Appendix K – Methyl Bromide Health Effects Division Risk Assessments

Soil Fumigant Risk Assessment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATE: April 10, 2007

SUBJECT: **Methyl Bromide**: Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Soil, Greenhouse, and Residential/Structural Uses. PC Code: 053201, DP Barcode: D337288

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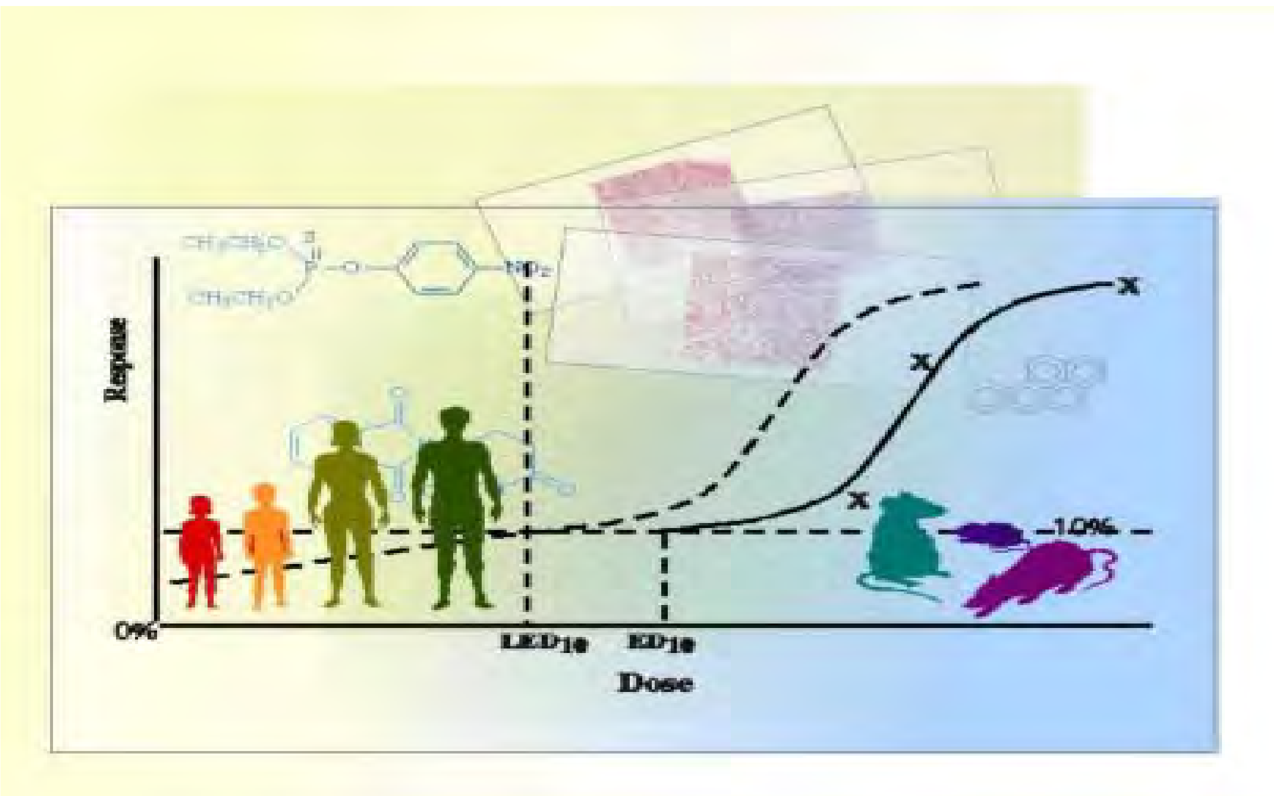
The risk assessment for the fumigant methyl bromide is attached. It builds upon the information that has been presented in previous assessments including the Phase 5 assessment for the commodity (i.e., food) uses of methyl bromide (D304623, 3/10/06 & its Addenda D304619, 7/12/06) and the Phase 1 and 3 assessments, previous to that, which addressed all uses of methyl bromide (D311945-1/31/05 & D316326-6/10/05). As indicated in D316326, methyl bromide can be used in 5 key industry sectors (4 of which are based on a similar structural analysis) including: (1) pre-plant soil; (2) greenhouse/potting soil; (3) commodity; (4) industrial facility; and (5) residential. The Phase 5 commodity assessment (D304623) directly addressed all uses related to the commodity and industrial facility uses (i.e., all uses with food tolerances and a few related others). Hence, this document contains no food or drinking water analyses nor does it address aggregate or cumulative exposure issues since potential risks from those exposures were addressed in D304623. In this assessment, all other non-food uses are addressed. However, in many cases, the analyses that were completed in D304623 are directly applicable to the greenhouse and residential uses and, as such, are cited as appropriate in this document rather than reproduce the information herein. This assessment also incorporates necessary modifications that were identified as a result of the comments received related to both assessments. Specific responses to these comments, however, will be provided in upcoming, separate documents. Both of the previous documents and supporting information can be found at www.Regulations.gov under methyl bromide.

This risk assessment addresses both exposures in the general population and for those occupationally exposed. The key concern is exposure that can occur in the general population primarily via inhalation for those in proximity to treated fields and facilities (i.e., bystanders). The key difference between the results presented in this document and the previous soil assessment is that the total applicable uncertainty factor (which establishes the Agency's level of concern) for acute bystander exposures has been reduced from 300 to 30 because the previous requirement for submission of a developmental neurotoxicity study has been met and the results indicate no need for an additional uncertainty factor. Information pertaining to the selection and use of air models for predicting off-target risks to bystanders has also been updated to reflect the methods that have been used to develop the risk estimates herein (i.e., based on the PERFUM model), to provide more extensive characterization of the modeling methods and to provide further clarification pertaining to the selection of PERFUM for this assessment and the potential utility of other modeling systems (e.g., FEMS or CALPUFF).

HUMAN HEALTH RISK ASSESSMENT

Methyl bromide



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HUMAN HEALTH RISK ASSESSMENT

Methyl bromide

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Table of Contents

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 chemical. This assessment begins phase 5 (public participation period) of the 6 phase public participation process for the non-food uses of methyl bromide that have not already been addressed in the previous risk assessment (D304623, 3/10/06) and its associated Addenda (D304619, 7/12/06). [Note: See www.Regulations.gov ,docket OPP-2005-0123 for further information.] In many cases, such as for the non-food greenhouse and residential uses addressed herein, the information contained in D304619 directly applies so it should be considered a companion document for this current assessment.

Methyl bromide is a broad-spectrum fumigant chemical 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 for 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 for use 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 irritating via both dermal and ocular routes of exposure (Toxicity Category I). Neurotoxicity is the most common toxic effect 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. Neurotoxic effects were also seen in the chronic/carcinogenicity inhalation study in mice (ataxia, limb paralysis, degenerative changes in the cerebellum), the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia), and the Developmental Neurotoxicity Study [DNT] (decreased motor activity). In addition, two subchronic studies showed dogs to be the most sensitive species to the neurotoxic effects of methyl bromide. 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.

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. An updated review of recent methyl bromide incidents report in three separate data sources shows that: there are fewer methyl bromide incidents with declines in recent years (2002-2005), possibly due to a combination of changing use patterns, State/local regulatory changes, and/or better worker education and outreach. There are still prevention opportunities until incidents are eliminated, as evidenced by 413 new methyl bromide incidents in California between 2002 and 2004.

Releases of fumigants such as methyl bromide fall into two categories. The first is used to address bystander exposures from single known application sites such as area (i.e., treated farm fields) or point (e.g., stacks from a greenhouse fumigation) sources. The second is to address exposures from many applications within a region (i.e., from evaluating ambient air monitoring data). 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., area sources such as farmfields and point sources such as stacks from greenhouses) 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 treated fields and facilities. Many of these indicate that there can be risks of concern associated with methyl bromide use. 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, different modeling systems for risk assessment purposes was instituted in order to develop a better understanding of the potential for risks associated with methyl bromide use under varied conditions. The EPA's Industrial Source Complex: Short-Term Model (ISCST3) was first used to develop risk estimates for bystanders associated with Methyl bromide uses (http://www.epa.gov/scram001/). In response to HED’s ISCST3 methodologies for assessing pre-plant soil fumigants, additional air models that all at that time used ISCST3 as their core processors but that also incorporated weather and emissions variability over time (PERFUM, FEMS, SOFEA) were evaluated by the Agency for suitability which included a review of each 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 that time, other modeling options have also been considered including CALPUFF and AERMOD. PERFUM has been used to evaluate bystander risks because it provides more breadth of appropriate information for risk managers than ISCST3 does but it is clear that other models could be used for similar purposes. Submissions based on the other aforementioned models (e.g., FEMS or CALPUFF), or other applicable and valid publicly available model, would be considered by the Agency in the course of developing its risk management decisions in context with the results of this assessment provided sufficient supporting information were also provided in order to document such analyses.

As indicated above, PERFUM was used in this assessment to evaluate the potential risks from methyl bromide uses because PERFUM incorporates actual weather data and flux distributions estimates then accounts for changes relative to the time of day and altering conditions. It is also capable of providing distributional outputs for varying receptor locations and using varied statistical approaches. At the upper percentiles of the exposure distributions generated with PERFUM, the results are markedly similar to those calculated with ISCST3. The power of using a system such as PERFUM, however, is inherent in the capability of providing outputs that can be used to examine the range of exposures one would expect based on the distributions it calculates. It is also clear that many different factors can impact the air concentrations (and hence, risks) in proximity to sources that have been treated with methyl bromide; these include many of the factors which have been investigated in this assessment. 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) at the edge of the treated fields or in proximity to a treated structure that NOAEL HECs generally are not exceeded given proper use of methyl bromide (i.e., with no uncertainty factors applied such as for inter-species variation from rats to humans and intra-species variability within humans) but conversely the distance predicted for MOEs between 10 and 30 are often times hundreds of meters for many scenarios where the appropriate uncertainty factors have been applied; (2) the methods used to evaluate methyl bromide exposure in this assessment generally agree and they are based on techniques that have been routinely used for regulatory purposes, they have also undergone a significant level of review; (3) the sensitivity of results to changes in key factors such as flux and meteorological conditions is generally within a factor 3X to 5X based on the varied inputs which have been evaluated but this could differ given a different set of inputs (e.g., flux from a cooler climate with high organic content soil); (4) PERFUM is an empirically based approach so the generation of additional flux and meteorological data would allow a broader analysis that could be applied more specifically to other regions of the country and application techniques; and (5) the identification of a result, *per se*, for any sort of regulatory action would depend upon careful consideration of the variability and uncertainty associated with each as well as any particular merits of the inputs associated with each.

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 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 methyl bromide 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 extrapolating seasonal CARB data 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 calculations. The results do however indicate a need for additional monitoring data for this scenario. Chronic exposures in urban environments were not of concern.

An extensive worker monitoring database was used for the evaluation of the risks associated with various occupational tasks that include the following: pre-plant field fumigation (e.g., tractor drivers, co-pilots, shovelers and tarp venters and removers) as well as for greenhouse and residential applications (e.g., remote applicators and aerators). Tarp removal operations generally occurred between 4 and 6 days after application and most data represent exposures from fields covered with high barrier films. Overall, data indicate that worker risks exceed the level of concern for all scenarios considered without respiratory protection (i.e., MOEs<30). If appropriate respiratory protection was used (i.e., air purifying respirators [APRs] with a methyl bromide specific canister for field and greenhouse uses or self contained breathing apparatus [SCBA] for residential uses), results were mixed. When air purifying respirators were evaluated with maximum exposure levels in order to assess acute exposures for field and greenhouse workers, in most cases, exposures were not reduced sufficiently to address risk concerns. When APRs were evaluated with mean exposure levels in order to assess short- or intermediate-term exposures, the results were varied with all greenhouse scenarios resulting in risks still exceeding the level of concern but risks from most field uses not being of concern. Risks for workers from exposures during residential treatments were not of concern if SCBA is used.

2.0 Ingredient Profile

Methyl bromide 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, was 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 methyl bromide 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 are in the 1 to 9 lb ai/1000 ft^3 range. Perishable commodities are generally not treated at rates higher than 4 lb ai/1000 ft^3 and typically many are treated at about 1 lb ai/1000 ft^3. Likewise, structural fumigations can be in the 1 to 9 lb ai/1000 ft^3 range. For risk assessment purposes, a pre-plant application rate of 430 lb ai/acre has been used since pre-plant field applications account for the majority of methyl bromide use [see Brom-O-Gas (5785-4 & -42) and Terr-O-Gas (5785-22), http://www.e1.greatlakes.com/agproduct/soil.html] For the non-food uses considered in this assessment (greenhouse and residential treatments) maximum application rates of 4 lb ai/1000 ft^3 and 3 lb ai/1000 ft^3 were used as the basis for risk assessment purposes (i.e., based on Meth-O-Gas 5785-41 for rhizomes, seeds, roots, bulbs, corms and tubers and Brom-O-Gas 5785-55 or -08 for residential uses).

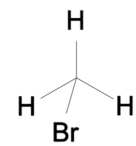
Methyl bromide application methods and equipment are quite varied depending upon the setting. Generally, the methods and equipment fall into three basic categories that include: (1) pre-plant agricultural field fumigations; (2) structural fumigations to industrial, commercial and residential sites; and (3) other specialized fumigations such as certain tree replant uses. Pre-plant agricultural field fumigations are completed with highly specialized equipment that generally includes a typical tractor outfitted with implements that are capable of carrying and delivering methyl bromide gas then sealing the gas in the treated soil.

Methyl bromide has been identified as an ozone depleting chemical and as such was scheduled for a phase-out by 2005 and it is subject to other restrictions under the Montreal Protocol entered into by the United States. However, in certain situations, agronomic needs warranted its use under the Montreal accord because of technical and economic reasons as well as 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 were 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" was reduced to 15 and the United States was allowed to consume 32 percent of the 1991 baseline of methyl bromide (i.e., approximately 18.0 million pounds). However, for both years the United States was allowed to use methyl bromide 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 methyl bromide 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. CDPR assessed exposures from various types of known area sources, such as a single treated agricultural field in proximity to residential areas, and then instituted a number of regulations that govern the application of methyl bromide in California for these situations. In California, applicators must apply for permits through local agricultural commissioners for each use. In each permit application, users describe the site, crop, or harvested commodity to be treated; the equipment to be used in the application; and any control technologies that will be used to reduce emission such as tarps in fields. In order to allow methyl bromide 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 methyl bromide 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). These permit conditions serve as the basis for much of this assessment; for example, the categories of application equipment and control technologies contained in the CDPR permit conditions are the basis for the Agency's dispersion modeling as the same categories and emission rates were used. [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. In order to do this, a proposal is currently being considered which sets an exposure limit on a regional basis (i.e., 6 by 6 mile townships are used). For workers, CPDR has also instituted restrictions for entry into treated fields and facilities based on the time after application or aeration patterns. These have been included in the discussion of occupational risks for comparative purposes.

2.1 Structure and Nomenclature

Table 1 provides the structures and relevant nomenclature for methyl bromide.

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 methyl bromide is provided in Table 2.

Table 2: Physical and Chemical Properties of Methyl Bromide	
Parameter	**Methyl Bromide**
Appearance	colorless, odorless gas at normal temperatures and pressures and a liquified gas under moderate pressure
Boiling Point	3.6 °C
Vapor Pressure	1400 mm Hg at 20 °C
Partition Coefficient	(log P_{ow}) 1.19
Solubility in Water	1.75 g/100 mL at 20 °C

3.0 Hazard Assessment and Characterization

3.1 Hazard Characterization

3.1.1 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 neurotoxicity 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.

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.

3.1.2 Endpoints

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

Neurotoxicity is the most common toxic effect for inhalation exposure, with neurotoxic effects seen throughout the data base in all tested species. Both acute and subchronic inhalation neurotoxicity studies in rats showed evidence of neurotoxic effects of methyl bromide characterized by decreased activity, tremors, ataxia and paralysis. Two 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), the developmental inhalation study in rabbits (lethargy, right side head tilt, ataxia), and the developmental neurotoxicity study in rats (decrease in motor activity). 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.

3.1.3 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. The risk assessment associated with dietary exposure was completed on July, 2006 (D304623, 3/10/06 & its Addenda D304619) and will not be addressed in this document.

3.1.3.1 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 ppm 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 ppm for agricultural bystander exposure, 40 ppm for greenhouse/structural bystander and commodity bystander exposure or 30 ppm for occupational 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 ppm for agricultural bystander exposure, 40 ppm for greenhouse/structural bystander and commodity bystander exposure or 30 ppm for occupational exposure, based on agenesis of the gall bladder and increased incidence of fused sternebrae. It is presumed that these developmental effects may be the outcome of an acute exposure thus this study is considered appropriate for this risk assessment. Acute and developmental neurotoxicity studies in rats were available for consideration, however, the developmental toxicity study in rabbits was selected since it yields the lowest HEC (most health-protective) presumed to occur after an acute exposure. Although the DNT would yield a lower HEC for the effect of decreased motor activity, this effect was not considered to be related to a single MeBr exposure since it was observed on PND21 and not at earlier time points (*i.e.*, no compound-related effects changes in motor activity on PND 13, 17). 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).[1] **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 ppm for agricultural bystander exposure or 4.4 ppm commodity bystander or occupational 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 ppm for agricultural bystander exposure or 4.4 ppm for commodity bystander or occupational 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

[1] Since no effects were reported at 11 ppm during the first 5 weeks (24 exposures), exposure concentration of methyl bromide was increased from 11 ppm to 158 ppm for 6 additional days.

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 methodology (see section 4.2 below).

3.1.3.2 Dermal Exposure

Under proper use practices, 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. Though incidents resulting in skin burns have been reported, these are typically associated with faulty containers or application equipment and are not expected to occur in the course of a typical MeBr application. 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.

3.1.3.3 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.

3.1.4 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 were 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.

[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.

3.2 Uncertainty Factors

When conducting inhalation risk assessments, the magnitude of the UFs applied is dependent on the methodology used to determine the appropriate point of departure. 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.

3.3 Summary of Toxicological Endpoint Selection

Table 3: Summary of Toxicological Dose and Endpoints for Use in MeBr Human Health Inhalation Risk Assessment						
		Study	**NOAEL/LOAEL**	**Endpoints**	**HED HECs**	**CPDR HECs**[¶]
Acute	Agricultural Bystander (ambient; 24 hr exposure)	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Developmental effects: agenesis of gallbladder, fused sternebrae	10 ppm UF = 30	21 ppm UF = 100 (child & adult)
	Greenhouse/Structural &Commodity Bystander	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Developmental effects: agenesis of gallbladder, fused sternebrae	40 ppm UF = 30	
	Occupational	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Developmental effects: agenesis of gallbladder, fused sternebrae	30 ppm UF = 30	
Short- and Intermediate -Term Inhalation (1 day to 6 months)	Ambient	Subchronic (5- to 7-week) inhalation toxicity study - dogs	NOAEL = 5 ppm LOAEL = 10ppm	Decreased responsiveness in females, fecal effects and eye irritation	1.0 ppm UF = 30	0.88 ppm UF = 100 (child)
	Occupational	Subchronic (5- to 7-week) inhalation toxicity study - dogs	NOAEL = 5 ppm LOAEL = 10ppm	Decreased responsiveness in females, fecal effects and eye irritation	4.4 ppm UF = 30	1.56 ppm UF = 100 (adult)
Long-Term Inhalation (>6 months)	Ambient	Chronic/Carcinogenicity - rats	No NOAEL identified. LOAEL = 3 ppm	Nasal lesions	0.13 ppm UF = 100	0.1 ppm UF = 100 (child)
	Occupational	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.

4.0 Public Health Data

An analysis of incidents related to methyl bromide use that considered data from the OPP Incident Data System (IDS), Poison Control Centers, CDPR, and National Pesticide Information Center was completed in 2004 which was updated on March 14, 2007. Methyl bromide has a number of different types of hazards associated with both agricultural and structural applications. It is often formulated with chloropicrin as a warning agent and 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. Methyl bromide is more likely to be involved when symptoms include headache, malaise, weakness, difficulty breathing (dyspnea), convulsions, and severe skin burns. Either chloropicrin or methyl bromide can be associated with vomiting and diarrhea, though methyl bromide would appear to be the more likely culprit if no odor is involved. Methyl bromide 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. Methyl bromide 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 methyl bromide 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 methyl bromide from 1982 through 1999, methyl bromide 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 methyl bromide 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 methyl bromide 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 methyl bromide exposure among structural fumigation workers*. Am J Public Health 88:1774-1780.)

The updated 2007 methyl bromide update is presented below:

- **<u>California data:</u>** From 2002-2004, California occupational surveillance data contained a total of 413 new incidents for methyl bromide with a downward trend over time: '02=391, '03=18 and '04=4 reported incidents. [A similar downward trend over the same three-year period was seen for chloropicrin (192 total incidents with '03=191, '04=1) and metam sodium (449 total incidents, and '02=384, '03=61, and '04=4 incidents.] The downward trend in incidents suggests the possibility of positive results from worker outreach/education and/or CDPR regulatory changes. However, 1,3-Dichloropropene (Telone) incidents were seen to increase at 101 incidents in '04 only. This increase in a year when other soil fumigant incidents are markedly down may be due to use pattern changes. Reasons for the temporal patterns observed are being further explored with CDPR incident data providers. Methyl bromide was not covered in any of the five CA soil fumigant ('02-'05) drift studies with plume modeling.

- **<u>NIOSH SENSOR data:</u>** Currently, twelve states report occupational poisoning incidents to a central database. The states are CA, WA, OR, NY, AZ, LA, TX, NM, FL, NC, MI, IA. For the time period '98-'03 covering 5899 total incident cases, 33 incidents were for methyl bromide, including 30 males and 3 females. States reporting are as follows: CA=25 methyl bromide incidents, FL=2, TX=4 and WA=2. Underreporting is a known problem with literature. Due to underreporting, there are generally few duplicates found among the multiple data sources. Duplicate incident cases are eliminated by matching the exact dates, locations and other incident case details.

- **<u>Poison Control Center (PCC) data:</u>** This is the only source of National incident coverage, encompassing 61 poison center that report in a standard format. Only PCC reports data on children, as well as occupational and non-occupational cases, symptom severity and medical outcome, including death. For the time period '92-'05, PCC reported 168 methyl bromide incidents, 77 occupational, 74 non-occupational, and 14 children. Of the 168 total incidnets 3 had unknown medical outcome. There were no deaths reported in recent years.

- **<u>6a2 and other data:</u>** A comprehensive incident data assessment for seven soil fumigants, including methyl bromide is in preparation. The interagency Agricultural Health Study (AHS) reported on an initial link with methyl bromide in the prospective prostate cancer study (Alavanja et al 2003, see www.aghealth.org for text). The chemical was rapidly declining in use in Iowa and North Carolina over the study period and preliminary indications from a follow-up study of the next 500+ prostate cancer appears to be negative for methyl bromide (personal communication Alavanja, el al. 2007).

In summary, there are fewer methyl bromide incidents in recent years (2002-2005), possibly due to a combination of changing use patterns, State/local regulatory changes, and/or better worker education and outreach. There are still prevention opportunities until incidents are eliminated.

5.0 Non-Occupational Exposure Assessment and Characterization

Monitoring data indicate that methyl bromide volatilizes after application to soil, facilities, and other premises and that inhalation exposure is possible when individuals are in proximity to specific application events. Inhalation exposures are also possible from ambient air levels if individuals live and/or work in regions where methyl bromide is used. Incidents associated with methyl bromide use (especially when it is combined with chloropicrin which has more distinct warning properties) also support the premise that inhalation exposures can occur for those in proximity to a methyl bromide application. Dermal exposures in the general population are not anticipated because of the volatility of methyl bromide and the fact that all methyl bromide products are restricted use pesticides which precludes direct dermal contact with the product because it is only a liquid that could get on the skin prior to application. Dermal incidents, generally attributable to accidents or equipment failure, have occurred in occupational populations who handle the concentrated products in liquid form. Contact with concentrated methyl bromide in liquid form would not occur in the general population so the incident pattern is consistent with the supposition that dermal exposures estimates for non-occupationally exposed individuals are not warranted.

Risks from ingestion associated with the food uses of methyl bromide (i.e., commodity and food handling establishments that require tolerances) or those possible through drinking water were previously addressed in the following:

- **Methyl Bromide:** Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses, PC Code: 053201, DP Barcode D304623, Authors: J. Dawson and E. Mendez, Issued: 3/10/06.

- **Methyl Bromide:** Addendum To Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses, PC Code 053201, DP Barcode D304619 Authors: J. Dawson E. Mendez, T. Goodlow, M. Metzger, Issued: 7/12/06.

Based on the premise described above this non-occupational assessment is limited in scope to inhalation exposures that could occur for a bystander in proximity to specific application events or an individual who can be exposed through ambient air concentrations. Methyl bromide is a highly volatile fumigant that is very mobile in soil and it can also readily infiltrate all spaces within treated structures or facilities. After application, methyl bromide typically volatilizes from soil rapidly after application with a large portion of the total mass being emitted in the first 24 hours. This is illustrated by the emissions profile from treated, tarped raised beds which a common cultural practice for tomato and strawberry production in many states (Figure 1). In other types of treatments (e.g., greenhouses or residential settings), then the emissions tend to be shaped by the nature of the treated structure (i.e., is it a tight or leaky building?) and how aeration is accomplished after treatment has been achieved (e.g., aeration type – passive or active, can impact off-target transport). Once emitted into the atmosphere, methyl bromide is sufficiently persistent so that exposures occurring within general regions where methyl bromide is used (i.e., ambient exposures) have also been addressed because methyl bromide has been routinely measured in studies designed for the purposes of elucidating ambient levels of airborne contaminants.

