UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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SUBJECT: **Methyl Bromide**: Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses. PC Code: 053201, DP Barcode: D304623

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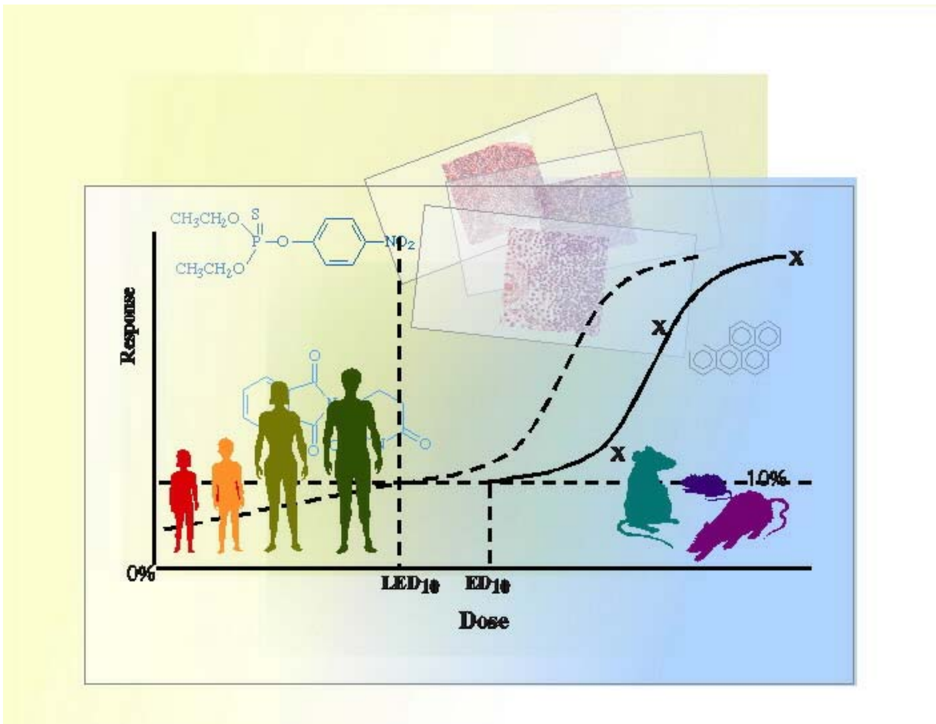
Based on the information received in the Phase 3 comment period, the Agency has developed a revised Phase 5 assessment for methyl bromide. However, the scope of this current assessment has been strictly limited by comparison to the Phase 3 assessment (see D316326 at www.Regulations.gov under the methyl bromide docket EPA-HQ-OPP-2005-0123) as it addresses only those uses with food tolerances as established in the 40CFR while D316326 considered all other methyl bromide use patterns as well (e.g., pre-plant soil fumigation). The scope of the assessment was modified to allow for the uses with tolerances to be evaluated in a timely manner in accordance with the schedule required by the Food Quality Protection Act tolerance reassessment process. The Agency is also engaged in an ongoing, systematic analysis of pre-plant soil fumigants in order to address the remaining uses. These revised soil fumigant assessments to be completed later this year. [Note: For efficiency, all non-food uses of methyl bromide (e.g., residential) will also be included in the upcoming soil fumigant cluster.]

Much of the basic data and calculations upon which this assessment is based remain unchanged from D316326. Since the bulk of the basic information has not been altered, readers may refer to the original Phase 3 Risk Assessment (D316326) for the underlying information as it has not been repeated in this document. However, key new sources of information and methods that have been considered include: a recently submitted inhalation developmental neurotoxicity study in rats, comments pertaining to the inputs used for calculating exposures to bystanders from commodity uses (e.g., USDA/PPQ provided information that allowed port facility fumigation event modeling to be significantly refined), and an upgrade of the PERFUM model was used to calculate the potential for bystander risks. In the previous assessment, the ISCST3 model was used. It should also be noted that slight modifications to the dietary and drinking water elements of this assessment have also been completed.

The recently submitted information allowed the Agency to reduce the uncertainty factor used for the bystander assessments from 300 to 30 based on the inhalation developmental neurotoxicity study, use 8 hour HECs (Human Equivalent Concentrations) to address bystander exposures that more correctly reflect the anticipated exposure patterns, and use the PERFUM model which has recently been upgraded with capabilities for addressing commodity and other non-field based exposure scenarios. The upgraded PERFUM model (V2.1.2) is available at http://www.sciences.com/perfum/index.html. Version 2.1.2 of PERFUM will eventually be placed on the Agency's website along with the older Version 1.1 http://www.epa.gov/opphed01/models/fumigant/.

HUMAN HEALTH RISK ASSESSMENT

Methyl bromide



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HUMAN HEALTH RISK ASSESSMENT

Methyl bromide

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Appendices

1.0 Executive Summary

The Health Effects Division (HED) of EPA's Office of Pesticide Programs has evaluated the methyl bromide database and conducted a human health risk assessment for the reregistration of the commodity uses of the chemical. [Note: Risks for other registered uses (e.g., pre-plant soil treatments) will be addressed in a separate document later this year.] This assessment begins phase 5 of the 6 phase public participation process. A summary of the key areas of this assessment are provided below. The attached appendices contain additional information that can be used to expand upon and characterize the risks presented in this document.

Methyl bromide is a broad-spectrum fumigant that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent. The most prevalent use pattern is as a soil fumigant; however, it is also used as a structural fumigant and post harvest treatment of commodities. Methyl bromide application methods and equipment vary depending upon the setting. Under the accords of the Montreal protocol, methyl bromide is scheduled for phase out; however, critical use exemptions will still be available under special circumstances.

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 toxic via both dermal and ocular routes of exposure (Toxicity Category I). Neurotoxicity is the major hazard concern for inhalation exposure, with neurotoxic effects seen throughout the data base in all tested species of animals. Both acute and 90-day inhalation neurotoxicity studies in rats showed evidence of neurotoxic effects characterized by decreased activity, tremors, ataxia and paralysis. Two subchronic studies showed 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) and in the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia). Risk assessment endpoints for the general population were based primarily on neurotoxic effects.

For acute inhalation risk assessments, the developmental rabbit study was selected since the fetal effects are presumed to occur after one exposure. In the case of short and intermediate risk assessments, two subchronic inhalation toxicity studies in dogs were assessed together for endpoint selection. The chronic/carcinogenic inhalation study in rats was selected for long term inhalation risk assessment. A NOAEL was not identified in this study. Thus, a LOAEL based on nasal lesions with basal cell hyperplasia was used as the point of departure (POD). Consequently, a 3x uncertainty factor was applied for the LOAEL to NOAEL extrapolation.

An acute dietary endpoint applicable to the U.S. general population was chosen from the acute inhalation neurotoxicity study in rats. The endpoint of concern identified in this study is neurotoxicity (decreased activity and alertness, decreased rears, decreased motor activity, increased piloerection, and decreased body temperature). These effects resulted from a single, 6-hour dosing period, and are therefore appropriate for acute (one-day) risk assessments. Developmental effects were the basis for acute dietary risk assessments for women of child-bearing age (females 13-50 years of age). Effects seen in the developmental inhalation toxicity study in rabbits included malformations (agenesis of the gall bladder and increased incidence of fused sternebrae) at exposure levels that also caused maternal toxicity.
The chronic dietary endpoint was selected from an oral rat chronic/carcinogenicity study in which

animals were dosed with micro encapsulated MeBr. In this study, MeBr exposure elicited decreases in body weight gain, body weight, and food consumption. It is noteworthy that these effects are less severe than those reported in the chronic/carcinogenicity study conducted via the inhalation route, thus suggesting that MeBr toxicity is greater via the inhalation route than the oral route of exposure.

Since clear NOAELs were identified for all studies used for endpoint selection, and their dose response was well defined, HED determined that the special FQPA factor could be reduced to 1x. The selected points of departure (PODs) will not underestimate the risk. In addition, the results of a recently submitted developmental neurotoxicity study also supports this conclusion.

Methyl bromide has been responsible for a number of incidents involving large clusters of people. The need for Hazmat teams, decontamination, and medical care make these cases significant, even though symptoms are often minor. Methyl bromide exposure has caused symptoms such as headache, malaise, weakness, difficulty breathing (dyspnea), convulsions, and severe skin burns in many of these incidents. Incidents have been associated with faulty containers and application equipment. Methyl bromide has also been responsible for a significant number of deaths, most involving individuals not directly involved in the application. Factors identified in the more serious cases included lack of training and proper protective equipment, fumigation of tree holes, inadvertent exposure to leaking structures or structures with unexpected conduits or openings, and working in soil or other areas where residues remained.

Releases of fumigants such as methyl bromide can be categorized in two distinct manners that include addressing bystander exposures from single known application sites such as stacks from a commodity fumigation and also by evaluating available ambient air monitoring data where residues could result from many applications within a region. Risks from known single sources were evaluated using monitoring data and modeling techniques. Risks from ambient air were evaluated solely on the basis of monitoring data from California.

When considering the potential risks of bystanders for single application sites that encompass single known sources (e.g., point sources such as stacks from commodity chambers) it is also important to understand that this has been an iterative process that reflects the evolution of HED's methodologies for calculating the potential risks associated with fumigant use. There are a number of volatility studies which quantified methyl bromide emissions from facilities. However, these data are limited in their utility because they provide results only for the specific conditions under which the experiment was conducted. Therefore, to provide more flexibility, ISCST3 or the Industrial Source Complex: Short-Term Model (http://www.epa.gov/scram001/) was also used to develop risk estimates for bystanders associated with methyl bromide commodity uses in the previous risk assessment (see the methyl bromide docket EPA-HQ-OPP-2005-0123 at www.Regulations.gov under D316326). In addition, in response to HED's ISCST3 methodologies for assessing pre-plant soil fumigants, three separate air models based on ISCST3 that incorporate weather and emissions variability over time (PERFUM, FEMS, SOFEA) were reviewed by the FIFRA SAP (http://www.epa.gov/scipoly/sap/2004/index.htm - see Aug. & Sept.). The SAP concluded that each of the three models could provide scientifically defensible results for risks associated with soil fumigation practices and also suggested modifications and additional data that could further refine risk estimates. Since the release of the previous assessment, the PERFUM model has been modified to be able to calculate risk estimates for commodity and other non-field uses. PERFUM is a refinement because it allows users to develop an understanding of the distributions of potential bystander exposures around the perimeter of a treatment facility or structure and thus more fully characterize the range of risks resulting to bystanders from commodity treatments This is a modification from the previously completed assessments because ISCST3 was used in a deterministic approach and PERFUM, or other similar tools were not available. ISCST3 is an integral part of the PERFUM model. The basic physics and code of ISCST3 remain unchanged. PERFUM essentially provides ISCST3 with daily meteorological data over the selected 5 years as well as user defined emissions inputs. PERFUM then uses this information to create distributional outputs for receptor locations around the treated structure.

In this assessment, monitoring data and the updated PERFUM model were used to calculate bystander risks. The results indicate that cute risks are of concern based on the monitoring data for locations in proximity to treated structures. In many situations, PERFUM predicted buffer distances are 1440 meters which is the maximum distance that the PERFUM model will predict even at lower percentiles of exposure (e.g., 50th). However, in other situations, PERFUM predicts that buffer distances can be in proximity to the treated structure or chamber even at the highest percentiles of exposure. It appears that the APHIS PPQ (i.e., a venting tube placed on the ground in secured areas) and portable stack aeration approaches consistently have the lowest buffer distances associated with them. No-stack situations (e.g., opening a door on a warehouse or Seavan) tend to have the highest buffer distances associated with them. It is clear that many different factors can impact the air concentrations (and hence, risks) in proximity to structures and chambers that are used for commodity treatments with methyl bromide.

With regard to exposure from ambient air, HED has reached similar conclusions to that of CDPR in that there are no imminent health concerns from methyl bromide levels in ambient air. In this analysis, HED considered both targeted monitoring data from high agricultural use areas during the season of use (i.e., known as CARB data) and data meant to establish background concentrations in urban environments (i.e., known as TAC data). Exposures for all durations ranging from acute to chronic were considered from MeBr levels in ambient air. Regardless of the data considered, risks do not exceed HEDs level of concern for acute, short- and intermediate-term exposures. HED calculated chronic exposure based on CARB data using a rangefinder approach because monitoring data specifically meant to establish chronic exposure levels in high use areas were not available. Based on this approach, in some cases, chronic risks exceed HEDs level of concern; however, HED believes that these results do not pose an imminent health concern to the general public due to the nature of the rangefinder calculations and the representativeness of the data related to the commodity uses of methyl bromide. The results do however indicate a need for additional monitoring data for this scenario. Chronic exposures in urban environments were not of concern. Finally, it should be noted that some of the urban monitoring stations are located in the same communities where major commodity fumigations occur (e.g., Long Beach CA) which should be considered in the interpretation of the results.

Acute and chronic dietary risks for MeBr from food intake for the general U.S. population and various population subgroups was also estimated. For all included commodities, the acute and chronic risks do not exceed HED's level of concern (<100% aPAD[1]) for the general U.S. population and all population subgroups.

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[1]aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

Estimated drinking water concentrations for MeBr were modeled using PRZM-EXAMS (Pesticide Root Zone Model - Exposure Analysis Modeling System) for surface water; however, groundwater concentration was not estimated for MeBr because the Environmental Fate and Effects Division (EFED) does not currently perform vapor phase transport of fumigants to groundwater. The maximum concentration for ground water, based on the data base of pesticides in groundwater, is used for both acute and chronic assessments.

For the acute and chronic dietary (food and water only) aggregate assessments, HED has no aggregate risks of concern. The dietary and drinking water exposures alone do not exceed the appropriate population adjusted doses. However, residential risks exceed HED's level of concern for several scenarios; therefore, additional exposures from dietary intake would result in even greater aggregate risks of concern. Therefore, aggregate risks for scenarios other than dietary intake and drinking water were not considered.

HED used an extensive worker monitoring database for the evaluation of the risks associated with various occupational tasks associated with commodity treatments that include the following: commodity applications (applicator, aerator, forklift drivers and line workers); and industrial applications (remote applicators, cannister openers and aerators). Overall, data indicate that worker risks exceed HED's level of concern for the majority of scenarios considered, even when appropriate mitigation measures were taken (e.g., respirators). Chronic exposures were of concern for all scenarios, regardless of whether or not respiratory protection of any sort is used. However, the number of chronically exposed workers is expected to be rather small in comparison to those who are exposed for shorter durations.

2.0 Ingredient Profile

MeBr is a broad-spectrum fumigant chemical that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent. Most use is on terrestrial non-food use sites but other commonly treated sites include indoor food and non-food use sites, residential settings, and commercial/industrial facilities. Approximately 47 million total pounds were applied annually during the years 1990 through 1999. Pre-plant field uses in agriculture accounted for about 41 million pounds per year while post-harvest commodity treatments accounted for another 4 million pounds and structural fumigations accounted for 2.3 million pounds per year. A 2001 update to that analysis for pre-plant soil fumigation of selected crop (tomatoes, strawberries, onions, and selected tree fruits and melons) for 8 major use states (CA, FL, NC, SC, MI, GA, WA, OH) indicates that 2001 use (22.4 million pounds) was 40 percent of the 1991 baseline (56.2 million pounds) for those crops and locations. Strawberries, eggplant, peppers, and tomatoes are the crops with the highest percentage of their overall acreage treated. The average annual percent crop treated for those crops, respectively, were 54, 43, 17, and 13 percent while the maximum percent crop treated, respectively, for those crops was 70, 75, 19, and 21 percent. Most crops were treated once per year and the average application rate for crops (lb ai/acre/application) ranged from a low of 5 lb ai/acre on cotton to a high of 260 lb ai/acre/application on cucumbers. Common pre-plant agricultural field uses for various crops have maximum application rates that range from the 200 lb ai/acre/application range up to around 430 lb ai/acre/application (e.g., 5785-4 and 5785-42). Very high rates such as the 890 lb ai/acre/application are generally reserved for more specialized applications such as tree planting scenarios. The treatment of perishable goods used 2,290,000 lb/year while durable good treatments and quarantine uses accounted for 1,373,000 and 530,000 lb/year, respectively. The use of MeBr as a structural fumigant is waning because of the availability of alternatives. Annual use averaged 2,300,000 lb/year with facilities and food handling establishments accounting for 755,000 lb/year; residential/museum/antique treatments accounting for 1,373,000 lb/year; and transport vehicles accounting for another 160,000 lb/year. Application rates for commodity fumigations can range from 1 to 20 lb ai/1000 ft^3 but most perishable goods that have an established food tolerance under 40CFR are in the 1 to 4 lb ai/1000 ft^3 range (e.g., grapes). Likewise, structural fumigations are in the 1 to 9 lb ai/1000 ft^3 range. For examples of methyl bromide labels, see http://www.e1.greatlakes.com/agproduct/]. This assessment is focused on commodity uses and a range of application rates from 1 to 15 lb ai/1000ft^3 have been considered which reflect the range of application rates identified in the Phase 3 public comment process. [Note: Analyses were completed in this assessment using application rates of 1, 4, 9, and 15 lb/1000 cubic feet. All modeling outputs are available but the results for the 1 and 4 lb/1000 cubic feet outputs have been summarized since they bracket uses for most commodities with established food tolerances and the purpose of this document is to address the food tolerances associated with methyl bromide in order to meet the August 2006 tolerance reassessment schedule for FQPA.]

MeBr application methods and equipment are quite varied depending upon the setting. Generally, the methods and equipment fall into four basic categories that include: (1) pre-plant agricultural field fumigations; (2) structural, industrial, and residential fumigations; (3) post-harvest commodity fumigations; and (4) other specialized fumigations. This assessment focuses on the post-harvest commodity uses of methyl bromide and associated structural/industrial uses that may impact commodities (e.g., flour mills). Future assessments will address the other use patterns.

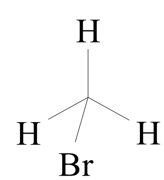
MeBr has been identified as an ozone depleting chemical and as such is scheduled for a phase-out by 2005 and it is subject to other restrictions under the Montreal accords entered into by the United States. However, in certain situations, agronomic needs can still warrant its use under the Montreal accord because of efficacy reasons and the lack of suitable alternatives. To account for and codify these uses, a process was established which allows for *"Critical Use Exemptions or CUEs"* which are redefined on an annual basis in the process established under the accords. In 2005, there are 19 distinct industry "sector" CUEs (pre-plant uses on cucurbits, tomatoes, strawberries, etc.) that allow the United States to consume 35 percent or so (i.e., approximately 19.7 million pounds) of the 1991 baseline annual total amount used of approximately 56.3 million pounds. For 2006 the number of industry "sectors" has been reduced to 15 and the United States will be allowed to consume 32 percent of the 1991 baseline of MeBr (i.e., approximately 18.0 million pounds). However, for both years the United States is allowed to use MeBr for quarantine and pre-shipment uses without any controls on the amount used.

HED has closely coordinated with the California Department of Pesticide Regulation (CDPR) during the development of this assessment since CDPR has considerable experience and has also instituted requirements governing MeBr use that are more restrictive than those contained in current Federal labels (http://www.cdpr.ca.gov/docs/dprdocs/methbrom/mebrmenu.htm). CDPR has also generated a majority of the data considered in this assessment. In order to allow MeBr users flexibility and reduce exposures, CDPR has opted to use buffer zones that are determined based on the factors included in permit applications. This is done through a series of look-up tables that MeBr users reference for their specific permits. These look-up tables are based on broad combinations of application equipment and control technologies (i.e., these categories are commonly referred to as permit conditions). [Note: Further discussion is provided below about how the modeled estimations were completed.] CDPR is also considering how to reduce nonpoint or ambient sources of exposure based on the use of township caps (i.e., 6 by 6 mile townships are used).

2.1 Structure and Nomenclature

Table 1 provides the structures and relevant nomenclature for MeBr.

Table 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

2.2 Physical and Chemical Properties

A listing of the physical and chemical properties of MeBr are provided in Table 2.

Table 2: Physical and Chemical Properties of MeBr	
Parameter	**MeBr**
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

3.0 Metabolism

3.1 Description of Primary Crop Metabolism

The qualitative nature of the residue in plants is adequately understood, based on studies in which the commodities maize, potato, alfalfa, peanuts, almonds, oatmeal, apples, oranges, and wheat were fumigated with radioactive methyl bromide at a rate equivalent to ~2x the registered rate. Residues consisted of methyl bromide and naturally occurring compounds such as methylated amino acids and nucleotides. The residue of concern is methyl bromide *per se.*

HED has determined that the pre-plant soil fumigation use is a non-food use. Treated soil must be fumigated for a minimum of two weeks to allow sufficient dissipation of residues; excessive residues of methyl bromide *per se* would be phytotoxic. Minimal methyl bromide residues are available for uptake by the plant at the end of the soil aeration period. Considering the highly reactive nature of methyl bromide, any residues taken up by the plant would be converted to natural constituents by the time of plant harvest. Therefore, tolerances are not needed to support the pre-plant fumigation use of methyl bromide. However, tolerances currently exist for post-harvest commodity fumigation uses of methyl bromide (see 40 CFR §180.123).

