United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508P)

May 2009

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

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(soil and non-food structural uses)

List A

Case No. 0335

Approved by: Richard P Keigwin, Jr.

Richard P. Keigwin, Jr., Director
Special Review and Reregistration Division

Date: 5/27/09

Glossary of Terms and Abbreviations

AHEF	Atmospheric Health Effects Framework
ai	Active Ingredient
ANLA	American Nursery and Landscape Association
APHIS	Animal and Plant Heath Inspection Service
APR	air-purifying respirator
ARS	Agricultural Research Service
ATV	all-terrain vehicle
BEAD	Biological and Economic Analysis Division
BrO	bromine monoxide
CDPR	California Department of Pesticide Regulation
CFC	chlorofluorocarbons
CFR	Code of Federal Regulations
ClO	chlorine monoxide
CMTF	Chloropicrin Manufacturers' Task Force
CSF	Confidential Statement of Formulation
CUE	Critical Use Exemption
CUN	Critical Use Nominations
DCI	Data Call-In
DNT	Developmental Neurotoxicity
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDMS	Federal Docket Management System
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FMP	Fumigant Management Plan
FQPA	Food Quality Protection Act
ft	feet
GAP	Good Agricultural Practices
GENEEC	GENeric Estimated Exposure Concentration model
GLN	Guideline Number
GPS	Global Positioning System
ha	hectare
HCFC	hydrochlorofluorocarbons
HDPE	High-density Polyethylene
HED	Health Effects Division
ISCST3	Industrial Source Complex Short Term model
KTS	Potassium Thiosulfate
lb	pound

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
MBAO	Methyl Bromide Alternatives Outreach
MBIP	Methyl Bromide Industry Panel
MBTOC	Methyl Bromide Technical Options Committee
MCFA	Minor Crop Farmer Alliance
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MITC	methyl isothiocyanate
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MSHA	Mine Safety and Health Administration
MUP	Manufacturing-Use Product
NAM	National Association of Manufacturers
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
OAP	Office of Atmospheric Programs
OAR	Office of Air and Radiation
ODP	ozone depletion potential
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
ORE	Occupational and Residential Exposure
OSHA	Occupational Safety and Health Administration
PC	Pesticide Chemical
PDCI	Product-specific Data Call-in
PERFUM	**P**robabilistic **E**xposure and **R**isk model for **Fum**igants
PLHCP	Physician or Other Licensed Health Care Professional
PPE	Personal Protective Equipment
ppm	Parts Per Million
PrG	Pressurized gas
PRZM/EXAMS	Pesticide Root Zone Model/Exposure Analysis Modeling System. A Tier II Surface Water Computer Model.
PSA	public service announcement
psi	pounds per square inch

PVC	Polyvinyl Chloride
QPS	Quarantine and Preshipment
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
RUP	Restricted Use Pesticide
SAB	Science Advisory Board
SCBA	self-contained breathing apparatus
SLA	State Lead Agency
SRRD	Special Review and Reregistration Division
TEAP	Technical and Economic Assessment Panel
TRED	Tolerance Reassessment and Risk Management Decision
TWA	time weighted average
UNEP	United Nations Environment Programme
USC	United States Code
USDA	United States Department of Agriculture
UF	Uncertainty Factor
UV	Ultraviolet
VIF	Virtually Impermeable Film
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
Susan Bartow, Chemical Review Manager for Methyl Bromide
Andrea Carone, Chemical Review Manager for Chloropicrin
Steven Weiss, Industrial Hygienist
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) amended decision regarding the reregistration eligibility of the registered soil and structural (non-food) uses of methyl bromide. This follows the 105-day public comment period on the Reregistration Eligibility Decision provided for stakeholders to have the opportunity to review and provide comments on issues related to the implementation of the risk mitigation measures. The Agency's risk conclusions for methyl bromide have not changed. In addition, all measures established in the July 2008 Reregistration Eligibility Document (RED) to reduce risks to bystanders and workers will still be required. However, the Agency has determined that certain modifications in how and when some measures will be implemented are appropriate. Products containing methyl bromide uses are eligible for reregistration provided that: (1) current data gaps are addressed; (2) the risk mitigation measures identified in the document are adopted; and (3) labels are amended to implement these measures.

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 RED for 1,3-D was completed in 1998. The Agency evaluated these 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 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

[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

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:

- 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;
- GAPs;
- 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 amendment to the 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*.

I. Introduction

This amends and supersedes the document, "Reregistration Eligibility Decision for Methyl Bromide," published by the U.S. Environmental Protection Agency (hereafter, EPA) on July 16, 2008. That day EPA opened a 60-day public comment period on the implementation aspects of the risk mitigation measures that were required as conditions of reregistration eligibility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA received requests to extend the comment period from the MBIP, California Specialty Crops Council, the Chloropicrin Manufacturers' Task Force (CMTF), the National Association of Manufacturers (NAM), the American Nursery and Landscape Association (ANLA), the California Strawberry Nurserymen's Association, the Agricultural Retailers Association, the American Forest and Paper Association, and McDermott, Will, and Emery LLP, on behalf of the Minor Crop Farmer Alliance (MCFA). In response to these requests, on August 29, 2008, EPA published a notice in the Federal Register extending the comment period for an additional 45 days. The comment period closed on October 30, 2008. EPA has completed its review of public comments as well as new scientific data and other information provided and determined that all measures established in the July 2008 RED to reduce risks to bystanders and workers will still be required. The Agency has determined that certain modifications in how and when some measures will be implemented are appropriate. The public comments and EPA's responses, as well as other supporting documents, may be found in the public docket for methyl bromide at EPA-HQ-OPP-2005-0123. EPA has determined that the modifications described herein will achieve the same protection goals for persons potentially exposed to methyl bromide but with a greater likelihood of compliance, fewer impacts on the benefits of methyl bromide use, and with less uncertainty regarding the protectiveness of the required measures. Please see Table 1 for a summary of the modifications.

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 amendment to the 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 and a synopsis of modifications from the 2008 soil fumigant RED. Section II provides a profile of the use and usage of the chemical. Section III provides a general overview of fumigants and summarizes methyl bromide's human health and ecological risk assessments, as well as benefit and impact 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**.**

Table 1. Modifications from 2008 to 2009 Amended Soil Fumigant REDs

	2008 REDs	2009 Amended REDs
Buffer Zones	Buffer zones based on available data	New chloropicrin data support smaller buffers and increased confidence in safety. New dazomet data support larger buffers
Buffer Credits	Credits allowed based on available data; capped at 50%	New data support additional credits and an increase in the cap to 80%
Rights of Way	Permission from local authorities must be granted if buffers extend onto rights of way	Permission from local authorities is only required when a sidewalk or permanent walkway is present
Buffer Overlap	Buffers may not overlap	Buffers may overlap; separate applications by 12 hours and increase emergency preparedness and response measures
Structures within Buffer Zones	Monitor with devices before reentry	Monitor with devices only for applications with < 20 % chloropicrin; otherwise monitor for sensory irritation before reentry
Restrictions Around Difficult to Evacuate Sites	¼ mile restriction around hard to evacuate areas including day care centers, nursing homes, schools; was to be in effect for the duration of the buffer zone period	Maintain ¼ mile restriction but allow a reduced restricted area of ⅛ mile for applications with smaller buffers (300 feet or less); is to be in effect during the application and for 36 hours following the start of the application
Posting	Posting required at buffer zones points of entry, where people are likely to approach, and areas between these locations	The posting requirement is retained but no longer requires areas between the entry areas to be posted Information required on the signs has been simplified to encourage reuse of signs
Handler Protection	Described tasks that may only be performed by handlers and situations when 2 handlers were required to be present while in the buffer zone	Tasks that may only be performed by handlers have been updated and clarified. The situations have been clarified requiring 2 handlers to be present based on the chemical properties of the different soil fumigants, and current label statements
Respiratory Protection	Required monitoring devices to trigger additional measures	Allow sensory irritation properties to trigger additional measures for MITC and chloropicrin Monitoring with devices still required to remove respirators Monitoring with devices still required for methyl bromide formulations with <20% chloropicrin
Tarp Perforation and Removal	Perforating tarps restricted to mechanical means only	Perforating tarps by hand is allowed for areas less than 1 acre in size and for flood prevention activities

	2008 REDs	2009 Amended REDs
Entry Prohibitions	Entry for non-handlers is prohibited for the duration of the entry restricted period, until tarps have been removed, or if 14 days has passed	No major changes
Restricted Use Classification	The MITC generating compounds required to be classified as restricted use	No change
GAPs	Certain GAPs required for all fumigant applications	Some clarifications and refinements have been made based on stakeholder comments
FMPs	FMPs required to be completed before fumigant application begins and post-application summary report required following the application	No major changes. Based on comments an example of an FMP has been included to illustrate how the required information may be presented effectively
Emergency Response and Preparedness	If neighbors are near buffers they must be provided with information or buffer zones must be monitored every 1-2 hours over 48 hours with monitoring devices	Same basic measures apply, however: monitoring required only during peak emission times of the day; irritation detection acceptable for MITC and chloropicrin in lieu of devices; methyl bromide requires direct read devices for formulations with <20% chloropicrin
Notice to SLAs	Applicators required to provide notice to the appropriate state/tribal lead agency before fumigating to facilitate compliance assistance and assurance	States may determine if they wish to receive this information All states required to include strategies for compliance assistance and assurance for soil fumigation in their cooperative agreements
Applicator Training	Certified applicators required to receive registrant soil-fumigant training every year	Certified applicators required to receive registrant soil-fumigant training every three years
Community Outreach and Education	Registrants required to develop and implement community outreach and education programs along with information for first responder in high fumigant use areas	Same basic requirement. The Agency is providing information on where registrants are required to focus these efforts

With regard to implementation timing, EPA has determined that most measures can be efficiently implemented via revised product labels by the 2010 use season. Other measures, in particular those related to buffer zones, will present greater compliance challenges and will require additional time for EPA to conduct the necessary outreach, and communication activities with states, tribes, other regulatory partners, fumigant users, and other stakeholders to facilitate transition. EPA has determined that these measures will be implemented via revised product

labels by the 2011 use season. As a result, all measures described in this amended RED that are necessary for reregistration eligibility will appear on product labels by 2011. Table 2 below shows the measures that will be implemented in 2010 and the additional measures that will be implemented in 2011.

Table 2. Implementation Schedule for Soil Fumigant Risk Mitigation Measures

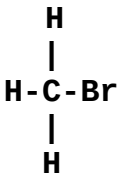
Risk Mitigation Measure	Currently	2010	2011
Restricted Use	●	●	●
New Good Agricultural Practices		●	●
Rate reductions		●	●
Use site limitations		●	●
New handler protections		●	●
Tarp cutting and removal restrictions		●	●
Extended worker reentry restrictions		●	●
Training information for workers		●	●
Fumigant Management Plans		○	●
First responder and community outreach		○	●
Applicator training		○	●
Compliance assistance and assurance measures		○	●
Restrictions on applications near sensitive areas			●
Buffer zones around all occupied sites			●
Buffer credits for best practices			●
Buffer posting			●
Buffer overlap prohibitions			●
Emergency preparedness measures			●

○ = under development
● = adopt completely

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, Ameribrom 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 into 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 quarantine and preshipment (QPS) exemption 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 QPS exemption, 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 thus, their increased 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, and 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
- Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369**,** Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits (Date May 14, 2009)

C. Stratospheric Ozone Depletion

In addition to methyl bromide's direct effects previously described in Section B, methyl bromide soil fumigant use poses 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 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 U.S. was 23,000,000 lbs (10,433 metric tons). Consistent with the intent of 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.

[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

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 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 phase-out. 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 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's Office of Atmospheric Programs (OAP) has not promulgated a regulation for the implementation of an emergency use exemption.

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
- Response to Public Comments on the 7/9/08 Methyl Bromide RED (DP Barcode 304616)

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 amendment to the 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].

[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

2. Exposure

a. Terrestrial Exposure

The Industrial Source Complex Short Term (ISCST3) model together with historical air monitoring data were 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 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 RQ 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 invertebrates. 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

F. Impacts of RED mitigation

Requirements in the July 2008 RED

The July 2008 RED acknowledged 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. However, the Agency believed that the options provided in the scalable buffer approach in the fumigant REDs would allow growers the flexibility to modify their practices to achieve smaller buffers; for example, by treating smaller application blocks, switching to a lower emission application method, or by switching to an alternative fumigant that would require smaller buffers. In addition, EPA noted that 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. Therefore, the Agency concluded that growers would be able to alter their fumigation applications, given the flexibility designed into the system, in a manner that would enable growers to minimize the impact on production. The Agency noted, however, that the buffers would significantly impact some growers by the use of more expensive high barrier film, delays in planting due to longer fumigation operations, additional planning, and more trips to the field for planting and other operations if fumigating in smaller blocks resulted in staggered operations. It was determined that some of these costs could be substantial in some production scenarios.

Comments on the July 2008 RED

The July 2008 RED requested commenters to submit a description of fumigation practices and provide maps of their property illustrating locations of fields, offices, residences, roads, and property lines so that the Agency could better understand the impacts of the mitigation plan. In response, various stakeholders, including several forest seedling nursery operations, submitted detailed information. From an analysis of the information submitted, including an analysis of a nursery and options they would have for compliance, the Agency concludes that it had overestimated the ease with which many growers and fumigators would be able to comply with the buffer requirements as presented in the July 2008 RED, and that potential impacts would be much greater than previously anticipated for some types of production. The analysis indicates that the buffer system identified in the July 2008 RED can be less flexible than expected for certain scenarios and the associated field topography, field infrastructure, and need for a consistent orientation in the application of a fumigant, which constrain how a field may be divided.

From the Agency's analysis, the primary driver of the impacts is the size of the buffer zones, which will require many growers to divide their fields into smaller fumigation blocks to achieve smaller buffer zone distances. Two other contributing factors are the prohibition on buffers overlapping in space and time and the duration of the buffer zone. Together, these requirements could result in the loss of part of a grower's field that can be effectively fumigated. Further, there may be substantial delays in completing fumigations and multiple trips to a field with fumigation equipment may often be necessary. Not only could there be delays in production activities in these instances, but it may also be difficult to maintain proper soil moisture over the period that multiple blocks would be fumigated. Soil moisture has been identified as a critical element in controlling emissions. Some growers will face numerous scheduling conflicts if they rely on commercial applicators, and the Agency estimates that growers would be more likely to conduct their own fumigations. In addition, repeated trips to the field to fumigate small blocks will increase costs, a further incentive for growers to conduct their own fumigations.

The Agency does agree that compliance with buffer zones requirements as outlined in the July 2008 RED would be a significant challenge for applicators and growers. However, field flux studies, monitoring data, modeling analyses, and information from incidents involving fumigants continue to support a conclusion that methyl bromide off-gasses and moves away from treated fields at concentrations that have the potential to cause adverse effects. Therefore, the Agency still believes that buffer zones that exclude bystanders are a critical aspect of mitigating risks from the use of methyl bromide.

In addition to these impacts, if emergency preparedness and response requirements were triggered due to proximity of neighbors, for example, the requirement in the July 2008 RED to monitor the buffer zone for its 48-hour duration was estimated to impose the highest direct costs. The Agency estimates that the cost of sampling tubes alone could range from $1,000 to over $3,000 for a field or enterprise, not including the cost of labor. These costs would fall disproportionately on growers with small acreage. As an alternative, growers could notify their neighbors of their intent to fumigate. However, the Agency understands and appreciates the

many comments indicating that notification may not be an attractive option due to the potential for neighbors to attempt to impede or block fumigant applications.

Finally, the Agency concludes that the development and implementation of workable fumigation strategies, considering buffer and other requirements, will require substantial new information and management skills on the part of growers and applicators. While the Agency's risk management approach provides flexibility to the grower, providing a reasonable period of time for growers to adapt would reduce impacts.

Based on this new information and EPA's analyses, the Agency has identified modifications to the mitigation which will maintain the important protections necessary for the health and safety of workers and bystanders, but will increase the ability of fumigant users to comply by reducing impacts associated with the mitigation. This includes allowing buffer zone overlap and changes in monitoring requirements. In addition, due to new data that have been submitted to the Agency, buffer zones distances for some scenarios have been refined for certain chemicals and additional buffer zone credits have been provided. The Agency also anticipates receiving additional field flux data for methyl bromide that may allow refinement of these buffer zone distances in the future. Although many aspects of the RED mitigation will appear on labels in 2010, the Agency will not require buffers until the 2011 growing season.

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). 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].

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

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;
- Respiratory protection;
- Tarp cutting/removal procedures;
- Entry-restricted period;
- Application method/practice restrictions;
- 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 had 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 were placed into two groups:

- **Group 1** included 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 CUEs).

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 determined in the July 2008 RED 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

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

http://www.epa.gov/ozone/mbr/cueinfo.html). Based upon those analyses, EPA 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 determined in the July 2008 RED 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 the RED were implemented. Therefore, products containing methyl bromide for these uses were eligible for reregistration as long as they have CUE or QPS status under the Montreal Protocol. Required label changes are described in Section V of this document. The Agency determined in the July 2008 RED 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 determined in the July 2008 RED that Group 2 uses were not eligible for reregistration. Substantial information 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, indicated that these uses have economically and technologically feasible alternatives.

The Agency determined that use sites in Group 2 for which no data is available to demonstrate high benefits or a lack of effective alternatives should be canceled following completion of the comment period on the July 2008 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. The RED stated that 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.

Following publication of the methyl bromide RED in July 2008, the Agency announced a public comment period for the RED and requested comments on the importance of the Group 2 uses. The Agency received comments on the Group 2 uses during the post-RED comment period. Following review of the comments, the Agency has determined that the benefits of the Group 2 uses are not high enough to allow them to be eligible for reregistration. However, the Agency has determined that certain uses do provide benefits for growers and EPA will allow these uses to continue for a finite period of time. These uses include; caneberries, fresh market tomatoes and peppers in California, Vidalia onions in Georgia, and ginger in Hawaii. The Agency has determined that tobacco growers, golf courses, or turf producers would not incur substantial impacts if they could not use methyl bromide. Alternative treatments to control pests appear to be available and no information was submitted demonstrating that the alternatives are

prohibitively expensive. Therefore, the Agency has determined that these uses should end immediately. The Agency will work with the registrants to cancel the Group 2 uses under Section 6(f) of FIFRA. If registrants do not request voluntary cancellation, EPA will take additional regulatory action. For more details on the benefits assessment for these uses, please refer to; *BEAD Response to Stakeholder Comments on Non-CUE Uses of Methyl Bromide and Methyl Bromide Rate Reductions* (DP# 363545) in the methyl bromide docket.

EPA believes that eliminating Group 2 uses will reduce the total amount of methyl bromide applied in the U.S., and therefore reduce the incidence of skin cancer resulting from stratospheric ozone depletion. 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.

USDA is currently conducting eradication programs to eliminate the potato cyst nematode in Idaho and the golden nematode in New York, federally recognized invasive, non-indigenous pests. These nematode species pose serious threats to the potato industries in these regions and can cause serious economic damage. Currently, limited acreage is infested with these nematodes. However, there is great concern that these pests could move into other potato growing areas. The USDA program goals include limiting the spread of the nematodes eradicating current infestations. These programs currently rely on use of high rates of methyl bromide. USDA supervises the fumigation of infested fields by professional commercial applicators. In their comments on the July 2008 REDs, USDA expressed concern that the mitigation measures as outlined in the 2008 methyl bromide RED could severely impact the effectiveness of these programs. USDA has implemented extensive outreach programs to increase community awareness in these areas, and has conducted air monitoring to help ensure early warning if methyl bromide concentrations exceed current action levels. EPA believes these steps greatly enhance the safety of methyl bromide use under these programs. While EPA believes that several of the amendments to the methyl bromide RED will reduce impacts on

benefits that these programs provide, EPA will continue to work with USDA on these specific uses to explore alternative methods to achieve safety goals while ensuring the benefits of these programs continue. Additionally, the studies the MBIP has committed to conduct, described later in this document, may allow for refinement of buffer distances which could further reduce the impacts.

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 bromide 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)

The Agency also opened a 60-day public comment period following the publication of the methyl bromide RED on July 16, 2008. The Agency received requests to extend the comment period, so in response to these requests, on August 29, 2008, EPA published a notice in the Federal Register extending the comment period for an additional 45 days. The comment period closed on October 30, 2008. The Agency has reviewed these public comments as well as new scientific data and other information provided and determined that all measures established in the July 2008 RED to reduce risks to bystanders and workers will still be required. The Agency has determined that certain modifications in how and when some measures will be implemented are appropriate. The following documents include EPA's responses to comments on the methyl bromide RED which may be found in the methyl bromide docket:

- Response to BEAD Related Public Comments Received on the Reregistration Eligibility Decision for Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide (DP# 363545).
- BEAD Response to Stakeholder Comments on Non-CUE Uses of Methyl Bromide and Methyl Bromide Rate Reductions (DP# 363545).
- Response to Public Comments on the 7/9/08 Completed Methyl Bromide RED (DP Barcode 304616).
- Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents (Date May 14, 2009).
- Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery (DP Barcode 363546)
- SRRD's Response to Post-RED Comments for the Soil Fumigants (May 27, 2009).

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, 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

Mitigation measures including 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.

In addition, GAPs, 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 the *Other Mitigation* section.

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:

- This preserves uses with high benefits and no alternatives, and eliminates uses with lower benefits and/or alternatives given the risks associated with methyl bromide use;
- reconciles inconsistency between phase-out of methyl bromide production and EPA registered uses;
- 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;
- restricts the use of stockpiled methyl bromide to uses with high benefits, critical uses, and other exempted uses; and
- contributes along with other mitigation 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 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

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 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 or greater) untarped shank applications for California orchard replant uses that qualify for a CUE or QPS exemption and tree-hole applications with deep (18 inches or greater) 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 July 2008 methyl bromide RED required a reduction in maximum rates for certain uses. These reductions were based on information from critical use nominations (CUNs) and CUEs and acknowledgements from MBIP and other stakeholders that current methyl bromide use rates are substantially less than the current maximum rates on registered labels. Maximum rates for QPS and emergency exemptions uses are not affected by this decision but must be identified on end use labels.

During the post-RED comment period, the Agency received comments from MBIP on the maximum application rates proposed in the RED. The Agency evaluated the comments and, in general, concludes that the rates proposed in the RED are in keeping with rates currently in use and should not pose significant problems to most growers. However, the rates specified in the RED are often near the average use rates and some growers may benefit from higher rates. The Agency also finds that vegetable producers may benefit if maximum rates are standardized at 200 lb methyl bromide/acre across vegetable crops as most producers plant a mix of crops. Most significantly, according to information recently obtained, nurseries (strawberry, orchard and forest seedlings) and some ornamental production facilities in California may occasionally be required to use a rate of almost 400 lb methyl bromide/acre in order to obtain pest-free certification.

Based on the Agency's review of the comments submitted by MBIP, EPA has determined that maximum rates for certain uses should be higher than what was described in 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)

July 2008 RED. These rates are still significantly lower than current labeled maximum rates and the Agency believes that these reductions in application rates will result in less methyl bromide applied and will help to reduce methyl bromide's role in the depletion of stratospheric ozone. The mitigation measures described in this document will address acute risks resulting from these rates and provide incentives to use the lowest efficacious rate. Therefore, the Agency believes that a majority of applications will use rates that are lower than the maximum rates. EPA's decision regarding maximum use rates is presented in Table 3.

