US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision (RED) for Methyl Bromide

July 9, 2008

United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508P)

EPA 738-R-08-005
July 2008

Reregistration Eligibility Decision for Methyl Bromide (soil and non-food structural uses)

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List A

Case No. 0335

Approved by:

Steven Bradbury, Director
Special Review and Reregistration Division

Date: 7/9/08

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.

MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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Methyl bromide Reregistration Eligibility Decision Team

Office of Pesticide Programs:

Human Health Risk Assessment
Jeffrey L. Dawson, Chemist/Risk Assessor
Elizabeth Mendez, Ph.D., Toxicologist/Risk Assessor
Toiya Goodlow, Chemist
Ruth Allen, MPH, Epidemiologist
Monica Hawkins, MPH, Environmental Health Scientist
Michael Metzger, Branch Chief

Biological and Economic Analysis Assessment
T J Wyatt, Ph.D., Senior Agricultural Economist
Jonathan Becker, Ph.D., Senior Science Advisor
Bill Chism, Ph.D., Senior Agronomist
David Donaldson, Agricultural Economist, Team Leader
Colwell Cook, Ph.D., Entomologist
Nicole Zinn, Biologist
Stephen Smearman, Economist
Leonard Yourman, Ph.D., Plant Pathologist
John Faulkner, Ph.D., Economist
Monisha Kaul, Biologist
William Phillips, II, Ph.D., Agronomist
Andrew Lee, Ph.D., Economist
Angel Chiri, Ph.D., Entomologist, Team Leader
Elisa Rim, Economist
Nikhil Mallampalli, Ph.D., Entomologist
Sunil Ratnayake, Ph.D., Botanist

Environmental Fate and Effects Risk Assessment
Mah Shamim, Ph. D., Branch Chief
Faruque Khan, Ph.D., Senior Fate Scientist
James Felkel, M.S., Wildlife Biologist
Gabriel Rothman, M.S., Environmental Scientist

Registration Support
Mary Waller, Product Manager for Methyl Bromide and Chloropicrin
Kathy Monk, Senior Advisor

Risk Management
Steven Weiss, Industrial Hygienist, Chemical Review Manager for Methyl Bromide
Andrea Carone, Chemical Review Manager for Chloropicrin
Eric Olson, Team Leader
John Leahy, Senior Advisor

Office of General Council:
Andrea Medici

Office of Enforcement and Compliance:
David Stangel

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered soil and structural (non-food) uses of methyl bromide.

The Agency has determined that methyl bromide-containing products for pre-plant soil uses that currently qualify for exemptions under the Montreal Protocol are eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and labels are amended to implement these measures. Throughout this document measures described as "required" are those necessary to be eligible for reregistration. Additionally, registrants must address data gaps that have been identified.

Concurrent to EPA's review of the soil fumigant uses of methyl bromide, EPA assessed the risks and developed risk management decisions for four other soil fumigant pesticides, including: chloropicrin, dazomet, metam sodium/metam potassium, and a new active ingredient, iodomethane. Risks of a fifth soil fumigant, 1,3-dichloropropene (1,3-D), were also analyzed along with the other soil fumigants for comparative purposes. The Reregistration Eligibility Document (RED) for 1,3-D was completed in 1998. The Agency evaluated these four soil fumigants concurrently to ensure that human health risk assessment approaches are consistent, and that risk tradeoffs and economic outcomes were considered appropriately in reaching risk management decisions. This review is part of EPA's program to ensure that all pesticides meet current health and safety standards.

The report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses was published on August 9, 2006 [1] (hereafter referred to as the Methyl Bromide TRED/RED). In January 2008, representatives of the Methyl Bromide Industry Panel (MBIP) presented to the EPA a preliminary summary of new emission studies for three flour mills. The information presented by the MBIP indicates that the new data could impact the Agency's modeling of buffer zones for commodity uses. A final report was submitted to the Agency on April 23, 2008 [2]. The Agency plans to make appropriate updates to the Methyl Bromide TRED/RED and respond to all comments upon review of the new data and based on comments submitted to the docket.

EPA has identified potential human health risks of concern associated with the registered methyl bromide uses described in this document from inhalation exposure to handlers, bystanders, and workers. EPA also has concerns for risks associated with methyl bromide's role in the depletion of stratospheric ozone. To reduce inhalation exposures and to address associated risks of concern, EPA is requiring a number of mitigation measures, such as:

[1] EPA-HQ-OPP-2005-0123-0231 The report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses

[2] MRID 47420302, Measurement of Structural and Ambient Methyl Bromide During Fumigation Activities at Food Processing Facilities: Final Report

- Removing of uses with low benefits and/or alternatives;
- Reducing maximum application rates;
- Limiting use of 98:2 formulations to essential crops;
- Buffer zones;
- Respiratory protection and air monitoring for handlers;
- Restrictions on the timing of perforating and removing tarps;
- Posting;
- Good agricultural practices (GAPs);
- Fumigant management plans (FMPs);
- Emergency preparedness and response plans;
- Notice to state lead agencies;
- Training for applicators and other handlers; and
- Community outreach and education programs.

The focus of the Agency's mitigation measures for this decision (and for the Methyl Bromide TRED/RED) is on reducing direct exposure to methyl bromide via the inhalation route. However, the Agency has concluded that many of these measures, combined with the methyl bromide phase-out mandated by the Montreal Protocol, will also further reduce the potential health effects (e.g., skin cancer) from ozone depletion that may be attributable to methyl bromide's uses.

End-use products for registered pre-plant soil uses of methyl bromide also contain chloropicrin. All formulations must contain at least 2% chloropicrin as a warning agent. Chloropicrin is also formulated with methyl bromide at higher concentrations as an active ingredient. A separate RED document has been completed for chloropicrin (see docket number EPA-HQ-OPP-2007-0350). In accordance with Agency policy, if the required risk mitigation measures differ for two active ingredients in a product, the more stringent mitigation measure is required on product labels.

The Agency is issuing this decision document for methyl bromide as announced in a Notice of Availability published in the *Federal Register*. Due to the broad scope of the decision for the soil fumigant group, there will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on issues related to the implementation of the risk mitigation measures.

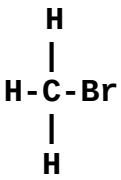
I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as EPA's review of all submitted data. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the Agency's reregistration eligibility decision for registered soil, and non-food structural uses of methyl bromide (i.e., uses not included in the August 2006 Methyl Bromide TRED/RED). The document consists of five sections. Section I contains the regulatory framework for reregistration. Section II provides a profile of the use and usage of the chemical. Section III provides a general overview fumigants and summarizes methyl bromide's human health and ecological risk assessments, as well as benefit assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Unless otherwise noted, all Agency references in this document are available for review in the methyl bromide docket (EPA-HQ-OPP-2005-0123) at www.Regulations.gov.

II. Chemical Overview

A. Chemical Identity

Chemical Structure:	
Empirical Formula:	CH_3Br
Common Name:	Methyl bromide
CAS Registry Number:	74-83-9
OPP Chemical Code:	053201
Case Number:	0335
Technical or Manufacturing-Use Registrants:	Albemarle Corporation, ICL-IP America Inc.[3], Great Lakes Chemical Corporation (a Chemtura Company), and TriCal. All four companies are members of the Methyl Bromide Industry Panel of the American Chemistry Council (MBIP).

[3] On July 1, 2008, Ameribron Inc. changed the corporate name to "ICL-IP America Inc."

B. Use and Usage Profile

Pesticide Type:	Methyl bromide is a broad-spectrum fumigant chemical that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent.
Target pests:	Methyl bromide controls a wide range of pests including spiders, mites, fungi, plants, insects, nematodes, rodents, and snakes.
Use patterns:	Methyl bromide's most prevalent use pattern is as a soil fumigant. It is also used as a post harvest treatment of commodities and structural fumigation. Structural non-food treatments (e.g., residential buildings) are reportedly no longer performed.
Formulations:	Pressurized gas (PrG) formulations are used for all methyl bromide applications. All methyl bromide products are classified as restricted use pesticides (RUP). The "Restricted Use" classification restricts a product, or its uses, to use by certified pesticide applicators or those working under the direct supervision of a certified applicator.
Methods of Application:	Soil uses: Methyl bromide is injected in to the soil at various depths using tractors equipped with shanks of varying shapes, sizes, and orientations. Applications have historically been done with and without tarps but tarp use is prevalent. With the hot gas method, methyl bromide is forced through a heat exchanger into the drip tubing under tarps. Applications can be made to flat areas of a field or in user created raised bed culture. Applications are typically accompanied by some degree of soil compaction or use of shank trace closure devices. Other Uses: Methyl bromide gas is injected into an enclosure, chamber, structure, or under a tarp remotely using flexible tubing connected to pressurized gas tanks.
Application Rates:	Soil uses: Common pre-plant agricultural field uses for various crops have maximum application rates that range from 200 lb ai/acre/application up to 430 lb ai/acre/application (e.g., EPA registration numbers 5785-4 and 5785-42). Rates as high as 2 lbs ai/100 square feet are generally reserved for more specialized applications such as hot gas applications and tree planting scenarios which are less prevalent. Other Uses: Application rates for commodity fumigations can range from 1 to 20 lb ai/1000 ft^3, but most perishable goods with established food

	tolerances under 40 CFR have application rates in the range of 1 to 4 lb ai/1000 ft^3 (e.g., grapes).
Annual Usage in the U.S.:	In 2007, 5,482 metric tons of methyl bromide were applied (4,269 metric tons from newly-produced material and 1,213 metric tons from pre-2005 stocks). This amount does not include QPS usage. QPS production is tracked by the Agency but usage is not. EPA's Office of Air and Radiation (OAR) reports that as of January 1, 2008, there were 6,458 metric tons of pre-2005 methyl bromide stocks. Additional information on the decline of the methyl bromide inventory can be found at: http://www.epa.gov/ozone/mbr/MeBr_FactSheet2008.html

C. Regulatory History

Methyl bromide was introduced as a pesticide in 1932 and first registered in the U.S. in 1961. Under the Clean Air Act and the Montreal Protocol on Substances that Deplete the Ozone Layer, as of January 1, 2005, U.S. production and import of methyl bromide is banned, except for uses that qualify for (1) a critical use exemption (CUE), (2) a quarantine and preshipment exemption (QPS), or (3) an emergency exemption. For more information about the phase out of methyl bromide, see http://www.epa.gov/ozone/mbr/.

III. Fumigant Overview and Agency Documents

A. General Overview of Soil Fumigants

Soil fumigants are pesticides that form gasses when applied to soil. Once in the soil, the fumigants work by controlling pests that can disrupt plant growth and crop production. Soil fumigants play a very important role in agriculture, but they also have the potential to pose risk concerns to people involved in application of the chemicals (handlers), workers who re-enter fumigated fields (workers), and people who may be near the treated area (bystanders).

B. Human Health Risks

The main risk of concern for handlers, workers, and bystanders associated with the soil uses of methyl bromide is from acute inhalation exposure as a result of fumigant off-gassing. Methyl bromide handlers also are at risk from direct fumigant exposure during applications. The term *handler* refers to persons involved in the application of methyl bromide. For soil applications, handlers also include persons involved in perforating and removing of tarps. The term *worker* in this document refers to persons performing non-handler tasks within the application block, after the fumigation process has been completed, such as planting. The term *bystander* refers to any person who lives or works in the vicinity of a fumigation site.

Estimating exposure to fumigants is different from non-fumigant pesticides due to fumigants volatility and ability to move off site during and after application. For example, pesticide spray drift is the physical movement of pesticide particulate or droplets from the target

site during the application and soon thereafter. In the case of soil fumigants, the pesticide moves as a gas (not as particulate or droplets) and movement off-site can occur for an extended period after application. Importantly, fumigants have a well-documented history of causing large-scale human exposure incidents up to several thousand feet from treated fields. Assessing fumigant exposure takes into account the size of the fumigated field, the amount of fumigant applied, and the rate at which the fumigant escapes from the treated field.

The term "flux rate" or "emission rate" defines the rate at which a fumigant off-gasses from a treated field. Many factors influence the rate of emissions from treated fields after the application of soil fumigants. Factors such as the application method, soil moisture, soil temperature, organic matter levels, water treatments, the use of tarps, biological activity in the soil, soil texture, weather conditions, soil compaction, and others influence the amount of fumigant that comes off the field and is available to move off-site to areas where bystanders may be located.

Neurotoxicity is a common toxic effect for methyl bromide inhalation exposure, with neurotoxic exposure effects seen in all tested species of animals. Both acute (1-day) 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, a subchronic study (5- to 7-week) showed dogs to be the most sensitive species to the neurotoxic effects of methyl bromide.

A non-reversible acute (1 day) inhalation endpoint was selected from a developmental rabbit study with a LOAEL based on agenesis of the gall bladder and increased incidence of fused sternebrae. Fetal effects are presumed to occur after one exposure. The human equivalent concentration used for the risk assessment was 10 ppm for a 24-hour time weighted average (TWA) to assess non-occupational bystanders and 30 ppm for an 8-hour TWA to assess occupational exposures. An uncertainty factor (UF) of 30 with a 3x for interspecies extrapolation and 10x for intraspecies variation was employed in the human health risk assessment. Please see the Agency's April 11, 2007 risk assessment and other human health risk documents listed at the end of this section for a more detailed explanation of the toxicity endpoints.

In assessing risks from methyl bromide, the Agency considered multiple lines of evidence, using the best available information from monitoring studies, modeling tools, and from incident reports.

- Monitoring: For the human health risk assessments completed for methyl bromide and the other soil fumigants within the group, several field-scale monitoring studies were considered, as well as monitoring of workers and handlers involved in various tasks. These studies quantify methyl bromide concentrations in and around fields at various times and distances during and after applications. Many of these data indicate that there can be risks of concern associated with methyl bromide use at a broad range of distances

from treated fields. However, these data are limited in their utility because they provide results only for the specific conditions under which the study was conducted.

- Modeling: Models enable the use of data from monitoring studies to estimate concentrations and potential risks under a wide range of conditions and use patterns. EPA used the Version 2.1.4 of the **P**robabilistic **E**xposure and **R**isk model for **Fum**igants (also called the PERFUM model), to evaluate potential risks at distances around treated fields. PERFUM incorporates actual weather data and flux distribution estimates, then accounts for changes and altering conditions. Analyses based on a variety of model outputs were used to compare the potential risks at a range of distances. The PERFUM model and users manual are public domain and can be downloaded at http://www.exponent.com/perfum/.

- Bystander, handler, and worker incident reports: Incidents for the soil fumigants generally occur at a low frequency relative to the total number of fumigant applications performed annually. However, when incidents occur, there are often many people involved. Incidents involving handlers and workers tend to occur more often than incidents with bystanders.

  Reconstructing incidents to examine the exact factors which led to the incident can be difficult, especially when bystanders are involved since all the factors that contributed to the incident may not have been documented. Some of the factors that have been linked to incidents in the past have included equipment failure, handler accidents, applicator failure to adhere to label recommendations and/or requirements, and temperature inversions. Incidents have occurred to bystanders close to fields and up to two miles away from the fumigated field.

Based on these lines of evidence, and as described in more detail in the risk assessments, EPA has determined that methyl bromide risks to handlers, workers, and bystanders are of concern given current labels and use practices. The human health risk assessments indicate that inhalation exposures to bystanders who live and work near agricultural fields and greenhouses where methyl bromide fumigations occur have the potential to exceed the Agency's level of concern without additional mitigation measures. There are also risks of concern for occupational handlers involved in methyl bromide applications and tarp perforation/removal activities, and for workers who may re-enter treated area shortly after fumigation or tarp perforation has been completed.

For more information about the specific information in the Agency's human health risk analyses, refer to the documents listed below:

- EPA-HQ-OPP-2005-0123-0285, Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Soil, Greenhouse, and Residential/Structural Uses
- June 2, 2008 addenda to April 10, 2007 Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Soil, Greenhouse, and Residential/Structural (DP Barcode: D350818)

- June 9, 2008 memo, Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach (DP Barcode: 306857)
- EPA-HQ-OPP-2005-0123-0317, Review of Fumigants Group Incident Reports
- EPA-HQ-OPP-2005-0123-0318, Summary Fumigants Group Incident Reports
- EPA-HQ-OPP-2005-0123-0319, Summary Fumigants Group Incidents

C. Stratospheric Ozone Depletion

In addition to methyl bromide's direct effects previously described in Section B on page 12, methyl bromide soil fumigant uses pose indirect chronic health risks, and is being phased out internationally, because it depletes the stratospheric ozone layer.

Ozone-depleting substances, including methyl bromide and other halogenated gases such as chlorofluorocarbons (CFCs), halons, and hydrochlorofluorocarbons (HCFCs), are very stable in the lower atmosphere. They eventually drift into the stratosphere, where they undergo a series of cyclical reactions that destroy ozone. In the presence of ultraviolet light, halogenated source gases react to release chlorine or bromine atoms, which quickly break down ozone molecules while producing the free radicals bromine monoxide (BrO) or chlorine monoxide (ClO). These chemicals continue to react and eventually regenerate the original bromine or chlorine, which begin the cycle again – enabling one chlorine or bromine atom to destroy 100,000 ozone molecules before being removed from the stratosphere.

The 2006 *Scientific Assessment of Ozone Depletion*, produced by the U.N. Environment Programme and the World Meteorological Organization, is the consensus work of hundreds of atmospheric scientists, many of them U.S. experts. The Executive Summary of the 2006 Assessment, released on August 18, 2006, noted that "bromine continues to play a major role in stratospheric ozone depletion" and that "methyl bromide abundance decreased by 14% between 1997 and 2004. This decrease was larger than expected and suggests that when anthropogenic emissions of bromine are reduced, its atmospheric abundance decreases more than previously thought."

Thinning of the ozone layer leads to an increase in ultraviolet (UV) radiation reaching the earth's surface, leading to increased incidence of skin cancer, cataracts, immunosuppression, and other ecological and economic impacts.

The Agency has previously undertaken and provided analyses of methyl bromide's role in stratospheric ozone depletion including estimates of mortalities and incidences of skin cancer.

These analyses were based in part, on the Atmospheric Health Effects Framework (AHEF). For more information about the specific information in the Agency's assessment of stratospheric ozone depletion, refer to the following documents:

- EPA-HQ-OPP-2005-0123-0165, Methyl Bromide: Science of Ozone Depletion and Health Effects Estimates
- EPA-HQ-OPP-2005-0123-0166, Human Health Benefits Of Stratospheric Ozone Protection

- EPA-HQ-OPP-2005-0123-0167, Regulatory Impact Analysis, Protecting Stratospheric Ozone: Process for Exempting Critical Uses from the Phaseout of Methyl Bromide
- EPA-HQ-OPP-2005-0123-0168, OAP's Economic Impact Analysis For Methyl Bromide Allocation In The United States
- EPA-HQ-OPP-2005-0123-0169, OAP's Benefits Analysis

The AHEF model predicts mortality and incidence for increased emissions of compounds that deplete stratospheric ozone, projects impacts of increased emissions on stratospheric ozone, models resulting changes in ground-level UV radiation, and uses a dose-response relationship to project incremental skin cancer mortality and incidence.

The AHEF model was peer-reviewed by EPA's EPA Science Advisory Board (SAB) several times for use in various regulatory decisions, most recently in 2003. The final SAB reports for the peer reviews are available on the EPA's internet site[4]. All comments of the peer reviewers were considered, and the AHEF was modified appropriately.

The starting point in the AHEF modeling performed by EPA assumed the total amount of methyl bromide applied in the US was 23,000,000 lbs (10,433 metric tons). As required by the Montreal Protocol the amount of methyl bromide applied, produced, and stockpiled has decreased since 2004 and is expected to continue to decline until supplies are exhausted. The Agency modeled 5 scenarios for continued methyl bromide use from 2005-2037, ranging from no drawdown (continued use at 23,000,000 lb per year) to full phase-out of all uses by 2017. For all uses, depending on the use scenario, 125 to 797 deaths and 24,221 to 155,020 incidences of skin cancer from 2005-2100 were estimated.

Skin cancer is the most common form of cancer in the U.S., with more than 1,000,000 new cases diagnosed annually[5]. Melanoma, the most serious form of skin cancer, is also one of the fastest growing types of cancer in the U.S.; melanoma cases in this country have more than doubled in the past two decades, and the rise is expected to continue[6]. In 2007, invasive melanoma was expected to strike more than 59,000 Americans and kill more than 8,000[7].

Nonmelanoma skin cancers are less deadly than melanomas, but left untreated they can spread, causing disfigurement and more serious health problems. The most common nonmelanoma skin cancer - basal cell carcinoma - grows slowly and rarely spreads to other parts of the body but can penetrate to the bone and cause considerable damage. Squamous cell carcinomas, by comparison, can develop into large masses and can spread to other parts of the body.

Actinic keratoses are skin growths that occur on body areas exposed to the sun, particularly the face, hands, forearms, and the "V" of the neck. Although premalignant, actinic

[4] EPA Science Advisory Board reports, http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD
[5] National Cancer Institute, "Common Cancer Types," at www.cancer/gov/cancertopics/commoncancers
[6] Ries, L., Eisner, M.P., Kosary, C.L., et al, eds. SEER Cancer Statistics Review, 1973-1999. Vol 2003. Bethesda (MD): National Cancer Institute; 2002.
[7] National Cancer Institute, "Melanomas," at www.cancer/gov/cancertopics/types/melanoma

keratoses are a risk factor for squamous cell carcinoma. Chronic exposure to the sun also causes premature aging, which over time can make the skin become thick, wrinkled, and leathery.

Research has shown that UV radiation increases the risk of certain cataracts - a form of eye damage in which a loss of transparency in the lens of the eye clouds vision. Other kinds of UV-related eye damage include pterygium (tissue growth that can block vision), skin cancer around the eyes, and degeneration of the macula (the part of the retina where visual perception is most acute).

Scientists have found that overexposure to UV radiation may suppress proper functioning of the body's immune system and the skin's natural defenses. All people, regardless of skin color, might be vulnerable to effects including impaired response to immunizations, increased sensitivity to sunlight, and reactions to certain medications.

Because of these impacts, methyl bromide and other ozone-depleting substances are being phased out worldwide under the Montreal Protocol on Substances that Deplete the Ozone Layer, the international agreement designed to reduce and eliminate the production and consumption of stratospheric ozone-depleting substances. The U.S. was one of the original signatories to the 1987 Montreal Protocol and the U.S. Senate ratified the treaty in 1988. The Clean Air Act Amendments of 1990, which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, ensure that the United States could satisfy its obligations under the Protocol.

In the United States methyl bromide is classified as a “Class I” ozone-depleting substance due to its high ozone depletion potential (ODP). A substance’s ODP is a measure of its ability to destroy stratospheric ozone molecules. The other Class I substances, such as chlorofluorocarbons (CFCs), halons, and carbon tetrachloride, were almost completely phased out in the 1990s. Methyl bromide is the only remaining Class I substance still commonly produced and used in the United States.

Under the Montreal Protocol, the U.S. and other developed countries were required to reduce the quantity of methyl bromide produced and consumed, relative to a 1991 consumption baseline, by 25 percent in 1999, 50 percent in 2001, 70 percent in 2003, and 100 percent (full phase out) by 2005.

The Montreal Protocol provides some exemptions from the phaseout. The first is an exemption permitting limited production and import of methyl bromide to meet critical uses for which technically and economically feasible alternatives are not yet available. The critical use exemption is designed to permit the production and import of methyl bromide for uses that do not have technically and economically feasible alternatives. In 2004, EPA established the framework for the critical use exemption; listed the approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from stocks and new production or import to meet the needs of approved critical uses. Since then, through the notice-and-comment rulemaking process, EPA has authorized critical uses of methyl bromide on an annual basis.

In Decision IX/6 (1997), the Parties to the Montreal Protocol agreed that "a use of methyl bromide should qualify as 'critical' only if the nominating Party determines that: (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and (ii) there are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and public health and are suitable to the crops and circumstances of the nomination." These criteria are reflected in EPA's definition of "critical use" at 40 CFR 82.3.

Under the annual critical use process, applicants requesting critical use exemptions provide data on the technical and economic feasibility of alternatives, their use of methyl bromide, research programs into the use of alternatives to methyl bromide, and efforts to minimize methyl bromide use and emissions. EPA reviews this information, as well as other data from governmental and academic sources, to establish whether there are technically and economically feasible alternatives available for a particular use of methyl bromide and whether there would be a significant market disruption if no exemption were available. In addition, EPA reviews other parameters of the exemption applications such as dosage and emissions minimization techniques and applicants' research or transition plans. Following this assessment, the U.S. Government submits the critical use nomination to the United Nations Environment Programme (UNEP) Ozone Secretariat. The Methyl Bromide Technical Options Committee (MBTOC) and the Technical and Economic Assessment Panel (TEAP), independent advisory bodies to Parties to the Montreal Protocol, review critical use nominations and make recommendations to the Parties, which then authorize critical uses and amounts. As required in Section 604(d)(6) of the Clean Air Act, for each exemption period, EPA consults with the United States Department of Agriculture and other federal agencies, and provides an opportunity for public comment on the amounts of methyl bromide that the Agency has determined to be necessary for critical uses and the uses that the Agency has determined meet the criteria of the critical use exemption.

A second exemption currently in use under the Montreal Protocol is an exemption for methyl bromide that is used for quarantine and preshipment (QPS). QPS fumigation is used for rapid treatment of imports and exports such as fresh fruits, vegetables, flowers, timber, and grains where necessary to meet official quarantine or sanitary requirements in other jurisdictions. An example of a quarantine use is the fumigation of commodities such as rice and spices that are subject to infestation by a specific and officially-recognized quarantine pest. Quarantine fumigation prevents the introduction of specific quarantine pests into a defined geographical area, such as an importing country. An example of a preshipment use is application to wheat because of official phytosanitary requirements at the shipment destination.

The Montreal Protocol also provides for a narrow "emergency use" exemption, under which a Party may produce or import up to 20 metric tons of methyl bromide to address an emergency event. This use, however, is to be subsequently reviewed by the Parties according to critical use criteria. EPA has not promulgated a regulation for the implementation of an emergency use exemption. An emergency use exemption would offer limited benefits given the strict Montreal Protocol criteria and limitations placed on its application.

D. Environmental Fate and Ecological Risks

The Agency's environmental fate and ecological effects risk assessments indicate that there are some concerns for non-target organisms that may be exposed to methyl bromide. For more information about the specific information in the Agency's assessment of environmental fate and ecological risks, refer to the following documents:

- EPA-HQ-OPP-2005-0123-0029, Revised Draft Methyl Bromide Environmental Fate and Ecological Risk Assessment - Following the Review of 30-Day Error Correction Comments
- EPA-HQ-OPP-2005-0123-0038, Reregistration Environmental Risk Assessment for Methyl Bromide

Since methyl bromide is highly volatile and is a gas at room temperature and standard pressure, inhalation of vapor following soil fumigation is the major exposure pathway for non-target mammals and birds. For aquatic organisms, exposure in surface water could result from runoff with soluble methyl bromide from fumigated fields.

The acute aquatic endangered species Level of Concern (LOC) is exceeded for aquatic invertebrates. However, the PRZM model does not account for the reduction in exposure that would likely result from using tarps. This reregistration eligibility decision requires tarps for all methyl bromide applications except for California Orchard Replant.

1. Hazard

Methyl bromide is considered moderately toxic to birds (oral LD50 is 73 mg ai/kg) and mammals (oral LD_{50} is 86 mg/kg) from oral exposure. No acute inhalation studies were available in registrant studies or in open literature studies for birds, so inhalation toxicity has been estimated based on the oral and inhalation data from mammals compared to the oral data for birds. For mammals, the LC_{50} for methyl bromide from the inhalation route is 780 ppm.

Methyl bromide is slightly to moderately toxic to fish by acute exposure (LC_{50} is 3.9 mg/L), and to aquatic invertebrates (LC_{50} of 2.6 mg/L). The no observed adverse effect level in a chronic fish toxicity study was 0.1 ppm. An unpublished aquatic plant study performed with a single species of algae resulted in an acute LC_{50} of 2.2 ppm[8].

2. Exposure

a. Terrestrial Exposure

The Industrial Source Complex Short Term (ISCST3) model together with historical air monitoring data was used to evaluate the range of methyl bromide air concentrations which might be found under different conditions of application rate, weather, source size and shape (e.g., field size in acres), tarping and distance from treated fields. The PERFUM model, which is described in the Human Health Risk Section, was not used to estimate exposures since terrestrial

[8] Data on the toxic effects of methyl bromide to algae are only available from a single study (Canton et al. 1980), which appears to be an internal report and not published in the peer-reviewed literature

acute risks of concern were not identified based on ISCST3 modeling (see Terrestrial Risks Section 3.a. for further details).

b. Aquatic Exposure

The aquatic exposure assessment for methyl bromide relied on Tier II aquatic models. The Pesticide Root Zone Model (PRZM version 3.12) simulates fate and transport on the agricultural field, while the water body is simulated with Exposure Analysis Modeling System (EXAMS version 2.98). Simulations are run for multiple (usually 30) years and the reported EECs represent the values that are expected once every ten years based on the thirty years of daily values generated during the simulation.