3.2 Description of Livestock Metabolism

Animal metabolism data are currently not required for methyl bromide. Potential feed items with registered post-harvest or storage fumigation uses include stored grain, soybeans, and processed animal feeds. The maximum tolerance for residues in any of these is 10 ppm, based on residues 24 hours after the aeration period that follows fumigation. The transfer of detectable residues from feed items to meat, milk or eggs, is not expected, and is a Category (3) situation under 40 CFR §180.6(a).

3.3 Description of Rat Metabolism

In a metabolism study (non-guideline, literature), 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 was as follows: carcass (14-17%), expired carbon dioxide (32%), urine (43%) and feces (less than 3%) (Medinsky et al. 1984). 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 (Medinsky et al. 1985).

4.0 Hazard Assessment and Characterization

4.1 Hazard Characterization

4.1.1 Database Summary

Studies available and acceptable (animal, human, general literature)
Data are available for both oral and inhalation routes and have been used accordingly in the risk assessments (Appendix A). The inhalation database includes: acute neurotoxicity study in rats, developmental toxicity studies in rats and rabbits, subchronic toxicity studies in rats and dogs, and chronic studies in mice and rats. Four studies conducted via the oral route in rats and dogs were also available. In addition, incident reports indicate that methyl bromide exposure results in a myriad of symptoms ranging from headaches to death.

Metabolism, toxicokinetic, mode of action data
A guideline metabolism study is not available. Data in the open literature indicate that methyl bromide is readily absorbed with approximately 27-50% of the compound inhaled absorbed after a six hour exposure (Medinsky et al. 1985).

Sufficiency of studies/data
The toxicological database for methyl bromide is sufficient for risk assessment purposes and includes a Developmental Neurotoxicity Study in Rats conducted *via* the inhalation route.

4.1.2 Endpoints

Neurotoxicity is the most prevalent hazard concern for inhalation exposure, with neurotoxic effects seen throughout the data base in all tested species. Both acute and 90-day inhalation neurotoxicity studies in rats showed evidence of neurotoxic effects of methyl bromide characterized by decreased activity, tremors, ataxia and paralysis. Two subchronic 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) and in the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia). Developmental effects described as increased incidence of agenesis of the gallbladder and fused sternebrae were also seen in the developmental inhalation study in rabbits. In addition, the multi generation reproduction toxicity study in rats revealed that methyl bromide exposure via the inhalation route resulted in decreases in pregnancy rates and body weights (pups and adults).

Four studies conducted via the oral route are available in the methyl bromide database. Since methyl bromide is a gas under standard atmospheric conditions, in dietary studies the test article was administered micro encapsulated, with the exception of one study where the feed was fumigated. Effects noted after dietary exposure were primarily decreases in body weight gain, body weight, and food consumption. Evidence of stomach lesions was seen in the 90 day oral toxicity study in rats.

Several studies in the database indicate that methyl bromide is a genotoxic agent. However, no indications of carcinogenesis were observed in the rodent bioassays. In contrast, an Agricultural Health

Study (AHS) suggest a link between prostate cancer and methyl bromide use in agriculture.

Incident reports indicate that methyl bromide exposure is likely to cause symptoms such as headache, malaise, weakness, difficulty breathing (dyspnea), convulsions, and severe skin burns. In some instances, exposure to methyl bromide has led to deaths due to disregard of posted warnings on treated, tented structures.

4.1.3 Dose-response

The general public may be exposed to fumigants in air because of their volatility following application. Specifically, fumigants can off-gas into ambient air and can be transported off-site by wind to non-agricultural areas. Based on air monitoring studies, exposures can be acute (less than 24 hours), short-term (1-30 days), intermediate-term (1 month-6 months), and/or long-term (> 6 months) in duration. In addition, the U.S. population may be exposed to methyl bromide through dietary intake.

4.1.3.1 Inhalation Exposure

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, and nasal histopathology observed in the chronic toxicity/carcinogenicity study in rats. In evaluating the risks that a compound may pose to human health after exposure via the inhalation route, different methodologies have been historically used by the U.S. EPA and CDPR. The two approaches differ in their use of species-specific parameters to derive HECs. Therefore, the differences noted in the risk assessments of each organization are due, in part, to their use of different methodologies and uncertainty factors (UFs). HED's approach to estimating risks due to inhalation exposure is based on the guidance methodology developed by ORD for the derivation of inhalation reference concentrations (RfCs) and human equivalent concentrations (HECs) for use in MOE calculations. An example of CDPR's methodology, and the species-specific parameters used in this approach can be found in the CDPR website and their methyl bromide risk assessment, Appendix G at the following web address (www.cdpr.ca.gov/docs/dprdocs/methbrom/append_g.pdf). As OPP understands the importance to harmonize, to the extent possible, with other regulatory agencies, this risk assessment will present HECs derived using both methodologies.

For this risk assessment, endpoint selection will be 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 differences between systemic *versus* portal of entry effects, arise from the use of different calculations to estimate the inhalation risk to humans which are dependent on the regional gas dose ratio (RGDR). In the case of systemic *versus* portal of entry effects, different RGDRs are derived for each type of toxicity. For agricultural bystander exposure (*i.e.*, non-occupational) *versus* worker exposure (*i.e.*,occupational), the differences arise because while it is presumed that non-occupational exposure may occur 24 hours/day, 7 days/week; occupational exposure occurs only during the course of an average workweek (8 hours/day and 5 days/week). For commodity bystanders (*i.e.*, non-occupational) exposed as a result of commodity fumigation in treatment facilities, it is presumed that exposure may occur during the course of an average workweek (8 hours/day and 5 days/week) while the treatment facility is in operation.

For further details on the critical studies used for endpoint selection refer to the Toxicology Chapter of the reregistration eligibility decision (RED) prepared by Dr. Paul Chin (DP Barcode: D271581, Submission: S586801, dated March 18, 2003). Additional information on the methodologies used in this risk assessment and HEC arrays is available in Appendix B.

Acute Inhalation Exposure
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 methyl bromide vapor for 6 hr/day on Days 6-16 of gestation.

The maternal NOAEL is 40 ppm (HEC = 10 for agricultural bystander exposure or 30 ppm for occupational and commodity bystander exposure) and the LOAEL is 80 ppm based on decreased appetite, lethargy, right side head tilt, ataxia and lateral recumbency.

The developmental toxicity NOAEL is 40 ppm (HEC = 10 for agricultural bystander exposure or 30 ppm for occupational and commodity bystander exposure) and the LOAEL is 80 ppm based on agenesis of the gall bladder and increased incidence of fused sternebrae which was supported by decreased fetal body weight (statistically not significant).

Dose and Endpoint for Risk Assessment: HEC of 10 or 30 ppm for non-occupational and occupational risk assessments, based on agenesis of the gall bladder and increased incidence of fused sternebrae. It is presumed that developmental effects such as agenesis of the gall bladder and fused sternebrae may be the outcome of an acute exposure thus this study is considered appropriate for this risk assessment. Though an acute neurotoxicity study in rats was available for consideration, the developmental toxicity study in rabbits was selected since it yields the lowest HEC (most health-protective). A 30X UF defines HED's level of concern (3X interspecies extrapolation and 10x intraspecies variation) in accordance with guidance provided in the RfC methodology (see section 4.2 below).

Short and Intermediate Inhalation Exposure

Short and intermediate inhalation risk assessments were based on two subchronic inhalation toxicity studies in dog. In a subchronic (5- to 7-week) inhalation toxicity study (MRID 43386802), methyl bromide (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). **The systemic toxicity NOAEL for 5 and 7 weeks is 26 ppm (HEC =5.41 ppm for agricultural bystanders or 22.75 ppm for occupational and commodity bystander exposure). The LOAEL is 53.1 ppm based on decreased activity.**

In a six-week nonguideline inhalation toxicity study (MRID 45722801), four groups of beagle dogs consisting of 4 males and 4 females/group were administered methyl bromide (Lot No: 1010PK15A; purity: 100% a.i.) by whole body exposure at concentrations of 0, 5.3, 10, and 20 ppm (equivalent to 0, 1.8, 3.4 and 6.9 mg/kg/day). The exposures were for seven hours/day, five days/week for six weeks (total of 30 exposures).

The NOAEL is 5.3 ppm (HEC = 1.0 for agricultural bystander exposure or 4.4 ppm occupational and commodity bystander exposure), and the LOAEL for methyl bromide is 10 ppm based on the absence of proprioceptive placing and the increased incidence of feces-findings (soft, mucoid feces, and/or diarrhea).

Dose and Endpoint for Risk Assessment: HEC = 1.0 for agricultural bystander exposure or 4.4 ppm for occupational and commodity bystander exposure based on the absence of proprioceptive placing and the increased incidence of feces-findings (soft, mucoid feces, and/or diarrhea). This study is of the appropriate duration for these risk assessments and yield the lowest HECs of the studies of this duration. An UF of 30X defines HED's level of concern in accordance with guidance provided in the RfC methodology (see section 4.2 below).

Chronic Inhalation Exposure

In a chronic toxicity/carcinogenicity study (MRIDs 41213301, 42418301, 44359101), 50 Wistar (Cpb:Wu) rats/sex/dose were exposed to methyl bromide (>98.8% a.i.) by whole body exposure at concentrations of 0, 3, 30 or 90 ppm (0, 0.0117, 0.117 or 0.335 mg/L) for 127 weeks (males) or 129 weeks (females).

No NOAEL was identified for local respiratory effects. The LOAEL for local respiratory irritation is 3 ppm (HEC = 0.13 ppm for agricultural bystander exposure or 0.55 ppm for occupational and commodity bystander exposures) based on increased incidence of basal cell hyperplasia of the nasal cavity in both sexes.

The NOAEL for systemic toxicity is 30 ppm (HEC =5.36 ppm for agricultural bystanders or 22.5 ppm for occupational and commodity bystander exposures). The LOAEL is 90 ppm 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.

Dose and Endpoint for Risk Assessment: HEC of 0.13 ppm for agricultural bystander exposure or 0.55 ppm for occupational and commodity bystander exposures based on increased incidence of basal cell hyperplasia of the nasal cavity in both sexes. This study is of the appropriate duration and yields the lowest HECs for this risk assessment. Since a NOAEL was not identified for the effect of concern (nasal histopathology) a 3X UF for LOAEL to NOAEL extrapolation is recommended.[2] Thus an UF of 100X (3X interspecies extrapolation, 10X intraspecies variation, and 3X LOAEL to NOAEL extrapolation) defines HEDs level of concern in accordance with guidance provided in the RfC

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[2] 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.

methodology (see section 4.2 below).

4.1.3.2 Dietary Exposure

Acute Dietary Exposure for Females 13-50 Years of Age

For acute dietary exposure for females of child bearing age, refer to section 4.1.4.1 Inhalation Exposure, *Acute Inhalation Exposure*.

Dose and Endpoint for Risk Assessment: NOAEL of 40 ppm (14 mg/kg/day) based on agenesis of the gallbladder and fused sternebrae. For acute reference dose derivation, a 100X uncertainty factor is applied (10x interspecies extrapolation and 10x intraspecies variation see section 4.2 below). HED considers this to be a health protective dose and endpoint for dietary risk assessment purposes since an inhalation study was used, which is likely to overestimate the internal dose that would result from an oral exposure since chemicals will enter the circulation before many of the detoxification processes associated with oral exposure (e.g. first pass effect) occur. Moreover, chemicals in the respiratory tract enter the blood stream more readily than chemicals in the gastrointestinal tract (GI)since only ~ 2µM separate the chemical in the alveolar space of the lung and the blood stream while several cellular layers separate the chemicals in the lumen of the GI tract from the blood stream..

Acute Dietary Exposure for General Population

In an acute neurotoxicity study (MRID No. 42793601), CD rats (15 rats/sex/dose) were exposed by whole body inhalation to 0, 30, 100 or 350 ppm methyl bromide vapor for 6 hours (equivalent to males: 0, 27, 90 or 314 mg/kg/day and females: 0, 30, 101, or 354 mg/kg/day). The NOAEL is 100 ppm and the LOAEL is 350 ppm decreased activity, increase in number of animals with drooping/half-closed eyelids and alertness as measured in a FOB examination, decreased rears, decreased motor activity, increased piloerection and decreased body temperature in males and females after dosing.

Dose and Endpoint for Risk Assessment: NOAEL is 100 ppm (90 mg/kg/day) based on decreased activity, increase in number of animals with drooping/half-closed eyelids and alertness as measured in a FOB examination, decreased rears, decreased motor activity, increased piloerection and decreased body temperature. For acute reference dose derivation, a 100X uncertainty factor is applied(10x interspecies extrapolation and 10x intraspecies variation; see uncertainty factors discussion below). Once again, HED considers this to be a health protective dose and endpoint for dietary risk assessment purposes since an inhalation study was used, which is likely to overestimate the internal dose that would result from an oral exposure since chemicals will enter the circulation before many of the detoxification processes associated with oral exposure (e.g. first pass effect) occur. Moreover, chemicals in the respiratory tract enter the blood stream more readily than chemicals in the gastrointestinal (GI) tract since only ~ 2µM separate the chemical in the alveolar space of the lung and the blood stream while several cellular layers separate the chemicals in the lumen of the GI tract from the blood stream.

Chronic Dietary Exposure

In a combined chronic toxicity/carcinogenicity 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 were equivalent to 0, 0.02, 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. The NOAEL is 50 ppm (2.20 mg/kg/day for males and 2.92 mg/kg/day for females). 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.

Dose and Endpoint for Risk Assessment: The NOAEL is 50 ppm (2.20 mg/kg/day for males and 2.92 mg/kg/day for females) based on decreased body weight, body weight gain and food consumption. For chronic reference dose derivation, a 100X uncertainty factor is applied (10x interspecies extrapolation, 10x intraspecies variation; see section 4.2 below).

4.1.3.3 Dermal Exposure

Dermal exposure to methyl bromide of any significance 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. Therefore, a quantitative dermal exposure assessment has not been completed. Since HED does not have adequate data to quantify dermal risk, PPE for dermal protection should be based on the acute toxicity of the end-use product as described in the Worker Protection Standard and mitigation measures for dermal exposure described in PR Notice 93-7.

4.1.3.4 Classification of Carcinogenic Potential

At this time, methyl bromide is classified as a not likely human carcinogen; consequently, no q_1* or cancer risk quantification is required. However, initial results of an Agricultural Health Study (AHS) suggest a link between prostate cancer and ,ethyl bromide use in agriculture. Study information is being updated and review of family history and possible confounding factors are being considered. EPA will consider revising the cancer classification when these results become available.

4.1.4 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, methyl bromide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.2 Uncertainty Factors

HED determined that the special FQPA factor could be reduced to 1x based on the present toxicological database and adequacy of uncertainty factors assigned to chosen endpoints. Clear NOAELs were identified for all studies used for endpoint selection, and their dose response was well defined. Consequently, selected points of departure (PODs) will not underestimate the risk. A Developmental Neurotoxicity Study in rats has been received and reviewed by the Agency. Therefore, the database uncertainty factor (UFDB) of 10x previously retained for lack of the DNT has been removed for all risk assessments in accordance to current HED policy.

When conducting inhalation risk assessments, the magnitude of the UFs applied is dependent on the methodology used to estimate risk. This risk assessment is based on the RfC methodology developed by ORD for the derivation of inhalation RfCs and HECs for use in MOE calculations. Since the RfC methodology takes into consideration many pharmacokinetic (PK) differences but not pharmacodynamic (PD) differences, the UF for interspecies extrapolation may be reduced to 3x (to account for the PD differences) while the UF for intraspecies variation is retained at 10x. Thus, the UF when using the RfC methodology is customarily 30x.

Uncertainty factors may also be applied to account for LOAEL to NOAEL extrapolations. In the case of methyl bromide, no NOAEL was identified for the portal of entry effects observed in the chronic/carcinogenicity inhalation study in rats that was used for the long-term inhalation risk assessment. Since the effects noted at this dose level were not severe, an uncertainty factor of 3x was applied for the LOAEL to NOAEL extrapolation.

4.3 Summary of Toxicological Endpoint Selection

Table 3: Summary of Toxicological Dose and Endpoints for Use in MeBr Oral Human Health Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	Dev. NOAEL = 14 mg/kg/day UF = 100 **Acute RfD = 0.14 mg/kg/day**	FQPA SF = 1X **aPAD** = acute RfD / FQPA SF **= 0.14 mg/kg/day**	**Developmental Toxicity - Rabbit (Inhalation)** LOAEL = 28 mg/kg/day based on agenesis of the gall bladder and increased incidence of fused sternebrae.
Acute Dietary (General population including infants and children)	NOAEL = 90 mg/kg/day UF = 100 **Acute RfD = 0.9 mg/kg/day**	FQPA SF = 1X **aPAD** = acute RfD / FQPA SF **= 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 3: Summary of Toxicological Dose and Endpoints for Use in MeBr Oral Human Health Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF* and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Chronic Dietary (All populations)	NOAEL= 2.2 mg/kg/day UF =100 **Chronic RfD = 0.02 mg/kg/day**	FQPA SF = 1X **cPAD** = chronic RfD / FQPA SF **= 0.02 mg/kg/day**	**Chronic/carcinogenicity study -- rats (Microencapsulated MeBr)** LOAEL = 11.1 mg/kg/day based on decreased body weight, body weight gain and food consumption
Cancer	Classification: Not likely to be carcinogenic to humans		

Table 4: Summary of Toxicological Dose and Endpoints for Use in MeBr Human Health Inhalation Risk Assessment						
Risk Assessment*		**Study**	**NOAEL/LOAEL**	**Endpoints**	**HED HECs**	**CPDR HECs¶**
Acute	Agricultural Bystander	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Maternal: Right head tilt, ataxia. Developmental effects: agenesis of gallbladder, fused sternebrae	10 ppm UF = 30	21 ppm UF = 100 (child & adult)
	Occupational & Commodity Bystander	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Maternal: Right head tilt, ataxia. Developmental effects: agenesis of gallbladder, fused sternebrae	30 ppm UF = 30	
Short- and Intermediate-Term Inhalation (1 day to 6 months)	Agricultural Bystander	Subchronic (5- to 7-week) inhalation toxicity study - dogs	NOAEL = 5 ppm LOAEL = 10ppm	Decreased responsiveness in females, fecal effects and eye irriation	1.0 ppm UF = 30	0.88 ppm UF = 100 (child
	Occupational & Commodity Bystander	Subchronic (5- to 7-week) inhalation toxicity study - dogs	NOAEL = 5 ppm LOAEL = 10ppm	Decreased responsiveness in females, fecal effects and eye irriation	4.4 ppm UF = 30	1.56 ppm UF = 100 (adult)

Table 4: Summary of Toxicological Dose and Endpoints for Use in MeBr Human Health Inhalation Risk Assessment						
Risk Assessment*		**Study**	**NOAEL/LOAEL**	**Endpoints**	**HED HECs**	**CPDR HECs¶**
Long-Term Inhalation (>6 months)	Agricultural Bystander	Chronic/Carcinogenicity - rats	No NOAEL identified. LOAEL = 3 ppm	Nasal lesions	0.13 ppm UF = 100	0.1 ppm UF = 100 (child)
	Occupational & Commodity Bystander	Chronic/Carcinogenicity - rats	No NOAEL identified. LOAEL = 3 ppm	Nasal lesions	0.55 ppm UF = 100	0.2 ppm UF = 100 (adult)
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, by definition. Commodity bystanders are all based on 8 hour durations.
¶ Though CDPR and USEPA based their risk assessments on the same critical studies and endpoints, different algorithms were used by each organization to calculate HECs. For further details, please refer to Appendix B of this document.

5.0 Public Health Data

An analysis of incidents related to MeBr use that considered data from the OPP Incident Data System (IDS), Poison Control Centers, CDPR, and National Pesticide Information Center was completed. MeBr has a number of different types of hazards associated with both agricultural and structural applications. Often formulated with chloropicrin as a warning agent, a sizeable number of cases result from the irritating properties of the chloropicrin which can cause skin, eye, and respiratory irritation which may result in tearing and cough. MeBr is more likely to be involved when symptoms include headache, malaise, weakness, difficulty breathing (dyspnea), convulsions, and severe skin burns. Either chloropicrin or MeBr can be associated with vomiting and diarrhea, though MeBr would appear to be the more likely culprit if no odor is involved. MeBr formulated with or without chloropicrin has been responsible for a number of incidents involving large clusters of people. The need for Hazmat teams, decontamination, and medical care make these cases significant, even though symptoms are often minor. Incidents have been associated with faulty containers and application equipment. MeBr has also been responsible for a significant number of deaths, most involving individuals not directly involved in the application. Fifteen deaths in California (1982-99) and 4 deaths reported in the Incident Data System (all in Florida) involved burglars, residents, and other persons ignoring posted warnings and breaking through the tented covering. There were two deaths, one in a California apartment and one in an Iowa restaurant, where death occurred after the structure was deemed safe to reenter. Seven deaths were reported when persons in adjacent structures were exposed to MeBr without any warning. In addition to these deaths, other cases of severe poisoning have been associated with exposure in structures adjacent to those being fumigated. In California, nearly 70 percent of the poisonings were occupational and half of those occurred in agricultural settings. Of the 278 cases attributed to MeBr from 1982 through 1999, MeBr was definitely considered the causal agent in 42 percent of cases, probable in 32 percent, and possible in 26 percent. Factors identified in the more serious cases included lack of training and proper protective equipment, fumigation of tree holes, inadvertent exposure to leaking structures or structures with unexpected conduits or openings, and working in soil or other areas where residues remained.

