for all durations with or without the use of a respirator.

- *Commodity venters (APR/PF 10 used for respiratory protection, SCBAs are not applicable to this scenario):* risks are of concern for all durations with or without the use of a respirator.

- *Forklift drivers (APR/PF 10 used for respiratory protection, SCBAs are not applicable to this scenario):* risks are not of concern without a respirator only when the duration is acute (i.e., single day). Risks are of concern for short/intermediate-term and chronic exposures without the use of a respirator. Risks are not of concern for any duration when an APR respirator is worn.

- *Line workers (APR/PF 10 used for respiratory protection, SCBAs are not applicable to this scenario):* risks are of concern without a respirator for all durations. Risks are not of concern for acute and short/intermediate-term when an APR respirator is worn but are of concern for those who could be exposed in a chronic manner.

**Table D.5. Commodity MeBr Application Workers Exposure and Risk (from** D304619**).**

| Scenario | Number of ND Samples | Duration of Maximum Sample Result | Sample time (minutes) | Max. Conc.[1] Monitored PF10 Resp. | Acute MOE | Mean Conc.[1] Monitored PF10 Resp. | Short- and Intermediate-term MOE | Chronic MOE Based On Mean Conc. |
|---|---|---|---|---|---|---|---|---|
| Commodity Applicators (N=39) | 1 | 5 minutes | 3 and 614 | 12 | 2.5 | 2.0 | 2 | <1 |
| | | | | 1.2 | 25 | 0.20 | 22 | 3 |

| Table D.5. Commodity MeBr Application Workers Exposure and Risk (from D304619). | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Scenario** | **Number of ND Samples** | **Duration of Maximum Sample Result** | **Sample time (minutes)** | **Max. Conc.[1] Monitored PF10 Resp.** | **Acute MOE** | **Mean Conc.[1] Monitored PF10 Resp.** | **Short- and Intermediate-term MOE** | **Chronic MOE Based On Mean Conc.** |
| Commodity Venting (n=30) | 9 | 5 minutes | 3 and 585 | 33 | <1 | 2.3 | 2 | <1 |
| | | | | 3.3 | 9 | 0.23 | 19 | 2 |
| Forklift Driver (n=27) | 0 | 15 minutes | 10 and 536 | 0.80 | 38 | 0.17 | 26 | 3 |
| | | | | 0.080 | 375 | 0.017 | 259 | 32 |
| Line Workers (89) | 4 | 37 minutes | 14 and 621 | 7.9 | 4 | 0.55 | 8 | 1 |
| | | | | 0.79 | 38 | 0.055 | 80 | 10 |

[1] Concentrations are measured in ppm.

## For industrial settings (refer to Table D.6 below):

- *Remote applicators (APR/PF 10 used for respiratory protection, SCBAs are not applicable to this scenario):* risks are of concern for all durations without the use of a respirator. Risks are not of concern with a respirator only when the duration is acute (i.e., single day). Risks are also of concern for short/intermediate-term and chronic exposures with the use of a respirator.

- *Canister Openers (SCBAs/PF 10,000 used for respiratory protection, APRs are believed to be insufficient to sufficiently reduce risks for this scenario):* risks are of concern for all durations without the use of a respirator. Risks are not of concern with a respirator only when the duration of exposure is acute (i.e., single day) or of a short/intermediate-term nature. Chronic exposures are of concern even with the use of a respirator.

- *Aerator/venters (SCBAs/PF 10,000 used for respiratory protection, APRs are believed to be insufficient to sufficiently reduce risks for this scenario):* risks are of concern for all durations without the use of a respirator. Risks are not of concern with a respirator only when the duration of exposure is acute (i.e., single day) or of a short/intermediate-term nature. Chronic exposures are of concern even with the use of a respirator.

**Table D.6. MeBr Industrial Applicators Exposures and Risks (from** D304619**).**

| Scenario | Number of ND Samples | Duration of Maximum Sample Result | Sample time | Max. Conc.[1] Monitored PF10 Resp.* | Acute MOE | Mean Conc. [1] Monitored PF10 Resp.* | Short- and Intermediate-term MOE | Chronic MOE Based On Mean Conc. |
|---|---|---|---|---|---|---|---|---|
| Remote Applicator (n=10) | 3 | 9 | 0.35 to 101 | 6.5 | 5 | 2.6 | 2 | <1 |
| | | | | 0.65 | 46 | 0.26 | 17 | 2 |
| Cannister Opener (n=13) | 1 | 5 | 5 to 91 | 6100 | <1 | 1100 | <1 | <1 |
| | | | | 0.62 | 48 | 0.11 | 40 | 5 |
| Aerator/ Venter (n=32) | 7 | 19 | 6 to 406 | 9500 | <1 | 590 | <1 | <1 |
| | | | | 0.95 | 32 | 0.059 | 75 | 9 |

[1] Concentrations are measured in ppm.
*For remote applicator, a PF 10 respirator is generally used for mitigation. For the others SCBA is generally used and has a 10,000 protection factor associated with it.