Table 3. Maximum Application Rates for Pre-plant Soil Methyl Bromide Uses

Approved Critical Uses	Maximum Broadcast Equivalent Rates (lb a.i./acre)		
	Current Label	2008 RED	RED Amendment
Cucurbits	435	200	200
Eggplant	400	170	200
Pepper, Bell	480	170	200
Tomato, Fresh Market	870	160	200
Sweet Potato Slips	870	200	200
Strawberry Fruit	870	200	235
Strawberry Nursery	870	260	400
Orchard Nursery	435	200	400
Forest Seedling Nursery	870	260	400
Orchard Replant (walnut, almond, stone fruit)	870	200	250
Orchard Replant (grape)	870	250	250
Ornamentals	870	360	400

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 and implemented training and community outreach and education programs, will help reduce risk. Additionally, EPA will continue to work 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 margin of exposures (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 site specific response and management, notice to state lead agencies, training, and community outreach and education, as well as labeling changes.

i. Buffer Zones

The human health risk assessments indicate bystanders may be exposed to methyl bromide air concentrations that exceed the Agency's level of concern based on current label requirements. In general, the risk from inhalation exposures decreases as the distance from the field where bystanders are located increases. Because of this relationship, the Agency has determined that a buffer zone must 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 risks or eliminate incidents caused by equipment failure, human error, adverse weather (e.g., temperature inversions), or other events. 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.

ii. General Buffer Zone Requirements

General Requirements in the July 2008 RED

The 2008 methyl bromide RED described general buffer zone requirements for methyl bromide and other soil fumigants. This included the definition of a buffer zone, the requirement to exclude non-handlers from the buffer zone during the buffer-zone period, and the definition of the application block.

The RED also did not allow buffer zones to overlap and fumigations were prohibited within 0.25 miles of difficult to evacuate sites such as schools, state licensed day care centers, nursing homes, and hospitals, if occupied during the buffer zone period. Exemptions for vehicular and bicycle traffic were allowed on roadways through the buffer zone. However, bus stops or other locations where persons wait for public transit were not permitted within the buffer zone. Structures within the buffer zone were also not allowed to be occupied during the buffer zone period and air samples were required before bystanders could enter the structure following expiration of the buffer-zone period. In addition, before a buffer zone could extend onto adjacent private or public property, the applicator needed to obtain written permission from the

owner/operator or local authority to allow the buffer zone to extend onto the property. This was to ensure that non-handlers would not enter the buffer zone and that buffer zones did not overlap.

Comments on the July 2008 RED

During the post-RED comment period, the Agency received many comments from stakeholders concerning the buffer zone requirements. Many comments stated that the large buffer zone distances would make fumigation infeasible and the mitigation options were not flexible enough to allow some fumigations to occur; however other comments expressed concern that buffers EPA specified would not be large enough to protect bystanders.

The Agency also received numerous comments that buffer zone duration will present severe hardship for growers. Many commenters expressed concern that the buffer zone overlap restriction would have the unintended consequence of forcing some applications to occur during less-than-optimal weather and soil conditions, because the restriction could preclude nearby application blocks from being treated when weather and soil conditions would be optimal for reducing emissions. Hence, subsequent fumigations in adjacent fields would have an increased chance of occurring when weather and soil conditions are more conducive to off-gassing. Examples cited by commenters where this situation could occur include the Southeast and Pacific Northwest where optimal soil moisture conditions occur during a limited time period. The commenters felt that while the buffer zone is in effect, properly trained and equipped handlers should be allowed to enter adjacent application blocks to make applications. Several commenters felt that providing an exception to this prohibition would make buffers more workable, reduce delays, allow a more efficient use of equipment and labor, allow growers additional flexibility to achieve compliance with buffer requirements, and potentially reduce risk if applications could be made under more favorable soil and weather conditions. In addition, some comments suggested that allowing adjacent application blocks to be treated would not increase risk to bystanders since the Agency's mitigation measures encourage users to split application blocks into smaller treatment areas which result in less fumigant being applied, less exposure, and less potential risk.

Some comments also asked for clarification on various aspects of the buffer zone requirements, and some asked that EPA provide additional increments for acreages and application rates for buffer zone tables. In addition, many comments stated that buffer zone credits should be greater for the use of tarps and for certain environmental conditions. A number of comments indicated that obtaining written permission from local authorities for buffers to extend over roads and rights-of-way would be extremely difficult, and that neighbors may not provide permission. EPA also received additional field emissions (flux) data for some fumigants, as well as additional information regarding factors that affect fumigant emissions.

Based on EPA's review of the comments, and new data and information, the Agency has determined that certain amendments to the buffer zone requirements are appropriate. EPA believes these amendments will maintain the important protections for bystanders but will increase the feasibility of compliance with buffers and will reduce potential impacts of buffers on the beneficial uses of soil fumigants. The Agency does agree that compliance with buffer zone requirements as outlined in the July 2008 RED would be a significant challenge for applicators

and growers. However, field flux studies, monitoring data, modeling analyses, and information from incidents involving fumigants continue to support a conclusion that methyl bromide off-gasses and moves away from treated fields at concentrations that have the potential to cause adverse effects. Therefore, the Agency still believes that buffer zones that exclude bystanders are a critical aspect of mitigating risks from the use of methyl bromide. The Agency believes the modifications to the buffer requirements, specified below, will increase compliance feasibility and encourage further adoption of emission reduction application techniques, while still protecting human health and the environment.

Amended RED Requirements

EPA has determined that no changes to several aspects of the general buffer zone requirements from the 2008 RED are appropriate. This includes:

- the definition and duration of a buffer zone;
- the requirement to exclude field workers, nearby residents, pedestrians, and other bystanders from the buffer zone during the buffer zone period;
- the exemption for transit through buffer zones;
- the definition of the application block;
- the minimum buffer of 25 feet and maximum buffer of ½ mile.
- the requirement limiting entry into buffer zones to handlers who have been properly trained and equipped according to EPA's Worker Protection Standard;
- the prohibition on including in buffer zones bus stops or other locations where persons wait for public transit;
- the prohibition against including in buffer zones buildings under the control of the owner/operator of the application block used for storage such as sheds, barns, garages, etc., unless the storage buildings are not occupied during the buffer zone period, and the storage buildings do not share a common wall with an occupied structure;
- the prohibition against including in buffer zones residential areas that are not under the control of the owner/operator unless occupants agree in writing that they will voluntarily vacate the buffer zone until the buffer zone period expires;
- the prohibition against including in buffer zones agricultural areas that are not under the control of the owner/operator unless the owner/operator of the other area provides written agreement that they, their employees, and other persons will not enter the buffer zone; and
- the prohibition against including in buffer zones publicly owned and/or operated areas such as parks, sidewalks, walking paths, playgrounds, and athletic fields without first obtaining written permission from local authorities.

EPA has determined that certain other amendments to the July 2008 RED requirements are appropriate; these are discussed in greater detail below. The amended buffer zone requirements are summarized at the end of this section.

Buffer Zone Proximity - Exception to Allow Buffer Zone Overlap

The Agency is concerned that emissions from multiple fields located close to one another could be higher than air concentrations from individually treated fields. As a result, bystanders outside of buffers for individual application blocks could be exposed to concentrations of concern particularly if peak concentrations from multiple application blocks in proximity to each other coincide. To reduce the potential for off-site movement of fumigant emissions beyond buffer zones for multiple fumigated fields, the July 2008 RED prohibited buffer zones from multiple application blocks from overlapping, including application blocks fumigated by other property operators.

EPA has considered the comments submitted and has determined that allowing an exception to the buffer zone overlap prohibition, under the conditions specified below, is reasonable and will not demonstrably alter the protection goals provided to bystanders in the July 2008 RED. EPA has determined that buffer zones from nearby application blocks may overlap one another provided at least 12 hours have elapsed from the end of one application until the start of the next application. By separating the application times by at least 12 hours the fumigant emission peaks are less likely to occur at the same time, which would sufficiently reduce potential exposure outside buffer zones and meets the Agency's protection goals.

The Agency is maintaining the requirement for buffer zones around each application block to be in effect for 48 hours and that only properly trained and equipped handlers are allowed to enter into buffers zones.

To clarify, below are conditions when buffer zones may or may not overlap:

- A buffer zone may NOT overlap buffer zones from other application blocks that are already in effect UNLESS a minimum of 12 hours has elapsed from the time the first application ends until the second application begins.

EPA has determined that when fumigators exercise the exception to allow buffers to overlap, the emergency preparedness and response measures described later in this document must be implemented if there are homes, businesses, or property not within the control of the fumigator within 300 feet of the buffer zone regardless of the size of the buffer zone.

To ensure handlers are aware that they are working in an existing buffer from an overlapping buffer zone area, the labels will require the certified applicator, before beginning the application, to determine whether the application block or its resulting buffer will overlap with a buffer that is already in effect. If so, the certified applicator must inform handlers of this and the health effects, early signs of exposure, and respiratory protection and PPE requirements for products applied in both the application block in which they are working and the other application block. The Agency is requiring that all treatment areas and buffers be clearly posted with proper signage to ensure handlers entering a treatment area are aware of previous treatments and the existence of buffers. In addition, certified applicators must obtain permission from other landowners when buffers extend onto other lands, which provides an additional mechanism to ensure handlers are aware when they are working in a buffer zone and that they have the

necessary information regarding health effects, warning properties, and respiratory/PPE requirements for all products to which they may be exposed.

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

For areas not under the control of the owner/operator of the application block, the requirements remain unchanged except (1) air samples do not need to be taken to allow occupants to reenter buildings or homes after the buffer zone period has expired, and (2) buffer zones may include publicly owned and/or operated roads, including rights of ways, without first obtaining written permission from local authorities; however, if a sidewalk or permanent walking path is associated with the road or right-of-way, written permission must be given by the appropriate state and/or local authorities.

In summary, areas of a buffer zone not under the control of the owner/operator of the application block, 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 the occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period. Air samples for methyl bromide and chloropicrin do not need to be taken before the occupants can re-enter a building, home, or outdoor area that was vacated in order to permit the fumigation to occur unless the methyl bromide product applied is formulated with less than 20% chloropicrin. The Agency determined that the concentrations of the fumigants 48 hours after completion of the application were likely to be below the Agency's level of concern, and that the warning properties of chloropicrin would alert persons reentering the site if concentrations were of concern. However, because methyl bromide is odorless and colorless, EPA is not confident that chloropicrin in low-concentration formulations would be an effective warning agent 48 hours after treatment. Therefore, monitoring of buildings and outdoor areas after termination of the buffer zone is not necessary and will no longer be required except as noted for methyl bromide when it is applied in formulations with less than 20% chloropicrin.

Buffer zones may still not include agricultural areas owned/operated by persons other than the owner/operator of the application block unless 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, taking into account the amended requirements for overlapping buffers. In addition, the applicator must still receive written permission from the owner/operator of areas that are not under the control of the applicator stating that the owner, their employees, and other persons other than handlers, consistent with buffer overlap provisions, will stay out of the buffer zone during the entire buffer zone period. The goal of this agreement is to ensure that a property owner of an agricultural field adjacent to an area that will be treated with a fumigant is aware when the fumigation will occur. This will allow the applicator to post on the adjacent property and take other required safety measures to ensure that persons on the property will not be exposed to a fumigant at levels above the Agency's level of concern. Informing the property owner of the adjacent field will enable them to take any appropriate safety measures they deem necessary. The Agency believes that requiring the applicator to obtain written permission will be an enforceable measure that will meet the goal of protecting workers and bystanders on adjacent properties that fall within a buffer zone.

In addition, buffer zones still may include publicly owned and/or operated areas such as parks, sidewalks, walking paths, playgrounds, and athletic fields only if the area is not occupied during the buffer zone period and entry by non-handlers is prohibited during the buffer zone period. Written permission from the appropriate state and/or local authorities to include these public areas in the buffer zone is also still required.

However, for roads and rights-of-ways, EPA has determined that these may be included in buffers, subject to local laws and regulations, as long as it is posted according to the requirements of this amended RED. If, as discussed above, the road or right-of-way has an associated sidewalk or permanent walking path, then written permission would also be required to include the area in the buffer zone. The Agency believes that if a town or county has invested resources into building a sidewalk or establishing a walking path, it is reasonable to anticipate pedestrian traffic at that location. In such circumstances EPA believes a local authority would be best positioned to make a determination about the practicality of preventing non-handlers from entering the buffer zone. EPA acknowledges that laws and regulations vary from jurisdiction to jurisdiction and that the requirement to post points of entry into buffer zones may necessitate additional steps on the part of fumigant applicators before a road or right-of-way can be included in a buffer.

Maximum Application Block Sizes

The maximum application block sizes allowed in the 2008 RED for methyl bromide applications were:

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

These block size limits were based on the upper end of the range of acres treated under current practices and constraints of modeling for these scenarios. No comments were provided regarding these limits.

Buffer zone distances - Requirements in the July 2008 RED

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 (the target MOE) at high percentiles of the of the outputs from PERFUM model Version 2.1.4, one of the resources EPA used to help inform decisions regarding buffer zone distances. See Appendix B for more information on the PERFUM model. 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.

As discussed in the July 2008 RED, 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[12]). 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, the buffers specified in the July 2008 RED achieved this goal for protection. EPA also believed that the 2008 RED buffer zone distances would be manageable for most growers using existing cultural practices because of the flexibility and options provided to modify buffers by altering certain aspects of fumigation practices.

For the 2008 RED, the Agency developed buffer zone distances that were scaled based on application method, application rate, and application block size. For each of the outdoor pre-plant soil emission profiles for the July 2008 RED, 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 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 risks associated with the buffer zone distances, which are presented in Tables 4, 5, 6, 7 and 8, are characterized as follows:

- 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).
- The PERFUM model Version 2.1.4 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.

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

- 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.

Minimum and Maximum Distances

A minimum buffer zone of 25 feet was required in the July 2008 RED 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. While modeling may support no buffer zone in some cases, a minimum buffer was required because of variability in the emission rates over a field and other factors not accounted for in the modeling; as such the Agency determined that a 25 foot minimum buffer zone was a good agricultural practice. Also, in the 2008 RED, application scenarios requiring buffer zone distances of more than ½ mile (2,640 feet) were prohibited. EPA believes that for areas where methyl bromide is used, buffers greater than ½ mile are not practical and difficult to enforce.

"Greenhouse" Uses

The "greenhouse" industry sector is extremely varied because of the diversity 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". In typical "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-translucent 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 4, 5, and 7).

Methyl Bromide – Chloropicrin Formulations

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. However, the user must consult the label for the specific formulation intended for use to ensure the required buffer zone distances for the particular product are employed.

The July 2008 RED also provided detailed descriptions of the PERFUM model inputs and outputs. These descriptions have not changed and are included in this Amended RED in Appendix B.

Comments on the July 2008 RED Buffer Distances and Amended RED Determinations

Additional Acreage and Rate Increments

During the post-RED comment period, the Agency received comments requesting buffer zone distances for additional acreage increments for small fields and additional application rate increments for tarped bedded and tarped broadcast scenarios. In response, the Agency determined buffer distances for smaller block sizes (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 acres) as well as more application rates for tarped bedded and tarped broadcast scenarios. EPA believes this will help to better refine the buffer distances for these use scenarios (Tables 4 and 5), and will provide additional options for growers to achieve more workable buffers.

Although the Agency added additional acreage and rate increments, not all increments may be captured by the tables presented. If the tables do not capture a specific acreage or rate, round up to the nearest acre or rate. For example, when applying to a 9.5 acre field, round up to 10 acres.

New Flux (Emissions) Studies

Since the RED was published in July 2008, the Agency has received new flux data that have allowed the Agency to refine buffer zone distances for certain fumigants. While no new methyl bromide studies were submitted, the MBIP has submitted a letter committing to conduct new field flux studies for methyl bromide that may allow EPA to further refine the buffer zone distances specified in the tables below. The studies will be conducted in San Joaquin Valley and Ventura County, California, and in Plant City, Florida. Emissions from various application methods will be conducted including:

- Broadcast shallow tarped under standard high-density polyethylene (HDPE)
- Broadcast shallow tarped under virtually impermeable film (VIF)
- Broadcast shallow tarped under VIF with potassium thiosulfate soil spray
- Deep, tarped strip under VIF
- Bedded tarp shank injection with VIF
- Bedded tarp shank injection with VIF and additional emissions reduction treatment
- Bedded tarp shank injection with metalized film

The studies are scheduled to be conducted in spring 2009 through winter 2010 and final reports are scheduled to be submitted to the Agency by March 2010. As noted above, the information from these studies may enable EPA to refine buffer zone distances that will appear on labels in 2011. See letter from Tracy Heinzman, Wiley Rein, LLP, to Debbie Edwards, "Methyl Bromide Reregistration -- Development of New Data to Calculate Flux Rates/Emission Factors and Update EPA's By-Stander Exposure Assessment," March 31, 2009, located in the methyl bromide docket.

In addition, new fumigant data submitted during the post-RED comment period has also allowed the Agency to refine and update buffer zone credits for tarps, certain application techniques, and environmental conditions. As a result, although the buffer zone distances specified in the tables in the July 2008 RED for methyl bromide have not changed except as noted to add rate and acreage increments, buffers for growers who use emission-reducing tarps or application methods, or have site conditions that qualify for credits will have smaller buffers than those specified in the 2008 RED. 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 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. The amended credits are discussed in detail below in the section, *Buffer Zone Reduction Credits*.

Methyl bromide buffer distances, amended as noted above, are specified in Tables 4-8 below. Table 9, from the July 2008 RED, summarized the required buffer zone distances and corresponding PERFUM modeling results for the pre-plant soil uses that qualify for critical use exemptions with typical application rates (based on information identified in the Agency's benefits assessments). The buffer zone distances have been updated to incorporate additional rates. Focusing on tomatoes as an example (last row of Table 9), the buffer zone is 185 feet for a 10 acre application block in the Southeast at a rate of 120 lbs ai/A. At 185 feet, the PERFUM model 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, Florida). (See Appendix B for more details on the PERFUM model inputs and outputs.) 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 185 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, Florida).

Table 4. Tarped Bedded Buffer Zone Distances (feet)

Broadcast Equivalent Application Rate (lb ai/A)	Application Block Size (acres)																						
	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	50	60	70	80	90	100
25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
30	25	25	25	25	25	25	25	25	25	25	25	25	25	25	28	31	34	38	41	44	45	47
35	25	25	25	25	25	25	25	25	25	25	25	25	25	25	31	38	44	50	56	63	66	69
40	25	25	25	25	25	25	25	25	25	25	25	25	25	25	34	44	53	63	72	81	86	91
45	25	25	25	25	25	25	25	25	25	25	25	25	25	25	38	50	63	75	88	100	106	113
50	25	25	25	25	25	25	25	25	25	25	25	25	25	25	41	56	72	88	103	119	127	134
55	25	25	25	25	25	25	25	25	25	25	25	25	25	25	44	63	81	100	119	138	147	156
60	25	25	25	25	25	25	25	25	25	25	25	25	25	25	47	69	91	113	134	156	167	178
65	25	25	25	25	25	25	25	25	25	25	25	25	25	25	50	75	100	125	150	175	188	200
70	25	27	28	30	31	33	35	36	38	40	46	52	56	60	86	113	144	175	204	233	249	265
75	25	28	31	34	38	41	44	48	51	54	67	79	88	96	123	150	188	225	258	292	311	331
80	25	30	34	39	44	49	54	59	64	69	88	106	119	131	159	188	231	275	313	350	373	396
85	25	31	38	44	50	57	63	70	77	83	108	133	150	167	196	225	275	325	367	408	435	462
90	25	33	41	48	56	65	73	81	90	98	129	160	181	202	232	263	319	375	421	467	497	527
95	25	34	44	53	63	73	83	93	103	113	150	188	213	238	269	300	363	425	475	525	559	593
100	25	36	47	58	69	80	92	104	115	127	171	215	244	273	305	338	406	475	529	583	621	658
105	25	38	50	63	75	88	102	115	128	142	192	242	275	308	342	375	450	525	583	642	683	723
110	25	39	53	67	81	96	111	126	141	156	213	269	306	344	378	413	494	575	638	700	744	789
115	25	41	56	72	88	104	121	138	154	171	233	296	338	379	415	450	538	625	692	758	806	854
120	25	42	59	77	94	112	130	149	167	185	254	323	369	415	451	488	581	675	746	817	868	920
125	25	44	63	81	100	120	140	160	180	200	275	350	400	450	488	525	625	725	800	875	930	985
130	27	48	69	90	112	133	154	175	196	217	295	373	427	481	521	562	665	768	848	927	987	1047
135	29	52	76	100	123	145	168	190	212	235	315	396	454	512	555	598	705	811	895	979	1044	1109
140	31	57	83	109	135	158	182	205	228	252	336	419	481	542	588	635	744	854	943	1031	1101	1171
145	33	61	89	118	146	171	195	220	245	269	356	442	508	573	622	671	784	897	990	1083	1158	1233
150	35	65	96	127	158	183	209	235	261	287	376	465	535	604	656	708	824	940	1038	1135	1215	1295
155	37	70	103	136	169	196	223	250	277	304	396	488	562	635	689	744	864	983	1085	1187	1272	1357
160	38	74	110	145	181	209	237	265	293	321	416	512	588	665	723	781	904	1027	1133	1238	1328	1418
165	40	78	116	154	192	222	251	280	309	338	437	535	615	696	757	817	943	1070	1180	1290	1385	1480
170	42	83	123	163	204	234	265	295	325	356	457	558	642	727	790	854	983	1113	1228	1342	1442	1542
175	44	87	130	173	215	247	278	310	342	373	477	581	669	758	824	890	1023	1156	1275	1394	1499	1604

Table 4. Tarped Bedded Buffer Zone Distances (feet)																						
	Application Block Size (acres)																					
	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	50	60	70	80	90	100
180	46	91	137	182	227	260	292	325	358	390	497	604	696	788	858	927	1063	1199	1323	1446	1556	1666
185	48	96	143	191	238	272	306	340	374	408	517	627	723	819	891	963	1103	1242	1370	1498	1613	1728
190	50	100	150	200	250	285	320	355	390	425	538	650	750	850	925	1000	1143	1285	1418	1550	1670	1790
195	56	108	159	211	263	298	333	369	404	440	556	673	776	879	957	1035	1185	1334	1471	1608	1735	1861
200	63	116	169	222	275	311	347	383	418	454	575	696	802	908	990	1071	1227	1383	1525	1667	1799	1932
205	69	123	178	233	288	324	360	396	433	469	594	719	828	938	1022	1106	1269	1433	1579	1725	1864	2003
210	75	131	188	244	300	337	373	410	447	483	613	742	854	967	1054	1142	1312	1482	1633	1783	1928	2073
215	81	139	197	255	313	350	387	424	461	498	631	765	880	996	1086	1177	1354	1531	1686	1842	1993	2144
220	88	147	206	266	325	363	400	438	475	513	650	788	906	1025	1119	1213	1396	1580	1740	1900	2058	2215
225	94	155	216	277	338	375	413	451	489	527	669	810	932	1054	1151	1248	1439	1629	1794	1958	2122	2286
230	100	163	225	288	350	388	427	465	503	542	688	833	958	1083	1183	1283	1481	1678	1848	2017	2187	2357
235	106	170	234	298	363	401	440	479	518	556	706	856	984	1113	1216	1319	1523	1728	1901	2075	2251	2428
240	113	178	244	309	375	414	453	493	532	571	725	879	1010	1142	1248	1354	1565	1777	1955	2133	2316	2498
245	119	186	253	320	388	427	467	506	546	585	744	902	1036	1171	1280	1390	1608	1826	2009	2192	2380	2569
250	125	194	263	331	400	440	480	520	560	600	763	925	1063	1200	1313	1425	1650	1875	2063	2250	2445	2640