PRZM/EXAMS simulates a 10 hectare (ha) field immediately adjacent to a 1 ha pond, 2 meters deep with no outlet. The location of the field is specific to the crop being simulated using site specific information on the soils, weather, cropping, and management factors associated with the scenario. The crop/location scenario in a specific state is intended to represent a high-end vulnerable site on which the crop is normally grown. Based on historical rainfall patterns, the pond receives multiple runoff events during the years simulated. PRZM has limited capabilities in capturing the amount of a volatile chemical in air, water and sediment. The estimated concentrations of chemicals like methyl bromide in surface water bodies may be upper bound.

To simulate field application of methyl bromide, multiple scenarios were selected, including Florida strawberry, California tomato and California grape scenarios that were assessed with an application rate of 400 lbs ai/A. A North Carolina tobacco scenario was also assessed at the maximum rate of 855 lbs ai/A. The scenarios with the highest exposure of methyl bromide were the California tomato and Florida strawberry scenarios, even though the maximum application rate for the North Carolina tobacco scenario was more than twice as high.

There is an uncertainty in estimating methyl bromide exposure in water bodies due to post-application tarping of the treated area. If tarping is used to minimize the volatilization of methyl bromide, the loading of the chemical through runoff will be limited until the tarp is sliced or removed from the field. The present version of PRZM model has limited capabilities in simulating the transport of a volatile chemical escaping the soil after removal of a tarp, and the resulting surface-water concentrations should be considered upper-bound values.

3. Risk

a. Terrestrial Risk

The most likely route of exposure to methyl bromide for terrestrial animals is through inhalation of methyl bromide volatilizing from a treated field. The concentration of methyl bromide in air used in the assessment came from two sources. The first represented the highest concentration measured in field monitoring studies. This value of 27 ppm was detected in a 1987 study in which air concentrations 25 feet from a treated mill were measured 5 to 90 minutes after fumigation. Available historical monitoring after soil fumigations resulted in concentrations ranging as high as 3.35 ppm. The second source of concentrations used in the

terrestrial risk assessment was based on air dispersion modeling, which estimated a concentration of about 9.1 ppm adjacent to a 40-acre field treated with 400 lb ai/A of methyl bromide.

These concentrations were compared to acute inhalation toxicity values to evaluate potential risk. Mammalian acute inhalation toxicity data were available, but avian acute inhalation toxicity endpoints had to be estimated using the mammalian inhalation and oral toxicity data, avian oral toxicity data, and a factor used to account for inhalation physiology differences between birds and mammals. The Agency has not set a LOC for inhalation exposure, but the resulting RQs for both estimated air concentrations were below the standard acute LOCs of 0.1 and 0.5 used for dietary risk assessments. The Agency will require that avian inhalation acute toxicity studies be submitted to confirm the results of this risk assessment performed with estimated toxicity endpoints.

The volatility of methyl bromide causes it to disperse quickly from a treated field when it is not constrained to remain in the soil. However, it is possible that animals could potentially be exposed repeatedly if their range were to extend over several adjacent fields which were treated over multiple days. Available toxicity data from the dog 5 to 7 week inhalation test resulted in a no observed effect level of 5.3 ppm, which was higher than the peak short-term concentration from soil treatments observed in historical data, and higher than a range of ambient air concentrations found in historical monitoring data.

b. Aquatic Risk

The only aquatic risks that were above the Agency's LOC are the acute risk to endangered or threatened aquatic invertebrates species. The acute aquatic listed species LOC (0.05) is exceeded for aquatic invertebrates in two of the four modeled scenarios (CA tomatoes, 0.06 and FL strawberries, 0.07), but not with CA grapes or NC tobacco. However, the PRZM model does not account for the reduction in exposure that would likely result from tarping the field immediately after methyl bromide application. Given the low levels of exceedence (RQs of 0.06 to 0.07), the potential effect of tarping will likely lower the RQs values below the LOC.

Bromide ion is one degradation product of methyl bromide that is formed in soil. The risk assessment evaluated the potential for risk to aquatic organisms from bromide ion generated by methyl bromide degradation using the Tier 1 surface-water exposure model GENEEC. This assessment calculated the potential concentration from runoff that could occur from the highest application rate of 575 lb ai/A, assuming that 20% of applied methyl bromide is lost to volatilization, and that the remainder of the methyl bromide degrades to bromide ion on site. This conservative screening assessment resulted in an EEC of 5.4 ppm, which is below the most sensitive available toxicity endpoint of 7.8 ppm, for chronic risk to freshwater invertebraes. The next lowest bromide ion toxicity endpoint for aquatic animals was an order-of-magnitude less sensitive.

E. Benefits

Soil fumigation can provide benefits to both food consumers and growers. For consumers it means more fresh fruits and vegetables can be cheaply produced year-round

because severe pest problems can be efficiently controlled. Growers benefit because crops grown in fumigated soil produce fewer blemished products, which translates into an increase in marketable yields. Fumigation can also provide benefits to growers by increasing crop management flexibility. This includes shorter crop rotational intervals (i.e., less time when fields are left fallow), improved ability to meet quarantine requirements (which are imposed when states or other jurisdictions require a pest-free harvested product), and consistent efficacy against critical pests. The magnitude of benefits depends on pest pressure, which varies over space and time, and the availability and costs associated with the use of alternatives.

There are a number of benefits assessments that have been completed by the Agency to estimate the value of these chemicals to various industries. Below is a list of the specific benefits assessments that include methyl bromide.

- EPA-HQ-OPP-2005-0123-0321, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Metam-Sodium, and Methyl Bromide in Eggplant Production
- EPA-HQ-OPP-2005-0123-0322, Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries
- EPA-HQ-OPP-2005-0123-0323, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, Dazomet, Metam Potassium and Metam Sodium for Use in Raspberry Nurseries, Fruit and Nut Deciduous Tree Nurseries, and Rose Bush Nurseries in California
- EPA-HQ-OPP-2005-0123-0324, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam-sodium In Onion Production
- EPA-HQ-OPP-2005-0123-0325, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Grape Production
- EPA-HQ-OPP-2005-0123-0326, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Tree Nut Production
- EPA-HQ-OPP-2005-0123-0327, Assessment of the Benefits of Soil Fumigation with Chloropicrin, and Methyl Bromide In Pome Fruit Production
- EPA-HQ-OPP-2005-0123-0328, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium In Stone Fruit Production
- EPA-HQ-OPP-2005-0123-0329, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-Sodium in Bell Pepper Production
- EPA-HQ-OPP-2005-0123-0330, Assessment of the Benefits of Soil Fumigation with Metam-sodium in Potato Production
- EPA-HQ-OPP-2005-0123-0331, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium In Strawberry Production
- EPA-HQ-OPP-2005-0123-0332, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production
- EPA-HQ-OPP-2005-0123-0333, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium In Sweet Potato Production
- EPA-HQ-OPP-2005-0123-0334, Assessment of the Benefits of Soil Fumigation with Chloropicrin In Tobacco Production

- EPA-HQ-OPP-2005-0123-0335, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium in Tomato Production
- EPA-HQ-OPP-2005-0123-0336, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Carrot Production
- EPA-HQ-OPP-2005-0123-0337, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production
- EPA-HQ-OPP-2005-0123-0338, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production
- EPA-HQ-OPP-2005-0123-0339, Summary of the Benefits of Soil Fumigation with Methyl Bromide in Crop Production
- EPA-HQ-OPP-2005-0123-0340, BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing methyl bromide.

The Agency has completed its assessment of the dietary (water), residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient methyl bromide. Dietary (food) risks were assessed in the 2006 Methyl Bromide TRED/RED and associated tolerances were reassessed[1]. The TRED/RED, which covered commodity fumigation, included similar mitigation measures required in this document (e.g., fumigation management plans, buffer zones, respiratory protection, air monitoring, etc.). The uses covered by this document (i.e., those not included in the TRED/RED) are not considered food/feed uses and do not have associated tolerances. In addition to the risk assessments, the Agency completed benefit assessments on crops with significant methyl bromide usage[9].

In Phase 5, the Agency published a risk mitigation options paper[10]. This document detailed potential mitigation options and sought public comment on these options. The following is a list of potential mitigation discussed in the Agency's paper:

- Buffer zones;
- Sealing methods;
- Timing of applications;
- Application block size limitations;

[9] EPA-HQ-OPP-2005-0123-0340, BEAD's Planned Impact Assessments on Agricultural Site with Significant Use of Soil Fumigants

[10] EPA-HQ-OPP-2005-0123-0282, Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications

- Respiratory protection;
- Tarp cutting/removal procedures;
- Entry-restricted period;
- Application method/practice restrictions;
- Fumigant management plans (FMPs);
- FMP certification;
- Responsible parties;
- Record keeping/reporting/tracking;
- Restricted Use Pesticide Classification (this option does not apply to methyl bromide, since it is already a RUP).
- Notification and posting;
- Good agricultural practices;
- Fumigant manuals; and
- Stewardship programs.

Based on a review of the methyl bromide data base and public comments on the Agency's assessments for the active ingredient methyl bromide, the Agency has sufficient information on the human health, ecological effects, stratospheric ozone depletion, and benefits of methyl bromide to make decisions as part of the reregistration process under FIFRA. For the purposes of determining reregistration eligibility, methyl bromide uses have been placed into two groups:

- **Group 1** includes only methyl bromide uses, users, and locations that qualify for exemptions under the Montreal protocol (see http://www.epa.gov/ozone/mbr/cueuses.html for further details on methyl bromide uses that qualify for critical use exemptions)

Given the high acute risks associated with methyl bromide use and methyl bromide's status as an ozone depleting substance which contributes to the destruction of stratospheric ozone and incidence of skin cancer, EPA has determined that only uses with very high benefits and no economically or technologically feasible alternatives are eligible for reregistration. The robust processes set forth in the Montreal Protocol and EPA's implementing regulations for determining the critical uses of methyl bromide, and for identifying uses with economically and technologically feasible alternatives, provide a clear picture of uses for which methyl bromide has very high benefits (for further details see "The 2010 Critical Use Exemption Nominations from the Phaseout of Methyl Bromide" at http://www.epa.gov/ozone/mbr/cueinfo.html). Based upon those analyses, EPA has determined that the uses in Group 1, those that qualify for exemptions under the Montreal protocol, have benefits which justify reregistration eligibility.

Because of their high benefits, the Agency has determined that Group 1 uses of methyl bromide will not pose unreasonable risks or adverse effects to humans or the environment provided that the risk mitigation measures and label changes outlined in this RED are implemented. Therefore, products containing methyl bromide for these uses are eligible for reregistration as long as they are granted CUE and QPS status under the Montreal Protocol. Required label changes are described in Section V of this document. The Agency has determined that any Group 1 uses that no longer qualify for CUE and QPS status should be

canceled. The list of critical uses of methyl bromide, as well as the limiting critical conditions for its use, is found in 40 CFR Part 82, Subpart A, Appendix L.

- **Group 2** uses are uses that do not qualify for exemptions under the Montreal Protocol. The import or production of new methyl bromide for these uses is prohibited. Currently, only methyl bromide produced before 2005 and stockpiled may be used for Group 2 use-sites.

Based on a consideration of the risks and benefits, EPA has determined that Group 2 uses are not eligible for reregistration. Substantial information currently available to EPA as a result of (1) the exemption processes under the Montreal Protocol, (2) OPP's benefits assessments for the soil fumigants, and (3) public comments provided during OPP's Six-Phase Public Participation Process for methyl bromide's reregistration review, indicates that these uses do not have high benefits and/or have economically and technologically feasible alternatives.

The Agency has determined that use sites in Group 2 for which no data is available to demonstrate high benefits should be canceled following completion of the comment period on this RED and EPA's consideration of those comments to determine whether sufficient benefits data on any additional Group 2 uses warrant reconsideration of any part of this decision. If stakeholders are able to provide new information during the comment period on this decision indicating that certain uses have high benefits and/or do not have feasible alternatives, EPA will consider whether to allow continued use for a finite period of time to allow for the orderly transition among users to alternate pest control products and/or methods.

Should methyl bromide registrants request voluntary cancellation of some or all of these uses under Section 6(f) of FIFRA, there will also be a public comment period on that request before a cancellation order is issued by EPA. If registrants do not request voluntary cancellation and EPA does not receive data to support continued use on these sites until existing stocks are depleted, EPA will take additional regulatory action.

EPA believes that eliminating Group 2 uses will reduce the total amount of methyl bromide applied in the US, and therefore reduce the incidence of skin cancer resulting from stratospheric ozone depletion. EPA estimates that in 2007 approximately 291 metric tons and in 2006 approximately 1519 metric tons of methyl bromide was applied for uses with low benefits and/or have feasible alternatives and which do not qualify for exemptions under the Montreal Protocol. While the Agency acknowledges that limiting use to only Group 1 uses may slow the drawdown of the pre-2005 stockpile, it is reasonable to expect that new production for exempted uses will also continue to decline as there will be more pre-2005 stockpile material available for critical uses.

Based on its evaluation of methyl bromide, the Agency has determined that methyl bromide products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of methyl bromide. If all changes outlined in this document are incorporated into the product labels, then current risks for methyl bromide will be adequately mitigated for the purposes of this determination under FIFRA.

A substantial amount of research is currently underway or is expected to begin in the near term to (1) address current data gaps, and (2) refine understanding of factors that affect fumigant emissions. Additionally, a number of new methods and technologies for fumigation are emerging. EPA plans to move the soil fumigants forward in Registration Review, from 2017 to 2013, which will allow EPA to consider new data and information relatively soon, determine whether the mitigation included in this decision is effectively addressing the risks as EPA believes it will, and to include other soil fumigants which are not part of the current fumigant group review.

The Registration Review process for methyl bromide and the other soil fumigants will also include a comprehensive endangered species assessment. Once that endangered species assessment is completed, further changes to methyl bromide labels may be necessary.

B. Public Comments and Responses

The Phase 3 public comment period on the preliminary risk assessments and related documents lasted from July 13 through October 12, 2005. EPA-HQ-OPP-2005-0123-0284 contains the Agency responses to Phase 3 public comments related to methyl bromide soil uses.

After the Phase 3 comment period, the Agency revised the human health risk assessment, completed benefit assessments, and developed risk mitigation options. These documents were put out for public comment on May 2, 2007 and the comment period ended on November 3, 2007. Comments on issues which were significant to many stakeholders and directly influenced EPA's decisions are highlighted in this decision document, as well as EPA's responses to those comments. The following documents include the EPA's responses to comments. These documents are located in the methyl bromode docket, EPA-HQ-OPP-2005-00123.

- HED Component of Response To Comments Document On Methyl Bromide Phase 5 Fumigant Risk Assessment (DP Barcode 353907)
- Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants (DP Barcode 353940)
- Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide. June 25, 2008. (DP Barcode 353940)
- SRRD's Response to Phase 5 Public Comments for the Soil Fumigants (July 2008)

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that Group 1 methyl bromide uses described above are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. This decision considers the risk assessments conducted by the Agency and the significance of methyl bromide use.

As detailed in Section III on page 12, there are risks of concern to humans and the environment resulting from methyl bromide use. Understanding these risks and also the benefits of methyl bromide (also outlined in Section III), the Agency's goal for this decision is to be protective, especially of severe and irreversible effects, encourage best practices, and to reduce the potential impacts on benefits. To reach this goal, EPA considered a range of factors including:

- characteristics of bystander and other populations exposed to methyl bromide;
- hazard characteristics of methyl bromide (the methyl bromide endpoint is based on a severe and irreversible effect);
- hazard characteristics of chloropicrin (the chloropicrin endpoint is based on a minor and reversible symptom, eye irritation) since all products are formulated with at least 2% chloropicrin;
- methyl bromide's ozone depletion potential;
- the phasing out of methyl bromide under the Montreal Protocol,
- available information on levels of exposure, feasibility, cost, and effectiveness of various risk mitigation options;
- bystander, handler and worker incident reports;
- potential impacts of mitigation on growers ability to produce crops;
- uncertainties and assumptions underlying the risk and benefit assessments; and
- public comments.

Considering these factors, EPA determined that a suite of complimentary measures designed to reduce risks, along with a flexible approach allowing for some site-specific decisions, would best meet the overall objective of reducing risk and minimizing impacts on users.

The following is a summary of the rationale for managing risks associated with the use of methyl bromide. Where labeling revisions are warranted, specific language is set forth in the summary table in Section V of this document.

a. Generic Risk Management

Restricting use sites, reducing maximum applications rates, limiting formulations with high percentages of methyl bromide to specified crops/use sites, and only allowing untarped application with California orchard replant are described below. These mitigation measures will reduce risks for handlers, bystanders, and workers (i.e., human health) as well as ecological and stratospheric ozone risks.

Good agricultural practices (GAPs), fumigant management plans (FMPs), and a stewardship/training program ensure consistent achievement of sound fumigation applications which are the foundation to minimizing the potential for adverse effects to bystanders, handlers, and worker risks and are described below in Section III, *Other Mitigation* (page 61).

1) Use Sites

Any methyl bromide uses that do not currently qualify for exemptions under the Montreal Protocol (i.e., critical use, quarantine and pre-shipment, or other exempted uses) are not eligible for reregistration. The following describes the rationale for this decision:

- Given the risks associated with methyl bromide use, this decision preserves uses with high benefits and no alternatives, and eliminates uses with lower benefits and/or alternatives;
- This decision reconciles inconsistency between phase-out of methyl bromide production and EPA registered uses;
- This decision does not inhibit methyl bromide use that growers and the international community have determined to be critical and that are permitted under the Montreal Protocol;
- This decision restricts the use of stockpiled methyl bromide to uses with high benefits, critical uses, and other exempted uses; and
- Along with other mitigation, this decision contributes to the reduction of methyl bromide use and thus the reduction of stratospheric ozone depletion and associated skin cancers (see stratospheric ozone depletion risk management section on page 80 of Section IV for further details).

2) Formulations

The Agency's risk assessment for methyl bromide indicates that risks for the 98:2 (methyl bromide:chloropicrin) formulations are higher than for other formulations. When 98:2 formulations are used, the amount of methyl bromide applied is generally higher compared to amount applied for other formulations which results in higher human health, ecological, and stratospheric ozone risks. Additionally, EPA is concerned that 2% chloropicrin is not adequate to be an effective warning agent[11]. Therefore, the Agency has decided to only reregister 98:2 formulations for uses that have been determined to be essential, which include:

- Orchard replant
- Ornamentals (hot gas method only)
- Forest seedlings
- Quarantine uses

The Agency is asking for stakeholders to comment regarding other current uses of 98:2 formulations and whether other formulations can be used effectively.

3) Application Methods

The Agency is requiring that in all cases, except very limited circumstances, that methyl bromide applications be tarped. The human health risk assessment indicates that untarped shank applications for typical rates and application blocks result in bystander risks that exceed the

[11] June 2, 2008 addenda to April 10, 2007 Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Soil, Greenhouse, and Residential/Structural (DP Barcode: D350818)

Agency's LOC at significant distances from the field. These methods of application are rarely used in the U.S., and when they are used it is reported only for California orchard replant. Therefore, the Agency is allowing only deep (18 inches) untarped shank applications for California orchard replant uses that qualifies for a CUE or QPS exemption and tree-hole applications with deep (18 inches) injection auger probes. EPA is requiring tarps for all other methyl bromide applications that are shank injected or applied with the hot-gas method.

4) Maximum Application Rates

The Methyl Bromide Industry Panel (MBIP) and other stakeholders have acknowledged that current methyl bromide use rates are substantially less than the current maximum rates on registered labels. As a result, the Agency is requiring registrants to reduce the maximum application rates to rates that are currently used and shown to be efficacious. This will prevent future applications at rates greater than needed to effectively control target pests.

The Agency has analyzed information from the most recent critical use nominations (CUNs) and CUEs and is requiring registrants to amend labels to specify maximum label rates listed in **Table 1**. Maximum rates for QPS and emergency exemptions uses are not affected by this decision but must be identified on end use labels.

Table 1. Maximum Application Rates for Pre-plant Soil Methyl Bromide CUEs

Approved critical uses	Maximum Broadcast Equivalent Rates (lb ai/A)	
	New	Current
Eggplant	170	400
Cucurbits (including muskmelons, cantaloupe, watermelon, cucumber, squash, pumpkin, and gourds)	200	435
Forest Nursery Seedlings	260	870
Orchard Nursery Seedlings (raspberry, deciduous trees, roses)	200	435
Strawberry Nurseries	260	870
Orchard Replant [1] (walnuts, almonds, stone fruit, table and raisin grapes, wine grapes)	200	870
Orchard Replant (grapes)	250	870
Ornamentals	360	870
Pepper, Bell	170	480
Strawberry Fruit	200	870
Sweet Potato Slips	200	870
Tomato (grown for fresh market)	160	870

[1] The maximum application rate when applying methyl bromide to individual tree holes using handheld equipment is 1.5 lb ai/100 ft^2

b. Human Health Risk Management

For details on the methyl bromide human health risk assessment, please refer to the Human Health Risk Assessments and addenda for methyl bromide described in Section III of this document. These documents are also available in the public docket EPA-HQ-OPP-2005-0123, located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

The human health risk assessments indicate that inhalation exposures to bystanders who live and work near agricultural fields and greenhouses where methyl bromide fumigations occur and to handlers involved in the application of methyl bromide have the potential to exceed the Agency's level of concern without additional mitigation measures.

To reduce the potential for exposure to bystanders, handlers, and workers and to address subsequent risks of concern, EPA is requiring a number of mitigation measures which include:

- Removing of uses with low benefits and/or alternatives;
- Reducing maximum application rates;
- Limiting use of 98:2 formulations to essential crops;
- Buffer zones;
- Respiratory protection and air monitoring for handlers;
- Restrictions on the timing of perforating and removing tarps;
- Posting;
- Good agricultural practices;
- Fumigant management plans;
- Emergency preparedness and response plans; and
- Notice to state lead agencies;

The Agency also believes that registrant developed training and community outreach and education programs, which are also implemented by the registrant, will help reduce risk. Additionally, EPA is interested in working with registrants to identify additional measures that could be implemented as part of product stewardship. These additional measures should include efforts to assist users' transition to the new label requirements.

Some of the required mitigation measures only address one group of potentially exposed individuals (i.e., bystanders, handlers, or workers), while other measures will help reduce risk to more than one group. All mitigation measures are designed to work together to reduce exposures, enhance safety, and facilitate compliance and enforcement. The Agency has based its risk mitigation decision on a flexible approach which EPA believes will be protective and allow users to make site-specific choices to reduce potential impacts on benefits of the use. While some of these measures, buffer zones for example, can be used to estimate MOEs, others such as emergency preparedness and response and community education will contribute to bystander safety, but are difficult to express in terms of changes to quantitative risk estimates such as MOEs. However, EPA has determined that these measures, working together, will prevent unreasonable adverse effects on human health.

EPA recognizes that California has many similar requirements for methyl bromide but also includes permits for every application which are issued and administered by County

Agricultural Commissioners. California's approach has been effective at addressing bystander, handler, and worker risks.

1) Bystander Risk Mitigation

Bystanders are persons who live and/or work near fumigated fields and are potentially exposed to fumigant emissions that travel off-site. In some cases the bystanders are workers performing agricultural tasks in nearby fields. If they are employed by the grower who has control of the fumigated field, they are more likely to be aware that a fumigant application has occurred.

Bystander risks for people that live near treated fields differ from other human health risks evaluated under FIFRA, for example residential and worker reentry risks. Unlike residential exposures resulting from use of products to control pests in and around the home, non-occupational bystanders receive no direct benefit from the pesticide which was applied elsewhere. These bystanders have not made a decision to purchase a pest control product or service, and as a result they have little access to information about the product (e.g., hazards, safety information, first aid, etc.) or symptoms of exposure. Additionally, non-occupational bystander exposures to fumigants are largely involuntary and unanticipated. In this regard non-occupational bystander exposure is similar to dietary exposure in that people consuming foods or drinking water expect to be safe from possible adverse effects associated with pesticide residues that could be present in their food and drinking water.

Unlike workers, non-occupational bystanders typically receive no safety information or training related to the pesticide to which they may be exposed. Whereas workers are generally expected to play an active role in protecting themselves from pesticide risk, no such expectation exists for non-occupational bystanders. Workers who experience symptoms of pesticide exposure are also more likely to link their symptoms to the pesticide and take steps to receive appropriate treatment. Conversely, bystanders are much less likely to attribute adverse effects to pesticide exposures or to have access to information needed to take appropriate steps to mitigate the effects of the exposure. Thus, EPA's mitigation includes elements for emergency preparedness and response, notice to state lead agencies, training, and community outreach as well as labeling changes.

i. Buffer Zones

The human health risk assessment indicates bystanders may be exposed to methyl bromide air concentrations that exceed the Agency's level of concern. In general, the risk from inhalation exposures decreases as the distance from the field to where bystanders are located increases. Because of this relationship, the Agency is requiring that a buffer zone be established around the perimeter of each application block where methyl bromide is applied. The Agency acknowledges that buffer zones alone will not mitigate all inhalation risks and eliminate incidents caused by equipment failure, human error, and weather or other events (e.g., temperature inversions). The Agency however does believe that buffer zones along with other mitigation measures required by this decision described below will mitigate risks so that bystanders will not experience unreasonable adverse effects.

The Agency considered various buffer zone schemes ranging from fixed buffer zones for every application to site-specific buffer zones. During the most recent comment period, the Agency received input in favor of a flexible buffer approach that would allow fumigant users to determine the buffer zone distance based on site conditions and application practices. While the Agency believes that site-specific buffer zones would provide the most flexibility for users, the EPA currently does not have sufficient data to support this scheme. As a result, the Agency has developed a scalable buffer zone system that does provide flexibility by setting buffer zones for different application methods at various acreages and application rates. These rates have also been captured in "Look-up Tables" presented below [see Tables 2, 3, 4, 5 and 6 which begin on page 39].

Version 2.1.4 of the **P**robabilistic **E**xposure and **R**isk model for **Fum**igants (also called the PERFUM model) combined with monitoring data and incident data were used to characterize the risk for specific buffer zone distances corresponding to the range of application scenarios anticipated. A CD containing all of the PERFUM input/output files and files with the PERFUM MOE/air concentration analysis that were considered for this decision are available upon request at the OPP Docket Office. Additional information on the PERFUM inputs and outputs can be found in the Agency risk assessment[12], (EPA-HQ-OPP-2005-0123-0285), in a June 2006 a peer-reviewed article describing the model (http://www.sciencedirect.com/science/journal/13522310), and/or the PERFUM user's guide which can be download from the internet (http://www.exponent.com/perfum/).

(a) General Buffer Zone Requirements

The following describes the general buffer zone requirements for methyl bromide and other soil fumigants currently going through the reregistration process:

- "Buffer zone" is an area established around the perimeter of each application block or greenhouse where a soil fumigant is applied. The buffer zone must extend from the edge of the application block or greenhouse perimeter equally in all directions.
- All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the buffer zone period except for transit (see exemptions section).
- An "application block" is a field or portion of a field treated with a fumigant in any 24-hour period [see Figures 1 and 2 on page 36 for further explanation].
- The "buffer zone period" starts at the moment when any fumigant is delivered/dispensed to the soil within the application block and lasts for a minimum of 48 hours after the fumigant has stopped being delivered/dispensed to the soil.

Buffer zone distances

- Buffer zone distances must be based on look-up tables on product labels (25 feet is the smallest distance regardless of site-specific application parameters).

[12] EPA-HQ-OPP-2005-0123-0285, Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Soil, Greenhouse, and Residential/Structural Uses

- For selective replant fumigation in an orchard using hand held application methods (e.g., deep injection auger probes), the minimum buffer zone will be 25 feet measured from the center of each injection site (i.e., tree hole).

Authorized entry to buffer zones

- Only authorized handlers who have been properly trained and equipped according to EPA's Worker Protection Standard (WPS) and label requirements may be in the buffer zone during the buffer zone period.

Buffer zone proximity

- To reduce the potential for off-site movement from multiple fumigated fields, buffer zones from multiple methyl bromide application blocks may not overlap (including blocks fumigated by adjacent property owners, see below for exemptions for areas not under the control of owner/operator of application block).
- No fumigant applications will be permitted within 0.25 miles of schools, state licensed day care centers, nursing homes, assisted living facilities, elder care facilities, hospitals, in-patient clinics and prisons if occupied during the buffer zone period.

Exemptions for transit through buffer zones

- Vehicular and bicycle traffic on public and private roadways through the buffer zone is permitted. "Roadway" means that portion of a street or highway improved, designed or ordinarily used for vehicular travel, exclusive of the sidewalk or shoulder even though such sidewalk or shoulder is used by persons riding bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately. (This definition is based on the definition of roadway in the Uniform Vehicle Code prepared by the National Committee on Uniform Traffic Laws and Ordinances. See http://www.ncutlo.org/ for more details)
- Bus stops or other locations where persons wait for public transit are not permitted within the buffer zone.
- See the Posting Section on page 48 for additional requirements that may apply.

Structures under the control of owner/operator of the application block

- Buffer zones may not include buildings used for storage such as sheds, barns, garages, etc., **UNLESS,**
  1. The storage buildings are not occupied during the buffer zone period, and
  2. The storage buildings do not share a common wall with an occupied structure.
- See the Posting Section on page 48 for additional requirements that may apply.