Severe chronic effects, sometimes resulting in lifetime disability, have been reported from MeBr poisoning. For example, four such cases included worker with slow cognition, depression, swings in mood, weakness and persistent muscle pains; a case that was hospitalized for 16 months after exposure with paranoia and depression; and a case off work for eight months due to fatigue and inability to carry out normal work activities. Nearly all of the chronic effects described above resulted from heavy exposure and severe acute poisoning. Other studies of more moderately exposed workers did not reveal such effects. For example, a study by Calvert *et al* considered 123 structural applicators in Florida and concluded "few health effects were associated with MeBr exposure." (Calvert GM, Mueller CA, Fajen JM, Chrislip DW, Russo J, Briggle T, Fleming LE, Suruda AJ, Steenland K. (1998) Health effects associated with sulfuryl fluoride and MeBr exposure among structural fumigation workers. Am J Public Health 88:1774-1780.)

6.0 Non-Occupational Exposure Assessment and Characterization

This section describes the potential non-occupational exposure scenarios associated with the use of methyl bromide. These include residential bystander exposure from two key sources including: known sources from an application site (e.g., a source such as from a ventilation stack on a treated commodity chamber during aeration) and ambient air levels that result from many applications within a region where the sources are not quantified. There are no residential uses of methyl bromide by homeowners so this aspect of the risk assessment focuses on those types of exposures that may occur from commercial uses of methyl bromide that can lead to exposures in residential environments. HED also considered potential dietary exposures from food and drinking water. *Section 6.1: Residential Bystander Exposure And Risk Estimates* describes how exposure and risk estimates were calculated for the general population who may be exposed living in proximity to individual application sites or within regions where Methyl bromide use routinely occurs. *Section 6.2: Bystander Risk Characterization* describes the factors that should be considered when interpreting the results of this risk assessment. *Section 6.3: Residue Profile* describes the residue data that were considered for the dietary risk assessment. *Section 6.4: Acute and Chronic Food Dietary Exposure And Risk* describes the dietary assessment completed for Methyl bromide. *Section 6.5: Water Exposure/Risk Pathway* describes issues related to the potential for drinking water exposure.

6.1 Residential Bystander Exposure and Risk Estimates

Methyl bromide is a widely used fumigant product where the predominant usage, in terms of pounds domestically applied, is accounted for by pre-plant soil fumigation in cropland intended for the cultivation of crops such as strawberries and tomatoes. Previously, the Agency completed a preliminary assessment that addresses all use patterns associated with methyl bromide (see www.Regulations.gov and methyl bromide docket EPA-HQ-OPP-2005-0123). However, the scope of the preliminary assessment has been modified by separating out commodity uses from other use patterns which will be assessed at a later time. As such, this document addresses only those exposure patterns which have an associated commodity use as defined by established food tolerances in 40CFR. Other similar uses which do not have a food tolerance are included as well as appropriate (e.g., timber and forest product exports).

Residential bystander exposure from commodity treatments may occur because of emissions from chambers, buildings and other structures, or stored commodities themselves. These emissions can travel to non-target areas which could lead to negative impacts on human health and will be referred to simply as bystander risks in this assessment. Bystander exposures can occur as a result of being in contact with residues that were emitted from a known source and also from non-quantified source(s) within a localized region. For clarity, a known source in this assessment is intended to represent area sources from a single application (e.g., a large warehouse or mill the is undergoing treatment) or point sources from a single application (e.g., stack used to dissipate residues from a treated commodity chamber). [Note: Methyl bromide use practices can dictate that multiple, sequential applications such as in adjacent warehouses during high import season activity for some commodities (e.g., grapes) could lead to multiple known sources. At this time, the Agency will further evaluate such situations during risk management in order to tailor results to particular risk management needs.]

When considering the potential risks of bystanders for known sources from single applications (e.g., a commodity chamber) it is important to consider the iterative process that reflects the evolution of HED's methodologies for calculating the potential risks associated with fumigant use. There are a number of volatility studies which quantified methyl bromide emissions from treated facilities. However, these data were limited in their utility because they provide results only for the specific conditions under which the experiments were conducted. Therefore, to provide flexibility, HED also used ISCST3 or the Industrial Source Complex: Short-Term Model (Version 3) to develop risk estimates for bystanders (http://www.epa.gov/scram001/). [See http://www.epa.gov/scram001/guidance/guide/appw_03.pdf for additional information concerning the development and validation of ISCST3.] HED's methodology in using ISCST3 and the results achieved are considered deterministic because fixed meteorological conditions were used rather than actual meteorological data. As such, in addition to HED's methodologies based on ISCST3 for assessing risks for pre-plant soil fumigants, three other models that incorporate ISCST3 variability in weather and emissions (PERFUM, FEMS, SOFEA) were reviewed by the FIFRA SAP in August and September of 2004 (http://www.epa.gov/scipoly/sap/2004/index.htm). The SAP concluded that each of the three models could provide scientifically defensible results for risks associated with soil fumigation practices and also suggested modifications and additional data that could further refine risk estimates. Since then, PERFUM has been updated in order to address additional source types instead of just agricultural fields (http://www.sciences.com/perfum/index.html). The updated version of PERFUM is capable of estimating results for agricultural fields of different sizes and shapes. Additionally, PERFUM can model releases from structures (e.g., greenhouses and chambers of different sizes and shapes), appropriate for evaluating potential releases from commodity treatments. The other two models which were evaluated by the SAP in 2004 (i.e., FEMS & SOFEA) at this point do not have the capability of addressing use patterns of this nature.

HED also believes PERFUM, instead of the techniques employed using ISCST3, provide more appropriate information for risk managers for evaluating the risks associated with commodity fumigation. PERFUM has the capability to provide distributional outputs which better characterizes the anticipated range of exposures that can be expected to be associated with the commodity use pattern. As such, HED recommends results derived from PERFUM to be the basis for risk management decisions rather than those generated with ISCST3. HED would also evaluate submissions based on the other appropriate models if detailed training and documentation accompanied any such submission.

For exposures from ambient air (i.e., attributable to many non-quantified application(s) in a region), air concentrations of MeBr are estimated from monitoring data collected to represent such conditions within regions of use and also from urban levels. In this analysis, two types of data have been used: data targeted towards areas and seasons of high MeBr use (i.e., referred to as California Air Resources Board data or CARB available at http://www.cdpr.ca.gov/docs/dprdocs/methbrom/mebrmenu.htm described as ambient air monitoring data), and data representing background levels in non-agricultural, urban environments (i.e., referred to as Toxic Air Contaminant data or TAC available at http://www.arb.ca.gov/adam/toxics/toxics.html).

Exposures from single known sources (e.g., stacks from commodity chamber) for bystanders are described below in *Section 6.1.1: Bystander Exposures And Risks From Known Sources* while ambient air exposures are described below in *Section 6.1.2: Ambient Bystander Exposure From Multiple Regional Sources*.

6.1.1 Bystander Exposures And Risks From Known Sources

As noted, residential bystander exposure may occur because of emissions due to single applications from known sources such as chambers, buildings and other structures, or stored commodities. The techniques used to assess the exposures and risks vary and are described below in *Section 6.1.1.1: Methods Used To Calculate Bystander Exposures And Risks From Known Sources*. The results calculated for all scenarios of interest based on the most appropriate method for that scenario are presented in *Section 6.1.1.2: Bystander Exposures And Risks From Known Sources*.

6.1.1.1 Methods Used To Calculate Bystander Exposures And Risks From Known Sources

As indicated above, the Agency's calculation of bystander exposures and risks from known sources has been an iterative process. The methods used to estimate these types of exposures are described below along with a discussion of the results and how they can be used to represent the exposures and risks that could be expected from actual methyl bromide use.

HED considered a large database of information in its development of the commodity assessment for methyl bromide. The citations are included in a bibliography attached as Appendix C (refer to studies with COM prefix). This bibliography lists the numbers of studies and other documents (e.g., guidance) that have been considered. HED screened these studies to determine their usefulness in assessing human health risks. Data from those determined to be applicable were extracted and used as appropriate for the analysis described below.

Three methods have been used for assessing the potential risks associated with the commodity uses of methyl bromide including: direct use of air monitoring data collected during actual commodity treatments with methyl bromide which is referred to as the *(1) Monitoring Data Method*; the use of ISCST3 air model referred to as the *(2) ISCST3 Modeling Method*; and the use of PERFUM referred to as the *(3) PERFUM Modeling Method*. Each method has been a critical element of the Agency's evaluation of methyl bromide but the Agency also believes that the PERFUM approach best represents the overall range of potential risks that would be anticipated for the commodity uses of methyl bromide because it provides flexibility in that different climatic conditions, chamber types, emission rates, and many other factors can be evaluated.

(1) Monitoring Data Method**:** In the monitoring data method, air concentrations are estimated using actual air monitoring data. In these studies, the fumigant is applied to a chamber, building, or other areas, and air samplers positioned in and around the treated area continuously sample the air by pulling the air through a filter (e.g., charcoal) which captures the chemical for later analysis. Sampling times can vary widely but generally range from about 2 to 12 hours, so that the samples represent the average air concentrations for the sampling intervals used. Usually shorter times are used at the beginning because fumigants can quickly volatilize into the atmosphere and, for commodity uses, active aeration is often used which enhances this occurrence.

There are several uncertainties associated with the use of the direct sampling method which limit its utility. First, the air concentrations represent only those for the conditions under which the study was carried out. Air concentrations around treated chambers, buildings, or other areas are influenced by a number of factors including how a chemical is applied, application rate, techniques to control emissions (e.g., chamber structure), and weather conditions. Varying weather conditions, for example, can significantly change the profile of air concentrations around a treated area; and since there is such a large range of potential weather conditions, it is not possible for these studies to represent the entire range of potential exposures which could result from different weather situations. Second, the air concentrations are measured by fixed samplers positioned at various directions around the treated area, both downwind and upwind, as well as at points in between. Air concentrations downwind will be relatively high since the fumigant plume will be pushed by the wind in that direction, while concentrations upwind will be low or close to zero since the plume is pushed by the wind in the opposite direction. Therefore, there can be a very large difference between upwind and downwind air concentrations. For areas where there is a predominant wind direction, averaging of the air concentrations from these various samplers should not be done since persons around treated areas will generally be in one location relative to the wind and not exposed to an average of these concentrations. Third, samplers are positioned at specific distances from the treated area, and represent air concentrations only at those distances. Since air concentrations vary greatly by distance, the air concentrations estimated from direct measures represent a very narrow range of the possible levels to which people could be exposed. The available monitoring data are presented in Appendix D. Overall trends in the monitoring data have also been used to characterize the results calculated with modeling methods and are referenced as appropriate. The Agency believes that results based on monitoring data provide estimates of exposure and risk that are representative of the conditions under which the data were collected and also which suffer limitations due to the number of samplers used and their placement. As such, the Agency does not believe that monitoring data provide the most informative approach for considering the risks associated with methyl bromide use because other field conditions and risks at different distances from the source can be evaluated with modeling approaches. [Note: If desired, results based on monitoring data can be evaluated based on the information in Appendices C, D, and E. Appendix C provides citations for all monitoring data. The actual data are presented in Appendix D and a summary of the data in a manner appropriate for this analysis is presented in Appendix E.]

(2) ISCST3 Modeling Method: The ISCST3 modeling method uses the Agency model, Industrial Source Complex Short Term (ISCST3) coupled with input values that describe emissions from treated chambers, buildings or other facilities in order to model the range of concentrations which might be found under different conditions of application rate, weather, source size and shape (e.g., building size), and distances from the treated building, structure, or other area. Before a modeling analysis can be done, one of the most important parameters for ISCST3, the flux or rate of pesticide emissions from the treated buildings or structures must be determined. As an example, for commodity treatments flux could be expressed as a percentage of the treatment concentration that escapes over time because the chamber or structure being used for fumigation purposes is not completely sealed. The absolute amount of what escapes (i.e., a fugitive emission in this case) is then defined as the product of the size of the treated structure and the treatment concentration. In essence, flux represents how quickly the pesticide moves or volatilizes into the surrounding atmosphere from the treated area, building or structure. Numerous factors can influence flux rates after commodity-type applications and these include application rate, durations of treatment, nature of the media being treated, type and efficacy of chambers or structures being used for treatment, and ventilation criteria used to evacuate methyl bromide after treatments are completed. Flux is also difficult to determine. There are three generally recognized methods are used to estimate flux from soil applications including (1) the chamber method; (2) the aerodynamic flux method; and (3) the indirect flux method. While all three techniques are generally considered appropriate for use in determining flux from treated fields, they are generally not equally applicable to commodity situations. As such, the only the principle method that is applied typically for commodity and other non-field uses, the indirect flux method, is described below in any detail.

> **ISCST3 Flux Method: Indirect Back-Calculation** The method most often used to determine flux rates is the indirect or back-calculation method which is described at http://www.cdpr.ca.gov/docs/empm/pubs/ehapreps/eh9903.pdf. This method uses measured air concentrations from various positions around structure or facility taken while monitoring a typical fumigation. Using the dimensions of the fumigation chamber, the location of the samplers relative to the fumigation chamber, and weather information collected during the period of fumigation, ISCST3 is run using a nominal flux rate (usually 0.01 $g/^{m^2}$-s for area sources and 1 g/s for point sources). The results from the ISCST3 run are compared to the measured air concentrations and a best fit, linear relationship is determined. The slope of the line from this best fit is the estimate flux rate from the fumigation.

Defining flux estimates for all of the scenarios to be considered in an assessment is necessary before ISCST3 can be run. Other key inputs must also be defined such as the size and shape of a treated chamber or structure, wind direction, wind speed, and atmospheric stability. ISCST3 calculates downwind air concentrations using hourly meteorological conditions that include wind speed and atmospheric stability. Lower wind speeds and a more stable atmosphere generate higher the air concentrations closer to a treated chamber or structure because emissions are not pushed as far from a source and diluted as much as they would be under more turbulent conditions. Conversely, if wind speed increases or the atmosphere is less stable, then air concentrations are reduced. Atmospheric stability is essentially a measure of how turbulent the atmosphere is at any given time. Stability is affected by solar radiation, wind speed, cloud cover, and temperature among other factors. If the atmosphere is unstable, then more off-source movement of airborne residues is possible without a large increase in air concentrations because the residues are carried up into the atmosphere and moved away from the field or other source, thereby lowering the air concentration in proximity to the field/source. In the ISCST3 modeling method, to simplify modeling the transport of fumigant vapors from a source, a single wind direction, wind speed, and stability category are used for a given exposure duration for methyl bromide which is consistent with the HEC duration. The Agency has not determined if a particular set of meteorological conditions should be used for regulatory purposes, so results were developed based on a variety of different conditions. A range of atmospheric conditions representing the continuum from relatively stable (low windspeed & calm) to unstable conditions (high windspeeds & unsettled) was evaluated using ISCST3 (Figure 1). Under relatively stable atmospheric conditions, the modeling produces results that represent highly exposed individuals (i.e., ISCST3, as used, results in exposure estimates at the upper percentiles of an anticipated exposure distribution). Two key inputs are the basis for this conclusion. First, only a constant downwind direction is considered with no fluctuation the way ISCST3 was used in the previous assessment (see D316326). This type of situation would be highly unlikely in any outdoor environment. Secondly, the quantitative inputs used to define atmospheric stability conditions were also held constant which also will not occur in an outdoor environment. Conversely, unsettled conditions may reduce risk estimates but it is believed that even these conditions can result in conservative estimates because wind direction is constrained to a single vector over the period of concern.

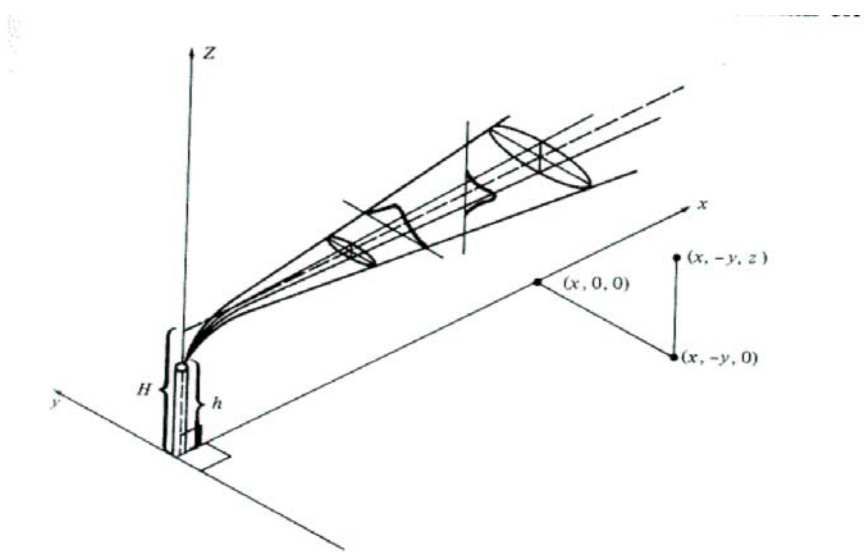

Figure 1: Illustration Of ISCST3 Gaussian Plume Approach

ISCST3 can provide useful results because it allows estimation of air concentrations reflecting different conditions based on changing factors such as application rates, structure sizes, downwind distances, wind and weather conditions, and other factors, which cannot be done using the monitoring data method. Results for the various major use categories for methyl bromide, including for commodity uses, based on the *ISCST3 Modeling Method* were included in the previous version of the risk assessment [see document D316326 available at www.Regulations.gov under the methyl bromide docket (EPA-HQ-OPP-2005-0123)]. For the purposes of this assessment, results based on ISCST3 have not been recalculated because the Agency believes that a tiered approach best represents the risks associated with methyl bromide commodity uses and that PERFUM results represent more refined risk estimates (see description below). Also, since the latest methyl bromide assessment was completed (D316326) the Agency has also revised its inputs to reflect the most recently available use information and does not want to expend additional resources for completing an ISCST3 analysis when PERFUM results will be available (e.g., chamber or structure sizes). Finally, the flux estimates in this assessment have not been quantitatively defined by the Agency using the indirect flux method. This method has been used by CADPR to define ranges of loss rates upon which their commodity permit conditions for methyl bromide use have been based. These represent a range of possible fumigation events but the breadth of possible scenarios can be much greater. As such, a broad range of performance criteria based on information obtained from several stakeholders (e.g., APHIS PPQ, DPR permit conditions, and general commodity treatment schedules) has been used to define the flux values used for this assessment. These are expressed as a percentage loss from a treatment and are categorized in one of two ways including (1) during treatment - which represents how much a chamber may leak during use (i.e., 1 to 50% of total administered has been used to represent this, varies with quality of chamber) and (2) during aeration - which represents the percentage of material purposefully removed from a chamber after treatment is complete (i.e., 50 to 99% of total administered has been used to represent this, again varies with quality of the chamber). [Note: DPR calculated commodity flux rates using the back-calculation method have been verified by the Agency. These values have been used for risk characterization purposes in order to evaluate the flux inputs used by the Agency herein. See the PERFUM assessment described below for further details.]

(3) PERFUM Modeling Method: The monitoring data and ISCST3 methods described above are deterministic in nature and the ISCST3 method, by design, provides high-end point estimates of exposure and risk. OPP is coordinating with EPA's Office of Air, the CDPR, and others to evaluate and implement the PERFUM modeling approach based on ISCST3 which incorporates actual meteorological data and refined flux inputs which are based on available data and other information. [Note: As indicated above, the Agency would also evaluate submissions based on similar modeling approaches if available although it does not know of an alternative approach which is currently available for developing distributions of exposure that result from commodity fumigations.] PERFUM allows users to develop an understanding of the distributions of potential bystander exposures around the perimeter of a treatment facility or structure and thus more fully characterize the range of risks resulting to bystanders from commodity treatments This is a modification from the previously completed assessments because ISCST3 was used in a deterministic approach and PERFUM, or other similar tools were not available. PERFUM has now been modified to be capable of defining a source term for commodity type applications (i.e., PERFUM V2.1.2 is available at http://www.sciences.com/perfum/index.html). For comparative purposes, PERFUM V1.1 is available at http://www.epa.gov/opphed01/models/fumigant/ . ISCST3 is an integral part of the PERFUM model (see Figure 2 below and for further details see http://www.epa.gov/scipoly/sap/2004/index.htm). The basic physics and code of ISCST3 remain unchanged. PERFUM essentially provides ISCST3 with daily meteorological data over the selected 5 years as well as user defined flux inputs. PERFUM then uses this information to create distributional outputs for receptor locations around the treated structure (see Figure 3).