Table 5. Tarped Broadcast Buffer Zone Distances (feet)

Broadcast Equivalent Application Rate (lb ai/A)	Application Block Size (acres)																					
	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	50	60	70	80	90	100
45	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
55	25	25	25	25	25	25	25	25	25	25	25	25	27	29	35	42	48	54	63	71	77	83
65	25	25	25	25	25	25	25	25	25	25	25	25	29	33	46	58	71	83	100	117	129	142
75	25	25	25	25	25	25	25	25	25	25	25	25	31	38	56	75	94	113	138	163	181	200
85	25	25	25	25	25	25	25	25	25	25	25	25	33	42	67	92	117	142	175	208	233	258
95	25	25	25	25	25	25	25	25	25	25	25	25	35	46	77	108	140	171	213	254	285	317
105	25	25	25	25	25	25	25	25	25	25	25	25	38	50	88	125	163	200	250	300	338	375
115	25	28	31	34	36	39	42	45	47	50	59	68	88	107	149	191	236	282	339	395	442	489
125	25	31	36	42	48	53	59	64	70	75	93	111	138	164	210	257	310	364	427	491	547	602
135	25	34	42	51	59	67	75	84	92	100	127	155	188	220	272	323	384	445	516	586	651	716
145	25	36	48	59	70	81	92	103	114	125	161	198	238	277	333	389	458	527	605	682	756	830
155	25	39	53	68	82	95	109	123	136	150	195	241	288	334	394	455	532	609	693	777	860	943
165	25	42	59	76	93	110	126	142	159	175	230	284	338	391	456	520	606	691	782	873	965	1057
175	25	45	65	85	105	124	143	162	181	200	264	327	388	448	517	586	680	773	870	968	1069	1170
185	25	48	70	93	116	138	160	181	203	225	298	370	438	505	578	652	753	855	959	1064	1174	1284
195	25	51	76	102	127	152	176	201	225	250	332	414	488	561	640	718	827	936	1048	1159	1278	1398
205	25	53	82	110	139	166	193	220	248	275	366	457	538	618	701	784	901	1018	1136	1255	1383	1511
215	25	56	88	119	150	180	210	240	270	300	400	500	588	675	763	850	975	1100	1225	1350	1488	1625
225	25	61	98	134	170	202	234	266	298	330	438	545	639	732	824	916	1053	1190	1325	1461	1608	1755
235	25	66	108	149	191	225	258	292	325	359	475	591	690	789	885	982	1130	1279	1426	1573	1728	1884
245	25	72	118	165	211	247	282	318	353	389	513	636	741	845	947	1048	1208	1369	1526	1684	1849	2014
255	25	77	128	180	232	269	306	344	381	418	550	682	792	902	1008	1114	1286	1458	1627	1795	1969	2143
265	25	82	139	195	252	291	330	370	409	448	588	727	843	959	1069	1180	1364	1548	1727	1907	2090	2273
275	25	87	149	211	273	314	355	395	436	477	625	773	894	1016	1131	1245	1441	1637	1828	2018	2210	2402
285	25	92	159	226	293	336	379	421	464	507	663	818	945	1073	1192	1311	1519	1727	1928	2130	2331	2532
295	25	97	169	241	314	358	403	447	492	536	700	864	997	1130	1253	1377	1597	1816	2029	2241	2451	2661
305	25	102	180	257	334	380	427	473	520	566	738	909	1048	1186	1315	1443	1675	1906	2129	2352	2572	2791
315	25	107	190	272	355	403	451	499	547	595	775	955	1099	1243	1376	1509	1752	1995	2230	2464	2692	2920
325	25	113	200	288	375	425	475	525	575	625	813	1000	1150	1300	1438	1575	1830	2085	2330	2575	2813	3050

Table 5. Tarped Broadcast Buffer Zone Distances (feet)

	Application Block Size (acres)																					
	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	50	60	70	80	90	100
335	34	126	218	310	402	452	502	552	602	652	847	1041	1195	1350	1495	1641	1907	2173	2426	2680	2924	3168
345	43	140	236	333	430	480	530	580	630	680	881	1082	1241	1400	1553	1707	1984	2260	2522	2784	3035	3286
355	52	153	255	356	457	507	557	607	657	707	915	1123	1286	1450	1611	1773	2060	2348	2618	2889	3147	3405
365	61	167	273	378	484	534	584	634	684	734	949	1164	1332	1500	1669	1839	2137	2436	2715	2993	3258	3523
375	70	181	291	401	511	561	611	661	711	761	983	1205	1377	1550	1727	1905	2214	2524	2811	3098	3369	3641
385	80	194	309	424	539	589	639	689	739	789	1017	1245	1423	1600	1785	1970	2291	2611	2907	3202	3481	3759
395	89	208	327	447	566	616	666	716	766	816	1051	1286	1468	1650	1843	2036	2368	2699	3003	3307	3592	3877
405	98	222	345	469	593	643	693	743	793	843	1085	1327	1514	1700	1901	2102	2445	2787	3099	3411	3703	3995
415	107	235	364	492	620	670	720	770	820	870	1119	1368	1559	1750	1959	2168	2521	2875	3195	3516	3815	4114
425	116	249	382	515	648	698	748	798	848	898	1153	1409	1605	1800	2017	2234	2598	2962	3291	3620	3926	4232
435	125	263	400	538	675	725	775	825	875	925	1188	1450	1650	1850	2075	2300	2675	3050	3388	3725	4038	4350

Table 6. 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	1,070	1,150
20	25	88	150	295	440	585	725	865	1,000	1,140	1,275	1,410	1,540	1,670	1,800
30	25	125	225	410	590	770	950	1,125	1,300	1,475	1,650	1,825	2,000	2,175	2,350
40	25	163	300	515	725	940	1,150	1,365	1,575	1,790	2,000	2,215	2,425	2,640	2,850

Table 7. 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	1,050	1,140	1,225	1,315	1,400
10	50	250	450	610	765	920	1,075	1,210	1,340	1,470	1,600	1,735	1,865	1,995	2,125

Table 8. Greenhouse Hot Gas Buffer Zone Distances (feet)

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

Table 9. 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 Sixe (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	454	>95	>95	>40	>45
				20	696	>95	>97	>40	>45
	Southeast	Tarped Shank Bedded	120	10	185	>95	>97	>40	>45
				20	323	>95	>97	>35	>40
Eggplant	Southeast	Tarped Shank Bedded	120	10	185	>95	>97	>40	>45
				20	323	>95	>97	>35	>40
Forest Seedlings	Southeast	Tarped Shank Broadcast	236	10	389	>99	>99.9	>45	>50
				20	636	>99	>97	>45	>50
			350	10	707	>97	>99	>50	>60
				20	1,123	>99	>97	>50	>60
Nursery, Fruit, Nut, and Rose	National	Tarped Shank Broadcast	180	10	225	>99	>99.9	>45	>50
				40	652	>99	>99.9	>45	>50
Stone Fruit, Tree Nut Orchard Replant, Grape Vineyards	CA	Tarped Shank Broadcast	182	10	225	>99	>99.9	>45	>50
				40	652	>99	>99.9	>45	>50
Ornamentals	CA	Tarped Shank Broadcast	235	10	359	>99	>99.9	>45	>50
				20	591	>99	>97	>45	>50
	FL	Tarped Shank Broadcast	390	10	816	>99	>97	>55	>60
				20	1,286	>99	>97	>55	>60
Pepper, Bell	MI	Tarped Shank Bedded	200	10	454	>95	>95	>40	>45
				20	696	>95	>97	>40	>45
	Southeast	Tarped Shank Bedded	120	10	185	>95	>97	>40	>45
				20	323	>95	>97	>35	>40
Strawberry Fruit	CA	Tarped Shank Broadcast	175	10	200	>99	>99.9	>45	>50
				20	327	>99	>99.9	>45	>50
	FL	Tarped Shank Bedded	120	10	185	>95	>97	>40	>45
				20	323	>95	>97	>35	>40
Strawberry Nursery	CA	Tarped Shank Broadcast	235	10	359	>99	>99.9	>45	>50
				20	591	>99	>97	>45	>50
	NC	Tarped Shank Bedded	235	10	556	>95	>97	>35	>40
				20	856	>95	>97	>35	>35
		Tarped Shank Broadcast	235	10	359	>99	>99.9	>45	>50
				20	591	>99	>97	>45	>50
Tomato, Fresh	Southeast	Tarped Shank Bedded	120	10	185	>95	>97	>40	>45
				20	323	>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 unreasonable adverse effects. The Agency is anticipating new emissions data from studies conducted by MBIP which may allow the Agency to determine if buffer zones of different sizes would meet or exceed the level of protection that the Agency established in the July 2008 RED. Reports from these studies are scheduled to be submitted to the Agency by March 2010. Therefore, buffer zone distances that are scheduled to be on methyl bromide labels in 2011 may be different from the distances provided in this document.

Amended Buffer Zone Requirements

The following describes the general buffer zone requirements, as amended, for methyl bromide:

- "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).
- 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.
- An "application block" is a field or portion of a field treated with a fumigant in any 24-hour period. See exception provided in the *Buffer zone proximity* section below. (See Figures 1 and 2 of Appendix B for further explanation.)

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 UNLESS:
    - A minimum of 12 hours have elapsed from the time the earlier application(s) for which a buffer is in place end(s) until the latter application begins, and
    - Emergency preparedness and response measures specified later in this document have been implemented if there are any homes, businesses, or property not within the control of the fumigator within 300 feet of each buffer zone, regardless of the size of the buffer zone.

Buffer zone distances

- Buffer zone distances must be based on look-up tables on product labels. Twenty-five feet is the minimum buffer distance regardless of site-specific application parameters.
- 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.

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 if 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 of this document 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 of this document 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,
     - Sensory irritation is not experienced, and
     - for structures in buffer zones for methyl bromide applications with less than 20% chloropicrin: Two consecutive air samples for methyl bromide taken in the structure at least 1 hour apart show concentrations of methyl bromide are less than 1 ppm.
- 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, except as provided for above, and
  2. The owner/operator of the adjacent areas (i.e., areas that are not under the control of the owner/operator of the application block) 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 must not include roads and rights of way **UNLESS,**
  1. The area is not occupied during the buffer zone period, and
  2. Entry by non-handlers is prohibited during the buffer zone period.
  3. Applicators must comply with all local laws and regulations.
- For all other publicly owned and/or operated areas such as parks, side walks, walking paths, playgrounds, and athletic fields, buffer zones must not include these areas **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.
  4. Applicators must comply with all local laws and regulations.
- See the *Posting* section of this document for additional requirements that may apply.

iii. Buffer Zone Reduction Credits

Requirements in the July 2008 RED

In preparing for the July 2008 RED, the Agency undertook a significant effort to evaluate available empirical data results, modeling, and scientific studies reported in the 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,"[13] in the methyl bromide docket. The Agency also coordinated and led fora 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 data, the 2008 methyl bromide RED gave buffer zone reduction credits for high barrier tarps, soils with high organic matter, and for soils with high clay content. The RED noted that changing current use practices or site conditions to utilize these credits may be a challenge. The Agency did determine, however, that in addition to reducing bystander risk and the size of buffer zones, the credit for high barrier tarps had the potential to decrease application rates, increase efficacy, and reduce depletion of stratospheric ozone. The methyl bromide RED stated that buffer zone credits were additive but could 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).

Comments on the July 2008 RED

Data were submitted since the July 2008 RED was issued that show greater reductions in emissions from the use of tarps and environmental conditions than what was determined in the July 2008 RED. In addition, the information submitted during the comment period indicated an

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

additive effect in reducing emissions when multiple factors were combined. As a result, EPA has updated the buffer reduction credits and determined that the 45% credit cap should be increased to 80%. The new credits for individual factors and the cap on credits are detailed below. For details on the Agency's analysis please see the May 14, 2009 memo; "Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations For Good Agricultural Practices and Associated Buffer Credits", in the methyl bromide docket.

- High barrier tarps

Credits in the July 2008 RED

The July 2008 RED determined that a 25% buffer credit for methyl bromide was appropriate for the following high barrier tarps: Bromostop® (1.38 mil), IPM Clear VIF (1.38 mil), and Eval/Mitsui (1.38 mil). The Agency believed that the actual reduction for tarps could be higher for certain conditions but that a 25% credit was appropriate based on uncertainties in the available data.

Comments on the July 2008 RED

Since the RED was published, data have been submitted by the United States Department of Agriculture- Agricultural Research Service (USDA-ARS) and other organizations that have shown a greater reduction in emissions for a larger number of tarps.

Credits for the Amended RED

From these data, the Agency has increased the credit for certain tarps and increased the number of tarps that are given credits. The Agency has determined that the tarps tested can be divided into two groups based on results in the emissions tests mentioned above. The first group includes the Canslit Heatstrip Silver and Canslit Metalized high-barrier tarps, which will be given a buffer credit of 30%. The second group includes the Olefinas Embossed VIF, Klerks VIF, Pliant Blockade, Bromostop® (1.38 mil), Eval/Mitsui TIF (1.38 mil), Hytiblock 7 Black (0.00125"), XL Black Blockade (0.00125"), Hytibar (1.5 mil), and IPM Clear VIF (1.38 mil) high barrier tarps, which will be given a buffer credit of 60%.

It is important to note, however, that when considering the credits selected for high-barrier tarps for each fumigant, a number of issues must be taken into account, including: different tarp and fumigant combinations result in different degrees of emission control; difficulty in determining the exact impact that high-barrier tarps have on emissions in a full field flux study unless a co-located field is also monitored in the same vicinity using a standard tarp; and the lack of a standard fumigant tarp testing procedure.

The Agency is currently validating a standard fumigant tarp testing procedure, developed at USDA, that measures the mass transfer coefficients of tarps. The purpose of this research is to develop a standardized method of testing and rating permeability of tarps based on mass transfer

coefficients. From these results a permeability database and a standardized method for testing tarp permeability will be developed. The database will allow the Agency to evaluate potential buffer zone credits for additional tarps. In addition, the method can be used by other laboratories or tarp manufacturers to test the permeability of their tarps which could augment the number of tarps that receive buffer credits. For more details on USDA's research, please refer to the Agency's May 14, 2009 memo; "*Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations For Good Agricultural Practices and Associated Buffer Credits*".

The Agency has also co-funded a grant with USDA-ARS to conduct several flux studies in the southeastern U.S. These studies will provide field data on the emission reduction potential of certain barrier films to further enhance EPA's understanding of the emission reduction value of various agricultural films, and possibly support additional buffer reduction credits and an affordable and reliable hybrid field/lab test to evaluate the many barrier films available to growers.

- Soil conditions

Credits in the July 2008 RED

Like high barrier tarps, inherent soil conditions (e.g., organic matter and soil type) do have an impact on fumigant emissions. However, while the use of high barrier tarp is a choice an applicator can make, soil conditions are factors 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 where they exist.

In the July 2008 RED, the Agency determined that a 10 percent buffer zone credit was 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. This was based on the review of literature available before the July 2008 RED and modeling with the CHAIN_2D model.

Comments on the July 2008 RED

Since the July 2008 RED, information from the CMTF has been submitted that has allowed the Agency to reevaluate credits for soil organic matter. Analysis of peak emissions of chloropicrin in five studies with very similar soil factors, except for organic matter, concluded that peak flux was reduced by approximately 50% for soils that were composed of approximately 1.5% organic matter compared to soils that were composed of approximately 0.5% organic matter.

Credits for the Amended RED

From these studies the Agency has determined that a credit can be given when applying methyl bromide in soils with certain levels of organic matter because the affect of organic matter

in soil on emission would be relevant to other fumigants in addition to chloropicrin. This is based on modeling with CHAIN2D that shows the impact of changes in organic content is not fumigant specific. A 10% credit will be given if methyl bromide is applied in soils with an organic matter range of >1% - 2%; a 20% credit for soils with an organic matter range of >2% - 3%; and a 30% credit for soils with an organic matter range of >3%. No credit will be given for soils with less than 1% organic matter.

The Agency has not received any new data that would result in changes to the credit for soil type. Therefore, the credit for clay content of greater than 27% will remain at 10%.

- Soil moisture

Credits in the July 2008 RED

The Agency's document; "Factors Which Impact Soil Fumigant Emissions - Evaluation For Use In Soil Fumigant Buffer Zone Credit Factor Approach. DP Barcode D306857 (6/9/08)", reviewed data examining the effects of proper soil moisture levels prior to application on fumigant emissions. Through review of these data it was determined that soil moisture is a critical parameter to reduce emissions for certain fumigants. However, in the July 2008 RED, the Agency did not provide a credit for soil moisture because the Agency could not justify credits based on the available data. The Agency established mandatory GAPs for soil moisture conditions.

Comments on the July 2008 RED

The Agency received comments that buffer zone credits should be considered for soil moisture. For chloropicrin in particular, this fact was further supported by a chloropicrin field flux study (performed in Wasco, CA) recently submitted to the Agency by CMTF. This study was conducted at soil moisture field capacities in the 70-75% range. When this study was compared to previous studies done with the same application methods at much lower field capacities, in the 35-55% range, and all other factors being relatively equal, a 3-4 fold reduction in emissions was observed.

Credits for the Amended RED

There are currently not sufficient data available to provide a credit for field capacity for methyl bromide. However, the MBIP has committed to conducting a number of new field flux studies in 2009/2010 for methyl bromide. These studies may provide more information about the effect of soil moisture on methyl bromide emissions. Soil moisture credit/GAP decisions for methyl bromide may be revisited if necessary after review of these data.

- Potassium thiosulfate (KTS) and tarps

Credits in the July 2008 RED

EPA gave a 5% credit for applications of KTS. The KTS credit was based on a field study conducted by Dr. Husein Ajwa that indicated reductions in chloropicrin emissions when KTS is applied to the top of tarps after the fumigation. In the 2008 RED, if KTS was used in conjunction with one of the approved high barrier tarps, the buffer zone could be reduced by 45%. If KTS was used with any other tarp, the buffer zone reduction credit was 5%.

Comments on the July 2008 RED

The Agency received comments that buffer zone credits should be greater than 5% for KTS. In addition, results from Ajwa's 2007 and 2008 research were published by the California Strawberry Commission titled, "Reduce Fumigant Emissions Using Impermeable Film and Water Seal in Strawberry Raised Beds. California Strawberry Commission Annual Production Research Report 2007-2008," show that applying a water seal/KTS combination over the bedded tarped field resulted in a reduction in the peak flux of chloropicrin and the total mass of chloropicrin lost. The water seal/KTS combination resulted in an approximate reduction of peak flux of 36% and total mass loss was reduced by approximately 20% at Salinas when compared to the standard tarp water seal scenario. The water seal/KTS combination resulted in an approximate reduction of peak flux of 32% and total mass loss was reduced by approximately 10% at the Oxnard site when compared to the standard tarp scenario. Because laboratory data looking at all halogenated fumigants, including methyl bromide, methyl iodide, chloropicrin, and 1,3-D (Wang et. al., 2000), support application of an emission reduction credit for KTS to these compounds, EPA has determined that a credit for KTS would also apply to methyl bromide.

Credits for the Amended RED

Based on the data, the Agency determined that a conservative credit of 15% is appropriate for KTS when applied with ¼ to ½ inch of water over a tarp. When used with one of the high-barrier tarps listed above, the 15% credit will be added to the tarp credit. For example if KTS is applied over Bromostop® (1.38 mil) which qualifies for a 60% credit, the total credit would be 75%. If KTS is used with another tarp, the credit is 15%.

- Water seals

Credits in the July 2008 RED

The July 2008 RED did not give credits for the application of water seals.

Comments on the July 2008 RED

The Agency received comments that buffer zone credits should be considered for water seals. In addition, results from Ajwa's 2008 research study published by the California Strawberry Commission titled; "Reduce Fumigant Emissions Using Impermeable Film and

Water Seal in Strawberry Raised Beds. California Strawberry Commission Annual Production Research Report 2007-2008," show that that applying a water seal over the bedded tarped field resulted in a reduction in the peak flux of chloropicrin and the total mass of chloropicrin lost. The water seal resulted in an approximate reduction of peak flux of 30% and total mass loss was reduced by approximately 39% at Salinas when compared to the standard tarp scenario.

Credits for the Amended RED

Based on the data, the Agency determined that a conservative credit of 15% is appropriate when ¼ to ½ inch of water is applied over a tarp. When used with one of the high-barrier tarps listed above, the 15% credit will be added to the tarp credit. For example when a water seal is applied over Bromostop® (1.38 mil) which qualifies for a 60% credit, the total credit would be 75%. If a water seal is used with another tarp, the credit is 15%.

- Soil temperature

A credit for soil temperature will currently not be given for methyl bromide based on its extremely high vapor pressure. As with soil moisture, a soil temperature credit for methyl bromide may be revisited if the MBIP studies discussed above provide more information around the effect of soil temperature on methyl bromide emissions. Based on review of available data with certain soil fumigants, increased soil temperature typically corresponds to increased fumigant emissions. This is not a factor that growers can manipulate in the field but is directed more at different regions in the country where low soil temperatures may be typical during the fumigation season.

- Buffer zone credit cap

Credits in the July 2008 RED

In the July 2008 RED, the Agency determined that credits would be additive. This meant, for example, that a 25% credit for a tarp could be added to a 10 % credit for organic matter and to a 10% credit for clay content to achieve a total credit of 45%. The Agency placed a limit, or "credit cap," of 45% on the total size of the credit allowed for methyl bromide.

Comments on the July 2008 RED

During the comment period, the Agency received new data concerning a number of factors that impact fumigant emissions as well as a number of comments indicating that there should not be a cap on credits or that the cap should be raised. Some suggested that the 45% cap would be a disincentive to growers considering whether to adopt emission-reducing application methods.

Credits for the Amended RED

Upon review of the new data and public comments, the Agency has decided to raise the credit cap to 80%. The Agency has reviewed the new studies to evaluate the extent to which the

various factors that reduce emissions act independently, and has reconsidered the earlier studies. As a result of this evaluation, the Agency concludes that credits be additive up to a cap of 80% for all fumigants. This revised credit cap is based on studies that show a greater-than-50% reduction in emissions when two or more factors are combined. Further, EPA believes that increasing the credit cap to 80% will encourage adoption of emission reduction techniques, result in lower off-site fumigant concentrations, and will allow for reduced application rates for various tarps.

- 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 60%. The resulting buffer zone distance for this case is 80 feet. If the organic matter in the application block is two percent and Bromostop® (1.38 mil) high barrier tarp is used, the total credit would be 80% (60% for the tarp and 20% for organic content), and the resulting buffer zone distance would be 40 feet.