Areas not under the control of owner/operator of the application block

- Buffer zones may not include residential areas (including employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas) **UNLESS,**
  1. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and
  2. Reentry by occupants and other non-handlers must not occur until,
     - The buffer zone period has ended, and

- Two consecutive air samples for methyl bromide have been taken in the structure at least 1 hour apart must indicate less than 1 ppm methyl bromide, and
- Two consecutive air samples for chloropicrin have been taken in the structure at least 1 hour apart must indicate than less than 0.15 ppm chloropicrin is present.

- Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, **UNLESS,**
  1. The owner/operator of the application block can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, and
  2. The owner/operator of the areas that are not under the control of the application provides written agreement to the applicator that they, their employees, and other persons will stay out of the buffer zone during the entire buffer zone period.
- Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields, etc), **UNLESS,**
  1. The area is not occupied during the buffer zone period,
  2. Entry by non-handlers is prohibited during the buffer zone period, and
  3. Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.
- See the Posting Section on page 48 for additional requirements that may apply.

(b) PERFUM Model Inputs

The major input parameters for the modeling are: application rates, application block sizes, application method emission profiles, weather conditions, and the target air concentration (based on acute inhalation endpoint and uncertainty factors). The following summarizes the key points for each of these *input* parameters.

- Rates

The Agency modeled up to 430 lb ai/acre for broadcast applications and 250 lbs ai/acre effective broadcast rate for bedded applications. Although labels permit higher broadcast equivalent rates, such values were not evaluated because the rates considered were found to be the upper bound of methyl bromide rates used. According to EPA proprietary data for 2004-2005, approximately 95% of methyl bromide was applied at a rate of 250 lb ai/acre or less. This is illustrated in the Agency's benefits assessments by crop and region that include a more detailed analysis of use rates. These assessments are available for review in the methyl bromide docket (EPA-HQ-OPP-2005-0123) at www.Regulations.gov. Values assumed for rates were based largely on recent critical use nominations (CUNs) and applications by grower groups for critical use exemptions (CUEs).

Rates for bedded or strip applications (lb ai per treated area) were converted to broadcast equivalent application rates to determine the minimum buffer zone distance. In Figures 1 and 2 (shown below), the dashed line represents the perimeter of the field, the shaded area is the portion of the field that is treated, and the un-shaded area is the area of the field that is untreated. Assuming that both fields are 10 acres, and only 50% of field in Figure 2 is fumigated, the *rate*

per treated acre is 400 lbs ai/A for both Figure 1 and 2. The *broadcast rate* for Figure 1 is 400 lb ai/A but the *effective broadcast equivalent rate* for Figure 2 is 200 lbs ai/A.

Labels may express rates as lbs per treated acre under the application instructions but they must identify buffer zone distances based on the broadcast or effective broadcast equivalent rates. [Note: In the risk assessment, a 60 percent value of field treated was used in the calculations.]

Figure 1. Broadcast Application

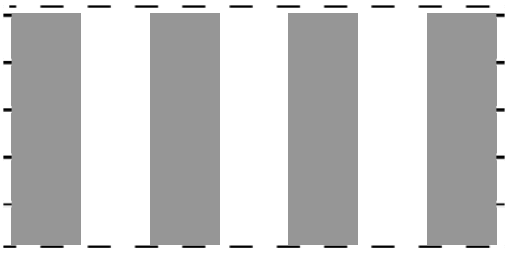


Figure 2. Bedded Application

- Block Sizes

The Agency has limited information available on the size of application blocks typically treated in a given day but estimates that each crew or application rig treats less than 40 acres for most treatment methods. However several commercial applicators have indicated they sometimes use multiple rigs and crews to treat blocks of more than 80 acres per day.

The application block size pertains to size of the field and not the size of the area treated. The area inside the dashed lines in both Figures 1 and 2 is the application block. In this example the application block size for both figures is 10 acres. For both figures, 10 acres would be used to determine the buffer zone distance.

- Emission Profiles

The Agency's risk assessment includes modeling of 5 outdoor pre-plant soil application methods: (1) tarped broadcast, (2) tarped bedded, (3) shallow untarped broadcast, (4) deep untarped broadcast, and (5) tarped hot gas. The modeling performed by EPA was based on 5 emission profiles developed by the California Department of Pesticide Regulation (CDPR) derived from 17 studies conducted in California from 1992 to 1999. Buffer zone distances for other application methods were also derived by the EPA from these profiles (e.g., buffer zone distances for strip applications were derived from broadcast emission profile). It should be noted that the profiles modeled do not reflect the performance of today's high barrier tarps. The profiles also may not be representative of some methods/equipment used outside California. In the U.S., tarped bedded and tarped broadcast are the most common methods, hot gas and deep untarped use is somewhat limited, while shallow untarped application is reportedly no longer used. Note that only tarped uses will be allowed henceforth except in limited circumstances as described in the Generic Risk Management sections above.

The Agency has modeled greenhouse pre-plant soil applications scenarios using a conservative estimate of the emission profile (see the June 2, 2008, addenda to April 10, 2007, Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Soil, Greenhouse, and Residential/Structural in the methyl bromide docket)

- Weather

The largest methyl bromide use in the US occurs in Florida and California followed by Michigan. Based on these high-use areas, five weather data sets were modeled (Ventura, CA;

Bakersfield, CA; Bradenton, FL; Tallahassee, FL; and Flint, MI). The California and Florida locations are intended to represent inland and coastal weather conditions. Each modeling run used five years of weather Data (e.g., 1825 potential application days) for each weather location. Generally, Ventura, and Bradenton weather data result in the largest buffer zone distances, followed by Bakersfield and Tallahassee. Flint, MI data resulted in significantly smaller buffers compared to the other four locations.

- Target Air Concentration

As described in Section III, a non-reversible acute inhalation endpoint was selected from a developmental rabbit study with a LOAEL based on agenesis of the gall bladder and fused sternebrae. The human equivalent concentration is 10 ppm for a 24-hour TWA with uncertainty factor of 30 (i.e., target MOE of 30 and a target air concentration of 0.33 ppm). Based on several factors including the severity, irreversibility of the effect, and the quality of the hazard database, the buffer zone distances chosen focused on achieving an MOE of 30 at upper percentiles of both whole field and maximum distance distributions (these terms are described below) from PERFUM modeling outputs, as well as achieving an MOE of 30 or greater at 99th percentile air concentration from PERFUM outputs.

(c) PERFUM Model Outputs

The PEFRUM model outputs are presented in percentiles for "whole field" and the "maximum distance" distributions. The model also provides outputs as distributions of air concentrations from which margins of exposure (MOEs) can be estimated. The following summarizes the key points for each of these *output* parameters.

The maximum distance distribution is a compilation of the farthest predicted distances (i.e., the farthest downwind points) over 5 years of weather. The whole field distribution differs because it includes all points around the perimeter of the application block for the same period. Another way to consider the difference between the distributions is that maximum distance results are a subset of the whole field results and that maximum distances allow for more resolution at the upper percentiles of this distribution. Version 2.1.4 of PERFUM also allows for direct consideration of air concentrations at various distances around treated fields. These air concentrations and MOEs were also considered in the decision making process.

An analysis based on a variety of PERFUM outputs was used in the buffer distance determinations. This involved consideration of the typical maximum and whole-field results, which are predictions of the distances where a target concentration of concern is achieved at varying percentiles of exposure. In addition, a complementary approach, which determined the percentiles of exposure for maximum and whole-field buffers at predetermined buffer distances, was employed. Air concentration data were also used to calculate risk estimates (i.e., MOEs) at predefined buffer distances and varied percentiles of exposure.

This overall approach allowed the Agency to utilize more of the information available from PERFUM so that a more comprehensive view of the risks could be considered. Buffer distances indicated by this type of analysis along with information from monitoring studies and

incidents were valuable in determining buffer distances to manage potential risks from methyl bromide use when coupled with other mitigation measures.

(d) Buffer Zone Distances

Because the methyl bromide target air concentration is based on a severe, irreversible effect, EPA believes it is important that the buffer zones required for methyl bromide result in an MOE of 30 at high percentiles of the of the PERFUM model outputs. EPA believes the buffer zone distances that achieve this result will be protective of all potentially exposed bystanders including females at a critical phase of pregnancy. MOEs for non-pregnant bystanders would be higher.

The Agency has developed required buffer zone distances based on application method, application rate, and application block size. These distances are summarized in Tables 2, 3, 4, 5 and 6.

For each of the outdoor pre-plant soil emission profiles, distances were first chosen for the rates identified in the risk assessment as the 10%, 25%, 50%, 75% and 100% of the maximum rates (i.e., 25, 63, 125, 188, and 250 lb ai/A for tarped bedded were provided in the tables) with application block sizes of 1, 5, 10, 20, 30, 40, 60, 80, and 100 acres. Distances for the other rates in the buffer zone tables were scaled by assuming a linear relationship between the 10%, 25%, 50%, 75% and 100% maximum rates (e.g., distance at 37.5% rate = [distance at 25% rate + distance at 50% rate]/2). This scaling was necessary to provide an adequate incremental spread of rates and buffer zone distances. It should be noted that the distances in the lookup tables are not model outputs, although as described above the model outputs were used to inform the selection of buffer zone distances.

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 to interpret the required buffer zone distances for “greenhouses”. 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, 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 except they typically occur on a smaller scale (e.g., 1 acre applications or less). As a result, the minimum buffer zone distances for these types of use patterns must be determined from the applicable outdoor pre-plant soil lookup tables (i.e., Tables 2, 3, and 5).

Methyl bromide formulations used for pre-plant soil uses are always formulated with at least 2 percent chloropicrin. The Agency has also completed a RED for chloropicrin which includes buffer zone distances based on risks associated with chloropicrin. In accordance with Agency policy, when a pesticide contains more than one active ingredient, the product labeling shall bear the more restrictive measures of pesticides in the mixture. Generally, formulations with higher concentrations of methyl bromide will have buffers zone distances based on methyl

bromide, while the formulations with higher concentrations of chloropicrin will have buffers zone distances based on chloropicrin.

- Minimum and Maximum Distances

A minimum buffer zone of 25 feet will be required regardless of site-specific application parameters. In some instances the PERFUM model predicts that the risks reach the target at the edge of the field, but the Agency believes that a 25 foot minimum buffer is a good agricultural practice (GAP). While modeling may support no buffer in some cases, a minimum buffer is being required because of variability in the emission rates over a field and other factors not accounted for in the modeling. Application scenarios requiring buffer zone distances of more than ½ mile (2,640 feet) are prohibited. EPA believes that for areas where methyl bromide is used, buffers greater than ½ mile are not practical and difficult to enforce.

- Maximum Application Block Sizes

The maximum application block sizes allowed for methyl bromide applications are:

- 100 acres for tarped bedded and broadcast applications,
- 40 acres for untarped deep applications (i.e., California orchard replant),
- 10 acres for outdoor hot gas applications, and
- 45,000 square feet for greenhouse hot gas applications.

Table 2. Tarped Bedded Buffer Zone Distances **(feet)**

Block Size **(acres)**	Broadcast Equivalent Application Rate **(lb ai/acre)**														
	25	44	63	79	94	110	125	141	157	172	188	204	219	235	250
1	25	25	25	25	25	25	25	25	25	45	50	70	90	110	125
5	25	25	25	45	65	85	100	140	175	215	250	290	325	365	400
10	25	25	25	70	115	160	200	260	315	370	425	470	515	560	600
20	25	25	25	110	190	270	350	425	500	575	650	720	790	960	925
30	25	25	25	135	240	345	450	550	650	750	850	940	1025	1115	1200
40	25	50	75	190	300	425	525	645	765	885	1000	1115	1215	1320	1425
60	25	75	125	275	425	375	725	865	1005	1145	1285	1435	1580	1730	1875
80	25	100	175	350	525	700	875	1045	1215	1385	1550	1725	1900	2075	2250
100	25	150	200	400	600	790	985	1190	1390	1590	1790	2010	2215	2430	2640

Table 3. Tarped Broadcast Buffer Zone Distances **(feet)**															
Block Size **(acres)**	Broadcast Equivalent Application Rate **(lb ai/acre)**														
	43	**75**	**108**	**134**	**161**	**188**	**215**	**242**	**269**	**296**	**323**	**350**	**377**	**403**	**430**
1	25	25	25	25	25	25	25	25	25	25	25	50	75	100	125
5	25	25	25	60	90	120	150	210	265	320	375	450	525	600	675
10	25	25	25	95	165	235	300	385	465	545	625	700	775	850	925
20	25	25	25	145	265	385	500	625	750	875	1000	1115	1225	1340	1450
30	25	38	50	210	365	520	675	835	980	1145	1300	1440	1575	1115	1850
40	25	75	125	310	490	770	850	1035	1215	1395	1575	1760	1940	2120	2300
60	25	115	200	425	650	875	1100	1350	1595	1840	2085	2330	2570	2810	3050
80	25	165	300	565	825	1090	1350	1660	1965	2270	2575	2865	3150	3440	3725
100	25	200	375	690	1000	1315	1625	1985	2340	2695	3050	3375	3700	4025	4350

Table 4. Deep Untarped Buffer Zone Distances **(feet)**															
Block Size **(acres)**	Broadcast Equivalent Application Rate **(lb ai/acre)**														
	43	**75**	**108**	**134**	**161**	**188**	**215**	**242**	**269**	**296**	**323**	**350**	**377**	**403**	**430**
1	25	25	25	25	25	25	25	45	65	85	100	135	165	200	225
5	25	25	25	85	140	195	250	315	375	440	500	560	615	770	725
10	25	25	25	135	240	345	450	545	640	735	825	910	990	1070	1150
20	25	88	150	295	440	585	725	865	1000	1140	1275	1410	1540	1670	1800
30	25	125	225	410	590	770	950	1125	1300	1475	1650	1825	2000	2175	2350
40	25	163	300	515	725	940	1150	1365	1575	1790	2000	2215	2425	2640	2850

Table 5. Outdoor Tarped Hot Gas Buffer Zone Distances **(feet)**															
Block Size **(acres)**	Broadcast Equivalent Application Rate **(lb ai/acre)**														
	43	**75**	**108**	**134**	**161**	**188**	**215**	**242**	**269**	**296**	**323**	**350**	**377**	**403**	**430**
1	25	25	25	85	140	195	250	285	325	345	375	415	450	490	525
5	25	150	275	385	490	595	700	790	875	965	1050	1140	1225	1315	1400
10	50	250	450	610	765	920	1075	960	840	720	600	985	1365	1745	2125

Table 6. Greenhouse Hot Gas Buffer Zone Distances **(feet)**									
Broadcast Equivalent Application Rate **(lb ai/ 100 square feet)**	Block Size **(square feet)**								
	5,000	**10,000**	**15,000**	**20,000**	**25,000**	**30,000**	**35,000**	**40,000**	**45,000**
0.25	25	25	25	25	25	25	50	50	75
0.5	25	50	100	125	150	175	200	225	250
0.75	50	125	175	225	250	300	350	375	400
1	100	200	250	300	350	400	450	475	500

The buffer zones distances were not based on the selection of a specific percentile or distribution from the PERFUM modeling results. Rather, EPA used a weight of evidence

approach to set the buffers which included consideration of the hazard profile of methyl bromide, information from incident reports, monitoring data, stakeholder comments along with comprehensive analysis of results from PERFUM modeling and consideration of results using other models (e.g., Industrial Source Complex Model[13]). The analysis of PERFUM results considered distances at various percentiles of the whole field and maximum distance distributions, and predicted MOEs for various distances. The risk assessment characterizes additional types of analysis that were performed. EPA's goal for risk management was to achieve buffer distances where associated risks were at or above target concentration levels at high percentiles of exposure. For methyl bromide, this goal was achieved and the determined buffer zone distances are also believed to be manageable using existing cultural practices. The following characterizes the risks associated with the buffer zone distances summarized in Tables 2, 3, 4, 5 and 6:

- For outdoor and greenhouse pre-plant soil applications, the buffer zone distances result in MOEs ≥ 30 at the upper percentiles (usually 95th percentile or greater) on the maximum distance and whole field distributions for all weather stations modeled.
- The risk level corresponding to the buffer zone distances at the 95th percentile maximum distribution is equivalent to saying a person at the location on the perimeter of the buffer zone where the maximum concentration occurs during the worst case 24 hour period following the fumigation of a specific field during a 5 year period would have at least a 95 percent chance of having of an acceptable level of exposure (i.e., MOE of ≥ 30).
- For some of the weather stations modeled, the distances result in MOEs much higher than 30 at the 99th percentile on the maximum distance distribution.
- The PERFUM model was modified since the Agency last released its risk assessment for public comment. Version 2.1.4 now provides outputs that show air concentrations at each of the modeled ring distances. The Agency has used this information to estimate the MOEs at various distances for each of the five weather stations. MOEs for the 99th percentile air concentrations at the distances selected exceed 30 for all the weather stations modeled.
- The exposure time frame for which buffer zone distance modeling was performed was 24 hours, which is longer than the duration that agricultural workers in nearby fields or other work areas are likely to be present.
- It was assumed that methyl bromide air concentrations inside homes and other occupied structures are equal to outside concentrations. These structures could act as a barrier which could in some cases reduce potential inside air concentrations. However, there is insufficient data to quantify differences between indoor and outdoor concentrations.
- The use of GAPs, FMPs, and other mitigation measures required by this decision will contribute to an additional decrease in risk (see pages 61 and 66, respectively, for GAP and FMP Sections).

Table 7 summarizes the required buffer zone distances and corresponding PERFUM modeling results for the pre-plant soil uses that qualify for critical use exemptions with current typical application rates (based on information identified in the Agency's benefits assessments). Focusing on tomatoes as an example (last row of Table 7), the buffer zone for a 10 acre application block in the Southeast at a rate of 120 lbs ai/A is 200 feet. At 200 feet, the PERFUM

[13] http://www.epa.gov/scram001/dispersion_alt.htm#isc3

model to predicts greater than the 99.9th percentile for the whole field distribution and greater than the 95th percentile for the maximum field distribution for the worst case weather station modeled (i.e., Bradenton, FL). The risk level corresponding to this buffer zone distance at the 99.9th percentile whole field distribution is equivalent to saying a person at any location on the perimeter of the buffer zone during the 24 hour period following the fumigation of a specific field during a 5-year period would have at least a 99.9 percent chance of having of an exposure below the level of concern (i.e., MOE of 30 or higher). The risk level corresponding to the buffer zone distances at the 95th percentile maximum distribution is equivalent to saying a person at the location on the perimeter of the buffer zone where the maximum concentration occurs during the worst case 24 hour period following the fumigation of a specific field during a 5-year period would have a 95 percent chance of having of an exposure below the level of concern (i.e., MOE of 30) for these typical use scenarios. Using the PERFUM model outputs of air concentrations to predict MOEs at the 99th percentile, at 200 feet for these application parameters, the MOE at the 99th percentile is greater than 40 for the worst case weather station modeled (i.e., Bradenton, FL)

Available data indicate that for some crops and regions, pest control efficacy may be improved with high barrier tarps that may enable growers to use the buffer zone credits (see page 44) and utilize lower application rates, resulting in further reductions of the buffer zone distances. Some growers in the Southeast are commonly using high barrier tarps and lower rates.

Table 7.
Projected Buffers Zones for Methyl Bromide Critical Use Exemptions Based on Current Typical Application Rates

Crop	Region	Application Method [1]	Broadcast Equivalent Rate (lb ai/A)	Block Size (acres)	Buffer Zones without credits (ft)	Maximum Distribution Percentile where MOE reaches 30 [2]		MOE for 99th Percentile Air Concentration from PERFUM2 output	
						Bradenton	Ventura	Bradenton	Ventura
Cucurbits	MI	Tarped Shank Bedded	200	10	470	>95	>95	>40	>45
				20	720	>95	>97	>40	>45
	Southeast	Tarped Shank Bedded	120	10	200	>95	>97	>40	>45
				20	350	>95	>97	>35	>40
Eggplant	Southeast	Tarped Shank Bedded	120	10	200	>95	>97	>40	>45
				20	350	>95	>97	>35	>40
Forest Seedlings	Southeast	Tarped Shank Broadcast	236	10	385	>99	>99.9	>45	>50
				20	625	>99	>97	>45	>50
			350	10	700	>97	>99	>50	>60
				20	1115	>99	>97	>50	>60
Nursery, Fruit, Nut & Rose	National	Tarped Shank Broadcast	180	10	235	>99	>99.9	>45	>50
				40	775	>99	>99.9	>45	>50
Stone Fruit, Tree Nut Orchard Replant, Grape Vineyards	CA	Tarped Shank Broadcast	182	10	235	>99	>99.9	>45	>50
				40	670	>99	>99.9	>45	>50
Ornamentals	CA	Tarped Shank Broadcast	235	10	385	>99	>99.9	>45	>50
				20	625	>99	>97	>45	>50
	FL	Tarped Shank Broadcast	390	10	850	>99	>97	>55	>60
				20	1340	>99	>97	>55	>60
Pepper, Bell	MI	Tarped Shank Bedded	200	10	470	>95	>95	>40	>45
				20	720	>95	>97	>40	>45
	Southeast	Tarped Shank Bedded	120	10	200	>95	>97	>40	>45
				20	350	>95	>97	>35	>40
Strawberry Fruit	CA	Tarped Shank Broadcast	175	10	235	>99	>99.9	>45	>50
				20	285	>99	>99.9	>45	>50
	FL	Tarped Shank Bedded	120	10	200	>95	>97	>40	>45
				20	350	>95	>97	>35	>40
Strawberry Nursery	CA	Tarped Shank Broadcast	235	10	385	>99	>99.9	>45	>50
				20	625	>99	>97	>45	>50
	NC	Tarped Shank Bedded	235	10	560	>95	>97	>35	>40
				20	856	>95	>97	>35	>35
		Tarped Shank Broadcast	235	10	380	>99	>99.9	>45	>50
				20	625	>99	>97	>45	>50
Tomato, Fresh	Southeast	Tarped Shank Bedded	120	10	200	>95	>97	>40	>45
				20	350	>95	>97	>35	>40

[1] Broadcast (flat fume) may be applied as strips with non-treated areas in between (e.g., for forest seedlings and orchards)

[2] The whole field percentile where MOEs reach 30 is > 99.9 for all of the weather stations modeled

The Agency believes that the buffer zone distances described above, combined with other risk mitigations described herein, will provide protection against any unreasonable adverse effects.

(e) Buffer Zone Reduction Credits

The Agency has undertaken a significant effort to evaluate available empirical data, modeling, and literature regarding the factors and control methods that may reduce emissions from soil fumigants. For details on the Agency's analysis please see the June 9, 2008 memo "Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach,"[14] in the methyl bromide docket. The Agency has also coordinated and led forums to discuss this issue at the 2006 and 2007 Methyl Bromide Alternatives Outreach (MBAO) Conferences with leading researchers and other stakeholders. A general description of the MBAO sessions can be found at http://mbao.org.

Based on the Agency's analysis of the current data, the Agency has developed methyl bromide buffer zone reduction credits for: high barrier tarps, soils with high organic matter, and for soils with high clay content. To take advantage of the credit for high barrier tarps, users can modify their current application practices. Organic matter and clay content are difficult to change and these credits may only be applicable for areas where these characteristics already exist. Changing current practices or site conditions to utilize these credits may be a challenge, but the Agency believes that in addition to reducing bystander risk and the size of buffer zones, the credit for high barrier tarps has the potential to decrease application rates, increase efficacy, and reduce depletion of stratospheric ozone. None of the buffer zone credits apply to hot gas applications.

Methyl bromide buffer zone credits are additive but can not exceed 45 percent in total (i.e., 25 percent credit for listed tarps, 10 percent for ≤ 3 percent organic content, and 10 percent for ≥ 27 percent clay content).

- High Barrier Tarps

EPA has determined that 25% buffer credit for methyl bromide is appropriate for the following high barrier tarps: Bromostop® (1.38 mil), IPM Clear VIF (1.38 mil), and Eval/Mitsui (1.38 mil). The credits are based primarily on laboratory studies performed by Dr. Husein Ajwa[15] from the University California-Davis as described in the Agency's emission factors analysis[14]. There have been no methyl bromide empirical field studies on emission or permeability for modern high barrier tarps submitted to EPA. The Agency believes that the actual reduction for tarps could be higher for certain conditions but that a 25% credit is appropriate based on uncertainties in the available data. Other high barrier tarps could qualify for credits if supporting data are provided to the Agency.

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[14] Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach, June 9, 2008, DP Barcode: 306857

[15] Ajwa, H., A. 2007. Testing Film Permeability to Fumigants Under Laboratory and Field Conditions. 2007 Methyl Bromide Alternatives Outreach Conference. http://mbao.org/2007/PDF/Preplant/PP3/Ajwa(16).pdf

The use of high barrier tarps may not be feasible or applicable to all situations where methyl bromide is currently used. For example, growers using broadcast applications have reported that high barrier tarps are difficult to use because of problems with gluing or bonding the edges of the tarps together. Researchers and other stakeholders are reportedly exploring alternate methods to accomplish this task (e.g., using heat to weld the tarps together). Also, California currently prohibits the three high barrier tarps listed above and other virtually impermeable films (VIFs) for methyl bromide applications based on risk concerns for handlers when tarps are being cut. The EPA believes these handler risks will be adequately addressed with mitigation required by this decision (e.g., new requirements for tarp perforation, respirators, air monitoring, application rates, tarp removal plans, etc.)

Tarp emission reduction data reviewed by EPA show that tarps have varying degrees of effectiveness. There is no current standard to evaluate tarps performance under field conditions, and in the absence of a standard, EPA has established conservative buffer reduction factors based on available data. EPA requested assistance from USDA's Agricultural Research Service (ARS) in this effort to identify those tarps that have demonstrated low permeability and reduced emissions under field conditions[16]. USDA's research includes a hybrid field-lab performance test where tarps are stretched out over beds, subjected to atmospheric and soil conditions, and then tested in the lab. The Agency believes that this approach to evaluating the permeability of agricultural tarps could simulate more realistic field conditions especially if conducted with concurrent field measurements, and EPA requested the results of tarp permeability testing currently being conducted in support of USDA's Area-wide Pest Management Projects for both the Pacific Region and the South Atlantic Regions.

In a response to EPA's request, USDA indicated that at least several months are needed for data review, and that it was not able to provide the data in a timeframe for EPA's current decisions[17]. USDA did offer to provide samples of tarp taken from its ARS experiments for testing in EPA laboratories. EPA is evaluating the feasibility of this option.

EPA plans to work with USDA, registrants, and other stakeholders to develop a protocol for measuring the performance of tarp materials (e.g., using the mass transfer coefficient for each fumigant) and performance criteria that could be used to evaluate additional tarps to derive emission credits. Although there are several protocols being evaluated, there is no consensus on a method. The Agency's factors analysis discusses methods that could be employed [14]. Guidelines for conducting flux studies in the field to use as point of comparison to performance testing are already well established.

EPA (through OPP's Environmental Stewardship Branch) has proposed to co-fund a grant with USDA-ARS for several flux studies in the southeastern U.S. These studies would provide (1) field data on the emission reduction potential of certain low permeability barrier films to support possible, additional, buffer reduction credits as well as to (2) help develop an affordable and reliable hybrid field/lab test to evaluate the many barrier films available to growers. EPA has also prepared a document to describe possible research and study designs to

[16] EPA-HQ-OPP-2005-0123-0459, USDA's Film Testing
[17] EPA-HQ-OPP-2005-0123-0460, USDA Letter to Peter Caulkins on Agricultural Film Testing

reduce uncertainties in understanding emission factors in the context of different films and seals, agricultural practices, and environmental conditions[18]. During the 60-day comment period the Agency anticipates learning more about ongoing and planned research from the scientific community that will address these uncertainties to help the Agency identify potential studies that would help refine the current risk-based mitigation decisions. The EPA will defer decisions regarding calling-in any data to address uncertainties identified with regard to these and other factors until comments provided during the 60-day comment period have been reviewed.

- Soil Conditions

Like high barrier tarps, inherent soil conditions (e.g. organic matter and soil type) do have an impact on fumigant emissions. However, soil conditions differ from the high barrier tarp credits because soil conditions are factors that are essentially beyond a grower's ability to change. Although a grower may not be able to manipulate organic matter or soil type, the Agency's factors document indicates that soil conditions can reduce fumigant emissions, and is offering credits for these conditions. EPA acknowledges that some variability in soil characteristics within a given field is likely. If users are unsure whether the fields they intend to treat meet the criteria for a credit, they may consult with their local agriculture extension office or soil conservation district for assistance in determining soil characteristics.

The Agency's factors document not only reviews available literature regarding soil conditions, but also describes modeling exercises that estimate the impact of organic matter and soil type using the Chain_2D model[14]. Chain_2D is a first principles model that takes into consideration factors such as boundary layers or moisture that could impact fumigant emissions. The Agency used Chain_2D as modified by Dow AgroSciences' Steve Cryer and Ian van Wesenbeek in the sensitivity analysis[19]. Cryer and van Wesenbeek modified the original source code to create a more usable graphical user interface, this included incorporating a new air/soil boundary condition proposed by Wang in 1998[20.] See the Agency's factors analysis for further details about the Chain_2D model[14].