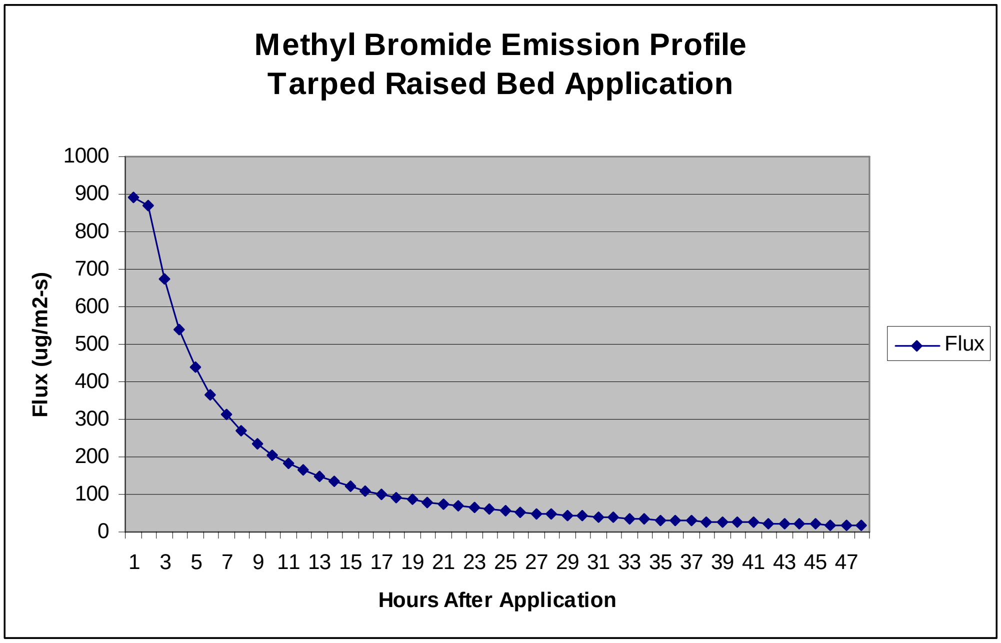


Figure 1

Because most mass of methyl bromide is rapidly emitted into the atmosphere after field applications or during structural treatment aerations, acute exposure scenarios are of key concern to residential bystanders (i.e., those who are in the proximity of the emissions resulting from a methyl bromide application). Bystander exposure to methyl bromide, or any fumigant for that matter, depends on two main factors: (1) the rate of emissions from a treated field or facility into the atmosphere (described as flux) and (2) how those resulting emissions are dispersed in the air over and around the treated field or structure. Emission rates from treated fields are affected primarily by the amount of fumigant applied (which is proportional to the rate and area treated), the application method and equipment used, sealing technologies use to reduce emission levels, and the field conditions where factors such as soil type, moisture, and amount of organic material may impact emission rates. Emissions from treated structures can also be affected by several factors that can include the tightness of the structure which is treated, the absorptive capacity of the materials within the treated structure, the duration of the treatment, and the nature of the aeration used to evacuate the structure after treatment if complete. Once methyl bromide, or any other fumigant, has been emitted into the atmosphere, meteorological conditions, the topography at the site, and/or the nature of the treated structure determine how the fumigant is dispersed. For example, if winds are high and the atmosphere is unstable, then emitted fumigant concentrations are more likely to be reduced because greater mixing and dispersion will occur. Under such conditions, the likelihood of a bystander being exposed to a fumigant at a concentration of concern is relatively lower. On the other hand if winds are light and the atmosphere is stable, then the emitted fumigant is more likely to build in concentration and be at higher levels in proximity to the treatment area. Topography, as well as other factors, can also cause winds from certain directions to be predominant which can predispose certain populations to higher exposure levels (e.g., a school located in a valley where prevailing winds approach it and the treatment area is upwind or a similar situation with prevailing onshore coastal winds in California or Florida).

This section describes the potential exposure scenarios associated with the use of methyl bromide. These include residential bystander exposure from two key sources including: known sources from a single application site (i.e., point sources such as from a ventilation stack on a treated commodity chamber during aeration or area sources such as at the edge of a treated field) and ambient air levels that result from many applications within a region. 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 professional uses of methyl bromide that can lead to exposures in residential environments. *Section 5.1: 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 5.2: Bystander Risk Characterization* describes the factors that should be considered when interpreting the results of this risk assessment.

5.1 Residential Bystander Exposure and Risk Estimates

Residential bystander exposure may occur because of emissions from buildings and other structures or treated fields as indicated above. A tiered approach has been used to calculate risks from known sources from a single application site that is based on various models, incident information, and monitoring data. Ambient exposures have been addressed solely using monitoring data since no predictive model and reliable input data for this purpose are available at this time.

When considering the potential risks of bystanders for single application known sources (e.g., a farm field or a structure), it is important to note that they were developed based on an iterative process that reflects an evolution in the methodologies used to calculate them. It is also important that results based on incidents, monitoring data, and modeling be considered in conjunction with one another to ensure consistency in the overall characterization of the risks associated with methyl bromide use. This approach is considered a tiered approach by the Agency because each additional method allows for more predictive capability to other use situations (i.e., it is less constrained by the circumstances of the incident or particular field study). There are a number of volatility studies which quantified methyl bromide emissions from treated fields and facilities. However, these data are limited in their utility because they provide results only for the specific conditions under which the experiments were conducted. In cases where incidents associated with methyl bromide use occurred, that Agency has also attempted to characterize them in a manner that explains the particular event and how it relates to the overall risk picture for methyl bromide but the degree of such analyses is also constrained by the particulars of the event and the level of information that is available with which to analyze it. Models have also been used to estimate potential risks from methyl bromide to bystanders under varying conditions. The first modeling approach was based on the deterministic use of the Agency's *Industrial Source Complex* model (ISCST3) which provides off-site air concentration estimates and the second approach which is based on a distributional model called the *Probabilistic Exposure and Risk Model For Fumigants* (PERFUM) which calculates distances at which target concentrations are achieved at varied percentiles of exposure. PERFUM also can provide distributions of air concentrations at varied distances from the perimeter of treated fields. It develops distributions based on 5 years of meteorological data. It can also probabilistically address emissions but for methyl bromide insufficient information was available to utilize that function.

As indicated above, the use of monitoring data provide the only means with which to assess the potential risks associated with methyl bromide exposures in ambient air. At the time this assessment was developed, the only known monitoring data designed to quantify ambient methyl bromide air concentrations were developed by the California Air Resources Board. These data have been used as the basis for this assessment and have been cited as appropriate.

The potential risk related to exposures from single application area (e.g., farmfields) or point (e.g., stacks from a treated structure) sources for bystanders are described below in *Section 5.1.1: Bystander Exposures And Risks From Known Sources* while the potential risks associated with exposures to ambient air are described below in *Section 5.1.2: Ambient Bystander Exposure From Multiple Regional Sources*. Each section provides a description of the methods used and the results.

5.1.1 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 treated fields or structures. The methods used to assess the exposures and risks related to these uses are described below in *Section 5.1.1.1: 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 5.1.1.2: Bystander Exposures And Risks From Known Sources*.

5.1.1.1 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 based on the ability to provide additional predictive capabilities yet consider all possible sources of information that could be used to characterize the overall risk picture associated with a chemical. The interrelationship of these factors is illustrated in Figure 2. This approach is also consistent with general Agency guidance on the use of air models.

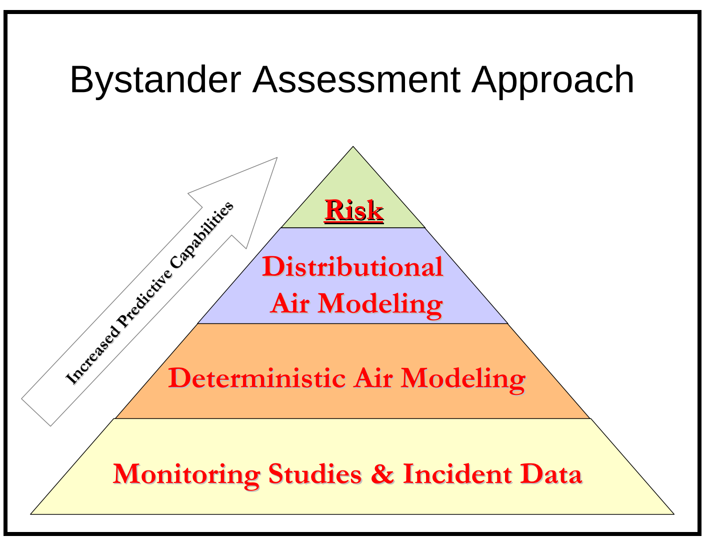


Figure 2

As indicated in Figure 2 above, three sources of information have been used for assessing bystander risks. Each source has a unique level of predictive capability but each result has been carefully considered in context with each other in order to develop an overall characterization of the risks associated with methyl bromide use. Each method is described below along with a description of how they were used and how they should be interpreted in the context. Regardless of which approach is utilized, it is clear that there can be possible human health effects associated with the use of soil fumigant chemicals based on calculated risk estimates.

Source Type 1: Field Level Monitoring Studies & Incident Data

Incident Data - Fumigants have been used for a number of years in agricultural settings and for a variety of structural treatments. Throughout this history of use, there have been reported incidents where bystanders have experienced noticeable symptoms from various fumigants which have ranged from mild and reversible in nature to more serious symptoms up to and including death. When using incident reports to characterize the results of fumigant risk assessments, the number of incidents for a particular fumigant compared to its total use throughout the country along with the causes and severity of major incident events are considered. Typically, the circumstances that led to a specific incident are examined to the extent possible including factors such as application method, sealing method, meteorological factors, and possibility of misuse as well as others specific to each case. It is also important to examine the specific health effects experienced by exposed individuals because they provide insight as to whether or not the endpoints selected for risk assessment purposes have occurred under adverse field conditions which could illustrate a level of consistency among the approaches used to evaluate a chemical. If not, it indicates that further investigation is warranted if possible. The incident analysis that has been completed for methyl bromide is presented above in *Section 4: Public Health Data*.

In most cases, it is hard to reconstruct the exact conditions of specific incidents which make predicting fumigant concentrations to which bystanders were exposed during an incident extremely difficult. This is generally because all necessary information to reconstruct the incident through predictive modeling is not available. For example, emission rates at the time of the incident specific to the way that particular application was completed would not be measured so any reconstruction for modeling purposes would have to utilize another source of emissions data that would be applied to the specific incident situation. Additionally, without on-site meteorological monitoring data, the same type of approach would have to be used in order to develop weather inputs for modeling purposes. In summary, without site-specific emissions and weather data collected at or near the time of an incident it is difficult to reconstruct the conditions of an incident and therefore accurately predict concentrations for exposed individuals.

The overall reliability of fumigant incident information can also be circumspect because some toxic effects are not immediately recognizable (e.g., developmental effects identified as the basis of acute bystander risk analysis for methyl bromide - see Table 3). Therefore, the likelihood that incidents may be reported could be lower for fumigants which have effects that are not immediately recognizable. Accordingly, incident reports will be considered in this context when characterizing the risks associated with fumigants.

Monitoring Studies **-** Field volatility studies typically measure fumigant air concentrations produced by a single fumigant application under specific conditions (e.g., application rate and method, area treated, soil conditions, meteorological conditions). In these studies, air samplers positioned in and around a treated field continuously sample air after the fumigant has been applied in order to quantify the emissions from that specific field. Sampling times can vary but generally range from about 4 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 generally off-gas the most within the first 24 hours after application and shorter sampling times provide a better means for characterizing peak emission periods that are expected to be associated with higher exposures. For methyl bromide, a number of monitoring studies were considered in the development of the risk assessment. These have been described in detail in the previous assessments (D316326, 7/13/05). An example of the information that can be generated by a field monitoring study is illustrated by Figure 3. This figure summarizes the nature of the application used in Field Study #8 and the sampling results at each location around the perimeter of the treated field. All sample locations describe the distance and location relative to the field and 12-hour time-weighted average concentrations that resulted from the application where sampling began with the initiation of the application. [Note: Structural monitoring studies would provide a similar type of result. The only difference would be that the parameters of the application and the nature of the emissions would differ.]

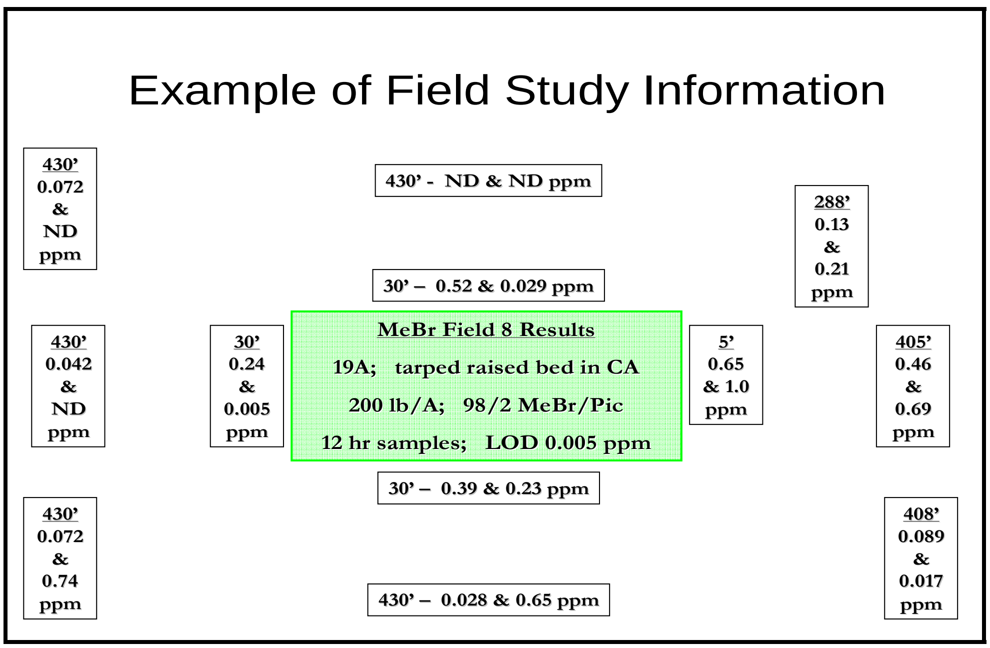


Figure 3

Results based on using monitoring data directly from field volatility studies for risk assessment purposes are summarized below. There are several limitations to this approach that should be considered in the overall context of related methods available for calculating risks associated with fumigant use. Essentially, the monitoring data are both spatially and temporally limited. For example, data do not reflect the values that would occur under different conditions. Air concentrations around treated fields are influenced by a number of factors including how a chemical is applied, application rate, emission reduction methods (e.g., tarps, water seals), soil conditions, and weather conditions. Varying weather conditions, for example, can significantly change the air concentrations at specific sites around a treated area. Since there is such a large range of potential weather conditions which could exist, it is not possible for monitoring studies to inherently capture the entire range of potential exposures which could result. Another example would be that air concentrations are measured by fixed samplers positioned at various distances and directions around the treated area, both downwind and upwind, as well as at points in between. This makes it difficult to interpolate between sampler locations, if so desired, to develop risk estimates in-between the locations. Based on these factors, the use of monitoring data for trends analysis is difficult without a modeling approach. This premise is consistent with the general Agency approach for the use of air monitoring data related to the air permitting process. More information regarding the utility of monitoring data and its limitations described above can be found in Appendix W to 40CFR51which presents Agency policy related to the selection and use of air models (http://www.epa.gov/scram001/guidance/guide/appw_05.pdf). Essentially, monitoring data in this assessment were used in a manner consistent with this guidance.

Source Type 2: Deterministic Air Modeling

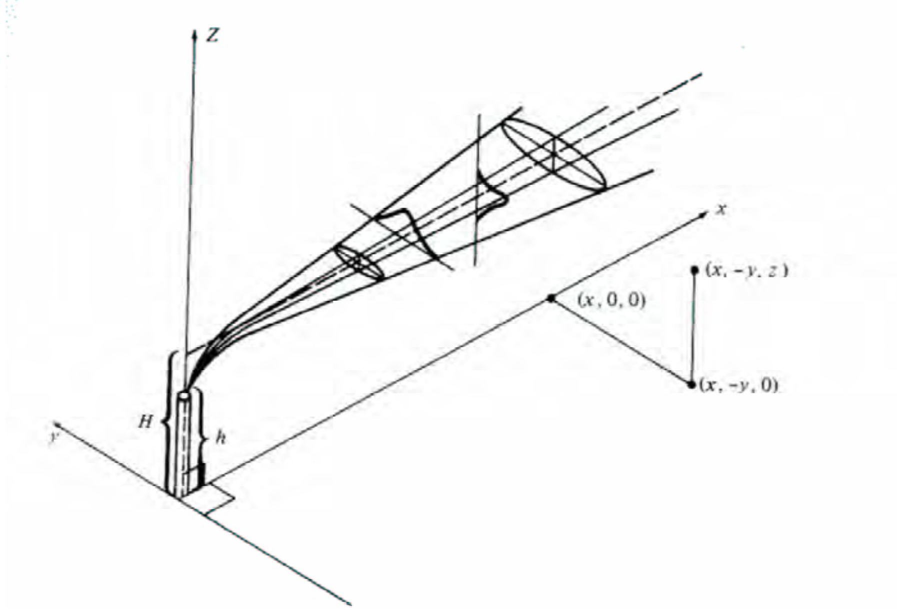
Air dispersion modeling uses mathematical formulas to characterize how atmospheric processes will disperse a pollutant emitted by a source. For the fumigants, the Agency has used dispersion models to estimate the downwind concentration of fumigants emitted from sources such as treated fields or structures for this purpose as is consistent with the guidance provided in 40CFR51. This treatment is consistent with standard model development and implementation methods. Dispersion models require the categorization and/or input of data which includes:

- Meteorological conditions such as wind speed and direction as well as the amount of atmospheric turbulence (also known as the "stability class");
- Flux rate (the mass of fumigant emitted per area per time);
- Surface roughness (accounts for topography effects); and
- Application Specifics (application method, sealing techniques, application rate, field size, etc.).

The Agency maintains a *Guideline on Air Quality Models* (hereafter, Guideline), which is published as Appendix W to 40CFR51 (http://www.epa.gov/scram001/guidance/guide/appw_05.pdf). The Guideline provides the Agency's guidance on the regulatory applicability of air quality dispersion models in general. In order to be included in Appendix W, as a recommended model, models must go through an extensive peer review and testing process. This peer review process defines how specific models can be used in an acceptable manner to calculate dispersion estimates for variety of sources like point (e.g., a stack on a building) and area sources (e.g., a fumigated field). This assessment was developed based on the guidance provided in Appendix W.

In producing the fumigant risk assessments, the Agency considered various air dispersion models that are currently listed or have previously been listed in Appendix W. The first of these models is the Industrial Source Complex Short Term Model (V3) (ISCST3) model which was utilized for a number of years by the Agency to quantify the movement of airborne pollutants for a variety of regulatory situations. ISCST3 was the Agency's recommended air dispersion model up until the end of 2005. It was also used as the sole basis for the earliest methyl bromide assessments. ISCST3 was replaced by the American Meteorological Society/Environmental Protection Agency Regulatory Model **(**AERMOD) in December of 2005 as the preferred air dispersion model for near-field, steady state sources. Both ISCST3 and AERMOD are "Gaussian Plume" models, in which airborne concentrations are assumed to have a normal probability distribution. Figure 4 illustrates the basic premise of ISCST3 and the Gaussian plume concept. It should also be noted that neither ISCST3 or AERMOD retain a memory of the movement of the fumigant plume from hour to hour (e.g., they would not track changes in an emitted plume should the wind direction change) and they do not quantitatively address calm conditions. For this assessment, a process has been used where calm conditions (e.g., hours with calm wind conditions) are dropped from calculations and a time-weighted average result is calculated without those values. This approach is consistent with how ISCST3 has been historically used. For chemicals such as methyl bromide the impact on the calculated exposures due to handling calms in this manner is attenuated because 24 hour time-weighted averages are the basis for the results. However, for chemicals where risk estimates are based on shorter duration toxicity endpoints (e.g., 1 hour), this phenomena can significantly impact the results if the weather data used in the assessment include a high percentage of calm periods. AERMOD has enhancements from ISCST3 related to how structural releases are modeled such as improved downdraft algorithms for building effects. The third model that the Agency considered was CALPUFF v.5 which was recently adopted by the Agency as the preferred model for assessing near-field air concentrations under complex meteorological conditions. CALPUFF is a "Gaussian Puff" model and is similar to ISCST3 and AERMOD in that it assumes that air concentrations follow a normal probability distribution. Unlike the plume model, however, CALPUFF retains a memory of the movement of the fumigant plume from hour to hour which allows it to track emitted plumes that change direction with shifting wind patterns. It also has an enhanced treatment of calm conditions relative to ISCST3 or AERMOD because it can account for the plume being stable in calm conditions then moving again once winds pick up instead of skipping over such conditions. ISCST3, AERMOD, and CALPUFF are described in more detail in Appendix C. [Note: There is a yet unapproved version of CALPUFF (v6) which has not been officially accepted by the Agency. The major upgrade is that it can complete sub-hourly calculations where v5 can only do calculations based on hourly increments. This is described as well in Appendix C.] It should be noted that the Agency used ISCST3 as the basis for its deterministic assessments. At the time the results based upon ISCST3 were developed neither AERMOD nor CALPUFF v5 were approved models. At this time, the Agency has not opted to use them directly since neither can readily be used in the distributional manner that is currently being employed by the Agency as described below. The Agency would accept and review submissions using these modeling platforms as they are accepted models in the Agency Guideline as outlined in Appendix W.

Figure 4: Illustration of ISCST3 Gaussian Plume Approach



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 fields, buildings or structures per unit area per unit time, must be determined. As an example, for field applications it is usually expressed in units of micrograms per square meter per second (ug/m^2/sec). In essence, flux represents how quickly the pesticide moves or volatilizes into the surrounding atmosphere from a treated surface. Numerous factors can influence flux rates such as application rate, depth of soil injection, type of application (e.g., drip vs. soil injection vs. granule application), techniques used to control emissions (e.g., tarps), temperature, wind and weather conditions, soil type, and others. Three general methods are used to estimate flux from treated fields. These are discussed briefly below. The first two methods measure flux from sampling directly in treated fields, and the third is an indirect, back-calculating method that estimates flux using samples from downwind locations and solves for them using ISCST3. For methyl bromide, most flux estimates for pre-plant field applications were completed using the indirect back-calculating method. [Note: For the structural uses addressed in this document, flux estimates were developed using a different approach. Please refer to D304623, 3/10/06 & its Addenda D304619, 7/12/06 for further information.]

<u>ISCST3 Flux Method 1: Chamber</u> The first method is a direct sampling method for determining flux that uses emission data measured in a flux chamber placed in a treated field. A flux chamber is basically a box which encloses a small defined area of a treated field, from which air samples are obtained representing defined durations (e.g., air is pulled through a charcoal trap collecting emitted pesticide over a continuous length of time such as 4 hours). Since the surface area is defined by the area of the chamber, and the quantity of pesticide emitted per unit time is defined by the air concentration, this method directly measures flux. A possible issue with flux chambers is that the conditions within the chamber (e.g., temperature, wind, air stability) are not generally identical to those outside the chamber in the treated field; since flux rates can be significantly affected by these factors, flux rates measured in these chambers may not always represent actual flux rates in the field. Flux chambers are not often used for estimating flux and, in fact, no such field study data were available for use in this assessment.

<u>ISCST3 Flux Method 2: Aerodynamic Flux</u> A second direct method used is known as the aerodynamic flux method.[3] In this method, air samplers are set up in treated fields at various heights on a mast (e.g., 15, 30, 90, and 150 cm from the ground). Using measured air concentrations at these various heights, a vertical gradient of concentrations can be estimated for different time points which can be integrated across all heights to estimate the flux rate at each time point after application. Some studies are available using this method to determine flux rates.

<u>ISCST3 Flux Method 3: Indirect Back-Calculation</u> The method most often used to determine flux rates is the indirect or back-calculation method. [Note: EPA used CDPR's technique (http://www.cdpr.ca.gov/docs/empm/pubs/ehapreps/eh9903.pdf).] This method uses measured air concentrations taken in a typical field fumigation study in which air samplers are located at various positions around the field. The measured air concentrations, together with information about weather conditions which occurred when the samples were obtained, are used as inputs into the ISCST3. The model assumes that these air concentrations result from a Gaussian plume, the plume being distributed around the treated field as a result of the wind and weather conditions. The model then estimates the flux rate that would be required to emit the plume and to obtain the air concentrations measured.

Aside from the estimation of the flux for all application methods, there are a number of other key inputs that must also be defined such as the size and shape of a treated field or other sources (e.g., greenhouses or fumigation chambers), wind speed, and atmospheric stability in order to run ISCST3. Atmospheric stability is 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-field/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. To simplify the ISCST3 modeling process, the transport of fumigant vapors from a source, a single wind direction, wind speed, and stability category are used for a given period.

A range of atmospheric conditions representing the continuum from relatively stable (low windspeed & calm) to unstable conditions (high windspeeds & unsettled) were evaluated using ISCST3. Under relatively stable atmospheric conditions, the modeling produces results that represent highly exposed individuals (i.e., ISCST3, as used for these situations, results in exposure estimates at the upper percentiles of an anticipated exposure distribution). Two key inputs are the basis for this conclusion.

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3 Majewski, MS, Glotfelty, DE, Seiber, JN. 1989. A comparison of the aerodynamic and the theoretical-profile-shape methods for measuring pesticide evaporation from soil. Atmospheric Environment, 23:929-938

Majewski, MS, Glotfelty, DE, Kyaw Tha Paw U, Seiber, JN. 1990. A field comparison of several methods for measuring pesticide evaporation rates from soil. Environmental Science and Technology, 24:1490-1497.

Parmele, LH, Lemon, ER, Taylor, AW. 1972. Micrometerological measurement of pesticide vapor flux from bare soil and corn under field conditions. Water Air Soil Pollut. 1:433-451

First, only a constant downwind direction is considered which would be highly unlikely in any outdoor environment. Secondly, the quantitative inputs used to define atmospheric conditions are based on constant wind speed and atmospheric stability over a particular period, which are also unlikely to occur in an outdoor environment over a 24 hour period such as considered for methyl bromide field uses. 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 direction over a particular period.

Source Type 3: Distributional Air Modeling

The monitoring data and ISCST3 methods described above are deterministic methods that provide results that are limited in utility. For example, it is difficult to extrapolate to varying distances using monitoring data and analyses using ISCST3 which provide high-end point estimates of exposure and risk because of the manner in which meteorological data are input, especially for a stable atmosphere. In response to these methods, the pesticide industry developed three models that are essentially pre- and post-processors for the air models described above that incorporate the ability to complete distributional and/or probabilistic analyses. Each of the three has ISCST3 as their core processor while FEMS has an option for selecting between processors based on ISCST3 or CALPUFF (V 5 or 6). The three models which were developed include: **P**robabilistic **E**xposure and **R**isk model for **Fum**igants (PERFUM), the **F**umigant **E**missions **M**odeling **S**ystem (FEMS), and the **So**il **F**umigant **E**xposure **A**ssessment System (SOFEA). Each model was reviewed by the FIFRA Scientific Advisory Panel (SAP) in 2004 during the August and September meetings (http://www.epa.gov/oscpmont/sap/meetings/2004/index.htm). The SAP concluded that each of the three models could provide scientifically defensible estimates of the bystander exposures and risks associated with soil fumigation practices and also suggested modifications and additional data that could further refine risk estimates. See Appendix C for more details regarding each model including contact information pertaining to how one could obtain the system.

PERFUM and FEMS were designed specifically to take the concentration outputs from the air dispersion models and use them to produce buffer zone outputs in a distributional format. [Note: In the context of presenting modeling results the term "buffer zone" does not refer to any manner of regulatory decision pertaining to risk mitigation for methyl bromide. It refers to the distances determined based on a target concentration defined by the HEC or Human Equivalent Concentration adjusted by an uncertainty factor. Different uncertainty factor values were evaluated in this assessment to ascertain their impact upon the predicted results.]

Recently, PERFUM was modified to also provide air concentration information for selected distances from the perimeter of the treated field. PERFUM also has been modified since the SAP version in order to be able to evaluate structural sources which were addressed in the recent assessment for the food uses of methyl bromide (see D304623, 3/10/06 & its addenda D304619, 7/12/06 for further information). SOFEA was designed to calculate fumigant concentrations in air arising from treated fields for multiple sources across entire agricultural regions. A generalized flowchart for these models is shown in Figure 5.