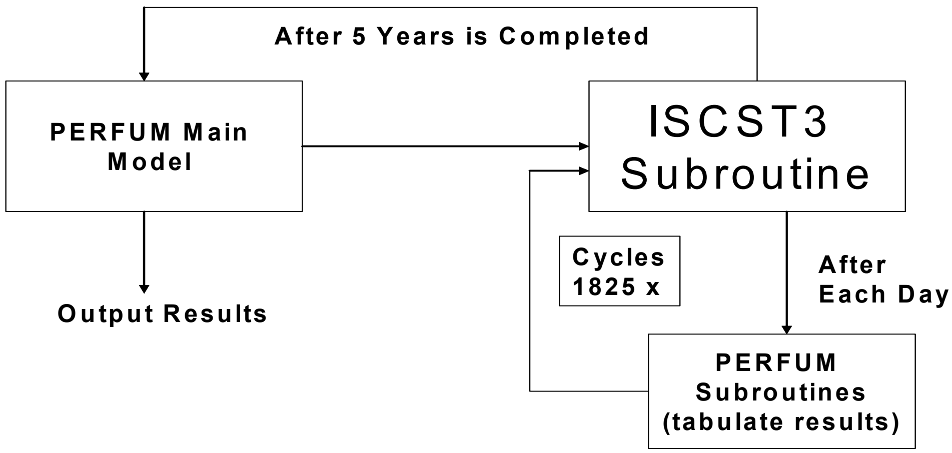

Figure 2: Operational Flowchart For PERFUM

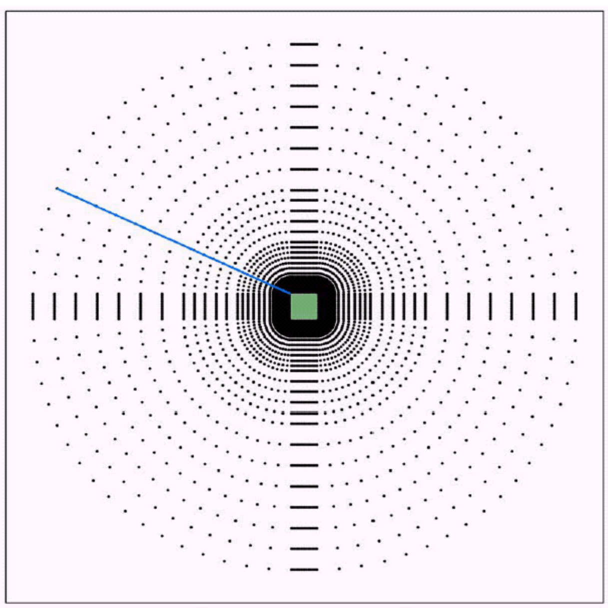

Figure 3: Example PERFUM Receptor Grid

PERFUM V2.1.2 has an algorithm that establishes the receptor grid which differs from

PERFUM V1.1 where the grid locations were hardwired. The maximum distance allocated is still 1440 meters from the edge of the source in question. Since actual meteorological data are integrated into PERFUM for each analysis, data representative of the locations where methyl bromide use occurs were identified and used in the analysis. For example, major commodity uses occur in the coastal regions of Florida and California at ports and significant levels of commodity production also occurs in these coastal regions so data from these locales were used. In addition, data from Flint Michigan were also used to represent inland uses of methyl bromide. The following locations and sources of meteorological data were used in this assessment:

- Ventura California (Source: CIMIS or California Irrigation Management Information System) to represent coastal California locations;
- Flint Michigan (Source: NWS or National Weather Service) to represent central Michigan and other upper midwest locations; and
- Tallahassee Florida (Source: NWS or National Weather Service) to represent inland Florida locations.

In this assessment, 5 years or 1825 days of meteorological data were considered in each calculation. Ventura data were in the range of 1995 through 1999 but Tallahassee and Flint were in the late 1980s through early 1990s. [Note: Please refer to the SAP background documents for PERFUM for further information concerning these data including how they were processed for incorporation into PERFUM and any quality control issues related to these data (http://www.epa.gov/scipoly/sap/2004/index.htm).] Figure 4 provides a comparison of the distributions of daily average windspeeds for selected stations in California and Florida. These can be used to help characterize the deterministic assessments and to illustrate different PERFUM results for the different stations. [Note: As an example, CDPR regulated Methyl bromide at 1.4 m/s windspeed.]

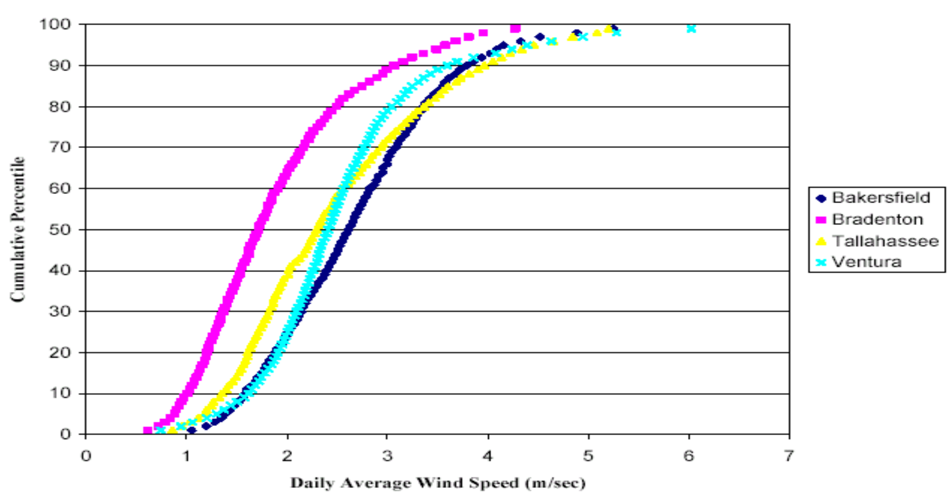

Figure 4: Distribution of Daily Average Windspeeds At Selected Meteorological Stations

References & Sources Used For PERFUM Analysis: The domestic treatment of commodities is an extremely varied undertaking because of the nature of the commodities being treated, the nature of the pest complexes being controlled, the amount of daily throughput required, and the ranges of facilities (e.g., tarped chambers) and processes used for routine treatments (e.g., active aeration). Because the use of methyl bromide on commodities is so varied, the Agency considered a number of sources for information pertaining to these types of applications. The key sources include:

- ***Reference Manual: Methyl Bromide Commodity Fumigation***. CDPR. August 8, 1994 [available at: http://www.cdpr.ca.gov/docs/enfcmpli/manuals/mbcomfum.pdf]

- ***United States Department of Agriculture, Agricultural Plant Health Inspection Service, Plant Protection and Quarantine - Treatment Manual**,* Last Updated 2/6/06 [available at: http://www.aphis.usda.gov/ppq/manuals/port/Treatment_Chapters.htm.]

- ***2005 Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions***, Conference program and presentations [available at: http://mbao.org/2005/0006%202005%20Conf%20Program.pdf.]

Treatment Types & Exposure Scenarios: Based on these documents, comments received in the Phase 3 public comment period, and interactions with various stakeholders the Agency has developed a series of input parameters for the PERFUM modeling which has been completed in order to assess the risks associated with the commodity uses of methyl bromide. These factors stipulate the nature of the buildings, chambers, or structures being treated; application rates and treatment durations; and emission rates and factors. A compilation of these factors lead to categorization of the major use patterns, for risk assessment purposes, into the following major scenarios that include:

- **Scenario 1 - Chamber During Treatment:** This scenario represents what leaks from a chamber during treatment (also referred to as a fugitive emission) where the desire is to retain methyl bromide according to the *CxT* (concentration x time) schedules until a desired level of efficacy is reached.

- **Scenario 2 - Aeration With No Stack:** This scenario represents what is emitted from a chamber after treatment is complete and the desire is to remove remaining methyl bromide as quickly as possible. In this scenario, methyl bromide is purposely vented but there is no stack available to transport emissions further up into the atmosphere so the results reflect a warehouse or other structure that is treated where, for aeration, a door is opened.

- **Scenario 3 - Aeration With Stack:** This scenario represents what is emitted from a chamber after treatment is complete and the desire is to purposely vent remaining methyl bromide as quickly as possible. In this scenario, methyl bromide is purposely vented through a stack to transport emissions further up into the atmosphere to reduce buffer distances and enhance dilution. The results reflect a warehouse or other structure that is treated where a stack is on the roof for ventilation purposes. The impacts of near building downwash effects are accounted for in this scenario.

- **Scenario 4 - Aeration With Portable Stack Not Near Building:** This scenario represents an APHIS PPQ practice where methyl bromide is vented through portable tubing to a stack in an area adjacent to a treated structure or chamber. The scenario represents what is emitted from a chamber after treatment is complete and the desire is to purposely vent remaining methyl bromide as quickly as possible. In this scenario, methyl bromide is purposely vented through a stack to transport emissions further up into the atmosphere to reduce buffer distances and enhance dilution. The results reflect a warehouse or other structure that is treated where methyl bromide is transported to a portable stack, typically within 200 feet of the facility for ventilation purposes. The near building downwash effects are minimized because of the placement of the stacks in this scenario.

- **Scenario 5 - Aeration With Mobile Ground Level Source Not Near Building:** This scenario represents an APHIS PPQ practice where methyl bromide is vented through portable tubing where the output is laid on the ground in an area adjacent to a treated structure or chamber. The scenario represents what is emitted from a chamber after treatment is complete and the desire is to purposely vent remaining methyl bromide as quickly as possible. In this scenario, methyl bromide is purposely vented through the tubing to transport emissions away from the chamber or facility to reduce buffer distances. The results reflect a warehouse or other structure that is treated where methyl bromide is transported through tubing with the output typically within 200 feet of the facility for ventilation purposes. The near building downwash effects are minimized because of the placement of the vent tubes in this scenario.

PERFUM Model Inputs: In order to assess the potential levels of exposures that could be associated with the 5 exposure scenarios described above, the Agency has developed a series of input parameters for the PERFUM modeling that is meant to bracket the range of possible exposures associated with the methyl bromide treatment of commodities under various common use practices. The modeled conditions are also thought to encompass and expand upon the permit conditions currently used in California to mitigate commodity applications. [Note: A discussion of how these inputs translate to common commodity practices is described below in the results and characterization sections - see below for further information concerning such specific situations.] The factors which have been used include:

- **Treatment Concentrations (derived from labels & CxT tables):**
  -Food Commodities: 1 and 4 lb ai/1000 cubic feet; and
  -Other Materials (e.g., logs): 9 and 15 lb ai/1000 cubic feet.

- **Retention & Emission Rates (expressed as % of treatment concentrations):**
  -Chambers During Treatment (Scenario1): 1, 5, 10, 25, and 50% of treatment concentration; and
  -For Aeration (Scenarios 2-5): 50, 75, 90, 95, 99, and 100% of treatment concentration is released and varies based on how airtight the chamber is during active treatment or how much is absorbed by the materials or commodities being treated.
  [Note: DPR Permit conditions establish loss rates during treatment from 0.2 to 3.0 lb mebr/1000 ft^3 and during aeration from 0.4 to 6 lb mebr/1000 ft^3.]

- **Chamber/Structure Volume:**
  -Small scale: 1000, 2000, 5000 cubic feet;
  -Mid scale: 10000, 25000, 50000 cubic feet; and
  -Large scale: 100000, 250000, 500000, 750000, 1000000 cubic feet.

- **Chamber/Structure Height:**
  -Small scale: 1000 cu. ft = 10 feet tall, 2000 cu. ft. = 12 feet tall, 5000 cu. ft. = 17 feet tall;
  -Mid scale: 25 feet tall
  -Large scale: 75 feet tall

- **Stack & Release Heights:**
  -All fixed stack heights = stack, 10 feet above roof of chambers or structures [Note absolute release height then varies when added with specific building height]
  -Portable stack height = 50 feet

- **Active Air Exchange Rates:**
  -1 air exchange/minute;
  -0.5 air exchanges/minute; and
  -0.05 air exchanges/minute.
  [Note: Fixed fan capacities = 2000 ft/minute for structures up to and including 100,000 cubic feet. For larger structures a fan velocity of 5000 ft/minute was used. These have been empirically observed by CDPR under actual use conditions. For no stack scenarios, aeration is passive and it is treated as an area source in PERFUM.]

- **Stack Diameters:**
  -PERFUM can only accommodate a single stack so the diameters are varied in order to achieve the proper cross sectional ventilation areas for each combination of chamber/structure size and air exchange value. The results for larger chambers or high concentration treatments, therefore, may be based on very large diameter stacks which would not occur in reality to achieve proper ventilation (i.e., 0.2 m to 5 m). Under actual conditions, multiple stacks would be used in order to achieve target air exchange rates. The architecture of PERFUM requires that these analyses be done in this manner. This approach is not expected to be a negative bias in the results. In fact, this approach is likely a conservative method because all emitted methyl bromide is forced out at one location making the predicted distances higher.

- **Treatment Frequency & Emission Profiles:**
  -A number of frequency and emission profiles were considered in order to simulate the practices associated with methyl bromide commodity use. In many applications (e.g., import grapes) the active application duration is a matter of a couple of hours or so followed by a quick ventilation process which takes on the order of 15 minutes or less. In some cases, multiple chambers are being released in sequence because of the number of batches required to keep up with through-put requirements at ports and other facilities. Finally, there are other cases where the treated materials (e.g., logs and timber) offgas for up to several days, but where most material comes off in the first day or so. Based on this information, the Agency considered 4 frequency and emission profiles in the assessment:

-1 hour, single emission: based on a single application and short-lived emission period such as 15 minutes. Actual modeling used a 1 hour emission profile, as the smallest interval permitted in PERFUM is 1 hour. As the HEC used in the assessment is an 8 hour endpoint, a 1 hour emission profile was thought to be a more accurate comparison;

-4 hour, single emission: based on a single application and short-lived emission period such as 15 minutes. As with the 1 hour, single emission scenario, a 1 hour emission profile was used for the release. This release was then followed by 3 hours without a release.

-4 hour, multiple emissions: based on multiple, sequential emissions and short-lived emission periods such as 15 minutes. This is similar to the 1 hour, single emission scenario, except the resulting concentrations were averaged over a 4 hour period. This scenario is used model sequential batches resulting in multiple emissions events that are occurring during high through-put periods of activity not uncommon at many ports for seasonal commodities; and

-24 hour, continuous single emission: based on a single application and an extended emission period from materials that may absorb methyl bromide residues (e.g., logs and timbers), the duration of most concern is the first 24 hours. The basis of this assessment is that the majority of methyl bromide emissions would be expected in that interval.

- **Target Concentrations (HECs/UF):**
  -8 Hour NOAEL HEC (30 ppm) and Uncertainty Factors 30, 10, 3, and 1 ; and
  -24 Hour NOAEL HEC (10 ppm) and Uncertainty Factors 30, 10, 3, and 1 for selected scenarios where offgassing from a treated commodity (e.g., logs or timber) would be expected over extended periods of time.
  [Note: The 8 hour duration is longer than the durations associated with the frequency and emission profiles described above. However, based on the available hazard information, this is the shortest recommended duration for an HEC the Agency believes to be justifiable.]

PERFUM calculates outputs based on each day's worth of meteorological data and the result is illustrated by Figure 5 which shows the distances from the commodity facility (i.e., chamber or building) where airborne concentrations meet a threshold of concern around its perimeter (i.e., the irregularly shaped line). The concentric circle represents an example 95th percentile distance value around the perimeter (i.e., the distance for that day where MOEs are not of concern for 95% of those exposed). The cross hatch area represents the locations where distances exceed the 95th percentile value (i.e., MOEs are of concern at these distances for 5% of the exposed population). These exceedances have been examined using the PERFUM MOE program and other approaches (see SAP site for more details) in order to provide risk managers with a better understanding of how many factors can influence predicted buffer distances, including how predicted buffers change with changing margins of exposure.

PERFUM generates the type of output illustrated by Figure 5 for each day over a 5 year period (i.e., 1825 days) then summarizes the information by providing two types of results that include the *"Maximum Buffer"* distance and the *"Whole Field Buffer"* distance. Each is reported as a distribution. The *"Maximum Buffer"* distribution is based on the maximum distance needed to reach a threshold level of concern (i.e., HEC adjusted by uncertainty factor) calculated using PERFUM for each day (i.e., a distribution of the farthest single points on the irregular line for each day). This results in a distribution that contains 1825 values and in this assessment, the results have been reported for selected percentiles from those distributions. The *"Whole Field Buffer"* is also based on values from each day, except the distances on which the distribution is based include those on each spoke where the threshold concentration is achieved for each day (i.e., a distribution of the distances on all spokes on the irregular line where it intersects each spoke). The number of values in the distributions vary and are based on 1825 days (or more intervals if averaging time is less than 24 hours) multiplied by the number of spokes around the field which relates to field size. As with the *"Maximum Buffer"* distances, results from selected percentiles from the distribution have been reported.

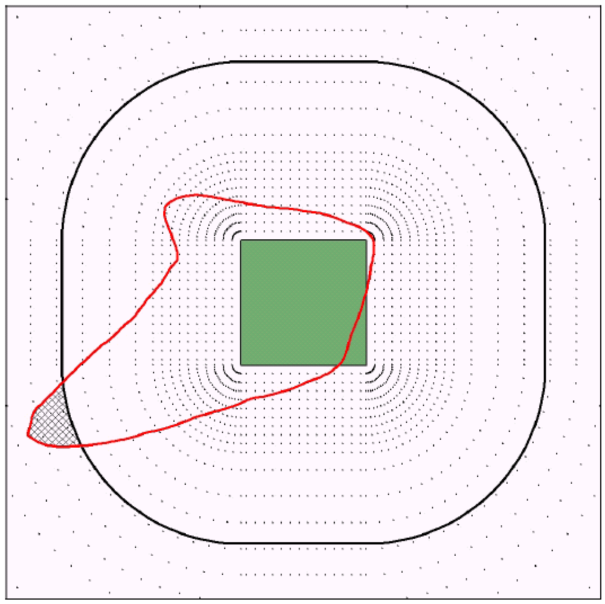

Figure 5: Example Daily PERFUM Output

6.1.1.2 Bystander Exposures And Risks From Known Sources

The risks for bystanders from various types of known sources are presented in this section (e.g., commodity chamber, etc.). For the purposes of this assessment, known sources are thought to represent a point source from a single application (e.g., a stack on the roof of a commodity treatment chamber) or an area source when no stack emissions are considered (e.g., an opened door or a stack used to dissipate residues from a treated commodity chamber). Because of the refinements offered by the PERFUM modeling approach, it is believed results based on this method should be considered as the most appropriate for evaluating the risks associated with commodity uses methyl bromide. However, it should be noted that results from all of the approaches described above were used to characterize the range of risks associated with methyl bromide.

The monitoring data which are applicable to the commodity uses of methyl bromide are presented summarized in Appendices D and E of this document. The data are resultant from various monitoring studies, predominantly conducted by CDPR staff in facilities thought of as traditional commodity treaters and also larger facilities like a rice mill. Previously, these larger scale treatments were considered to be more of an industrial nature but it is clear that these data are also applicable to the commodity uses of methyl bromide. The exposure concentrations and associated risk estimates that have been calculated based on the commodity and applicable industrial data are presented in Table 5 below. The results indicate a risk concern for acute exposures in proximity to a treatment chamber or facility. Generally, short-term exposures are not of concern. If short-term exposures were calculated using a 24 hour HEC of 1 ppm then MOEs would be of concern but this is likely to be an overestimate of risk. Based on this information, however, it is clear that acute exposures are of more concern and thus any mitigation of those exposures would similarly reduce short-term exposures thus further decreasing concerns over short-term exposures. As such, the Agency has focused on evaluating the potential risks associated with acute exposure patterns.

Table 5: Acute and Short-term Bystander Risks Calculated Based On Methyl Bromide Monitoring Data After Commodity And Applicable Industrial Treatments

Data Type	Location	[Methyl Bromide] (ppm)		MOEs*	
		Maximum	Mean	Acute	Short-term
Commodity	acute ~320 ft. mean - range	6.79	0.10	4.4	44
Industrial (fenceline monitoring)	<200 ft	1.10	0.12	27	37
	200 to 700 ft	0.09	0.01	323	400
	700 to 1000 ft	0.05	0.01	625	400
	>1000 ft	0.01	0.002	3800	2095

* Target MOE or UF = 30, MOEs calculated using 8 hr HEC (30 ppm for acute and 4.4 ppm for short-term). Air concentrations are time-weighted averages of differing durations from 5 hours or so to a 24 hr twa but use of a 24 hour HEC would lead to a likely overestimation of risks based on the nature and frequency of commodity uses for the vast majority of expected exposure scenarios.

The ISCST3 model (i.e., Industrial Source Complex, Short-term Model, V3) was also used in the earlier assessment (D316326) to calculate margins of exposure at downwind distances under weather conditions that varied from calm to a turbulent atmosphere. Results were as expected with receptors close to the field (i.e., 100s of meters in some cases)having risk concerns while those further away or those in a more turbulent atmosphere had less overall risk concerns. In some cases, risks were not of concern even when directly adjacent to the treatment area. Revised ISCST3 risk estimates were not recalculated for this assessment since the PERFUM model has been revised and the Agency believes that it offers a more refined estimate of risks since its calculations are based on 5 years of weather data as opposed to the deterministic approach that has been used with ISCST3 (i.e., fixed downwind direction, windspeed, and stability class - i.e., level of turbulence).