## Appendix E. Bland-Altman Analysis

To enhance the potential utility of the collected data presented in D395248 (J. Dawson, 05/30/2012), an analysis was completed to evaluate how the worker monitoring results and stationary air monitoring results agree with one another. This is important because stationary air monitoring represents a possible approach, which is less complex to implement, for facility operators who want to more actively manage exposures of their employees in real-time (e.g., fixed stationary monitors could trigger cease work alarms or automated ventilation systems). A *Bland-Altman* graphical approach was used for this analysis[38]. This method is the most common for evaluating the relative agreement between two analytical methods that measure the continuous variables measured on the same scale. An example of one the plots completed for this analysis is provided as Figure 1.[39] If the mean difference is greater than zero, it implies the overall direction of bias is positive. The results of this analysis indicate that at higher levels of exposure, there is a slight tendency for the stationary air-monitoring method to over-estimate high worker exposure values and to under-estimate low worker exposure values. As such, it would be appropriate for facility operators to use stationary monitoring as a method to actively manage exposures for their employees because higher level exposures would trigger remedial actions and the approach has an inherent level of protection due to the observed bias.

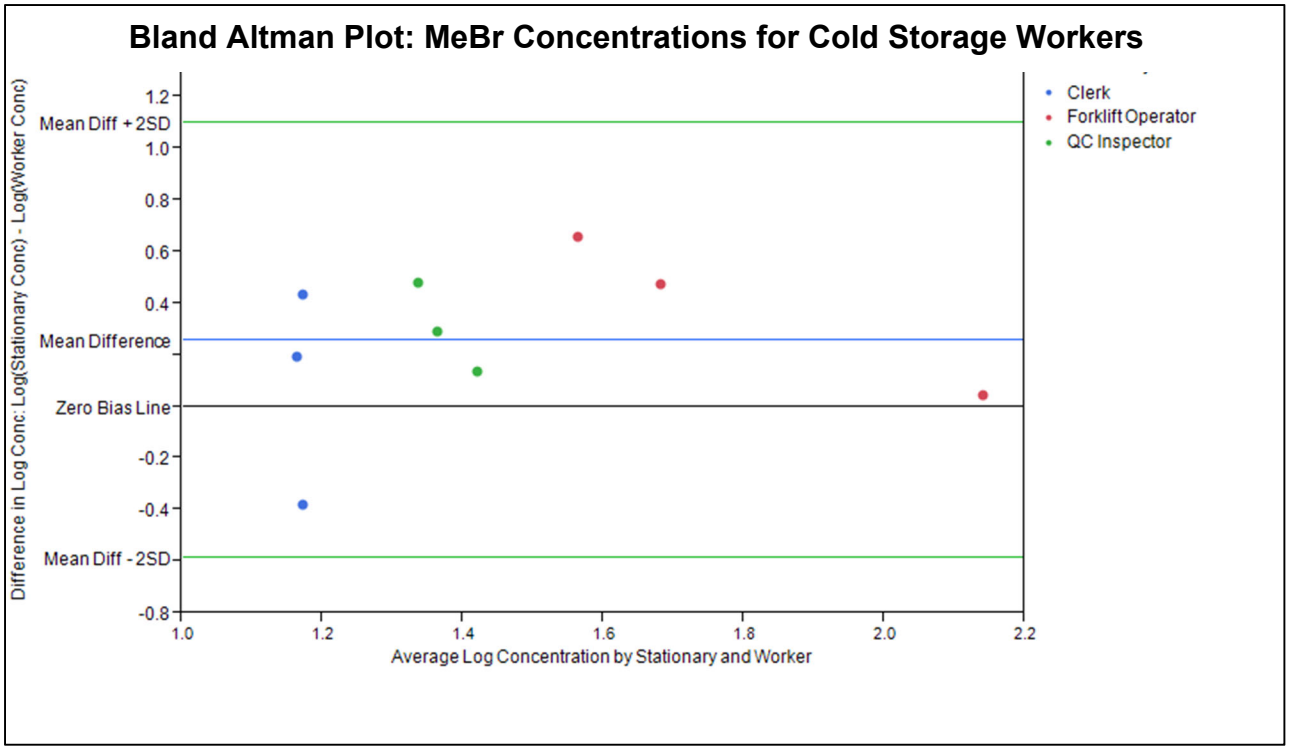



**Figure 1: Bland-Altman Plot For Cold Storage Workers (Log Transformed Data)**

[38] Altman DG, Bland JM. Statistical methods for assessing agreement between two methods of clinical measurement: *Lancet*, 1986; **i**:307-310.

[39] Specific details of the analysis can be provided upon request.

[Note: In Figure 1, the data for monitoring event MU 7 was split into 2 sample collection periods. The combined results are presented in the figure.]