- Other buffer zone credits considered

The Agency's revised document; "Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits (5/14/09)", reviewed several other factors such as field preparation and compaction. The Agency determined that those factors could not be used to justify credits based on the available data. However, EPA has established mandatory GAPs for these conditions. See the *GAP* section 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. The Agency will consider such data in future decisions if new data become available. Such data may also support the Agency's decisions on additional emission credits in the future.

iv. Restriction for Schools and Other Difficult to Evacuate Sites

Certain types of sites are difficult to evacuate should an incident occur. EPA determined that additional measures to reduce the potential need to evacuate these types of sites were necessary to reduce risk of exposure to occupants and address potential challenges associated with an accident. There were many comments on this measure including: requests to delete this requirement; suggestions to reduce the size of the restricted area; a proposal to use a scalable approach to calculate the distance; requests to define and refine the places included on this list so that facilities such as research universities were excluded; suggestions to shorten the duration of the requirement so applicators may be able to take advantage of weekends to fumigate; questions

about how to determine where these sites are located, and other suggestions to change the required measures.

Based on a review of the comments, the Agency has retained this mitigation measure to ensure the protection goals are still achieved and encourage lower-emission application methods. This mitigation measure has been refined such that compliance is more effective in achieving the protection goal. Modifications to this requirement include: shortening the duration of the restriction so weekends may be used to fumigate near schools and day care centers; clarifying the types of schools that are covered by this requirement; removing the term "elder care facilities" from the list since many of the same facilities are included in the terms, " assisted living facilities, nursing homes, and in-patient clinics;" and reducing the restricted area from ¼ mile to ⅛ mile for application blocks with less than 300 foot buffers. The ⅛ mile (660 feet) distance is more than twice the required buffer distance and remains protective of people who may be difficult to evacuate while reducing the potential challenges of complying with the restrictions for some users who may be fumigating in close proximity to these types of institutions. EPA has determined that these modifications achieve the same protection goals as the 2008 RED but provide additional clarity and flexibility that will enhance users' ability to practically and effectively comply with the requirements. EPA also believes that reducing the restricted area for blocks with buffers less than 300 feet will provide an incentive for some users to adopt lower-emission application methods or practices. The revised measures are summarized below.

- "Difficult-to-evacuate" sites include schools (preschool to grade 12), state licensed day care centers, nursing homes, assisted living facilities, hospitals, in-patient clinics, and prisons.
- No fumigant application with a buffer zone greater than 300 feet is permitted within ¼ mile (1,320 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the application.
- No fumigant application with a buffer zone of 300 feet or less is permitted within ⅛ mile (660 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the start of application.

v. Posting

Posting is an effective means of informing workers and bystanders 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 zone to ensure they do not enter designated areas.

In addition to alerting bystanders, posting a buffer zone will help handlers determine where and when they are required to use PPE. As described in the *Handle*r section, handlers working in treated areas or 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 buffer zones for bystanders and handlers, the perimeter of the fumigant buffer zones must be posted.

Comments received in response to the July 2008 RED decisions recommended some changes to the posting requirements to make them easier to understand and implement. Based on EPA's review and consideration of these comments, EPA has slightly revised the posting requirements and provided additional clarification as described below.

EPA had included two exceptions for the buffer zone posting requirement. The first exception did not require posting in situations where the land 300 feet from the edge of the buffer was under the control of the property operator. Based on comments that this measure was too complicated and confusing this exception has been removed. There were also comments that the examples provided in the description of a physical barrier may lead to misinterpretation of the requirement. EPA agrees and believes that a performance standard is a more effective means of communicating the requirement. Therefore, to reduce the potential for confusion, the examples have been removed.

In the 2008 RED, signs were required to be posted at usual points of entry and likely routes of approach to buffer zones. If there were no usual points of entry or likely routes of approach, then posting was required in the corners of buffer zones, and between the corners, so signs could be viewed from one another. Many comments expressed concern over the burden and potential confusion with the number of signs that may need to be posted and how many signs may need to be posted depending on the configuration of the field. EPA agrees that signs posted in areas where there is low likelihood of workers or others approaching or accessing the buffer provide little risk reduction, but can add substantially to the challenges of compliance. As a result, the Agency has revised the criteria for location of signs since the areas that are of most concern are those where people are most likely to enter (e.g., roads, footpaths), and at likely routes of approach such as the perimeter of a buffer that faces a housing development.

Comments also indicated that the requirement to include certain application-specific information on the posted signs would make reuse of the signs more difficult and would also substantially increase the amount of time needed to prepare signs before posting. These comments stated that the primary purpose of signs is to communicate to bystanders the buffer zone locations. EPA generally agrees with these comments; therefore certain application-specific details on the posted signs, like the date and time of the fumigation and buffer zone restrictions, have also been reduced to allow the signs to be reused more easily.

Comments also stated that the posting example included in the 2008 RED was confusing. Since the posting restrictions have been simplified by removing the distance criteria, the example has been removed from this document. There were no substantive comments suggesting a change to the exception for posting multiple contiguous blocks and no changes have been made in this Amendment.

The revised posting requirements are listed below and have been included in the revised label table.

Requirements

- Posting of a **buffer zone** is required unless there is a physical barrier that prevents bystander access to the buffer zone.

- 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.
  - Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.
  - Some examples of likely routes of approach are the area between a buffer zone and a roadway, or the area between a buffer zone and a housing development.

- 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. The Agency is requiring registrants to submit proposals for these materials through the data call-ins that will accompany this RED.

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 up to 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,"
-- "Methyl Bromide 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,"
-- "Methyl Bromide OR [Name of product] Fumigant BUFFER ZONE,"
-- contact information for the certified applicator in charge of the fumigation

2) Occupational Risk Mitigation

i. Handler Definition

Based on stakeholder comments provided during the Phase 5 comment period, the July 2008 RED clarified fumigation tasks that meet EPA's definition of *handler* activities, as currently defined in the WPS and on fumigant labels. During the post-RED comment period the Agency received some comments from stakeholders who were concerned that the Agency was redefining *handlers*. It was not the Agency's intention to change the current definition. As a result, the Agency has slightly changed the language from the July 2008 RED so it is clear that the Agency is just clarifying the existing definition and not writing a new definition. Below is the revised language.

The following activities are prohibited from being performed in the fumigant application block or surrounding buffer zone during the buffer zone period by anyone other than persons who have been appropriately trained and equipped as handlers in accordance with the requirements in the WPS (40 CFR Part 170), from the start of the application until the entry-restricted period ends. Those activities include those persons:

- Participating in the application as supervisors, loaders, drivers, tractor co-pilots, shovelers, cross ditchers, or as other direct application participants (note: the application starts when the fumigant is first introduced into the soil and ends after the fumigant has stopped being delivered/dispensed to the soil);
- Using devices to take air samples to monitor fumigant air concentrations;
- Persons cleaning up fumigant spills (this does not include emergency personnel not associated with the fumigation application);
- Handling or disposing of fumigant containers;

- Cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues;
- Installing, repairing, or operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period;
- Entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;
- 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 after application.

In addition to the above, persons outside the perimeter of the buffer zone who monitor fumigant air concentrations must also be trained and equipped as handlers in accordance with the requirements in the WPS (40 CFR Part 170).

ii. Handler Requirements

Currently, methyl bromide labels require that 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 on-site trained personnel will help to reduce these risks. Therefore, to address these risks, the July 2008 RED required that a certified applicator maintain visual contact with any fumigant handler while the fumigant is being incorporated into the soil. The Agency also stated that the certified applicator supervising the fumigation may also perform fumigant handler tasks.

During the post-RED comment period the Agency received many comments that stressed the difficulty of implementing a requirement that mandates certified applicators to maintain visual contact with handlers. The commenters also indicated that for longer applications this requirement would be a significant burden. Other stakeholders stated that the Agency should modify the requirement to ensure that the certified applicator is on-site, while others commented EPA should require that all handlers are certified applicators, which would eliminate the need for direct handler supervision.

The Agency has considered the comments and has determined that the revisions outlined below accomplish the same handler-protection goals as the July 2008 RED mitigation while somewhat reducing the burden on users. The revised language is:

- For all applications, from the start of the application until the fumigant has stopped being delivered/dispensed into the soil, i.e., after the soil is sealed, the certified applicator must be at the fumigation site and must directly supervise all persons performing handling activities.
- For fumigant handling activities that take place after the fumigant has been delivered/dispensed into the soil until the entry restricted period expires, the certified

applicator does not have to be on-site, but must have communicated in writing to the site owner/operator and handlers the information necessary to comply with the label and procedures described in the FMP (e.g., emergency response plans and procedures).

The July 2008 RED also required that certified applicators complete a registrant administered methyl bromide training program within the preceding 12 months before they apply a methyl bromide product. The Agency is still requiring that certified applicators complete the registrant training; however, the Agency is now requiring that certified applicators successfully complete the training every 36 months. Please see *Soil Fumigation Training for Applicators and Other Handlers* section for further details.

In addition to the certified applicator supervision requirement, the Agency also required in the July 2008 RED that a minimum of two WPS trained handlers were on-site during all fumigation handling activities. This mitigation measure addresses the concern that handlers could be overcome with fumigant vapors and be unable to leave the area while they are performing handler tasks. The Agency did receive some comments offering suggestions and others asking clarifying questions. The Agency has modified the language of the requirement for clarity; however, the mitigation measure itself is not changing. Comments related to this requirement are more fully addressed in the following document; *SRRD's Response to Post-RED Comments for the Soil Fumigants* (May 27, 2009). The revised language for this mitigation measure is as follows:

- For all fumigant handling tasks at least two handlers trained under the provisions of the WPS 40 CFR 170.230 must be present.

iii. Respiratory Protection

The Agency's human health risk assessment indicates that inhalation risks exceed the Agency's level of concern without respirator protection for many handler activities. The addendum to the April 10, 2007 risk assessment (DP 350818) 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.

To address acute, short-, and intermediate-term inhalation risks the July 2008 methyl bromide RED required air monitoring with colorimetric tubes or other real-time monitoring devices every two hours as a means of determining when respirators may be needed. The tubes were required to have a sensitivity of at least 1 ppm for methyl bromide and 0.15 ppm for chloropicrin, which is the level that corresponds to early signs of exposure. If air samples indicated methyl bromide levels were above the Agency LOC (5 ppm), chloropicrin levels were above the Agency's LOC (0.15 ppm), or if any handler experienced sensory irritation indicative of chloropicrin exposure, then handlers were required to wear air-purifying respirators.

The Agency's decision to require respiratory protection only if certain triggers were reached took into consideration current label requirements[14], the identified risks, and stakeholder comments that respirators are not necessary because (1) chloropicrin's warning properties are sufficient to alert handlers if there are unsafe concentrations; (2) respirators inhibit communication which could increase the risk of an accident; and (3) in warm weather respirators can cause heat stress and other ailments.

During the post-RED comment period, the Agency received several comments on the *Respiratory Protection* section. For methyl bromide, comments focused on the feasibility, reliability, and protectiveness of using colorimetric tubes due to the current sensitivity and accuracy of the tubes, and the cost of the tubes. Other comments stated that handlers should have the option of ceasing the application until air concentrations of methyl bromide and chloropicrin are less than the action level. Comments also suggested that tractor drivers do not need to be monitored if occupants are in an enclosed cab that meets certain specifications.

After reviewing the comments, the Agency is adding a stop work option for formulations of methyl bromide with 80 % or less methyl bromide where handlers can leave the field and surrounding buffer zone in lieu of putting on a respirator. If handlers remain in the field, EPA has determined that respiratory protection requirements are still needed to mitigate risks if concentrations reach a certain level. However, EPA is revising the required procedures for determining when respirators must be used due to technological limitations of the monitoring devices that are currently available for field use. The Agency is aware of several commercial systems for monitoring methyl bromide and chloropicrin including colorimetric tubes from manufacturers including: Matheson/Kitagawa, Sensidyne, and Dräger. While these tubes have detection limits that are less than 0.15 ppm, the Agency has opted not to require monitoring with colorimetric tubes or other devices as a trigger to put on respiratory protection because EPA believes that these devices are not consistently reliable at fumigant concentrations at or just below 0.15 ppm, the Agency's action level for chloropicrin. EPA's action level is typically at the lower end of the range for which the devices are rated, in fact, some of these action levels are at or near the device's detection limits. Additionally, colorimetric devices provide snapshot measurements of the environment in which individuals are working. In conditions that are likely to be more static (e.g., monitoring an indoor fumigation such as a grain mill or warehouse) it is likely that minute to minute changes in conditions would not be as great as those anticipated for the more dynamic conditions characteristic of outdoor field fumigation where exposure concentrations could shift because of weather changes or stratification in soil conditions across a single treated field. Furthermore, commenters' experience indicates that handlers will likely experience early sensory irritation before the air samples show concentrations at or above the action level. As such, the Agency does not believe that initial monitoring to trigger the use of respirators significantly reduces handler risks. In addition EPA is aware that monitoring with these devices adds significant costs to fumigations, please see (*Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery (DP Barcode 363546)*) for more details. EPA is also concerned that monitoring with devices that are not reliable could cause handlers to believe that concentrations

14 Current methyl bromide 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.

are below the action level despite other indications such as eye irritation. As a result, the Agency is removing the initial monitoring requirement.

EPA does believe, however, that monitoring devices that are currently available will generally be reliable at higher concentrations of chloropicrin and that there is high value in air monitoring using currently available devices in certain situations. As a result, EPA is maintaining the monitoring requirement once use of respirators has been triggered and respirators are being worn. This will enable handlers to detect concentrations that would exceed the upper working limit of the respirator. Additionally monitoring will still be required to help enable handlers to determine if concentrations have decreased and whether it is safe to either remove respirators or to resume the application if the fumigator has opted to cease the application rather than have handlers wear respirators.

The Agency is modifying the procedures for respiratory protection because of technological limitations of currently available devices. However, the Agency does believe that quantitative air monitoring would enhance worker safety if the appropriate technology were available. Some equipment manufacturers have indicated interest in developing devices that would be more functional and reliable for field fumigation applications (e.g., badge-type monitors). EPA encourages such efforts and plans to stay abreast of developments and improvements in monitoring devices and will consider this issue again in Registration Review or sooner should such monitors become available in the short term.

Respiratory Requirements

Based on the Agency's review of the comments as described above in the *Respiratory Protection* section, EPA has amended the requirements that trigger the need for respiratory protection. In addition to the revised respiratory protection requirements below, the Agency believes that GAPs, FMPs, and other mitigation measures will reduce inhalation risks to concentrations below the EPA's level of concern. 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. See the *Amended Reregistration Eligibility Decision for Chloropicrin* for detailed information regarding the chloropicrin action levels.

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 on whether 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.

The following procedures must be followed for all formulations with **80 % or less methyl bromide**:

- If at any time any handler experiences sensory irritation (tearing, burning of the eyes or nose) then either:
    - An air-purifying respirator (APR) must be worn by all handlers who remain in the application block and surrounding buffer zone, or
    - Operations must cease and handlers not wearing respiratory protection must leave the application block and surrounding buffer zone.
- Handlers can remove respirators or resume operations if two consecutive breathing-zone samples taken at the handling site at least 15 minutes apart show that levels of methyl bromide have decreased to less than 1 ppm and levels of chloropicrin have decreased to less than 0.15 ppm, provided that handlers do not experience sensory irritation. Samples must be taken where the irritation was first experienced.
- When respirators are worn, air monitoring samples 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) a handler experiences any sensory irritation when wearing a respirator, or (2) a methyl bromide air sample is greater than 5 ppm or a chloropicrin air sample is greater than or equal to 1.5 ppm, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone. If operations cease the emergency plan detailed in the FMP must be implemented.
- Handlers can resume work activities without respiratory protection if two consecutive breathing-zone samples taken at the handling site at least 15 minutes apart show levels of methyl bromide have decreased to 1 ppm and levels of chloropicrin have decreased to less than 0.15 ppm, provided that handlers do not experience sensory irritation.
- During the collection of air samples an air-purifying respirator must be worn by the handler taking the air samples. Samples must be taken where the irritation is first experienced.
- Work activities may resume if the following conditions exist provided that the appropriate respiratory protection is worn:
    - two consecutive breathing zone samples for methyl bromide taken at the handling site at least 15 minutes apart must be less than 5 ppm,
    - two consecutive breathing zone samples for chloropicrin taken at the handling site at least 15 minutes apart must be less than 1.5 ppm,
    - handlers do not experience sensory irritation while wearing the APR,
    - cartridges have been changed, and
    - during the collection of air samples an air-purifying respirator must be worn by the handler taking the air samples. Samples must be taken where the irritation is first experienced.

The following procedures must be followed for all 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.
- In order to resume work activities:
  - Two consecutive air samples for methyl bromide and chloropicrin taken in the treatment area at least 15 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.

Figure A provides an illustration of the requirements when handlers cease operations. Figure B provides an illustration of the requirements when handlers put on a respirator.

Figure A. Requirements for when handlers should cease operations.

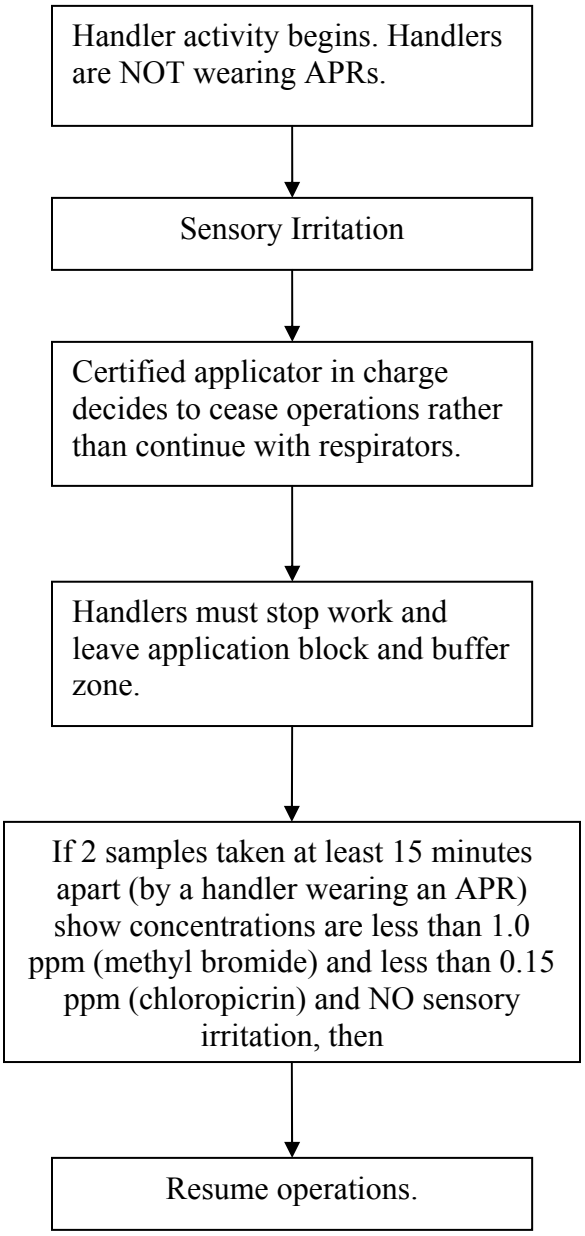
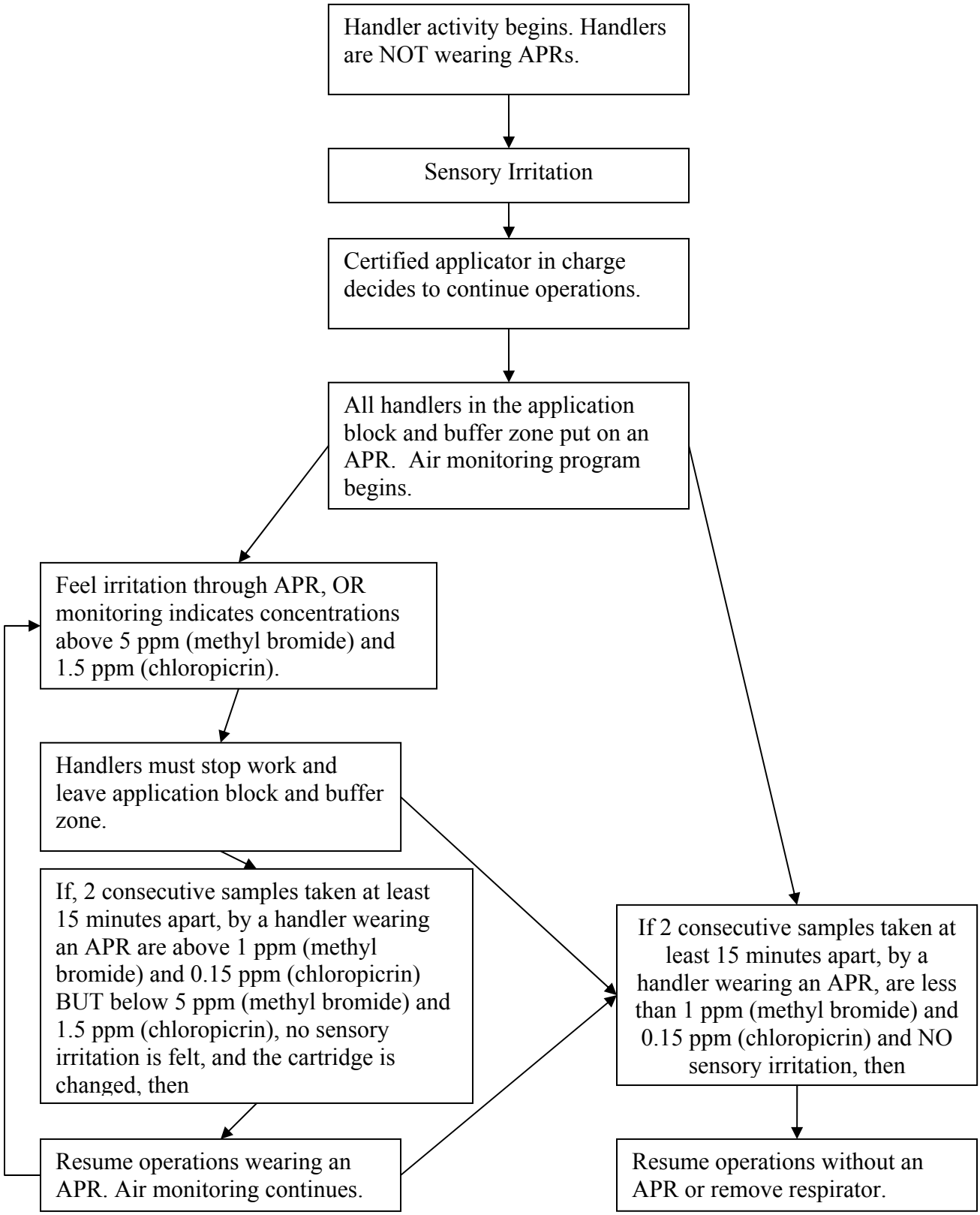


Figure B. Requirements for when handlers should put on a respirator.



Respiratory Protection Equipment

The purpose of this section in the July 2008 RED was to establish general conditions and requirements for respiratory protection equipment. Below is a summary of what was included in the July 2008 RED.