The Agency believes the ***PERFUM Modeling Method*** provides the most refined, scientifically defensible approach for calculating and characterizing risks because it incorporates actual weather data, and it links flux profiles to the appropriate time of day when calculating results. It also uses as its core processor the proven technology of ISCST3. The remainder of this section presents the potential risks for bystanders which have been calculated using the PERFUM model for those downwind of commodity treatments. A large number of model calculations have been completed based on the factors described above but for the purposes of this assessment the Agency has focused on summarizing the results that are most applicable to the commodity uses of methyl bromide that are subjected to the tolerance reassessment requirements of 2006. Also, the Agency has limited the numbers of results that have been summarized by evaluating results for Ventura California and application rates of 1 and 4 lb/1000 cubic feet as well as other factors. The number of permutations that are possible based on the input variables described above and that have been summarized for the purposes of this assessment are presented in Table 6 below. [Note: PERFUM outputs are available for the various combinations described in Table 6. These are available for review but are not included in this assessment, per se. The 2000 or so combinations that have been summarized by the Agency are included as summary documents in the form of appendices to this assessment. The appendices only contain a summary of the PERFUM outputs and not the actual output files.]

Table 6: PERFUM Model Permutations Considered In Analysis Of Methyl Bromide Commodity Uses

# Weather Sources	# UF	# Durations	# Appl .Rate	# Aeration Types	# Structures (ft^3)	# Percent Emitted	# PERFUM Outputs	Total
3	4	4	4	10	11	8	2	~300,000*

* Indicates possible number of iterations of PERFUM model output. These estimates have all been calculated and are available as PERFUM output files for interested parties. For the purposes of this assessment, ~2000 different combinations were summarized based on: Ventura CA weather, 1&4 lb/ft3 rates, 5 aeration types, 5 structure sizes, 10 percent emitted values, and 2 PERFUM output types.

The PERFUM outputs have been summarized in Appendix F for each combination described in Table 6. Appendix F contains 21 subappendices which are described below. Twenty of these are data files that represent a specific combination of exposure duration, application rate, and aeration type and one file is a summary analysis file. In each of the 20 data files there are results for possible 100 combinations based on changes in structure size (5), percent emitted (10), and PERFUM outputs (2). Appendix F includes the following:

- **Appendix F1.Ventura.F301Hr1lbMS05:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 1 lb/1000 ft^3, minimum stack height results, and an air exchange rate of 0.05 times/minute.

- **Appendix F1.Ventura.F301Hr1lbMSFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 1 lb/1000 ft^3, minimum stack height results, and an air exchange rate based on full exit velocity of 1 time/minute.

- **Appendix F1.Ventura.F301Hr1lbNS:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 1 lb/1000 ft^3, and results for no stack (i.e., opening a door).

- **Appendix F1.Ventura.F301Hr1lbPortFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 1 lb/1000 ft^3, portable stack results, and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F1.Ventura.F301Hr1lbPPQFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 1 lb/1000 ft^3, PPQ-type emissions (i.e., a tube lying on its side in a secured flat area), and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F2.Ventura.F301Hr4lbMS05:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 4 lb/1000 ft^3, minimum stack height results, and an air exchange rate of 0.05 times/minute.

- **Appendix F2.Ventura.F301Hr4lbMSFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 4 lb/1000 ft^3, minimum stack height results, and an air exchange rate based on full exit velocity of 1 time/minute.

- **Appendix F2.Ventura.F301Hr4lbNS:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 4 lb/1000 ft^3, and results for no stack (i.e., opening a door).

- **Appendix F2.Ventura.F301Hr4lbPortFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 4 lb/1000 ft^3, portable stack results, and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F2.Ventura.F301Hr4lbPPQFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 1 hour emission, an application rate of 4 lb/1000 ft^3, PPQ-type emissions (i.e., a tube lying on its side in a secured flat area), and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F3.Ventura.F304Hr1lbMS05:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 1 lb/1000 ft^3, minimum stack height results, and an air exchange rate of 0.05 times/minute.

- **Appendix F3.Ventura.F304Hr1lbMSFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 1 lb/1000 ft^3, minimum stack height results, and an air exchange rate based on full exit velocity of 1 time/minute.

- **Appendix F3.Ventura.F304Hr1lbNS:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 1 lb/1000 ft^3, and results for no stack (i.e., opening a door).

- **Appendix F3.Ventura.F304Hr1lbPortFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 1 lb/1000 ft^3, portable stack results, and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F3.Ventura.F304Hr1lbPPQFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 1 lb/1000 ft^3, PPQ-type emissions (i.e., a tube lying on its side in a secured flat area), and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F4.Ventura.F304Hr4lbMS05:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 4 lb/1000 ft^3, minimum stack height results, and an air exchange rate of 0.05 times/minute.

- **Appendix F4.Ventura.F304Hr4lbMSFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 4 lb/1000 ft^3, minimum stack height results, and an air exchange rate based on full exit velocity of 1 time/minute.

- **Appendix F4.Ventura.F304Hr4lbNS:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 4 lb/1000 ft^3, and results for no stack (i.e., opening a door).

- **Appendix F4.Ventura.F304Hr4lbPortFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 4 lb/1000 ft^3, portable stack results, and an air exchange rate based on a full exit velocity of 1 time/minute.

- **Appendix F4.Ventura.F304Hr4lbPPQFullEV:** contains a summary of the results using Ventura CA weather data, an uncertainty factor = 30, 4 hour emission, an application rate of 4 lb/1000 ft^3, PPQ-type emissions (i.e., a tube lying on its side in a secured flat area), and an air exchange rate based on a full exit velocity of 1 time/minute.

- **AppendixF5.Analysis:** contains a summary of the 2000 PERFUM results.[Note: This appendix also contains a summary table that provides risk calculations based on the data where the target uncertainty factor of 30 has been altered to illustrate how risks change with varying distances.]

It should be acknowledged that a myriad of micro-environmental conditions and factors can impact how methyl bromide will both volatilize and disperse from any given commodity treatment on any given day.

With this premise, it would be logical to evaluate basic factors which could influence dispersion (e.g., temperature, absorptive properties of chambers, etc.) and also micro-climates (e.g., topography, downdraft potential, etc.) and thus ultimately impact results. However, PERFUM cannot easily address specific changes in many of these factors because it is not a 1^{st} Principles Model where the approach would be to build a predictive tool from basic fate characteristics. Instead, PERFUM is an empirical model which utilizes user inputs in this case that have been defined based on empirical monitoring data and use information along with actual meteorological data to predict results. Since such data are the basis for the PERFUM predictions it follows that results based on empirical monitoring and those calculated with PERFUM would be similar (see guidance pertaining to air model validation at http://www.epa.gov/scram001/guidance/guide/appw_03.pdf for additional information).

It should also be acknowledged that the nomenclature incorporated into PERFUM uses the term "buffer zone" which equates to the distance downwind at which a specific target concentration (i.e., combination of HEC and UF) is met based on the desired statistical parameters. The use of this term does not imply any regulatory decision. In the context of this risk assessment, it should only be considered as the predicted distance for a specific target concentration. A number of differing factors were considered to evaluate the sensitivity of the results to changes in various inputs.

Based on the range of input parameters that have been considered in this analysis and the various outputs that are available, some general conclusions can be drawn with regard to the trends observed in the results including:

- In many situations, predicted buffer distances are 1440 meters which is the maximum distance that the PERFUM model will predict even at lower percentiles of exposure (e.g., 50^{th}). However, in other situations, PERFUM predicts that buffer distances can be in proximity to the treated structure or chamber even at the highest percentiles of exposure. It appears that for the scenarios which have been summarized that the APHIS PPQ and Portable Stack aeration approaches consistently have the lowest buffer distances associated with them and that no-stack situations tend to have the highest buffer distances associated with them.

- Given all of the complexity of the input values, the Agency does not believe that use of a particular source of weather data (e.g., Flint or Tallahassee) will impact the general trends in the results.

- The commodity treatment industry is extremely broad and it is clear that the situations where methyl bromide is used vary extensively from highly sophisticated negative pressure chambers to other situations as simple as fumigation of a Sea-Van or tarped, palletized commodities sitting on a loading dock. As such, the Agency has attempted to capture the range in this assessment. It is clear that as several factors increase that predicted buffer distances increase. These include: structure size, application rate, and percentage aerated. Increases in other factors are inversely proportional to buffer distance and these include such factors as exit velocity and stack height.

- PERFUM has the capability of evaluating how risks (i.e., MOEs) change at a specific location if different percentiles of exposure or other statistics are selected. It appears that, in general, risk estimates are not extremely sensitive to changes in the selected percentile at the upper percentiles of exposure (e.g., 95^{th} to 99^{th}). This phenomenon appears to be due to the flatness of the Gaussian curve upon which ISCST3 is based at the upper percentiles of exposure.

It is clear that given the number of possible permutations of PERFUM inputs and ways of presenting the outputs that there are many possible approaches for interpreting the results. The central goal, however, is to quantify how potential risks change with changes in various input factors. Each of these factors have been considered and very detailed results pertaining to each are available in the appendices referenced above. In order to summarize the analyses which have been completed and to illustrate the general approach, a selected number of tabular and graphical interpretations of the results are presented below. In the examples below, the basic trends have been illustrated using results for the 4 hour duration and 4 lb methyl bromide/1000 cubic feet scenarios because the application rate is at or slightly above the maximum application rate for most commodities with a food tolerance and use of the 4 hour duration (i.e., 1 hour emission and 3 hours no-emissions to calculate a time weighted average) provides the closest comparison to the 8 hour HEC (30 ppm) which is the hazard basis for these calculations. [Note: The results in this category are contained in Appendix F4 as described above.] In addition to the basic trends it is also important to illustrate how inputs such as uncertainty factor, duration of exposure, and application rate can also impact results.

An important premise for evaluating commodity treatments is that the concept is simplistic in that the objective is to place a commodity in a room or chamber, apply methyl bromide to it at a specific air concentration for a specific time during which the goal is to retain methyl bromide so it can be efficacious. Once a treatment duration is complete the goal is to aerate methyl bromide from the room or chamber as quickly as possible. During treatment, it is a given that chambers leak to some extent or another unless the chamber is extremely well engineered, maintained, and the operators are highly trained and experienced. The amount of leakage during treatment can be very low but it still likely occurs even in the best situations (e.g., 1 to 10% of the treatment amount). Conversely, in the worst situations, leakage during treatment can be very high (e.g., 10 to 50%). The Agency has considered this in these results. After treatments are complete the objective is to aerate as quickly as possible but the mass being aerated depends upon how well the chamber worked at retaining methyl bromide. Again, there is a range where the best chambers can likely retain 99 percent or so of the administered methyl bromide but more typically it would be expected that between 75 and 95 percent or so of the administered may be available at the beginning of aeration. These ranges have all been considered in the assessment. Figures 6, 7, 8, and 9 below illustrate how changes in aeration type can vary based on the nature of the aeration practice (i.e., all are PERFUM maximum buffer results for illustrative purposes). Figure 6 presents the results for a minimum stack scenario using chambers from 1000 to 100,000 cubic feet and an air exchange rate of 0.05X/minute. Figure 7 is similar except the air exchange has been increased to the APHIS PPQ standard of 1 air exchange/minute. Figure 8 presents results for a no-stack scenario which essentially represents what would happen if a chamber was treated and aeration occurred by opening a door. Figure 9 presents the results for the APHIS PPQ standard method of an air exchange per minute using ground-level portable output vents in secured areas near a chamber (e.g., parking lot). APHIS PPQ use of a portable 50 tall stack was also evaluated but all analyses resulted in a 0 meter buffer distance prediction. Figure 10 illustrates how whole-field results may differ from the maximum buffer distances using the no stack scenario for comparison (i.e., compare to Figure 8).

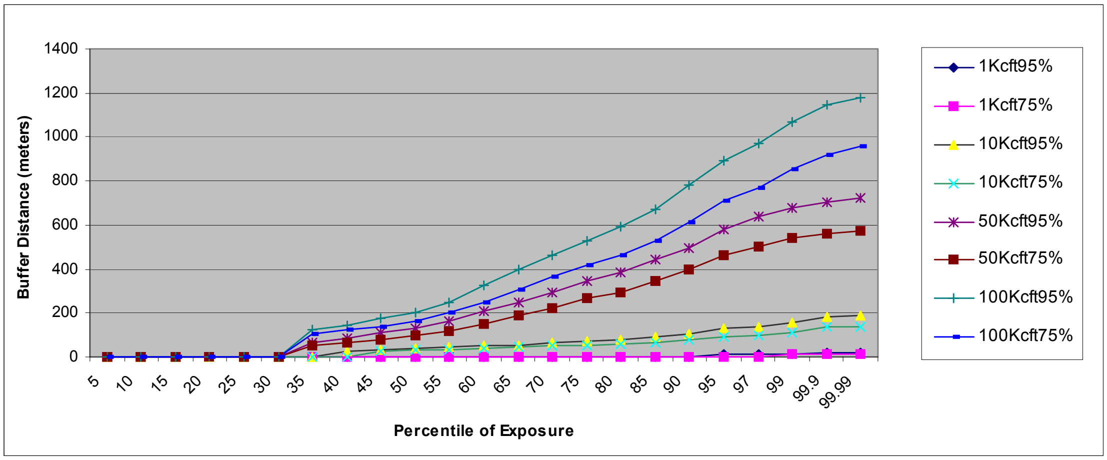

Figure 6: Methyl Bromide Maximum Distance Buffers Based On UF30, Ventura Weather, 4 hour Duration, 4 lb/1000 cu. ft., Minimum Stack Aeration (0.05 exch/min.) - 75 & 95% Mass Release

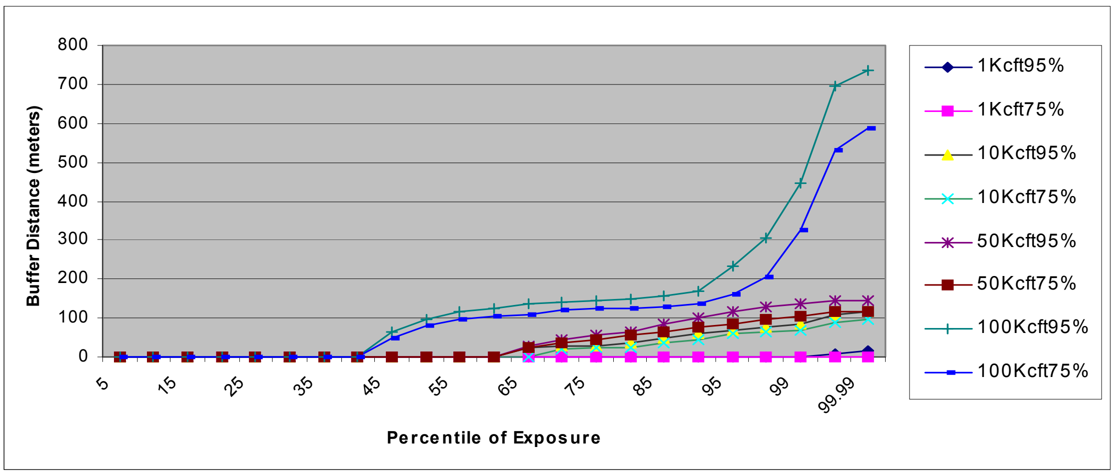

Figure 7: Methyl Bromide Maximum Distance Buffers Based On UF 30, Ventura Weather, 4 hour Duration, 4 lb/1000 cu. ft, Minimum Stack Aeration (1 exch/min.) - 75 & 95% Mass Release

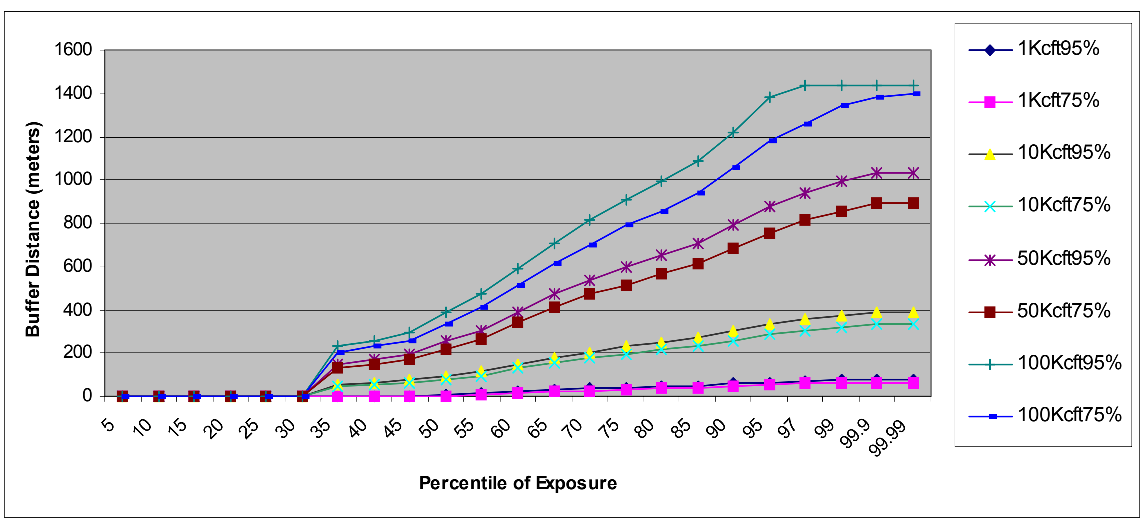

Figure 8: Methyl Bromide Maximum Distance Buffers Based On UF30, Ventura Weather, 4 hour Duration, 4 lb/1000 cu. ft, No Stack Aeration - 75 & 95% Mass Release

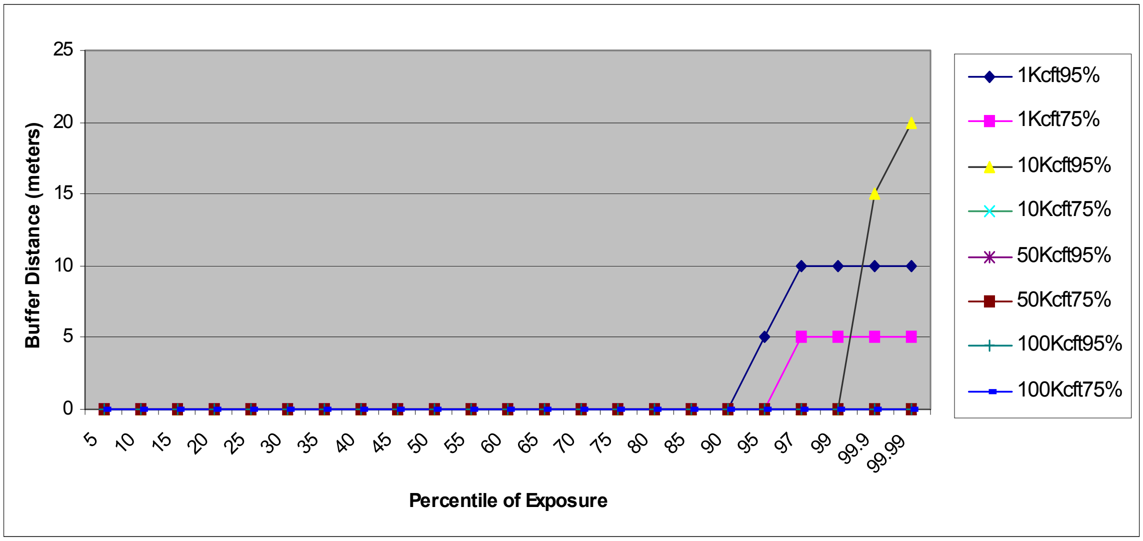

Figure 9: Methyl Bromide Maximum Distance Buffers Based On UF 30, Ventura Weather, 4 hour Duration, 4 lb/1000 cu. ft, PPQ Aeration (1 air exch./min.) - 75 & 95% Mass Release

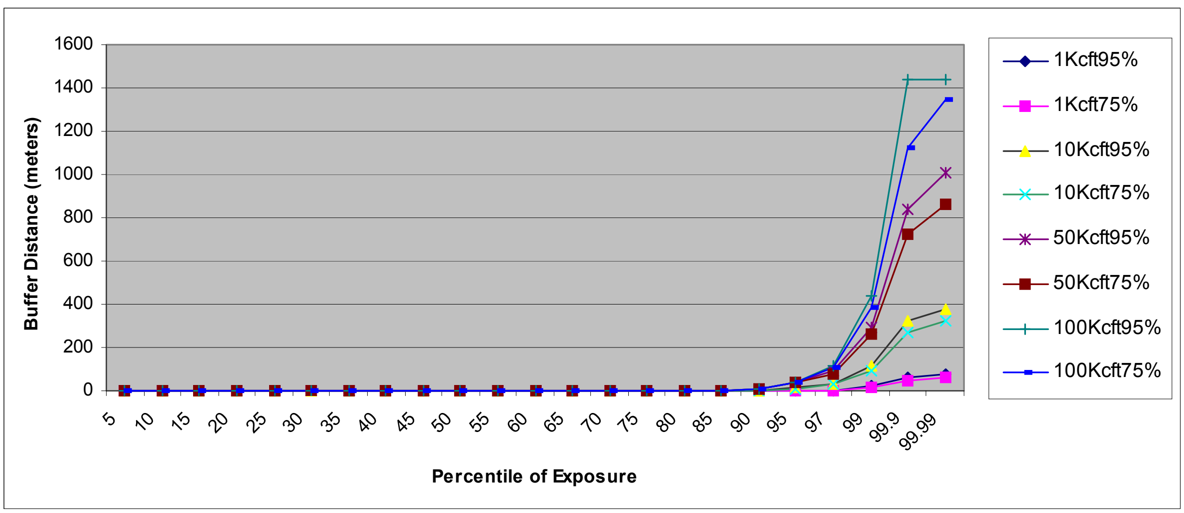

Figure 10: Methyl Bromide Whole Field Buffer Distances Based On UF30, Ventura Weather, 4 hour Duration, 4 lb/1000 cu. ft, No Stack Aeration - 75 & 95% Mass Release

The results presented in Figures 6 through 10 indicate that except for the PPQ and portable stack aeration procedures that at higher percentiles of exposure 100 meters or more buffer distance is required even for smaller chambers such as 10,000 cubic feet (i.e., a room approximately 40x25x10 feet). In some cases, the smaller 1000 cubic feet chambers require much less buffer distance. In many cases such as larger chambers and the highest percentiles, predicted buffer distances exceed 1000 meters and even achieve the maximum PERFUM distance of 1440 meters. Based on stakeholder inputs, buffer distances of 100+ meters would require substantial operational changes in order to be compliant in many situations because of the physical layout, surrounding properties, and topography of many use sites. For larger chambers at the highest percentiles, consideration of either whole or maximum buffer results has little or no impact because of the typical operational constraints of many users. Table 7 below provides a summary of some of the values included in Figures 6 through 10 for illustrative purposes. [Note: Refer to Appendix F4 and Appendix F5, Tables 16 through 20 for more information.]