Based on the review of available literature and modeling with the CHAIN_2D model, EPA believes 10 percent buffer zone credits are appropriate if the application block contains soil with organic matter of greater than 3 percent and/or for clay content of at least 27 percent.

The Agency's Chain_2D sensitivity analysis suggests that organic matter can have a small impact on emissions. There is generally a high correlation between the organic matter content of the soils and the dissociation constant (K_d) value. Increasing K_d value by 10 or 25 percent generally reduced emissions by 10 or 20 percent. Decreasing the K_d value by 10 or 25 percent increased emissions by 10 or 20 percent (see figures 157-159 of the factors analysis for further details).

[18] Health Effects Division Recommendation for Fumigant Data Requirements, Dawson and Smith, June 2008
[19] Cryer, S.A. (2007) Air/Soil Boundary Conditions For Coupling Soil Physics and Air Dispersion Modeling. Unpublished report of Dow AgroSciences LLC (Report # DN241493)
[20] Wang, D; Yates, S.R.; Jury, W.A. (1998) Temperature Effect on Methyl Bromide Volatilization: Permeability of Plastic Cover Films. J. Environ. Qual. 27, 821-827.

Generally, clay loam and sandy clay loam soils tended to show significantly lower emissions than other soil types, sometimes showing 50 percent lower reductions. Conversely, loamy sand and loam soils tended to show higher emissions than other soil types (see figures 176-179 of the factors analysis for further details).

- Buffer Zone Credit Example

Focusing on tomatoes grown in the Southeast as an example, the buffer zone distance for a 10 acre application block at a rate of 120 lbs ai/A is 200 feet without any credits (see last row in Table 7). If the grower uses Bromostop® (1.38 mil) high barrier tarp, the buffer zone can be reduced by 25 percent. The resulting buffer zone distance for this case is 150 feet. If the organic matter in the application block is greater than 3 percent and Bromostop® (1.38 mil) high barrier tarp is used, the resulting buffer zone distance would be 130 feet.

- Other Buffer Zone Credits Considered

Other factors such as soil moisture content, field preparation, water sealing, and application injection depth could not be used to justify credits based on the available data. However, EPA has established mandatory good agricultural practices (GAPs) for these conditions. See the GAP Section (page 61) of this document for further discussion.

The Agency has used the best available data to estimate potential methyl bromide bystander risks and has both quantitatively and qualitatively evaluated the impact of potential emission control measures on bystander risk. The Agency recognizes that there is substantial research being conducted by stakeholders to further quantify emission reductions, and will consider such data in future decisions if new data becomes available. Such data may also support the Agency's decisions on additional emission credits in the future.

(f) Buffer Zone Impacts

EPA acknowledges that even with the use of credits, there could be significant economic impacts to some growers who may not be able to accommodate large buffers based on their current application practices. As part of the most recent public comment period on fumigant risk assessments and proposed mitigation, several stakeholders submitted analyses estimating the impact of buffer zones around fumigated agricultural fields. The Agency's review of these studies and discussion of an EPA contracted study using the same approach for Kern County, California is included in the docket[21]. While buffers may restrict certain application practices, this decision allows growers the flexibility to modify their practices to achieve smaller buffers; for example treat smaller application blocks, or switch to a lower emission application method. Available data indicate that for some crops and regions, pest control efficacy may be improved with high barrier tarps which may enable growers to use the buffer zone credits and utilize lower application rates, resulting in further reductions of the buffer zone distances. Some growers in the Southeast are commonly using high barrier tarps and lower rates at present.

[21] Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants (DP# 353940)

The Agency has also looked at how buffer zones have impacted California practices [21]. California currently requires buffer zones for pre-plant soil fumigations with methyl bromide. California's buffers are based on local conditions and use practices, while the buffers EPA is establishing in this decision are based on conditions and practices nation wide. The CDPR has indicated that their buffer zone distances will not be reduced in cases where buffer zones required by EPA are less. In cases where EPA buffers are larger, however, California would increase their buffers to be consistent with EPA's buffers.

Table 8 shows a comparison of current CDPR buffers to EPA buffers for applicable CUEs using the same typical application rates and block sizes included in Table 7. In California methyl bromide is predominantly applied using the broadcast method.

Table 8. EPA Methyl bromide buffers vs. Current CDPR Buffer Zones for CUEs in CA

Crop[1]	Application Method	Broadcast Equivalent Rate (lb ai/A)	Block Size (acres)	EPA Buffer Zones without credits [2] (ft)	California Buffer Zones [3] (ft)
Orchard Replant	Tarped Shank Broadcast	182	10	235	160 - 1000
			40	670	370 - 2200
Orchard Replant	Deep Untarped Shank Broadcast	182	10	345	370
			40	940	810
Ornamentals	Tarped Shank Broadcast	235	10	385	240 - 1300
			20	625	360 - 1900
Strawberry Fruit	Tarped Shank Broadcast	175	10	235	120 - 930
			20	285	240 - 2000
Strawberry Nursery	Tarped Shank Broadcast	235	10	385	240 - 1300
			20	625	360 - 1900

[1] CUE crops are generally applied using the broadcast method in California
[2] EPA buffer zone period ends 48 hours after application ends
[3] For above scenarios, California's buffer zone period ends 36 hours after application ends. Longer buffer zone periods (up to 84 hrs) are required depending on rate and block size. California buffer distances vary depending on application equipment used (See page 33 of http://www.cdpr.ca.gov/docs/county/training/methbrom/mebrman.pdf for further details)

ii. Posting

Posting is recognized as an effective means of informing workers and others about areas where certain hazards and restrictions exist. Current soil fumigant labels require treated areas to be posted, and handlers are required to wear specific PPE when they are in a treated area. For buffer zones to be effective risk mitigation, bystanders, including agricultural workers in nearby areas, need to be informed of the location and timing of the buffer to ensure they do not enter areas designated as part of the buffer zone.

(a) Posting Requirements

In addition to alerting bystanders, posting a buffer zone will help handlers determine where and when they are required to use PPE. As described below, handlers working in buffers during the buffer zone period must use label-specified PPE and meet other requirements under the WPS. Therefore, EPA has determined that to ensure the protectiveness of buffers for bystanders and handlers, the perimeter of the fumigant buffer zones must be posted as described below and in the example that follows.

- Posting of a **buffer zone** is required **except** when one of the following conditions exist:
  (1) a physical barrier that is reasonably likely to prevent bystander access to the buffer zone (e.g., a fence or wall) separates the edge of the buffer zone from bystander access.
  OR
  (2) the area within 300 feet of the edge of the buffer zone is controlled by the application block owner/operator. That is, if land under someone else's control is within 300 feet from the edge of the buffer zone, the buffer zone must be posted.

  A buffer within 300 feet of an area that includes worker housing must be posted even if the area is under the control of the land owner/operator.

- Buffer zone posting signs must:
  - Be placed at all usual points of entry and along likely routes of approach from areas where people not under the land operator's control may approach the buffer zone.
  - When there are no usual points of entry, be posted in the corners of the buffer zone, between the corners of the buffer zone, and along sides so that one sign can be viewed (not read) from the previous one. Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.

- Buffer zone posted signs must meet the following criteria:
  - The printed side of the sign must face away from the treated area toward areas from which people could approach.
  - Signs must remain legible during entire posting period and must meet the general standards outlined in the WPS for text size and legibility (see 40 CFR §170.120).
  - Signs must be posted before the application begins and remain posted until the buffer zone period has expired.
  - Signs must be removed within 3 days after the end of the buffer zone period.
  - Registrants must provide generic buffer zone posting signs which meet the criteria above at points of sale for applicators to use.

Exception: If multiple contiguous blocks are fumigated within a 14-day period, the entire periphery of the contiguous blocks' buffer zones may be posted. The signs must remain posted until the last buffer zone period expires and signs may remain posted until 3-days after the buffer zone period for the last block has expired.

Additional requirements for treated area posting:

- The treated area posted signs must remain posted for no less than the duration of the *entry restricted period* after treatment.

- Treated area signs must be removed within 3 days after the end of the entry-restricted period.
- Signs must meet the general standards in the WPS for placement, text size, and location (40 CFR §170.120).

Contents of Signs

The **treated area** sign (currently required for fumigants) must state the following:
-- Skull and crossbones symbol

-- "DANGER/PELIGRO,"
-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"
-- "[*Name of fumigant*] Fumigant in USE,"
-- the date and time of fumigation,
-- the date and time entry prohibition is lifted
-- Name of this product, and
-- name, address, and telephone number of the certified applicator in charge of the fumigation.

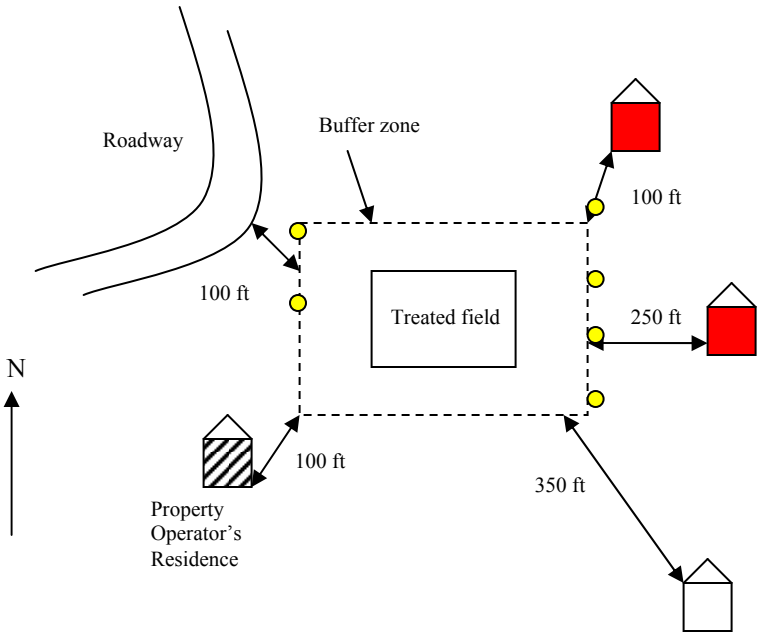
The **buffer zone** sign must include the following:
-- Do not walk sign

-- "DO NOT ENTER/NO ENTRE,"
-- "[*Name of fumigant*] Fumigant BUFFER ZONE,"
-- the date and time of fumigation,
-- the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires)
-- Name and EPA registration number of the product applied, and
-- name, address, and telephone number of the certified applicator in charge of the fumigation

(b) Posting Example

To clarify the posting requirements, the following example has been included.

Figure 3. Posting Example



Red Houses = Structure within 300 feet of the buffer zone edge. Yellow dots = posted signs

- The structures in **red** are (1) within 300 feet of the edge of the buffer zone, and (2) there is no physical barrier between the two structures and the buffer zone, and (3) the land operator does not control these structures.
- Although the **property operator's building** (striped building) is within 100 feet of the edge of the buffer zone, since it is controlled by the property operator, **no posting** of the buffer zone is necessary here.
- There is a **road** within 100 feet of the edge of the buffer zone. Since there is a possibility of people from the road entering the buffer zone area, the buffer zone needs to be posted in the northwest corner.

(c) Buffer zone posting considerations

The Agency received comments on the burden for applicators to post the entire perimeter of a buffer zone due to the large distance it covers. In an effort to reduce the burden on growers, but retain the posting requirement for situations where people are most likely to enter a buffer zone, EPA believes posting area where people are most likely to enter buffers will be protective. USDA also noted that as growers break their fields into smaller application blocks to result in smaller buffer zones, the posting requirements would be burdensome in that users would need to put up and take down signs for multiple adjacent, sequential applications. To address this concern, EPA is allowing signs for contiguous application blocks to be placed on the edge of the buffer zone area for all blocks treated within a 14-day period. EPA believes this will be protective and potentially less burdensome.

2) Occupational Risk Mitigation

i. Handlers Definition

Based on stakeholder comments, a clarification of EPA's definition of handler activities, as currently defined in the WPS and fumigant labels, is needed. Persons engaged in any of the following activities will be defined as *handlers* on product labels.

- Persons participating in the application as supervisors, drivers, co-pilots, shovelers, or as other direct application participants;
- Persons taking air samples to monitor fumigant air concentrations;
- Persons cleaning up fumigant spills;
- Persons handling or disposing of fumigant containers;
- Persons cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues;
- Persons installing, repairing, operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period;
- Persons entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;
- Persons installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps - until
    - After tarps are perforated and removed if tarp removal is completed less than 14 days after application; or
    - 14 days after application is complete if tarps are not perforated and removed during those 14 days, or
    - 48 hours after tarps are perforated if they will not be removed prior to planting.

ii. Handler Requirements

Currently all handlers involved in a methyl bromide application must be under the supervision of a certified applicator who may not necessarily be on-site. Since many incidents are caused by human error and equipment failure, EPA believes the presence of onsite trained personnel will help to reduce these risks. Therefore, a certified applicator must maintain visual contact with any fumigant handler while the fumigant is being incorporated into the soil. The person monitoring other handlers may also be engaged in fumigant handling tasks during the monitoring period and two qualified monitors may monitor one another simultaneously.

Before applying this product the certified applicator supervising that application must have, within the preceding 12 months, successfully completed a methyl bromide training program, made available by the registrant (see page 77). The FMP described on page 66 of Section IV must document when and where the training program was completed.

For cases when the certified applicator leaves the site after the application portion of the fumigation process is complete and other parties will be performing handler tasks (e.g., tarp perforating/removal, water application, etc.), the certified applicator must communicate in writing to the site owner/operator and other handlers key information needed to comply with label requirements (e.g. PPE requirements, location of buffers, when buffer zone ends, reentry restrictions, minimum times for perforating tarps, etc.).

When handlers are fixing tarps, moving irrigation equipment or performing other handling tasks as defined above, the Agency is requiring at least two WPS trained handlers be present for all activities. Due to the volatile nature of the fumigants there is a possibility that handlers could be overcome with the vapors and have difficulty leaving the area while they are performing handling tasks. Therefore, EPA is requiring at least two WPS trained handlers be on site during all post-fumigation handling activities.

iii. Respiratory Protection

The Agency's risk assessment indicates that there is an inhalation risk concern for handlers without respirator protection for a majority of handler tasks. The addendum to the April 10, 2007 risk assessment (D350818) contains additional risk characterization regarding the use of air monitoring and the role of chloropicrin's warning properties for methyl bromide-chloropicrin products. The combination of air monitoring, chloropicrin warning properties and respiratory protection along with the use of GAPs, FMPs, and other mitigation measures is expected to reduce methyl bromide inhalation risks to levels that are below EPA's level of concern.

During the most recent public comment period, the Agency received comments from applicators that respirators are not necessary because (1) chloropicrin's warning properties are sufficient to alert handlers if there has been an unsafe exposure, (2) respirators inhibit communication which could cause an accident; and (3) in warm weather respirators can cause heat stress and other ailments. On the other hand, some stakeholders are in favor of mandatory respiratory protection because they believe if fumigants are continued to be used that respirators are the only effective means to protect workers from chloropicrin exposures. These stakeholders have also stated that handlers will not be given access to respirators and other PPE unless it is required on the label.

Current product labels require respirators when the air concentration exceeds 5 ppm for methyl bromide and 0.1 ppm for chloropicrin but do not require that any measurements be taken.

(a) Air monitoring

Air monitoring requirements herein will ensure that acute, short-, and intermediate-term risks are not exceeded and will ensure that 5 ppm upper working limit of the respirator cartridge has not been exceeded.

There are several commercial systems for monitoring methyl bromide and chloropicrin air concentrations. Methyl bromide colorimetric tubes (pn 10-131-10) from RaeSystems have a working range of (1-18 ppm methyl bromide) or an extended range of (0.5-36 ppm methyl bromide). The Ultra Rae (pn 012-3024-005) sensitivity is 0.2 ppm but this piece of equipment is more expensive and difficult to use. Chloropicrin colorimetric tubes are available from varied manufacturers including: Matheson/Kitagawa # 172, sensitivity 0.1 ppm; Sensidyne #134, sensitivity 1-60 ppm; Draeger, #1-a, sensitivity 1-15 ppm.

(b) Respiratory requirements

There are two regimens which differ based on the concentration of chloropicrin that is formulated with methyl bromide. Certain criteria apply if applications involve less than or equal to 80 percent methyl bromide and other criteria apply if applications involve greater than 80 percent methyl bromide relative to the amounts of chloropicrin used.

As the amount and percentage of chloropicrin applied increases, there is a greater likelihood handlers will immediately experience sensory irritation if exposed to air concentrations above the Agency's level of concern. Respiratory protection is required whenever handlers experience sensory irritation.

The EPA assumes that air-purifying respirators have a protection factor of between 10 and 50 depending if a half-face or full-face respirator is used. The current upper limit of air-purifying respirator cartridges available for methyl bromide is 5 ppm (see "respirator cartridges used with air purifying respirators" section below for further details). A self-contained breathing apparatus (SCBA) has a protection factor of 1,000 but must only be used for brief durations to take actions to reduce air concentration levels or in case of an emergency.

- Formulations with 80% or less methyl bromide

The use of air purifying respirators is mandated in this approach only when warranted by monitoring air concentrations during applications. If certain triggers are met then respirators are required. The following air monitoring procedures must be followed for all formulations with 80 percent or less methyl bromide to determine whether respiratory protection is required for any person performing a fumigant handling task:

- Air monitoring samples for methyl bromide and chloropicrin must be collected at least every 2 hours in the breathing zone of a handler performing a representative handling task.
- If at any time (1) methyl bromide concentrations are greater than or equal to 1 ppm or (2) chloropicrin concentrations are greater than or equal to 0.15 ppm or (3) any handler experiences sensory irritation, then a air-purifying respirators must be worn by all handlers at the handling site.
- If two consecutive breathing zone air samples taken at least 30 minutes apart, show levels have decreased to less than 1 ppm for methyl bromide and less than 0.15 ppm for chloropicrin, then handlers may remove the respirators.
- If at any time (1) a handler experiences any sensory irritation when wearing a respirator, or (2) any air sample is greater than or equal to 5 ppm for methyl bromide, or (3) any air sample is greater than or equal to 1.5 ppm for chloropicrin, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken.
- During the corrective actions if methyl bromide air concentrations are greater than or equal to 5 ppm or if chloropicrin air concentrations are greater than or equal to 1.5 ppm, a SCBA must be worn.
- In order to resume work activities:

- Two consecutive air samples for methyl bromide and chloropicrin taken at the handling site at least 30 minutes apart must be less than 5 ppm for methyl bromide and less than 1.5 ppm for chloropicrin.
- During the collection of air samples, an air purifying respirator must be worn by the handler taking air samples.
- If methyl bromide concentrations are greater than or equal to 1 ppm or if chloropicrin concentrations are greater than or equal to 0.15 ppm, then handlers resuming their handler activities must wear air-purifying respirators

■ Formulations with more than 80 % methyl bromide

If the fumigant applied contains greater than 80 percent methyl bromide (e.g., 98:2 formulations), air purifying respirators must be worn during all handler tasks and the following air monitoring procedures must be followed to ensure that the upper protection limit of the respirator plus respirator cartridge is not exceeded (i.e., 5 ppm for methyl bromide and 1.5 ppm for chloropicrin):

- Air monitoring samples for methyl bromide and chloropicrin must be collected at least every hour in the breathing zone of a handler performing a representative handling task.
- If at any time (1) a handler experiences any sensory irritation while wearing a respirator, or (2) any air sample is greater than or equal to 5 ppm for methyl bromide, or (3) any air sample is greater than or equal to 1.5 ppm for chloropicrin, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken.
- During the corrective actions if methyl bromide air concentrations are greater than or equal to 5 ppm or if chloropicrin air concentrations are greater than or equal to 1.5 ppm, then a SCBA must be worn.
- In order to resume work activities:
  - Two consecutive air samples for methyl bromide and chloropicrin taken in the treatment area at least 30 minutes apart must be less than 5 ppm for methyl bromide and less than 1.5 ppm for chloropicrin.
  - During the collection of samples an air purifying respirator must be worn by the handler taking air samples.

■ Hot gas tarped applications

During hot gas applications in greenhouses, the fumigant must be introduced from outside of the greenhouse. For outdoor hot gas applications, the fumigant must be introduced from outside of the application block. Once the fumigation has started, if entry into the greenhouse enclosure or the outdoor treatment area is required to perform a function necessary for the application, a SCBA must be worn. Handlers must wear SCBA to reenter the greenhouse/treated areas for a minimum of 48 hrs after the fumigant has stopped being delivered/dispensed to the soil.

■ Deep probe injection

No exposure data were provided for using handheld equipment to apply methyl bromide. This method of application is done primarily with 98:2 formulations. The methyl bromide risk assessment indicates that the fumigation of tree holes was one of the factors identified in the more serious incident cases. Since air purifying respirators may only be used for concentrations up to 5 ppm, EPA is requiring that SCBA be worn when applying methyl bromide with handheld equipment.

- Tarp Repair

An air purifying respirator must be worn by handlers performing tarp repair operations before the entry prohibitions have ended. The Agency is requiring respiratory protection during tarp repair since the duration of the activity is likely to be short and because methyl bromide concentrations are unknown, but could be high, especially if the tarp repair occurs shortly after the fumigation is completed.

- Respirator fit testing, medical qualification, and training

The respirator protection factors described above are based on the following assumptions: 1) the respirator is fit-tested, 2) proper respirator training occurs, and 3) an annual medical evaluation and clearance is done. Without these requirements, it is unclear whether the reduction in inhalation exposure that is assumed by the protection factor will be achieved. In order to ensure that the respiratory protection EPA is assuming is being achieved in the field, respiratory requirements will include fit testing, respirator training, and annual medical evaluation. The following language must be added to product labels:

"Employers must also ensure that all handlers are:

- Fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134)
- Trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134)
- Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change."

- Respirator cartridges used with air purifying respirators

Currently, there are no air-purifying respirator cartridges certified by the Mine Safety and Health Administration-National Institute for Occupational Safety and Health (MSHA-NIOSH) for protection against methyl bromide. While NIOSH does not have a test procedure to certify air-purifying filters for protection against methyl bromide, the 3M 60928 is a NIOSH-approved combination organic vapor/acid gas chemical cartridge/P100 particulate filter, this combination

cartridge is recommended by 3M for use against radioiodine or methyl bromide at ambient concentrations up to 5 ppm and for not more than one shift. For further details on the 3M's recommendations, see February 2001 "3M Technical Data Bulletin #146 Use Recommendations for 3M 60928 Cartridge/Filter"[22]. The EPA has decided that the use of 3M air purifying respirators (APRs) equipped with 3M Model 60928 Organic Vapor/Acid Gas/P100 cartridges may be used for concentrations up to 5 ppm, and not for more than one work shift per day. Respirator APR-cartridge combinations for other manufacturers will also be considered by the Agency, provided written certification of their efficiency against methyl bromide is provided.

The maximum chloropicrin air concentration that handlers may be exposed to without respiratory protection is 0.15 ppm. When wearing an air purifying respirator with organic vapor cartridges, the maximum chloropicrin air concentration allowed is 1.5 ppm. For further details regarding chloropicrin respiratory protection requirements, see the chloropicrin RED (chloropicrin docket EPA-HQ-OPP-2007-0350).

- Respirator availability

The handler employer must confirm and document in the fumigant management plan that the following are immediately available:

- at least one air rescue device (e.g., SCBA) on-site in case of an emergency, and
- air-purifying respirators and cartridges for each handler.

iv. Tarp Perforation and Removal

The Agency's risk assessment indicates that there is a risk concern for handlers during the perforation (cutting, poking, punching, or slicing) and removal of tarps, particularly when high barrier tarps are used. In addition to respiratory protection requirements described above, the Agency is requiring the following to mitigate risks from inhalation exposure:

- Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after shank injection of the fumigant product and tarps (if used) have been laid or after drip lines have been purged and tarps have been laid, unless an adverse weather condition exists for broadcast applications.
- If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete.
- If tarps will not be removed after perforation, planting or transplanting cannot begin until at least 48 hours after tarp perforation is complete.
- If tarps are left intact for at least 14 days after fumigation injection into the soil is complete, planting or transplanting may occur while the tarps are being perforated.
- Adverse Weather Conditions Exemption for Broadcast Applications Only (See Figure 8): Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that:
    - At least 48 hours have passed after the fumigant injection is complete,

[22] http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666BraCOrrrrQ-

    - The buffer zone period is extended until 24 hours after tarp removal is complete, and
    - Subsequent fumigations of untreated areas within the application block do not occur for at least 24 hours after tarp removal is complete.
- To reduce exposure to handlers perforating tarps
    - Tarps used for fumigations must be perforated only by mechanical methods.
    - Perforation by hand or with hand-held tools is prohibited.
- Each tarp panel used for broadcast fumigations must be perforated using a lengthwise cut. This measure is to reduce the likelihood of the tarp blowing away prior to tarp removal.

v. Entry Prohibitions

Current methyl bromide labels allow reentry to the treated field by workers 48 hours after application. The methyl bromide risk assessment indicates that risks exceed EPA's LOC for workers entering fields at this time period. However the risk assessments indicates that extending this period decreases the risk. In addition, stakeholder comments indicate that non-handler entry to perform postapplication (i.e., non-handler) tasks is generally not needed for at least 10 to 14 days following the completion of the application.

Due to the volatile nature of methyl bromide and the potential for worker exposure, the Agency is prohibiting entry into the treated area or buffer zone by anyone other than a protected handler. The prohibition differs from a Restricted Entry Interval (REI) that are currently required for most convention pesticides which contains exceptions for workers doing certain tasks before the REI has expired (e.g., scouting). Workers permitted entry under the REI, will now be prohibited for soil fumigants.

EPA believes that risks will not exceed the Agency's LOC provided entry (including early entry that would otherwise be permitted under the WPS) by any person – other than a correctly trained and PPE-equipped handler who is performing a handling task – is prohibited from the start of the application until:

- 5 days (120 hours) after application has ended for untarped applications, or
- After tarps are perforated and removed if tarp removal is completed less than 14 days after application, or
- 48 hours after tarps are perforated if they will not be removed prior to planting, or
- 5 days (120 hours) after application is complete if tarps are not perforated and removed 14 days after the application is complete.

Figures 4, 5, 6, 7, and 8 provide a graphical depiction of mitigation required to mitigate worker risk in various methyl bromide fumigant application scenarios.