- The Agency required half-face respirators with organic vapor cartridges when respirators are necessary. In the RED EPA noted that although currently there are no APR cartridges certified by the Mine Safety and Health Administration-National Institute for Occupational Safety and Health (MSHA-NIOSH) for protection against chloropicrin specifically, NIOSH/OSHA does recommend respirators with organic vapor cartridges for chloropicrin use. EPA also stated that it would consider other APR-cartridge combinations, provided written certification of their efficacy against chloropicrin is submitted to the Agency.
- EPA assumes half-face respirators have a protection factor of 10, therefore these respirators are protective up to methyl bromide concentrations of 5 ppm; and if concentrations exceed 5 ppm operations must cease.
- SCBA has a protection factor of 1,000, but, due to practical limitations, SCBA should only be used for short durations.

EPA is making revisions to the requirements above taking into consideration the comments and the revisions to the *Respiratory Requirements* section. Since the Agency is relying on the warning properties of chloropicrin to indicate when an air-purifying respirator must be worn, the Agency does not believe that a half-face respirator would be appropriate because the handler would still experience eye irritation if a half-face respirator is worn. Therefore, EPA has determined that when handlers opt to continue operations when the action level for respiratory protection is triggered (i.e., sensory irritation is recognized), handlers must wear a full-face respirator.

The Agency received additional comments regarding the cartridge recommendations, SCBA use, and the respirator protection factor. EPA is providing a clarification to address the concerns brought up in the comments. This was the Agency's intention in the July 2008 RED. Others remarked that use of goggles should be prohibited. The Agency agrees with the comments regarding goggles and it was not EPA's intention to imply a change in current label language with regard to closed goggles in the July 2008 RED. For more detailed responses on the above comments please see *Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents* (Date May 14, 2009).

As a result of the changes discussed above the amended requirements are listed below:

- The Agency is requiring full-face respirators with organic-vapor cartridges when respirators are necessary.
- If methyl bromide concentrations exceed 5 ppm operations must cease.

Tarp Repair

The July 2008 RED required handlers to wear APRs if they perform tarp repair operations before the entry-restricted period has ended. The requirements were different from other handling activities because the duration of tarp repair activities was believed to be shorter than other handling tasks and therefore tarp repair activities would not trigger the initial monitoring requirement. Upon consideration of comments the Agency received on this requirement, which are addressed in detail in *Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents* (Date May 14, 2009)., EPA has determined that respiratory protection for tarp repair activities should be handled consistently with other handler activities, i.e., handlers repairing tarps are not required to wear respirators unless sensory irritation is experienced. Additionally, the Agency believes that tarp repair like other handling activities described above would benefit from the development of sensitive monitoring devices to reliably inform handlers if and when concentrations are above the action level for respiratory protection. EPA will reevaluate this measure during Registration Review or sooner if such devices are available in the short term.

Respirator fit testing, training, and medical qualification

To ensure that respirators are mitigating inhalation risk, the July 2008 RED respirator requirements included fit testing, respirator training, and an annual medical evaluation. Without these requirements, it is unclear whether the reduction in inhalation exposure that is assumed by the use of respirators will be achieved.

During the comment period the Agency received a variety of comments ranging from full support of the requirement, to comments about the cost and time burden associated with fit-testing, training, and medical exams. The Agency also received several comments regarding the details of this requirement, for example, some commenters questioned who conducts the fit-testing and medical exam and what the medical exam entails. Detailed responses to these comments are included in the following document, *SRRD's Response to Post-RED Comments for the Soil Fumigants* (May 27, 2009).

While EPA recognizes that there is a cost associated with the fit-testing, training, and medical exam requirements, the Agency still believes these are necessary to ensure respirators perform as intended. Also note that, in response to suggestions from several fumigators, EPA is now allowing fumigators the option to *cease operations* and have handlers leave the application block and surrounding buffer zone in lieu of wearing a respirator and continuing fumigation activities. Only handlers who will wear a respirator must be fit-tested, trained, and medically examined. For fumigators who exercise the *cease operations* option, the Agency believes that this revision will reduce the cost associated with the respirator requirement, while maintaining the same level of protection for the handlers that wear respirators. The following revised language takes into account the new *cease operations* option and must be added to product labels:

"Employers must also ensure that any handler who uses a respirator is:

- 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. Handlers must be reexamined by a qualified medical practitioner at least annually or if their health status or respirator style or 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"[15]. 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).

15 http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666BraCOrrrrQ-

Respirator Availability

The July 2008 RED required that every handler had the appropriate respiratory protection equipment available. This requirement has been slightly modified as a result of the *cease operations* option. The new language requires that the handler's employer must confirm and document in the FMP that an air-purifying respirator and cartridge is immediately available for each handler who will wear one. The Agency is requiring that at minimum two handlers have the appropriate respirator and cartridges available and that these handlers are fit-tested, trained, and medically examined.

Air-Rescue Device Availability

EPA slightly altered the air-rescue device availability language from the July 2008 RED to include that the device is not only on-site, but also ready to use. This change was made to clarify the Agency's previous requirement, and the following language must be added to product labels:

- The fumigation handler employer must confirm and document in the FMP that at least one air rescue device (e.g., SCBA) is on-site and is ready for use in case of an emergency.

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, and notes potential for increased risk when high barrier tarps are used. To address these risks EPA required the following mitigation in the July 2008 RED:

- Tarps cannot be perforated until a minimum of 5 days (120 hours) after fumigation was complete.
- Tarps cannot be removed until 24 hours after tarp perforation is complete.
- If tarps are not removed after perforation, planting cannot start until 48 hours after perforation is complete.
- If tarps are left intact for at least 14 days after the fumigation is complete then planting can take place as tarps are being perforated.
- Broadcast tarps could be removed before 5 days if adverse weather compromised the integrity of the tarp provided that at least 48 hours had passed since the fumigation was completed, the buffer zone was extended until 24 hours after the tarp removal was complete, and untreated areas in the application block are not treated for at least 24 hours after tarp removal is complete.
- Tarp perforation must be done using mechanical methods.
- Each broadcast tarp panel must be perforated using a lengthwise cut.

During the post-RED comment period the Agency received comments on the tarp perforation and removal requirements. In particular the Agency received comments on: the adequacy of the 5 day requirement for high barrier tarps to protect workers; the feasibility of leaving tarps down for 5 days in areas that use seepage irrigation for flood prevention; the difficulty implementing the 24 hour period between tarp perforation and removal; and concerns

regarding the weather condition exceptions, mechanical perforation, and broadcast panel perforation.

There is some uncertainty regarding potential risks if high barrier tarps are perforated after 5 days. This is because worker exposure data used in the risk assessments are generally based on what has been the industry standard tarping technology, i.e., low or high density polyethylene tarps, typically with higher application rates and no significant emphasis on using the GAPs as defined in the RED. Data indicate that high barrier tarps are effective measures to reduce fumigant emissions (See *Factors Which Impact Soil Fumigant Emissions - Evaluation For Use In Soil Fumigant Buffer Zone Credit Factor Approach*. DP Barcode D306857 (6/9/08) and *Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits* (5/14/09)). While this reduction decreases the risk to bystanders, it could increase the risk to handlers perforating or removing tarps because more fumigant could be trapped between the soil surface and the tarp—currently California Department of Pesticide Regulation (CDPR) prohibits the use of methyl bromide with certain high barrier tarps due to worker concerns.

Based on CDPR's prohibition and stakeholder's comments, EPA considered requiring a longer interval such as 10 days before allowing high barrier tarps to be perforated. However, EPA was concerned that adding such a requirement could discourage fumigators from using high barrier tarps which potentially allow for lower application rates and reduce bystander risk associated with offgassing. New studies currently underway which involve use of high barrier tarps may enable EPA to refine estimates of handler risk in the future. EPA will consider these data during Registration Review, or sooner as the information becomes available.

Since the Agency has designed the mitigation measures to work together and believes that measures to address handler risks are likely to protect these handlers when the reduced rates are considered in conjunction with other measures such as respiratory protection, GAPs, FMPs, and training, EPA is not increasing the number of days before high barrier tarps can be perforated.

In the comment period EPA learned from stakeholders that leaving the tarps on for 5 days would pose problems for current flood prevention activities. According to the comment, for flood prevention fields must be properly drained. To ensure proper drainage, tarps must be manually cut, soil removed, and then tarps retucked. The Agency understands that the 5 day requirement before tarps can be perforated and the restriction on manual tarp perforation would be difficult for this situation and the Agency has added language to address this situation.

During earlier comment periods EPA heard from various stakeholders that windy conditions sometimes caused tarps to blow off fields and create other hazards, e.g., to motorists on nearby roadways. As a result, in the July 2008 RED the Agency provided an exception to allow tarps to be removed after 48 hours under adverse weather conditions. During the post-RED comment period EPA received comments that this exception did not fully address the issue since the mitigation required waiting a minimum of 48 hours after fumigation but tarps could

blow of fields sooner than that. Commenters also said waiting 24 hours between tarp perforation and removal and the requirement to cut every broadcast tarp panel added to the potential for tarps to blow off fields and create other hazards: once tarps are cut they are prone to blowing off when windy conditions occur. To decrease the potential of tarps blowing off commenters also suggested that the Agency add flexibility to the 24 hour requirement by giving tarp removers the option to remove tarps 2 hours after tarp perforation if monitoring indicated levels below the Agency's LOC. Commenters also suggested that every 1-3 tarp panels should be cut based on the professional judgment of the handler.

Upon review of the comments the Agency agrees that the mitigation should be revised somewhat to allow for tarp removal at any time if the tarp is no longer performing its intended function and it is creating other types of risk. Therefore, EPA is revising the exception outlined in the RED to address these comments. EPA notes that handlers undertaking these tasks must follow the respiratory protection procedures detailed in the *Respiratory Protection* section; this change still provides handler protection while reducing the unintended consequences of tarps creating other hazards.

The Agency believes cutting every panel allows the fumigant trapped beneath each panel to offgas before the tarp is removed. If each panel is not cut, it is not likely that necessary off-gassing can take place to reduce risks to handlers removing tarps. The Agency understands that the main concern for not cutting every panel is due to the potential for tarps to blow off and has determined that this concern is best addressed by modifying the 24-hour wait period. Tarps may be removed 2 hours after tarp perforation is complete provided that tarp removers follow the procedures set forth in the *Respiratory Protection* section; therefore the risk to handlers will not increase as a result of this modification.

The Agency received comments supporting the requirement for mechanical tarp perforation, though other commenters stated that for some situations mechanical cutting is not feasible. Examples cited included at the start of a row when a mechanical device such as an ATV will be used to cut the tarps on the field, during flood prevention activities and for small fields. Based on comments, EPA believes these are necessary short-duration activities. Provided the respiratory protection procedures for handlers are followed, these activities would not increase the risk to handlers. With regard to small fields where mechanical cutting is not feasible, the Agency considered the duration of the activity and the respiratory protection considerations and will permit manual perforation only for application blocks that are 1 acre or less in size.

As a result of the Agency's review and consideration of comments, the following summarizes the revised mitigation measures to address inhalation risks from tarp perforation and removal activities:

- As described in the *Handler Definition* section (link the document) tarp perforators and removers are considered handlers for a specified duration and every handler must adhere to the respiratory protection procedures outlined in the *Respiratory Protection* section.
- Tarps must not be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after injection of the fumigant product and tarps have been laid or after drip lines have been purged and tarps have been

laid), unless a weather condition exists which necessitates the need for early perforation or removal. (See *Early Tarp Removal for Broadcast Applications Only* and *Early Tarp Perforation for Flood Prevention Activities* sections below.)

- If tarps will be removed before planting, tarp removal must not begin until at least 2 hours after tarp perforation is complete and two air monitoring samples are less than 1 ppm methyl bromide. (If two air monitoring samples have methyl bromide levels between 1 ppm and 5 ppm, then respirator protection is required before tarp removal can begin.)
- If tarps will not be removed before planting, planting or transplanting must not 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.
- Each tarp panel used for broadcast fumigation must be perforated.
- Tarps used for fumigations may be perforated manually ONLY for the following situations:
    - At the beginning of each row when a coulter blade (or other device which performs similarly) is used on a motorized vehicle such as an ATV.
    - In fields that are 1 acre or less.
    - During flood prevention activities.
- In all other instances tarps must be perforated (cut, punched, poked, or sliced) only by mechanical methods.
- Tarp perforation for broadcast fumigations must be completed before noon.
- For broadcast fumigations tarps must not be perforated if rainfall is expected within 12 hours.
- Early Tarp Removal for Broadcast Applications Only:
    - Tarps may be removed before the required 5 days (120 hours) if adverse weather conditions have compromised the integrity of the tarp, provided that the compromised tarp poses a safety hazard. *Adverse weather* includes high wind, hail, or storms that blow tarps off the field and create a hazard, e.g., tarps blowing into power lines and onto roads. A *compromised tarp* is a tarp that due to an adverse weather condition is no longer performing its intended function and is creating a hazard.
    - If tarps are removed before the required 5 days have elapsed due to adverse weather, the events must be documented in the post fumigation summary section of the FMP.
- Early Tarp Perforation for Flood Prevention Activities
    - Tarp perforation is allowed before the 5 days (120 hours) have elapsed.
    - Tarps must be immediately retucked and packed after soil 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 after 48 hours. However, the risk assessment indicates that extending this period decreases workers' risks. In addition, stakeholder comments prior to the July 2008

RED indicated that non-handler entry to perform post-application (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, in the July 2008 RED the Agency restricted entry into the treated area by anyone other than a properly trained and protected handler. This restriction differs from Restricted Entry Intervals (REIs) that are currently required for most conventional pesticides where dermal exposure is the primary pathway of exposure. Under the WPS, exceptions allow certain tasks to take place before the REI has expired as long as dermal contact with treated surfaces will be limited; however for fumigants where inhalation exposure is the primary risk concern, entry to a treated area is further restricted.

During the post-RED comment period the Agency received some comments that expressed concern that extending the entry-restricted period for fumigants could prevent certain important activities from taking place, contrary to the comments received during earlier comment periods. Based on discussions with stakeholders, EPA's review of public comments, and the risks identified in EPA's risk assessment, EPA does not believe any change to the entry-restricted period is warranted. EPA's review of comments indicates that extending the entry-restricted period to protect workers will not have a substantial impact on agricultural operations. Therefore, the Agency is not making any changes to this section of the July 2008 RED. The mitigation is listed below.

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 (see Figure C), or
- after tarps are perforated and removed if tarp removal is completed less than 14 days after application (see Figure D), or
- 48 hours after tarps are perforated if they will not be removed prior to planting (see Figure E), or
- 5 days (120 hours) after application is complete if tarps are not perforated and removed until 14 days after the application is complete (see Figure F).

Figures C, D, E, and F provide illustrations of tarp perforation/removal and entry prohibition mitigation required for various methyl bromide applications. The intervals depicted are the minimum that must be followed.

Figure C. Untarped Applications

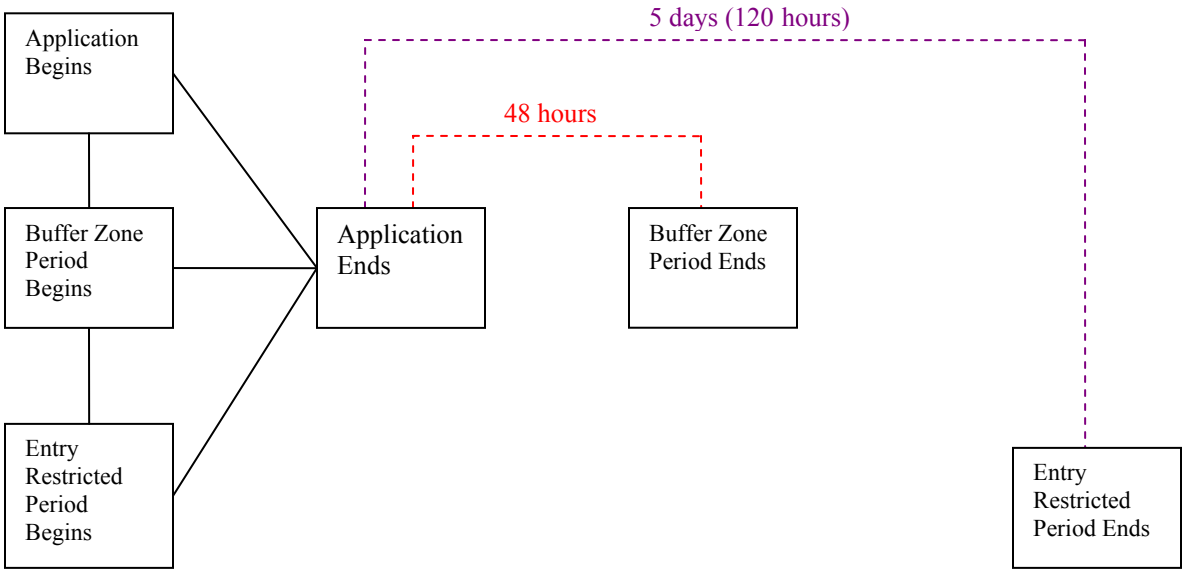


Figure D. Tarp Broadcast Applications (tarps removed before planting)

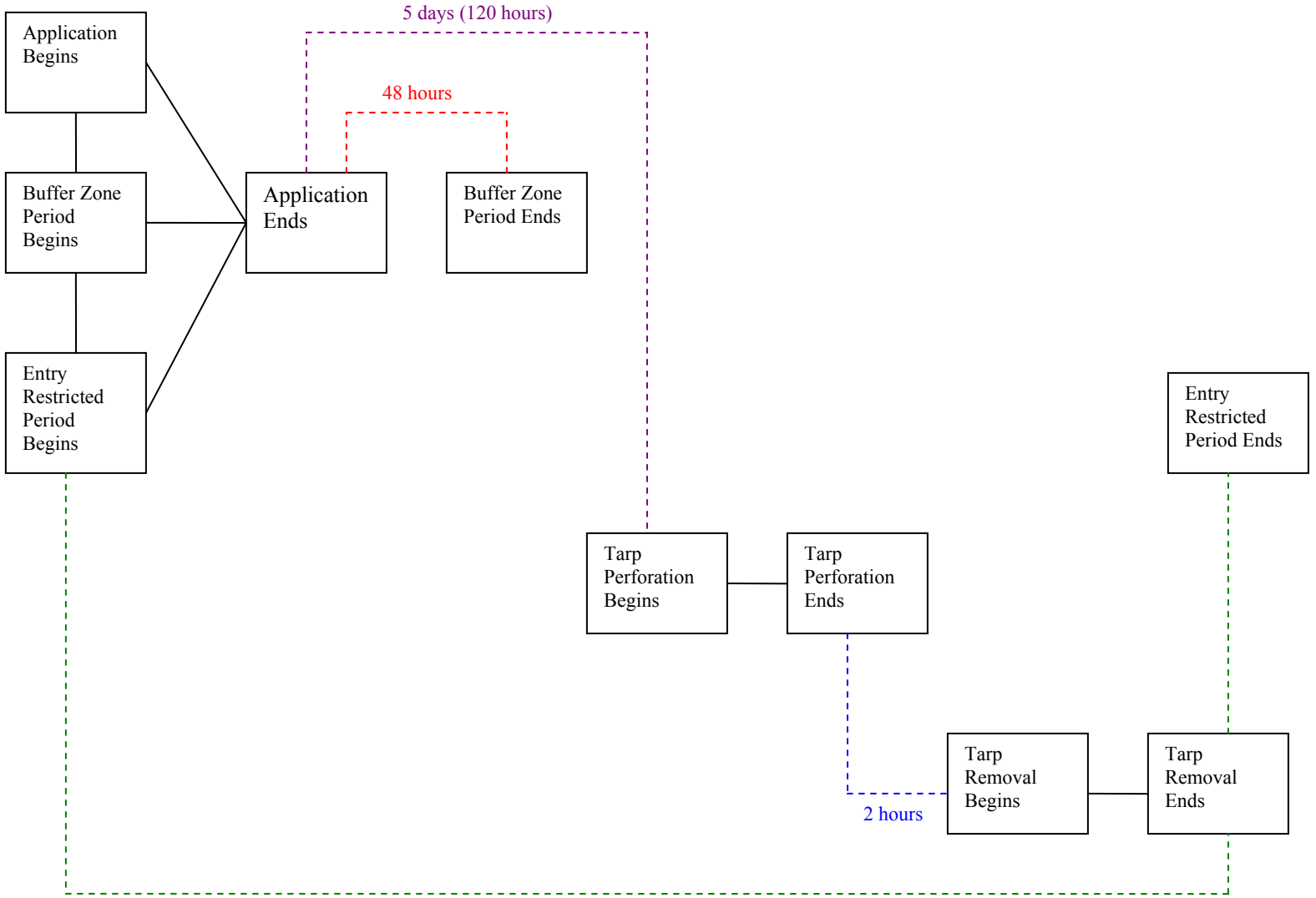


Figure E. Tarp Bed Applications (Tarps not removed before planting)