Table 7: PERFUM Methyl Bromide Buffer Distances (meters) For All Aeration Processes Considered Based On UF30, 4 hour Exposure Duration, 4 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released									
Aeration Type	Percentile	1000 Cubic Feet		10000 Cubic Feet		50000 Cubic Feet		100000 Cubic Feet	
		95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release
Maximum Buffer Distances.									
Minimum Stack 0.05 xch/min	95	10	0	130	90	580	460	895	710
	99	15	10	155	110	680	540	1065	855
	99.9	20	15	185	140	705	560	1145	920
Minimum Stack 1 xch/min	95	0	0	70	60	115	85	235	160
	99	0	0	85	70	135	105	445	325
	99.9	10	0	110	90	145	115	695	530
No Stack	95	65	55	335	285	875	755	1380	1180
	99	75	60	370	320	995	855	1440	1340
	99.9	80	65	385	335	1030	890	1440	1385
Portable Stack 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0
	99.9	0	0	0	0	0	0	0	0
PPQ 1 xch/min.	95	5	0	0	0	0	0	0	0
	99	10	5	0	0	0	0	0	0
	99.9	10	5	15	0	0	0	0	0
Whole Field Buffer Distances.									
Minimum Stack 0.05 xch/min	95	0	0	0	0	40	35	0	0
	99	0	0	50	40	200	160	280	230
	99.9	10	0	120	85	535	425	850	675
Minimum Stack 1 xch/min	95	0	0	0	0	0	0	0	0
	99	0	0	20	0	45	40	105	90
	99.9	0	0	65	50	105	80	220	155
No Stack	95	0	0	15	10	35	35	40	35
	99	20	15	115	95	295	260	440	385
	99.9	60	50	320	270	835	720	1440	1125
Portable Stack 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0
	99.9	0	0	0	0	0	0	0	0

Table 7: PERFUM Methyl Bromide Buffer Distances (meters) For All Aeration Processes Considered Based On UF30, 4 hour Exposure Duration, 4 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released									
Aeration Type	Percentile	1000 Cubic Feet		10000 Cubic Feet		50000 Cubic Feet		100000 Cubic Feet	
		95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release	95% Mass Release	75% Mass Release
PPQ 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0
	99.9	0	0	0	0	0	0	0	0

In addition to concerns over appropriate buffer distances and other mitigation strategies during the aeration phase of methyl bromide use in commodity treatments, it is also important to consider how much material may leak from a chamber during the treatment phase (Table 8). In order to simulate this, low percentage mass release values were used to mimic such situations. These estimates were calculated based on all aeration types but it is believed that the no-stack scenario best represents real-world conditions because of a lack of active aeration (i.e., no fans are used to push methyl bromide from the chamber in the no-stack aeration, it essentially represents a leaky box which is what would be expected during treatment in most situations). It is clear that based on the results presented in Table 8 that in most circumstances some sort of buffer distance or other mitigation option (e.g., a performance criteria for leaking less than a specific percentage of the applied mass) needs to be in place to reduce exposures for those in proximity to a structure during treatment itself except for the smallest chambers considered.

Table 8: PERFUM Methyl Bromide Buffer Distances (meters) During Treatment Based On UF30, 4 hour Exposure Duration, 4 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released									
Aeration Type	Percentile	1000 Cubic Feet		10000 Cubic Feet		50000 Cubic Feet		100000 Cubic Feet	
		10% Mass Release	1% Mass Release	10% Mass Release	1% Mass Release	10% Mass Release	1% Mass Release	10% Mass Release	1% Mass Release
Maximum Buffer Distances.									
No Stack	95	0	0	60	0	205	0	335	35
	99	0	0	75	0	230	0	375	45
	99.9	0	0	80	0	240	0	390	50
Whole Field Buffer Distances.									
No Stack	95	0	0	0	0	10	0	20	0
	99	0	0	15	0	75	0	120	0
	99.9	0	0	55	0	195	0	320	30

Along with the factors examined above, the Agency also investigated the impact varying both the duration of exposure in order to more closely mimic real-world conditions (i.e., 1 hour durations) and also to present more realistic risk estimates (i.e., 4 hour durations). The 1 hour duration exposure intervals are as close as the PERFUM model can represent many commodity treatment situations where aeration is rapidly completed. The issue is, however, that albeit a better simulation of many actual exposure events the 1 hour duration does not provide a more realistic risk estimate because the HEC used to calculate risks is based on a 8 hour exposure interval. The available hazard data do not allow for a more refined HEC estimate. In order to better approximate likely risks 4 hour exposure durations were also considered which were calculated by including 1 hour of emission coupled with 3 hours of no emissions. This approach more closely approximates the 8 hour HEC, which is based on continuous exposure over that time, but the comparison is still somewhat conservative. [Note: In some ports and other treatment facilities, the frequency of treatments, or number of batches treated on a daily basis is high. In order to address these types of occurrences, the Agency completed PERFUM calculations using a 4 hour - 4 event scenario. However, these calculations have not been summarized for the purposes of this assessment to save resources because any likely mitigation strategy based on a single event would also impact these estimates. The PERFUM outputs can be provided to interested parties for examination is so desired.] Application rate is also a key factor in determining buffer distances using the PERFUM approach. All of the summaries presented above are based on an application rate of 4 lb/1000 cubic feet which is the maximum rate or just slightly above (i.e., it is 3.5 lb/1000 cubic feet for many crops) for most commodities that have an associated food tolerance. It has also been noted by many stakeholders that a significant portion of methyl bromide applications do not occur at that rate but occur at much lower rates. In order to examine the effect of lowering the application rate a value of 1lb/1000 cubic feet was also used to illustrate a more typical use situation. Figures 11, 12, 13, and 14 below illustrate how changes in exposure duration and application rates can impact predicted buffer distances. Figure 11 presents the results for a minimum stack scenario using 10,000 and 100,000 cubic feet chambers and an air exchange rate of 0.05X/minute. Figure 12 is similar except the air exchange has been increased to the APHIS PPQ standard of 1 air exchange/minute. Figure 13 presents results for a no-stack scenario which essentially represents what would happen if a chamber was treated and aeration occurred by opening a door. Figure 14 presents the results for the APHIS PPQ standard method of an air exchange per minute using ground-level portable output vents in secured areas near a chamber (e.g., parking lot). APHIS PPQ use of a portable 50 tall stack was also evaluated but all analyses resulted in a 0 meter buffer distance prediction.

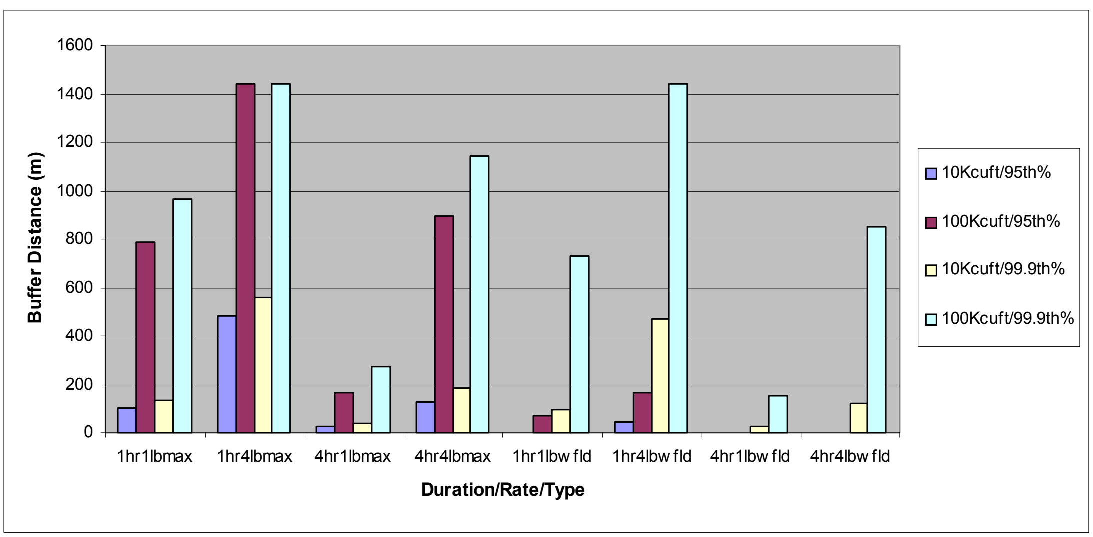

Figure 11: Methyl Bromide Minimum Stack (0.05 xch/min.) 95th & 99.9th Percentile Buffer Distances Based On UF30, & Varied Structure Size, Duration, Application Rate

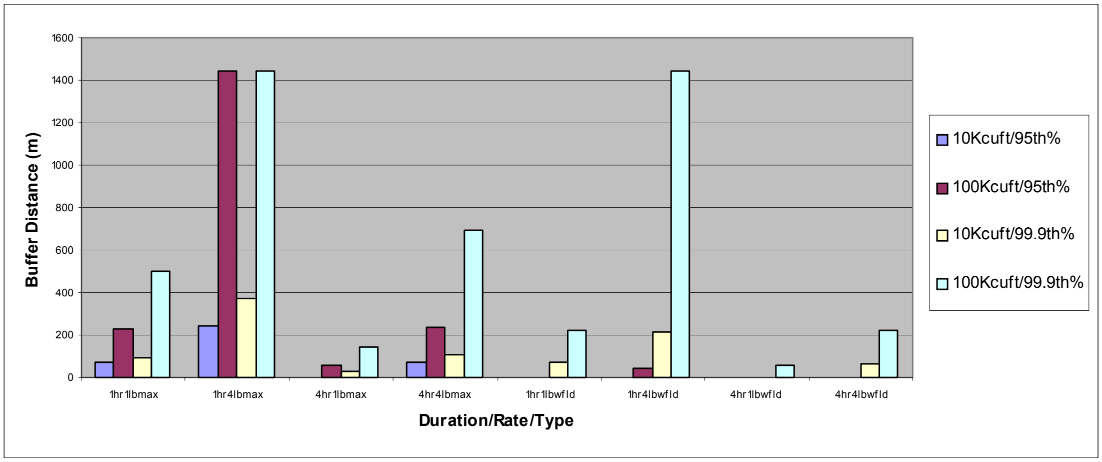

Figure 12: Methyl Bromide Minimum Stack (1 xch/min.) 95th & 99.9th Percentile Buffer Distances Based On UF 30 & Varied Structure Size, Duration, Application Rate

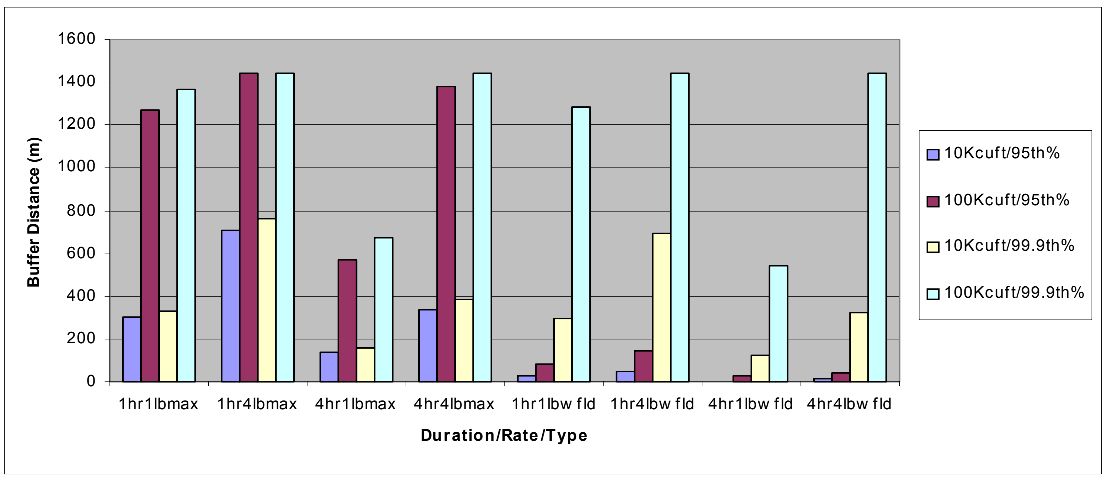

Figure 13: Methyl Bromide No Stack Aeration 95th & 99.9th Percentile Buffer Distances Based On UF 30 & Varied Structure Size, Duration, Application Rate

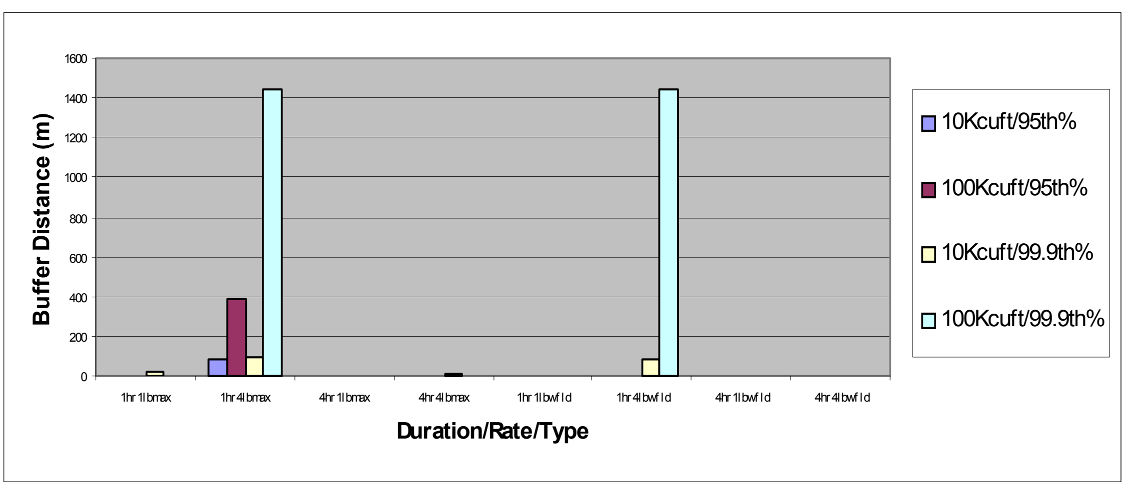

Figure 14: Methyl Bromide PPQ Aeration (1 xch/min.) 95th & 99.9th Percentile Buffer Distances Based On UF 30 & Varied Structure Size, Duration, Application Rate

The results presented in Figures 11 through 14 indicate that the PPQ and portable stack aeration procedures as well as the minimum stack at full exit velocity have smaller associated buffer distances. For larger structures at lower aeration velocities, predicted buffer distances are large and likely will result in operational changes by users regardless of whether 1 or 4 hour durations are considered or even based on application rate. It is also clear from Figures 11 through 14 that lower application rates have lower associated buffer distances as would be expected. It is also clear that the longer the averaging time for a single exposure event the lower the associated buffer distances as also would be expected. The Agency reaffirms that the 4 hour duration results probably represent the most refined risk estimates because they result in a closer comparison to the 8 hour HEC. The values presented in Figures 11 through 14 above represent the losses that would be expected during aeration after treatment. PERFUM outputs were also summarized to examine similar results during treatment (i.e., at 1 and 10 percent applied mass loss as above). The trends were similar for those observed above in Table 8 where predicted buffer distances were much lower as expected and the general relationship between exposure duration and application rate with predicted buffer distances also still applies. Table 9 below provides a summary of some of the values included in Figures 11 through 14 for illustrative purposes. [Note: Refer to Appendix F5, Tables 21 through 28 for more information.]

Table 9: PERFUM Methyl Bromide Buffer Distances (meters) For All Aeration Processes Considered Based On UF30, 95% Applied Mass Release, & Varied Structure Size, Exposure Duration, Application Rate

Aeration Type	Percentile	1 Hour & 1 lb/1000 cu. ft		1 Hour & 4 lb/1000 cu. ft		4 Hour & 1 lb/1000 cu. ft		4 Hour & 4 lb/1000 cu. ft	
		10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft
Maximum Buffer Distances.									
Minimum Stack 0.05 xch/min	95	100	790	480	1440	25	165	130	895
	99	120	860	515	1440	30	215	155	1065
	99.9	135	965	560	1440	35	275	185	1145
Minimum Stack 1 xch/min	95	70	225	245	1440	0	55	70	235
	99	85	360	340	1440	25	75	85	445
	99.9	95	500	370	1440	30	140	110	695
No Stack	95	305	1270	710	1440	135	570	335	1380
	99	320	1340	750	1440	150	645	370	1440
	99.9	330	1365	765	1440	155	670	385	1440
Portable Stack 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0
	99.9	0	0	0	0	0	0	0	0
PPQ 1 xch/min.	95	0	0	85	385	0	0	0	0
	99	0	0	90	1005	0	0	0	0
	99.9	0	0	95	1440	0	0	0	0

Table 9: PERFUM Methyl Bromide Buffer Distances (meters) For All Aeration Processes Considered Based On UF30, 95% Applied Mass Release, & Varied Structure Size, Exposure Duration, Application Rate									
Aeration Type	Percentile	1 Hour & 1 lb/1000 cu. ft		1 Hour & 4 lb/1000 cu. ft		4 Hour & 1 lb/1000 cu. ft		4 Hour & 4 lb/1000 cu. ft	
		10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft	10K cu. ft	100Kcu. ft
Whole Field Buffer Distances.									
Minimum Stack 0.05 xch/min	95	0	70	45	165	0	0	0	0
	99	60	315	230	1105	0	80	50	280
	99.9	95	730	470	1440	25	155	120	850
Minimum Stack 1 xch/min	95	0	0	0	40	0	0	0	0
	99	25	125	95	460	0	0	20	105
	99.9	70	220	215	1440	0	55	65	220
No Stack	95	25	85	45	145	0	25	15	40
	99	145	585	345	1330	45	200	115	440
	99.9	295	1285	695	1440	125	545	320	1440
Portable Stack 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0
	99.9	0	0	0	0	0	0	0	0
PPQ 1 xch/min.	95	0	0	0	0	0	0	0	0
	99	0	0	50	0	0	0	0	0
	99.9	0	0	80	1440	0	0	0	0

An issue that has been recurrent throughout the development of this and other similar fumigant risk assessments is the reliability of predicted buffer zones. Often, this has been examined by ascertaining what risks for an individual might be if they happened to have an excursion within an established buffer distance. This situation, by definition, would represent an individual in a situation where the Agency's level of concern would be exceeded. In order to examine the relative change in buffer distance with changing uncertainty factor (i.e., MOE change with distance) an analysis was completed using no stack aeration maximum buffer distances, 75 and 95 percent mass releases, 4 hour duration, 4 lb/1000 cubic feet application rate, and a 100000 cubic feet chamber (Figure 15). As expected, as the target uncertainty factors decrease the predicted buffer distances also decreased. At an MOE or UF = 1 (i.e., the NOAEL HEC) predicted buffers are < 200 meters and at a UF = 3 predicted buffers <400 meters even at the highest percentiles of exposure. At the uncertainty factor = 30 buffer distances are 1440 meters at the highest percentiles of exposure. All totaled it appears that the relative change in distance with changing uncertainty factors is best represented by what could be described as a gradual slope which indicates that even if an individual had an excursion event within an established buffer zone that their associated risks would not change dramatically with that event.