Figure 4. Untarped Applications (only for CA Orchard Replant)

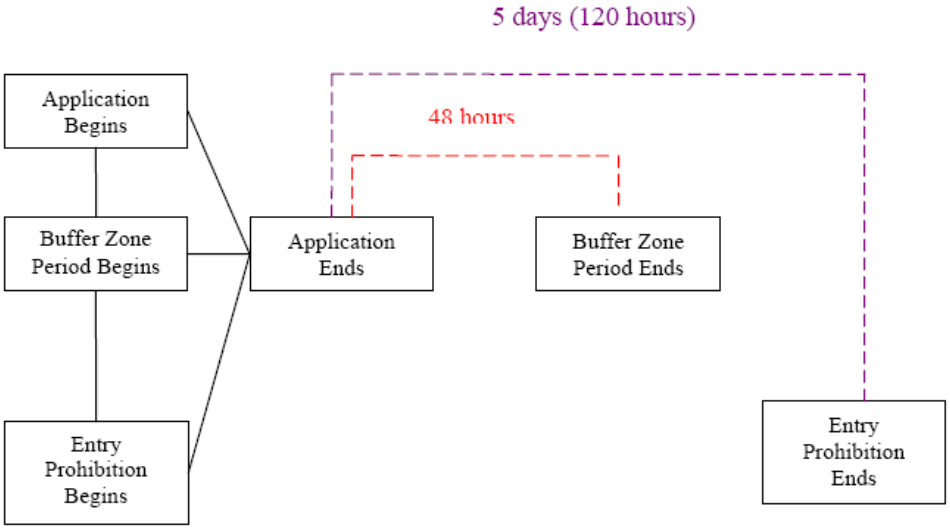


Figure 5. Tarps removed before planting

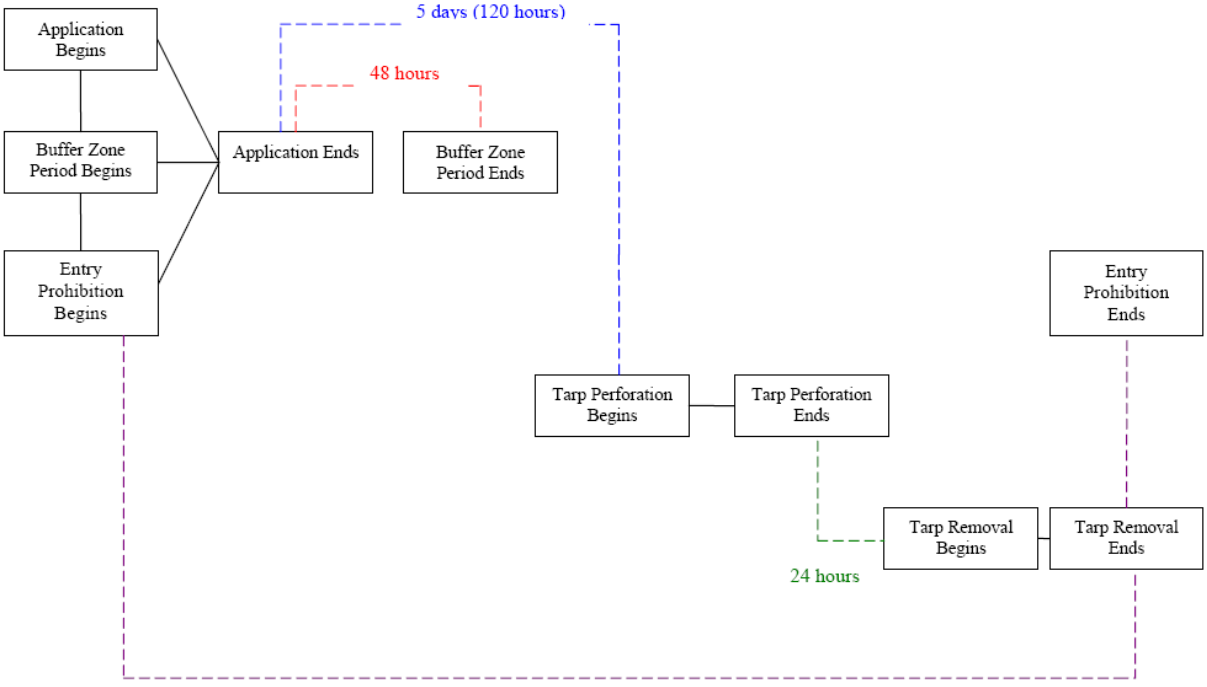


Figure 6. Tarps NOT Removed Before Planting

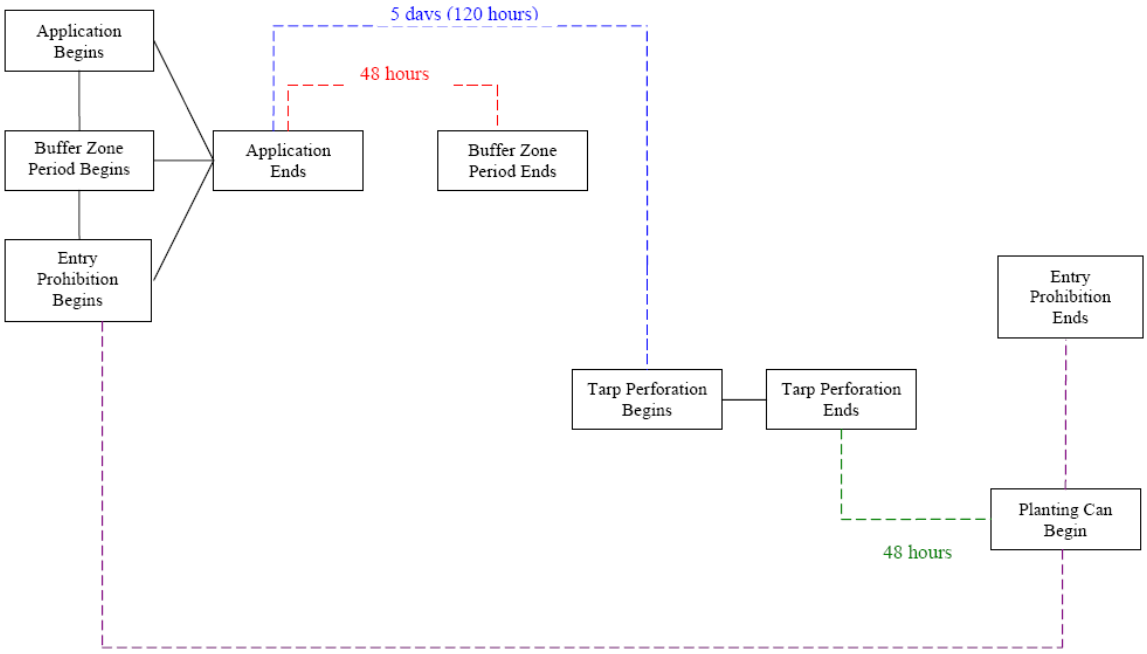


Figure 7. Tarps NOT Removed Before Planting and NOT punched until 14 days after the application

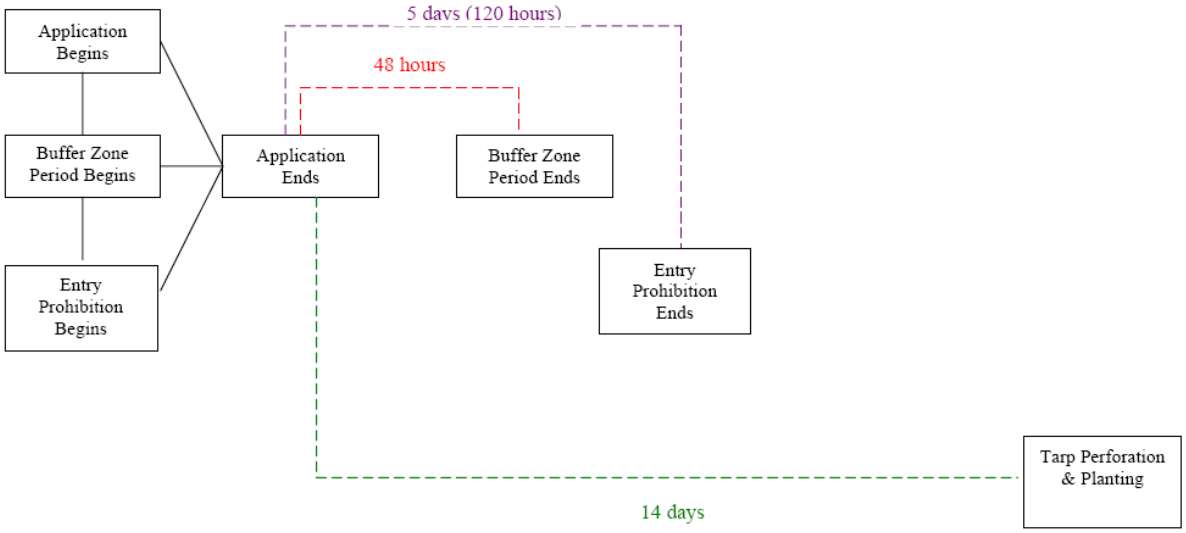
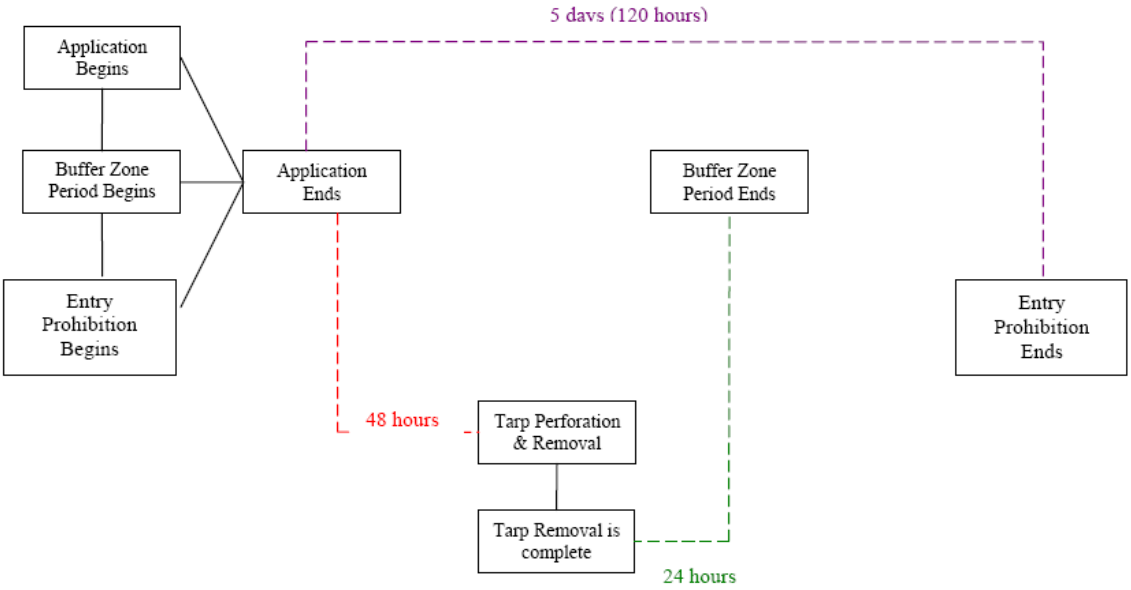


Figure 8. Adverse Weather Conditions Exemption (Broadcast tarp applications ONLY)



3) Other mitigation

Below are requirements for FMPs, GAPs, emergency preparedness and response, notice to lead agencies, training, and community outreach that the Agency concludes are needed to mitigate risks and the likelihood of incidents caused by human error, equipment failure, and weather events such as temperature inversions.

i. Good Agricultural Practices (GAPs)

Since the application methods and work practices of the handlers have direct impact on the amount of fumigant applied and emitted, the Agency believes that labeling should describe proven practices that will reduce risks to handlers, bystanders, and the environment. Registrants, applicators, growers, and other stakeholders have consistently reported to the Agency that GAPs are the best mitigation measure to reduce the amount of fumigants applied and emitted.

The following GAPs must be followed during all fumigant applications. The registrants have the option to develop additional optional GAPs to be listed on product labels. All measurements and other documentation planned to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the post-application summary report.

Tarps (for all applications except for deep shank CA orchard replant and hand held tree-hole applications)

- Tarps must be installed prior to starting hot gas applications.
- Tarps must be installed immediately after the fumigant is applied to the soil for bedded or broadcast applications.
- A written tarp plan must be developed that includes:
  - schedule and procedures for checking tarps for damage, tears, and other problems

- plans for determining when and how repairs to tarps will be made, and by whom
- minimum time following injection that tarp will be repaired
- minimum size of tarp damage that will be repaired
- other factors used to determine when tarp repair will be conducted:
  - schedule, equipment, and methods used to perforate tarps
  - aeration plans and procedures following perforation of tarp, but prior to tarp removal or planting/transplanting
  - schedule, equipment, and procedures for tarp removal

The written tarp plan must be included in the site specific FMP as described in the FMP section below.

Weather Conditions

- Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigant application must be checked.
- Do not apply fumigant if ground-level winds are less than 2 mph.
- Applications must not occur during a temperature inversion or when temperature inversions are forecasted to persist for more than 6 consecutive hours for the 36-hour period after application.
  - Visual features that could indicate an inversion is occurring are misty conditions during day or night, and clear night skies.
- Detailed local forecasts for sky conditions, weather conditions, wind speed, and forecasted temperature inversions may be obtained on-line at http://www.nws.noaa.gov.
- For further guidance, contact the local National Weather Service Forecasting Office.

Soil Temperature

- The maximum soil temperature at the depth of injection shall not exceed 90 degrees F at the beginning of the application.
  - If air temperatures have been above 100 degrees F for more than three hours in any of the three days prior to application, then soil temperature shall be measured and recorded in the FMP.

Soil Moisture

- The soil must be moist two to six inches below the surface. The amount of moisture needed in this zone will vary according to soil type and shall be determined using standard feel testing methods (see below). Surface soil generally dries rapidly and must not be considered in this determination.
- If there is insufficient moisture two to six inches below the surface, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below six inches, soil moisture can be brought to the surface by discing or plowing before or injection. To conserve existing soil moisture, pretreatment or treatment tillage should be done as close to the time of application as possible.

  Soil moisture determination

The soil shall contain at the time of application enough moisture two to six inches below the surface to meet the following criteria as appropriate for the soil texture.

- For **fine textured soils** (clay loam, silty clay loam, sandy clay, silty clay, sandy clay loam and clay) there must be enough moisture so that the soil is pliable, not crumbly, but does not form a ribbon when squeezed between the thumb and forefinger.
- For **coarse soils** (sand and loamy sand) there must be enough moisture to allow formation of a weak ball when compressed in the hand. Due to soil texture, this ball is easily broken with little disturbance.
- Fo**r medium textured soils** (coarse sandy loam, sandy loam, and fine sandy loam) there must be enough moisture to allow formation of a ball which holds together with moderate disturbance, but does not stick between the thumb and forefinger.
- For **fields with more than one soil texture**, soil moisture content in the lightest textured (most sandy) areas must comply with this soil moisture requirement. Whenever possible, the field should be divided into areas of similar soil texture and the soil moisture of each area should be adjusted as needed. Coarser textured soils can be fumigated under conditions of higher soil moisture than finer textured soils; however, if the soil moisture is too high, fumigant movement will be retarded and effectiveness of the treatment will be reduced. Previous and/or local experience with the soil to be treated or the crop to be planted can often serve as a guide to conditions that will be acceptable. If there is uncertainty in determining the soil moisture content of the area to be treated, local extension service or soil conservation service specialist or pest control advisor (ag consultant) should be consulted for assistance.

Soil Preparation

- Soil shall be properly prepared and at the surface generally be free of clods that are golf ball size or larger. The area to be fumigated shall be tilled to a depth of 5 to 8 inches.
- Field trash must be properly managed. Residue from a previous crop must be worked into the soil to allow for decomposition prior to fumigation. Little or no crop residue shall be present on the soil surface. Crop residue that is present must not interfere with the soil seal.

Soil Sealing

- *For Broadcast Untarped Applications:* Use a disc or similar equipment to uniformly mix the soil to at least a depth of 3 to 4 inches to eliminate the chisel or plow traces. Following elimination of the chisel trace, the soil surface must be compacted with a cultipacker, ring roller, and roller in combination with tillage equipment.
- *For Bedded Applications*: Performed beds shall be sealed by disruption of the chisel trace using press sealers, bed shapers, cultipackers, or by re-shaping (relisting, lifting and replacing, etc.) the beds immediately following injection. Beds formed at the time of application shall be sealed by disrupting the chisel trace using press sealers, or bed shapers.
- *Soil Sealing for Tarped Applications*: The use of a tarp does not eliminate the need to minimize chisel traces prior to application of the tarp, such as by using a nobel plow or other injection shank that disrupts the chisel traces.

<u>Methyl Bromide Bedded and Broadcast Shank Applications: Additional GAPs</u>

In addition to the GAPs required for all soil fumigation applications, the following GAPs apply for injection applications:

Tarps

- Tarps must be installed immediately after the fumigant is applied to the soil.

Soil Preparation

- Trash pulled by the shanks to the ends of the field must be covered with tarp, or soil, depending on the application method before making the turn for the next pass.

Application Depth

- *For Tarped-Broadcast and Tarped-Bedded Applications:* The injection point shall be a minimum of 8 inches from the nearest final soil/air interface. For tarped bedded applications the injection depth must not be deeper than the lowest point of the tarp (i.e., the lowest point of the tuck).
- *For Untarped-Bedded Applications*: The injection point shall be a minimum of 12 inches from the nearest final soil/air interface.
- *For Untarped-Broadcast Applications (CA orchard replant only):* The injection point shall be a minimum of 18 inches from the nearest final soil/air interface.

Prevention of End Row Spillage

- Do not apply or allow fumigant to drain onto the soil surface. For each injection line either have a check valve located as close as possible to the final injection point, or drain/purge the line of any remaining fumigant prior to lifting injection shanks from the ground.
- Do not lift injection shanks from the soil until the shut-off valve has been closed and the fumigant has been depressurized (passively drained) or purged (actively forced out via air compressor) from the system.

Calibration, Set-up, Repair, and Maintenance for Application Rigs

- Brass, carbon steel or stainless steel fittings must be used throughout. Polyethylene tubing, polypropylene tubing, Teflon® tubing or Teflon® -lined steel braided tubing must be used for all low pressure lines, drain lines, and compressed gas or air pressure lines. All other tubing must be Teflon® -lined steel braided.
- Galvanized, PVC, nylon or aluminum pipe fittings must not be used.
- All rigs must include a filter to remove any particulates from the fumigant, and a check valve to prevent backflow of the fumigant into the pressurizing cylinder or the compressed air system.
- Rigs must include a flowmeter or a constant pressure system with orifice plates to insure the proper amount of fumigant is applied.
- To prevent the backflow of fumigant into the compressed gas cylinder (e.g. nitrogen, other inert gas or compressed air), if used, applicators must:
    - Ensure that positive pressure is maintained in the cylinder at not less than 200 psi during the entire time it is connected to the application rig, if a compressed gas cylinder is used. (*This is not required for a compressed air system that is part of the application rig because if the compressor system fails the application rig will not be operable*)
    - Ensure that application rigs are equipped with properly functioning check valves between the compressed gas cylinder or compressed air system and the fumigant

cylinder. The check valve is best placed on the outlet side of the pressure regulator, and is oriented to only allow compressed gas to flow out of the cylinder or compressed air out of the compressed air system.
    - Always pressurize the system with compressed gas or by use of a compressed air system before opening the fumigant cylinder valve.
- Before using a fumigation rig for the first time, or when preparing it for use after storage, the operator must check the following items carefully:
    - Check the filter, and clean or replace the filter element as required.
    - Check all tubes and chisels to make sure they are free of debris and obstructions.
    - Check and clean the orifice plates and screen checks, if installed.
    - Pressurize the system with compressed gas or compressed air, and check all fittings, valves, and connections for leaks using soap solution.
- Install the fumigant cylinder, and connect and secure all tubing. Slowly open the compressed gas or compressed air valve, and increase the pressure to the desired level. Slowly open the fumigant cylinder valve, always watching for leaks.
- When the application is complete, close the fumigant cylinder valve and blow residual fumigant out of the fumigant lines into the soil using compressed gas or compressed air. At the end of the application, disconnect all fumigant cylinders from the application rig. At the end of the season, seal all tubing openings with tape to prevent the entry of insects and dirt.
- Application equipment must be calibrated and all control systems must be working properly. Proper calibration is essential for application equipment to deliver the correct amount of fumigant uniformly to the soil. Refer to the manufacturer's instructions on how to calibrate your equipment, usually the equipment manufacturer, fumigant dealer, or Cooperative Extension Service can provide assistance.

<u>Hot Gas Soil Applications (Greenhouse and Outdoor): Mandatory GAPs</u>

- All delivery tubes shall be placed under the tarp in such a way that they do not move during the application of methyl bromide.
- The fumigant must be introduced from outside of the greenhouse/application block (see entry restrictions and respiratory protection sections for further details).
- All fittings, connections, and valves must be checked for methyl bromide leaks prior to fumigation. If cylinders are replaced during the fumigation process, the connections and valves must be checked for leaks prior to continuing the job.

<u>Tree Replant Application: Mandatory GAPs</u>

In addition to the GAPs required for all soil fumigation applications, the following GAPs apply for tree replant applications. This application method is used when methyl bromide is applied to individual tree sites in an existing orchard where shank application are not possible:

Site Preparation

- Each individual tree-site must remove the tree stump and primary root system with a back-hoe or other similar equipment, for example an auger.
- The hole must be backfilled with soil before application.

Application Depth

- The fumigant must be injected at least 18 inches into the soil.

System Flush

- Before removing the application wand from the soil the wand must be cleared using nitrogen or compressed air.

Soil Sealing

- After the wand is cleared and removed from the soil, the injection hole must be either covered with soil and tamp or the soil must be compacted over the injection hole.

ii. Fumigant Management Plans (FMPs)

The Agency is requiring FMPs to be completed before a fumigant application occurs. FMPs will reduce risks by requiring that applicators develop a series of performance criteria for their given application situation that are intended to minimize risks according to the Agency's guidance provided below, then review those criteria before a fumigation occurs. Fumigant management plans (FMPs) will reduce potential risks to bystanders as well for handlers. The FMPs will also require that applicators verify compliance with the criteria after application events are completed. In cases where errors may have occurred, a post-application summary may also prevent similar problems from occurring during future applications. As an additional benefit, the Agency believes FMPs will ensure directions on the product labels have been followed and that the conditions for the fumigation are documented.

FMPs may should aide in the proper response of the applicator or others involved in the application should an incident occur. A proper and prompt response will reduce the potential risk to bystanders from potential high exposure situations (e.g., readily available first responder contact information could reduce response times to impacted bystanders and carefully thought out emergency response plans can help ensure appropriate actions are taken in case of unforeseen events).

There is information from various sources that health and safety plans, FMPs in this context, typically reduce workplace injuries and accidents by prescribing a series of operational requirements and criteria. In fact these plans are widely implemented in a variety of industries and are recommended as standard approaches for occupational health and safety management by groups such as American Industrial Hygiene Association[23] (i.e., through "Administrative" and "Workplace" controls). The Centers for Disease Control provides guidance for developing health and safety plans in agricultural settings.[24] The effectiveness of similar plans has also been evaluated in the literature. Examples include "lookback" reviews conducted by the Occupational Safety and Health Administration (OSHA) which essentially implemented standards in various

[23] Ignacio and Bullock (2006) A Strategy For Assessing and Managing Occupational Exposures (Third Edition), American Industrial Hygiene Association, AIHA Press 2700 Prosperity Avenue, Suite 250 Fairfax VA 22031 (ISBN 1-931504-69-5)

[24] Karsky (2002) Developing a Safety and Health Program to Reduce Injuries and Accident Losses, Centers For Disease Control National Ag Safety Database, available at http://www.cdc.gov/nasd/docs/d001501-d001600/d001571/d001571.html

industries then reviewed their effectiveness in this process as they are required to determine whether the standards should be maintained without change, rescinded or modified. OSHA is required by Section 610 of the Regulatory Flexibility Act (5 U.S.C. 610) and Executive Order 12866 to conduct the "lookback" reviews. These reviews are conducted to make the subject final standards more effective or less burdensome in achieving their objectives, to bring them into better alignment with the objectives of Executive Order 12866, and to make them consistent with the objectives of the Regulatory Flexibility Act. Two examples of "lookback" reviews that support the use of FMPs for soil fumigant health and safety management include: ethylene oxide use as a fumigant/sterilant, and grain handling facilities requirements.[25]

According to stakeholder comments, most of the information required for the site-specific FMP is already being documented by users. Most industry stakeholders support mandatory FMPs provided they are not too restrictive and do not result in an excessive administrative burden.

Each site-specific FMP must contain the following elements:

- General site information
  - Site address or description of location
  - Site operator/owner's name, address, and, phone number
  - Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, public roads, bus stops, water bodies, wells, rights-of-ways inside buffers, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ mile buffer zones (e.g., prisons, schools, hospitals, state licensed day care centers) with distances from the application site labeled
- Applicator information (license #, address, phone, contact information for person supervising the fumigation with location and date for completing registrant methyl bromide training program)
- Authorized on-site personnel (Names of all handlers and the tasks they are authorized and trained to perform)
- Application procedures
  - Fumigation window (target application date, earliest and latest possible date of fumigation)
  - Product information (brand name, registration number)
  - Type of fumigation (e.g., shank, broadcast, drip, raised bed, strip, etc.)
  - Target application rate and application block size
- Good Agricultural Practices (GAPs)
  - Description of applicable mandatory GAPs (registrants may also include optional GAPs)
  - Measurements and other documentation planned to ensure GAPs are achieved (e.g. measurement of soil and other site conditions; tarp repair/perforating/removal plans; etc.)
- Buffer zones
  - Calculations and rationale for buffer zones distances (e.g. specify table from label that distances based on, rate and block size, applicable credits applied)
  - Start and stop times for buffer zones

[25] United States Department of Labor, Occupational Safety and Health Administration (2008) Lookback Reviews available at http://www.osha.gov/dea/lookback.html

- Respirators and other personal protective equipment (PPE) for handlers (respirator type, respirator cartridge, and other PPE selection; verification that respirator training/fit-testing/medical exams is current; and maintenance/storage procedures)
- Air monitoring
  - Type of samples that will be collected (e.g., occupational, in occupied structures, outside buffer zone area if site monitoring is conducted, etc.)
  - When and where samples will be collected
  - Duration of samples
  - Sampling methods and equipment
  - Name, address, and, phone number of person taking samples
- Posting (names of persons who will post signs, location of posting signs, procedures for posting and sign removal)
- Site-specific response and management
  - Fumigant site monitoring
    - Description of who, when, where, and procedures for monitoring buffer zone perimeter
  - Response information for neighbors
    - List of residences and businesses informed (neighboring property owners)
    - Method of sharing information
- State and tribal lead agency notification
  - Include the information that is sent to the lead agency
- Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (tarp cutters/removers, irrigators, etc.)
- Record keeping procedures
- Emergency procedures (evacuation routes, locations of telephones, contact information for first responders, local/state/federal contacts, key personnel and emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).
- Hazard communication (product labels, material safety data sheets, etc.)

For situations where an initial FMP is developed and certain elements do not change for multiple fumigation sites (e.g. applicator information, authorized on-site personnel, record keeping procedures, emergency procedures, etc.) only elements that have changed need to be updated in the site-specific FMP provided the following:

- The certified applicator supervising the application has verified that those elements are current and applicable to the application block before it is fumigated and has documented the verification in the site-specific FMP.
- Recordkeeping requirements are followed for the entire FMP (including elements that do not change)

Once the application begins, the certified applicator and owner/operator of the application block must provide a copy of the FMP to handlers involved in the fumigation, workers in

adjacent areas to the application block, and federal/state/local enforcement personnel, upon request.

Within 30 days of completing the application portion of the fumigation process, the certified applicator supervising the application must complete a post fumigation application summary that describes any deviations from FMP that have occurred, measurements taken to comply with GAPs as well as any complaints and/or incidents that have been reported to him/her. The summary must include the actual date of the application, application rate, and size of application block fumigated.

In addition to recordkeeping requirements from 7 CFR part 110 "Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides", this decision requires that both the applicator and owner/operator of the application block must keep a signed copy of the site-specific FMPs and the post-application summary record for 2 years from the date of application.

Applicators and other stakeholders have the flexibility to prepare FMPs templates or use software with certain elements listed above in check-list and/or fill in the blank format. Below are examples of other FMP templates available on the internet for structural fumigations that may be useful to users when developing FMPs for methyl bromide soil applications:

- http://www.cardinalproproducts.com/Misc/FMP%20Version%203.pdf
- http://www.pestcon.com/techlibrary/fum_mgmt_plan.doc
- http://www.agr.state.ne.us/division/bpi/pes/fumigation_plan.pdf
- http://www.agr.state.ne.us/division/bpi/pes/fumigation_plan2.pdf
- http://nmdaweb.nmsu.edu/pesticides/Management%20Plans%20Required%20for%20Fumigations.html

iii. Emergency Preparedness and Response

EPA believes measures for ensuring preparedness for situations when accidents or emergencies occur are an important part of the suite of measures necessary to address risks posed by fumigants. Therefore, EPA is requiring such measures at the community level in the form of education for first responders, and information for specific sites to ensure early detection and quick response to situations as they arise.

Although EPA believes buffers and other mitigation will prevent many future incidents, it is likely that some incidents will still occur due to accidents, errors, and/or unforeseen weather conditions. Early detection and appropriate response to accidental chemical releases is an effective means of reducing risk, as well as addressing the source of the release. Reducing risks associated with incidents that may occur in the future is a key part of EPA's soil fumigant decisions. By combining buffers with GAPs, FMPs, and effective emergency response, EPA is able to reach a "no unreasonable adverse effects" finding under FIFRA.

To ensure that appropriate response mechanisms are in place in the event of a fumigant exposure incident, EPA is requiring that registrants provide training and information, in the

context of their community outreach and education programs (see page 78) to first responders in high-fumigant use areas and areas with significant interface between communities and fumigated fields. In addition, applicators must provide on-site monitoring of buffer zone perimeters in areas where residences and other occupied structures are present. As an alternative to on-site monitoring, applicators may provide emergency response information directly to neighbors. Each element is discussed in more detail below.

(a) First Responder Education

EPA is requiring registrants through their community outreach and education programs (see page 78) to ensure that emergency responders have the training and information that they need to effectively identify and respond to fumigant exposure incidents. EPA believes this will help ensure, in the case of a fumigant accident or incident that first responders recognize the exposure as fumigant related and respond appropriately. The information/training to be provided to first responders will include: how to recognize the early signs and symptoms of fumigant exposure, how to treat fumigant exposures, how fumigant exposure differs from other pesticide exposure, plus the material safety data sheet(s) (MSDS) for the fumigant(s) applied.

The Agency is interested in comments from state and/or local officials about the extent to which first responders are currently receiving information on soil fumigants, for example can they recognize fumigant exposures, and are they aware of the appropriate steps to take to mitigate the exposures and address the source of the exposure. In California, for example, where soil fumigation is common in many areas, the state administers training and outreach for first responders to help raise awareness and improve skills in responding to incidents. If registrants can document that effective state programs are already in place, additional training may not be required. However, registrants must work with state and local emergency response coordinators to identify needs and opportunities to supplement any information already included in state and local training for first responders about soil fumigants specifically.

(b) Site Specific Response and Management

▪ Fumigation Site Monitoring

EPA has determined that monitoring of the buffer zone perimeter would be an effective approach to protect bystanders. Under this approach, if measured concentrations anywhere along the buffer perimeter reach a level of concern specified on product labels, or if the person monitoring the air concentrations experiences eye irritation, an early sign of exposure to concentrations that exceed the Agency's LOC, then the emergency response plan stated in the FMP Section (see page 66) must be implemented. If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. Because data indicate that peak concentrations sometimes occur on the second day following applications, EPA decided that this monitoring must be done for the full buffer zone period to ensure concentrations do not exceed the action level which will be specified on product labels.