Several issues should be considered in the interpretation of these study results. These include:

- Both worker and stationary monitoring data illustrate that methyl bromide air concentrations consistently exceeded the Agency's LOCs for both acute and short-/intermediate-term durations of exposure. This was observed at ports and in cold storage facilities involved in the fumigation and subsequent storage of Chilean grapes.[40]

- In some cases, stationary air concentrations and levels measured in the breathing zone of workers were observed at levels similar to where effects in test animals occur (~9 ppm – the approximate LOAEL in the study used to define the short-term POD). It should be noted no deleterious health impacts were reported by the subjects over the course of this study.

- Data are limited as monitoring was completed for only one site of the three planned in this study. As such, an analysis of the data to determine whether or not it achieves the statistical goals outlined in the sampling plan could not be evaluated. The benchmark objective for this study is that the number of random MUs (monitoring a particular worker on a particular workday) be sufficient to insure the upper 95% bound on fold-relative accuracy (fRA95 or K factor) is 3-fold or less for the exposure statistics: arithmetic mean, geometric mean, and 95$^{th}$ percentile.

- Stationary air monitoring appears to be a reasonable predictor of worker exposure based on the *Bland-Altman* analysis.

- The data appear to be of high quality based on the review which has been completed (e.g., analytical results are correct, worker activities are well documented, etc.).

- Applications associated with the fumigated fruit were documented, but were not directly conducted as part of this research. They were, however, completed in compliance with applicable USDA regulations for the import of Chilean grapes (e.g., CxT criteria outlined in the Treatment Manual).

- The sites monitored in this study appear to be good representations of the types of operations that would be expected in this industry. However, the design of facilities and how they are operated could uniquely impact the exposures of those working there. For example, worker movements within facilities, storage strategies for fumigated fruit within

[40] The California Department of Pesticide Regulation also took samples alongside of samples taken in study. These results are available at https://mbao.org/static/docs/confs/2011-sandiego/papers/73aFarnsworth.pdf. They indicate similar trends as the MBIP data.

facilities, the design of structures, how make-up air is provided, whether or not scrubbers are used, or how ventilation systems are designed may impact exposures.

- The study was conducted before any known systematic effort by operators to reduce exposures through good management practices, widespread use of ventilation systems, monitoring programs, or scrubbing technologies. Further investigation would be required to evaluate exposure conditions when those approaches are more widespread to evaluate if they are effective in impacting exposures.

- This study collected worker exposure and stationary measurements over a very short timeframe. Because of the seasonal nature of the import business for cold chain commodities like grapes and asparagus, many ships are received over the course of a season and the imported commodities are treated similarly. As such, it is not unreasonable to surmise that the exposures quantified in this study to date (i.e., from port and cold storage workers in Long Beach CA) would represent those which would be anticipated throughout the course of a season under similar exposure conditions (i.e., short-term exposures similar to those in this study would reasonably be expected).

## Appendix F. Summary of Methyl Bromide Human Equivalent Concentrations (HECs) Determinations for Relevant Exposure Scenarios.

**Table F.1. Methyl Bromide Human Equivalent Concentration Summary.**

| Scenario | Relevant Study | LOAEL (ppm) | NOAEL (ppm) | Da | Dh | Wa | Wh | RGDR[1] | HEC[2] (ppm) |
|---|---|---|---|---|---|---|---|---|---|
| *Acute* | | | | | | | | | |
| Agricultural Bystander and Ambient | Developmental Rabbit | 80 | 40 | 6 | 24 | 1 | 1 | 1 | 10 UF=30 |
| Structural Commodity Bystander | Developmental Rabbit | 80 | 40 | 6 | 6 | 1 | 1 | 1 | 40 UF=30 |
| Occupational | Developmental Rabbit | 80 | 40 | 6 | 8 | 1 | 1 | 1 | 30 UF=30 |
| *Short-/Intermediate-Term* | | | | | | | | | |
| Ambient | Subchronic Dog | 10 | 5 | 7 | 24 | 5 | 7 | 1 | 1.0 UF=30 |
| Occupational | Subchronic Dog | 10 | 5 | 7 | 8 | 5 | 5 | 1 | 4.4 UF=30 |
| *Long-term* | | | | | | | | | |
| Ambient | Rat Chronic/Carcinogenicity | 3 | NA | 6 | 24 | 5 | 7 | 0.244 | 0.13 UF=100 |
| Occupational | Rat Chronic/Carcinogenicity | 3 | NA | 6 | 8 | 5 | 5 | 0.244 | 0.55 UF=100 |

[1] Acute and short-/intermediate-term based on systemic effects; therefore, RGDR = 1. Long-term RGDR calculated based on nasal lesions observed in the rat chronic/carcinogenicity study (i.e., extrathoracic region). Da: daily animal exposure (hrs/day). Dh: anticipated daily human exposure (hrs/day). Wa: weekly animal exposure (days/week). Wh: anticipated weekly human exposure (days/week). RGDR: regional gas dose ratio. HEC: human equivalent concentration. POD: point of departure.

[2] HEC = POD * (Da/Dh) * (Wa/Wh) * RGDR. UF: uncertainty factor.