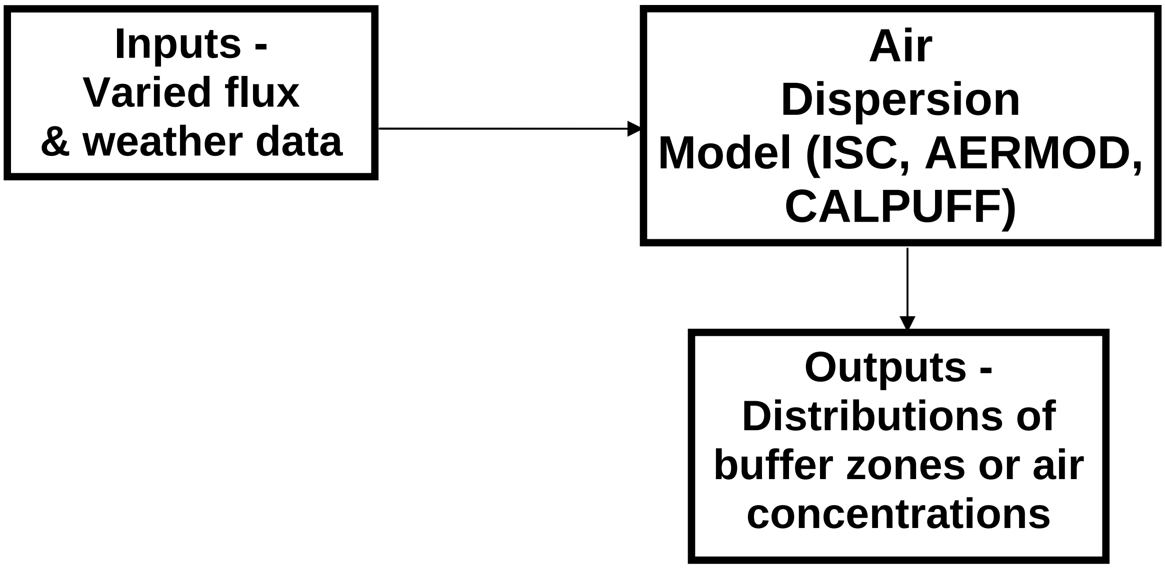


Figure 5: Operational Flowchart For Distributional Models Such As PERFUM

Selection of a Distributional Model - The conclusions of the 2004 SAP meetings were that all three of the distributional and/or probabilistic modeling options were scientifically viable and represented a level of refinement above the deterministic analyses that had been completed using ISCST3. For a number of reasons detailed below, PERFUM was selected at that time to evaluate bystander risks from pre-plant soil applications including:

- PERFUM's developers revised the model to incorporate some of the SAP's recommended changes in time for the Agency to use PERFUM in the revised Phase 1 risk assessments for the soil fumigants;

- PERFUM was significantly faster and more efficient to run than FEMS at that point in time; and

- PERFUM provided greater resolution than the other options on the period of peak emission and highest potential exposure which is of key interest to the Agency because of the acute toxicity associated with soil fumigants. At that time, FEMS used emissions from a single field over a whole year so that the few days of fumigant exposure occurring after an application were attenuated over that entire year.

It is believed that results from a distributional and/or probabilistic model, instead of the deterministic results based on ISCST3, provide more comprehensive information for risk managers when evaluating the potential risks associated with pre-plant soil fumigation. PERFUM remains the model which has been used to develop the Agency's fumigant assessments but it should be noted that the Agency believes that submissions based on the other aforementioned distributional/probabilistic models such as FEMS or SOFEA can be of equal scientific validity and would also be evaluated and considered in its risk management process provided all appropriate supporting documentation were available for review (e.g., documentation of flux rate calculations and weather data analysis).

For the other single application event exposure scenarios including greenhouse and residential fumigations, PERFUM is the only one of the three distributional models which can accommodate a non-field structural source such as a treated building (see D304623, 3/10/06 & its addenda D304619, 7/12/06 for further information). The use of PERFUM for this purpose, coupled with its use for evaluating pre-plant soil fumigations also adds consistency to the Agency's fumigant analyses.

Use of the Probabilistic Exposure and Risk model for Fumigants (PERFUM) - PERFUM allows users to develop an understanding of the distributions of potential bystander exposures and thus more fully characterize the range of risks resulting to bystanders around treated fields. In this assessment, the PERFUM model has been used in order to calculate differing percentiles of exposure associated with pre-plant soil fumigation. ISCST3 is an integral part of the PERFUM model and in fact the basic physics and code of ISCST3 remain unchanged. Many of the inputs used for PERFUM are similar to those used for modeling done using the ISCST3 model (e.g., field sizes and back-calculated flux rates). There are major differences with the inputs in a PERFUM analysis as opposed to an ISCST3 assessment. Each PERFUM analysis that is summarized in this assessment is based on 5 years worth of meteorological data and a flux profile specific to a unique methyl bromide application method. [Note: The meteorological data were used for both the pre-plant field uses of methyl bromide as well as the structural uses. Please refer to D304623, 3/10/06 & its addenda D304619, 7/12/06 for further information pertaining to the flux values used for the structural uses considered herein.]

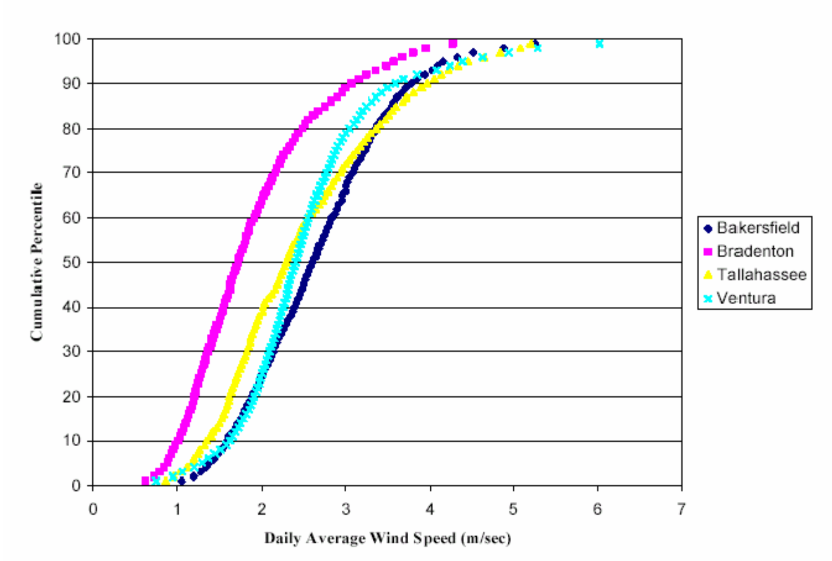
Since actual meteorological data are integrated into PERFUM for each analysis, data representative of the locations where methyl bromide use occurs were identified and used in the analysis. For example, major uses occur on strawberries and tomatoes in Florida and California. Some use in Michigan (or elsewhere in that region) also occurs on various crops. As a result, the following locations and sources of meteorological data were used in this assessment:

- Bakersfield California (Source: ASOS or Automated Surface Observing System operated by the FAA) to represent inland California locations;
- 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;
- Tallahassee Florida (Source: NWS or National Weather Service) to represent inland Florida locations; and
- Bradenton Florida (Source: FAWN or Florida Automated Weather Network) to represent coastal Florida.

In this assessment, 5 years or 1825 days of meteorological data were considered in each calculation. Bradenton, Bakersfield, and Ventura data were in the range of 1997 through 2003 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, pertinent quality control issues associated with the data, and additional information related to their selection (http://www.epa.gov/scipoly/sap/2004/index.htm).]
Figure 6 provides a comparison of the distributions of daily average windspeeds for selected stations in California and Florida that can help characterize the deterministic assessments and different PERFUM

results for the different stations. [Note: For context, CDPR regulated methyl bromide at 1.4 m/s windspeed.]

Figure 6: Distribution of Daily Average Windspeeds At Selected Meteorological Stations



Flux inputs (i.e., field volatility or emissions) for PERFUM were categorized in a manner similar to that used for the ISCST3 analysis described above. In the ISCST3 analysis for methyl bromide, calculations were based on the emission ratios developed by the CDPR that categorized emissions based on application method and sealing technology. These formed the basis for the different CDPR permit conditions for methyl bromide (Table 4). Emission functions were used in the PERFUM assessment as the basis for the calculations. These were also developed by CDPR to describe the change in flux rate over time in order to define the duration of restricted entry intervals. These functions allow PERFUM results to account for changes in flux to occur at appropriate times of day which is more reflective of actual field situations. Table 4 below also illustrates the analyses that were completed using PERFUM based on different combinations of flux and weather data. [Note: All emission ratios included in Table 4 are based on the use of LDPE or HDPE films. High barrier film use is not reflected herein.]

Table 4: Summary Of PERFUM Analyses Completed For Methyl Bromide

Weather Station Location	Flux Study Summary & Corresponding Emission Ratios and CDPR Permit Conditions				
	Tarped [ER = 0.25]	**Shallow Untarped** [ER = 0.40]	**Deep Untarped** [ER = 0.40]	**Bedded Tarped** [ER = 0.80]	**Hot Gas** [ER = 1.0]
Ventura CA	X	X	X	X	X
Bakersfield CA	X	X	X	X	X
Flint MI	X	X	X	X	X
Tallahassee FL	X	X	X	X	X
Bradenton FL	X	X	X	X	X

Table 4: Summary Of PERFUM Analyses Completed For Methyl Bromide					
Weather Station Location	Flux Study Summary & Corresponding Emission Ratios and CDPR Permit Conditions				
	Tarped [ER = 0.25]	**Shallow Untarped** [ER = 0.40]	**Deep Untarped** [ER = 0.40]	**Bedded Tarped** [ER = 0.80]	**Hot Gas** [ER = 1.0]
X = analysis completed PERFUM flux profiles and categories (i.e., Permit Conditions) based on the following information from CDPR: To link above flux profiles to CDPR Permit Conditions, please refer to Table 1 in the "Buffer Zone Determination" document completed under Reg. 03-004 (effective 11/3/04) http://www.cdpr.ca.gov/docs/legbills/03004buffer_zones.pdf. Determination of the appropriate Permit Condition category should be based on the emission ratio (ER noted above) and description of the fumigation method. Johnson, Bruce (1999) Memorandum to Randy Segawa on Buffer Zone Duration (November 29, 1999). Johnson, Bruce and Segawa, Randy (2000) Memorandum to John Sanders on Re-analysis of decline rate for Methyl Bromide flux rates and buffer zone durations (May 31, 2000). Johnson, Bruce (2004) Memo To Kean S. Goh, Additional Help On Air Modeling Provided To The United States Environmental Protection Agency - Hot Gas Flux Profile (December 28, 2004)					

The Agency utilized flux inputs for modeling methyl bromide emissions from pre-plant soil applications that were developed by CDPR as indicated above. The following describes the process and data upon which the analyses to develop these profiles were based. In January 2000, CDPR generated a memorandum outlining their recommendations for methyl bromide buffer zones for field fumigations ("Recommendations For Methyl Bromide Buffer Zones For Field Fumigations" Segawa, et al, 2000). These recommendations were based on a number of air monitoring studies dating from 1992 through 1999 that were used to define the emission ratios which are used in the permit conditions described in Table 6 above. [Note: The studies cited in the Segawa 2000 document were also evaluated by the Agency in the previous methyl bromide risk assessment (D316326, 6/13/05). As such, they are available on the EPA docket at www.Regulations.gov .] During the development and implementation of the methyl bromide permit conditions, CDPR also identified a need for establishing the duration of a buffer zone. In order to do this, it was decided that quantifying how the rate of emissions, defined based on the back-calculation method described above, change over time was the most appropriate approach. The following equation that describes the dissipation of methyl bromide after field applications was developed as a result of this effort ("Buffer Zone Duration" Johnson, 1999).

$$y = Ae^{-0.5\left[\frac{\ln\left(\frac{x}{B}\right)}{C}\right]^2}$$

Where:

Y	=	fraction of applied mass emitted per hour;
X	=	time in hours after the start of application;
A	=	constant that scales the overall function height and area;
B	=	constant that determines where the peak is; and
C	=	constant that determines the width of the function.

This equation has other utility in that it also has been used to define flux values for modeling purposes for each application method associated with the permit conditions. To estimate flux rate for an hour, the area underneath the curve generated by this equation was used. For each hour, values of Y were calculated for each minute which were multiplied by the application rate to estimate instantaneous flux rates on a per minute basis. The area underneath the curve for a one minute time step was estimated using the area of a trapezoid, A=1/2h(a+b), where h=x2-x1, and a and b are the incremental values of the instantaneous flux rate (see Figure 7). The areas for an hour were summed to provide an estimate of the flux rate over that hour.

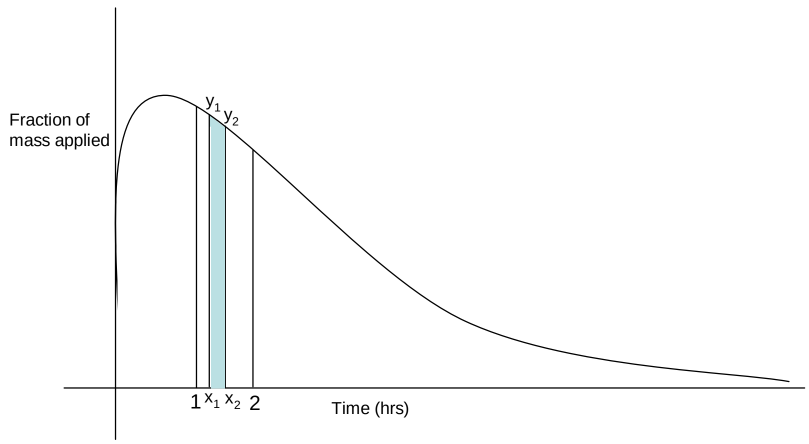


Figure 7: Flux Rate Estimation, Area Under the Curve

CDPR developed profiles for each emission ratio that is described in Table 4 above. The data which CDPR used as the basis for the flux profile analysis is described for each application method in Table 5.

Table 5: Summary Of Field Study Parameters Used To Develop Methyl Bromide Flux Profiles For PERFUM Modeling

Application Method	Study Code	Study Conductors	Study Date	County	Application Rate (lbs/total acre)	Total Acreage (acres)
Shallow, untarped, bedded [1]	SE1.1	Siemer and Associates	8/19/1992	Monterey	186	19
	SE1.2	Siemer and Associates	9/24/1992	Monterey	180	15
	SE1.3	Siemer and Associates	10/27/1992	Monterey	180	15
Tarped, broadcast [1]	TC199	Trical, Inc	6/30/1992	Kern	396	20
	EH9503/EH127-1	Environmental Hazards Program, DPR	10/26/1992	Monterey	235	10
Bedded, tarped [1]	BR787.1C	Bolsa Research	6/24/1999	Orange	176	1
	BR787.2B	Bolsa Research	6/30/1999	San Luis Obispo	245	1

Table 5: Summary Of Field Study Parameters Used To Develop Methyl Bromide Flux Profiles For PERFUM Modeling

Application Method	Study Code	Study Conductors	Study Date	County	Application Rate (lbs/total acre)	Total Acreage (acres)
	BR787.1B	Bolsa Research	6/24/1999	Orange	177	1
	BR787.2C	Bolsa Research	6/30/1999	San Louis Obispo	174	1
	EH9503	Kim and Segawa, 1998	10/6/1998	San Louis Obispo	206	9
Deep, untarped, broadcast [2]	SE2.2	Siemer and Associates	10/21/1992	Kern	396	15
	S104.2-1	Siemer and Associates	3/8/1993	Fresno	396	40
	S100B1.1	Siemer and Associates	3/13/1993	Madera	400	20
	S110.1	Siemer and Associates	10/31/1995	San Joaquin	450	7
Hot-drip gas [3]	EH150-1	Environmental Hazards Program, DPR	12/11/1996	Riverside	200	25
	EH150-3	Environmental Hazards Program, DPR	1/20/1997	Kern	200	14
	EH150-4	Environmental Hazards Program, DPR	1/27/1997	Imperial	200	14

[1] Flux profile and derivation described in CDPR memo entitled: *Buffer Zone Duration* Johnson, 1999

[2] Flux profile and derivation described in CDPR memo entitled: *Re-analysis of Decline Rates For Methyl Bromide Flux Rates And Buffer Zone Determinations* Johnson and Segawa, 2000

[3] Flux profile and derivation described in CDPR memo entitled: *Additional Help On Air Modeling Provided To The United States Environmental Protection Agency – Hot Gas Flux Profile* Johnson, 2004

Table 6 depicts the results of the CDPR analysis for each parameter described in the equation above. Subsequently, Table 7 presents the flux rates for each application method used corrected to the maximum application effective broadcast rate of 430 lb ai/acre which have been calculated for methyl bromide for the first 24 hours after application (i.e., the period of key concern). As indicated above, the effective broadcast rate for tarped raised beds differs from application methods that involve 100 percent of the area of a field. In raised bed applications only a percentage of the total land mass is actually treated (i.e., 60 percent for the purposes of this assessment based on BR787.2B from Table 5) that results in an effective maximum broadcast rate of 250 lb ai/acre for that application method. The flux rates included in Table 8 are those which have been used as the basis for the PERFUM distributional modeling. If an output file for PERFUM was examined, these values would be included as model inputs in that file. However, it should be noted that the hour depicted in Table 7 reflects the time from the start of application and not the hour of the day. For PERFUM runs involving methyl bromide, applications were assumed to begin at 9:00 am. Therefore, the Hour 1 flux rates shown in Table 7 appear at Hour 10 (9:00 am – 10:00 am) in the PERFUM files, with subsequent flux rates appearing in the corresponding hours.

Table 6: Coefficients Used for Field Use Flux Rate Estimation

Application Method	Application Rate (lb ai/acre)	A	B	C
Shallow, untarped	200	0.021113	15.5127	0.84929
Tarped	400	0.013723	15.5127	0.84929
Bedded, tarped	250	0.132867	0.602401	1.53484
Deep, untarped	400	0.016618	12.36407	1.081679
Drip, hot gas	225	1.11E-01	6.414006	0.495166

Table 7: Flux Rates (ug/m2-s), by Application Method, for Methyl Bromide Field Use

Hour	Shallow, untarped	Tarped	Bedded, Tarped	Deep, untarped	Drip, hot gas
1	0.31	0.2	889.64	4.42	0.15
2	7.12	4.63	868.23	33.61	29.26
3	28.53	18.54	675.28	74.48	254.32
4	60.97	39.63	537.65	112.35	703.00
5	97.73	63.52	439.43	143.49	1143.44
6	134.01	87.1	366.93	167.83	1409.25
7	167.1	108.61	311.71	186.25	1481.21
8	195.8	127.26	268.53	199.78	1412.05
9	219.75	142.83	234.03	209.39	1264.36
10	239.08	155.4	205.97	215.87	1086.08
11	254.18	165.21	182.78	219.87	907.12
12	265.5	172.57	163.38	221.92	743.25
13	273.55	177.8	146.95	222.42	601.04
14	278.8	181.21	132.92	221.71	481.74
15	281.68	183.09	120.81	220.05	383.86
16	282.59	183.68	110.30	217.65	304.74
17	281.86	183.2	101.10	214.68	241.43
18	279.78	181.85	93.01	211.28	191.10
19	276.61	179.79	85.84	207.55	151.27
20	272.56	177.16	79.47	203.59	119.82
21	267.81	174.07	73.77	199.45	95.02
22	262.52	170.63	68.66	195.2	75.47
23	256.81	166.92	64.05	190.88	60.05
24	250.79	163.01	59.89	186.53	47.88

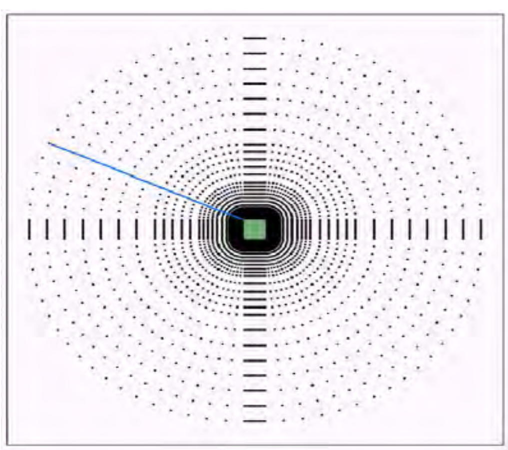
PERFUM works by establishing a grid with receptor points around a field built with spokes and rings then it calculates air concentrations at each point for each day over 5 years of weather data. The numbers of receptors for varying sized fields is summarized in Table 8 and Figure 8 below. The information calculated at each grid location is then used to calculate distances in each array (or spoke protruding outwards from the treated field in the center of Figure 8) where a target concentration of concern is achieved. Target concentrations are defined by dividing the HEC by the uncertainty factor of interest for that particular analysis. PERFUM compiles these results for each array (or spoke) then ultimately compiles them across all spokes and weather days using two techniques (i.e., referred to as a "whole field" or "maximum" buffer results which are described below). Each receptor corresponds to an x- and y-coordinate. Figures 9, 10 and 11 below, provide an example of daily PERFUM output where a contour plot has been developed that describes the distances where a target concentration has been achieved around the perimeter of a treated field for three distinct weather days. Each plot pertains to one application using the same emission rate and field size but the difference between the plots is that each presents the results (i.e., distance where a target concentration of concern is achieved) for a single, separate day of varied weather conditions.

Table 8: Receptor Points for Various Field Sizes in PERFUM

Grid Type	Field Size (Acres)	Number of Spokes	Number of Rings	Numbers of Receptors (Spokes * Distances)
Fine	1	96	28	2,688
	5	132	28	3,696
	10	152	28	4,256
	20	188	28	5,264
	40	232	28	6,496
Coarse	1	24	28	672
	5	33	28	924
	10	38	28	1,064
	20	47	28	1,316
	40	58	28	1,624

Note: Fine grid option was used for methyl bromide analysis.
The maximum distance used for PERFUM calculations on each spoke is ≥1440 meters.

Figure 8: PERFUM Receptor Grid



Whole field buffer results are calculated using PERFUM by compiling the results for all arrays (i.e., using the entire perimeter) of each days contour line outputs. PERFUM compiles all of the locations (i.e., x and y coordinates) along the contours in each of the plots into one distribution and essentially produces an overall contour plot for the 5 years of weather data (see Figure 12 below). The user can then select a percentile of the distribution of interest (e.g., 95th percentile or 99th percentile). In essence, the "whole field" buffer results represent the entire range of possible exposures regardless of location relative to the treated field.

Maximum buffer results from PERFUM are calculated by compiling only the farthest distances from the contours produced for each weather day. The black dot in each plot (Figures 9 through 11) represents the maximum distance buffer for that day which would be the only point selected for that day used in this calculation. PERFUM also generates these maximum distance buffers across 5 years of weather data which is presented in Figure 12 below. The user can then select a percentile of the distribution of interest (e.g., 95th percentile or 99th percentile). In summary, the maximum buffer results can be thought of as a way of providing more resolution around the upper percentiles of possible exposure. In a physical sense, it can also possibly be applicable to individuals who live in an area with strong prevailing winds due to topography or other factors (e.g., in a valley or coastal situation where on-shore winds are predominant).

Note that in Figure 12 the whole field buffer contour is within the boundary of the maximum buffer contour. This trend would always be expected if the percentiles considered in each case were of the same numerical value (e.g., 95th %tile whole and 95th%tile maximum) because the maximum buffer distribution represents only the farthest distance for each weather day and not all of the values as in the whole field buffer distribution.

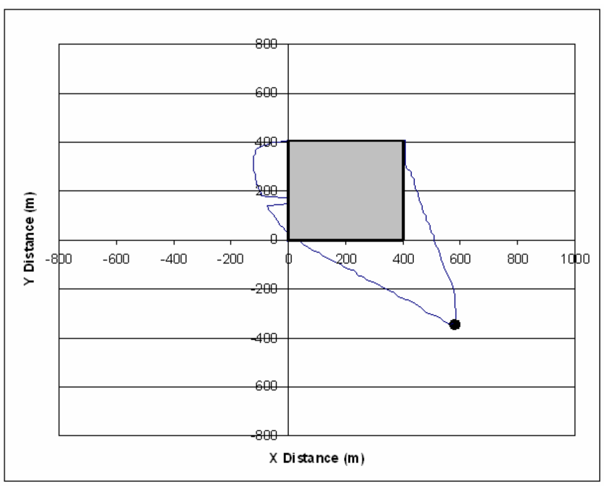


Figure 9: Example PERFUM Output - Day 1

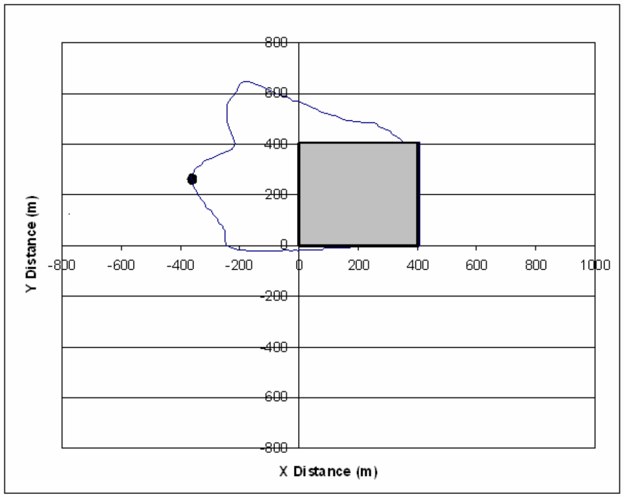


Figure 10: Example PERFUM Output - Day 2

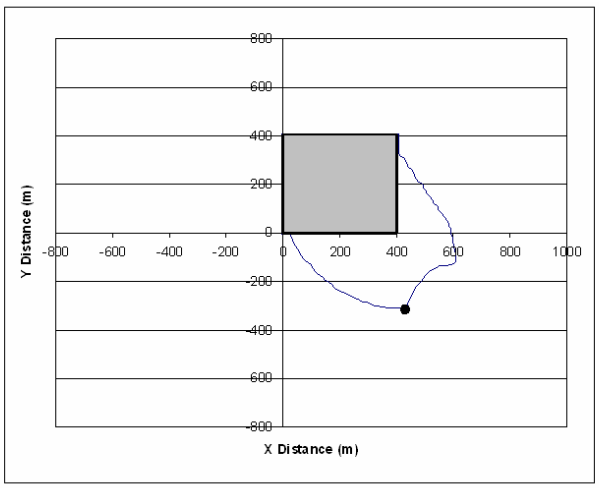
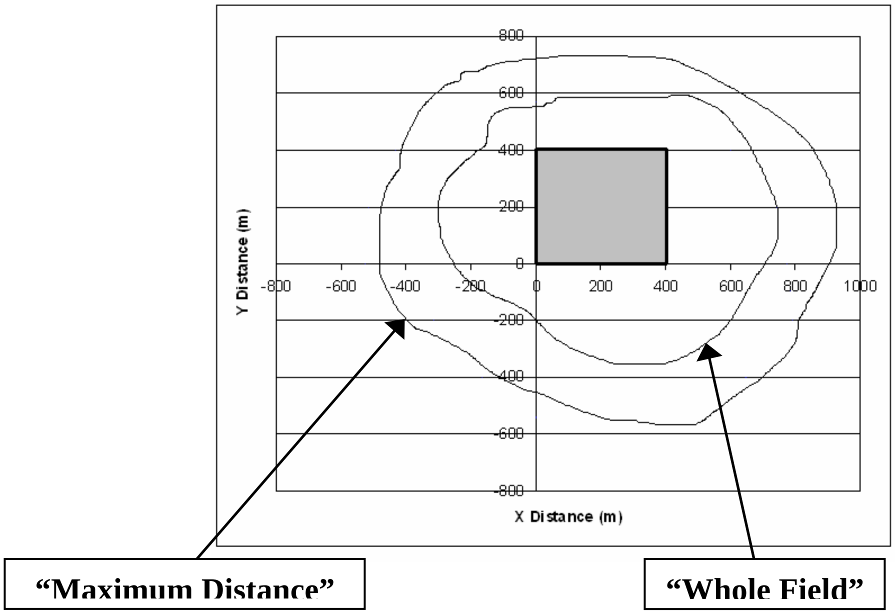


Figure 11: Example PERFUM Output - Day 3

Figure 12: Whole Field vs. Maximum Buffer Distance Example



PERFUM can generate the types of outputs discussed above for different exposure periods from 1 to 24 hours depending on the exposure duration and toxicity concern for the fumigant. When the distributional results from PERFUM are considered, they can be described by the following statements:

- **Maximum Distance Buffer:** The maximum concentration (e.g., at 95th percentile) provides a buffer zone whereby there will not be an exceedence for 95 percent of application days. It follows that if a person was at the location of the maximum concentration on any given day they would have a 95 percent chance of being at a location with a concentration less than the target.