Specific requirements include:

- Monitoring must take place from the beginning of the fumigant application until the buffer zone period expires.
- Monitoring must be conducted by a certified applicator or someone under his/her supervision.
- Monitoring of air concentration levels of the fumigant must take place in the area between the buffer zone and the residences or other occupied areas.
- The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period.
- A direct reading detection device, such as a Draeger device with a sensitivity of at least 1 1 ppm for methyl bromide and 0.15 ppm for chloropicrin must be used to monitor the air concentration levels of chloropicrin.
- If at any time (1) methyl bromide air concentrations are greater than or equal to 1 ppm, OR (2) chloropicrin air concentrations are greater than or equal to 0.15 ppm, OR (3) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations.
- If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.
- The results of the air concentration monitoring must be recorded in the FMP.

EPA is interested in comments from fumigant users, researchers, and equipment manufacturers about the extent to which mechanical devices are available or are under development that can both monitor air concentrations and also notify the person responsible for the fumigation when air concentrations approach levels of concern. Such devices are routinely used to monitor environmental conditions in laboratories, and could represent an effective alternative to posting a person on site. EPA also requests input from stakeholders who have experience conducting air monitoring and use of devices on whether more effective, efficient, or practical alternative approaches exist. For example, with specific application methods, fumigants, and/or regional weather conditions, what frequency and duration of sampling would be equally as effective as what is specified in the mitigation?

While protective, this site monitoring might be burdensome for users fumigating in areas with few or no people. Therefore, EPA is allowing users the alternative option of providing emergency response information directly to neighbors.

- **Response Information for Neighbors**

As an alternative to on-site monitoring, the certified applicator supervising the fumigation (or someone under his/her direct supervision) would need to ensure that residences and businesses that meet the criteria outlined below have been provided the information below at least 48 hours prior to fumigant application in a specified field. If after 2 weeks, the fumigation has not yet taken place, the information must be delivered again.

- Information that must be provided includes:
  - Location of the application block

- Name of fumigant products(s) applied including EPA Registration number
- Applicator and property owner/operator contact information
- Location of buffer zones
- Time period in which the fumigation is planned to take place and the duration of buffer zone period
- Early signs and symptoms of exposure to the fumigant(s) applied, what to do, and who to call if you believe you are being exposed (911 in most cases).

The method for distributing information to neighbors must be described in the FMP and may be accomplished through mail, telephone, door hangers, or through other methods that can be reasonably expected to effectively inform residences and businesses within the required distance from the edge of the buffer zone.

Who Needs to be Informed?:

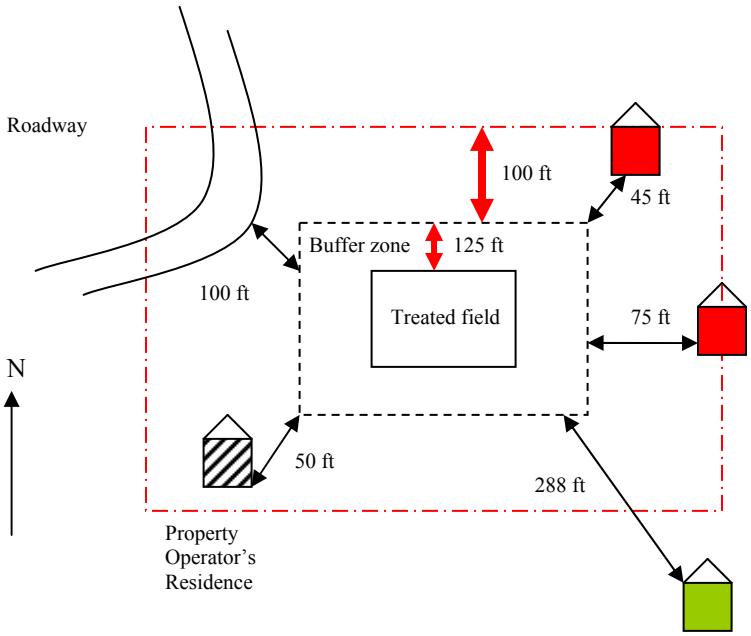
If the buffer zone is less than or equal to:	**People within this distance from the edge of the buffer zone must be informed:**
Buffer ≤ 100 feet	50 feet
100 feet < Buffer ≤ 200 feet	100 feet
200 feet < Buffer ≤ 300 feet	200 feet
Buffer > 300 feet	300 feet

To clarify this option, the following example is provided:

- IF the buffer zone is **125 feet**, people within 100 feet of the buffer zone must be provided emergency response information. So the **red** houses would need to be informed, **but** the **green** house would not.

- This requirement does not impact the roadway or the property operator's residence (striped).

Figure 9. Example Site Map for Informing Neighbors



If there are no residences or other occupied structures within 300 feet of the edge of the buffer zone, no site monitoring or advising of neighbors will be required.

(c) Emergency Preparedness and Response Considerations

EPA received comments from many stakeholders about the Agency's Phase 5 proposal for notification. Users have commented that notification is burdensome and that it is unnecessary if buffer zones are also required. However, community groups have commented on the importance of bystanders being informed when fumigations are occurring, since this group of pesticides, compared to other pesticides, has a greater potential to move off site and affect people not involved in the application. State regulators have different views on this requirement. Some support the sharing of information with neighbors, and some states have notification requirements for fumigations with certain products or for certain application methods. In addition, some states require notification to chemically sensitive individuals in proximity to pesticide applications. Others also had concerns about the enforceability of this type of measure and the possible burden on the states to enforce a notification requirement.

California currently requires notification of persons within 300 feet of a methyl bromide buffer zone. California strawberry growers consider the 300 foot notification area for methyl bromide applications to be an extension of the buffer zone. In areas where a large number of people would need to be notified about a planned methyl bromide application, strawberry growers state that they would rather not use methyl bromide because some communities could mobilize to prevent the fumigation from taking place. Some stakeholders also commented that it would be protective and less burdensome if EPA required the user to monitor fumigant air

concentrations at the edge of the buffer for 24 hours after the application to ensure the fumigant does not move beyond the buffer at concentrations that exceed EPA's level of concern. If concentrations of concern were detected, the user would be required to implement the emergency response measures specified in the fumigant management plan.

EPA has concluded that bystanders could take steps to protect themselves if they had basic information about fumigations and the appropriate steps to take if they experienced symptoms of exposure. In a number of fumigant incidents that have occurred, the magnitude and severity of the incident could have been significantly reduced if people had such information. Similarly, having on-site monitoring will enable site managers to take remedial action (i.e., activate the control plan in the FMP) to lower emissions sooner, also resulting in fewer and less severe exposures. And, if necessary, site managers would activate the emergency response elements of the FMP.

Providing communities with information about local chemical releases is an important part of emergency preparedness programs and is recognized as an effective means of addressing risk at the local level. Some states, like Florida and Wisconsin, have requirements for providing information to chemically-sensitive individuals about chemicals used nearby so they can take steps to protect themselves from potentially harmful exposures (see http://edis.ifas.ufl.edu/pi004 and http://www.legis.state.wi.us/rsb/code/atcp/atcp029.pdf). Wisconsin also requires fumigators applying metam sodium products through chemigation to provide written notice to the county public health agency and to every individual or household within ¼ miles of the chemigation application site (see http://www.legis.state.wi.us/rsb/code/atcp/atcp030.pdf). EPA agrees that information about how to recognize and address exposures can help citizens reduce potential risk.

EPA understands that difficult challenges exist when agricultural land borders urban or suburban communities. While EPA's decisions for the fumigants will not alleviate challenges that already exist, EPA is allowing options for ensuring emergency preparedness in an effort to lessen potential impact on growers.

If users opt, based on their site conditions, to provide emergency response information to neighbors rather than monitor, EPA believes that scaling the size of the informed area will be protective and helps address concerns expressed by some fumigant users. When the informed area is scaled to the size of the buffer, small buffers which generally result from applications to small areas, at low application rates, and/or using low-emission application techniques, will have small or no areas to inform, while larger applications will have larger areas to inform.

EPA is not requiring a specific method of providing the information to neighbors, but rather that it be done in a way that effectively communicates, in a manner the recipients will understand. Some methods may not result in documentation that would be retained. To address concerns about enforcement, EPA is requiring that information on how and when the emergency response information was delivered and to whom, be included in the FMP.

EPA is interested in input on the importance and usefulness of information specifying the location of the application block and buffer. EPA recognizes that such information may be

difficult to convey clearly and concisely, especially if there are no easily recognizable land marks nearby. While such information may be helpful, it may not be critical to ensuring an appropriate response to early signs and symptoms of exposure.

iv. Notice to State Lead Agencies

EPA believes that when state, tribal and local enforcement officials have information about when and where applications take place they are better able to plan and execute compliance assistance and assurance activities. Therefore, EPA is requiring notification of the appropriate state or tribal lead agency before an application begins to assist enforcement agencies in compliance monitoring.

The information that must be provided includes the following:

- Applicator contact information (name, telephone number, and applicator license number)
- Property owner/operator contact information
- Location of the application block
- Name of fumigant(s) products(s) applied including EPA Registration number
- Time period in which the fumigation is planned to take place and the duration of buffer zone period

Assuring compliance with new label requirements is an important component of the fumigant risk mitigation package. Notice to enforcement officials allows them to target inspections around periods when fumigations are expected to occur to ensure label requirements designed to mitigate risks of concern for bystanders, handlers, and workers, have been followed and that the conditions for the fumigation have been documented in the FMP. In states such as California, where permitting processes are already in place, additional notice to state and tribal lead agencies will not be required.

v. Soil Fumigation Training for Applicators and Other Handlers

Soil fumigation is an inherently complex activity involving specialized equipment and application techniques. Additionally, the mitigation measures required as part of these decisions will introduce new requirements in the form of more detailed instructions and restrictions on soil fumigations. Failure to adequately manage fumigant applications increases risks to handlers involved in the fumigation, workers nearby, and other bystanders. Incident data show that a number of fumigant incidents are the result of misapplications, failure to follow label requirements and safe use procedures, and other errors on the part of fumigant applicators. Although states have certification programs, some of which include a specific category for soil fumigation, there currently is not a consistent standard across states and regions where soil fumigation is done, and the federal certification program currently has no category for soil fumigation. Proposed changes in the federal certification program and worker safety regulations to include a soil fumigation category are not, however, anticipated in the near future.

EPA believes that training is an effective way to increase applicators' skill and knowledge so they are better prepared to effectively manage soil fumigation and are able to understand and comply with revised labeling. EPA has determined that training, developed and implemented by registrants to foster product stewardship, will help reduce potential risks associated with failure to adequately manage the complexities of fumigation, and failure to comply with fumigant product labeling. Additionally, EPA believes that providing safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from risks of exposure.

It is important to note that training developed and provided by registrants as required by this RED is separate and distinct from state certification programs. EPA encourages registrants, in developing their training proposals, to work with states where their products are used to identify opportunities to build on and complement state programs. However, the training programs required as part of this decision will be separate from the state certification process and will be developed and administered by registrants. Individual state regulatory agencies have the option of working with registrants on these activities, but are not required to do so. It is important to note that some fumigant registrants have already developed product-specific training that will serve as a good basis for this expanded effort.

(a) Training for Applicators Supervising Fumigations

Registrants will be required to develop and implement training programs for applicators in charge of soil fumigations on the proper use and GAPs for soil fumigants. EPA is requiring registrants to submit proposals for these programs as data requirements in the Data Call-In that will accompany this RED. The training programs must address, at minimum, the following elements: how to correctly apply the fumigant; how to protect handlers and bystanders; how to determine buffer zone distances; how to develop a FMP and complete the post fumigation application summary; how to determine when weather and other site-specific factors are not favorable for fumigant application; how to comply with required GAPs and document compliance in the FMP. The training program must be made available to applicators at least annually. The registrant shall provide documentation, such as a card or certificate, to each applicator who successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion.

The registrant must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion. Applicators supervising fumigations must have successfully completed the program within the preceding 12 months and must document when and where the training program was completed in the FMP. The registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training and (2) make this database available to state and/or federal enforcement entities upon request. In addition, the applicator must provide to federal, state, or local enforcement personnel, upon request, documentation that verifies completion of the appropriate training program(s).

Product labels will state that before applying the product, the certified applicator supervising the application must have successfully completed, within the preceding 12 months, a chloropicrin training program made available by the registrant, and that the FMP must document when and where the training program was completed.

EPA encourages registrants to include in their proposals additional stewardship elements such as technical support information and resources for certified applicators and/or handlers (e.g., hotlines to answer technical questions from applicators about product use and provide emergency preparedness and response), and equipment verification programs to assist applicators with calibration and testing of soil fumigation equipment. The Agency is soliciting input during the post-RED comment period from states, user groups, registrants, and other stakeholders on content and how best to implement training programs and other stewardship elements.

(b) Training Materials for Handlers

EPA has determined that registrants must prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. EPA is requiring registrants to submit proposals for these materials as data requirements in the Data Call-Ins that will accompany this RED. The training materials must address, at minimum, the following elements: (1) what fumigants are and how they work, (2) safe application and handling of soil fumigants, (3) air monitoring and respiratory protection requirements for handlers, (4) early signs and symptoms of exposure, (5) appropriate steps to take to mitigate exposures, (6) what to do in case of an emergency, and (7) how to report incidents. Registrants must provide this training information through channels open to the public (e.g., via a website). Pesticide labels will require that applicators supervising fumigations provide this training information to handlers under their supervision before they perform any fumigant handling task, or they must ensure that handlers have been provided the required information within the preceding 12 months. The label will also require that the training information be provided in a manner that the handler can understand. Applicators supervising fumigations must ensure the FMP includes how and when the required training information was provided to the handlers under their supervision. Below is the language that must appear on the label.

"The certified applicator must provide fumigant safe handling information to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months."

(c) Soil Fumigation Training Considerations

In comments on fumigant risk management options, stakeholders were broadly supportive of additional training for applicators and handlers. During the most recent comment period, the vast majority of stakeholders, including growers, community groups, farm workers, states, and registrants expressed strong support for increased training for applicators and other handlers. Several comments noted that fumigant incidents affecting both fumigant workers and bystanders could have been prevented or mitigated if applicators had better training about correct practices and procedures.

The Agency agrees that additional training and technical support for fumigant applicators and handlers will help educate and inform these workers, thus decreasing the likelihood of both incidents and noncompliance. EPA believes fumigant-specific training for applicators and handlers also will help reduce the magnitude and frequency of exposure incidents and, coupled with the other mitigation measures described in this decision, will address risks of unreasonable adverse effects from the use of soil fumigants.

As noted above, several states have high-quality certification programs for fumigators which include exams to test the competency of fumigators. EPA recognized that for applicators to become certified in those states, they must acquire the knowledge and skill necessary to pass the exam. But several stakeholders commented that training opportunities are varied across the country, and the scope and detail of information provided in available training is not consistent. EPA is also concerned that information in existing programs will need to be updated as a result of new requirements associated with this decision and the label changes which will result. Although the federal program will be revised eventually and will establish a consistent standard, EPA believes that registrants must play a central role in developing and delivering training in the interim.

EPA stresses that registrant training programs will be separate from the state certification process and will be developed and administered by registrants in coordination with EPA. EPA will, however, work with state organizations and training experts to explore opportunities for the registrant programs to supplement state programs to provide additional training opportunities for fumigators. EPA will work with registrants in reviewing training program proposals and in developing the content for the programs and materials. EPA will also work with states to identify ways in which registrant training programs can be tailored to complement existing state programs. EPA's goal in requiring registrant training is to add to training resources. EPA is aware of the need to coordinate carefully with states to ensure that new training does not become a burden on state agencies. EPA specifically requests comments from states on the best implementation approaches to meet these goals, and plans to meet with states during and after the public comment period to discuss options.

The Agency also expects that FMPs will serve as tools with which fumigant users can maintain records of their compliance with training requirements in addition to the other measures described in this document. Thus, FMPs would serve as an additional tool for verification state enforcement personnel to verify compliance.

vi. Community Outreach and Education Programs

EPA understands from public comments, site visits, and stakeholder meetings, conducted as part of the soil fumigant review, that there is often a fundamental lack of information and communication within communities where soil fumigation occurs, which has raised health and safety concerns among community members. This lack of information and communication has led to inappropriate responses in cases where fumigants have moved off site and into communities. This also has led in some cases to unwarranted concern and anxiety among communities about the risks associated with the use of fumigants. The Agency believes that

outreach and education to communities where soil fumigation occurs is an important component of the overall package of measures to address bystander risk. This outreach and education will address the risk of acute bystander exposure by educating community members in high-use areas about buffer zones and their characteristics and purpose; the importance of not entering these zones; how to recognize early signs of fumigant exposure, and how to respond appropriately in case of an incident. The first responder education discussed on page 70 is a significant part of this program.

Therefore, the Agency is requiring registrants to develop and implement community outreach programs, including programs for first responders, to address these needs. EPA encourages registrants' proposals to work with existing community resources, such as community health networks, for dissemination of information and implementation of their programs. Registrants' proposals must also include criteria and a plan for identifying and selecting the communities that will be receive outreach programs.

Community outreach and education programs must include the following elements, at minimum: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident.

EPA expects registrants' proposals for the first responder programs described above (see page 70) will also be designed to integrate with existing local first-response and emergency preparedness networks.

The community outreach and education proposal and supporting materials for communities and first responders, as well as a plan for evaluating the effectiveness of the programs, will be included as data requirements in the Data Call-In that will accompany this RED.

As with the training for fumigant applicators and handlers, the community outreach and education program that the Agency is requiring is intended to be part of the registrants' long term product stewardship. State governments are not required to participate in the program, but have the option of working with EPA and registrants to develop and track this and any other stewardship components which the registrants may include in their proposals.

c. Environmental Risk Management

For details on the methyl bromide ecological fate and effects risk assessment, please refer to the ecological risk assessment and other related documents for methyl bromide. These documents are available in the public docket EPA-HQ-OPP-2005-0123, located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

As mentioned in Section III.D, the Agency is concerned about both aquatic and terrestrial risks. The Agency believes that mitigation measures detailed in the Human Health Risk Mitigation Section will also reduce ecological risks. Although buffer zones and GAPs do not directly reduce the potential risk to ecological organisms, they do provide an incentive to reduce

fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

The Agency still has concerns regarding methyl bromide's potential to leach into groundwater and surface water, and therefore is requiring the following language for both tarped and untarped methyl bromide applications, "While methyl bromide has certain properties and characteristics in common with chemicals that have been detected in groundwater (methyl bromide is highly soluble in water and has low adsorption to soil), volatilization is this chemical's most important route of dissipation." The Agency recognizes that managing soil moisture is an important factor that may be used to reduce peak emissions, and the requirements related to soil moisture described in the GAP section will not result in the leaching of methyl bromide into ground or surface water.

In addition to the language above, to reduce the potential for methyl bromide to leach into groundwater when tarps are used in broadcast applications, tarps must be perforated and/or removed before noon and only when rainfall is not expected within 12 hours. Falling temperatures typically found in the late afternoon and evening will not promote dissipation of remaining methyl bromide under the perforated tarp and rainfall may cause remaining methyl bromide under the perforated tarp to leach into ground water. For raised bed applications, rainfall is not a factor since planting occurs with the tarp in place and perforation and/or tarp removal occurs after methyl bromide has dissipated.

When methyl bromide applications are not tarped, the Agency has concerns about methyl bromide's potential to leach into both groundwater and surface water if a rainfall event occurs shortly after application. Methyl bromide may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. Leaching and runoff of this product will be reduced by avoiding applications when heavy rainfall is forecasted to occur within 24 hours.

The Agency also is requiring several ecological fate and effect studies to address data gaps identified in the ecological risk assessment. See Section V of this document for details on those studies.

d. Stratospheric Ozone Depletion Risk Management

While a quantitative reduction of methyl bromide's role in the depletion of stratospheric ozone resulting from the mitigation measures required by this decision can not be estimated, EPA believes that when looking at the mitigation as a whole, it can be qualitatively determined that a reduction will result. The following supports this conclusion:

Required Mitigation Measure	Rationale for expecting a reduction of Stratospheric Ozone Depletion

• Removal of uses with low benefits and/or available alternatives (i.e., ineligibility for uses that do not qualify for exemptions from the Montreal Protocol)	► EPA estimates that in 2007 approximately 1,213 metric tons of methyl bromide were applied for uses with low benefits and/or have feasible alternatives which do not qualify for exemptions under the Montreal Protocol. While the Agency acknowledges that limiting use to only Group 1 uses may slow the drawdown of the pre-2005 stockpile, it is reasonable to expect that new production for exempted uses will also continue to decline as there will be more pre-2005 stockpile material available for critical uses. The Agency believes that that this measure could contribute to the reduction of methyl bromide applied annually.
• Reducing maximum application rates;	► The Agency is limiting the labeled maximum application rates for CUE uses based rates from the most recent CUNs. Any reduction in application rate will result in less methyl bromide applied.
• Limiting use of 98:2 formulations to essential crops	► When 98:2 formulations are used, the amount of methyl bromide applied is generally higher compared to amount applied for other formulations. Limiting the use of 98:2 formulations to only essential crops will result in less methyl bromide applied.
• Buffer zones	► In order to achieve manageable buffer zones distances many growers will be required to change their current cultural practices, including lowering rates, using high barrier tarps, using more efficacious application methods, using alternatives, etc. Overall, these changes will result in lower application rates and less methyl bromide volatilizing into the atmosphere.
• Good agricultural practices (GAPs) and Fumigant management plans (FMPs)	► GAPs and FMPs will both result in better planning of fumigations and increase the likelihood of a safe and effective application. The Agency believes that these measures will also, to some degree, result in less methyl bromide volatilizing into the atmosphere.

2. Endocrine Disruptor Effects

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, 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. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, dazomet may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species Considerations

The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. To analyze the potential of registered pesticide uses that may affect any particular species, the Agency uses basic toxicity and exposure data developed for the REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of methyl bromide "may affect" listed species or their designated critical habitat, the Agency will employ the provisions in the Services' regulations (50 CFR Part 402). Until the species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to methyl bromide at levels of concern. The Agency is not requiring specific methyl bromide label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Program.

D. Conclusions

In this document, the Agency has described a package of mitigation measures with elements that are designed to work together to reduce risk to human health and the environment. Due to methyl bromide's volatility, the Agency believes that all of the mitigation measures required by this decision will mitigate risks so that methyl Bromide use will result in no unreasonable adverse effects.

Stakeholder comments and Agency analyses indicate that mitigation may impact the benefits of fumigant use. One analysis the Agency completed quantifies the potential impact of buffer zones[21]. The Agency believes that some impact will occur in order to protect human health and the environment from unreasonable adverse effects. EPA believes that impacts have

been minimized because the mitigation package incorporates flexibility which allows users to make choices that minimize potential impacts. For example a current application practice might require a large buffer that a user is not able to implement. However, instead of setting a fixed buffer for all applications regardless of application-specific parameters, this decision allows growers the flexibility to modify their practices to achieve smaller buffers; for example treat smaller application blocks, or switch to a lower emission application method. Also, the buffer zone reduction credits allow users to take advantage of site conditions (e.g., soil conditions) or other emission reduction factors such as high barrier tarps to lessen the impact. In addition the Agency believes that flexibility decreases the impacts associated with respiratory protection mitigation. Instead of requiring respirators for all handling tasks, the monitoring scheme indicates when respiratory protection is needed. This mitigation is protective of handlers while not increasing the burden to users by mandating respirators that may hinder communication or could potentially cause heat stress.

Taking into consideration the risk and benefit assessments and stakeholder comments, the Agency believes the mitigation required by this document will be protective and minimize impacts.

V. What Registrants Need to Do

The Agency has determined that the products containing methyl bromide are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. EPA recognizes that the extent and complexity of the mitigation needed for methyl bromide will require continued coordination among state regulatory agencies, the EPA, registrants, growers and other stakeholders. This is necessary to ensure that all provisions of the RED are understood, that data are developed and evaluated expeditiously, and that bystander and worker protection measures are implemented as soon as practicable. EPA also acknowledges that certain provisions of the RED, such as the worker training program and community education, will take time to develop in terms of both the content of the program as well as a strategy for implementation.

EPA envisions the following approximate schedule for implementation of the methyl bromide RED:

June 2008	Methyl Bromide RED issued
Fall 2008	Comment period closes
Early 2009	EPA responds to comments, amends RED if appropriate
Mid 2009	EPA issues product and generic DCIs
Mid 2009	Registrants submit revised labels to EPA
Late 2009	EPA reviews/approves new labeling
During 2009	Registrants develop worker and community training and outreach plans and submit to EPA; approved plans implemented
Early 2010	Products bearing new labels enter the market; training and outreach programs expand
2009-2012	Registrants develop data per DCI
2013	EPA begins Registration Review for methyl bromide and other fumigants

The Agency is issuing this decision document for methyl bromide, as announced in a Notice of Availability published in the Federal Register. Due to the broad scope of the decision for the soil fumigant group, there will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on issues related to the implementation of the risk mitigation measures. After considering public comment, the Agency will issue a public determination as to whether modifications to this decision are appropriate.

Labeling

Registrants will need to amend their product labeling to incorporate the label statements set forth in Table 9. The Agency will consider post-RED comments prior to finalizing labeling. The Agency anticipates that label amendments will need to be submitted approximately 1 year from the issuance of the RED.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of methyl bromide's preplant soil uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

a. Human health risk

Toxicity: none

Dietary Exposure: none

Occupational and Residential Exposure (ORE):

OPPTS Guideline Number	Data Requirement	Study type
OPPTS Guideline 835.8100	Field volatility from soil	Field Emissions

The following data are needed on methyl bromide for human health risk assessment.

- **Field Emissions/Volatility:** The current estimates of emissions which are critical in the calculation of modeling estimates used to define buffer zones are limited only to California and are not based on the most current cultural practices. These data will enable a more refined inhalation risk assessment to be completed for buffer zone determinations that will allow evaluations to be completed in all of the major use regions of the country and that are reflective of the most current cultural practices. It is believed that application practices have rapidly evolved over the last few years to account for the requirements of the Montreal Protocol implementation and phase out strategy for methyl bromide.

b. Environmental fate and ecological risk

Environmental fate: none

Ecological effects:

OPPTS Guideline Number	Data Requirement	Study type
Special	Avian acute inhalation	ECO
850.1075	Acute Fish Toxicity - bluegill trout	ECO
850.1075	Acute Marine/Estuarine Fish	ECO
850.1025	Acute Marine/Estuarine Mollusk	ECO
850.1035	Acute Marine/Estuarine Shrimp	ECO
850.4225	Seedling Emergence – Tier II	ECO
850.4250	Vegetative Vigor – Tier II	ECO
850.4400	Aquatic Plant Growth – Tier II	ECO
850.3020	Honeybee Acute Contact	ECO

The following data are needed on methyl bromide (and the bromide ion, where indicated) for ecological risk assessment[26].

- Avian acute inhalation. The current estimate of avian risk is based largely on the mammal assessment. This study will enable an inhalation risk assessment specific to birds.
- Acute Fish Toxicity - bluegill trout. RQs for bluegill trout approach the EPA's LOC. The risk assessment is currently relying on a Supplemental study for rainbow trout and various general literature toxicity values for other species.
- Acute Marine/Estuarine Fish. Given the use patterns of methyl bromide, marine/estuarine species could be exposed. This study will enable a risk assessment specific for marine/estuarine species exposure.
- Acute Marine/Estuarine Mollusk. Given the use patterns of methyl bromide, marine/estuarine species could be exposed. This study will enable a risk assessment specific for marine/estuarine species exposure. It will also improve certainty with the endangered species risk assessment, as this test species may be more representative of endangered freshwater mussels than the freshwater *Daphnia.*
- Acute Marine/Estuarine Shrimp. Given the use patterns of methyl bromide, marine/estuarine species could be exposed. This study will enable a risk assessment specific for marine/estuarine species exposure.
- Seed Gerrnination/Seedling Emergence - Tier II. Methyl bromide is used in part due to its phytotoxicity at the application site, and a wide range of open literature and other non-guideline studies indicate the potential for plant damage. This study will enable the assessment of risk to nontarget terrestrial plants off-site.

[26] EPA-HQ-OPP-2005-0123-0038, Reregistration Environmental Risk Assessment for Methyl Bromide, June 8, 2004, DP Barcode 304641

- Vegetative Vigor - Tier II. Methyl bromide is used in part due to its phytotoxicity at the application site, and a wide range of open literature and other non-guideline studies indicate the potential for plant damage. This study will enable the assessment of risk to non-target terrestrial plants off-site.
- Aquatic Plant Growth - Tier II. Methyl bromide is used in part due to its phytotoxicity at the application site, and a wide range of open literature and other non-guideline studies indicate the potential for plant damage. This study will enable the assessment of risk to non-target aquatic plants off-site. The current assessment used a non-guideline open literature toxicity value.
- Honeybee Acute contact - This basic study is now being requested for virtually all outdoor uses, and will help determine the need for, and specifics of, bee hazard labeling.

c. Other data requirements

OPPTS Guideline Number	Data Requirement	Study type
Special	Community Outreach and Education Program	Special
Special	Training for Applicators Supervising Fumigations	Special
Special	Training Materials for Handlers	Special

- Special Study - Community Outreach and Education Program

The Agency is requiring registrants to develop and implement community outreach programs, including programs for first responders, to address these needs. Community outreach programs must include the following elements, at minimum: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident. EPA expects registrants' proposals for the first responder programs described in Section IV will also be designed to integrate with existing local first-response and emergency preparedness networks.