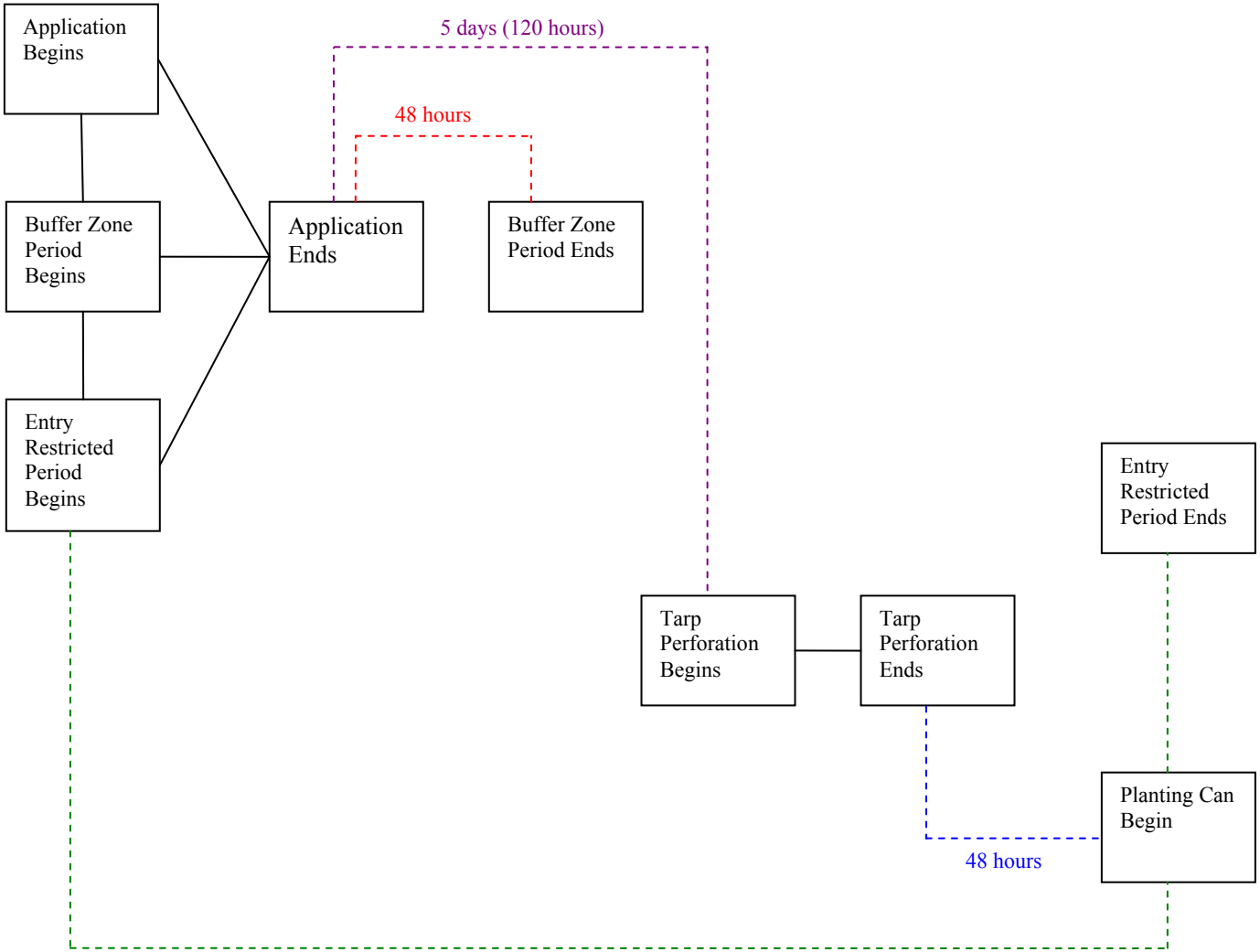
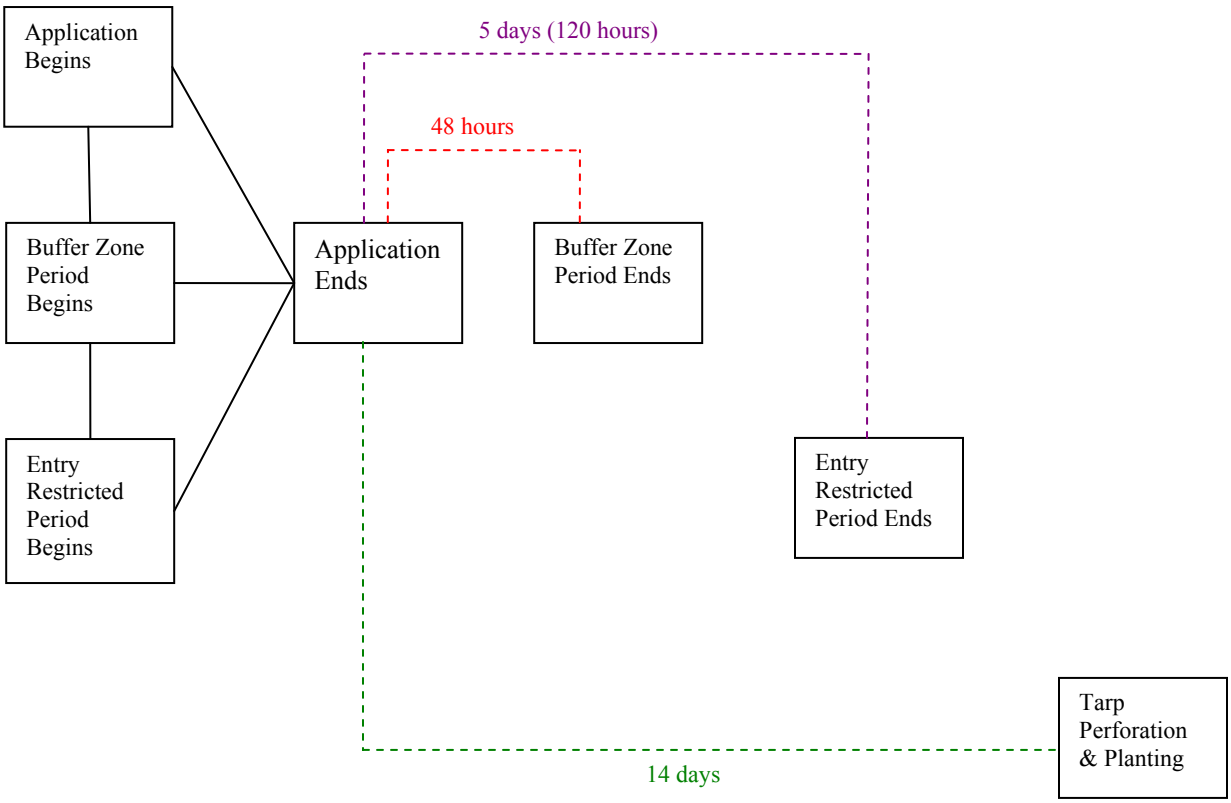


Figure F. Tarp Bed/Broadcast Applications (Tarps are not perforated until 14 days after application)



3) Other mitigation

Below are requirements for FMPs, GAPs, emergency preparedness and response, notice to state 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 fumigators have direct impacts on the amount of fumigant applied and emitted, the Agency determined that labeling should require 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 a key mitigation measure to reduce the amount of fumigants applied and fumigant emissions.

The purpose of this section in the July 2008 RED was to specify GAPs that were required for soil applications of methyl bromide. The practices specified contribute to reducing emissions and thereby are expected to reduce potential for worker and bystander exposures.

The Agency received comments regarding the GAPs outlined in the July 2008 RED. These comments addressed a range of topics:

- making the GAPs voluntary rather than mandatory label requirements,
- buffer zone credits associated with GAP implementation,
- wind speed requirements and the description of inversion conditions,
- crop residue requirements,
- application equipment requirements,
- soil moisture and temperature requirements,
- flexibility in the event that new GAPs are developed,
- enforceability of GAPs, and
- university research exemptions.

These comments are addressed in detail in the Special Review and Reregistration Division's response to comments document. Based on the comments, the Agency has revised some of the GAPs.

The GAPs outlined in the RED, and this RED amendment, have been shown to reduce emissions and bystander exposures and will continue to be mandatory label requirements. Buffer zone credits have been reanalyzed and additional credits have been calculated for various GAPs depending on the soil fumigant used (see *buffer zone credit* section).

The Agency has clarified the language regarding inversions and wind speed requirements. The Agency agrees that erosion control is an important consideration. However, removing the crop residue prior to fumigation is important to limit the natural "chimneys" that will occur in the soil when crop residue is present. These "chimneys" allow the soil fumigants to move through the soil quickly and escape into the atmosphere. This may create potentially harmful conditions for workers and bystanders and will limit the efficacy of the fumigant. To accommodate both of these important considerations (erosion control and human health protection), the Agency encourages that the field be cleared of crop residue as close to the timing of the fumigation as possible to limit the length of time that the soil would be exposed to potentially erosive weather conditions.

Requirements for soil temperature monitoring have been revised from "air temperatures have been above 100 degrees F <u>for more than three hours</u> in any of the three days prior to application" to "air temperatures have been above 100 degrees F in any of the three days prior to application."

The GAPs outlined below must be followed during all fumigant applications. Registrants may develop additional optional GAPs to include on product labels provided they do not conflict with the required practices. All measurements and other documentation necessary to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the post-application summary report as described in the *FMP* section.

- Tarps

Required for all applications except for deep shank orchard replant [California only] 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 and included in the FMP 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 how and 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

The Agency is concerned with off gassing occurring during temperature inversion. In many reported incidents, a temperature inversion is often given as a potential contributing factor. To address this concern in the July 2008 RED, the Agency prohibited applications during periods of temperature inversion, or when the wind speed is less than 2 mph, which can sometimes be an indication an inversion is occurring. In addition, the Agency provided additional information on the label as guidance to applicators in determining if an inversion exists.

The Agency received many comments related to the inversion label language including concern that some of the characteristics of inversion conditions (like misty conditions or clear skies at night) do not always indicate the presence of an inversion; relying on a weather forecast to predict inversions is unreliable and not enforceable; and that prohibiting application during inversions does not address concerns of inversions during the off-gassing period.

Based on these comments the Agency has revised the *weather conditions* section of the GAPs that relates to temperature inversions to clarify that parts of the weather conditions that are requirements and those that are included to help guide the applicator to identify temperature inversions. The measures have also been updated to prohibit application only if temperature inversion conditions are forecasted to persist for more than 18 of the 48 hours after the start of the application since this will filter out conditions when diurnal temperature inversions may occur, though even diurnal temperature inversions could contribute to exposures to fumigant concentrations outside buffers. As such, EPA believes that the measures described below in the *emergency preparedness and response* section of this document are important to address potential risks associated with shorter-term diurnal inversions. The Agency is also changing the wind speed requirement so winds may either be 2 mph at the start of application or be forecasted to reach 5 mph during the application. These changes are designed to prevent applications when inversion conditions are predicted to occur after the application has begun, since this is the time

when the peak off-gassing is expected to occur. In summary, EPA has determined that applicators must (1) check the weather forecast and make a decision whether to proceed with a planned fumigation, based on conditions that are predicted, (2) only begin a fumigant application if wind speed is a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application, and (3) not fumigate if there will be a persistent low-level local inversion or an air stagnation advisory is in effect. EPA believes advisory language providing more detailed information on how to identify inversions and adverse weather conditions will increase the likelihood that applicators will proceed with applications only when weather conditions are or are forecast to be favorable for safe fumigations. See below and the label table in Section V of this document for label statements.

Stakeholders also questioned where the inversion conditions must exist and to what extent the temperature inversion must exist that would prevent an application. The Agency has provided additional temperature inversion details and has added a prohibition for application during an air-stagnation advisory. Air-stagnation advisories are issued through the National Weather Service and usually capture long periods of air stillness that may remain in an area from one to several days. EPA has determined that these modifications achieve the same goals as the July 2008 RED since they provide additional clarity that will enhance users' ability to practically comply with the requirements. The revised statements are stated below.

> Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigation *must* be checked to determine if unfavorable weather conditions exist or are predicted and whether fumigation should proceed.
>
> Wind speed at the application site must be a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application.
>
> Do not apply if a shallow, compressed (low-level) temperature inversion is forecast to persist for more than 18 consecutive hours for the 48-hour period after the start of application, or if there is an air-stagnation advisory in effect for the area in which the fumigation is planned.
>
> Detailed local forecasts for weather conditions, wind speed, and air stagnation advisories may be obtained on-line at: http://www.nws.noaa.gov. For further guidance, contact your local National Weather Service Forecasting Office.
>
> *Unfavorable Weather Conditions*
>
> Unfavorable weather conditions block upward movement of air, which results in trapping fumigant vapors near the ground. The resulting air mass can move off-site in unpredictable directions and cause injury to humans, animals or property. These conditions typically exist prior to sunset and continue past sunrise and persist as late as noontime. Unfavorable conditions are common on nights with limited cloud cover and light to no wind and their presence can be indicated by ground fog or smog and can also be identified by smoke from a ground source that flattens out below a ceiling layer and moves laterally in a concentrated cloud."

- 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 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 9 inches below the surface. The amount of moisture needed in this zone will vary according to soil type and shall be determined using the USDA Feel and Appearance Method for testing (see below). Surface soil generally dries rapidly and must not be considered in this determination.
- If there is insufficient moisture 9 inches below the surface, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below 9 inches, soil moisture can be adjusted by discing or plowing before fumigant injection. To conserve existing soil moisture, pretreatment irrigation or pretreatment tillage should be done as close to the time of application as possible.
- Measure soil moisture at a depth of 9 inches at either end of the field, no more than 48 hours prior to application.

Soil moisture determination

The soil shall contain at the time of application enough moisture at 9 inches below the surface to meet the following criteria defined in the USDA Feel and Appearance method for estimating soil moisture as appropriate for the soil texture.

- For **coarse** textured soils (fine sand and loamy fine sand), the soil is moist enough (50 to 75 percent available soil water moisture) to form a weak ball with loose and clustered sand grains on fingers, darkened color, moderate water staining on fingers, will not ribbon.

- For **moderately coarse** textured soils (sandy loam and fine sandy loam), the soil is moist enough (50 to 75 percent available soil water moisture) to form a ball with defined finger marks, very light soil/water staining on fingers, darkened color will not stick.

- For **medium** textured soils (sandy clay loam, loam, and silt loam), the soil is moist enough (50 to 75 percent available soil water moisture) to form a ball, very light staining on fingers, darkened color, pliable, and forms a weak ribbon between the thumb and forefinger.

- For **fine** textured soils (clay, clay loam, and silty clay loam), the soil is moist enough (50 to 75 percent available soil water moisture) to form a smooth ball with defined finger marks, light soil/water staining on fingers, ribbons between 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, a local extension service or soil conservation service specialist or pest control advisor (agriculture 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. Removing the crop residue prior to fumigation is important to limit the natural "chimneys" that will occur in the soil when crop residue is present. These "chimneys" allow the soil fumigants to move through the soil quickly and escape into the atmosphere. This may create potentially harmful conditions for workers and bystanders and will limit the efficacy of the fumigant. However, crop residue on the field serves to prevent soil erosion from both wind and water and is an important consideration. To accommodate erosion control, fumigant efficacy, and human health protection, clear fields of crop residue as close to the timing of the fumigation as possible to limit the length of time that the soil would be exposed to potentially erosive weather conditions.

- 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*: Preformed beds shall be sealed by disruption of the chisel trace using press sealers, bed shapers, cultipackers, or by re-shaping (e.g., relisting, lifting, replacing) 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 equipment that disrupts the chisel traces.

Methyl Bromide Bedded and Broadcast Shank Applications: Additional GAPs

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 fumigant to, or allow fumigant to drain onto, the soil surface. For each injection line either a check valve must be located as close as possible to the final injection point, or equipment must 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.

Hot Gas Soil Applications (Greenhouse and Outdoor): Mandatory GAPs

- 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.

Tree Replant Application: Mandatory GAPs

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)

As noted elsewhere in this document, soil fumigation is a complex site-specific activity. Failure to adhere to label requirements and procedures for safe use has led to accidents affecting workers involved in fumigations as well as bystanders. Information from various sources shows 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, plans like these 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[16] (i.e., through "Administrative" and "Workplace" controls). The Centers for Disease Control provides guidance for developing health and safety plans in agricultural settings.[17] 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 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

[16] 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)

[17] 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

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.[18]

In the July 2008 RED, EPA required FMPs to be completed before a fumigant application occurs. EPA concluded that FMPs will reduce potential risks to bystanders as well as handlers by requiring that applicators have carefully planned, in writing, each major element of the fumigation. In this context, an FMP is a set of performance criteria for each application, including how the fumigator intends to comply with label requirements. As added benefits, the Agency determined that FMPs would ensure directions on the product labels were followed and that the conditions under which fumigation occurred were documented. EPA also concluded that FMPs would help ensure an appropriate response by the applicator or others involved in the application should an incident occur since a proper and prompt response would 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).

The July 2008 RED provided a list of each major element FMPs would need to address. These included general site and applicator information, application procedures, and a description of how the fumigator planned to comply with label requirements for GAPs, buffer zones, monitoring, worker protection, posting, and providing notification to the state or tribal lead agency. FMPs also were required to include plans for communication between the applicator and others involved in the fumigation, documentation, and handling emergency situation. Additionally, EPA required that applicators complete a post fumigation summary that described any deviations from the FMP, measurements taken to comply with GAPs, and information about any problems such as complaints or incidents that occurred as a result of the fumigation. The RED also specified requirements for record keeping and that FMPs must be provided, upon request, to enforcement officials and handlers involved in the fumigation.

According to stakeholder comments in earlier comment periods, much of the information required for the site-specific FMP was already being documented by users, and most industry stakeholders supported mandatory FMPs provided they are not too restrictive or complex and do not result in an excessive administrative burden.

During the post-RED comment period, EPA received several comments regarding FMPs. Several comments from industry and user stakeholders expressed concern that FMP requirements would increase paperwork burden without providing significant risk reduction, though others supported FMPs provided they did not result in an excessive administrative burden. A number of comments suggested that the level of detail EPA had required was too great and could result in voluminous, resource-intensive plans. Some of these comments suggested that a checklist format would be more efficient and far less burdensome. Some comments expressed reservations about the ability of FMPs to enhance compliance with label requirements. Some commenters were concerned about the feasibility of providing a copy of the

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

FMP to on-site handlers or enforcement personnel, though others said that copies of the FMP should be provided to workers in areas adjacent to the application block.

Following EPA's review of the post-RED comments, the Agency still believes that FMPs will reduce potential risks to bystanders as well as handlers and are a key component of the package of measures to reduce risks. EPA believes that FMPs will also enhance compliance by requiring that applicators verify and document compliance with the label requirements during and 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. However, in response to comments, the Agency has somewhat modified the list of elements that must be addressed in the FMP (as described below) to make it more streamlined and thus less burdensome to applicators and growers. In addition, the Agency has developed a sample template in which many of the elements are covered in checklist format, which fumigators have the option of downloading and modifying to meet the needs of their specific fumigation situations. See [http://www.epa.gov/pesticides/reregistration/soil_fumigants/]. EPA will also continue to work with stakeholders to refine the FMP template and potentially develop others so it is a more useful tool for ensuring the safe application of methyl bromide.

The Agency estimates that, if a certified applicator decides not to use the FMP template and decides to prepare a narrative FMP, a carefully designed FMP could take several days to develop the first time. Subsequent FMPs should require substantially less time to develop because much of the information can be reused from the initial plan. In addition, an enterprise fumigating multiple application blocks as part of a larger fumigation may format their FMP in a manner whereby all of the information that is common to all the application blocks is captured once, and any information unique to a particular application block or blocks is captured in subsequent, separate sections.

Amended FMP Requirements

Consistent with the July 2008 RED, the Agency is not requiring FMPs to be submitted to state or local agencies. They must, however be maintained by the applicator and grower (if the grower is not the applicator) for a period of 2 years.

The Agency agrees with comments that having both the applicator and the owner/operator provide copies of the FMP to handlers is unnecessarily duplicative and that providing each worker with a hardcopy of the FMP wastes paper. The Agency also agrees that it is not necessary for the FMP to be provided to the workers in areas adjacent to the application block. Workers in adjacent areas will be notified of the fumigation by buffer posting requirements and, in the case of neighbors whose land is part of a buffer zone, the adjoining neighbor has responsibility for workers in areas adjacent to the application for which permission was granted to use as part of a fumigation buffer. The Agency has revised the following requirement that was included in the 2008 RED, "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." The RED Amendment requires the

certified applicator to make a copy of the FMP available for viewing by handlers involved in the fumigation. The certified applicator or the owner/operator of the application block must provide a copy of the FMP to any federal, state, tribal, or local enforcement personnel who request the FMP. In the case of an emergency, the FMP must be made available when requested by federal/state/local emergency response and enforcement personnel.

The Agency agrees with comments that the term "etc." complicates enforcement activities and has removed that term from the label tables.

Each site-specific FMP must contain the following elements:

- Applicator information (name, phone number, license number, employer name, employer address, date of completing registrant methyl bromide training program)
- General site information
  - Application block location (e.g., address or global positioning system (GPS) coordinates)
  - Name, address, and, phone number of owner/operator of the application block
  - Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, roads, rights-of-ways, sidewalks, permanent walking paths, bus stops, water bodies, wells, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ or ⅛ mile buffer zones (e.g., schools, state licensed day care centers, nursing homes, assisted living facilities, hospitals, in-patient clinics, and prisons) with distances from the application site labeled
- General application information (target application date/window, brand name of fumigant, EPA registration number)
- Tarp information and procedures for repair, perforation and removal(if tarp is used)
  - Brand name, lot number, thickness
  - Name and phone number of person responsible for repairing tarps
  - Schedule for checking tarps for damage, tears, and other problems
  - Maximum time following notification of damage that the person(s) responsible for tarp repair will respond
  - Minimum time following application that tarp will be repaired
  - Minimum size of damage that will be repaired
  - Other factors used to determine when tarp repair will be conducted
  - Name and phone number of person responsible for cutting and/or removing tarps (if other that certified applicator)
  - Equipment/methods used to cut tarps
  - Schedule and target dates for cutting tarps
  - Schedule and target dates for removing tarps
- Soil conditions (description of soil texture in application block, method used to determine soil moisture)
- Weather conditions (summary of forecasted conditions for the day of the application and the 48-hour period following the fumigant application)
  - Wind speed
  - Inversion conditions (e.g., shallow, compressed (low-level) temperature inversion)
  - Air stagnation advisory

- Buffer zones
  - Application method
  - Application rate from lookup table on the label (lb ai/A)
  - Application block size from lookup table on the label (acres)
  - Credits applied
  - Buffer zone distance
  - Description of areas in the buffer zone that are not under the control of the owner/operator of the application block
- Respirators and other personal protective equipment (PPE) for handlers (handler task, protective clothing, respirator type, respirator cartridge type, respirator cartridge replacement schedule, eye protection, gloves, other PPE)
- 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, complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).
- Posting procedures (person(s) who will post signs, location of posting signs, procedures for sign removal)
- Site-specific response and management (if applicable)
  - Fumigant site monitoring
    - Description of who, when, where, and procedures for monitoring buffer zone perimeter
  - Response information for neighbors
    - List of residences, businesses, and neighboring property owners informed
    - Name and phone number of person doing notification
    - Method of providing the information
- State and tribal lead agency notification (If state and/or tribal lead agency requires notice, provide a list of contacts that were notified and date notified.)
- Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (e.g., tarp cutters/removers, irrigators) for complying with label requirements (e.g., buffer zone location, buffer zone start/stop times, timing of tarp cutting and removal, PPE).
  - Name and phone number of persons contacted
  - Date contacted
- Authorized on-site personnel
  - Names, addresses and phone numbers of all handlers
  - Employer name, addresses, and phone numbers for all handlers
  - Tasks that each handler is authorized and trained to perform
  - Date of PPE training for each handler
  - For handlers designated to wear respirators respiratory protection is required (minimum of 2 handlers), date of medical qualification to wear a respirator and date of fit testing for respirator.
- Air monitoring plan
  - For buffer zone monitoring:
    - Name, address, and, phone number of handler to perform monitoring activities
    - Location and timing of monitoring for the buffer zone

- For handlers without respiratory protection:
  - If sensory irritation is experienced, indicate whether operations will be ceased or operations will continue with respiratory protection
  - If intend to cease operations when sensory irritation is experienced, provide the name, address, and phone number of the handler that will perform monitoring activities prior to operations resuming
- For handlers with respiratory protection:
  - Representative handler tasks to be monitored
  - Monitoring equipment to be used and timing of monitoring
- For buffer zone monitoring when using **methyl bromide formulations with < 20% chloropicrin**:
  - Name, address, and phone number of person(s) to perform sampling
  - Identify areas or structures to be monitored before reentry is permitted
  - Monitoring equipment to be used and timing of the monitoring
- For monitoring the breathing zone when using **methyl bromide formulations with < 20% chloropicrin**:
  - Representative handler tasks to be monitored
  - Monitoring equipment to be used and timing of the monitoring

❖ Good Agricultural Practices (GAPs)
- Description of applicable mandatory GAPs (registrants may also include optional GAPs)
- Measurements and documentation to ensure GAPs are achieved (e.g., measurement of soil and other site conditions)

❖ Description of hazard communication. (The buffer zone around the application block has been posted in accordance with the label. Pesticide product labels and material safety data sheets are on-site and readily available for employees to review.)

❖ Record-keeping procedures (the owner/operator of the application block, as well as the certified applicator, must keep a signed copy of the site-specific FMP and the post application summary for 2 years from the date of application).

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) 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 must make a copy of the FMP available for viewing by handlers involved in the fumigation. The certified applicator or the owner/operator of the application block must provide a copy of the FMP to any federal, state, tribal, or local enforcement personnel who request the FMP. In the case of an emergency, the

FMP must be made available when requested by federal/state/local emergency response and enforcement personnel.

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 the 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.