- **Whole Field Buffer:** The whole field distribution (e.g., at 95th percentile) provides, on average, 95 percent of the perimeter of the buffer zone will have a concentration below the target. It follows if a person was placed randomly onto the perimeter of a buffer zone on a random day they would have a 95 percent chance that the concentration at their location is less than the target.

5.1.1.2 Bystander Exposures And Risks From Known Sources

The risks for bystanders from various types of known sources (e.g., farmfields and structures) are presented in this section. As noted above, known sources represent either an area source from a single application such as a treated farm field or a point source from a single application such as a stack used to dissipate residues from a treated structure.

<u>Distributional Air Modeling:</u> This approach is based on the PERFUM model and is believed to provide 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 is also based on the proven technology of ISCST3. PERFUM has been used to address results from the pre-plant soil uses as well as the structural uses for methyl bromide.

Deterministic Air Modeling: Deterministic air modeling based on ISCST3 was completed for all methyl bromide uses. However, since the distributional air modeling described below is based on PERFUM that contains ISCST3 as its core processor ISCST3 results have not been presented herein. It is also believed that PERFUM results represent a refinement of the ISCST3 approach (see Phase 3 = D316326, 7/13/05 & Phase 1 = D311945, 1/31/05 if so desired to review the ISCST3 analyses).

Monitoring Studies And Incident Data: A series of monitoring studies were reviewed, most of which were conducted by the CDPR. The information extracted from these studies data were summarized in the previous assessments and should be referenced as appropriate (Phase 3 = D316326, 7/13/05 & Phase 1 = D311945, 1/31/05). The summarized results are presented below for comparison to the modeling results. To the extent possible, information pertaining to methyl bromide incidents will be obtained and summarized in order to characterize the results of the quantitative risk assessment.

An overview of how this section is organized is presented below. Results have been summarized based on the industry sector. Monitoring data provide empirical results for calculating risks but are limited as described above. Conversely, PERFUM provides the most refined risk estimates for the pre-plant agricultural uses of methyl bromide as described above. In addition to the results summarized herein, more details pertaining to the monitoring data are included in the previous risk assessments (Phase 3 = D316326, 7/13/05 & Phase 1 = D311945, 1/31/05).

- ***Section 5.1.1.2.a: Bystander Exposures And Risks From Pre-Plant Agricultural Use*** The recommended results summarized in this section are based on monitoring data and the use of the PERFUM model. The data contained in ***Appendix D: PERFUM Output Summary Spreadsheets For Pre-Plant Soil Uses*** are spreadsheets which summarize the PERFUM analyses that have been completed for this scenario. [Note: These spreadsheets do not contain all information related to these analyses such as input parameters and some outputs such as monthly buffer zone distributions. This information is contained in the corresponding PERFUM input and output files are available upon request.]

- ***Section 5.1.1.2.b: Bystander Exposures And Risks From Greenhouse Use*** The recommended results summarized in this section are based on monitoring data and the use of the PERFUM model.

- ***Section 5.1.1.2.c: Bystander Exposures And Risks From Residential Use*** The recommended results summarized in this section are based on monitoring data and the use of the PERFUM model.

5.1.1.2.a: Bystander Exposures And Risks From Pre-Plant Agricultural Use

Exposures to bystanders from single pre-plant agricultural field fumigation events and their associated risks, calculated using the PERFUM modeling approach, are presented in this section. Results based on monitoring data are also presented for comparative purposes. The PERFUM modeling results included in this section represent elements of the information presented in Appendix D. Detailed monitoring study information is provided in previous assessments as described above. Appendix D contains 26 files that provide results for the various combinations of application methods (flux estimates) and meteorological stations considered (see Table 5 for more details above). These include:

- **Appendix D1. PERFUM Analysis:** contains a summary of the PERFUM results for all flux and meteorological combinations. The analyses presented below that compare results for different weather stations and flux types are included in this file.

- **Appendix D1a-D1e.Ventura CA:** 5 files that contain PERFUM results for all field sizes, application rates, and flux profiles for Ventura California meteorological data, also contains results for varied uncertainty factor levels (i.e., 1, 3, 10, 30).

- **Appendix D2a-D2e. Tallahassee FL:** 5 files that contain PERFUM results for all field sizes, application rates, and flux profiles for Tallahassee Florida meteorological data, also contains results for varied uncertainty factor levels (i.e., 1, 3, 10, 30).

- **Appendix D3a-D3e. Flint MI:** 5 files that contain PERFUM results for all field sizes, application rates, and flux profiles for Flint Michigan meteorological data, also contains results for varied uncertainty factor levels (i.e., 1, 3, 10, 30).

- **Appendix D4a-D4e. Bradenton FL:** 5 files that contain PERFUM results for all field sizes, application rates, and flux profiles for Bradenton Florida meteorological data, also contains results for varied uncertainty factor levels (i.e., 1, 3, 10, 30).

- **Appendix D5a-D5e. Bakersfield CA:** 5 files that contain PERFUM results for all field sizes, application rates, and flux profiles for Bakersfield California meteorological data, also contains results for varied uncertainty factor levels (i.e., 1, 3, 10, 30).

The analyses which were completed using PERFUM are based on the 25 combinations of flux and meteorological data which are available (refer to Table 5 above). In addition, the impact of field size and shape, application rates, "whole vs. maximum buffer" statistics, and target concentrations (i.e., HECs coupled with uncertainty factor) were evaluated. The field sizes and shapes (N=9) that were considered include:

- 1 acre (square, rectangle oriented on its side, rectangle oriented on its end);
- 5 acres (square, rectangle oriented on its side, rectangle oriented on its end);
- 10 acres (square);
- 20 acres (square); and
- 40 acres (square).

The maximum broadcast application rate that was considered for pre-plant soil applications in this assessment is 430 lb ai/acre while the maximum effective broadcast rate that has been utilized to assess raised bed cultural production is 250 lb ai/acre. The effective broadcast rate for raised beds is based on 60 percent of the gross acreage being covered by raised beds that are actually treated with methyl bromide. In addition to these maximum application rates, a range of other application rates were evaluated in order to assess the impact of lowering rates including 75, 50, and 25 percent of the maximums for each use pattern.

The impact of altering target concentrations (i.e., the combination of HEC coupled with uncertainty factor) was also considered to allow for a broader characterization of the risks associated with methyl bromide. The target concentrations that were considered in for each flux profile and meteorological input combination (N=25) include:

- [Target] = 0.33 ppm based on NOAEL HEC (10 ppm) and Uncertainty Factor = 30;
- [Target] = 1.0 ppm based on NOAEL HEC (10 ppm) and Uncertainty Factor = 10;
- [Target] = 3.3 ppm based on NOAEL HEC (10 ppm) and Uncertainty Factor = 3; and
- [Target] = 10.0 ppm based on NOAEL HEC (10 ppm) and Uncertainty Factor = 1

All totaled, when varied application methods (N=5), meteorological data (N=5), field sizes/shapes (N=5), application rates (N=4) and target concentrations (N=4) are considered, 3600 PERFUM analyses were completed in order to evaluate the potential risks associated with pre-plant uses in agricultural fields.

It should be acknowledged that a myriad of micro-environmental conditions and factors can impact how methyl bromide will volatilize and disperse from any given treated field on a particular day. With this premise, it would be logical to evaluate basic factors which could influence flux (e.g., soil type, soil temperature, percent water, etc.) and also micro-climates (e.g., topography) and thus ultimately impact results. However, PERFUM cannot easily address specific changes in these factors because it is not a First Principles Model where the approach would be to build a predictive tool from basic fate characteristics. Instead, PERFUM is an empirical model which utilizes field study and actual meteorological data to predict results and since field study 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 http://www.epa.gov/scram001/guidance/guide/appw_03.pdf for additional guidance pertaining to air model validation).

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 with regard to the implementation of buffer zones associated with updating methyl bromide labels. Any required label modifications to methyl bromide will be developed in the Agency's extensive public participation regulatory process.

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, was to quantify how potential risks change with factors such as application method, distance from the treated field, percentile of exposure, selected statistical basis (i.e., whole vs. maximum buffer approach), application rate, and field size/shape. Each of these factors has 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. Most of the information presented below is based on the Ventura California meteorological data inputs as an example. A similar analysis and summary could be completed based on the results for any source of weather data.

Tables 9 and 10 present PERFUM results (i.e., predicted buffer distances) based on Ventura California weather data and the tarped flux emission profile for methyl bromide for 10 and 40 acre fields, respectively. In these tables results are presented for different percentiles of exposure, different application rates, the nature of the PERFUM output (i.e., maximum distance or whole field buffers), and different uncertainty factors. It should be noted that PERFUM analyses were completed for an uncertainty factor = 1 but they are not included in these tables because essentially all predicted buffer results were 0 meters. For a 10 acre field, the maximum and whole field buffer distances were 225 and 115 meters, respectively, at the 99th percentile of exposure at the maximum application rate and an uncertainty factor of 30. If any factors are reduced then predicted buffer distances change, but in a non-linear Gaussian fashion. For example, if all other factors are held constant and the application rate was reduced to a more typical 215 lb ai/acre (1/2X) then distances would be 60 and 5 meters, respectively, for maximum and whole field buffers. Similar trends can be observed in the results for a 40 acre field. In a 40 acre field, the corresponding buffer distances at the 99th percentile of exposure at the maximum application rate and an uncertainty factor of 30 would be 555 and 330 meters, respectively. Appendix D contains information for all of the PERFUM analyses that were completed. There is a summary section of each file so similar information could be obtained for any of these analyses if so desired.

Table 9: Methyl Bromide PERFUM Buffer Distributions For A 10 Acre Square Field Based On Ventura California Weather And Tarped Flux Profile Data								
Percentiles	Max (430 lb/Acre)		75% (323 lb/Acre)		50% (215 lb/Acre)		25% (108 lb/Acre)	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
UF=30								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
30	5	0	0	0	0	0	0	0
35	5	0	0	0	0	0	0	0
40	5	0	0	0	0	0	0	0
45	5	0	5	0	0	0	0	0
50	20	0	5	0	0	0	0	0
55	30	0	5	0	0	0	0	0
60	40	0	5	0	0	0	0	0
65	50	0	5	0	0	0	0	0
70	65	0	5	0	0	0	0	0
75	80	0	25	0	5	0	0	0
80	90	0	40	0	5	0	0	0
85	110	5	55	0	5	0	0	0
90	135	5	75	5	5	0	0	0
95	165	35	95	5	5	5	0	0
97	185	65	115	20	25	5	0	0
99	225	115	150	65	60	5	5	0
99.9	290	195	195	130	85	50	5	5
99.99	315	275	220	180	105	85	5	5
UF=10								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0
95	5	0	0	0	0	0	0	0
97	5	0	0	0	0	0	0	0
99	5	5	5	0	0	0	0	0
99.9	5	5	5	5	0	0	0	0
99.99	5	5	5	5	0	0	0	0
UF=3								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0

Table 9: Methyl Bromide PERFUM Buffer Distributions For A 10 Acre Square Field Based On Ventura California Weather And Tarped Flux Profile Data								
Percentiles	Max (430 lb/Acre)		75% (323 lb/Acre)		50% (215 lb/Acre)		25% (108 lb/Acre)	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
75	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0
97	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
99.99	0	0	0	0	0	0	0	0

Table 10: Methyl Bromide PERFUM Buffer Distributions For A 40 Acre Square Field Based On Ventura California Weather And Tarped Flux Profile Data								
Percentiles	Max (430 lb/Acre)		75% (323 lb/Acre)		50% (215 lb/Acre)		25% (108 lb/Acre)	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
UF=30								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	5	0	0	0	0	0	0	0
20	10	0	0	0	0	0	0	0
25	30	0	5	0	0	0	0	0
30	40	0	5	0	0	0	0	0
35	60	0	5	0	0	0	0	0
40	70	0	15	0	0	0	0	0
45	85	0	30	0	5	0	0	0
50	110	0	40	0	5	0	0	0
55	125	0	55	0	5	0	0	0
60	145	0	70	0	5	0	0	0
65	170	0	85	0	5	0	0	0
70	200	5	110	0	5	0	0	0
75	230	5	130	5	25	0	0	0
80	260	10	150	5	40	0	0	0
85	305	30	180	5	65	0	0	0
90	350	70	220	25	90	5	5	0
95	430	150	280	80	125	5	5	0
97	470	210	320	125	150	35	5	0
99	555	330	390	215	200	90	5	5
99.9	725	510	500	355	265	190	20	5
99.99	760	680	555	485	305	265	60	45
UF=10								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0
75	5	0	0	0	0	0	0	0
80	5	0	0	0	0	0	0	0
85	5	0	0	0	0	0	0	0
90	5	0	5	0	0	0	0	0
95	5	5	5	0	0	0	0	0
97	30	5	5	0	0	0	0	0
99	70	5	5	5	5	0	0	0
99.9	105	65	20	5	5	5	0	0
99.99	140	125	60	45	5	5	0	0
UF=3								
5	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0

Table 10: Methyl Bromide PERFUM Buffer Distributions For A 40 Acre Square Field Based On Ventura California Weather And Tarped Flux Profile Data								
Percentiles	Max (430 lb/Acre)		75% (323 lb/Acre)		50% (215 lb/Acre)		25% (108 lb/Acre)	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
55	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0
97	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
99.99	0	0	0	0	0	0	0	0

The information that is included in Tables 9 and 10 can also be graphically presented (as can the results of any of the completed PERFUM analysis). Figures 13 and 14 present the maximum buffer distances based on uncertainty factors of 30 and 10, respectively, that were calculated using the Ventura California weather data and the tarped flux profile. In these graphs, buffer distance results are plotted versus the percentile of exposure for 1, 10 and 40 acre fields at varying application rates including the maximum, 75 percent and 50 percent rate (i.e., 1 acre tables are not presented above for simplicity but the information is included in the graphs for comparison). Figures 15 and 16 are similar in nature except they present the whole field buffer results instead of the maximum buffer results. When reviewing the results in Figures 13 through 16 note that the scale of the "y" axis are similar for direct comparison.

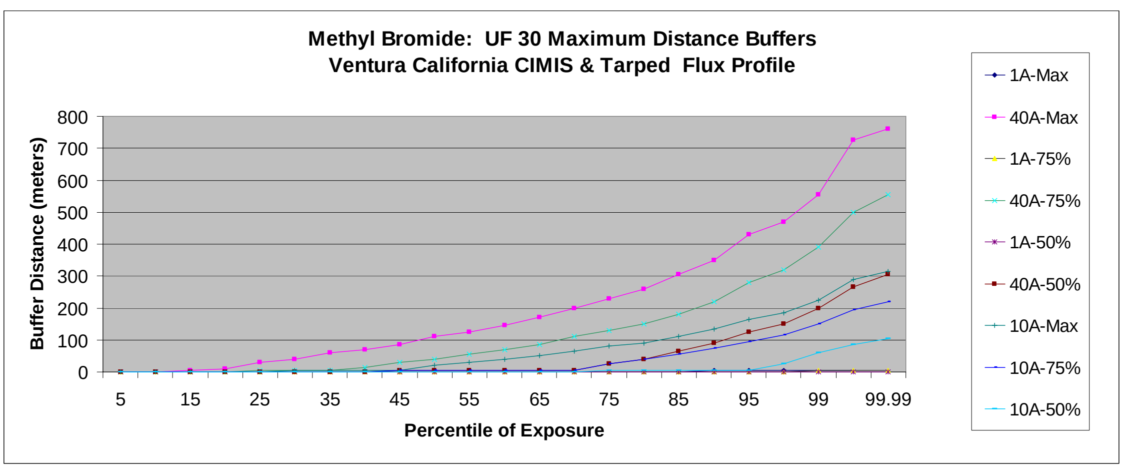


Figure 13

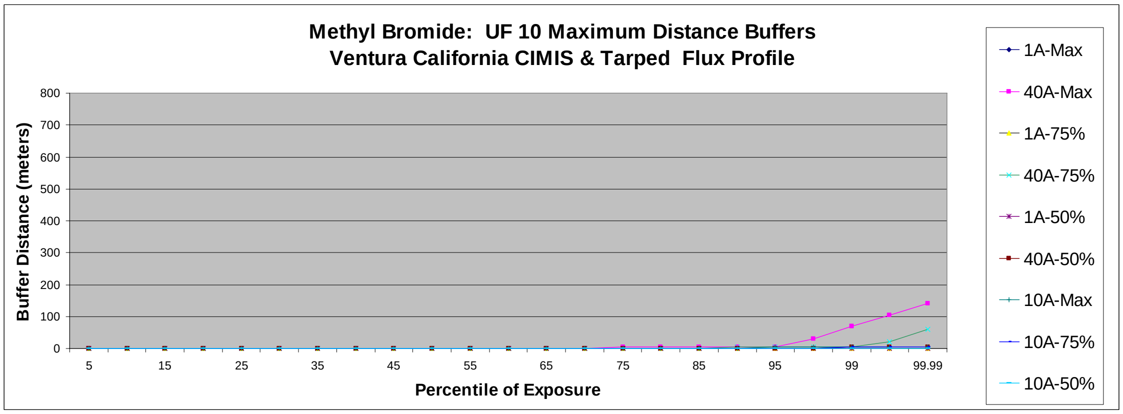


Figure 14

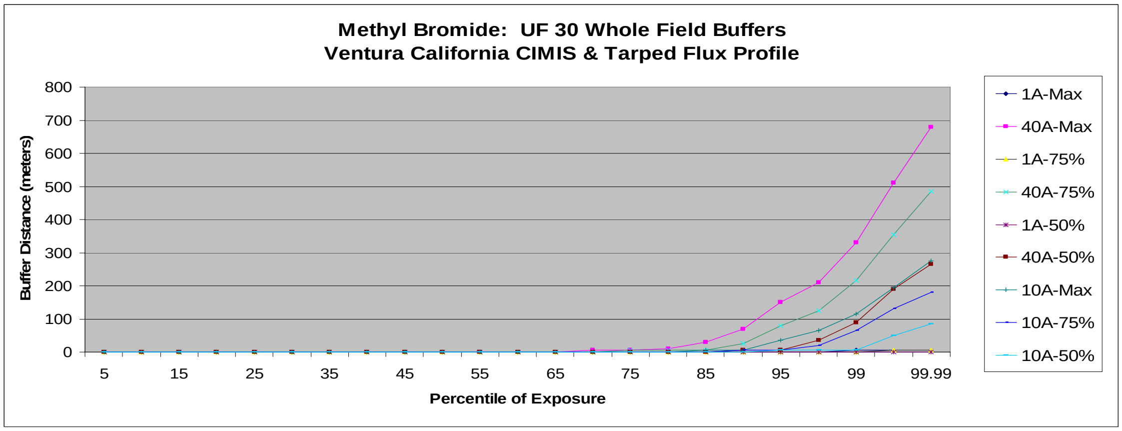


Figure 15

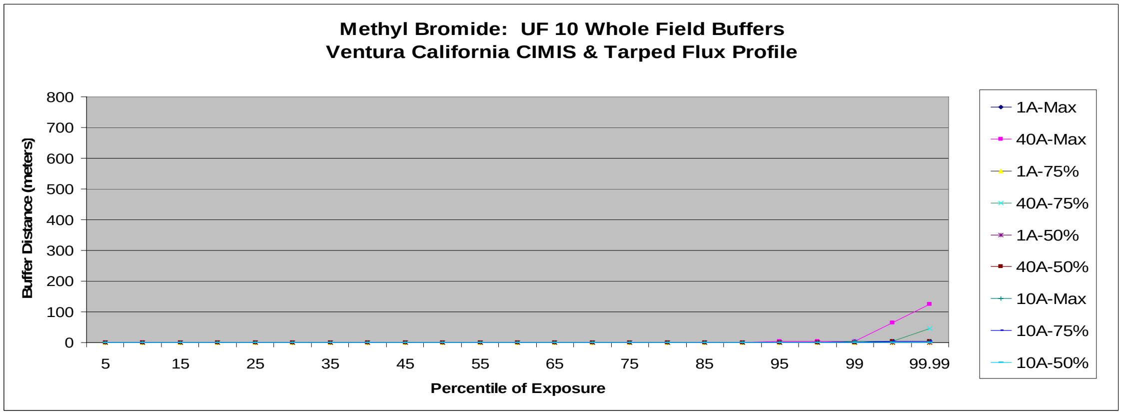


Figure 16

For comparative purposes, similar graphs are presented below in Figures 16, 17, and 18 that are based on results for Ventura California weather data but flux profiles for different application methods. In Figure 17, the flux profile is for raised bed applications (i.e., bedded tarped) while Figure 18 presents hot gas application method results (i.e., also known as drip application). The hot gas method is the highest emitting application method (i.e., it has the highest flux rates). As a result, it is the one where buffer zones greater than 25 to 50 meters or so were identified at a combined uncertainty factor of 3 (as opposed to 10 for the others above) so these results are included as Figure 19.

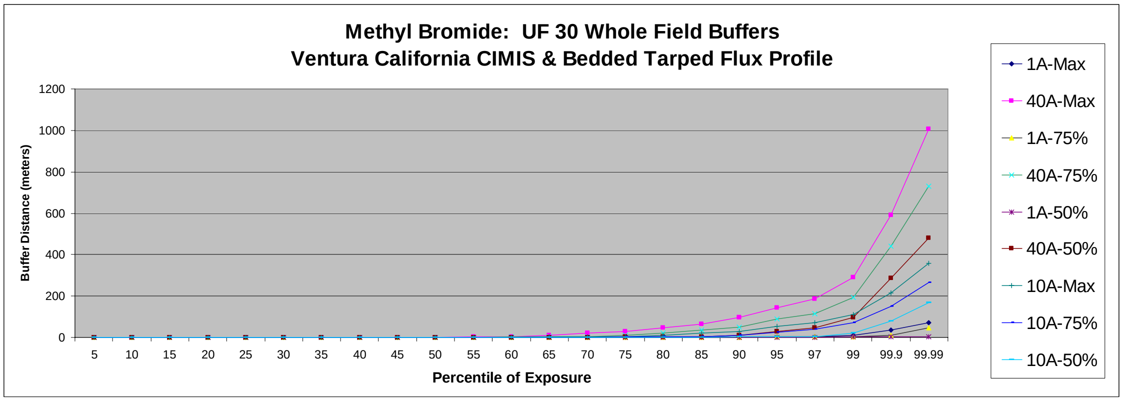


Figure 17

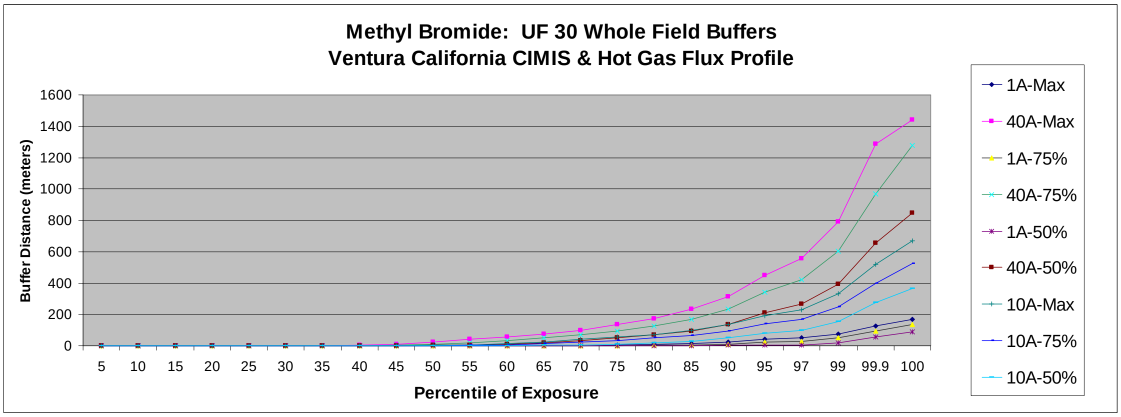


Figure 18

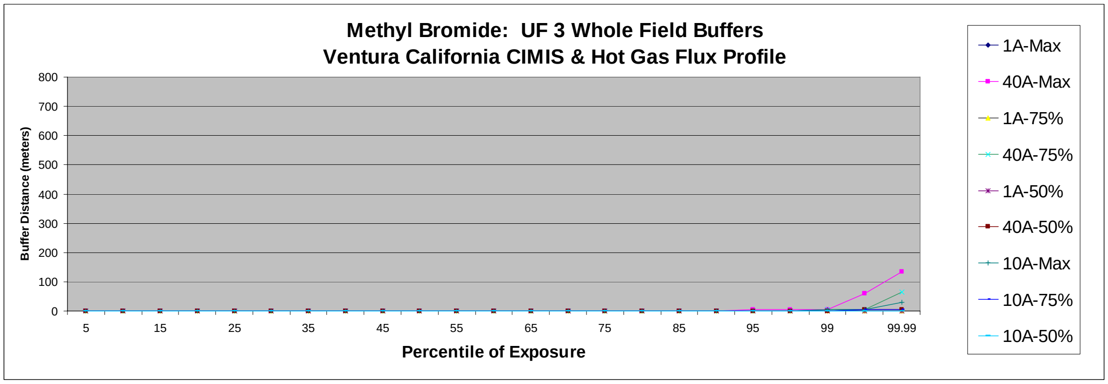


Figure 19

Table 11 provides a comparison of results for selected percentiles of exposure among flux profiles for a 40 acre field at varied application rates and an uncertainty factor of 30. The results essentially track with the relative differences in emission ratios that are described above in Table 5 with the tarped application method having the lowest associated emission and lowest predicted PERFUM buffer results. Conversely, the relative ranking of the hot gas and bedded tarped application methods as having the highest and penultimate emission ratios is also consistent with the PERFUM results provided below. The relative trends illustrated in Table 11 would be expected to be similar regardless of the choice of meteorological data selected for the analysis. Figure 20 illustrates these trends for varied application rates based on a combined uncertainty factor of 30. Figure 21 provides similar information but also provides results for a combined uncertainty factor of 10 for comparative purposes. As expected, the absolute values are decreased with a lower uncertainty value so the effect appears to be attenuated among flux types.