- Special Study - Training for Applicators Supervising Fumigations

EPA has determined that training, developed and implemented by registrants to foster product stewardship, will help reduce potential risks associated with failure to adequately manage the complexities of fumigation, and failure to comply with fumigant product labeling. Additionally, EPA believes that providing safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from risks of exposure.

Registrants are required to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and GAPs for soil fumigants. EPA is requiring registrants to submit proposals for these programs. The training programs must address, at minimum, the following elements: how to correctly apply the fumigant; how to protect handlers

and bystanders; how to determine buffer zone distances; how to develop a FMP and complete the post fumigation application summary; how to determine when weather and other site-specific factors are not favorable for fumigant application; how to comply with required GAPs and document compliance in the FMP. The training program must be made available to applicators at least annually. The registrant shall provide documentation, such as a card or certificate, to each applicator who successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion. The registrant must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion. Applicators supervising fumigations must have successfully completed the program within the preceding 12 months and must document when and where the training program was completed in the FMP. The registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training and (2) make this database available to state and/or federal enforcement entities upon request. In addition, the applicator must provide to Federal, State, or local enforcement personnel, upon request, documentation that verifies completion of the appropriate training program(s).

- Special Study - Training Materials for Handlers

EPA has determined that registrants must prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. The training materials must address, at minimum, the following elements: (1) what fumigants are and how they work, (2) safe application and handling of soil fumigants, (3) air monitoring and respiratory protection requirements for handlers, (4) early signs and symptoms of exposure, (5) appropriate steps to take to mitigate exposures, (6) what to do in case of an emergency, and (7) how to report incidents. Registrants must provide this training information through channels open to the public (e.g., via a website). Pesticide labels will require that applicators supervising fumigations provide this training information to handlers under their supervision before they perform any fumigant handling task, or they must ensure that handlers have been provided the required information within the preceding 12 months. The label will also require that the training information be provided in a manner that the handler can understand. Applicators supervising fumigations must ensure the FMP includes how and when the required training information was provided to the handlers under their supervision.

2. Labeling for Manufacturing-Use Products

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. Also, various use and safety information will be required for labeling of all end-use products containing methyl bromide. The following table describes how language on the labels should be amended.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers must be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 9: Summary of Labeling Changes for Methyl Bromide Pre-plant Soil Fumigation

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into a pre-plant soil fumigant for the following use-sites: Uses, users, and locations that qualify for exemptions under the Montreal Protocol (e.g., critical use exemption or Quarantine and preshipment exemption uses). All end use products that contain directions for use as for crops/use sites that do not qualify for exemptions under the Montreal Protocol must be changed to remove those crops/use sites. All structural/space uses have been cancelled." "Methyl bromide formulated into end-use products containing 98% methyl bromide must contain directions for use only for the following uses: orchard replant, ornamentals (hot gas method only), forest seedlings, and quarantine uses. All other use sites and use patterns are prohibited and must be removed from the end-use product labeling." "Methyl bromide cannot be formulated into end-use products labeled for pre-plant uses without the use of tarps with the exception of California orchard replant for CUE use using the deep broadcast application method." "Methyl bromide cannot be formulated into end-use products labeled for pre-plant or pre-transplant uses unless the registrant makes available to certified applicators who purchase or apply the end-use product a training program approved by EPA that provides information on how to correctly apply the fumigant including how to protect themselves, other handlers and bystanders, how to determine buffer zone distances, how to develop a Fumigant Management Plan, and how to determine when weather and other site-specific factors are not favorable for fumigant application. The training program must be made available to the certified applicators at least annually and the registrant must be able to provide, upon request, the names, addresses, and certified applicator license number of persons who successfully complete the training program." "Methyl bromide cannot be formulated into end-use products labeled for pre-plant	Directions for Use

	or pre-transplant uses unless the registrant assures warning signs suitable for posting buffer zones are available to end-use product users at the point of sale." "The buffer zone sign must meet the following standards: o Signs must remain legible during entire posting period. o The size and type of the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting." **Contents of Sign**  -- "DO NOT ENTER/NO ENTRE," -- "[*Name of fumigant*] Fumigant BUFFER ZONE," -- a space for the date and time of fumigation, -- a space for the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires) -- brand name of this product, and -- a space for the name, address, and telephone number of the certified applicator in charge of the fumigation	
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to mammals and birds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use		
Restricted Use Requirement for all products that contain soil use	"Restricted Use Pesticide due to acute inhalation toxicity to humans. For retail sale to and use by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."	Top of the front panel
Certified applicator must complete annual training program	"The certified applicator supervising that application must successfully complete a methyl bromide training program made available by the registrant within the last 12 months. The Fumigant Management Plan (see details elsewhere on this label) must document when and where the training program was completed."	Directions for Use Under the section "protection for handlers"

Fumigation Handlers	Persons engaged in any of the following activities are defined as fumigant handlers: • Persons participating in the application as supervisors, loaders, drivers, co-pilots, shovelers, or as other direct application participants (application starts when the fumigant is first introduced into the soil and ends after the fumigant has stopped being delivered/dispensed to the soil); • Persons taking air samples to monitor fumigant air concentrations; • Persons cleaning up fumigant spills; • Persons handling or disposing of fumigant containers; • Persons cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues; • Persons installing, repairing, operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period; • Persons entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks; • Persons installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps: ➢ until 14 days after application is complete if tarps are not perforated and removed during those 14 days, or ➢ until tarp removal is complete if tarps are both perforated and removed less than 14 days after application; or ➢ until 48 hours after tarp perforation is complete, if they will not be removed within 14 days of application NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated.	Directions for Use Under the section "protection for handlers"
For pre-plant soil use. Supervision of Handlers	"The certified applicator supervising the application must be at the fumigant application site and able to maintain visual contact with every handler participating in the application starting when the fumigant is first introduced into the soil and ending after the fumigant has stopped being delivered/dispensed to the soil and the soil is sealed. The certified applicator must provide fumigant safe handling information to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months. For all other fumigant handling tasks (as defined on this label), at least two WPS-trained handlers must be present to monitor one another."	Directions for Use Under the section "protection for handlers"
Exclusion of Non Handlers from Application Block and Buffer Zone	The certified applicator supervising the application and the owner/operator of the establishment where the fumigation is taking place must make sure that all persons who are not trained and PPE-equipped and who are not performing one of the handling tasks defined in this labeling are: • excluded from application block during the entry prohibition period, and • excluded from the buffer zone during the buffer zone period.	Directions for Use Under the section "protection for handlers"
Providing, cleaning, and maintaining PPE	The employer of the fumigant handlers must make sure that all handlers in the application block and the surrounding buffer zone are provided and correctly wear the required PPE. The PPE must be cleaned and maintained as required by the Worker Protection Standard for Agricultural Pesticides.	Directions for Use Under the section "protection for handlers"

Respirator Availability	"In case of emergency or the need for immediate respiratory protection, the fumigation handler employer must make sure that the following PPE are immediately available to all persons performing fumigant handling activities: • at least one air rescue device (e.g., SCBA) must be on-site in case of an emergency, and • unless an air-purifying respirator is being worn by each person performing a handling task at the site, enough air-purifying respirators and face-sealing goggles (if the respirator is a half-face style) of the type specified in the PPE section of this labeling must be immediately available at the site for each handler.	Directions for Use Under the section "protection for handlers"
PPE Requirements Established by the RED for all Formulations with 80% or less methyl bromide	"**All fumigant handlers must wear:** • Loose-fitting long-sleeved shirt and long pants • Shoes and socks, and • Loose fitting protective eyewear. (a full face shield or safety glasses with brow, temple, and side protection), except when a respirator is required. In addition, when air monitoring indicates a respirator is required **OR** when repairing an unperforated tarp within 14 days after the end of application, fumigant handlers must wear: • a NIOSH-approved half-face, full-face, or hood-style respirator with a cartridge or canister certified by the manufacturer for protection from exposure to methyl bromide at concentrations up to 5 ppm (e.g., a 3M air-purifying respirator equipped with 3M Model 60928 Organic Vapor/Acid Gas/P100 cartridges) • face-sealing goggles when a half-face respirator is worn. IMPORTANT: an air-supplying respirator [i.e., a respirator connected directly to a clean air source or a self-contained breathing apparatus (SCBA)] is not permitted for routine fumigant handler tasks. Such respirators are only permitted in emergencies such as a spill or leak or when corrective action is needed to reduce air levels to acceptable levels."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Fumigant Air Monitoring for all Formulations with 80% or less methyl bromide	**Fumigant Air Monitoring:** The following air monitoring procedures must be followed to determine whether respiratory protection is required for any person performing a fumigant handling task as defined in this labeling. • Air monitoring samples for methyl bromide and chloropicrin must be collected in the breathing zone of a handler performing a representative handling task starting approximately 30 minutes from the handler's initial exposure and at least once every 2 hours thereafter • To monitor air concentration levels, a direct reading detection device, such as a Matheson-Kitagawa, Draeger, or Sensidyne device must be used. The devices must have sensitivity of at least 1 ppm for methyl bromide and 0.15 ppm for chloropicrin. • If at any time: (1) methyl bromide concentrations are greater than or equal to 1 ppm or (2) chloropicrin concentrations are greater than or equal to 0.15 ppm or (3) any handler experiences sensory irritation, then an air-purifying respirator as specified in the PPE section of this label must be worn by all handlers. • If two consecutive breathing zone air samples taken at least 30 minutes apart show levels have decreased to less than 1 ppm for methyl bromide and less than 0.15 ppm for chloropicrin, then handlers may remove the respirators. • If at any time (1) a handler experiences any sensory irritation when wearing a respirator, or (2) any air sample is greater than or equal to 5 ppm for methyl bromide, or (3) any air sample is greater than or equal to 1.5 ppm for chloropicrin, then all handler activities must cease and	Directions for Use

	handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken. • During the corrective actions if methyl bromide air concentrations are greater than or equal to 5 ppm or if chloropicrin air concentrations are greater than or equal to 1.5 ppm, then a self-contained breathing apparatus (SCBA) must be worn. • In order to resume work activities: ➢ Two consecutive air samples for methyl bromide and chloropicrin taken at the handling site at least 30 minutes apart must be less than 5 ppm for methyl bromide and less than 1.5 ppm for chloropicrin. ➢ During the collection of air samples, an air purifying respirator must be worn by the handler taking air samples. ➢ If methyl bromide concentrations are greater than or equal to 1 ppm or if chloropicrin concentrations are greater than or equal to 0.15 ppm, then handlers resuming their handler activities must wear air-purifying respirators and face-sealing goggles (if the respirator is a half-face style) of the type specified in the PPE section of this labeling.	
PPE Requirements Established by the RED[1] For Formulations with > 80% Methyl Bromide (i.e., 98:2) (This is different from the formulations with 80% or less MEBr because handlers must wear air-purifying respirators when performing handling tasks and the monitoring requirements are different.)	"**All handlers must wear:** • Loose-fitting long-sleeved shirt and long pants • Shoes and socks • NIOSH-approved half-face, full-face, or hood-style respirator with a cartridge or canister certified by the manufacturer for protection from exposure to methyl bromide at concentrations up to 5 ppm (e.g., a 3M air-purifying respirator equipped with 3M Model 60928 Organic Vapor/Acid Gas/P100 cartridges), and • face-sealing goggles when a half-face respirator is worn IMPORTANT: an air-supplying respirator (i.e., a respirator connected directly to a clean air source or a self-contained breathing apparatus (SCBA) is not permitted for routine fumigant handler tasks. Such respirators are only permitted in emergencies such as a spill or leak or when corrective action is needed to reduce air levels to acceptable levels.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Fumigant Air Monitoring for all Formulations with > 80% methyl bromide (i.e., 98:2)	**"Fumigant Air Monitoring Requirements:** The following air monitoring procedures must be followed to ensure that the upper protection limit of the respirator plus respirator cartridge or canister is not exceeded (i.e., 5 ppm for methyl bromide and 1.5 ppm for chloropicrin) • Air monitoring samples for methyl bromide and chloropicrin must be collected at least every hour in the breathing zone of a handler performing a representative handling task. • To monitor air concentration levels, a direct reading detection device, such as a Matheson-Kitagawa, Draeger, or Sensidyne device must be used. The devices must have sensitivity of at least 5 ppm for methyl bromide and 1.5 ppm for chloropicrin • If at any time (1) a handler experiences any sensory irritation while wearing a respirator, or (2) any air sample is greater than or equal to 5 ppm for methyl bromide, or (3) any air sample is greater than or equal to 1.5 ppm for chloropicrin, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken. • During the corrective actions if methyl bromide air concentrations are greater than or equal to 5 ppm or if chloropicrin air concentrations are greater than or equal to 1.5 ppm, then a self-contained breathing apparatus (SCBA) must be worn. • In order to resume work activities: ➢ Two consecutive air samples for methyl bromide and chloropicrin taken in the treatment area at least 30 minutes apart, must be less than 5 ppm for methyl bromide and less than 1.5 ppm for chloropicrin. ➢ During the collection of samples an air purifying respirator must be worn by the handler taking air samples.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Recommendations	**"User Safety Recommendations** Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
PPE Requirements Established by the RED[1] For all Formulations	**"Respirator fit testing, medical qualification, and training** Employers must ensure that all fumigant handlers are: • Fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134) • Trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134) • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical	Directions for Use Under the section "Protection for Handlers"

	practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health statue or respirator style or use-conditions change.	
Application Requirements, when tarps are used: Tarp Perforation and/or /Removal	**"Tarp Perforation and/or Removal** IMPORTANT: Persons perforating, repairing, removing, and/or monitoring tarps are defined, within certain time limitations, as fumigant handlers (see definition of fumigant handlers in this labeling) and must be provided the PPE and other protections for handlers as required on this labeling and in the Worker Protection Standard for Agricultural Pesticides. Tarps used for fumigations must be perforated (cut, punched, poked, or sliced) only by mechanical methods. Perforation by hand or with hand-held tools is prohibited. Each tarp panel used for broadcast fumigation must be perforated using a lengthwise cut. Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after shank injection of the fumigant product and tarps (if used) have been laid or after drip lines have been purged, unless an adverse weather condition exists for broadcast applications. See below. If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete. If tarps will NOT be removed after perforation, planting or transplanting cannot begin until at least 48 hours after the tarp perforation is complete If tarps are left intact for a minimum of 14 days after fumigant injection into the soil is complete, planting or transplanting may take place while the tarps are being perforated. Adverse Weather Conditions Exception for broadcast applications only: Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that: • At least 48 hours have passed after the fumigant injection into the soil is complete, • The buffer zone period is extended until 24 hours after tarp removal is complete, • Subsequent fumigations of untreated areas within the application block do not occur for at least 24-hours after tarp removal is complete, and • Appropriate PPE, respiratory protection, air monitoring and other requirements for the protection of handlers are met."	Direction For Use
Monitoring Air Concentration Levels	**"MONITORING AIR CONCENTRATION LEVELS** **Monitoring Air Concentrations in the Buffer Zone Areas:** When air concentration levels must be monitored (i.e., as specified in the general buffer zone requirements section), use a direct reading detection device, such as a	Directions for Use under the heading "General Buffer Zone

	Matheson-Kitagawa, Draeger, or Sensidyne device. The devices must have sensitivity of at least 1 ppm for methyl bromide and 0.15 ppm for chloropicrin."	Requirements"
Agriculture Use Requirements box	**Agricultural Use Requirements** After the standard paragraphs for the Agricultural Use Requirements box, substitute the following text for the standard restricted-entry interval and double notification requirements: "For entry prohibition and notification requirements, see the *'Application Block Entry Prohibition and Notification'* section of this labeling."	Agricultural Use Requirements box
Entry Prohibitions	**"Entry Prohibitions** Entry (including early entry that would otherwise be permitted under the WPS) by any person – other than a correctly trained and PPE-equipped handler who is performing a handling task listed on this labeling – is PROHIBITED -from the start of the application until: • 5 days (120 hours) after application has ended for untarped applications. • 5 days (120 hours) after application is complete if tarps are not perforated and removed for at least 14 days following application, or • 48 hours after tarp perforation is complete if they will not be removed for at least 14 days following application, or • after tarps are removed if tarps are both perforated and removed less than 14 days after application. NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated.	Directions for Use under the heading "heading "Application Block Entry Prohibition and Notification"
Notification Requirement for the treated area	NOTIFICATION: Notify workers of the application by warning them orally and by posting fumigant warning signs. The signs must bear the skill and crossbones symbol and state: -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "[*Name of fumigant*] Fumigant in USE," -- the date and time of fumigation, -- the date and time the entry prohibition period is over -- Name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation. Post the fumigant warning sign instead of the WPS sign for this application but follow all WPS requirements pertaining to location, legibility, size, and timing of posting and removal. Post the fumigant warning signs at all entrances to the application block.(i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period))	Direction for Use under the heading "Application Block Entry Prohibition and Notification"
Mandatory Good Agricultural Practices for all formulations	"**Mandatory Good Agricultural Practices (GAPs)** The following GAPs must be followed during all fumigant applications. All measurements and other documentation planned to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the postapplication summary report. **Tarps** (for all applications except for deep shank CA orchard replant and hand held tree-hole applications)	Directions for Use

- Tarps must be installed prior to starting hot gas applications.
- Tarps must be installed immediately after the fumigant is applied to the soil for bedded or broadcast applications.
- A written tarp plan must be developed that includes:
  - schedule and procedures for checking tarps for damage, tears, and other problems
  - plans for determining when and how repairs to tarps will be made, and by whom
  - minimum time following injection that tarp will be repaired
  - minimum size of tarp damage that will be repaired
  - other factors used to determine when tarp repair will be conducted:
    - schedule, equipment, and methods used to perforate tarps
    - aeration plans and procedures following perforation of tarp, but prior to tarp removal or planting/transplanting
    - schedule, equipment, and procedures for tarp removal

Weather Conditions

- Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigant application must be checked.
- Do not apply fumigant if ground-level winds are less than 2 mph.
- Applications must not occur during a temperature inversion or when temperature inversions are forecasted to persist for more than 6 consecutive hours for the 36-hour period after application.
  - Visual features that could indicate an inversion is occurring are misty conditions during day or night, and clear night skies.
- Detailed local forecasts for sky conditions, weather conditions, wind speed, and forecasted temperature inversions may be obtained on-line at http://www.nws.noaa.gov.
- For further guidance, contact the local National Weather Service Forecasting Office.

Soil Temperature

- The maximum soil temperature at the depth of injection shall not exceed 90 degrees F at the beginning of the application.
  - If air temperatures have been above 100 degrees F for more than three hours in any of the three days prior to application, then soil temperature shall be measured and recorded in the FMP.

Soil Moisture

- The soil must be moist two to six inches below the surface. The amount of moisture needed in this zone will vary according to soil type and shall be determined using standard feel testing methods (see below). Surface soil generally dries rapidly and must not be considered in this determination.
- If there is insufficient moisture two to six inches below the surface, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below six inches, soil moisture can be brought to the surface by discing or plowing before or-injection. To conserve existing soil moisture, pretreatment or treatment tillage should be done as close to the time of application as possible.

Soil moisture determination

Feel Method: The soil shall contain at the time of application enough moisture two to six inches below the surface to meet the following criteria as

appropriate for the soil texture.

- For **fine textured soils** (clay loam, silty clay loam, sandy clay, silty clay, sandy clay loam and clay) there must be enough moisture so that the soil is pliable, not crumbly, but does not form a ribbon when squeezed between the thumb and forefinger.
- For **coarse soils** (sand and loamy sand) there must be enough moisture to allow formation of a weak ball when compressed in the hand. Due to soil texture, this ball is easily broken with little disturbance.
- For **medium textured soils** (coarse sandy loam, sandy loam, and fine sandy loam) there must be enough moisture to allow formation of a ball which holds together with moderate disturbance, but does not stick between the thumb and forefinger.
- For **fields with more than one soil texture**, soil moisture content in the lightest textured (most sandy) areas must comply with this soil moisture requirement. Whenever possible, the field should be divided into areas of similar soil texture and the soil moisture of each area should be adjusted as needed. Coarser textured soils can be fumigated under conditions of higher soil moisture than finer textured soils; however, if the soil moisture is too high, fumigant movement will be retarded and effectiveness of the treatment will be reduced. Previous and/or local experience with the soil to be treated or the crop to be planted can often serve as a guide to conditions that will be acceptable. If you do not know how to determine the soil moisture content of the area to be treated, consult your local extension service or soil conservation service specialist or pest control advisor (ag consultant) for assistance.

Soil Preparation

- Soil shall be properly prepared and at the surface generally free of clods that are golf ball size or larger. The area to be fumigated shall be tilled to a depth of 5 to 8 inches.
- Field trash must be properly managed. Residue from a previous crop must be worked into the soil to allow for decomposition prior to fumigation. Little or no crop residue shall be present on the soil surface. Crop residue that is present must not interfere with the soil seal.

Soil Sealing

- *For Broadcast Untarped Applications:* Use a disc or similar equipment to uniformly mix the soil to at least a depth of 3 to 4 inches to eliminate the chisel or plow traces. Following elimination of the chisel trace, the soil surface must be compacted with a cultipacker, ring roller, and roller in combination with tillage equipment.
- *For Bedded Applications*: Performed beds shall be sealed by disruption the chisel trace using press sealers, bed shapers, cultipackers, or by re-shaping (relisting, lifting and replacing, etc.) the beds immediately following injection. Beds formed at the time of application shall be sealed by disrupting the chisel trace using press sealers, or bed shapers.
- *Soil Sealing for Tarped Applications*: The use of a tarp does not eliminate the need to minimize chisel traces prior to application of the tarp, such as by using a nobel plow or other injection shank that disrupts the chisel traces.

<u>Bedded and Broadcast Shank Applications: Additional Mandatory GAPs</u>

In addition to the GAPs required for all soil fumigation applications, the following GAPs apply for injection applications:

Tarps

- Tarps must be installed immediately after the fumigant is applied to the soil.

Soil Preparation

- Trash pulled by the shanks to the ends of the field must be covered with tarp, or soil, depending on the application method before making the turn for the next pass.

Application Depth

- *For Tarped-Broadcast and Tarped-Bedded Applications:* The injection point shall be a minimum of 8 inches from the nearest final soil/air interface. For tarped bedded applications the injection depth must not be deeper than the lowest point of the tarp (i.e., the lowest point of the tuck).
- *For Untarped-Bedded Applications*: The injection point shall be a minimum of 12 inches from the nearest final soil/air interface.
- *For Untarped-Broadcast Applications (CA orchard replant only):* The injection point shall be a minimum of 18 inches from the nearest final soil/air interface.

Prevention of End Row Spillage

- Do not apply or allow fumigant to drain onto the soil surface. For each injection line either have a check valve located as close as possible to the final injection point, or drain/purge the line of any remaining fumigant prior to lifting injection shanks from the ground.
- Do not lift injection shanks from the soil until the shut-off valve has been closed and the fumigant has been depressurized (passively drained) or purged (actively forced out via air compressor) from the system.

Calibration, Set-up, Repair, and Maintenance for Application Rigs

- Brass, carbon steel or stainless steel fittings must be used throughout. Polyethylene tubing, polypropylene tubing, Teflon® tubing or Teflon® -lined steel braided tubing must be used for all low pressure lines, drain lines, and compressed gas or air pressure lines. All other tubing must be Teflon® -lined steel braided.
- Galvanized, PVC, nylon or aluminum pipe fittings must not be used.
- All rigs must include a filter to remove any particulates from the fumigant, and a check valve to prevent backflow of the fumigant into the pressurizing cylinder or the compressed air system.
- Rigs must include a flowmeter or a constant pressure system with orifice plates to insure the proper amount of fumigant is applied.
- To prevent the backflow of fumigant into the compressed gas cylinder (e.g. nitrogen, other inert gas or compressed air), if used, applicators must:
    - If a compressed gas cylinder is used, make sure that positive pressure is maintained in the cylinder at not less than 200 psi during the entire time it is connected to the application rig. (*This is not required for a compressed air system that is part of the application rig because if the compressor system fails the application rig will not be operable*)
    - Ensure that application rigs are equipped with properly functioning check valves between the compressed gas cylinder or compressed air system and the fumigant cylinder. The check valve is best placed on the outlet side of the pressure regulator, and is oriented to only allow compressed

gas to flow out of the cylinder or compressed air out of the compressed air system.
    - Always pressurize the system with compressed gas or by use of a compressed air system before opening the fumigant cylinder valve.
- Before using a fumigation rig for the first time, or when preparing it for use after storage, the operator must check the following items carefully:
    - Check the filter, and clean or replace the filter element as required.
    - Check all tubes and chisels to make sure they are free of debris and obstructions.
    - Check and clean the orifice plates and screen checks, if installed.
    - Pressurize the system with compressed gas or compressed air, and check all fittings, valves, and connections for leaks using soap solution.
- Install the fumigant cylinder, and connect and secure all tubing. Slowly open the compressed gas or compressed air valve, and increase the pressure to the desired level. Slowly open the fumigant cylinder valve, always watching for leaks.
- When the application is complete, close the fumigant cylinder valve and blow residual fumigant out of the fumigant lines into the soil using compressed gas or compressed air. At the end of the application, disconnect all fumigant cylinders from the application rig. At the end of the season, seal all tubing openings with tape to prevent the entry of insects and dirt.
- Application equipment must be calibrated and all control systems must be working properly. Proper calibration is essential for application equipment to deliver the correct amount of fumigant uniformly to the soil. Refer to the manufacturer's instructions on how to calibrate your equipment, usually the equipment manufacturer, fumigant dealer, or Cooperative Extension Service can provide assistance.

<u>Tree Replant Application: Mandatory GAPs</u>

In addition to the GAPs required for all soil fumigation applications, the following GAPs apply for tree replant applications. This application method is used when methyl bromide is applied to individual tree sites in an existing orchard where shank application are not possible:

Site Preparation

- Each individual tree-site must remove the tree stump and primary root system with a back-hoe or other similar equipment, for example an auger.
- The hole must be backfilled with soil before application.

Application Depth

- The fumigant must be injected at least 18 inches into the soil.

System Flush

- Before removing the application wand from the soil the wand must be cleared using nitrogen or compressed air.