Specifically the Post-Application Summary must contain the following elements:

- Actual date of the application, application rate, and size of application block fumigated
- Summary of weather conditions on the day of the application and during the 48-hour period following the fumigant application
- Soil temperature measurement (if air temperatures were above 100 degrees F in any of the 3 days prior to the application)
- Tarp damage and repair information (if applicable)
  - Location and size of tarp damage
  - Description of tarp/tarp seal/tarp equipment failure
  - Date and time of tarp repair
- Tarp removal details (if applicable)
  - Description of tarp removal (if different than in the FMP)
  - Date tarps were cut
  - Date tarps were removed
- Complaint details (if applicable)
  - Person filing a complaint (e.g., on-site handler, person off-site)
  - If off-site person, name, address, and phone number of person filing a complaint
  - Description of control measures or emergency procedures followed after a complaint
- Description of incidents, equipment failure, or other emergency and emergency procedures followed (if applicable)
- Details of elevated air concentrations monitored on-site or outside the buffer zone (if applicable)
  - Location of elevated air concentration levels
  - Description of control measures or emergency procedures followed
  - Air monitoring results
    - When sensory irritation experienced:
      - Date and time of sensory irritation
      - Handler task/activity
      - Handler location where irritation was observed
      - Resulting action (e.g., cease operations, continue operations with respiratory protection)
    - When using a direct read instrument:
      - Type of sample (e.g., area, breathing zone, structure)
      - Sample date and time
      - Handler task/activity (if applicable)

    - Handler location or structure location
    - Air concentration
    - Sampling method
- ❖ Date of sign removal
- ❖ Any deviations from the FMP

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 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 use EPA's template, prepare their own FMPs templates, or use other commercially available 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. Site Specific Response and Management

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 educational materials for first responders, and measures for specific sites to ensure early detection and quick and appropriate 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 such as diurnal inversions. 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 information, in the context of their community outreach and education programs to first responders in high-fumigant use areas and areas with significant interface between communities and fumigated fields. In

addition, for situations in which people, homes, or other structures are in close proximity to buffer zones, applicators must either monitor buffer zone perimeters or, alternatively, provide emergency response information directly to neighbors. Each element is discussed in more detail below.

First Responder Education

EPA is requiring registrants through their community outreach and education programs (see the *Community Outreach and Education* section), 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. Additional details are included in the *Community Outreach and Education* section of this document.

Emergency Preparedness and Response Considerations for the 2008 RED

Prior to the July 2008 RED the EPA received comments from many stakeholders about the Agency's emergency preparedness and response option. 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 indicated 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). The requirements in Florida do not apply to agricultural chemical applications. 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, while maintaining the Agency's protection goals.

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.

Emergency Preparedness and Response Revisions

To reduce risks to people who may be near a buffer zone (e.g., at their home, working in a nearby field) in the July 2008 RED, EPA required applicators to either monitor buffer zone perimeters or, alternatively, provide emergency response information directly to neighbors. This measure is intended to ensure protection in places people may be found. Whether measures are required depends on the size of the buffer zone and how close land, not within the control of the owner/operator of the application block (e.g., residential properties), may be to the buffer zone.

The Agency received many comments about the Emergency Preparedness and Response requirements that suggested the requirements were too complex and confusing. To address these concerns, EPA has revised the structure and content of the requirements in the RED Amendment to improve clarity. As was outlined in the 2008 RED, it is important to note that site-specific Emergency Preparedness and Response measures are only required if there are people, homes or businesses within a specified distance from the edge of the buffer zone.

Some comments were received that questioned the rationale behind scaling the Emergency Preparedness and Response measures. EPA believes that scaling the size of the

Emergency Preparedness and Response area will be protective. Generally the larger the buffer distance the higher the application rate or the size of the treated area translates to a greater total amount of fumigant being applied and potentially higher exposure in the area surrounding the application block. The buffer distances for triggering the Emergency Preparedness and Response requirements are scaled to allow the amount of fumigant used (a surrogate for potential exposure) to determine the applicable distance for implementing this requirement. When the area is scaled to the size of the buffer, small buffers which result from applications to small areas, at low application rates, and/or using low-emission application techniques, will have small or no areas to monitor or inform, while larger applications will have larger areas to monitor or inform. In addition, to create additional incentive to achieve the smallest buffer possible, EPA has included an exception for application blocks with the smallest required buffer (25 feet) which would not be subject to this requirement, since they are most likely using lower application rates, applying to smaller areas, and/or using lower emission application methods. Based on changes to the *buffer zone* section regarding overlapping buffer zones, any buffer zone that overlaps with another buffer zone must use the maximum distance in the Emergency Preparedness and Response measures to determine if monitoring or providing information to neighbors is needed. None of the other distances have changed.

Many stakeholders also expressed concern over the potential burden the July 2008 RED requirements may have on applicators and growers. Specifically, the frequency and cost of monitoring using sampling devices such as colorimetric tubes were of concern. Several of these comments noted concerns with the reliability of such devices at low concentration. Stakeholders felt the inherent warning properties of chloropicrin and MITC (i.e., eye irritation) were better indicators of exposure than available devices. Additionally, several stakeholders indicated that monitoring is most appropriate and effective at dawn and dusk, the times of day when off-site movement of concentrations is most likely. Based on these comments, the Agency has revised the requirement so monitoring is required during those periods when risk of high concentrations of fumigant moving beyond buffers is greatest (i.e., at dawn and dusk). As a precaution, monitoring is also required once during the night and during the day.

Additionally, as noted in the *Respiratory Protection* section of this document, due to limitations on currently available technology for monitoring, use of sampling devices such as colorimetric tubes will not be required at this time unless methyl bromide constitutes more than 80% of the product. EPA believes that currently available devices are likely to be more reliable at fumigant concentrations which exceed EPA's action level concentrations. In fact, some of these action levels are at or near the detection limits for the devices available for some fumigants. Additionally, colorimetric devices provide snapshot measurements. In conditions that are likely to be more static (e.g., monitoring an indoor fumigation such as a grain mill or warehouse) it is likely that minute to minute changes in conditions would not be as great as those anticipated for the more dynamic conditions characteristic of outdoor field fumigation where exposure concentrations could shift because of weather changes or stratification in soil conditions across a single field.

The Agency is modifying the procedures for monitoring buffer zones because there are technological limitations of currently available MITC and chloropicrin monitoring devices such that these devices are neither practical nor reliable for field use. However, the Agency does

believe that quantitative air monitoring would enhance safety if the appropriate technology were available as it is for methyl bromide. Some equipment manufacturers have indicated interest in developing devices that would be more functional and reliable for field fumigation applications (e.g., badge-type monitors). EPA encourages such efforts and plans to stay abreast of developments and improvements in monitoring devices and will consider this issue again in Registration Review or sooner should such monitors become available in the short term. In the interim, buffer monitoring for chloropicrin and the MITC generating chemicals will rely on sensory indicators (e.g., eye and/or nose irritation) to trigger a response instead of using tubes. Monitoring tubes are still required for measuring products that contain more than 80 % methyl bromide.

Finally some comments provided suggestions to increase flexibility in how a grower may comply with these measures as well as the effectiveness of the option to provide information to neighbors. EPA agrees with the importance of users being able to comply with these measures and has modified some aspects of the requirements for this option to reduce the number of notices an applicator may need to provide to a given neighbor. Also, to enhance the effectiveness of the information neighbors would receive, EPA is requiring that the information is provided close to when the application is planned to take place and early enough for neighbors to make use of the information. EPA believes these modifications will enhance compliance and effectiveness of the information if the emergency response criteria are met and applicators exercise this option.

Emergency Preparedness and Response Requirements

When are Emergency Preparedness and Response Measures Needed?

If the buffer zone is:	**AND**	**There is land (e.g., residential properties and businesses) NOT in the control of the property operator within this distance from the edge of the buffer zone:**
25 feet < Buffer ≤ 100 feet		50 feet
100 feet < Buffer ≤ 200 feet		100 feet
200 feet < Buffer ≤ 300 feet		200 feet
Buffer > 300 feet or buffer zones overlap		300 feet

Then either monitoring of the buffer zone perimeter or providing emergency response information to neighbors is required.

If the buffer zone is 25 feet, the minimal buffer zone size, then the Emergency Preparedness and Response requirements are not applicable. Also, if all of the land within 300 feet of the edge of the buffer zone is under the control of the property operator, then no site monitoring or informing neighbors would be required regardless of the size of the buffer zone.

Fumigation Site Monitoring

EPA has determined that monitoring of the buffer zone perimeter for fumigants moving beyond buffers is an effective approach to protecting bystanders. Under this approach, if the person monitoring the buffer perimeter experiences eye or nasal irritation, an early sign of exposure to concentrations that exceed the Agency's action level, then the emergency response plan specified in the FMP 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, and the greatest potential for concentrations outside buffers may be observed at dawn and dusk, EPA has decided that this monitoring must be done at least four times per day during the full buffer zone period at dawn, dusk, and once during the night and during the day, to ensure concentrations do not exceed the action level which will be specified on product labels.

Specific requirements include:

- Monitoring must take place beginning on the day the application begins until the buffer zone period expires.
- Monitoring must be conducted by a certified applicator or someone under his/her supervision.
- Monitoring for air concentrations above the action level for the fumigant, as determined by sensory irritation, must take place in areas between the buffer zone perimeter and residences or other occupied areas that trigger this requirement. Air concentrations of methyl bromide must be measured using a direct-read instrument if the methyl bromide product applied contains less than 20% chloropicrin.
- The persons monitoring for perceptible levels must start monitoring approximately 1 hour before sunset of the day the application begins and continue once during the night, once at 1 hour after sunrise, and once during the day until the end of the buffer zone period.
- If at any time the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented.
- If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.
- The location and results of the air monitoring must be recorded in the FMP.

While protective, this site monitoring might be burdensome for users fumigating in areas with few 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, businesses, or other sites that meet the criteria outlined below have been provided the required information at least one week prior to the fumigant application in a specified field. If after four weeks, the fumigation has not yet taken place, the information must be delivered again.

- Information that must be provided includes:
  - The general location of the application block,

- Fumigant(s) applied including the active ingredient, name of the fumigant products(s), and the EPA Registration number,
- Contact information for the applicator and property owner/operator,
- Time period in which the fumigation is planned to take place (must not range more than 4 weeks),
- Early signs and symptoms of exposure to the fumigant(s) applied, what to do, and what emergency responder phone number to call (911 in most cases), and
- How to find additional information about fumigants.

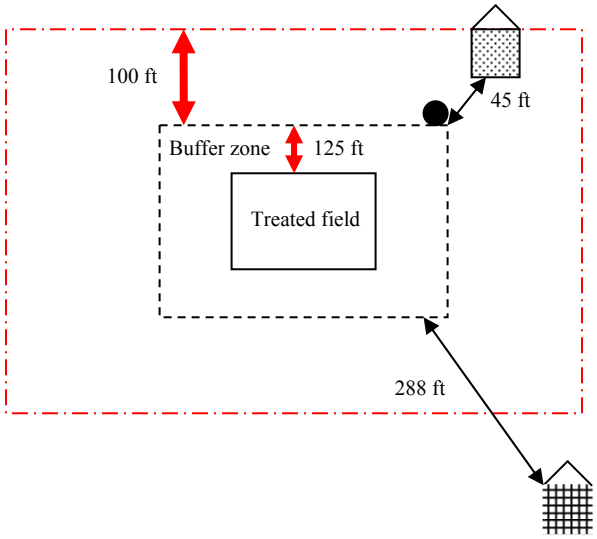
The method for distributing information to neighbors must be described in the FMP and may be accomplished through mail, telephone, door hangers, or through other methods that can be reasonably expected to effectively inform people at residences and businesses within the required distance from the edge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

To clarify this measure, the following example is provided (see Figure G):

- If the buffer zone is **125 feet**, then these requirements apply to residences within 100 feet of the buffer zone. Either the applicator must monitor the area between the dotted house and the buffer zone or residents of the dotted house must be provided emergency response information.
- The location of the cross-hatched house would not prompt any action.

If there are no residences or other occupied structures within 300 feet of the edge of the buffer zone, or if the buffer distance is the minimum of 25 feet, neither site monitoring nor providing information to neighbors is required.

Figure G. Example Site Map for Informing Neighbors



iv. Notice to State Lead Agencies

Ensuring fumigant users understand and comply with the new label requirements is an important component of the fumigant risk mitigation package since these requirements are designed to mitigate risks of concern for bystanders, handlers, and workers. Knowledge of the location and timing of fumigant applications allows enforcement officials to focus their compliance assistance and inspection efforts around periods when, and places where, fumigations are expected to occur. Therefore, in the July 2008 RED, the Agency required written notification of the appropriate state or tribal lead agency prior to fumigant applications.

Following publication of the July 2008 REDs, the Agency received feedback from some states that were interested in receiving the notice because it would enhance their ability to provide technical assistance and assure compliance. However, the Agency also received comments from states that were concerned about the notification requirement largely due to resource constraints. Some states also indicated that they are already well-informed about when and where fumigations take place, and receiving specific notice of applications would create a paperwork burden rather than aid their compliance assistance and assurance programs. Some states recommended that, in lieu of receiving notice of fumigations, states could modify their cooperative agreements with EPA to incorporate specific strategies for assuring compliance with the new fumigant labels. States also suggested that rather than providing notice directly to states, fumigators could enter application information into a registrant-developed and maintained database. They suggested this would be an appropriate mechanism because it would standardize and streamline the process for applicators to provide the required information, and states could access and utilize information more quickly, with greater ease, and using fewer state resources.

Based on consideration of public comments, the Agency still believes that compliance assistance and assurance is a critical component of the soil fumigant mitigation. EPA agrees that some states already have mechanisms in place to provide them with information needed to assist and assure compliance with new fumigant requirements, but other states are in need of additional information to accomplish this objective. The Agency also believes that all states in which fumigants are used will need to modify their cooperative agreements, to some extent, to incorporate strategies for compliance assistance and assurance to aid the transition from current labels to labels that reflect the new mitigation.

While the Agency will continue to work with all state and tribal lead agencies on efficient ways to obtain the information needed to plan and implement compliance assistance and assurance activities, the Agency is currently retaining the notification requirement only for state and tribal lead agencies that choose to be notified of fumigant applications. The Agency plans to provide a website listing these state and tribal lead agencies and how and when these agencies want applicators to provide to them the following information:

- Applicator and property owner/operator contact information (name, telephone number, and applicator license number)
- Location of the application block(s)
- Name of fumigant(s) products(s) applied including EPA Registration number
- Time period in which fumigation may occur

The Agency will work with all states to amend their cooperative agreements to include strategies for compliance assistance and assurance, which will be particularly important over the next several years as the new mitigation measures are implemented. For states that do not choose to be notified of fumigant applications, modification of their cooperative agreements must include the methods these agencies will use to survey fumigation application periods and locations.

v. Soil Fumigation Training for Applicators and Training Information for 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, nearby workers, and other bystanders. Incident data show that a number of fumigant incidents are the result of misapplications, failure to follow label requirements and other safety precautions, and other errors on the part of fumigant applicators. Although states have certification programs, some of which include a specific category or subcategory for soil fumigation, there currently is not a consistent standard across states and regions where soil fumigation is done. Additionally, the federal certification program currently has no category for soil fumigation, and while EPA is considering the development of a category for soil fumigation, the potential changes to the federal certification program and worker safety regulations to include a soil fumigation category are not 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 the complexities and risks associated with soil fumigation. Further, training is a means of ensuring fumigators are able to understand and comply with revised fumigant labeling. Therefore, EPA determined that training designed to establish a national baseline for safe fumigant use, developed and implemented by registrants, will help enhance fumigators' ability to adequately manage the complexities of soil fumigation and enhance compliance with fumigant product labeling. EPA also determined that providing additional safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from risks of exposure.

Soil Fumigation Training Considerations

In comments on fumigant risk management options, stakeholders were broadly supportive of additional training for applicators and handlers. During the Phase 5 and post-RED comment periods, the 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 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 additional training information for 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.

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 are intended to 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 soil fumigant training programs that will serve as a good basis for this expanded effort.

As noted above, several states have high-quality certification programs for fumigators that 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 substantially updated as a result of new requirements associated with this decision and the label changes which will implement it. Although EPA is considering revisions to the federal certification and training program in the future to include a soil fumigation category/subcategory, EPA believes that registrants have access to resources and materials to best develop and deliver 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 any existing state programs to provide additional training resources for fumigators working in those states. EPA will also work with state lead agencies and extension programs to review training program proposals, the content for the programs and materials, and proposed vehicles for delivery.

During the post-RED comment period, the Agency received comments from several states asking that the applicator training requirements be coordinated with existing state certification and training programs. The Agency agrees that for states that have existing soil fumigation certification programs that address the same training elements required of the registrant soil fumigant training programs, as outlined in this section of the RED addendum, applicators should be able to complete the state certification program in lieu of completing the registrant soil fumigation training. For the state soil fumigation certification program to qualify, both EPA and the state must agree that the program satisfies the applicator training elements required in the RED.

Pesticide labels will state that "Before applying the product, the certified applicator supervising that application must successfully complete a methyl bromide training program made available by the registrant within the last 36 months. The Fumigant Management Plan (see details elsewhere on this label) must document when and where the registrant-provided training program or state certification was completed. This requirement for registrant-provided applicator training does not supersede or fulfill state requirements, unless the state has expressly acknowledged that the registrant training may substitute for state requirements."

Training for Applicators Supervising Fumigations

The July 2008 RED required registrants to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and best management practices for soil fumigants. During the public comment period on the proposed mitigation measures and the post-RED comment period, stakeholders were broadly supportive of additional training for fumigators, but concerns were raised with regard to implementation of the training. The Agency also received comments from state representatives and pesticide applicator training organizations, such as the Association of American Pesticide Control Operators, Association of American Pesticide Safety Educators, and Certification & Training Assessment Group, expressing concern over EPA's decision to implement the training via labeling and raising questions over compliance and state enforcement of such a requirement and the potential for conflict or redundancy with state certification and training programs. Various stakeholders recommended that, rather than a label-mandated training requirement, the Agency, instead, should require registrants to develop and implement training for soil fumigant applicators as a condition of registration.

The Agency's goal in requiring soil fumigation training for applicators is to ensure that all applicators in charge of soil fumigations understand the safe use of soil fumigants and in how to apply products in compliance with new product labeling, including provision required by the RED. Given the unique properties of soil fumigants and their application and safety procedures compared with other agricultural and non-agricultural pest control practices, the inherent complexities involved in soil fumigant applications, and the additional complexities that will arise with the implementation of the REDs, the Agency feels that additional training, beyond that available currently, will be needed. The states that currently have certification programs that include soil fumigation categories will not have requirements pertaining to the new mitigation and their programs will need to be modified. EPA agrees that making the required training programs a condition of registration is an important means of ensuring that such training is ultimately developed and implemented. However, it would not ensure that all individuals in charge of soil fumigant applications avail themselves of the training. The Agency believes that making successful completion of the training a condition of use is also important to achieve this goal. Therefore, EPA has decided that development and delivery of training will be included in the DCI that accompanies this RED and successful completion of the training will remain a condition of use.

Each registrant must develop and implement training programs for applicators in charge of soil fumigations on the proper use of and best practices for soil fumigants. In addition, registrants will be required to submit proposals for these programs as data requirements that will

accompany this RED. EPA will review each program and determine whether it adequately addresses the requirements specified in the DCI. The proposal must address, among other elements, both the content and the format for delivering training. The Agency acknowledges the value of hands-on training in the field, but recognizes that may not be feasible in all instances. The Agency welcomes and is actively seeking participation from state lead agencies and extension programs in the evaluation of the registrant training proposals and materials that are submitted.

The training programs must address, at a minimum, the following elements: (1) how to correctly apply the fumigant, including how to comply with new label requirements; (2) how to protect handlers and bystanders; (3) how to determine buffer zone distances; (4) how to develop a FMP and complete the post-fumigation application summary; (5) how to determine when weather and other site-specific factors are not favorable for fumigant application; and (6) how to comply with required GAPs and how to document compliance with GAPs in the FMP. In addition, based on comments received during the post-RED comment period, the Agency is adding a seventh training element—training programs must also include information on how to develop and implement emergency response plans—to ensure that applicators are prepared in the event that a problem develops during or shortly after the fumigant application. EPA is also requiring registrants to incorporate a mechanism for evaluating the effectiveness of their training programs at conveying the required information to participants and for determining whether participants have successfully completed the training program.

To assist states in enforcing these training requirements, the registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training, (2) make this database available to state and/or federal enforcement entities upon request, and (3) provide documentation (e.g., a card) to each training participant who successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion. Applicators must provide to federal, state, or local enforcement personnel, upon request, this documentation that verifies successful completion of the appropriate training program(s).

In the July 2008 RED, the Agency required applicators supervising fumigations to complete the training annually. During the post-RED public comment period, the Agency received comments from various stakeholders indicating that the substance and content of training would not change significantly from year to year, and that an annual training requirement for applicators would be excessive and burdensome to both applicators and registrants and was unnecessary. As a result of these comments, the Agency has decided to require applicators supervising fumigations to have successfully completed the program within the preceding 36 months and to document when and where the training program was completed in their FMPs. This may be accomplished, for example, by simply attaching a copy of the training documentation provided by the registrant to the FMP. The registrant also 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.

Based on questions received during the post-RED comment period, the Agency is clarifying that the applicator training requirements are active ingredient-specific rather than product-specific. That is, applicators who apply more than one of the soil fumigant active ingredients (i.e., methyl bromide, chloropicrin, metam sodium/potassium, or dazomet) will be required to complete training for each soil fumigant active ingredient they apply, but not for each different product containing the same active ingredient(s). Further, EPA encourages the soil fumigant registrants to jointly develop programs to reduce the redundancy of this training requirement. For example, a substantial portion of the required training is universal to all soil fumigants. Therefore modules addressing the information common to all could be generic and each fumigator would participate in those modules, while separate modules addressing active ingredient-specific content could be provided to those fumigators supervising applications with those active ingredients only. Documentation provided to trainees could indicate the active ingredient modules completed. While EPA sees efficiencies in such an approach, it will be the registrants' choice as to how they will comply with the requirement to develop and implement training programs.

Training Materials for Handlers

EPA is requiring registrants to 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 Agency is requiring registrants to submit proposals for these materials through the data call-ins that will accompany this RED. EPA will review these materials to determine whether they adequately address the requirements specified in the DCI. The Agency welcomes and is actively seeking participation from state lead agencies and extension programs in the evaluation of these handler training materials.

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.

> "The certified applicator must provide fumigant safe handling information to each handler involved in the application in a manner that they can understand prior to performing any fumigant handling task or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months."

During the post-RED comment period, no substantive comments were received that resulted in changes to the RED requirements for training materials for handlers, as a result, these requirements are identical to those published in the July 2008 RED. However, during the comment period, the Agency received comments indicating that there was some confusion about whether fumigant handlers working under the supervision of the certified applicator would be required to be trained, i.e., participate in a training program developed by the soil fumigant registrant(s), or whether handlers would need only to be provided with training information and materials. The Agency wishes to clarify that handler participation in a registrant training program, per se, is not required. As noted above, applicators supervising a soil fumigation will be required to provide the registrant-developed, EPA-approved training information to handlers in a manner that they can understand prior to performing any fumigant handling task, or applicators must ensure that the handler has been provided the required information within the proceeding 12 months.