Table 11: Comparison Of Results For Methyl Bromide PERFUM Buffer Distributions Based On A 40 Acre Square Field, Ventura California Weather Data, And All Flux Profiles At A UF=30

Percentiles	Max (430 lb/Acre)		75% (323 lb/Acre)		50% (215 lb/Acre)		25% (108 lb/Acre)	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
Flux Profile = Tarped Application Method								
50	110	0	40	0	5	0	0	0
75	230	5	130	5	25	0	0	0
90	350	70	220	25	90	5	5	0
95	430	150	280	80	125	5	5	0
99	555	330	390	215	200	90	5	5
99.9	725	510	500	355	265	190	20	5
99.99	760	680	555	485	305	265	60	45
Flux Profile = Shallow Untarped Application Method								
50	245	0	150	0	45	0	0	0
75	425	30	290	10	135	5	5	0
90	615	150	430	90	230	30	20	0
95	710	285	510	190	290	85	50	5
99	895	565	665	400	410	225	110	30
99.9	1185	835	855	610	520	365	150	105
99.99	1205	1130	880	810	575	500	185	170
Flux Profile = Hot Gas Application Method								
50	505	25	360	10	200	5	35	0
75	705	135	510	95	305	50	85	5
90	985	315	725	235	450	135	150	25
95	1185	450	880	340	565	210	210	60
99	1440	790	1250	605	795	395	355	150
99.9	1440	1285	1440	970	1205	655	500	315
99.99	1440	1440	1440	1275	1330	845	545	455
Flux Profile = Deep Untarped Application Method								
50	165	0	85	0	5	0	0	0
75	305	20	195	5	70	0	0	0
90	450	105	305	55	140	5	5	0
95	530	200	370	125	185	40	5	0
99	695	420	490	285	290	140	45	5
99.9	875	635	630	445	365	260	110	45
99.99	935	850	700	605	430	350	115	100
Flux Profile = Bedded Tarped Application Method (Note: Effective Maximum Broadcast Maximum Application Rate = 250 lb ai/Acre)								
50	135	0	70	0	10	0	0	0
75	200	30	115	10	40	5	5	0
90	295	95	190	50	80	10	5	0
95	395	145	260	90	120	30	5	5
99	670	290	525	195	305	95	85	5
99.9	1225	590	925	440	555	285	210	85
99.99	1305	1005	955	730	565	480	230	205

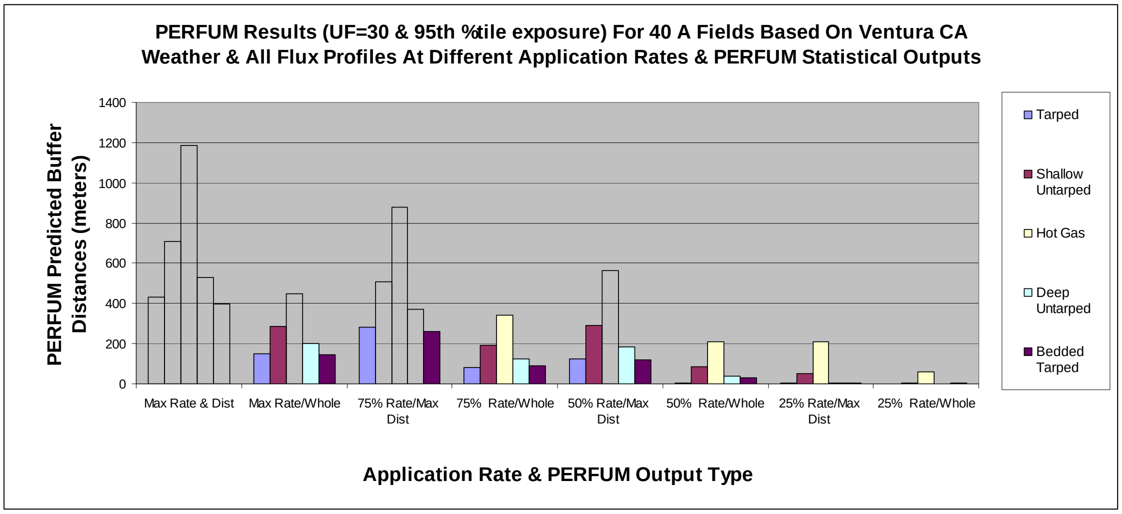


Figure 20

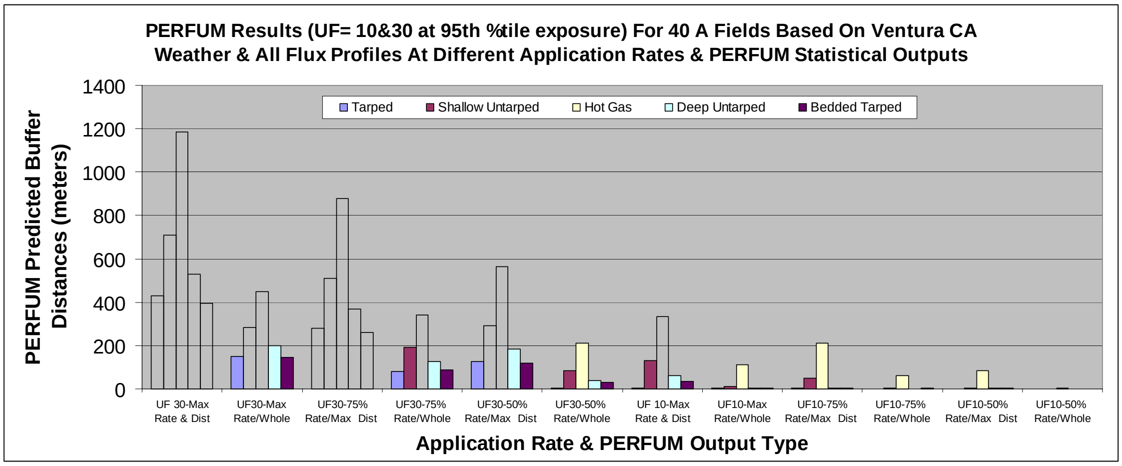


Figure 21

In addition to the comparisons described above among flux types, a comparison was also completed that evaluated differences concurrently among meteorological data and flux profile (Table 12 & Figure 22). The relative difference based on flux profile is similar regardless of the weather data used for the analysis. For results based on the selection of meteorological data, it appears that results for Bradenton Florida have higher associated buffer distances than (in order) Ventura California, Tallahassee Florida, Flint Michigan, and Bakersfield California. These results are consistent with the sensitivity analysis completed by the model developer and presented at the 2004 FIFRA Scientific Advisory Panel meeting (http://www.epa.gov/oscpmont/sap/meetings/2004/index.htm). The results presented in Table 13 are based on a 40 acre field and an uncertainty factor of 30 at the maximum application rate for each method. It is anticipated that the general trends observed in Table 12 and Figure 22 would also still apply regardless of the field size, uncertainty factor basis, or application rate.

Table 12: Comparison Of Results For Methyl Bromide PERFUM Buffer Distributions Based On A 40 Acre Square Field, All Weather Data, And All Flux Profiles At A UF=30 And Maximum Application Rate										
%tiles	Ventura California		Tallahassee Florida		Flint Michigan		Bakersfield California		Bradenton Florida	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
Flux Profile = Tarped Application Method										
50	110	0	60	0	50	0	95	0	155	0
75	230	5	130	5	115	5	145	15	290	15
90	350	70	225	50	190	40	200	65	420	105
95	430	150	290	95	240	85	235	105	510	185
99	555	330	435	215	385	185	315	190	695	350
99.9	725	510	620	415	515	360	390	295	905	575
99.99	760	680	630	585	580	500	395	375	935	790
Flux Profile = Shallow Untarped Application Method										
50	245	0	150	0	130	0	195	5	305	0
75	425	30	265	25	240	25	280	65	500	50
90	615	150	410	110	350	105	365	145	695	185
95	710	285	515	185	425	170	410	205	855	305
99	895	565	770	375	650	330	540	330	1130	555
99.9	1185	835	1050	690	905	605	640	495	1405	925
99.99	1205	1130	1065	995	960	860	705	625	1440	1340
Flux Profile = Hot Gas Application Method										
50	505	25	485	20	370	5	455	65	670	35
75	705	135	705	135	495	120	605	195	950	175
90	985	315	970	315	695	265	800	335	1320	380
95	1185	450	1170	460	850	365	935	435	1435	530
99	1440	790	1440	820	1365	625	1285	665	1440	940
99.9	1440	1285	1440	1395	1440	1110	1440	1040	1440	1435
99.99	1440	1440	1440	1440	1440	1440	1440	1435	1440	1440
Flux Profile = Deep Untarped Application Method										
50	165	0	105	0	90	0	135	5	220	0
75	305	20	195	10	170	10	200	40	375	35
90	450	105	310	80	255	70	265	100	530	145
95	530	200	390	140	315	120	305	145	645	235
99	695	420	605	290	490	245	400	245	865	435
99.9	875	635	810	540	680	455	500	375	1160	725
99.99	935	850	830	745	725	625	530	475	1255	995

Table 12: Comparison Of Results For Methyl Bromide PERFUM Buffer Distributions Based On A 40 Acre Square Field, All Weather Data, And All Flux Profiles At A UF=30 And Maximum Application Rate										
%tiles	Ventura California		Tallahassee Florida		Flint Michigan		Bakersfield California		Bradenton Florida	
	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field	Max Distance	Whole Field
Flux Profile = Bedded Tarped Application Method (Note: Effective Maximum Broadcast Maximum Application Rate = 250 lb ai/Acre)										
50	135	0	135	0	100	0	85	5	170	5
75	200	30	205	35	150	25	125	35	235	50
90	295	95	280	100	205	75	175	70	315	125
95	395	145	350	150	265	115	210	100	385	175
99	670	290	500	270	415	200	320	165	475	285
99.9	1225	590	605	455	1025	380	440	285	665	440
99.99	1305	1005	650	580	1440	1245	485	440	715	600

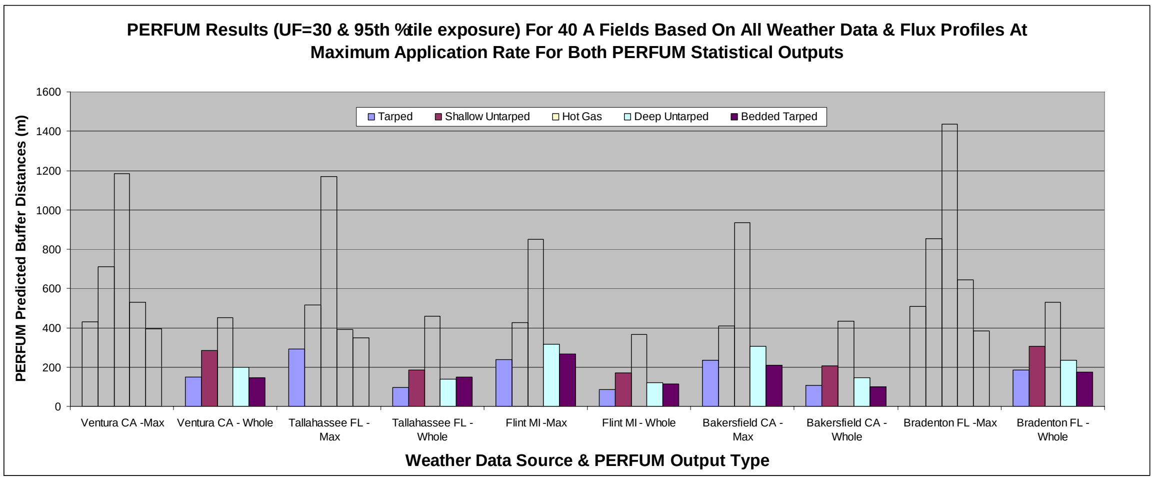


Figure 22

In addition to the comparative analyses presented above, other factors were evaluated relative to their possible impacts on PERFUM-based buffer zone predictions. These included evaluating the effect of field size and shape on results as well as discerning if there are significant seasonal differences in results since many fumigant use patterns are seasonal in nature. Figure 23 illustrates differences associated with increasing field sizes and the results indicate that, as expected, buffer distances increase relative to field size. Similar trends are observed regardless of the application rate or whether or not the results are based on maximum or whole field buffer results.

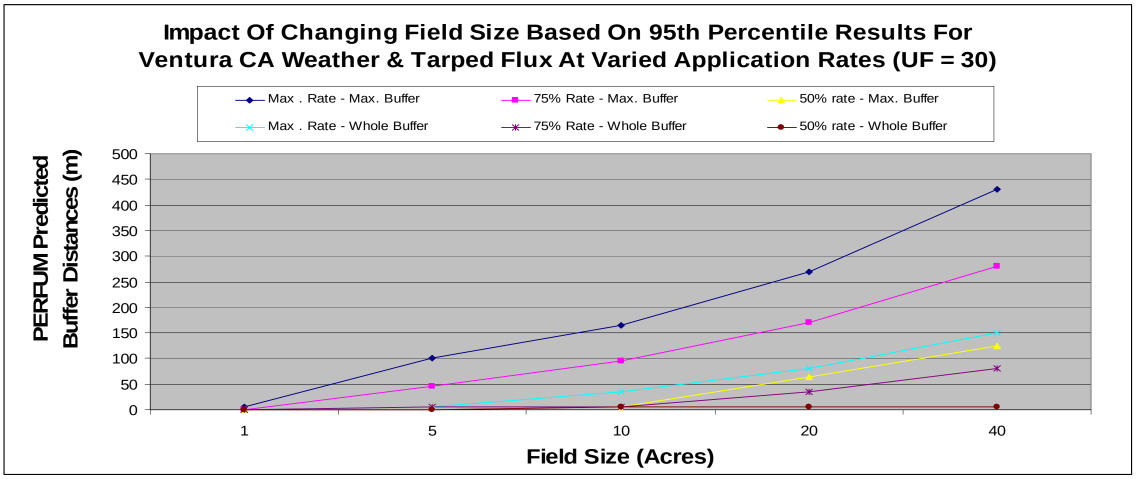


Figure 23

Figure 24 illustrates differences based on field shape. In this analysis, results for a square 5 acre field and rectangular fields (i.e., based on a 2:1 aspect ratio) oriented alternatively on perpendicular sides were calculated. Results were essentially similar for all types but the "long" field orientation always provided lower buffer estimates. The results of this analysis may also be sensitive to different weather conditions, site topography, and field aspect ratio but these factors were not evaluated in more detail because their relevance is likely more significant to specific use sites than to the development of generally applicable buffer estimates using PERFUM.

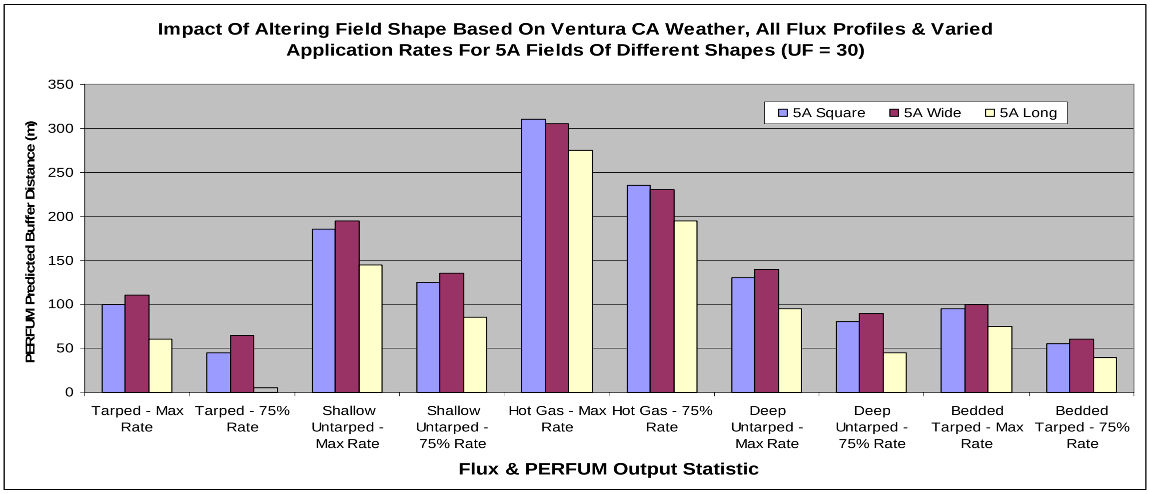


Figure 24

The seasonal impacts of changing weather patterns have been evaluated in every PERFUM analysis. Table 13 below provides an example of the outputs that are available. In this type of analysis PERFUM compiles distributions based on only the specific month's worth of meteorological data from the 5 years used for the analysis so each of the distributions is based on 5 months instead of 5 years worth of data. [Note: For comparative purposes, the corresponding 5 year distribution for Table 13 is included in

Table 9 above for whole fields, maximum application rate with an uncertainty factor of 30 (i.e., 95th %tile = 35 m; 99th %tile = 115 m; etc.).] It appears in this case that longer buffer distances are predicted in the cooler winter months which may be due to an overall trend toward a more stable atmosphere in those months due to less convective heating and atmospheric turbulence than in the spring and summer months.

Table 13: Methyl Bromide PERFUM Monthly Whole Field Buffer Distributions For A 10 Acre Square Field Based On Ventura California Weather And Tarped Flux Profile At The Maximum Application Rate And With An Uncertainty Factor = 30

Percentile Of Exposure	PERFUM Monthly Buffer Distributions											
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
5	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0
80	5	5	5	0	0	0	0	0	0	0	5	5
85	5	5	5	5	5	5	5	5	5	5	5	5
90	25	25	20	5	5	5	5	5	5	5	5	10
95	75	65	55	40	25	15	5	15	20	40	50	40
97	110	95	85	60	45	35	30	40	45	70	75	80
99	170	145	130	105	85	70	65	75	95	125	135	130
99.9	265	240	195	175	140	155	120	120	145	175	240	195
99.99	330	290	235	200	170	185	185	160	185	200	260	275

As indicated above, monitoring data in the previous phase 3 risk assessment for methyl bromide (D316326, 6/13/05) were identified and summarized. None of this information or analysis has changed since the previous assessment. Table 14 below provides a summary of these data and presents margins of exposure (i.e., MOEs) calculated based on them (i.e., MOEs > 30 are not of concern). Note a trend for maximum concentration estimates is not observed. For consideration, this can be due to many factors such as building characteristics, absorption rates of treated materials, differences in aeration, and prevailing weather conditions.

Table 14: Risks From Methyl Bromide Exposure Based On Maximum 24 Hour TWA Concentrations Based On Pre-Plant Agricultural Field Volatility Data		
Distance From Treated Field (feet) & No. Samples	Max. 24 Hour [TWA] (ppm)	Acute MOE
26 to 34 ft (N = 206)	1.4	7
35 to 79 ft (N = 80)	0.59	17
80 to 115 ft (N = 27)	0.470	21
> 115 ft (N = 90)	1.5	7

The results indicate that the potential risks which have been calculated for methyl bromide emissions from treated fields are of concern as calculated acute MOEs are less than 30 for all distances from the field where data are available. It should be noted that within each distance category described in Table 14 that there are a number of samples. If MOEs were calculated for many of these they would be greater than 30 and thus, would not be of concern. This would not be unexpected. If one were to review PERFUM outputs for various analyses it would also indicate that for many circumstances predicted buffer distances would be small (e.g., <10 meters or so) at lower percentiles of exposure. In summary, monitoring data support the types of results that have been calculated using the PERFUM model. Additionally, the limitations associated with the use of monitoring data can be illustrated based on the summarized data where there are different numbers of samples in each distance category and the distance categories themselves were defined based on the data and not conversely which would be more appropriate. If so desired, the previous risk assessment and its associated appendices that contain all of the monitoring data information can be found at www.Regulations.gov under docket OPP-2005-0123 (i.e., key various elements include: OPP-2005-0123-007 – bibliography; OPP-2005-0123-008 – field monitoring data). [Note: ISCST3 results are not summarized in this document since PERFUM uses ISCST3 as its core processor and PERFUM-based results provide more realistic estimates of risk based on actual meteorological data.]

In conclusion, it is clear that many different factors can impact the air concentrations (and hence, risks) in proximity to agricultural fields that have been treated 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) at the edge of the treated fields that NOAEL HECs (i.e., UF=1) generally are not exceeded given proper use of methyl bromide but conversely the distance predicted for higher uncertainty factors (i.e., UF=30) are hundreds of meters for many scenarios; (2) the methods used to evaluate methyl bromide exposure in this assessment generally agree and they are based on techniques that have been routinely used for regulatory purposes, they have also undergone a significant level of review; (3) the sensitivity of results to changes in key factors such as flux and meteorological conditions is generally within a factor of 4 or 5 for those which have been evaluated; (4) PERFUM is an empirically based approach so the generation of additional flux and meteorological data would allow a broader analysis that could be applied more specifically to other regions of the country and application parameters; and (5) the identification of a result, *per se*, for any sort of regulatory action (e.g., a percentile of exposure or maximum/whole field) would depend upon careful consideration of the variability and uncertainty as well as any particular merits of the inputs associated with each.

5.1.1.2.b: Bystander Exposures And Risks From Greenhouse Use

The "greenhouse" industry sector is extremely varied because of the breadth of the facilities that are used across the country and because of the nature of the products that are produced. As a result, some clarification is required in order to interpret the results presented below. Certainly, in common "greenhouse" operations, many types of containerized ornamental plants and vegetable starter sets are produced in either closed structures that will be referred to as "greenhouses" or in other related nursery operations such as small fields, or in what are commonly known as "shade" houses (i.e., essentially fields with an overhead sunblock of some sort typically a semi-transluscent black shade cloth). In the latter type of operation, cultural practices related to methyl bromide use are essentially identical to the pre-plant field uses described above in ***Section 5.1.1.2.a*** except they typically occur on a smaller scale (e.g., 1 acre applications or less). As a result, for risk estimates related to these types of use patterns, please refer to the results presented above for pre-plant soil uses and smaller sized fields.

For the actual greenhouse operations considered in this assessment, a maximum application rate of 4 lb ai/1000 ft^3 was used based on the Meth-O-Gas label (EPA Reg. No. 5785-41) for rhizomes, seeds, roots, bulbs, corms and tubers. A process has been defined, based on the PERFUM model described above, for characterizing the off-site dissipation of methyl bromide that has been released either intentionally during aeration after treatment is complete or that leaked from a structure during treatment. Aeration can be accomplished using several techniques that employ different devices and/or locations relative to the treated structure. In summary, aeration is predominantly accomplished using either portable industrial fans that are typically rated to move air volumes up to 5000 CFM (i.e., cubic feet per minute) or much larger static ventilation systems that can move much larger quantities of air.

Based on the observations above pertaining to "greenhouse" uses, it follows that the methods used to quantify potential risk estimates in the recently completed commodity assessment (i.e., that addressed the food uses) for methyl bromide are applicable to this industry. In both cases, a structure is treated and the methyl bromide is held in accordance to a "CxT" (i.e., concentration by time) table in order to achieve the desired level of efficacy; then the material is typically actively aerated from the treated structure using various methods. This type of operation would occur regardless of whether or not food commodities were in the structure. The only elements which may differ would be the amount retained because of the absorptive capacity of the materials in the structure being treated. Food use or not, insufficient information is available to quantify this phenomenon for more than a handful of situations so it is believed that the analysis and methods developed and used for the commodity assessment are directly applicable to the greenhouse use pattern. Identification of the applicable results will depend on how individual fumigation events occur. In the risk management strategy for addressing food use patterns the Agency decision was to allow for flexibility among users depending upon the aeration method used which is also anticipated for this use pattern. These methods and applicable results are presented in detail in the following documents:

- **Methyl Bromide:** Phase 5 Health Effects Division (HED) Human Health Risk Assessment For

Commodity Uses, PC Code: 053201, DP Barcode D304623, Authors: J. Dawson and E. Mendez, Issued: 3/10/06.

- **Methyl Bromide:** Addendum To Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses, PC Code 053201, DP Barcode D304619 Authors: J. Dawson E. Mendez, T. Goodlow, M. Metzger, Issued: 7/12/06

A coding error in the calculation algorithms of the PERFUM model was identified that pertained to the minimum stack aeration scenario. The results summarized below are based on the corrected version of PERFUM. It should also be noted that there have been comments pertaining to the method used to evaluate the PPQ aeration method (i.e., placing an exhaust fan and vent in the middle of a parking lot attached to the treated structure by a flexible large hose). In essence, the issue pertained to accounting for the orientation of the output orifice and two options were considered (i.e., referred to as the "vertical stack" or "horizontal stack"). It was determined that the "horizontal stack" approach is the most appropriate, consequently, results based on this method are presented below. Additionally, comments were made pertaining to the averaging times used as the basis for both the time-weighted average air concentrations and the HEC for structural types of uses. Based on these comments, the values for exposure and the HEC have been matched for risk calculation purposes (i.e., both are based on 6 hours). Active aeration or leakage during treatment are thought to occur over short periods so exposure estimates are based on 1 hour emissions followed by 5 hours of zero emissions in order to reflect anticipated actual occurences and to reflect an appropriate time basis calculating risks. At times, greenhouse and nursery operators also tarp quantities of potting soil and treat it with methyl bromide. It is believed that the no stack scenario (akin to no active aeration) is the most representative for determining risks reflective of this use pattern. In addition, there are times when orchard and tree replanting activities occur in order to replace whole blocks or individual trees that may have died due to disease or other factors. These should not be considered a greenhouse operation. If whole blocks of trees are being replaced, cultural practices related to methyl bromide use are essentially identical to the pre-plant field uses described above in ***Section 5.1.1.2.a*** except they typically occur on a smaller scale (e.g., 1 acre applications or less). If single (or a few) trees are being replaced, a handheld injector is typically used. No emissions data are available for this pattern, however, it is believed that this technique presents minimal risks for bystander populations because of the low amount used.

Table 15 presents a summary of some the results of the PERFUM analyses that were completed to assess events during treatment (from leakage) associated with the greenhouse uses of methyl bromide. The commodity assessment documents D304623 and D304619 detail the PERFUM iterations that were completed which could apply to greenhouse treatments. The scenarios presented in Table 15 have been selected for illustrative purposes because they represent many typical greenhouse settings and they also represent the maximum application rate, uncertainty factor of 30, and typical to high end emissions during treatment (i.e., 1 and 10 percent leakage of the nominal application concentration). Additional PERFUM output files which can be provided for review of other situations if so desired.