Soil Sealing

	• After the wand is cleared and removed from the soil, the injection hole must be either covered with soil and tamp or the soil must be compacted over the injection hole.	
Mandatory Good Agricultural Practices for Hot Gas Applications (98:2 formulations only)	**"Hot Gas Applications** <u>Hot Gas Soil Applications (Greenhouse and Outdoor): Mandatory GAPs</u> • All delivery tubes shall be placed under the tarp in such a way that they do not move during the application of methyl bromide. • The fumigant must be introduced from outside of the greenhouse/application block (see entry restrictions and respiratory protection sections for further details). • All fittings, connections, and valves must be checked for methyl bromide leaks prior to fumigation. If cylinders are replaced during the fumigation process, the connections and valves must be checked for leaks prior to continuing the job."	Directions for Use
Site-Specific Fumigation Management Plans for all methyl bromide end-use products containing directions for use for pre-plant soil fumigation	"**Site-Specific Fumigation Management Plan (FMP)** Prior to the start of fumigation, the certified applicator supervising the application must verify that a site-specific fumigation management plan (FMP) exists for each application block (i.e., a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period). The FMP may be prepared by the certified applicator, the site owner/operator, registrant, or other party. The certified applicator must verify in writing the site-specific FMPs reflects current site conditions before the start of fumigation. • General site information o Site address or description of location, o Site operator/owner's name, address, and, phone number o Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, public roads, bus stops, water bodies, wells, rights-of-ways inside buffers, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ mile buffer zones (e.g., prisons, schools, hospitals, state licensed day care centers) with distances from the application site labeled • Applicator information (license number, address, phone number, contact information for person supervising the fumigation with location and date for completing the registrant's chloropicrin training program) • Authorized on-site personnel (Names of all handlers and the tasks they are authorized and trained to perform) • Application procedures o Fumigation window (target application date, earliest and latest possible date of fumigation) o Product information (brand name, registration number) o Type of fumigation (e.g., shank, broadcast, drip, raised bed, strip, etc.) o Target application rate and application block size • Good Agricultural Practices (GAPs) o Description of applicable mandatory GAPs (registrants may also include optional GAPs) o Measurements and other documentation planned to ensure GAPs are achieved (e.g. measurement of soil and other site conditions, tarp repair/perforation/removal plans, etc.) • Buffer zones o Calculations and rationale for buffer zones distances (e.g. specify table from label that distances are based on, rate and block size,	In the Directions for Use for Pre-plant soil fumigation under the heading "Site-Specific Fumigation Management Plan (FMP)"

	applicable credits applied) o Start and stop times for buffer zones • Respirators and other personal protective equipment (PPE) for handlers (respirator type, respirator cartridge, and other PPE selection; verification that respirator training/fit-testing/medical exams is current; and maintenance/storage procedures) • Air monitoring o Type of samples that will be collected (e.g., occupational, in occupied structures, outside buffer zone area if site monitoring is conducted, etc.) o When and where samples will be collected o Duration of samples o Sampling methods and equipment o Name, address, and, phone number of person taking samples • Posting (names of persons who will post signs, location of posting signs, procedures for posting and sign removal) • Site-Specific response and management o Fumigant site monitoring ▪ Description of who, when, where, and procedures for monitoring buffer zone perimeter o Response information for neighbors ▪ List of residences and businesses informed (neighboring property owners) ▪ Method of sharing information o State and tribal lead agency notification ▪ Include the information that is sent to the lead agency • Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (tarp cutters/removers, irrigators, etc.) • Record keeping procedures • Emergency procedures (evacuation routes, locations of telephones, contact information for first responders, local/state/federal contacts, key personnel and emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies). • Hazard communication (product labels, material safety data sheets, etc.) For situations where an initial FMP is developed and certain elements do not change for multiple fumigation sites (e.g. applicator information, authorized on-site personnel, record keeping procedures, emergency procedures, etc.) only elements that have changed need to be updated in the site-specific FMP provided the following: • The certified applicator supervising the application has verified that those elements are current and applicable to the application block before it is fumigated and has documented the verification in the site-specific FMP; and • Recordkeeping requirements are followed for the entire FMP (including elements that do not change) The employer of fumigant handlers must make the FMP available to each of their handler employees involved in the fumigation and workers in adjacent fields, upon request. The certified applicator supervising the fumigation and the owner/operator of	

	the agricultural establishment where the fumigation is taking place must, upon request, make the FMP available to any federal, state, tribal, or local enforcement personnel, upon request. Within 30 days of completing the application portion of the fumigation process, the certified applicator supervising the application must complete a post-fumigation application summary that describes any deviations from FMP that have occurred, measurements taken to comply with GAPs as well as any complaints and/or incidents that have been reported to him/her. The summary must include the actual date of the application, application rate, and size of application block fumigated." The certified applicator who supervised the fumigation and the owner/operator of the agricultural establishment where the fumigation took place must keep a signed copy of the site-specific FMPs and the post-application summary record for at least 2 years following the application and must make them available, upon request, to Federal, state, tribal, and/or local enforcement personnel.	
Information Exchange	"When the certified applicator supervising the application leaves the application site after the application portion of the fumigation process is complete and other persons will be performing handler tasks (see the handling activities listed elsewhere in this labeling), the certified applicator must communicate in writing all of the requirements on this labeling with respect to the fumigation process and protection of handlers to the owner/operator of the agricultural establishment where the fumigation is taking place. IMPORTANT: this requirement does not override the requirements in the Worker Protection Standard for Agricultural Pesticides for information exchange between owners/operators of agricultural establishments and commercial pesticide applicators."	
General Buffer Zones requirements for all formulations	**"General Buffer Zone Requirements** A "buffer zone" must be established for every fumigant application The following describes the general buffer zone requirements: • "Buffer zone" is an area established around the perimeter of each application block or greenhouse where a soil fumigant is applied. The buffer zone must extend from the edge of the application block perimeter equally in all directions. • All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the buffer zone period except for certain persons in transit (see exemptions section). • An "application block" is a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period (see Figures 1 and 2 above for further explanation). • The "buffer zone period" starts at the moment when any fumigant is delivered/dispensed to the soil within the application block and lasts for a minimum of 48 hours after the fumigant has stopped being delivered/dispensed to the soil. <u>Buffer zone distances</u> • Buffer zone distances must be based on look-up tables on product labels (25 feet is the smallest distance regardless of site-specific application parameters).	In the Directions for Use for Pre-plant soil fumigation under the heading "General Buffer Zone Requirements"

	• For selective replant fumigation in an orchard using hand held application methods (e.g., deep injection auger probes), the minimum buffer zone will be 25 feet measured from the center of each injection site (i.e., tree hole). Authorized entry to buffer zones • Only authorized handlers who have been properly trained and equipped according to EPA's Worker Protection Standard (WPS) and label requirements may be in the buffer zone during the buffer zone period. Buffer zone proximity • Methyl bromide buffer zones from multiple application blocks may not overlap (including blocks fumigated by adjacent property owners; see below for exemptions for areas not under the control of owner/operator of application block). • No fumigant applications will be permitted within 0.25 miles of schools, state licensed day care centers, nursing homes, assisted living facilities, elder care facilities, hospitals, in-patient clinics and prisons if occupied during the buffer zone period. Exemptions for transit through buffer zones • Vehicular and bicycle traffic on public and private roadways through the buffer zone is permitted. "Roadway" means that portion of a street or highway improved, designed or ordinarily used for vehicular travel, exclusive of the sidewalk or shoulder even though such sidewalk or shoulder is used by persons riding bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately. • Bus stops or other locations where persons wait for public transit are not permitted within the buffer zone. • See Posting Section for additional requirements that may apply. Structures under the control of owner/operator of the application block • Buffer zones may not include buildings used for storage such as sheds, barns, garages, etc., **UNLESS,** 1. The storage buildings are not occupied during the buffer zone period, and 2. The storage buildings do not share a common wall with an occupied structure. • See Posting Section for additional requirements that may apply. Areas not under the control of owner/operator of the application block • Buffer zones may not include residential areas (including employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas) **UNLESS,** 1. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and 2. Reentry by occupants and other non-handlers must not occur until, ° The buffer zone period has ended, and ° Two consecutive air samples for methyl bromide have been taken in the structure at least 1 hour apart must indicate less than 1 ppm methyl bromide, and ° Two consecutive air samples for chloropicrin have been taken in the structure at least 1 hour apart must indicate than less than	

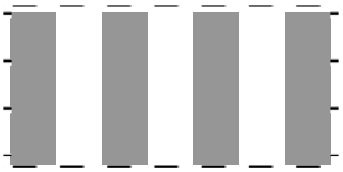
<table>
<tr><td></td><td>0.15 ppm chloropicrin is present.

• Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, UNLESS,
1. The owner/operator of the application block can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owner, and
2. The owner/operator of the areas that are not under the control of the application provides written agreement to the certified applicator supervising the fumigant application that they, their employees, and other persons will stay out of the buffer zone during the entire buffer zone period.
• Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields, etc), UNLESS,
1. The area is not occupied during the buffer zone period,
2. Entry by non-handlers is prohibited during the buffer zone period, and
3. Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.</td><td></td></tr>
<tr><td>Maximum Application Block Sizes for all formulations</td><td>“Maximum Application Block Sizes

The maximum application block sizes allowed for methyl bromide applications are:
• 100 acres for tarped bedded and broadcast applications
• 40 acres for untarped deep applications (i.e., California orchard replant)”</td><td>Directions for Use (see next row for 98:2 formulations)</td></tr>
<tr><td>Maximum Application Block Sizes for Hot Gas Applications (98:2 formulations only)</td><td>“The maximum application block sizes allowed for methyl bromide hot gas applications are:
• 10 acres for outdoor hot gas applications
• 45,000 square feet for greenhouse hot gas applications”</td><td>Directions for Use immediately after above row</td></tr>
<tr><td>Pre-plant Application Restrictions for all formulations</td><td>“Maximum Application Rates for Critical Use Exemptions (CUEs) under the Montreal Protocol

Maximum Application Rates for Pre-plant Soil Methyl Bromide CUEs
<table>
<tr><th>Crop</th><th>Maximum Broadcast Equivalent Rates (lb ai/A)</th></tr>
<tr><td>Eggplant</td><td>170</td></tr>
<tr><td>Cucurbits (including muskmelons, cantaloupe, watermelon, cucumber, squash, pumpkin, and gourds)</td><td>200</td></tr>
<tr><td>Forest Nursery Seedlings</td><td>260</td></tr>
<tr><td>Orchard Nursery Seedlings (raspberry, deciduous trees, roses)</td><td>200</td></tr>
<tr><td>Strawberry Nurseries</td><td>260</td></tr>
<tr><td>Orchard Replant [1] (walnuts, almonds, stone fruit, table and raisin grapes, wine grapes)</td><td>200</td></tr>
<tr><td>Orchard Replant (grapes)</td><td>250</td></tr>
<tr><td>Ornamentals</td><td>360</td></tr>
<tr><td>Pepper, Bell</td><td>170</td></tr>
<tr><td>Strawberry Fruit</td><td>200</td></tr>
<tr><td>Sweet Potato Slips</td><td>200</td></tr>
</table></td><td>In the Directions for Use for Pre-plant soil fumigation under the heading “Maximum Application Rates for Critical Use Exemptions under the Montreal Protocol” within its own box

(see below row for 98:2 formulations)</td></tr>
</table>

	Tomato (grown for fresh market) 160 [1] The maximum application rate when applying methyl bromide to individual tree holes using handheld equipment is 1.5 lb ai/100 ft^2 The maximum application rate for greenhouse hot gas applications is 1 lb ai/100 ft2 and the application block may not exceed 45,000 ft2."	
Pre-plant Application Restrictions for 98:2 formulations	"The maximum application rate when applying methyl bromide to individual tree holes using handheld equipment is 1.5 lb ai/100 ft^2 " "The maximum application rate for greenhouse hot gas applications is 1 lb ai/100 ft^2 and the application block may not exceed 45,000 ft^2"	Directions for Use immediately after above row
Pre-plant Application Restrictions	**"Quarantine Uses** This product may be used as a soil fumigant as part of a quarantine program established by the United States Department of Agriculture-Animal and Plant Heath Inspection Service (USDA-APHIS) under the Plant Protection Act (7 U.S.C. 7701 et seq.). Limitations including but not limited to application rates and methods and crops and cropping practices shall be in accordance with those established by the USDA-APHIS quarantine program."	In the Directions for Use for Pre-plant soil fumigation under the heading "Maximum Application Rates for Quarantine Uses " within its own box
Buffer Zone Distances for all formulations	"**Buffer Zone Distances** Buffer zone distances must be calculated using the application rate and the size of the application block.  **Figure 1.** Broadcast Application  **Figure 2.** Bedded Application In **Figures 1 and 2,** the dashed line represents the perimeter of the field, the shaded area is the portion of the field that is treated, and the un-shaded area is the area of the field that is untreated. Assuming that both fields are 10 acres, and only 50% of field in figure 2 is fumigated, the *rate per treated acre* is 400 lbs ai/A for both Figure 1 and 2. The *broadcast rate* for figure 1 is 400 lb ai/A but the *effective broadcast equivalent rate* for Figure 2 is 200 lbs ai/A." **NOTE TO REGISTRANTS***: Labels may express rates as lbs per treated acre under the application instructions but they must identify buffer zone distances based on the broadcast or effective broadcast equivalent rates.* "For selective replant fumigation in an orchard using hand-held application methods (e.g., deep injection auger probes), the minimum buffer zone will be 25 feet measured from the center of each injection site (i.e., tree hole). For all other applications, the following tables must be used to determine the minimum buffer distances. Round-up to the nearest rate and block size, where applicable." **"Buffer Zone Look-up Table for Shank Bedded with Tarps"** [See driver table below for each formulation. If methyl bromide is the driver insert Table 2 from Methyl Bromide RED. If chloropicrin is the driver insert appropriate chloropicrin look-up table for shank bedded with tarps from	In the Directions for Use for Pre-plant soil fumigation under the heading " Buffer Zone Distances"

	chloropicrin RED] **"Buffer Zone Look-up Table for Shank Broadcast with Tarps"** [See driver table below for each formulation. If methyl bromide is the driver insert Table 3 from Methyl Bromide RED. If chloropicrin is the driver insert appropriate chloropicrin look-up table for shank broadcast with tarps from chloropicrin RED] **"Shank Broadcast without Tarps (CA orchard replant only)"** [See driver table below for each formulation. If methyl bromide is the driver insert Table 4 from Methyl Bromide RED. If chloropicrin is the driver insert appropriate chloropicrin look-up table for shank deep broadcast with tarps from chloropicrin RED]	
Buffer Zone Distances for Hot Gas Applications (98:2 formulations only)	**"Outdoor Hot Gas with Tarps"** [insert from Table 5 from Methyl Bromide RED] **"Greenhouse Hot Gas with Tarps"** [insert from Table 6 from Methyl Bromide RED]	In the Directions for Use for Pre-plant soil fumigation under the heading "Buffer Zone Distances"
Buffer Zone Credits	**"Buffer Zone Credits** The buffer zone distances for bedded and broadcast applications may be reduced by the percentages listed below. The credits may not be used for hot gas applications. Credits may be added, but the minimum buffer zone distance is 25 feet regardless of buffer zone credits available. • 25% reduction in buffer zone distance, IF using Bromostop (1.38 mil), IPM Clear VIF (1.38 mil), or Eval/Mitsui (1.38 mil) tarps. Record the tarp brand name, manufacturer, lot number, batch number, part number, and thickness must be recorded in the FMP. • 10% reduction in buffer zone distance, IF the organic content of soil in the application block is greater than 3%. Record the measurements taken to verify the organic content in the FMP • 10% reduction in buffer zone distance, IF the clay content of the soil in the application block is greater than 27%. Record the measurements taken to verify the clay content in the FMP Example of how to calculate credit: Assuming a tarped bedded application, broadcast equivalent rate of 125 lbs ai/A, 20 acre application block, using Bromostop (1.38 mil) with a 25% credit, and 3.1% organic soil with a 10% credit, the buffer zone would be 130 ft (25% + 10% = 35%; 100% - 35% = 65%; 65% x 200 ft (from the lookup table) = 130 ft)"	In the Directions for Use for Pre-plant soil fumigation under the heading "Buffer Zone Credits"
Posting	**"Posting Fumigant Buffer Zones** • Posting all entrances to the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period) is required for all soil fumigants and use sites. The posting requirements for the application block are listed elsewhere in this labeling. • Posting of the fumigation **buffer zone** is required, **<u>except</u>** when one of the following conditions exist: (1) if there is a physical barrier that prevents access into the buffer zone, such as a fence or wall, that separates the edge of the buffer zone from workers or bystanders, or (2) if the area within 300 feet of the edge of the buffer zone is entirely controlled by owner/operator of the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period); however this exception does not apply to any area	In the Directions for Use for Pre-plant soil fumigation under the heading "Posting Fumigant Buffer Zones"

	under the control of the owner/operator that may be used as housing for workers or other employees. IMPORTANT: if there is public land or any land under someone else's control within 300 feet from the edge of the buffer zone, the buffer zone must be posted. • If the buffer zone must be posted, signs must be placed at all usual points of entry and along likely routes of approach from areas where people not under the control of the application block's owner/operator may approach the buffer zone. o Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails. o When there are no usual points of entry, signs must be posted in the corners of the buffer zone, between the corners of the buffer zone, and along sides so that one sign can be viewed (not read) from the previous one. o The buffer zone posting signs must remain posted at least until the end of the buffer zone period and must be removed within 3 days after the end of the buffer zone period. ▪ Contiguous Application Blocks Exception: If multiple contiguous application blocks are fumigated within a 14-day period, a buffer zone may be established starting from the outer edge of the contiguous application blocks. This buffer zone is in effect from the beginning of the first application until the buffer zone period for the last application block has expired. The periphery of the buffer zone must be posted during this entire period. Signs may remain posted until 3days after the buffer zone period for the last application block has expired. • The buffer zone posting should meet the following standards: o The printed side of the sign must face away from the buffer zone. o Signs must remain legible during entire posting period. o The signs at entrances to buffer zones must be removed by the certified applicator in charge of the fumigation (or someone under his/her supervision). o The general standards for size and type of signs for the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting. o The signs must remain visible and legible during the time they are posted." **Contents of Signs**	

	The **treated area** sign must state the following: -- Skull and crossbones symbol  -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "[*Name of fumigant*] Fumigant in USE," -- the date and time of fumigation, -- the date and time entry prohibition is lifted -- brand name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation.	The **buffer zone** sign must state the following: -- Do not walk sign  -- "DO NOT ENTER/NO ENTRE," -- "[*Name of fumigant*] Fumigant BUFFER ZONE," -- the date and time of fumigation, -- the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires) -- brand name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation	
Site specific response and management	"Site Specific Response and Management The certified applicator must either follow the directions under the "fumigant site monitoring" section or follow the directions under the "response information for neighbors" section. **Fumigation Site Monitoring** From the beginning of the fumigant application until the buffer zone period expires, a certified applicator or someone under his/her supervision must monitor the air concentration levels of the fumigant in the area between the buffer zone and any residences or businesses that trigger the 'response information for neighbors' requirement. • The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period. • A direct reading detection device, such as a Draeger device with a sensitivity of at least 1 ppm for methyl bromide and 0.15 ppm for chloropicrin must be used to monitor the air concentration levels of methyl bromide and chloropicrin. • If at any time (1) methyl bromide air concentrations are greater than or equal to 01 ppm, OR (2) chloropicrin air concentrations are greater than or equal to 0.15 ppm, OR (3) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations • If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. • The results of the air concentration monitoring must be recorded in the FMP. • Informing the appropriate federal, state or tribal lead agencies is still required.		In the Directions for Use for Pre-plant soil fumigation under the heading "Site specific response and management"

	Response Information for Neighbors The certified applicator (or someone under his/her supervision) supervising the fumigation must ensure that residences and owners/operators of businesses that meet the criteria below have been provided the emergency response information at least **48 hours** before fumigation occurs. The information provided may include application dates that range for no more than **2 weeks**. After 2 weeks, the information must be delivered again. Criteria for providing response information for neighbors: • If the buffer zone is less than or equal to **100 feet**, then residences and businesses within **50 feet** from the edge of the buffer zone must be informed. • If the buffer zone is greater than **100 feet** but less than or equal to **200 feet**, then residences and businesses within **100 feet** from the edge of the buffer zone must be informed. • If the buffer zone is greater than **200 feet** but less than or equal to **300 feet**, then residences and businesses within **200 feet** from the edge of the buffer zone must be informed. • If the buffer zone is greater than **300 feet**, then residences and businesses within **300 feet** from the edge of the buffer zone must be informed. Information that must be included: • Location of the application block and surrounding buffer zone • Fumigant(s) applied including EPA Registration # • Applicator and property owner/operator contact information • Time period that fumigation may occur (must not range more than 2 weeks) • Duration of buffer zone • The information must also include: o information on what is being applied, o signs and symptoms of exposure to the fumigant, o what to do and who to call if you believe you are being exposed (911 in most cases). • The method used to share the response information for neighbors must be described in the FMP and may be accomplished through mail, door hangers, or through other methods that will effectively inform people in residences and businesses within the required distance from the edge of the buffer zone."	
Notice to State and Tribal Lead Agencies	**"Notice to State and Tribal Lead Agencies** The state and tribal lead agency information must be provided to the appropriate state or tribal lead agency in a written format prior to the application. The information that must be provided to state and tribal lead agencies includes the following: • Location of the application block and surrounding buffer zone, • Fumigant(s) applied including EPA Registration #, • Applicator and property owner/operator contact information, • Time period that fumigation may occur (must not range more than 2 weeks),	Directions for Use under "Notice to State and Tribal Lead Agencies"

	• Duration of buffer zone."	
Environmental Hazards	"This pesticide is toxic to mammals and birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements immediately following the User Safety Recommendations
Surface and Ground Water Requirements	"This pesticide is toxic to mammals and birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements immediately following the User Safety Recommendations
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. While methyl bromide has certain properties and characteristics in common with chemicals that have been detected in groundwater (methyl bromide is highly soluble in water and has low adsorption to soil), volatilization is this chemical's most important route of dissipation. To reduce the potential for leaching to groundwater, especially in soils with shallow groundwater, for broadcast **tarped** applications, the tarps must be perforated (cut, punched, etc.) before noon and only when rainfall is not expected within 12 hours. For bedded **tarped** applications, rainfall is not a factor since planting occurs with the tarp in place. For untarped applications of methyl bromide potential leaching into groundwater and runoff into surface water can be reduced by avoiding applications when heavy rainfall is forecasted to occur within 24 hours."	Place in the Direction for Use directly above the Agricultural Use Box.

Methyl Bromide:Chloropicrin Drivers

Standard Tarp (no credits)								
Application Method	Formulation							
	98:2	**80:20**	**75:25**	**67:33**	**57:43**	**50:50**	**45:55**	**33:67**
Broadcast[1]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin	Chloropicrin
Bedded[2]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin
High Barrier Tarps: Bromostop (1.38 mil), IPM Clear VIF (1.38 mil), and Eval/Mitsui (1.38 mil) with credits of 25% for Methyl Bromide and 40% for Chloropicrin								
Application Method	Formulation							
	98:2	**80:20**	**75:25**	**67:33**	**57:43**	**50:50**	**45:55**	**33:67**
Broadcast[1]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin
Bedded[2]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin
Bedded*[3]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin
High Barrier Tarps: Hytiblock 7 black, Hytibar, and Black Blockade with no credit for Methyl Bromide and 40% credit for Chloropicrin								
Application Method	Formulation							
	98:2	**80:20**	**75:25**	**67:33**	**57:43**	**50:50**	**45:55**	**33:67**
Broadcast[1]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin
Bedded[2]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin
Bedded*[3]	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin
Deep (≥ 18 inches) Untarped								
Application Method	Formulation							
	98:2	**80:20**	**75:25**	**67:33**	**57:43**	**50:50**	**45:55**	**33:67**
Broadcast[4]	Methyl Bromide	Methyl Bromide	Chloropicrin	Chloropicrin	Chloropicrin	Chloropicrin	Chloropicrin	Chloropicrin

* When applications occur between 1 hour before sunset and 1 hour after sunrise.

[1]Where Methyl Bromide is listed for the appropriate buffer zone, see Table 3 in Methyl Bromide RED. Where Chloropicrin is listed, see Table 2 in the Chloropicrin RED.

[2]Where Methyl Bromide is listed, see Table 2 in Methyl Bromide RED. Where Chloropicrin is listed, see Table 2 in the Chloropicrin RED.

[3]Where Methyl Bromide is listed, see Table 2 in Methyl Bromide RED. Where Chloropicrin is listed, see Table 3 in the Chloropicrin RED.

[4]Where Methyl Bromide is listed, see Table 4 in Methyl Bromide RED. Where Chloropicrin is listed, see Table 6 in the Chloropicrin RED.

Appendix A

Methyl Bromide PC Code 053201 Pre-plant Soil Uses Eligible for Reregistration

Use Site	Formulation	Method of Application	Maximum Application Rate	Use Limitations
Eggplant	Pressurized gas with 80% or less methyl bromide	Shank Injected	170 lb ai/A	See applicable GAPs from Table 9 of RED
Cucurbits (including muskmelons, cantaloupe, watermelon, cucumber, squash, pumpkin, and gourds)	Pressurized gas with 80% or less methyl bromide	Shank Injected	200 lb ai/A	
Forest Nursery Seedlings	Pressurized gas (all methyl bromide: chloropicrin ratios including 98:2)	Shank Injected	260 lb ai/A	
Orchard Nursery Seedlings (raspberry, deciduous trees, roses)	Pressurized gas with 80% or less methyl bromide	Shank Injected	200 lb ai/A	
Strawberry Nurseries	Pressurized gas with 80% or less methyl bromide	Shank Injected	260 lb ai/A	
Orchard Replant (walnuts, almonds, stone fruit, table and raisin grapes, wine grapes)	Pressurized gas (all methyl bromide: chloropicrin ratios including 98:2)	Shank Injected	200 lb ai/A	
Orchard Replant (grapes)	Pressurized gas (all methyl bromide: chloropicrin ratios including 98:2)	Shank Injected	250 lb ai/A	
Orchard Replant (individual tree holes using)	Pressurized gas (all methyl bromide: chloropicrin ratios including 98:2)	handheld equipment	1.5 lb ai/ 100 ft^2	
Ornamentals	Pressurized gas with 80% or less methyl bromide	Shank Injected	360 lb ai/A	
Ornamentals	Pressurized gas with 98% methyl bromide	Hot Gas	360 lb ai/A	
Pepper, Bell	Pressurized gas with 80% or less methyl bromide	Shank Injected	170 lb ai/A	
Strawberry Fruit	Pressurized gas with 80% or less methyl bromide	Shank Injected	200 lb ai/A	
Sweet Potato Slips	Pressurized gas with 80% or less methyl bromide	Shank Injected	200 lb ai/A	
Tomato (grown for fresh market)	Pressurized gas with 80% or less methyl bromide	Shank Injected	160 lb ai/A	
Quarantine uses	Pressurized gas (all methyl bromide: chloropicrin ratios including 98:2)	Use sites defined as part of a quarantine program established by the United States Department of Agriculture-Animal and Plant Heath Inspection Service (USDA-APHIS) under the Plant Protection Act (7 U.S.C. 7701 et seq.). Limitations including but not limited to application rates and methods and crops and cropping practices shall be in accordance with those established by the USDA-APHIS quarantine program.		

Appendix B

This section is currently not available.

Appendix C

Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov. These documents include:

Human Health

1. EPA-HQ-OPP-2005-0123-0285, Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Soil, Greenhouse, and Residential/Structural Uses
2. June 2, 2008 addenda to April 10, 2007 Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Soil, Greenhouse, and Residential/Structural (DP Barcode: D350818)
3. June 9, 2008 memo, Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach (DP Barcode: 306857)
4. EPA-HQ-OPP-2005-0123-0317, Review of Fumigants Group Incident Reports
5. EPA-HQ-OPP-2005-0123-0318, Summary Fumigants Group Incident Reports
6. EPA-HQ-OPP-2005-0123-0319, Summary Fumigants Group Incidents

Stratospheric Ozone Depletion

7. EPA-HQ-OPP-2005-0123-0165, Methyl Bromide: Science of Ozone Depletion and Health Effects Estimates
8. EPA-HQ-OPP-2005-0123-0166, Human Health Benefits Of Stratospheric Ozone Protection
9. EPA-HQ-OPP-2005-0123-0167, Regulatory Impact Analysis, Protecting Stratospheric Ozone: Process for Exempting Critical Uses from the Phaseout of Methyl Bromide
10. EPA-HQ-OPP-2005-0123-0168, OAP's Economic Impact Analysis For Methyl Bromide Allocation In The United States
11. EPA-HQ-OPP-2005-0123-0169, OAP's Benefits Analysis

Environmental Fate and Ecological Risk

12. EPA-HQ-OPP-2005-0123-0029, Revised Draft Methyl Bromide Environmental Fate and Ecological Risk Assessment - Following the Review of 30-Day Error Correction Comments
13. EPA-HQ-OPP-2005-0123-0038, Reregistration Environmental Risk Assessment for Methyl Bromide

Benefits

14. EPA-HQ-OPP-2005-0123-0321, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Metam-Sodium, and Methyl Bromide in Eggplant Production
15. EPA-HQ-OPP-2005-0123-0322, Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries

16. EPA-HQ-OPP-2005-0123-0323, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, Dazomet, Metam Potassium and Metam Sodium for Use in Raspberry Nurseries, Fruit and Nut Deciduous Tree Nurseries, and Rose Bush Nurseries in California
17. EPA-HQ-OPP-2005-0123-0324, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam-sodium In Onion Production
18. EPA-HQ-OPP-2005-0123-0325, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Grape Production
19. EPA-HQ-OPP-2005-0123-0326, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Tree Nut Production
20. EPA-HQ-OPP-2005-0123-0327, Assessment of the Benefits of Soil Fumigation with Chloropicrin, and Methyl Bromide In Pome Fruit Production
21. EPA-HQ-OPP-2005-0123-0328, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium In Stone Fruit Production
22. EPA-HQ-OPP-2005-0123-0329, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-Sodium in Bell Pepper Production
23. EPA-HQ-OPP-2005-0123-0330, Assessment of the Benefits of Soil Fumigation with Metam-sodium in Potato Production
24. EPA-HQ-OPP-2005-0123-0331, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium In Strawberry Production
25. EPA-HQ-OPP-2005-0123-0332, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production
26. EPA-HQ-OPP-2005-0123-0333, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium In Sweet Potato Production
27. EPA-HQ-OPP-2005-0123-0334, Assessment of the Benefits of Soil Fumigation with Chloropicrin In Tobacco Production
28. EPA-HQ-OPP-2005-0123-0335, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium in Tomato Production
29. EPA-HQ-OPP-2005-0123-0336, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Carrot Production
30. EPA-HQ-OPP-2005-0123-0337, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production
31. EPA-HQ-OPP-2005-0123-0338, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production
32. EPA-HQ-OPP-2005-0123-0339, Summary of the Benefits of Soil Fumigation with Methyl Bromide in Crop Production
33. EPA-HQ-OPP-2005-0123-0340, BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants

Risk Management

34. SRRD’s Response to Phase 5 Public Comments for the Soil Fumigants. Rice, M. and McNally, R.; July 2008.
35. EPA-HQ-OPP-2005-0128-0031, Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications.

Response to Comments

36. HED Component of Response To Comments Document On Methyl Bromide Phase 5 Fumigant Risk Assessment (DP Barcode 353907)
37. Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants (DP Barcode 353940)
38. Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide. June 25, 2008. (DP Barcode 353940)
39. SRRD's Response to Phase 5 Public Comments for the Soil Fumigants (July 2008)