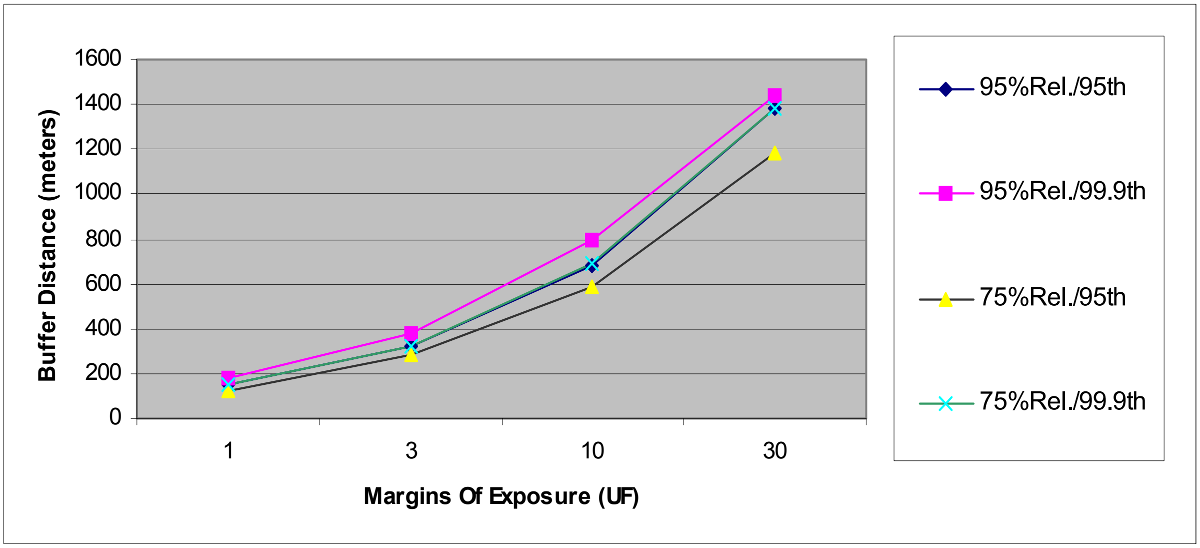

Figure 15: Methyl Bromide Buffer Distances At Varied Uncertainty Factors Based On No Stack Aeration, 100K cubic feet Structure, 4 hour Exposure Duration, 4 lb/1000 cubic feet Application Rate, & Varied Mass Releases

In conclusion, it is clear that many different factors can impact the air concentrations (and hence, risks) in proximity to structures and chambers that are used for commodity treatments with methyl bromide; these include many of the factors which have been investigated in this analysis. It is also important to acknowledge this issue so that stakeholders understand that the results of this analysis can be interpreted in many ways depending upon the factors which are considered. Many conclusions can be drawn, but the key ones include: (1) depending upon the scenario and inputs predicted buffer distances can range from adjacent to treatment structures to distances as far as 1440 meters, it appears that no-stack aeration results in the longest buffer distances while the APHIS PPQ methods result in the shortest general buffer distances, when stacks are used greater exit velocities seem to decrease buffer distances; (2) the sensitivity of results to changes in key factors is generally well within an order of magnitude for the factors which have been evaluated; (3) PERFUM is an empirically based approach so the generation of use, emissions, facility/structure and meteorological data would allow a broader analysis that could be applied more specifically to other situations across the country; and (4) the identification of a result, *per se*, for any sort of regulatory action would depend upon careful consideration of the variability and uncertainty as well as any particular merits of the inputs associated with each.

6.1.2 Ambient Bystander Exposure From Multiple Regional Sources

Ambient levels of methyl bromide are generally not attributable to specific application events, rather contributions may occur from multiple sources within a region. For example, it is likely that individuals could potentially be exposed to methyl bromide if they live in proximity to or otherwise frequent areas where significant uses occur such as a neighborhood located around a port facility during the season of use.

Exposures from ambient air that occur from non-point sources of methyl bromide were estimated from monitoring data collected to represent conditions at a regional level. CARB generated most of the data considered in this analysis. CARB is a widely recognized institution for these types of programs and it is part of the California Environmental Protection Agency. CARB conducts air monitoring studies for various types of chemicals throughout California. The studies conducted by CARB can generally be categorized as one of two types including: (1) targeted monitoring typically completed upon request to provide information related to specialized issues such as fumigant exposures in areas of high agricultural use during the season of use (Appendix G); and (2) routine monitoring for select pollutants via established networks in order to better quantify exposures in the general population (i.e., CARB established its Toxic Air Contaminant monitoring program or TAC for routinely quantifying toxic chemicals such as soil fumigants in air in urban areas). Additional data were considered that were generated by the Alliance of the Methyl Bromide Industry (AMBI). Review of the AMBI data identified quality control issues in some sample collection procedures and for this reason they are presented only for comparative purposes. For ease and clarity, the Agency has opted by convention to describe the available ambient bystander data used in this assessment as follows:

> **(1) "CARB Data":** includes targeted monitoring data generated by both CARB and AMBI focused on areas of high agricultural methyl bromide use in the season of use [Note: Targeted monitoring data are not specific for commodity uses but are the only such data available for this type of analysis.]; and
>
> **(2) "TAC Data":** includes data from CARB's Toxic Air Contaminant Network for Methyl bromide that quantifies background levels in non-agricultural, urban environments.

The results associated with the CARB data are presented in Section 6.1.2.1 below while the results associated with the TAC data are presented in Section 6.1.2.2.

6.1.2.1 Exposures From Regionally Targeted Non-Point Source Ambient Air Monitoring

In 2000 and 2001, CDPR requested that CARB conduct a series of studies to quantify ambient levels of methyl bromide (http://www.cdpr.ca.gov/docs/empm/pubs/tac/requests.htm).

> "Because most of California's pesticide applications normally occur in agricultural areas and are seasonal in nature, ARB conducts the monitoring studies to collect data during the worst-case situation - in the areas of high use during the season of peak use - instead of collecting samples throughout the State. This "worst-case" information can then be used to determine the ambient exposures of those people living near places where pesticides are used."

The CDPR also requested that the Alliance of the methyl bromide Industry (AMBI) conduct monitoring studies.

For the targeted ambient air analysis, HED evaluated different durations of exposure including single day acute exposures, short- and intermediate-term exposures, and chronic exposures (Table 10). Since samples were collected 3 to 4 times per week from each station, and the contribution of specific applications could not be determined, the statistics were calculated by station and not on a regional basis (e.g., county). Risks from acute exposures were calculated using the maximum 24 hour TWA values measured at each station and comparing them to the acute 24 hour ("agricultural") HEC and not the 8 hour ("commodity") HEC because these ambient air results are all 24 hour time-weighted averages.

Risks from short- and intermediate-term exposures (i.e., same HEC and uncertainty factors apply to both durations) were calculated using the mean of 8 weekly means calculated by DPR for samples taken over the course of the use season and comparing them to the short- and intermediate-term HEC. This approach was taken in order to statistically weigh equally each week's contribution to the overall seasonal mean because of differing numbers of samples in some weeks. Concentrations over the course of a season monitored in these studies did not vary extensively so calculation of average concentrations for shorter durations (e.g., 4 weeks) or even the use of an overall mean of all samples would not expected to be dramatically different than estimates used in this assessment. This supposition is supported physically because these studies spanned high use seasons in high use areas and use would not be expected to dramatically change at these locations during use seasons. It should be noted that the statistical summaries of the available data were completed by DPR and that the Agency reviewed and concurred with this approach. There are many possible ways to calculate exposure estimates given the available data for completing a short- and intermediate-term assessment. For example, a TWA over an entire season could be calculated or weekly TWAs could be calculated and then averaged over a season. The Agency agrees with DPR's use of the mean of 8 weekly means because it does not weigh results for the number of samples collected in a week (i.e., most weeks had 4 samples but some had 3) and it does not require a data filling procedure for the days missing each week (i.e., usually Wed., Sat., and Sun with most applications early in the weekend because of near school issues).

Chronic exposure estimates were also calculated using the targeted non-point source ambient data. These calculations should be considered as rangefinder estimates of exposure because of a lack of monitoring studies specifically designed for this purpose. Specifically, short- and intermediate-term estimates were amortized to reflect a potential for exposure of 180 days out of each calendar year in order to calculate chronic estimates of exposure. This was determined based on the approximate use patterns for methyl bromide over a year in high use areas. This approach does introduce the potential for significant uncertainty into the estimates, however, the Agency views the potential for chronic exposures in high use regions as significant and has addressed this scenario in order to be health protective. Because there are many uncertainties associated with the approach used in this assessment it is difficult to determine how these estimates either over- or under-predict actual chronic exposures for those living in high use areas. There are several factors that should be considered:

- Monitoring was specifically targeted toward areas of high use, this limits the populations for which these types chronic exposure estimates could be applied (i.e., for those living in such regions);

- More refined amortization approaches on a regional basis could be possible with use data, especially in California, but in most regions such data are not available; and

- Targeted monitoring was conducted during selected seasons of high use, but because the data are limited, the impacts of changing conditions (e.g., from different pest pressures, use patterns, or extended seasons) cannot be quantified, especially for different regions of the country with different climates, which could lead to potentially missing higher end exposures under some conditions.

Acute exposures for all of the monitoring stations considered (N = 30) do not exceed HED's level of concern (Table 10). Results were similar for the 8 week TWA exposures (short- and intermediate-term exposures), none of the monitoring stations exceed HED's level of concern, and in many cases by orders of magnitude. These results should be considered in conjunction with the fact that these studies were deemed to be worst-case situations as described by CDPR above. HED calculated chronic exposure based on CARB data using a rangefinder approach because monitoring data specifically meant to establish chronic exposure levels in high use areas were not available. Based on this approach, in some cases, chronic risks exceed HEDs level of concern (i.e., MOEs < 100 for 6 of 41 station-years); however, HED believes that these results do not pose an imminent health concern to the general public due to the nature of the rangefinder calculations as described above.

CDPR also reached similar conclusions that risks resulting from exposure to ambient air were of minimal concern.

Table 10: Results of 2000 Through 2002 California Ambient Monitoring In High Use Areas During Season Of Use

CA. County	Data Source	Site	Dates & Mon. Days (N)	Maximum 24 Hr. TWAs (ppb)	Acute MOE[1]	8 Week TWA (mean of means) (ppb)	Short and Intermediate-Term MOE[2]	Amortized 180 days (ppb)	Calculated Chronic MOE[3]
Kern	CARB	ARB	7/10-9/1, 2000 (25)	0.996	10040	0.189	5291	0.09	1444
			6/30-8/31, 2001	0.31	32258	0.12	8333	0.06	2166
		SHA	7/10-9/1, 2000 (26)	3.52	2841	0.792	1263	0.39	333
		CRS	7/10-9/1, 2000 (24)	14.2	704	2.16	463	1.07	121
			6/30-8/31, 2001	33.50	299	2.49	402	1.23	106
		MVS	7/10-9/1, 2000 (26)	0.487	20534	0.092	10870	0.05	2600
			6/30-8/31, 2001	0.23	43478	0.08	12500	0.04	3250
		VSD	7/10-9/1, 2000 (26)	0.247	40486	0.099	10101	0.05	2600
			6/30-8/31, 2001	0.23	43478	0.08	12500	0.04	3250
		MET	7/10-9/1, 2000 (26)	0.224	44643	0.084	11905	0.04	3250
			6/30-8/31, 2001	0.25	40000	0.07	14286	0.03	4333
		ARV	6/30-8/31, 2001	0.22	45455	0.07	14286	0.03	4333

Table 10: Results of 2000 Through 2002 California Ambient Monitoring In High Use Areas During Season Of Use									
CA. County	Data Source	Site	Dates & Mon. Days (N)	Maximum 24 Hr. TWAs (ppb)	Acute MOE[1]	8 Week TWA (mean of means) (ppb)	Short and Intermediate-Term MOE[2]	Amortized 180 days (ppb)	Calculated Chronic MOE[3]
Ventura	AMBI (CDPR Stats Used)	SHA	8/15-10/10, 2001	2.94	3401	0.50	2000	0.25	520
			7/10-8/31, 2002 (31)	5.77	1733	0.58	1724	0.29	448
		ABD	8/15-10/10, 2001	0.44	22727	0.18	5556	0.09	1444
			7/10-8/31, 2002 (30)	3.44	2907	0.76	1316	0.37	351
		UWC	8/15-10/10, 2001	4.35	2299	0.82	1220	0.40	325
			7/10-8/31, 2002 (26)	13.17	759	2.22	450	1.09	119
		PVW	8/15-10/10, 2001	3.17	3155	0.56	1786	0.28	464
			7/10-8/31, 2002 (32)	9.51	1052	1.62	617	0.80	163
Santa Barbara	AMBI (CDPR Stats Used)	PLN	8/23-10/9, 2001	2.69	3717	0.93	1075	0.46	283
		EDW	8/23-10/9, 2001	11.15	897	1.32	758	0.65	200
		AGC	8/23-10/9, 2001	1.16	8621	0.28	3571	0.14	929
		BLO	8/23-10/9, 2001	4.55	2198	0.73	1370	0.36	361
		SLO	8/23-10/9, 2001	1.12	8929	—	—	—	—
Monterey	CARB	SAL	9/11-11/3, 2000 (31)	7.91	1264	1.29	775	0.64	203
			9/8-11/7, 2001	9.25	1081	1.38	725	0.68	191
		OAS	9/11-11/3, 2000 (31)	1.84	5435	0.387	2584	0.19	684
		CHU	9/11-11/3, 2000 (31)	2.41	4149	0.644	1553	0.32	406
			9/8-11/7, 2001	1.84	5435	0.56	1786	0.28	464
		LJE	9/11-11/3, 2000 (30)	24.0	417	3.79	264	1.87	70
			9/8-11/7, 2001	14.49	690	2.82	355	1.39	94

Table 10: Results of 2000 Through 2002 California Ambient Monitoring In High Use Areas During Season Of Use									
CA. County	Data Source	Site	Dates & Mon. Days (N)	Maximum 24 Hr. TWAs (ppb)	Acute MOE[1]	8 Week TWA (mean of means) (ppb)	Short and Intermediate-Term MOE[2]	Amortized 180 days (ppb)	Calculated Chronic MOE[3]
	AMBI (CDPR Stats Used)	BBC	9/4-10/26, 2002 (32)	6.28	1592	2.08	481	1.03	126
		MAQ	9/4-10/26, 2002 (32)	4.53	2208	1.12	893	0.55	236
Santa Cruz	CARB	PMS	9/11-11/3, 2000 (31)	30.8	325	7.68	130	3.79	34
			9/8-11/7, 2001	21.08	474	2.99	334	1.47	88
		SES	9/11-11/3, 2000 (31)	16.4	610	2.60	385	1.28	101
			9/8-11/7, 2001	5.31	1883	1.22	820	0.60	217
		MES	9/8-11/7, 2001	36.64	273	5.51	181	2.72	48
		SCF	9/8-11/7, 2001	0.74	13514	Not Sampled	—	—	—
	AMBI (CDPR Stats Used)	WAT	9/4-10/26, 2002 (30)	16.38	611	3.79	264	1.87	70
		FRM	9/4-10/26, 2002 (31)	14.00	714	2.62	382	1.29	101
		CPW	9/4-10/26, 2002 (30)	11.12	899	2.06	485	1.02	127
		SCF	9/4-10/26, 2002 (7)	0.69	14493	NA	--	--	--
				Background site sampled only during 2 nonconsecutive weeks					

1. Acute MOE based on maximum 24 hr TWAs and 24 hour "agricultural" HEC as durations are similar.
2. Short term and intermediate term MOE are based on 8 wk. TWA (i.e., mean of weekly means).
3. Chronic MOE based on short-/intermediate-term exposures amortized for 180 days exposure per year.

6.1.2.2 Exposures From Urban Background Ambient Air Monitoring

In 2002, CARB added methyl bromide to its list of contaminants for which it routinely screens in its TAC program (see http://www.cdpr.ca.gov/docs/empm/pubs/tac/monitoring.htm). The location of these monitoring stations, however, shifted from a potential "worst-case", in-season use situation as described in section 6.1.2.1 above to the following:

> "The ARB has a network of stations that routinely monitor California's air for a variety of pollutants such as ozone, particulate matter, metals, and other toxic air contaminants. In 2002, ARB began monitoring for two pesticides, Methyl bromide and 1,3-dichloropropene, every 12 days at approximately 20 stations in primarily urban areas throughout the State."

The following should also be considered (see http://www.arb.ca.gov/aqd/toxics/toxuses.html):

> "The toxics sampling network was designed to produce a statewide annual average to support the determination of a statewide risk assessment. Where fewer than 12 continuous months of data are present, we believe that it is seldom appropriate to calculate an annual average. Most of the toxic substances show some seasonal variation, and some substances differ by as much as two orders of magnitude between the high and low periods of the year. If a month's data are missing, the calculated average could be radically different from the real average, the average that would have been calculated had the missing month's data been available."

TAC monitoring sites are located throughout California in urban environments that include urban areas such as Long Beach, Burbank, Los Angeles, Fremont, Fresno, San Francisco and San Jose. [Note: Long Beach is a major port facility that routinely uses methyl bromide for quarantine treatments of commodities and other items. The statistical summaries of the 2002/2003 CARB monitoring data are provided in Table 11.

They were taken directly from http://www.arb.ca.gov/adam/toxics/statepages/mbrstate.html. Maximum values at each station were compared to acute HECs to estimate acute MOEs. Short- and intermediate-term risks were estimated by comparing means to the short- and intermediate-term HECs. Means were selected for this analysis because they appear in most cases to be heavily influenced by the typical 6 to 8 week use season based on the relative contributions of a relatively small number of samples and that medians for most stations were reported as the level of detection. Medians from each location were used to calculate chronic MOEs. True chronic exposures (continuous exposures >6 months) in and around most of the monitored sites probably do not occur because the limit of detection (½ LOD or 0.015 ppb) has been reported as the median for approximately 75 percent of the stations for each year where there are data. These monitoring data indicate that exposure patterns track with seasonal use; therefore, shorter duration exposures are more prevalent which reflects the seasonal use of most methyl bromide in California.

No exposure levels reported by through the TAC program exceed HED's level of concern for any duration of exposure including acute (all MOEs >30), short-, intermediate-term (all MOEs >30), or chronic (all MOEs > 100) exposures in an urban environment (Table 11).

Table 11: Results of 2002 & 2003 California Ambient Monitoring In Urban Areas

Site	Year	N	Results of Annual MeBr Monitoring (ppb)					
			Maximum	Acute MOE[1]	Mean	Short and Intermediate-Term MOE[2]	Median	Chronic MOE[3]
Statewide	2002	440	0.91	10989	0.042	23810	0.015	8667
	2003	503	0.90	11111	0.040	25000	0.015	8667
Azusa	2002	27	0.14	71429	0.041	24390	0.03	4333
	2003	28	0.16	62500	0.036	27778	0.015	8667
Burbank	2002	30	0.14	71429	0.031	32258	0.015	8667
	2003	26	0.10	100000	NR	--	0.015	8667

Table 11: Results of 2002 & 2003 California Ambient Monitoring In Urban Areas								
Site	Year	N	Results of Annual MeBr Monitoring (ppb)					
			Maximum	Acute MOE[1]	Mean	Short and Intermediate-Term MOE[2]	Median	Chronic MOE[3]
Calexico	2002	29	0.11	90909	0.020	50000	0.015	8667
	2003	30	0.33	30303	0.036	27778	0.015	8667
Chula Vista	2002	29	0.06	166667	0.021	47619	0.015	8667
	2003	28	0.05	200000	NR	--	0.015	8667
El Cajon	2002	28	0.06	166667	0.020	50000	0.015	8667
	2003	30	0.05	200000	0.021	47619	0.015	8667
Los Angeles	2002	21	0.14	71429	NR	--	0.03	4333
	2003	29	0.10	100000	0.032	31250	0.015	8667
Long Beach	2002	25	0.11	90909	0.035	28571	0.015	8667
	2003	27	0.13	76923	0.035	28571	0.04	3250
Riverside	2002	25	0.13	76923	NR	--	0.015	8667
	2003	30	0.10	100000	0.028	35714	0.015	8667
Simi Valley	2002	26	0.91	10989	0.101	9901	0.05	2600
	2003	31	0.90	11111	0.120	8333	0.015	8667
Bakersfield	2002	29	0.22	45455	0.058	17241	0.04	3250
	2003	29	0.88	11364	0.080	12500	0.04	3250
Chico	2002	29	0.14	71429	0.026	38462	0.015	8667
	2003	31	0.15	66667	0.022	45455	0.015	8667
Fremont	2002	27	0.05	200000	0.018	55556	0.015	8667
	2003	30	0.11	90909	0.019	52632	0.015	8667
Fresno	2002	30	0.19	52632	0.049	20408	0.015	8667
	2003	31	0.19	52632	0.055	18182	0.05	2600
Roseville	2002	29	0.11	90909	0.021	47619	0.015	8667
	2003	31	0.03	333333	0.016	62500	0.015	8667
San Francisco	2002	15	0.08	125000	NR	--	0.015	8667
	2003	31	0.015	666667	0.015	66667	0.015	8667
San Jose - 4th Street	2002	8	0.09	111111	NR	--	NR	--
San Jose - Jackson St.	2002	6	0.05	200000	NR	--	NR	--
	2003	31	0.23	43478	0.031	32258	0.015	8667
Stockton	2002	27	0.90	11111	0.144	6944	0.05	8667
	2003	30	0.48	20833	0.088	11364	0.04	8667
Mexicali - Mexico	2002	19	0.10	100000	NR	--	0.015	8667
	2003	17	0.07	142857	NR	--	0.015	8667

Table 11: Results of 2002 & 2003 California Ambient Monitoring In Urban Areas								
Site	Year	N	Results of Annual MeBr Monitoring (ppb)					
			Maximum	Acute MOE[1]	Mean	Short and Intermediate-Term MOE[2]	Median	Chronic MOE[3]
Rosarito - Mexico	2002	25	0.05	200000	NR	--	0.015	8667
	2003	30	0.14	71429	0.027	37037	0.015	8667

1. Acute MOEs based on maximum 24 hr TWAs and 24 hour "agricultural" HEC as durations are similar.
2. Short term and intermediate term MOE are based on the mean concentrations.
3. Chronic MOEs are based on the median concentration.