Table 15: PERFUM Methyl Bromide Buffer Distances (meters) During Greenhouse 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	1,000 Cubic Feet		10,000 Cubic Feet		50,000 Cubic Feet		100,000 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	10	0	110	0	200	0
	99	0	0	20	0	125	0	225	0
	99.9	0	0	25	0	130	0	230	0
Whole Field Buffer Distances									
No Stack	95	0	0	0	0	0	0	10	0
	99	0	0	0	0	40	0	75	0
	99.9	0	0	10	0	105	0	190	0

Table 16 presents a summary of some the results of the PERFUM analyses that were completed to assess aeration events associated with the greenhouse uses of methyl bromide. The commodity assessment documents D304623 and D304619 detail the thousands of PERFUM iterations that were completed which could apply in some regard to the greenhouse industry, depending upon the size and configuration of the facility. The scenarios presented in Table 16 have been selected for illustrative purposes because they represent many typical greenhouse settings and they also represent the maximum application rate, uncertainty factor of 30, and typical to high end emissions after a treatment (i.e., 75 and 95 percent of the nominal application concentration). Additional PERFUM output files which can be provided for review of other situations if so desired.

Table 16: PERFUM Methyl Bromide Buffer Distances (meters) For All Greenhouse 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	1,000 Cubic Feet		10,000 Cubic Feet		50,000 Cubic Feet		100,000 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 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
No Stack	95	30	20	205	175	545	470	835	725
	99	35	25	225	195	600	520	930	805
	99.9	40	30	235	200	625	535	975	830
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 16: PERFUM Methyl Bromide Buffer Distances (meters) For All Greenhouse 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	1,000 Cubic Feet		10,000 Cubic Feet		50,000 Cubic Feet		100,000 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	5	0	20	15	0	0	105	0
	99	10	10	30	25	70	60	140	105
	99.9	15	10	70	60	160	140	170	170
Whole Field Buffer Distances									
Minimum 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
No Stack	95	0	0	10	5	25	25	30	25
	99	0	0	70	60	195	170	290	255
	99.9	30	20	195	165	520	450	810	700
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	10	5	15	10	25	0
	99	0	0	20	15	50	45	80	0
	99.9	5	5	30	25	70	60	105	20

As indicated above, monitoring data have been integral in the development of this risk assessment. In the previous phase 3 risk assessment for methyl bromide (D316326, 6/13/05), all of the monitoring data that were evaluated were identified and summarized. None of this information or analysis has changed since the previous assessment. Table 17 below provides a summary of these data and presents margins of exposure (i.e., MOEs) calculated based on them (i.e., MOEs > 30 are not of concern). Note that in some cases, air concentrations increase as the number of days after application increase. This appears incongruous but could be due to a number of factors including monitoring was completed at different facilities which could impact results, the absorptive properties of the facilities and treated material could retain methyl bromide until days after treatment, and wind patterns could have shifted to a particular sample collection location.

Table 17: Risks From Methyl Bromide Exposure Based On Maximum 24 Hour TWA Concentrations Using Greenhouse Volatility Data			
	Days After Application	Maximum 24 Hour [TWA] (ppm)	Acute MOE
50 feet	0	0.287	35
	1	0.292	34
	2	0.295	34
	3	1.870	5
150 feet	0	0.150	67
	1	0.127	79
	2	0.112	89
	3	0.820	12

The results indicate that the potential risks which have been calculated for methyl bromide emissions from treated greenhouses can be of concern as calculated acute MOEs in two cases out of 8 are less than 30. If one were to review PERFUM outputs for various analyses it would also indicate that for many circumstances predicted buffer distances would be small (e.g., <10 meters or so) at lower percentiles of exposure or depending upon the aeration method. In summary, monitoring data support the types of results that have been calculated using the PERFUM model. If so desired, the previous risk assessment and its associated appendices that contain all of the monitoring data information can be found at www.Regulations.gov under docket OPP-2005-0123 (i.e., key various elements include: OPP-2005-0123-007 – bibliography; OPP-2005-0123-009 – greenhouse monitoring data).

5.1.1.2.c: Bystander Exposures And Risks From Residential Use

The residential sector represents a small percentage of the overall use of methyl bromide. The maximum application rate used for this assessment is 3 lb ai/1000 ft^3 based on the Brom-O-Gas label for residential uses (EPA Reg. No. 5785-55 or -08). A process has been defined based on the PERFUM model described above for characterizing the off-site dissipation of methyl bromide that has been released either intentionally during aeration after treatment is complete or that leaked from a structure during treatment. Aeration can be accomplished using several techniques that employ different devices and/or locations relative to the treated structure. In summary, aeration is predominantly accomplished using portable industrial fans that are typically rated to move air volumes up to 5000 CFM (i.e., cubic feet per minute). [Note: As described with the greenhouse use above, the analysis for residential treatments is based on the previous commodity assessment and the related changes. For more information refer to the above.] In this evaluation, home volumes range from 10,000 to 50,000 cubic feet for small to large single family houses while a 100,000 cubic foot volume is intended to represent a multi-dwelling unit.

Table 18 presents a summary of some the results of the PERFUM analyses that were completed to assess events during treatment (from leakage) associated with the residential uses of methyl bromide. The commodity assessment documents D304623 and D304619 detail the PERFUM iterations that were completed which could apply to residential treatments. The scenarios presented in Table 18 have been selected for illustrative purposes because they represent many typical residential settings and they also represent the maximum application rate, uncertainty factor of 30, and typical to high end emissions during treatment (i.e., 1 and 10 percent leakage of the nominal application concentration). Additional PERFUM output files which can be provided for review of other situations if so desired.

Table 18: PERFUM Methyl Bromide Buffer Distances (meters) During Residential Treatment Based On UF30, 4 hour Exposure Duration, 3 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released

Aeration Type	Percentile	10,000 Cubic Feet		25,000 Cubic Feet		50,000 Cubic Feet		100,000 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	30	0	80	0	165	0
	99	0	0	40	0	90	0	180	0
	99.9	0	0	45	0	95	0	190	0
Whole Field Buffer Distances									
No Stack	95	0	0	0	0	0	0	5	0
	99	0	0	0	0	25	0	60	0
	99.9	0	0	30	0	70	0	155	0

Table 19 presents a summary of some the results of the PERFUM analyses that were completed to assess aeration events associated with the residential uses of methyl bromide. The commodity assessment documents D304623 and D304619 detail the thousands of PERFUM iterations that were completed which could apply in some regard to the residential uses depending upon the size of the structure being treated and the type of aeration used. The scenarios presented in Table 19 have been selected for illustrative purposes because they represent many typical residential settings (i.e., small to large, multi-unit structures) and they also represent the maximum application rate, uncertainty factor of 30, and typical to high end emissions after a treatment (i.e., 75 and 95 percent of the nominal application concentration). Additional PERFUM output files which can be provided for review of other situations if so desired.

Table 19: PERFUM Methyl Bromide Buffer Distances (meters) For All Residential Aeration Processes Considered Based On UF30, 4 hour Exposure Duration, 3 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released

Aeration Type	Percentile	10,000 Cubic Feet		25,000 Cubic Feet		50,000 Cubic Feet		100,000 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 1 xch/min	95	0	0	0	0	0	0	0	0
	99	0	0	0	0	0	0	0	0

Table 19: PERFUM Methyl Bromide Buffer Distances (meters) For All Residential Aeration Processes Considered Based On UF30, 4 hour Exposure Duration, 3 lb/1000 cubic feet Application Rate, Varied Structure Size & Varied Percent Mass Released									
Aeration Type	Percentile	10,000 Cubic Feet		25,000 Cubic Feet		50,000 Cubic Feet		100,000 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
	99.9	0	0	0	0	0	0	0	0
No Stack	95	170	145	295	255	455	395	705	605
	99	185	160	330	280	505	435	780	675
	99.9	195	165	340	290	520	450	810	695
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	20	15	40	35	60	50	90	75
	99	30	25	50	45	75	65	115	100
	99.9	40	30	65	55	90	80	140	120
Whole Field Buffer Distances									
Minimum 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
No Stack	95	5	5	15	15	25	20	25	25
	99	60	50	110	95	170	145	245	215
	99.9	160	135	285	245	440	375	680	580
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	10	5	10	5	15	10
	99	15	10	30	25	45	35	65	60
	99.9	20	15	40	35	60	50	90	75

As indicated above, monitoring data have been integral in the development of this risk assessment. In the previous phase 3 risk assessment for methyl bromide (D316326, 6/13/05), all of the monitoring data that were evaluated were identified and summarized. None of this information or analysis has changed since the previous assessment. Table 20 below provides a summary of these data and presents margins of exposure (i.e., MOEs) calculated based on them (i.e., MOEs > 30 are not of concern).

Table 20: Risks From Methyl Bromide Exposure Based On Maximum 24 Hour TWA Concentrations Using Residential Fumigation Volatility Data				
N	Number Monitors Not Detected	Timing and Distance from Structure	Maximum 24 Hour [TWA] (ppm)	Acute MOE
56	11	During Fumigation 10 ft	1.5	7
56	2	During Aeration 10 ft	0.611	16
35	0		0.077	130

The results indicate that the potential risks which have been calculated for methyl bromide emissions from treated residences can be of concern as calculated acute MOEs in two cases are less than 30. If one were to review PERFUM outputs for various analyses it would also indicate that for many circumstances predicted buffer distances would be small (e.g., <10 meters or so) at lower percentiles of exposure or depending upon the aeration method. In summary, monitoring data support the types of results that have been calculated using the PERFUM model in some circumstances. Additionally, the limitations associated with the use of monitoring data are also explicit based on the nature of the data. If so desired, the previous risk assessment and its associated appendices that contain all of the monitoring data information can be found at www.Regulations.gov under docket OPP-2005-0123 (i.e., key various elements include: OPP-2005-0123-007 – bibliography; OPP-2005-0123-012 – residential monitoring data).

5.1.2 Ambient Bystander Exposure From 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 several strawberry fields in California during the season of use.

Exposures from ambient air were estimated from monitoring data collected solely in California to represent conditions at a regional and state-wide level. The California Air Resources Board (hereafter referred to as 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 use during the season of use and (2) routine monitoring for select pollutants via established networks in order to better quantify exposures in the general population (i.e., CARB Toxic Air Contaminant monitoring program or TAC). 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:

> **<u>(1) "CARB Data":</u>** includes targeted monitoring data generated by both CARB and AMBI focused on areas of high methyl bromide use in the season of use (AMBI is for comparative purposes only); and
>
> **<u>(2) "TAC Data":</u>** 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 5.1.2.1 below while the results associated with the TAC data are presented in Section 5.1.2.2.

5.1.2.1 Exposures From Regionally Targeted 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). [Note: An additional study, which is not included below, was completed by CARB in Ventura California in 2005. This study is being repeated since it appeared not to quantify peak emission times based on the initiation date.] The CDPR also requested that the Alliance of the Methyl Bromide Industry (AMBI) conduct monitoring studies. Because most of California's pesticide applications normally occur in agricultural areas and are seasonal in nature, CARB 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.

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 21). 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 HEC.

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 significantly 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 the CDPR 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 ambient data. These calculations should be considered relatively uncertain estimates of exposure because of a lack of monitoring studies specifically designed for this purpose and the manner in which seasonal estimates were extrapolated. 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 (24 hour TWAs) for all of the monitoring stations considered (i.e., 30 stations), do not exceed the Agency's level of concern (i.e., all calculated MOEs > 30). Results were similar for the 8 week TWA exposures (short- and intermediate-term exposures) in that risks calculated based on results from none of the monitoring stations exceed the level of concern. For both durations of exposure, risks were orders of magnitude less than the level of concern (i.e., MOEs >30 in many cases, some by 2 or 3 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. Risk estimated from chronic exposure based on extrapolating seasonal CARB data were also calculated 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 exceeded the level of concern (i.e., MOEs < 100 for 13 of 46 stations/years); however, it is believed that these results do not pose an imminent health concern to the general public due to the nature of the calculations as described above. CDPR also reached similar conclusions that risks resulting from exposure to ambient air were of minimal concern.

Table 21: 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	966
			6/30-8/31, 2001	0.31	32258	0.12	8333	0.06	1521
		SHA	7/10-9/1, 2000 (26)	3.52	2841	0.792	1263	0.39	230

Table 21: 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]
		CRS	7/10-9/1, 2000 (24)	14.2	704	2.16	463	1.07	84
			6/30-8/31, 2001	33.50	299	2.49	402	1.23	73
		MVS	7/10-9/1, 2000 (26)	0.487	20534	0.092	10870	0.05	1984
			6/30-8/31, 2001	0.23	43478	0.08	12500	0.04	2281
		VSD	7/10-9/1, 2000 (26)	0.247	40486	0.099	10101	0.05	1843
			6/30-8/31, 2001	0.23	43478	0.08	12500	0.04	2281
		MET	7/10-9/1, 2000 (26)	0.224	44643	0.084	11905	0.04	2173
			6/30-8/31, 2001	0.25	40000	0.07	14286	0.03	2607
		ARV	6/30-8/31, 2001	0.22	45455	0.07	14286	0.03	2607
Ventura	AMBI (CDPR Stats Used)	SHA	8/15-10/10, 2001	2.94	3401	0.50	2000	0.25	365
			7/10-8/31, 2002 (31)	5.77	1733	0.58	1724	0.29	315
		ABD	8/15-10/10, 2001	0.44	22727	0.18	5556	0.09	1014
			7/10-8/31, 2002 (30)	3.44	2907	0.76	1316	0.37	240
		UWC	8/15-10/10, 2001	4.35	2299	0.82	1220	0.40	223
			7/10-8/31, 2002 (26)	13.17	759	2.22	450	1.09	82
		PVW	8/15-10/10, 2001	3.17	3155	0.56	1786	0.28	326
			7/10-8/31, 2002 (32)	9.51	1052	1.62	617	0.80	113
Santa Barbara	AMBI (CDPR Stats Used)	PLN	8/23-10/9, 2001	2.69	3717	0.93	1075	0.46	196
		EDW	8/23-10/9, 2001	11.15	897	1.32	758	0.65	138
		AGC	8/23-10/9, 2001	1.16	8621	0.28	3571	0.14	652
		BLO	8/23-10/9, 2001	4.55	2198	0.73	1370	0.36	250
		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	141
			9/8-11/7, 2001	9.25	1081	1.38	725	0.68	132

Table 21: 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]
		OAS	9/11-11/3, 2000 (31)	1.84	5435	0.387	2584	0.19	472
		CHU	9/11-11/3, 2000 (31)	2.41	4149	0.644	1553	0.32	283
			9/8-11/7, 2001	1.84	5435	0.56	1786	0.28	326
		LJE	9/11-11/3, 2000 (30)	24.0	417	3.79	264	1.87	48
			9/8-11/7, 2001	14.49	690	2.82	355	1.39	65
	AMBI (CDPR Stats Used)	BBC	9/4-10/26, 2002 (32)	6.28	1592	2.08	481	1.03	88
		MAQ	9/4-10/26, 2002 (32)	4.53	2208	1.12	893	0.55	163
Santa Cruz	CARB	PMS	9/11-11/3, 2000 (31)	30.8	325	7.68	130	3.79	24
			9/8-11/7, 2001	21.08	474	2.99	334	1.47	61
		SES	9/11-11/3, 2000 (31)	16.4	610	2.60	385	1.28	70
			9/8-11/7, 2001	5.31	1883	1.22	820	0.60	150
		MES	9/8-11/7, 2001	36.64	273	5.51	181	2.72	33
		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	48
		FRM	9/4-10/26, 2002 (31)	14.00	714	2.62	382	1.29	70
		CPW	9/4-10/26, 2002 (30)	11.12	899	2.06	485	1.02	89
		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. TWA.
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.

5.1.2.2 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 5.1.2.1 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. The statistical summaries of the 2002/2003 CARB monitoring data are provided in Table 22. They were taken directly from http://www.arb.ca.gov/adam/toxics/statepages/mbrstate.html. Additionally, state-wide summaries from 2004 and 2005 are included in Table 22. [Note: Station-specific results for 2004 and 2005 are also available but do not differ significantly from the earlier years (i.e., they do not alter the interpretation of the risks associated with urban background levels of methyl bromide). As such, they have not been included in Table 22 for brevity.]

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 the 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 22: Results of 2002 Through 2005 California Ambient Monitoring For Methyl Bromide In Urban Areas

Site	Year	N	Results of Annual Methyl Bromide 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	607
	2003	503	0.90	11111	0.040	25000	0.015	607
	2004	503	1.1	9090	0.036	27778	0.015	607
	2005	510	0.69	14493	0.036	27778	0.015	607
Azusa	2002	27	0.14	71429	0.041	24390	0.03	303
	2003	28	0.16	62500	0.036	27778	0.015	607

Table 22: Results of 2002 Through 2005 California Ambient Monitoring For Methyl Bromide In Urban Areas								
Site	Year	N	Results of Annual Methyl Bromide Monitoring (ppb)					
			Maximum	Acute MOE[1]	Mean	Short and Intermediate-Term MOE[2]	Median	Chronic MOE[3]
Burbank	2002	30	0.14	71429	0.031	32258	0.015	607
	2003	26	0.10	100000	NR	--	0.015	607
Calexico	2002	29	0.11	90909	0.020	50000	0.015	607
	2003	30	0.33	30303	0.036	27778	0.015	607
Chula Vista	2002	29	0.06	166667	0.021	47619	0.015	607
	2003	28	0.05	200000	NR	--	0.015	607
El Cajon	2002	28	0.06	166667	0.020	50000	0.015	607
	2003	30	0.05	200000	0.021	47619	0.015	607
Los Angeles	2002	21	0.14	71429	NR	--	0.03	303
	2003	29	0.10	100000	0.032	31250	0.015	607
Long Beach	2002	25	0.11	90909	0.035	28571	0.015	607
	2003	27	0.13	76923	0.035	28571	0.04	228
Riverside	2002	25	0.13	76923	NR	--	0.015	607
	2003	30	0.10	100000	0.028	35714	0.015	607
Simi Valley	2002	26	0.91	10989	0.101	9901	0.05	182
	2003	31	0.90	11111	0.120	8333	0.015	607
Bakersfield	2002	29	0.22	45455	0.058	17241	0.04	228
	2003	29	0.88	11364	0.080	12500	0.04	228
Chico	2002	29	0.14	71429	0.026	38462	0.015	607
	2003	31	0.15	66667	0.022	45455	0.015	607
Fremont	2002	27	0.05	200000	0.018	55556	0.015	607
	2003	30	0.11	90909	0.019	52632	0.015	607
Fresno	2002	30	0.19	52632	0.049	20408	0.015	607
	2003	31	0.19	52632	0.055	18182	0.05	182
Roseville	2002	29	0.11	90909	0.021	47619	0.015	607

Table 22: Results of 2002 Through 2005 California Ambient Monitoring For Methyl Bromide In Urban Areas									
Site	Year	N	Results of Annual Methyl Bromide Monitoring (ppb)						
			Maximum	Acute MOE[1]	Mean	Short and Intermediate-Term MOE[2]	Median	Chronic MOE[3]	
	2003	31	0.03	333333	0.016	62500	0.015	607	
San Francisco	2002	15	0.08	125000	NR	--	0.015	607	
	2003	31	0.015	666667	0.015	66667	0.015	607	
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	607	
Stockton	2002	27	0.90	11111	0.144	6944	0.05	182	
	2003	30	0.48	20833	0.088	11364	0.04	228	
Mexicali - Mexico	2002	19	0.10	100000	NR	--	0.015	607	
	2003	17	0.07	142857	NR	--	0.015	607	
Rosarito - Mexico	2002	25	0.05	200000	NR	--	0.015	607	
	2003	30	0.14	71429	0.027	37037	0.015	607	

1. Acute MOEs based on maximum concentrations.
2. Short term and intermediate term MOE are based on the mean concentrations.
3. Chronic MOEs are based on the median concentration.

5.2 Bystander Risk Characterization

It is believed that the data and methodologies used in the development of this assessment represent the state-of-the-science relating to pesticides that can be characterized as fumigants. However, it is clear that there is an ongoing evolution relating to the types of data that could be used to complete such assessments in the future. Essentially, all data that were currently available were used herein but those data clearly have limitations related to overall quality, as well as temporal and spatial limitations. It is also clear that the PERFUM modeling framework provides significant amounts of information appropriate for risk managers to consider but that there are other systems that could be considered as robust for the same types of analyses. As indicated above, submissions based on other viable modeling frameworks would be considered for risk management purposes.

Some of the limitations and considerations that have been identified that should be considered in the interpretation of these results include:

- All of the data used for this analysis have been generated in California; however, methyl bromide is used in many regions of the country. In fact it is possible that most methyl bromide use occurs in the Southeast but no emissions data are available for specifically modeling emissions from that region or any other region where methyl bromide is used. As a direct result of a lack of additional data, the results presented herein are based solely on California data and agricultural practices. Factors such as soil type, solar radiation levels, or farming practices themselves may impact the overall amounts of methyl bromide emitted and the rate at which it is emitted over time, thus buffer outputs predicted using PERFUM could be impacted but it is not possible to quantify this sensitivity at this point. PERFUM is not a first-principles model (i.e., it cannot predict results for incremental changes in soil conditions parameters such as soil temperature or percent moisture). Instead, PERFUM is an empirical model that is calibrated to specific emissions profiles that then serve as the basis for predicted results. This is a very common modeling approach when first-principles models are not available. Additionally, the flux profiles that were used as the basis for the PERFUM results in this assessment were defined based on what is known as the back-calculation method as opposed to direct reading or aerodynamic flux approaches. At this point, the Agency treats results based on all of these methods similarly as there is no information in the applicable literature to suggest that any are inherently biased to over- or under-prediction of flux. Flux inputs for the greenhouse and residential uses are based on the same approaches as D304623.

- Data quality associated with the calculation inputs also needs to be considered. For most of the data, it is believed that they are of reasonable quality for risk assessment purposes. A significant number of studies were generated by CARB and CDPR. Because of the rigorous quality control and quality assurance protocols employed by these Agencies, the resulting data are generally believed to be of high quality. Additionally, the industry group AMBI also generated a significant amount of data. Some technical issues have been identified with those data (i.e., problems with completeness and flow controller issues in some data) but they have been included for comparative purposes. AMBI-based results are generally similar to those observed based on the other data which indicates no major impacts based on data quality.

- The premise of the PERFUM-predicted buffer zones is based on a developmental effect which by definition, implies that a pregnant woman is at a location where the time-weighted average concentration of methyl bromide can be of concern. There are several probabilities related to an exposure event which must be met for such developmental effects to occur. These include:

  - An exposed individual must be female and at a critical phase of the pregnancy for the effect to occur;

  - An exposed individual has to be in proximity to a methyl bromide application/aeration event for a sufficient duration for the effect to occur - there are 3 key factors to consider for this element including:
    - that the types of applications considered in this assessment are either seasonal or infrequent which limits the number of possible adverse exposure events,
    - time-activity data indicate that many parts of the population move from site to site on a daily basis (e.g., to go to work and back) which limits the overall number of possible adverse exposures events, and
    - time-activity data indicate that most individuals spend a majority of their daily time indoors and for intermittent exposure sources such as this it is known that being indoors typically reduces exposures to contaminants relative to outdoor air but the PERFUM results do not account for this exposure reduction factor.

- A multi-faceted approach was used to evaluate risks using monitoring data, incidents, and the distributional model, PERFUM. Monitoring data have temporal and spatial limitations as has been discussed above. Incident data are informative but their use for characterization purposes is also limited because the exact conditions that lead to specific incident events are difficult, if not impossible, to quantify thus making any reconstruction of their circumstances limited unless blatantly obvious such as a railcar accident. However, for methyl bromide, most incidents in the general population are believed to be associated with a significant equipment failure, atmospheric inversion, or misuse of some sort, intentional or not. Because the endpoint of concern associated with methyl bromide is developmental in nature, it is highly likely that individuals in the general population would not associate such health issues with a previous exposure to methyl bromide. For this reason, it is possible that methyl bromide incidents in the general population could be under-reported. Effects that would be likely to be experienced in the general population after a methyl bromide incident would be irritant effects from its companion chemical, chloropicrin, for many applications. Symptoms experienced such as shortness of breath or chest tightness are not readily attributable to methyl bromide exposure.

- PERFUM modeling results (or any distributional model for that matter) can provide risk managers with much needed information about the range of risks expected in the general population. At this time, policy development is ongoing with regard to defining how appropriate selections of PERFUM outputs can be defined for risk management purposes

- It is believed that PERFUM provides the most refined estimates of risk because it can consider actual weather data and also integrate flux distributions in order to develop distributional estimates of buffer distances and concentrations at various distances from a source. PERFUM uses ISCST3 as its core processor which is an existing Gaussian plume technology that has been utilized for air permitting by the Agency for many years (see *Technology Transfer Network Support Center for Regulatory Air Models* at http://www.epa.gov/scram001/tt22.htm#isc). Several issues need to be considered related to the modeling analysis which was completed herein. These include:

  - It has been assumed that there is a linear relationship between application rate and flux, but this assumption has not been validated with emissions data conducted in similar conditions but at different application rates. The California Department of Pesticide Regulation has used this assumption in previous fumigant assessments.

  - The treatment of calm periods (wind speeds below 1 m/s) in PERFUM/ISCST3 is also an uncertainty. PERFUM runs the ISCST3 model in the "regulatory default option" (the default setting for ISCST3), which includes the use of the calms processing routine as is described in Agency guidance. The calms processing routine for wind speeds below 1 m/s essentially ignores any hourly sequence in the calculations that meets this criteria. This approach can possibly skew results for shorter averaging times because an analysis period that contained several calm hours would be dominated by any period where there was a windspeed above 1m/s. This is a common approach in Gaussian plume modeling. PUFF-based models such as CALPUFF have meander algorithms that can account for calm conditions by accounting for static or near static plume conditions and representing such events in the results. Whether or not buffer estimates are enhanced or under-reported as a result of this phenomenon depends upon the nature of the weather data used for the calculations. Preliminary analysis related to this issue do not indicate significant differences when hourly calculation steps are used especially when 24 hour time weighted average exposures are calculated. If less than hourly steps (e.g., minute by minute calculations such as in CALPUFF v6) are used, the effect is attenuated because the relative percentage of calm periods in the available weather data seems to be diminished.

- The PERFUM analyses completed for this assessment are based on the assumption that an application has an equal probability of occurring each day out of the 5 years of weather data. This method does not take into account the seasonal use patterns of fumigants in different regions of the country. Table 14 above provides an example of monthly distributional results which could be examined if so desired for every PERFUM output. The result for each month is based on 5 months worth of weather data instead of 5 years when all months are considered. It should also be noted that the selection of the sources of weather data for this assessment, as mentioned above, represent a range of mean windspeed values as described in the SAP document for PERFUM. The locations of the Florida and California stations were intentionally selected based on this range and their coastal and inland locations.

- Different field sizes and aspect ratios were considered in this assessment (most fields were square in shape for this analysis). As field size increases so do predicted buffer zones which is similar to what is noted based on increases in application rates. Field aspects were also examined and the orientation did impact results although it is difficult to ascertain any general prediction based on this analysis since field orientations relative to prevailing wind directions will vary from site to site or region to region.

- The use of a maximum 40 acre field in the risk assessment may possibly understate potential exposure received by bystanders near treated fields that are larger.

- PERFUM was recently modified to also produce distributions of concentrations at various receptor ring distances from the edge of a treated field or source. This capability was added near the completion timeframe of this assessment. As appropriate, this capability will be utilized in the development of risk management decisions.

- 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 that some data represent highly targeted monitoring in a region during the season of use and others represent urban background levels. Because of this, the results should be considered representative for the state of California for those types of situations. However, California has a number of restrictions and systems in place where the overall goal is to reduce environmental emissions from fumigant use. Consequently, it is difficult to quantify how the results presented above may apply to other regions of the country that do not have these types of programs in place.

6.0 Occupational Exposure

In this assessment, a number of chemical-specific monitoring studies were available to evaluate the exposures of applicators as well as those otherwise involved in that process (e.g., co-pilots, shovelmen, or greenhouse workers). Likewise monitoring data were also available to assess the possible exposures that could occur after application events such as for tarp cutters and tarp removers. [Note: Tarp cutter and tarp remover data were generated in a period 4 to 6 days (or greater) after an application and most data represent exposures from fields covered with high barrier films.] The monitoring data were not adjusted based on application rates because these data represent cultural practices that are allowable under current methyl bromide labels even though for many situations they could represent conservative estimates of exposure. This is because they were collected at higher application rates than is currently typical. Another consideration is the equipment that was used because most of the data were generated in the 1980s and early 1990s. Since that time, California DPR has restricted methyl bromide uses to types of equipment intended to minimize exposures. However, this evolution is not evident in all other areas of the country so the data, even though they were generated years ago for the most part in California, can still be considered to be representative of many methyl bromide domestic uses.

Overall, data indicate that worker exposure levels exceed the level of concern for all scenarios considered when no respiratory protection is used. The use of either air purifying respirators (APRs) or self contained breathing apparatus (SCBA) was also considered with varied results. 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 and recommended for reducing exposure levels, see the technical bulletin 146 for cartridge 60928 at www.3M.com for more information. Protection factors are derived based on individuals who have been trained, fit tested, and medically cleared for respirator use but are generally applied for risk assessment purposes.] Respirators would be the most practical personal protective equipment choice for reducing exposures for most workers. The use of engineering controls is also considered a viable option for reducing exposures. However, much of the field monitoring data used for this analysis already reflect the use of varied levels engineering controls such as tarps, tractor cabs, deep injection, or other devices including fans in proximity to drivers, Nobel plows, or various compaction methods.

When APRs were evaluated with maximum exposure levels in order to assess acute exposures, for most activities, exposures were not reduced sufficiently to address risk concerns. When APRs were evaluated with mean exposure levels in order to assess short-/intermediate-term exposures, the results were varied with all greenhouse scenarios resulting in risks still exceeding the level of concern but risks from most field uses not being of concern. The use of SCBA is not normally deemed to be a viable option for agricultural workers or for uses in greenhouses due to the difficulty in handling and maintaining these devices as well as the cost to implement them as an exposure reduction tool. However, in certain situations such as residential treatments, it is believed that SCBA may represent a viable option for reducing exposures for a limited number of workers. Risks from exposures during residential treatments were not of concern if SCBA is used.

Modeling has also been used to predict air concentrations at the edge of a treated field to determine if air concentrations have diminished to levels that are not of concern (e.g., use of concentration outputs from PERFUM at varied ring distances from field perimeter). This information, coupled with available monitoring data can be useful for defining how long the conduct of various post-application tasks or entry into previously treated areas should be restricted. Current requirements for entry of post-application workers into previously treated fields are dictated by the Worker Protection Standard as described in PR 93-7. For methyl bromide, such workers are excluded for 48 hours after treatment. PERFUM outputs representing air concentrations 5 meters from the treated field edge support the current 48 hour requirement for soil uses if tarps are not disturbed. However, tarp cutter and remover activities require APR use. Greenhouse and residential uses require active aeration to achieve levels that are not of concern (e.g., current labels specify a 5 ppm target concentration). Generally, this approach seems appropriate but the 5ppm target may be altered based on risk management considerations.

The occupational tasks commonly associated with the use of methyl bromide along with the corresponding risks are described below for each use sector considered. [Note: Risks from chronic exposures have not been calculated because methyl bromide use is highly seasonal. Methyl bromide is not expected to be used every working day for more than 6 months, for commercial applicators or large scale growers based on available information. Additionally, in smaller scale production, applications are thought to be infrequent because growers would often times just treat their own facilities.] Sections 6.1 through 6.3 provide risk estimates for each use pattern considered in this assessment while Section 6.4 describes the issues that should be considered when interpreting these results.

6.1 Pre-plant Agricultural Field Fumigations

Several tasks were identified that are associated with the application of methyl bromide to agricultural fields. The data for each scenario varied but essentially all available data for each was considered in this assessment. It should also be noted that for tarp cutters and tarp removers, these activities were monitored mainly between 4 and 6 days after application and in most cases the tarps were referred to as high barrier materials. The tasks considered in this assessment include:

a) First Tractor Driver,
b) Co-pilot
c) Second Tractor Driver
d) Shovelman
e) Irrigation Worker
f) Tarp Cutter
g) Tarp Remover

Table 23 indicates that if no respiratory protection is considered, risks exceed the level of concern for all scenarios and durations except for the second tractor drivers where risks were acceptable even without respiratory protection. As a result, the impact of the use of an APR (PF 10) with the recommended cartridge was evaluated to determine how their use would impact worker risks. Acute risks for all other application scenarios with the APR still exceed HED's level of concern (with MOE <30). Risks were not of concern for all tarp removal operations if an APR is used (i.e., MOEs are 63 and 231). Short- and intermediate-term risks without respiratory protection were of concern except for second tractor drivers as with the acute duration. However, short- and intermediate-term risks with the APR are not of concern for the majority of tasks (i.e., MOEs >30) except for tractor drivers and co-pilots where the MOEs are 18 and 11, respectively. [Note: Table 23 has been modified from the Phase 3 assessment based on comments submitted by the Methyl Bromide Industry Panel (MBIP) pertaining to the specific data used for this analysis. Essentially, many of the comments are correct and the Agency has adjusted the values in Table 23 accordingly. The MBIP comments are available in the methyl bromide docket at the following: www.Regulations.gov under docket number EPA-HQ-OPP-2005-0123-0127.]

As indicated above, restricting entry into previously treated fields can be evaluated using a modeling approach or based on the tarp removal monitoring data. It appears that a the emission profile (based on preliminary PERFUM outputs) indicates that concentrations will decrease to levels that are not of concern, even at high percentiles of exposure 3 days after treatment. This indicates that the current 48 hour restriction is adequately protective. However, if operations occur which disturbs the tarp of a treated field it is likely that air concentrations will be at levels of concern and that respirator use would be required to reduce them to levels not of concern.

Table 23: Methyl Bromide Worker Exposure Associated With Pre-Plant Agricultural Field Fumigation									
		Acute Risk Summary				Short/Intermediate-term Risk Summary			
Scenario	N	Maximum Monitored [mebr] (ppm)	Acute MOE With No Respiratory Protection	Maximum Monitored [mebr] With Air Purifying Respirator (PF10) (ppm)	Acute MOE With Air Purifying Respirator (PF10)	Average Monitored [mebr] (ppm)	Short-term MOE With No Respiratory Protection	Maximum Monitored [mebr] With Air Purifying Respirator (PF10) (ppm)	Short-term MOE With Air Purifying Respirator (PF10)
1st Tractor Driver	82	38.1	<1	3.81	8	2.5	2	0.25	18
Co Pilot	92	47.4	<1	4.74	6	4.1	1	0.41	11
2nd Tractor Driver	3	0.02	1500.0	0.002	15000	0.015	293	0.0015	2933
Shovelman	67	12.4	2	1.24	24	0.95	5	0.095	46
Irrigation	20	20.4	2	2.04	15	1.2	4	0.12	37
Tarp Cutter	7	4.8	6	0.48	63	0.67	7	0.067	66
Tarp Remover	22	1.3	23	0.13	231	0.48	9	0.048	92
Total number of monitoring events used for this analysis = 293 MOE = Margin of Exposure, Level of concern is MOE<30 Acute MOE = (30 ppm HEC/maximum [mebr]) Short/Intermediate-term MOE = (4.4 ppm HEC/mean [mebr])									

6.2 Greenhouse Fumigations

Several tasks were identified that are associated with the application of methyl bromide in greenhouse operations. The data for each scenario varied but essentially all available data for each was considered in this assessment. The tasks considered in this assessment include:

a) Greenhouse Applicators
b) Venters
c) Greenhouse Workers

Table 24 indicates for greenhouse applicators and workers, risks were of concern for all scenarios and durations considered even when respiratory protection such as an PF10 APR is used (i.e., all MOEs <30). Risks for greenhouse venters were of concern if no respirator is used but are not of concern if an APR is used regardless of the duration of exposure considered.

Determining when entry into previously treated greenhouse structures is not of concern is important in the greenhouse industry because of the many hand labor-based practices that are required to produce plant materials in these settings (e.g., transplanting). Currently, greenhouse uses require active aeration to achieve levels that are not of concern (e.g., current labels specify a 5 ppm target concentration). Generally, this approach seems appropriate but the 5ppm target may be altered based on risk management considerations. No further quantitative assessment has been completed for these scenarios because results will be specific to the structures which are treated.

Table 24: Methyl Bromide Worker Exposure Associated With Greenhouse Fumigation									
		Acute Risk Summary				Short/Intermediate-term Risk Summary			
Scenario	N	Maximum Monitored [mebr] (ppm)	Acute MOE With No Respiratory Protection	Maximum Monitored [mebr] With Air Purifying Respirator (PF10) (ppm)	Acute MOE With Air Purifying Respirator (PF10)	Average Monitored [mebr] (ppm)	Short-term MOE With No Respiratory Protection	Maximum Monitored [mebr] With Air Purifying Respirator (PF10) (ppm)	Short-term MOE With Air Purifying Respirator (PF10)
Greenhouse Applicators	11	2000	<1	200	<1	330	<1	33	<1
Greenhouse Venters	13	5.8	5	0.58	52	0.92	5	0.092	48
Greenhouse Workers	17	200	<1	20	2	25	<1	2.5	2
Total number of monitoring events used for this analysis = 41 MOE = Margin of Exposure, Level of concern is MOE<30 Acute MOE = (30 ppm HEC/maximum [mebr]) Short/Intermediate-term MOE = (4.4 ppm HEC/mean [mebr])									

6.3 Residential Fumigation

Several tasks were identified that are associated with the application of methyl bromide in residential operations (e.g., house preparation, application and aeration activities). The data for each scenario varied but essentially all available data for each was considered in this assessment. However, the data were limited so the the tasks considered in this assessment include:

a) Outside Worker
b) Inside Worker

Table 25 indicates for all scenarios and durations considered, risks without respiratory protection exceed the level of concern for all durations of exposure (i.e., all MOEs <30). As a result, HED evaluated how the use of a SCBA (PF 10,000) would impact worker risks since it is believed that these represent a possible risk mitigation measure for workers involved in residential fumigations. SCBA use reduces risks to levels where they are not of concern for all durations of exposure (i.e., MOE>30).

Determining when entry into previously treated residential structures is not of concern is important not to displace residents for extended periods of time. Currently, residential uses require active aeration to achieve levels that are not of concern (e.g., current labels specify a 5 ppm target concentration). Generally, this approach seems appropriate but the 5ppm target may be altered based on risk management considerations. No further quantitative assessment has been completed for these scenarios because results will be specific to the structures which are treated.

Table 25: Methyl Bromide Worker Exposure Associated With Residential Fumigation									
		Acute Risk Summary				Short/Intermediate-term Risk Summary			
Scenario	N	Maximum Monitored [mebr] (ppm)	Acute MOE With No Respiratory Protection	Maximum Monitored [mebr] With SCBA (PF10000) (ppm)	Acute MOE With SCBA (PF10000)	Average Monitored [mebr] (ppm)	Short-term MOE With No Respiratory Protection	Maximum Monitored [mebr] With SCBA (PF10000) (ppm)	Short-term MOE With SCBA (PF10000)
Outside Worker	12	57	<1	0.0057	5263	22	<1	0.0022	2000
Inside Worker	4	982	<1	0.098	306	357	<1	0.036	122

Total number of monitoring events used for this analysis = 16
MOE = Margin of Exposure, Level of concern is MOE<30
Acute MOE = (30 ppm HEC/maximum [mebr])
Short/Intermediate-term MOE = (4.4 ppm HEC/mean [mebr])

6.4 Occupational Risk Characterization

There are several issues that should be considered when interpreting the results of this risk assessment. Compared to most occupational assessments, the data used to complete this assessment are plentiful in that 293 chemical-specific monitoring events were considered in this analysis. Most data were generated by either CDPR or investigators with significant experience monitoring for methyl bromide using standard capture methods.

However, it should be considered that much of the data used in this assessment are 10 years old or older and may not necessarily reflect absolute state-of-the-art cultural practices in many areas of the country. For example, modern application controller systems, which are becoming more widespread, are highly sophisticated programmable devices that control applications in real-time by accounting for micro-changes in application conditions such as changing line pressures or tractor speeds. It is possible that these systems could reduce exposure levels but their impact is not reflected in the data upon which this assessment is based. Other examples of practices that may not be captured include state-of-the-art shank designs that are intended to reduce emissions or other emission reduction approaches such as high barrier films or compaction methods.

In some cases, varied engineering controls were used by those being monitored so they are inherent in the resulting exposure levels. Examples of such devices include fans located near the tractor driver to dilute potential methyl bromide exposures. Varying shank depths or soil sealing methods could also reduce exposures but again the impacts of a single factor are difficult to ascertain based on the available data. Rather than to attempt to further delineate the data based on these factors, the data were grouped as presented above recognizing that each task category presented above probably represents a range of exposures that could occur for that task based on varied available equipment. Alternatively, if an attempt was made to quantitatively assess each possible scenario the numbers of monitoring events for each category would sometimes be very low (i.e., in some cases, 1 or 2 events) which minimizes the ability to compare results among scenarios. In summary, the data used for this assessment should be considered acceptable for risk assessment purposes and that, if anything, current agricultural practices and systems would likely lead to lower exposure estimates than those presented above. This is likely because the intent of the evolving cultural practices over recent years has been to provide for more efficient and accurate application events in a manner that still achieves efficacy and to also reduce overall emissions and exposures.

The results of the occupational risk assessment should also be considered in the context of the available incident data. In many cases, occupational incidents involve skin sensitization or even chemical burns which are consistent with the toxicity profile for methyl bromide (i.e., it is a Category 1 acute dermal and eye irritant – see Appendix A). For this reason, loose fitting clothing is stipulated on methyl bromide labels so as not to trap residues close to the skin. Irritation effects are also often noted as described above which are difficult to differentiate from cholorpicrin exposure which is often companion applied with methyl bromide. As indicated above the bystanders, it is also not surprising that other types of incidents are not observed more frequently because some of the symptoms that could be expected from exposure to methyl bromide may not be readily attributable to those exposures.

[Note: If so desired, the previous risk assessment (D316326, 7/13/05) and its associated appendices that contain all of the monitoring data information can be found at www.Regulations.gov under docket OPP-2005-0123.]

7.0 Data Needs and Label Requirements

7.1 Toxicology

There are no additional data requirements at this time.

7.2 Residue Chemistry

Please refer to the Phase 5 risk assessment for the food uses of methyl bromide (D304623).

7.3 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 in order to ensure that exposures related to current cultural practices can be addressed in future assessments. Additionally, emissions data are required in order to quantify the impact of using technologies intended to improve efficacy and/or reduce emissions in order to develop model estimates reflective of those technologies (e.g., impacts of high barrier films on emissions).

The types of data, guideline citations, and examples of the scenarios which need to be addressed are presented below. It should also be noted that the general data requirements for fumigants are being evaluated. Factors such as application technologies, regions of use, possible emission reduction technologies, and timing of applications will be used to define factors such as the numbers of emissions studies which may be required for specific use patterns, the meteorological data requirements for modeling purposes, methods for flux calculations, and possible criteria for ambient monitoring. Other factors may include specific guidance for sampling methods, numbers of samples and frequency of sampling. Until this effort is complete, final determination of the types of studies to address each scenario below should be made in consultation with the Agency.

OPPTS Guideline 835.8100 - Field volatility from soil

Volatility Studies To Determine Flux For Modeling Purposes In Major Use Regions Of Country For Significant Application Methods (e.g., Florida or Washington for tarped raised beds or drip irrigation)

OPPTS Guideline 875.1300 - Inhalation exposure for applicators (outdoors)

Pre-Plant Field - (e.g., rig drivers & tenders, tarpers, tarp removers)

OPPTS Guideline 875.1400 - Inhalation exposure for applicators (indoors)

Greenhouse - (e.g., Fumigators, Media Handlers, Aerators)
Residential - (e.g., Fumigators, Tarpers, Aerators)

OPPTS Guideline 875.2500 - Inhalation exposure for postapplication workers

Pre-Plant Field - (e.g., planters)
Greenhouse - (e.g., forklift drivers, plant maintenance workers)

Requirements For Special Studies

Meteorological data for probabilistic modeling purposes

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

Indoor air concentrations from residences that are in proximity of treated areas

Ambient monitoring in high regions of use in the season of use.

Structural Fumigant Risk Assessment

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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: November 26, 2008

SUBJECT: **Methyl Bromide, PC Code 053201, DP Barcode 304612**; Health Effects Division (HED), Second Addenda To The 2006 (DP Barcode 304623) Phase 5 Human Health Risk Assessment For Commodity Uses

PC Code: 053201	**DP Barcode:** D304612
Decision No.: 345512	**Registration No.:** varied
Petition No.: N/A	**Regulatory Action:** RED Follow Up
Risk Assessment Type: Addenda to Phase 5	**Case No.:** N/A
T**XR No.:** N/A	**CAS No.:** 74-83-9
MRID No.: 474203-02, 474725-01, 474725-01	**40 CFR: N/A**

Ver.Apr.08

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This document is a second addendum to the phase 5 risk assessment for the commodity uses of methyl bromide (March 10, 2006; DP Barcode 304623). The first addendum was completed in July 2006 (DP Barcode 304619). Since the completion of the first addendum, the Methyl Bromide Industry Panel (MBIP) completed three monitoring studies in large grain mill facilities and also completed a series of accompanying modeling analyses based on those data and existing data from 11 other fumigation events. These data and analyses have been reviewed by the Agency in a separate Data Evaluation Record (DER) document (November 6, 2008; DP Barcode 353906). The results of this review suggest that the Agency should refine its estimates of the emission profiles and other factors used to calculate buffer estimates for structural/commodity uses within the limitations identified in the review. Once aspect of the review suggested that there is not a significant difference in buffer estimates predicted using either the AERMOD or PERFUM models. The Agency has relied on the PERFUM model for its analyses in previous documents and continues to do so in this assessment because of the results of the MBIP analysis and because PERFUM can provide distributional outputs based on 5 years of weather data from different locations around the country representative of methyl bromide use areas. The results of the PERFUM analysis indicate that predicted buffer distances have been greatly reduced in many circumstances based but are still of concern for several situations.

Table of Contents

1. Introduction

This document presents the second addendum to the commodity risk assessment for methyl bromide. Updated risk estimates based on information obtained from the recent studies and computer modeling analyses conducted by the Methyl Bromide Industry Panel (MBIP) are provided. These include PERFUM buffer outputs and risk estimates based on PERFUM air concentration outputs. The MBIP data and analyses can be identified by the following information:

- MRID 474203-02; *Measurement of Structural and Ambient Methyl Bromide During Fumigation Activities at Food Processing Facilities*; Author: Eric Winegar; 3/31/08; Applied Measurement Science Fair Oaks California; Sponsor: Methyl Bromide Industry Panel, American Chemistry Council, Washington D.C.

- MRID 474725-01; *Analysis of Methyl Bromide Building Fumigation Studies Conducted In the Early 1990s*; Author: Exponent, Inc.; February 2008; Exponent 1800 Diagonal Road, Suite 300 Alexandria Virginia 22314; Sponsor: Methyl Bromide Industry Panel, 1300 Wilson Boulevard, Arlington VA 22209

- MRID 474725-01; *Analysis of Methyl Bromide Building Fumigation Studies Conducted In the Early 1990s*; Author: Exponent, Inc.; February 2008; Exponent 1800 Diagonal Road, Suite 300 Alexandria Virginia 22314; Sponsor: Methyl Bromide Industry Panel, 1300 Wilson Boulevard, Arlington VA 22209

A data evaluation record (DER) for three documents cited above was completed separately (D353906; 11/6/08). A summary of the results of the DER document is presented in Section 2. Section 3 describes the parameterization of the PERFUM model based on the DER findings and additional changes which have been identified by the Agency. Additionally, the HEC value used as the basis for the calculations based on the study dosing duration. Risk estimates based on the updated PERFUM outputs are provided in Section 4. A risk characterization discussion and summary are presented in Section 5.

2. Data Evaluation Record Summary of MBIP Data

The Methyl Bromide Industry Panel (MBIP) conducted a series of field studies and computer modeling analyses to provide information that would further characterize emissions from treated structures. In this effort three large mill facilities were monitored after fumigation, an analysis of historical data was developed to examine different considerations for PERFUM modeling purposes, and an analysis of the mill study was conducted to develop a sampling strategy for the field study and to evaluate the collected data.

The data are considered to have utility for the purposes of the risk assessment process within the limitations which were identified. One of the critical conclusions of the 3 studies/analyses was that the Agency used a conservative approach for defining emissions in its previous risk assessments. MBIP suggested an exponential box model approach for modeling emission rates and the Agency concurs that this is applicable in most circumstances given appropriate parameterization of the model which is used for the calculations. It was also concluded that the loss rate factors selected by the Agency for establishing buffer estimates during the treatment and aeration phases of the fumigations were conservative because the data indicate higher amounts are lost during treatment than considered by the Agency and, conversely, less is emitted than expected by the Agency. Finally, MBIP identified some model parameterization factors such as building heights for treatment activities and passive aerations for consideration by the Agency in subsequent analyses.

The Agency did identify a number of critical issues which it does believe; however, limit the utility of the data and indicate a need for further auditing of the information to confirm the conclusions made by the investigators. Central to this criticism is that the monitoring data collected in the mill study did not appear to be conducted under the requirements of the Good Laboratory Practices and quality control issues were generally not addressed in the report. Also, in the historical data modeling analysis no information was provided which could be used to identify the studies used or further evaluate them from a quality control perspective. Additionally, the overarching goal of this effort by the MBIP was to provide information to characterize the conclusions made by the Agency with regard to representing the industry as a whole and not just using it to evaluate a limited number of study sites. The information provided in this regard was inadequate and, as such, the Agency does not have sufficient information to be able to apply the results with any rigor to the overall fumigation industry. There were also a number of decisions which were made to inform the modeling exercises and parameterize the model. These were not explained in sufficient detail. Finally, the investigators developed some recommendations for modifying the Agency approach for calculating buffer estimates using PERFUM (or any appropriate air emissions model for that matter). It is clear that these recommendations are appropriate for many circumstances. However, the investigators did not discuss possible limitations and uncertainties associated with these recommendations when it is clear a number of assumptions and modeling policy decisions were made to complete the analysis. These need to be identified and explained in more detail by the investigators. [Note: Please refer to D353906; Author J. Dawson dated 11/6/08 for more information.]

3. PERFUM Model Parameterization

The parameterization of the PERFUM model varies significantly from that used to complete the risk calculations provided in the Phase 5 risk assessment completed on March 10, 2006 (D304623; Authors Dawson and Mendez). However, the overall use of the PERFUM model and the interpretation of the results are similar to previous assessments unless noted. Please refer to that document for further information on the general use of the PERFUM model. The major changes which have been incorporated into the updated parameterization of PERFUM include:

- **Exponential Emission Rates –** In the 2006 risk assessment a constant emission rate term was used to eliminate all methyl bromide within a treated space over the course of 1 hour followed by a series of zero emission hourly periods to calculate the appropriate time weighted average air concentrations. In the recent review of the MBIP submissions the Agency concurs that a box-type exponential emissions model is a more appropriate approach for developing emission terms for modeling purposes given proper model parameterization to accompany its use. In this analysis, the Agency has developed calculations based on both approaches for comparative purposes. It is generally recommended that the box model exponential approach should be considered more appropriate for regulatory purposes.

- **Model Platform Selection –** The PERFUM model was used to develop the risk estimates in the previous analyses completed for the structural/commodity uses of methyl bromide. PERFUM uses the Agency model ISCST3 as its core processor rather than the more current regulatory accepted model AERMOD. [Note: For further information see http://www.epa.gov/scram001/.] However, PERFUM provides distributional outputs based on a consideration of 5 years of weather information which is not achievable with AERMOD in the same format at this time. MBIP conducted a sensitivity analysis of the results between the two modeling systems and found that the differences in the results were not statistically different. The Agency concurs with this assessment and, as such, has used PERFUM as the basis for these current calculations.

- **Source Term Determination –** There are many approaches which can be used to develop a source term for use in modeling with PERFUM, AERMOD or other model systems. For example, consideration of whether a source such as a large treated mill structure should be modeled as an area source which assumes leakage or aeration evenly across an entire structure, as a single point source which assumes all emissions are through a single stack, or as a structure with several point sources located at varied points across a structure is illustrative. In the MBIP analysis AERMOD was used and configured with several point sources to predict the results of the monitoring data which were generated in the 3 mill monitoring studies that were conducted. With this approach, there was relatively good agreement with the monitoring data. However, no explanation was provided regarding the rationale used to locate the point sources. It is theorized that this makes physical sense because small leaks could occur across the surface of a large treated structure such as this and, in a generic sense, locating such leakage points such that they would be representative of the industry would be problematic. Given this consideration and that multiple point source allocation is not possible at this time in PERFUM, several other approaches using an area source approach were investigated. Based on this analysis it appeared that use of an area source at ½ the building height seemed the most appropriate. This is also seems as physically plausible as the multiple point sources located across a building, especially since the approach has been used in a generic sense to emulate a typical structure and not a specific building during a specific fumigation event where more exact locations of sources (i.e., leaks) could possibly be determined.

- **Additional Scenarios Considered –** Based on the review of the data and other findings several additional scenarios were added to the analysis including: extremely large structures up to 10 million cubic feet were analyzed, an additional source of weather information from the Philadelphia area was added since many commodity fumigations occur there and in nearby Wilmington Delaware and various locations in New Jersey; and high air exchange rates were considered for certain sized structures up to 250,000 cubic feet. Also, additional portable and fixed stack height values were included to provide more consideration of the varied conditions which could exist in the industry.