6.2 Bystander Risk Characterization

Methyl bromide use to control pests in commodities that have established food tolerances can take many forms and by necessity results in a wide array of use situations. The situations can range from very small, infrequent batch processing to large scale, highly regimented processes that occur on a routine basis. The scale and frequency of such processes are dictated by the nature of the business of the users. Smaller scale users may be a local walnut producer in California while a large scale user may be a food processor or the USDA Plant Protection and Quarantine service at ports like Long Beach, California; Philadelphia, Pennsylvania; or Miami, Florida. It is clear that along with this wide array of users that there is a great diversity of practices and equipment currently in use across the country. The objective of this assessment was to attempt to capture some of this diversity in the bystander risk assessments using the monitoring data and the PERFUM model. Risks from methyl bromide exposure in ambient air were also calculated using data from California focused on agricultural use areas in the season of use and also from urban centers. These data may not provide the most precise estimates of risks related to the commodity uses of methyl bromide but at this point they are the only known source of information for such calculations.

In the initial commodity assessment for methyl bromide (please refer to D316326 at www.Regulations.gov under the methyl bromide docket EPA-HQ-OPP-2005-0123 for further information) the Agency generally based its calculations on the approaches used by the CADPR. This includes a tiered approach that calculated risks based on monitoring data and the use of the EPA's ISCST3 model for predicting downwind air concentrations and associated risks. The ISCST3 method is deterministic because it is based on the use of static meteorological conditions over an entire calculation period (i.e., windspeed and atmospheric stability are constrained which is unrealistic) and it generally identified risks of concern. The Agency also used the highest possible emission terms in the previous assessment to establish what possible real-world high-end risk situations may be like (i.e., emission values from the CADPR permit conditions for commodities were used). Additional analyses were not completed due to a lack of adequate use information. Based upon discussions with CADPR, it appears that these emissions estimates were loosely defined using monitoring data but they do establish an effective range of inputs for consideration that represent highly efficient (i.e., low loss rate) chambers through what could be categorized as less than efficient facilities. [Note: Based on various information sources, there are many possible novel technologies for scrubbing methyl bromide emissions from effluent streams. However, the Agency does not believe such systems to be able to readily implemented on a wide scale. Definitive emission reduction factors are also not available for such systems so they have not been quantitatively addressed in this assessment.]
The goal of this current assessment was to provide a much broader characterization of the risks that

could possibly be expected with the breadth of commodity treatment facilities across the country. This is difficult given a lack of use information for all possible situations and the sparse nature of the monitoring data that only provides what can be described as situational snapshots of a few facilities in California. After release of the previous assessment, the Agency received a number of comments pertaining to the initial commodity assessment which was completed. Most of these revolved around use practices and the size and nature of the facilities as well as the commodities that were treated. Additionally, the Agency is continuously seeking additional information through venues such as the methyl bromide alternatives conference (i.e., www.MBAO.ORG) and is actively engaged with USDA and the Plant Protection and Quarantine Service. With all of this newly identified information the Agency developed a series of refined modeling inputs that are described above (Section 6.1.1.1) in an attempt to bracket use situations across the country. Additionally, monitoring data were also used to directly calculate risks and (in the form of the CADPR permit condition emission factors) to "groundtruth" the refined inputs. The new inputs indeed bracket what is known from the monitoring data. However, the monitoring data are limited in scope and the newly developed inputs, by definition, are intended to provide a much broader consideration of the industry. It is difficult to attempt to overlay how actual methyl bromide use practices for commodity treatments overlay with the grid of new inputs because, in general, there is a lack of appropriate information with which to attempt to complete such an effort. For this reason, the results of this assessment should be considered to represent general categories within the commodity treatment industry. These may include small, medium, and large facilities or facilities with highly refined use practices and efficient chambers or facilities that are less refined. As additional use information becomes available, further characterization can be completed and a more refined consideration of how risk estimates may be applied to various sectors of the commodity industry can be completed.

With regards to the detailed aspects of the modeling that has been completed for residential bystanders, the major change is that the Agency has moved from using the deterministic ISCST3 method to a distributional approach using PERFUM which has been recently modified to consider sources such as structures or chambers which would be anticipated in commodity treatments. The PERFUM model which was used in this assessment (V2.1.2) is available at http://www.sciences.com/perfum/index.html. Version 2.1.2 of PERFUM will eventually be placed on the Agency's website along with the older Version 1.1 http://www.epa.gov/opphed01/models/fumigant/. In previous assessments using PERFUM, multiple sources of weather information were used and in this case data from coastal locations in California (i.e., Ventura) and Florida (i.e., Tallahassee) were also used along with information from Flint Michigan. All analyses were completed but only the Ventura California weather results were summarized. It is clear that so many factors could potentially impact buffer distances that it was felt this was sufficient. [Note: The additional PERFUM outputs are available and can be provided upon request.] The PERFUM modeling framework was subjected to an SAP review in 2004 where the general uncertainties associated with its use were discussed. Please refer to the SAP background documents and the SAP report for further information concerning these issues and the related use of PERFUM (http://www.epa.gov/scipoly/sap/2004/index.htm). One other consideration is that PERFUM uses ISCST3 as its core processor as described above. Recently, the Agency recommended (40CFR51, Appendix W) that modelers begin to replace the use of ISCST3 with an upgraded dispersion model (AERMOD). This recently occurred and 40CFR51 recommends a year transition period between new and outgoing systems. Additionally, the major upgrade from ISCST3 in AERMOD is that refined algorithms have been incorporated that better address the dispersion of buoyant plumes (i.e., heated output streams which would naturally rise in the atmosphere such as power plant effluents) but methyl bromide emissions are thought to be non-buoyant plumes (i.e., because they are not heated like a power plant type effluent). Major changes in the algorithms for non-buoyant plumes were not completed in AERMOD so it is likely that risks predicted using either approach should not provide significantly different results. The Agency is continuing to investigate these possible differences and will consider them when interpreting the results of this assessment.

Several factors also need to be considered in the interpretation of the results associated with the assessment of exposures from ambient air. It is clear from the characterization of the data provided by CARB and AMBI that some data represent highly targeted monitoring in agricultural regions during the season of use. Because of these criteria, the results should be considered conservative in nature for California agricultural regions. In addition, CARB has also developed monitoring data from its urban network which screens not only for methyl bromide but for other pollutants of concern such as persistent organic pollutants (POPs) and volatile organic compounds (VOCs). These data are intended to represent urban background levels. Some of these stations are located in the same communities where major commodity fumigations occur (e.g., Long Beach CA) which should be considered in the interpretation of the results. One other issue that should be considered in the interpretation of the estimates for ambient air is that California has a number of restrictions and systems in place where the overall goal is to reduce environmental emissions from fumigant use. As such, it is difficult to quantify how the results presented above may apply to other regions of the country who do not have these types of programs in place. In summary, it is not clear how these data may directly relate to commodity uses. It should be noted that short- and intermediate-term risks in general were well below any level of concern for the Agency. Chronic risks based on the urban background levels were also well below any level of concern. The only ambient risks of concern were for the chronic estimates that were calculated using amortized seasonal values which is an uncertain process at best. It is also not clear how the seasonal estimates relate to commodity uses since they were collected in high agricultural use areas.

6.3 Residue Profile

Sufficient residue chemistry data are available to conduct a reasonably reliable dietary exposure assessment. No additional residue chemistry studies are required, but the registrants must modify product labels so they are consistent with the residue studies (see 40 CFR §180.123).

For commodity fumigation uses, residues of both parent methyl bromide and inorganic bromide may be present. HED will not at this time 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 will frequently not be possible. Therefore, HED recommends that commodity fumigation tolerances for inorganic bromide (40 CFR §180.123) be revoked and replaced with tolerances for methyl bromide, *per* se (see D304618, 2/8/06, T. Goodlow).

Enforcement Methods. The head-space procedure of King *et al.* for determining methyl bromide has been forwarded to FDA for inclusion in PAM Vol. II. This method is adequate for data collection and would be suitable for tolerance enforcement on plant and processed food commodities. Analytical methods for secondary residues of methyl bromide in livestock commodities are not required.

Multi residue Method. FDA multi residue test methods are not applicable to methyl bromide. Protocols A and B are not applicable to monohalogenated alkanes. Although methyl bromide would be detectable in protocol C, residues would like not be recovered through any of the extraction techniques.

For more residue chemistry data considerations and tolerances, please refer to the residue chemistry chapter.

6.4 Acute and Chronic Food Dietary Exposure and Risk

Methyl bromide acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. Acute and chronic dietary risks for methyl bromide resulting from food intake were determined for the general U.S. population and various population subgroups. The partly refined Tier 2 acute and chronic dietary risk assessments were conducted for all supported (currently registered and proposed) methyl bromide food uses. Both the acute and chronic dietary exposure assessments for methyl bromide are based on anticipated residues derived from field trial and USDA monitoring data. Because methyl bromide is so volatile, HED assumed that residues in any food form that was heated would be zero. Use of minimal aeration time for methyl bromide treated commodities will likely overestimate residue levels and risks.

For all included commodities, the acute and chronic risks do not exceed HED's level of concern (<100% PAD[3]) for the general U.S. population and all population subgroups (Table 12). The acute dietary exposure estimate for females 13-49 years old, the highest exposed population subgroup is 2.4% of the aPAD. The chronic dietary exposure estimate for children (3 to 5 years old), the most highly exposed subgroup is 10% of the cPAD (for details, see dietary assessment D304603, 2/21/06). All dietary exposure estimates are listed in Table 12 below.

[3] aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

Table 12. Summary of Dietary Exposure and Risk for Methyl Bromide						
Population Subgroup**	Acute Dietary (95th%ile)			Chronic Dietary		
	aPAD mg/kg/day	Dietary Exposure (mg/kg/day)	% aPAD	cPAD mg./kg/day	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.9	0.004169	<1	0.022	0.000869	4.0
All Infants (< 1 year old)		0.000939	<1		0.000247	1.1
Children 1-2 years old		0.011300	1.3		0.002144	9.7
Children 3-5 years old		0.011771	1.3		**0.002288**	**10**
Children 6-12 years old		0.007208	<1		0.001280	5.8
Youth 13-19 years old		0.003127	<1		0.000551	2.5
Adults 20-49 years old		0.003253	<1		0.000660	3.0
Females 13-49 years old	**0.14**	**0.003369**	**2.4**		0.000642	2.9
Adults 50+ years old	0.9	0.003573	<1		0.000812	3.7

Although residues of the bromide ion may occur in food as a result of Methyl bromide use, these residues cannot be readily distinguished from background levels of bromide. Therefore, the dietary exposure assessment has been completed only for Methyl bromide, *per se*, which is expected to be the predominant contributor to dietary risk.

The values for the population with the highest risk for each type of risk assessment are bolded.

6.5 Water Exposure/Risk Pathway

Estimated drinking water concentrations (EDWCs) for methyl bromide were modeled using PRZM-EXAMS for surface water. Florida strawberry field use resulted in the highest surface water concentration of 357 µg/L for use in acute assessments and 1.0 µg/L for chronic assessment. Groundwater concentration was not estimated for methyl bromide because the model used for estimating groundwater concentration, SCIGROW, has limited capability to model vapor phase transport of methyl bromide to groundwater. 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 from 2.5 - 6.4 µg/L. The maximum concentration for ground water is used for both acute and chronic assessments. Values are reported in Table 13 below.

Table 13. Estimated and monitoring data for MeBr and bromide ion in surface water and groundwater			
Chemical	Surface Water (µg/L)		Groundwater (µg/L)
	Acute	Cancer/chronic	
MeBr	357[a]	1.0[a]	6.4[b]

[a] Based on 1-in-10 year exceedance probability (0.10). Values reflect output from PRZM/EXAMS multiplied by the percent crop area applied (0.87) for Florida Strawberry scenario.
[b] Recommended estimated drinking water concentrations (EDWCs) values for acute and chronic for groundwater (monitoring data)

7.0 Aggregate Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The aggregate assessments consider exposure from both food and drinking water (see section 7.1 below). HED did not estimate aggregate risks for short- and intermediate-term exposures because of the way bystander exposures have been estimated in this assessment. The results for these assessments, presented above, represent risks at various distances downwind from treated areas (e.g., farm fields) or from highly targeted ambient air monitoring studies. Since buffer zone distances or other mitigation approaches are still undefined, the appropriate bystander exposure estimates for aggregating with food and water have not yet been determined.

7.1 Acute and Chronic Aggregate Risk Assessments

Acute and chronic aggregate risks for methyl bromide resulting from food and water were determined for the general U.S. population and various population subgroups. Food exposures and either EDWCs from modeled values for surface water sources or groundwater sources as the drinking water source were included. Analyses were conducted for all supported (currently registered and proposed) methyl bromide food uses, and are based on anticipated residues derived from field trial and USDA monitoring data.

For the acute aggregate assessments, females 13-49 years old were the most highly exposed subgroup. At the 95th percentile of exposure, the estimated food and water exposure for females 13-49 years old utilized 2.5% and 13% of the aPAD for ground water and surface water sources, respectively. See Tables 14 and 15 for acute aggregate risks.

For the chronic aggregate assessments, children 3-5 years old were the most highly exposed subgroup. The estimated food and water exposure for children 3-5 years old utilized 11% of the cPAD for both ground water and surface water sources. See Tables 14 and 15 for chronic aggregate risks.

Table 14. Summary of Dietary Exposure and Risk for Methyl Bromide Incorporating Surface Water as a Drinking Water Source

Population Subgroup**	Acute Dietary (95th%ile)			Chronic Dietary		
	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% aPAD	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	357	0.020732	2.3	1.0	0.000890	4.0
All Infants (< 1 year old)		0.069891	7.8		0.000316	1.4
Children 1-2 years old		0.034553	3.8		0.002175	9.9
Children 3-5 years old		0.031361	3.5		**0.002317**	**11**
Children 6-12 years old		0.021637	2.4		0.001300	5.9
Youth 13-19 years old		0.016559	1.8		0.000566	2.6

Table 14. Summary of Dietary Exposure and Risk for Methyl Bromide Incorporating Surface Water as a Drinking Water Source

Population Subgroup**	Acute Dietary (95th%ile)			Chronic Dietary		
	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% aPAD	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% cPAD
Adults 20-49 years old		0.018523	2.1		0.000680	3.1
Females 13-49 years old		**0.018562**	**13**		0.000661	3.0
Adults 50+ years old		0.017040	1.9		0.000833	3.8

The values for the population with the highest risk for each type of risk assessment are bolded.

Table 15. Summary of Dietary Exposure and Risk for Methyl Bromide Incorporating Ground Water as a Drinking Water Source

Population Subgroup**	Acute Dietary (95th%ile)			Chronic Dietary		
	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% aPAD	EDWC (µg/L)	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	6.4	0.004296	<1	6.4	0.001004	4.6
All Infants (< 1 year old)		0.001847	<1		0.000689	3.1
Children 1-2 years old		0.011542	1.3		0.002344	11
Children 3-5 years old		0.012009	1.3		**0.002475**	**11**
Children 6-12 years old		0.007274	<1		0.001410	6.4
Youth 13-19 years old		0.003292	<1		0.000648	2.9
Adults 20-49 years old		0.003389	<1		0.000786	3.6
Females 13-49 years old		**0.003537**	**2.5**		0.000767	3.5
Adults 50+ years old		0.003728	<1		0.000945	4.3

The values for the population with the highest risk for each type of risk assessment are bolded.

8.0 Cumulative Risk Assessment and 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. Therefore, for the purposes of this tolerance action, EPA has not assumed that methyl bromide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

9.0 Occupational Exposure

Data indicate that worker exposures generally exceed HED's level of concern for all scenarios considered when no respiratory protection is used. HED also considered the use of either air purifying respirators (APRs) and self contained breathing apparatus (SCBA) with varied results. Generally, the trends in the results were similar for acute and short-/intermediate-term durations. Chronic exposures were always of concern for all tasks regardless of whether or not respiratory protection is used.

The use of an APR reduces exposure levels by a factor of 10 and the use of SCBA reduces exposure levels by a factor of 10,000. [Note: There are commercially available APR cartridges that have been evaluated or recommended for reducing exposure levels of methyl bromide, see the technical bulletin 146 for cartridge 60928 at www.3M.com for more information.] Respirators would be the most practical protective equipment choice for reducing exposures for most workers. The use of SCBA is not normally deemed to be a viable option. It is not from a lack of capability, but SCBA is too difficult to handle logistically and too costly to implement as an exposure reduction tool in most circumstances. However, in certain situations such as industrial treatments, HED believes that SCBA may represent a viable option for reducing exposures for a limited number of workers. Even with the high rate of protection associated with these devices, results were varied and exposures (especially of a chronic nature) were still of concern for certain tasks associated with industrial and residential settings.

The occupational tasks commonly associated with the use of methyl bromide along with the corresponding risks are described below for each use sector considered (i.e., commodity and industrial uses). [Note: Industrial facility occupational tasks are included in this assessment since they reflect the types of jobs that would be associated with methyl bromide uses on commodities in larger facilities such as grain and rice mills.]

9.1 Commodity Fumigations

Job tasks that would be expected with typical commodity fumigations include:

a) Applicator
b) Aerator: opens doors or tarp to begin aeration.
c) Post-Fumigation commodity workers

Table 16 indicates risks are of concern for all scenarios associated with commodity fumigation activities for all exposure durations if no respiratory protection is used (MOE <30 for acute & short-/intermediate-term and MOE <100 for chronic). As a result, HED evaluated how the use of an OVR (PF 10) would impact worker risks. Risks for the majority of commodity fumigation workers who use the air purifying respirator (PF 10) still exceed HED's level of concern; however, short- and intermediate-term risks for forklift drivers and line workers who use the purifying respirator (PF 10) do not exceed HED's level of concern (MOE >30). Chronic exposures are of concern (MOE<100) for all durations regardless of whether or not respirators are used but the population of chronically exposed individuals is expected to be small compared to all handlers of methyl bromide. The data upon which this analysis is based are presented and summarized in the previous assessment for methyl bromide; no modifications have been made to the exposure results so the data have not been presented herein (please refer to D316326 at www.Regulations.gov under the methyl bromide docket EPA-HQ-OPP-2005-0123 for further information; *Appendix V: Occupational Risks Associated With Commodity Fumigations*).

Table 16: Commodity MeBr Application Workers Exposure and Risk.

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
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 HECs used to calculated risks for each duration, see Table 4/page 15.

9.2 Industrial Fumigations

Job tasks that would be expected with typical industrial fumigations include:

a) Remote Application
b) Canister application
c) Aeration

Table 17 indicates risks are of concern for all scenarios associated with industrial fumigation activities for all exposure durations if no respiratory protection is used (MOE <30 for acute & short-/intermediate-term and MOE <100 for chronic). As a result, HED evaluated how the use of an OVR (PF 10) would impact worker risks. Additionally, SCBA (PF 10,000) were also considered as it is believed that these represent a possible risk mitigation measure for certain workers involved in industrial fumigations. For remote applicators, only acute duration risks are reduced to levels of no concern when air purifying respirators (PF 10) are used; risks for other durations still exceed HED's level of concern. When SCBA is used (i.e., for canister openers and venters), acute and short-/intermediate-term risks are not of concern (MOE>30). Chronic exposures are of concern (MOE<100) for all durations regardless of whether or not respirators are used but the population of chronically exposed individuals is expected to be small compared to all handlers of methyl bromide. The data upon which this analysis is based are presented and summarized in the previous assessment for methyl bromide; no modifications have been made to the exposure results so the data have not been presented herein (please refer to D316326 at www.Regulations.gov under the methyl bromide docket EPA-HQ-OPP-2005-0123 for further information; *Appendix W: Occupational Risks Associated With Industrial Fumigations*).

Table 17: MeBr Industrial Applicators Exposures and Risks.								
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
*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.								

1. Concentrations are measured in ppm. For HECs used to calculated risks for each duration, see Table 4/page 15.

10.0 Data Needs and Label Requirements

10.1 Toxicology

None at this time.

10.2 Residue Chemistry

Based upon the available residue data and/or changes in data requirements, HED is recommending changes to use directions. The recommended label amendments are listed in the *Reregistration of **Methyl bromide:** Product and Residue Chemistry Chapters to the Reregistration Eligibility Document* (DP Barcode D271583; C. Olinger memo date February 22, 2002).

10.3 Occupational and Residential Exposure

The assessment of occupational and residential risks associated with the use of methyl bromide is complex. There was a significant amount of data available but additional data are still required. These include both occupational monitoring of various workers in different industry sectors and data to better assess exposures in the general population. The types of data, guideline citations, and examples of the scenarios which need to be addressed are presented below. Final determination of the scenarios should be made in consultation with the Agency.

OPPTS Guideline 875.1400 - Inhalation exposure for applicators (indoors)

Commodity - (e.g., Fumigators, Material Handlers, Aerators)
Industrial - (e.g., Fumigators, Material Handlers, Aerators)

OPPTS Guideline 875.2500 - Inhalation exposure for postapplication workers

Commodity - (e.g., forklift drivers, sorters, packagers)
Industrial - (e.g., line workers, forklift drivers)

Requirements For Special Studies

Meteorological Data For Probabilistic Modeling Purposes

Product Use Information By Major Use Region, Frequency, Application Parameters (e.g., rate, amounts treated, data, application equipment and emission control technologies used)

Measurements of indoor air concentrations for residences in proximity of treated facilities.