- **Consistency with Human Equivalent Concentration (HEC) Database –** The HEC used to complete the acute risk assessment was derived based on the developmental effects observed in the rabbit study as described in the 2006 risk assessment (D304623; Authors Dawson and Mendez). In this assessment, HEC values for 3 distinct durations of exposure have been calculated to mimic the types of exposure patterns that are expected from the structural/commodity uses that are anticipated for methyl bromide. These include 6, 12, and 24 hour durations. The HEC values which have been considered are presented in Table 1 below. These values have been modified slightly from previous assessments because they better reflect the anticipated exposure patterns and the mirror the dosing regimen from the actual toxicological study.

Table 1: Summary of Toxicological Dose and Endpoints for Use in The Acute Methyl Bromide Human Health Inhalation Risk Assessment

Risk Assessment*		Study	NOAEL/LOAEL	Endpoints	HED HECs
Acute	24 hr exposure	Developmental Study in Rabbits	NOAEL = 40 ppm LOAEL = 80 ppm	Developmental effects: agenesis of gallbladder, fused sternebrae	10 ppm UF = 30
	12 hr exposure				20 ppm UF = 30
	6 hr exposure				40 ppm UF = 30

Based on the information described above, a series of updated analyses have been completed. The exact modifications which have been completed are presented in detail in Appendix A. Appendix A indicates that millions of permutations of the PERFUM model have been completed when all combinations of the analysis have been considered. These modifications are summarized below:

- **7 Weather Sources:** In the previous risk assessment weather data from 6 regions across the country were processed and used to develop PERFUM outputs. Since the completion of the 2006 risk assessment, an additional source of weather data has been included to represent the Philadelphia Pennsylvania and Wilmington Delaware area since a large number of commodity fumigations occur at those ports. This data set was used to complete a series of site specific analyses for various USDA APHIS fumigation sites (D304632; 8/30/07; Author: Dawson).

- **3 Exposure Durations:** In the previous assessments, exposure durations of 4 and 24 hours were used to calculate time-weighted average exposure concentrations which were compared to HEC values based on 8 and 24 hours to calculate risks. The shorter duration calculations were completed in this manner to be conservative because of the uncertainties associated with the emission terms that were used. In this current assessment, the Agency has revised its approach for calculating risks in order to eliminate this type of comparison as described above. Other durations of exposure were also included (i.e., 12 and 24 hour intervals) in order to consider emission patterns that could occur in those timeframes (e.g., mill treatments where holding times are extended up to 24 hours).

- **Target Levels of Concern:** The Agency level of concern for methyl bromide is established by applicable uncertainty factors to account for inter-species extrapolation and intra-species sensitivity which result in a total factor of 30. In this case, assessments were completed for other factor levels of 10, 3, and 1 to illustrate the sensitivity of the results to changes in this factor and to provide a broader characterization of the risks. [Note: This analysis of sensitivity does not alter the total factor of 30 defining the level of risk concern.]

- **Different Emission Types:** A variety of emission types were considered in this assessment. In the review of the MBIP mill study an exponential emissions profile based on the use of a box model was determined to be appropriate for all situations. Additionally, other scenarios were also considered for comparison purposes and to simulate specialized situations. A constant emission profile was used for evaluating treatment situations as well as the exponential profile. In this case, the constant emission approach could represent a structure which is leaking very rapidly and the amount of emissions was not limited by the selection of the emission type because the entire mass used in the treatment was emitted over the period of concern. A situation was also evaluated that involved a possible catastrophic breach of a containment where the premise is the treated mass is totally released in one hour to simulate such an event. In certain cases, multiple emissions were also evaluated to simulate situations (i.e., typically 250,000 ft^3 or less) where multiple sequential treatments are conducted and aerated in sequence.

- **6 Application Rates:** A range of application rates was considered in this assessment from 1 to 15 lb ai/1000 ft^3. The low end of the range (i.e., 1 to 4 lb ai/1000 ft^3) is typically used in many more fumigation events because it incorporates typical and the maximum allowable use rates on food commodities. The upper end of the range (i.e., 9 to 15 lb ai/1000 ft^3) is used only in non-food applications such as for tile, timber, or space treatments and these are less frequent than food use treatments.

- **9 Leakage/Aeration Types:** Different types of leakage/aeration are commonly used across the industry to remove methyl bromide from treated chambers and structures after treatments are complete. These treated areas are highly varied in design and construction materials. As such, a range of techniques are used to accomplish aeration. The types of aeration considered in this assessment include: passive methods intended to mimic leaking from a treated chamber or passive aeration by opening doors and/or windows (i.e., treated as an area source at ½ the building height derived after a modeling sensitivity analysis); using fixed stacks on rooftops (10 and 25 ft); using portable stacks which are attached to treated areas with flexible hoses that can be moved as desired during aeration (5, 10, 25, and 50 feet); and a technique used at times in APHIS fumigations where a portable fan arrangement, similar in nature to a portable stack, except that the discharge is oriented in a horizontal direction rather than orienting the discharge effluent in a vertical manner (i.e., modeled using a 0.6 m discharge height using an appropriate spatially large source with low vertical effluent velocity of 0.001 m/s).

- **10 Retention/Emission Rates (expressed as % of target treatment rates):** Intended to address a variety of situations that reflects a range of structure types from extremely airtight to highly leaking structures. The values which have been included are (% of rate): 1, 5, 10, 25, 50, 75, 90, 95, 99, and 100. It should be noted that monitoring data indicate both high retention and high leakage rates in field conditions which need to be considered with this factor in the interpretation of this factor (e.g., in recent mill studies leak rates were greater than 70 percent or so).

- **7 Air Exchange Rates (exchanges per hour):**
  0.05 – only applied to passive aeration methods or during leakage during treatment
  0.1, 0.2, 0.5, 1, 2 applied to all methods
  10 – only applied to structures ≤ 250000 cubic feet.

- **15 Structure Volumes (cubic feet):**
  Small scale: 1000, 2000, 5000
  Mid scale: 10000, 25000, 50000
  Large scale: 100000, 250000, 500000, 750000, 1million
  Extreme scale (new category): 2.5 million, 5 million, 7.5 million, 10 million

- **Chamber/Structure Height:**
  -Small scale: 1000 cu. ft = 10 ft, 2000 cu. ft. = 12 ft, 5000 cu. ft. = 17 ft
  -Mid scale: 25 ft
  -Large scale: 75 ft
  -Extreme scale: 100 ft

- **Stack Diameters:** Were calculated based on the specifics of the particular fumigation event.

Many of the factors described above have been used in the risk assessment process for the structural and commodity uses of methyl bromide over the last several years. Additionally, factors have been added or modified since the previous 2006 risk assessment. Some inputs which have been used in this assessment require that they be calculated such as flux estimates or the size of the source for APHIS style horizontal discharge aeration methods. These calculations and others as well as provided in Appendix B.

4. Risk Estimates

Risks were evaluated in this assessment using a variety of different permutations of the PERFUM model based on the factors described above in Section 3. Additionally, as in previous assessments, empirical monitoring data were also considered which in this case were the information provided in the mill monitoring studies recently reviewed by the Agency (11/6/08; DP Barcode 353906). The risks calculated for each approach are described below.

4.1 Empirical Monitoring Data

In the mill monitoring study, air sampling was conducted around the perimeters of 3 large mill structures both during treatment and aeration. The volumes treated in each of the three mills were approximately 2 million cubic feet and the nominal application rate was 1 lb methyl bromide per 1000 cubic feet treated. In all circumstances which were monitored, air concentrations did not exceed the Agency's level of concern during treatment or aeration activities. Sampling durations are generally less than 6 hours, especially during treatment and the first day or so of aeration which is where the majority of the emissions occur. Because this is the case, monitoring results were compared to a target concentration of 1.3 ppm (5177 $\mu g/m^3$) which was defined by the 6 hour HEC of 40 ppm divided by the applicable total uncertainty factor of 30.

At the first mill site, the highest levels of methyl bromide detected during the treatment phase occurred during the 4 to 8 hour sampling interval (776 to 1,126 $\mu g/m^3$ for the samplers closest to the facility, 78 to 660 $\mu g/m^3$ for the samplers further from the facility that were sampled). After the start of the aeration phase, the highest concentrations of methyl bromide occurred during the 0 to 2 hour sampling interval (543 to 1,009 $\mu g/m^3$ for the samplers closest to the facility, <1.94 to 815 $\mu g/m^3$ for the samplers further from the facility that were sampled).

At the second mill site, the highest levels of methyl bromide detected during the treatment phase occurred during the 4 to 8 hour sampling interval (175 to 1,126 $\mu g/m^3$ for the samplers closest to the facility). At this site passive aeration was used for the first 4 hours after treatment termination followed by an active aeration period. Methyl bromide concentrations for the first 24-hour sampling interval which covered the 20-hour treatment phase along with the first 4 hours of the passive aeration phase ranged from132 to 699 $\mu g/m^3$. At the end of the passive aeration period, active aeration (4 to 5 hour sampling interval) increased the concentrations by approximately a factor of 10, with concentrations ranging from 54.3 to 264 $\mu g/m^3$ for the samplers closest to the facility. The maximum methyl bromide concentration detected at the farther sampler locations was 167 $\mu g/m^3$ during the 0 to 2 hour sampling interval (passive aeration).

At the third mill site, the data indicated that the highest levels of methyl bromide detected during the treatment phase occurred during the 0 to 4 hour sampling interval, ranging from <3.88 $\mu g/m^3$ to 377 $\mu g/m^3$. After the start of the aeration phase, the highest concentrations of methyl bromide occurred during the 0 to 2 hour sampling interval, ranging from <3.88 $\mu g/m^3$ to 1,009 $\mu g/m^3$. Overall, the ambient concentrations were lower during the treatment phase than during the aeration phase. Concentrations rose sharply at the beginning of the aeration phase, declining over time to levels below the detection limit.

4.2 PERFUM Model Based Results

The PERFUM model has been parameterized to account for the changes described in Section 3 above. All of the files associated with the use of PERFUM in this assessment can be provided upon request. These files could be used to examine the detailed input and output files for each permutation of the model completed for this analysis. The amount of information included is quite extensive. As such, the Agency developed a series of spreadsheet files which summarize the results. These also provide an enormous amount of summary information for each model permutation. These files, as well, can also be provided upon request.

In order to illustrate the risk predictions calculated using PERFUM, a series of outputs have been summarized in Appendices C through J. The permutations of the model which have been selected represent Bradenton weather data which typically results in more conservative (i.e., farthest) buffer distance predictions. Results for different durations of exposure have also been summarized including 6, 12, and 24 hours. A range of application rates for the 24 hour results summary included a range from 1 to 15 pounds of methyl bromide per 1000 cubic feet. This broad application range has been summarized for the 24 hour averaging time but only an application rate of 4 pounds methyl bromide per 1000 cubic feet has been summarized for the shorter exposure durations of 6 and 12 hours. The trends which are observed in the results due to changes in the application rates would be consistent with changing application rates regardless of the exposure duration. It should be noted that even though that only selected PERFUM outputs have been summarized that all permutations of the model have been completed as described above and are available for review. Each appendix contains the results for a single application rate for varied building sizes, aeration methods, air exchange rates, emission profile type, and retention/emission rate (as % of nominal application rate). Appendices C through J can be specifically described by the following:

- **Appendix C – 10ppm HEC/Bradenton Weather/1 lb per 1000 cubic ft**
- **Appendix D – 10ppm HEC/Bradenton Weather/2 lb per 1000 cubic ft**.
- **Appendix E – 10ppm HEC/Bradenton Weather/3 lb per 1000 cubic ft**
- **Appendix F – 10ppm HEC/Bradenton Weather/4 lb per 1000 cubic ft**.
- **Appendix G – 10ppm HEC/Bradenton Weather/9 lb per 1000 cubic ft**
- **Appendix H – 10ppm HEC/Bradenton Weather/15 lb per 1000 cubic ft**.
- **Appendix I – 20ppm HEC/Bradenton Weather/4 lb per 1000 cubic ft**
- **Appendix J – 40ppm HEC/Bradenton Weather/4 lb per 1000 cubic ft**.

Along with the summaries of the modeling outputs which are included in Appendices C through J a further summary of the results has been developed to illustrate some of the trends which have been observed in the modeling results. Tables 2 through 4 provide a summary of the 24 hour results at a fixed application rate of 1 lb methyl bromide per 1000 cubic feet treated using Bradenton Florida weather for all modeled structure volumes. The application rate was selected because it is commonly used to treat commodities and also it is commonly used for space treatments in structures such as grain mills so it is illustrative but also directly applicable for many significant use patterns. In these tables all results are assumed to be at a value of 100 percent retention/emission which is conservative given what is known about absorption and structure leakage under real world conditions. The results for a range of aeration methods are also provided in order to illustrate sensitivity of the results based on different techniques for aeration. In PERFUM, air concentrations are calculated using concentric circles around the perimeter of a treated structure at prescribed distances from the edge of the structure (i.e., referred to as "rings"). Table 2 provides a summary of these results by indicating the distance and percentile of exposure at which the Agency target concentration of concern has first been exceeded as the ring distance increases from the perimeter of the building. The closer the rings are to the perimeter of the building and the lower the concentration percentiles are indicate scenarios of greater concern. For example, air concentrations for the 5 feet tall portable stack scenario exceed the target concentration more frequently than the other scenarios which were considered indicating it presents more of a risk concern than other aeration/leakage scenarios.

Table 2: PERFUM Ring Distance (meters) and Percentile Of Exposure At Which HED Target Concentration Is Exceeded At That Distance For Varied Fumigated Volumes At An Application Rate of 1 lb/1000 Cubic Feet Treated

Structure Volume (ft^3)	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1K	NE	NE	NE	NE	NE	NE	NE	NE	NE
2K	NE	NE	NE	NE	NE	NE	NE	NE	NE
5K	NE	NE	NE	NE	NE	5/99.9	NE	NE	NE
10K	NE	NE	NE	NE	NE	5/99	NE	NE	5/99.9
25K	NE	NE	NE	NE	NE	5/95	NE	NE	5/95
50K	NE	NE	NE	NE	NE	5/90	5/90	NE	5/90
100K	NE	NE	NE	NE	NE	5/85	5/95	NE	5/85
250K	NE	NE	NE	NE	NE	5/80	7/99	NE	5/80
500K	NE	NE	NE	NE	NE	5/75	5/75	5/85	5/80
750K	NE	NE	NE	NE	NE	5/80	5/80	5/95	5/80
1M	NE	NE	NE	NE	NE	5/85	5/85	5/97	5/80
2.5M	NE	NE	70/99.9	70/99.9	NE	5/85	5/85	5/85	5/80
5M	50/99.9	50/99.9	15/99.9	50/99	50/99.9	5/99	5/99	5/99	5/80
7.5M	15/99.9	15/99.9	5/99	50/97	50/99	7/99.9	7/99.9	7/99.9	5/75
10M	5/99.9	5/99.9	5/97	30/95	30/99	7/99.9	7/99.9	5/99.9	5/75

Notes:
Application rate for all results in this table is 1lb methyl bromide/1000 cubic feet treated and 24 hour exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
NE = Target Concentration Not Exceeded At Any Ring Distance of Percentile Of Exposure
AXR = Air Exchange Rate
Results reported as follows: Distance (meters) where first exceedance occurs/Percentile of exposure where exceedance occurs

PERFUM outputs also include the calculation of the whole-field and maximum distance buffers as has been described in previous assessments. For illustrative purposes, whole-field and maximum buffer results have been summarized in Tables 3 and 4, respectively. For each, the first percentile of exposure at which a buffer distance is not (0 meters) is presented along with the corresponding predicted distance. In many situations, buffer distances of (0 meters) are predicted. These are identified when they occur. Results mirror those described above for Table 2. In many scenarios, even based on the low application rate, predicted buffer distances are several hundred feet.

Table 3: PERFUM Whole Field Buffer Distances (meters) And Corresponding Percentile of Exposure For Varied Fumigated Volumes At An Application Rate of 1 lb/1000 Cubic Feet Treated

Structure Volume (ft^3)	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1K	NE	NE	NE	NE	NE	NE	NE	NE	NE
2K	NE	NE	5/99.99	NE	NE	NE	NE	NE	NE
5K	NE	NE	NE	NE	NE	5/99.9	NE	NE	10/99.99
10K	NE	NE	NE	NE	NE	10/99	NE	NE	10/99
25K	NE	NE	NE	NE	NE	15/95	NE	NE	15/95
50K	NE	NE	30/99.9	NE	NE	10/90	5/90	NE	10/90
100K	NE	NE	NE	NE	NE	10/85	10/90	NE	10/85
250K	NE	NE	NE	NE	NE	5/80	50/95	NE	5/80
500K	NE	NE	145/99.9	NE	NE	5/75	5/75	20/85	15/80
750K	NE	NE	125/99	NE	NE	15/80	15/80	15/85	15/80
1M	NE	NE	100/97	50/99.9	NE	10/80	10/80	60/90	5/75
2.5M	NE	105/99.9	125/95	210/99.9	100/99.9	15/80	15/80	20/80	10/75
5M	190/99.9	105/97	110/90	75/97	195/99	55/85	55/85	55/85	15/75
7.5M	180/99	165/95	60/85	80/95	140/97	165/90	165/90	165/90	20/75
10M	100/95	50/85	105/85	190/95	100/95	60/85	60/85	65/85	20/75

Notes:
Application rate for all results in this table is 1lb methyl bromide/1000 cubic feet treated and 24 hour exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
AXR = Air Exchange Rate
NE = Predicted whole-field buffer distance is (0 meters) at all percentiles of exposure
Results reported as follows:
Whole-field buffer distance (meters) where first non-0 meter value occurs/Percentile of exposure where exceedance occurs

Table 4: PERFUM Maximum Buffer Distances (meters) And Corresponding Percentile of Exposure For Varied Fumigated Volumes At An Application Rate of 1 lb/1000 Cubic Feet Treated

Structure Volume (ft^3)	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1K	NE	NE	NE	NE	NE	5/99.9	NE	NE	NE
2K	NE	NE	5/99.9	NE	NE	5/99.9	NE	NE	NE
5K	NE	NE	NE	NE	NE	5/90	NE	NE	10/99
10K	NE	NE	NE	NE	NE	5/60	NE	NE	60/5
25K	NE	NE	NE	NE	NE	5/5	NE	NE	5/5
50K	NE	NE	15/90	NE	NE	20/5	15/5	NE	20/5
100K	NE	NE	NE	NE	NE	35/5	20/5	NE	35/5
250K	NE	NE	NE	NE	NE	60/5	60/10	NE	60/5
500K	NE	NE	85/85	NE	NE	85/5	85/5	80/5	85/5
750K	NE	NE	85/55	135/99.99	NE	110/5	110/5	100/5	110/5
1M	NE	75/99.9	85/35	60/97	NE	125/5	125/5	105/5	130/5
2.5M	NE	100/97	160/20	105/85	250/97	155/5	155/5	170/5	160/5
5M	155/95	70/45	210/5	155/55	100/55	280/10	280/10	285/10	285/10
7.5M	85/60	110/15	300/5	155/35	110/25	245/10	245/10	275/10	255/10
10M	85/30	130/5	355/5	180/25	65/10	60/10	60/10	170/10	100/10

Notes:
Application rate for all results in this table is 1lb methyl bromide/1000 cubic feet treated and 24 hour exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
AXR = Air Exchange Rate
NE = Predicted maximum buffer distance is (0 meters) at all percentiles of exposure
Results reported as follows:
Maximum buffer distance (meters) where first non-0 meter value occurs/Percentile of exposure where exceedance occurs

In addition to summarizing the results for a fixed application rate over all fumigated structure sizes and aeration methods, an illustrative summary of results has also been completed by considering varied application rates and exposure durations, in some cases, for a fixed fumigated volume. This has been accomplished by summarizing the results for a single fumigated volume of 50,000 cubic feet, a 100 percent conservative emission/retention value as above, and additional application rates up to 15 lb methyl bromide/1000 cubic feet treated. A 24 hour averaging time and using the Bradenton Florida weather results were used as above. Additionally, the impact of exposure durations was also included in this evaluation by including results for a treatment rate of 4 lb methyl bromide/1000 cubic feet treated using both the 6 and 12 hour averaging times. As expected, buffer distances increase and/or the percentiles of exposure decrease as application rates rise. Results for the different durations of exposure are not significantly different between 6, 12, and 24 hours for most scenarios. Ring distance information is presented in Table 5 below. Whole-field and maximum PERFUM buffer distances are presented in Tables 6 and 7, respectively.

Table 5: PERFUM Ring Distance (meters) and Percentile Of Exposure At Which HED Target Concentration Is Exceeded At That Distance For Fixed Fumigated Volume of 50K Cubic Feet At Varied Application Rates Up To 15 lb/1000 Cubic Feet Treated And For Varied Durations At The To 4 lb/1000 Cubic Feet Treated Application Rate

Application Rate (lb/1K ft^3) & Exposure Duration	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1 lb/1K ft^3 24hr TWA	NE	NE	NE	NE	NE	5/90	5/90	NE	5/90
2 lb/1K ft^3 24hr TWA	NE	NE	5/97	NE	NE	5/85	5/90	NE	5/90
3 lb/1K ft^3 24hr TWA	NE	5/99.9	5/95	NE	15/99.9	5/85	5/85	NE	5/85
4 lb/1K ft^3 24hr TWA	10/99.9	5/99	5/90	NE	15/99	5/85	5/85	NE	5/85
9 lb/1K ft^3 24hr TWA	5/95	5/85	5/85	15/99	15/95	5/80	5/80	50/99.9	5/80
15 lb/1K ft^3 24hr TWA	5/85	5/75	5/80	15/97	15/95	5/75	5/75	70/97	5/75
4 lb/1K ft^3 12hr TWA	30/99.9	5/99.9	5/95	15/99.9	15/99	5/85	5/85	NE	5/85
4 lb/1K ft^3 6hr TWA	NE	5/99.99	5/95	15/99.9	15/99	5/85	5/80	NE	5/85

Notes:
Application rate for all results in this table is 1lb methyl bromide/1000 cubic feet treated and 24 hour exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
AXR = Air Exchange Rate
NE = Target Concentration Not Exceeded At Any Ring Distance of Percentile Of Exposure
Results reported as follows: Distance (meters) where first exceedance occurs/Percentile of exposure where exceedance occurs

Table 6: PERFUM Whole-Field Buffer Distances (meters) And Corresponding Percentile of Exposure For Fixed Fumigated Volume of 50K Cubic Feet At Varied Application Rates Up To 15 lb/1000 Cubic Feet Treated And For Varied Durations At The To 4 lb/1000 Cubic Feet Treated Application Rate									
Application Rate (lb/1K ft^3) & Exposure Duration	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1 lb/1K ft^3 24hr TWA	NE	NE	30/99.9	NE	NE	10/90	5/90	NE	10/90
2 lb/1K ft^3 24hr TWA	NE	25/99.99	15/95	NE	35/99.99	10/85	5/85	NE	10/85
3 lb/1K ft^3 24hr TWA	30/99.99	10/99	35/95	60/99.99	40/99.9	15/85	10/85	NE	15/85
4 lb/1K ft^3 24hr TWA	40/99.9	15/97	20/90	105/99.99	25/99	5/80	10/85	NE	5/80
9 lb/1K ft^3 24hr TWA	15/90	10/80	5/80	90/99	35/95	15/80	10/80	85/99	15/80
15 lb/1K ft^3 24hr TWA	15/80	5/70	15/80	40/95	15/90	10/75	5/75	100/97	10/75
4 lb/1K ft^3 12hr TWA	60/99.9	55/99	15/90	20/99	30/99	5/80	10/85	NE	15/85
4 lb/1K ft^3 6hr TWA	50/99.99	120/99.9	10/90	20/99	45/99	5/80	5/80	NE	20/85

Notes:
Application rate for all results in this table are noted above as is the exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
AXR = Air Exchange Rate
NE = Predicted whole-field buffer distance is (0 meters) at all percentiles of exposure
Results reported as follows:
Whole-field buffer distance (meters) where first non-0 meter value occurs/Percentile of exposure where exceedance occurs

Table 7: PERFUM Maximum Buffer Distances (meters) And Corresponding Percentile of Exposure For Fixed Fumigated Volume of 50K Cubic Feet At Varied Application Rates Up To 15 lb/1000 Cubic Feet Treated And For Varied Durations At The To 4 lb/1000 Cubic Feet Treated Application Rate									
Application Rate (lb/1K ft^3) & Exposure Duration	Treatment & Aeration No Stack Passive	Aeration No Stack 0.1 AXR	Aeration No Stack 1.0AXR	Aeration 10ft. Stack 1.0AXR	Aeration 25 ft. Stack 1.0AXR	Aeration 5 ft. Port. Stack 1.0AXR	Aeration 25 ft. Port. Stack 1.0AXR	Aeration 50 ft. Port. Stack 1.0AXR	Aeration Horizontal Portable Discharge 1.0AXR
1 lb/1K ft^3 24hr TWA	NE	NE	15/90	NE	NE	20/5	15/5	NE	20/5
2 lb/1K ft^3 24hr TWA	NE	35/99.9	15/35	NE	30/99	35/5	30/5	NE	35/5
3 lb/1K ft^3 24hr TWA	25/99	15/85	25/15	80/99.9	15/85	45/5	40/5	NE	45/5
4 lb/1K ft^3 24hr TWA	30/95	10/50	25/5	55/97	15/55	55/5	50/5	NE	55/5
9 lb/1K ft^3 24hr TWA	20/10	40/5	70/5	60/50	35/10	85/5	80/5	85/70	85/5
15 lb/1K ft^3 24hr TWA	55/5	75/5	100/5	75/15	60/5	115/5	110/5	90/25	115/5
4 lb/1K ft^3 12hr TWA	65/95	50/65	25/5	55/65	15/50	50/5	45/5	NE	50/5
4 lb/1K ft^3 6hr TWA	75/99	50/75	20/5	65/60	15/35	45/5	40/5	NE	45/5

Notes:
Application rate for all results in this table are noted above as is the exposure duration
All results based on a 100 percent emissions/retention factor based on nominal application concentration which is conservative
AXR = Air Exchange Rate
NE = Predicted whole-field buffer distance is (0 meters) at all percentiles of exposure
Results reported as follows:
Maximum buffer distance (meters) where first non-0 meter value occurs/Percentile of exposure where exceedance occurs

5. Risk Characterization and Summary

The recent DER or data evaluation record (D353906; 11/6/08) identified a series of issues associated with the conduct of the mill studies and computer modeling analyses developed in conjunction with that study. These issues are summarized above in Section 2 but more detailed information can be provided in the DER if so desired. Additionally, many inherent uncertainties have been addressed in previous risk assessments as well that should be consulted if more risk characterization information is desired.

In summary, the Agency generally concurs with the major suggestion by the MBIP to utilize an exponential box modeling approach as the basis for the emission profile within the limitations identified in the data review and the caveat that the remaining parameterization of PERFUM is appropriate. In many circumstances, predicted buffer distances have been substantially reduced based on the revisions which have been incorporated into the Agency modeling approach. However, there are still situations where predicted buffer distances are extensive (e.g., hundreds of meters).