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 about soil fumigants 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. Community outreach will address the risk of acute bystander exposure by informing community members in high-use areas about buffer zones and their characteristics and purpose, the meaning of posted warning signs, the importance of not entering buffer zones, how to recognize early signs of fumigant exposure, and how to respond appropriately in case of an incident.

In the July 2008 RED, the Agency required registrants to develop and implement community outreach and education programs to address these needs. At a minimum, these programs were to include the following elements: (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 as well as a plan for evaluating the effectiveness of these programs. Few details on how the programs would be implemented were provided in the RED. Rather, during the post-RED comment period, the Agency sought feedback from the registrants and other stakeholders on how best to design and target programs to community members in high-use areas. The Agency encouraged the registrants to work with existing community resources, such as community health networks, for disseminating information and implementing community outreach programs.

During the post-RED comment period, the Agency received some comments from stakeholders that suggested that having registrants develop and implement a community outreach and education program is unnecessary and likely to needlessly raise heath and safety concerns

among community members, and such a requirement could draw scarce resources from other registrant stewardship efforts. As noted previously, the Agency believes that providing basic information about soil fumigants and buffer zones as well as information on what to do in the event that an incident occurs to communities in high fumigant use areas is an important component of the overall package of risk mitigation measures to address bystander risk. EPA's community outreach requirements do not preclude other voluntary stewardship programs or activities targeted to community members or the applicator/grower community, but rather are meant to help ensure that community members in high fumigant usage areas are informed about soil fumigant safety and better able to respond appropriately if an incident were to occur.

Few recommendations and no specific proposals for these programs were received during the post-RED comment period. Therefore, the Agency is identifying minimum requirements that each registrant must fulfill when developing its community outreach programs in response to a DCI that will be issued. The Agency remains open to considering additional registrant outreach program elements that address the same needs and goals as the program requirements described below in their response to the DCI. EPA notes that registrants have suggested that programs focusing on specific target audiences, such as staff and managers of migrant health care and day care facilities, prison officials, and school nurses and principals, may be more effective in providing useful information in a meaningful way than broadcast messages to entire communities. Registrants have indicated that they will provide proposals for such programs in late May 2009. EPA looks forward to these proposals and will consider the extent to which they contribute to meeting the goals of the community outreach programs required by the RED.

In the absence of acceptable alternative proposals, registrants, will be required to provide information to communities in the form of monthly public service announcements (PSAs) distributed via local radio stations or newspapers in high-use fumigant areas during the fumigation season(s) in those areas. As per the requirements included in the July 2008 RED, at a minimum, registrants must include the following information in their community outreach messages: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure to methyl bromide, (4) appropriate steps to take to mitigate exposures to methyl bromide, (5) what to do in case of an emergency, and (6) how to report an incident as well as a plan for evaluating the effectiveness of these programs. Based on comments, EPA has decided that information on the meaning of posted warning signs is also important to help ensure the signs convey the needed information about the importance of staying out of buffer zones and treated areas.

The Agency is requiring registrants to implement their outreach programs in communities located in areas where there is high soil fumigant use. For the purposes of the RED addendum, high-use areas are considered at the county level. To identify these areas, the Agency is proposing a process for identifying high-use areas in the subsection following the section on information for first responders. However, the Agency is willing to consider alternative proposals for identifying high soil fumigant-use areas, based on additional data sources and alternate approaches identified by the registrant(s) and other stakeholders.

Information for First Responders

In the July 2008 RED, the Agency required registrants to ensure that first responders in areas with high fumigant usage have the training and information that they need to effectively identify and respond to fumigant exposure incidents. Specifically, the registrants were required to provide information and/or training to first responders, which at a minimum, included the following elements: (1) how to recognize the early signs and symptoms of fumigant exposure, (2) how to treat fumigant exposures, and (3) how fumigant exposure differs from other pesticide exposure. In addition, the registrants were required to provide material safety data sheets to first responders for the fumigant applied. Few details on how the education programs would be implemented were provided in the RED. Rather, during the post-RED comment period, the Agency sought feedback from the registrants and other stakeholders on how best to design and target programs to first responders in high-use areas. The Agency encouraged the registrants to 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.

During the post-RED comment period, the Agency received comments from several registrants indicating that rather than requiring registrants to implement face-to-face training programs, the Agency should consider allowing the required first responder training information to be conveyed via written materials to state and local emergency response agencies, which would provide these agencies the ability to incorporate this information into their existing training programs. Other comments indicated that even if training programs were developed, it would be difficult to ensure participation of first responders. The Agency's goal for the first responder training program is to ensure that first responders in high use fumigant areas have access to the information that they need to be able to quickly and effectively identify an exposure that is fumigant related and respond appropriately. The Agency agrees that this goal can be met by requiring the soil fumigant registrants to develop informational materials on the soil fumigants and distribute this information to first responders (i.e., police, fire, rescue, emergency medical services, and others who respond to "911" calls) in high soil fumigant-use areas. This would then provide the first responder entities the ability to incorporate this information into their existing first responder training programs as they best see fit. This recommendation has been incorporated into the RED amendments for the soil fumigants.

The Agency is willing to consider additional registrant proposals so long as they address the same needs and achieve the same goals as the program requirements described below. At a minimum, registrants will be required to develop and disseminate chemical-specific soil fumigant training materials to first responders (i.e., police, fire, rescue, emergency medical services, and others who respond to "911" calls) operating in high fumigant-use areas. As a data requirement in the DCIs that will accompany the REDs, registrants must submit proposals detailing how they will (1) identify the first responder entities in high soil fumigant-use areas to which they will disseminate the training materials, and (2) provide materials to the first responders in these areas. Additionally registrants must provide draft copies of the training materials for EPA review and approval. As per the requirements included in the July 2008 RED, at a minimum, the materials must convey the following information to first responders: (1) how to recognize the early signs and symptoms of methyl bromide fumigant exposure, (2) how to

treat methyl bromide fumigant exposures, and (3) how methyl bromide fumigant exposures differ from other pesticide exposures as well as (4) copies of material safety data sheet(s) for the fumigant applied as well as for the active compound generated, if applicable. Training materials can take a number of forms (e.g., brochures, fact sheets, CDs, videos, web-based training materials) as long as these materials incorporate, at a minimum, the information requirements identified above.

The Agency is requiring registrants to target their first responder training information to those communities located in high soil fumigant-use areas. For the purposes of the RED, high-use areas are considered at the county level. To identify these areas, the Agency is proposing the following process. However, the Agency is willing to consider alternative proposals in the registrants' response to the DCIs for identifying and targeting high-use soil fumigant areas, based on additional data sources and alternate approaches identified by the registrant(s).

Process for Identifying High-Use Fumigant Areas:

Identifying high-use areas for methyl bromide is a two-step process because reliable fumigant use data is not available at the county level from either publicly available data sources or EPA proprietary data sources. First, the states with high use of methyl bromide have been identified by the Agency using EPA proprietary data. Second, the high-use counties for methyl bromide within those states must be identified. The second step, identifying high-use counties, will be the registrant's responsibility, using the process defined below.

- Step 1: Identifying States with High Use of Methyl Bromide: The Agency is defining states with high usage of methyl bromide as those states where, on average, more than 100,000 lbs of methyl bromide or chloropicrin are applied annually. To determine those states where, on average, more than 100,000 lbs of methyl bromide or chloropicrin have been applied annually, the Agency obtained data on the average number of pounds of methyl bromide and chloropicrin applied in all states across a ten–year period (1999-2008) using EPA proprietary data. To view the Agency's analysis of this data, please see the Biological and Economic Analysis Division's (05/14/09) memo, "Process for Defining High-Use Fumigation Areas at the State and County Levels (DP# 364647)" and supporting documentation located in the methyl bromide docket at EPA-HQ-OPP-2005-0123. The states identified for methyl bromide and chloropicrin are Washington, Oregon, Idaho, South Carolina, Georgia, North Carolina, California, Florida, and Michigan.

- Step 2: Identifying Counties with High Use of Methyl Bromide: For each of the high-use states that the Agency identified in Step 1, the registrants will be required to identify the counties where use of methyl bromide may be high. Because county-level fumigant usage data is not publicly available and EPA proprietary data are not appropriate for this level of specificity, crop acreage should be used as a surrogate indicator for fumigant usage. Crop acreage can be obtained for major use sites of methyl bromide from the publicly available 2007 USDA Census of Agriculture. Crop acreages for each of the major use sites for methyl bromide should be and then summed by county. All counties making up at least the top 90% of acreage in a state are considered high-use areas.

Registrants will be required to target each of these high-use counties for community outreach programs.

For the purposes of this analysis, the Agency defines a "major use site" as any crop that has more than 5% crop treated annually or more than 100,000 lb of methyl bromide or chloropicrin applied annually. The crops identified for methyl bromide are cantaloupes, peppers, squash, strawberries, tomatoes, and watermelons.

Example Identifying High-Use Fumigant Areas for Metam Sodium in California:

To help explain the process for identifying high-use fumigant areas for methyl bromide the Agency is providing the following example, which identifies the high-use counties for the soil fumigant, metam sodium, usage in California.

- Step 1: Identify States with High Use of Metam Sodium:
  - Based on its analysis of proprietary data, the Agency has identified the following high-use states for metam sodium: California, Washington, Idaho, Oregon, Wisconsin, Michigan, Florida, Minnesota, North Carolina, Virginia, Arizona, Nevada, Georgia, Colorado, and North Dakota. This example will focus only on identifying the counties in California with high use of metam sodium. The same process would be applied to other high-use states.

- Step 2: Identify the Counties in California with High Use of Metam Sodium:
  - EPA has identified the following as the major use sites of metam sodium/potassium: artichokes, cabbage, cantaloupes, carrots, onions, peanuts, peppers, potatoes, spinach, squash, tomatoes, and watermelons.
  - Using the 2007 USDA Census of Agriculture, registrants will need to obtain harvested crop acreage data for each of the 12 major use sites for metam sodium identified above for each county in California. (An example of this analysis is provided as a supporting document to the Biological and Economic Analysis Division's (05/14/09) memo, "*Process for Defining High-Use Fumigation Areas at the State and County Levels* (DP# 364647)," which is located in the metam sodium docket at EPA-HQ-OPP-2005-0125.
  - Registrants will then need to sum the total number of combined crop acres for these major use sites for each county in California and then select all the counties that make up at least the top 90% of acreage in the county. [An example of this analysis is also provided as a supporting document to the Biological and Economic Analysis Division's (05/14/09) memo, "*Process for Defining High-Use Fumigation Areas at the State and County Levels* (DP# 364647)," which is located in the metam sodium docket at EPA-HQ-OPP-2005-0125.]

As with the training for fumigant applicators and handlers and the community outreach program that the Agency is requiring, the first responder training requirements are intended to be part of the registrants' long-term product stewardship. The Agency encourages registrants to work with appropriate state emergency response entities in these areas to ensure that the

appropriate first responder entities are being targeted and that the information being provided to first responders is both useful and presented appropriately.

c. Environmental Risk Management

In the July 2008 RED, EPA addressed the concerns for both aquatic and terrestrial risks which are mentioned in Section III.D. The July 2008 RED also stated that EPA believed that mitigation measures detailed in the *Human Health Risk Mitigation* section would also reduce ecological risks. The Agency stated that although buffer zones and GAPs do not directly reduce the potential risk to ecological organisms, these mitigation measures 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.

In the July 2008 RED, EPA deviated from the Label Review Manual language because dissipation of methyl bromide in aquatic environments is predominately dependent on volatilization and to a lesser extent on leaching and degradation. In addition, as discussed in the *Human Health Risk Mitigation* section managing soil moisture is an important factor that may be used to reduce peak emissions. Due to the importance of adequate soil moisture as described in the *GAP* section and the knowledge that volatilization is methyl bromide's most important route of dissipation, EPA required the following language in the July 2008 RED taking these factors into consideration , "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 still believes that a deviation from the recommended language in the Label Review Manual is necessary due to the importance of soil moisture and methyl bromide's volatility. While the Agency believes that volatilization is this chemical's most important route of dissipation, it is being removed from the groundwater statement because volatilization is addressed in other areas of the mitigation package. The new language will state, "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)."

EPA also discussed, in the July 2008 RED, the potential for methyl bromide to leach into groundwater when tarps are used in broadcast applications: falling temperatures typically found in the late afternoon and evening would 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 groundwater. 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. In the 2008 RED, EPA required that tarps for broadcast applications must be perforated before noon and only when rainfall is not expected within 12 hours. The Agency is keeping this requirement in the amended RED. The language is included in the *Tarp Perforation and Removal* section of this document.

The July 2008 RED also discussed the potential for methyl bromide to leach into groundwater and surface water if a rainfall event occurs after an untarped 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.

The Agency modified this language in the July 2008 RED due to the importance of soil moisture and methyl bromide's volatility. The Agency required the following language in the July 2008 RED, "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."

During the post-RED comment period commenters stated that the above July 2008 RED language was not clear or enforceable. EPA would like to clarify that the statement was meant to be advisory and not mandatory. However in an effort to clarify the requirement the Agency has revised the July 2008 RED language as follows, "For untarped applications, leaching, and runoff may occur if there is heavy rainfall after soil fumigation." This is more likely in areas with poor draining soils. The revised statement is based on information presented in a 2007 article by Zhang and Wang.[19]

In addition to the changes above, EPA 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 for revised label language and the 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:

19 Zhang, Y. and Wang, D. 2007. Emission, distribution, and leaching of methyl isothiocyanate and chloropicrin under different surface containments. Chemosphere, 2007 Jun; 68(3): 445-454.

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)	► 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	► To achieve manageable buffer zone 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.
• GAPs and 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, methyl bromide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species Considerations

The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether methyl bromide use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.

D. Conclusions

The Agency has determined that Group 1 uses of methyl bromide are eligible for reregistration as long as they have CUE or QPS status under the Montreal Protocol, and provided the risk mitigation measures outlined above are adopted and label amendments are made to reflect these measures. Where labeling revisions are warranted, specific language is set forth in the label table in Section V of this document. Any Group 1 uses that no longer qualify for CUE and QPS status should be canceled. Group 2 uses are not eligible for reregistration.

V. What Registrants Need to Do

EPA recognizes that the extent of the mitigation needed for methyl bromide and the other soil fumigants will require continued coordination among state regulatory agencies, EPA, registrants, growers and other stakeholders 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.

When the soil fumigant REDs were issued in July, 2008, EPA specifically requested comment on the mechanisms and timing of implementing the provisions of the REDs. After considering stakeholder comments largely focused on the challenges of implementing many new measures simultaneously, EPA has developed the following schedule:

July 2008	Methyl Bromide RED issued
October 2008	Comment period closed
May 2009	EPA responds to comments, amends RED as appropriate
Mid 2009	EPA issues product and generic DCIs
September 1, 2009	**Registrants must submit revised labels to EPA**, reflecting phase one of the mitigation measures as outlined in Table 2: restricted use, GAPs, rate reductions, limitations on use sites, new handler protection measures, tarp cutting and removal restrictions, extended worker re-entry restrictions,

	training information for workers, and relevant portions of the FMP requirements.
December, 2009	EPA reviews/approves new labeling for 2010 use season.
During 2009-10	EPA works with registrants, states and stakeholders to develop and begin implementation of first responder and community outreach, applicator training, and compliance assistance and assurance measures.
September 1, 2010	Registrants must submit revised labels to EPA reflecting all remaining mitigation measures outlined in Table 2 including: applicator training, restrictions on applications near sensitive sites, buffer zones, buffer credits, buffer zone posting and buffer overlap prohibitions and exceptions, and the full FMP requirements.
2009-2012	Registrants develop data per DCIs.
2013	EPA begins Registration Review for methyl bromide and other fumigants.

Labeling

Registrants must submit labeling reflecting phase one mitigation measures by September 1, 2009. All measures will need to be reflected on labels submitted to EPA by September 1, 2010. Because of the relatively large amounts of product shipped under a single label, e.g., 50 gallon drums and railroad tank cars, changes to fumigant labeling can be adopted relatively quickly. Therefore, the Agency anticipates that labeling approved late in 2009 would begin to appear on products used for the 2010 fumigation season.

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[20.]

- 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.*

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

- 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 Germination/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.
- 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, (6) how to report an incident, (7) information on how to develop and implement emergency response plans, and (8) a mechanism for evaluating the effectiveness of their training programs at conveying the required information to participants and for determining whether participants have successfully completed the training program. 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 36 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.

Special Study – Buffer Zone Posting Signs

EPA has determined that registrants must prepare and disseminate generic buffer zone posting signs which meet the following criteria: (1) signs must remain legible during the entire posting period, and (2) signs must meet the general standards outlined in the WPS for text size and legibility (see 40 CFR §170.120). The requirements for the contents of the sign are as follows:

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," -- "Methyl Bromide 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," -- "Methyl Bromide OR [Name of product] Fumigant BUFFER ZONE," -- contact information for the certified applicator in charge of the fumigation

Registrants must capture all of the information above, excluding the contact information for the certified applicator in charge of fumigating. However, registrants must provide appropriate space on the sign, and the sign must be made of material appropriate for applicators to write in this information on the buffer zone posting signs. Registrants must provide buffer zone posting signs at the point of sale for applicators to use. EPA is requiring registrants to submit proposals that must address their strategy for development and dissemination of the buffer zone posting signs.

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.

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.

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

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 label table
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
PERFUM Model Inputs and Outputs

Appendix B. PERFUM Model Inputs and Outputs

Inputs for PERFUM Model

The major input parameters for the fumigant emission and dispersion modeling were: application rates, application block sizes, application method emission profiles, weather conditions, and the target air concentration (based on acute inhalation endpoint and uncertainty factors).

- Rates

The Agency modeled up to 430 lb ai/acre for broadcast applications and 250 lbs ai/acre effective broadcast rate for bedded applications in the July 2008 RED. 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 the 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.]

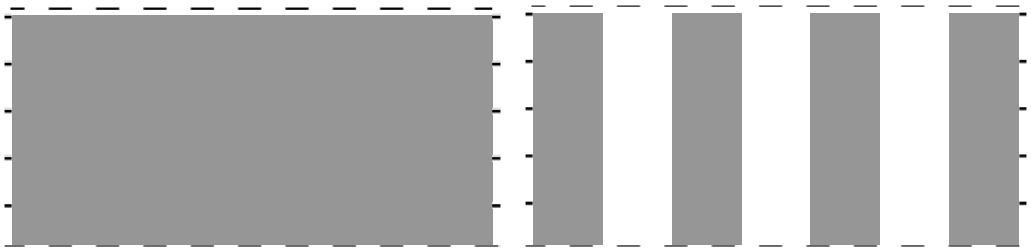


Figure 1. Broadcast Application

Figure 2. Bedded Application

- Block sizes

The Agency had 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 for the July 2008 RED included 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.

In the July 2008 RED, the Agency 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 U.S. occurs in Florida and California followed by Michigan. Based on these high-use areas, five weather data sets were modeled in the 2008 RED (Ventura, California; Bakersfield, California; Bradenton, Florida; Tallahassee, Florida; and Flint, Michigan). 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., 1,825 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, Michigan, data resulted in significantly smaller buffers compared to the other four locations. The methyl bromide RED addendum used the same weather data sets as inputs to the PERFUM model.

- 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 the 99th percentile air concentration from PERFUM outputs. This endpoint and concentration was used in the methyl bromide RED addendum.

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.

APPENDIX C
FMP Template for Methyl Bromide Soil Applications

FUMIGANT MANAGEMENT PLAN

Certified Applicator Supervising the Fumigation		
Name and phone number:	License number:	☐ Commercial applicator ☐ Private applicator
Employer name and address:		Date of completing registrant training program:

General Site Information
Application block location, address, or global positioning system (GPS) coordinates:
Name, address, and phone number of owner/operator of application block:

General Application Information		
		EPA Registration Number:

Tarps (check here if section is not applicable ☐)		
	Lot #:	Thickness:
Name and phone number of contact person responsible for repairing tarps:		
Schedule for checking tarps for damage, tears, and other problems:		
Maximum time following notification of damage that the person(s) responsible for tarp repair will respond:		
	Minimum size of damage that will be repaired:	
Other factors used to determine when tarp repair will be conducted:		
	Equipment/methods used to cut tarps:	
	Schedule and target dates for removing tarps:	

Soil Conditions	
	Description of method used to determine soil moisture level:

Weather Conditions

Summary of the weather forecast for the day of the application and the 48-hour period following the fumigant application (may attach a copy of printed forecast to FMP):

Buffer Zones

Application method: ☐ Bedded ☐ Broadcast ☐ Hot gas - outdoor ☐ Hot gas - greenhouse ☐ Hand held probes		Block size from lookup table on label (acres):	_____	Buffer zone distance: _____ ft

List and describe areas in the buffer zone that are not under the control of owner/operator of the application block:

Personal Protective Equipment for Handlers

Handler Task	Clothing	Respirator Type, Filter Cartridge Type and Change-out Schedule	Eye Protection	Gloves	Other

Emergency Response Plan

Description of evacuation routes:

Locations of telephones:

Contact information for first responders:	Local/state/federal contacts:	Other contact information for emergencies:

Emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).

Posting Signs

Name and phone number of person that is doing posting:

Location of posting signs:

Procedures for posting and sign removal:

Site Specific Response and Management	☐ Fumigation Site Monitoring or ☐Response Information for Neighbors

If **Response Information for Neighbors** has been selected, completed the following:

If buffer zone is 25-100 ft:	☐ Neighbors within 50 ft of buffer zone	☐ No neighbors within 50 ft of buffer zone
If buffer zone is 100-200 ft:	☐ Neighbors within 100 ft of buffer zone	☐ No neighbors within 100 ft of buffer zone
If buffer zone is 200-300 ft:	☐ Neighbors within 200 ft of buffer zone	☐ No neighbors within 200 ft of buffer zone
If buffer zone is > 300 ft:	☐ Neighbors within 300 ft of buffer zone	☐ No neighbors within 300 ft of buffer zone
If buffer zones overlap	☐ Neighbors within 300 ft of buffer zone	☐ No neighbors within 300 ft of buffer zone

List of residences and businesses informed (neighboring property owners):

Name, address, and phone number of person providing information:

Method used to provide information:

Notice to State Lead Tribal Agencies

	Date notified:

Communication Between Applicator, Land Owner/Operator, and Other On-site Handlers

Plan for communicating to the land owner/operator and all on-site handlers (e.g., tarp cutters/removers, irrigators) requirements to comply with label including location and start/stop times of buffer zones; timing of tarp cutting/removal, and PPE:

Names and phone numbers of persons contacted:	Date contacted:

Comments/notes:

Site Map

Location of application block: _____

Map Legend

Application block
Buffer zone
Property lines
Roads
Right-of-way
Walkway, sidewalk, path
B Bus stop
WB Water body
DC Daycare facility
Sch School
NAB Nearby application block
IPC Inpatient clinic
P Prison
Well
NH Nursing home
ALF Assisted living facility

Handler Information

Handler Name, Address, and Phone Number	Employer Name, Address, and Phone Number	Tasks They are Trained and Authorized to Perform	Date of PPE Training	Date of Medical Qualification to Wear a Respirator	Date of Fit Testing for Respirator

Air Monitoring Plan

For Buffer Zone Monitoring: (check here if section is not applicable ☐)

Name of handler performing monitoring activities	Handler address	Handler phone number	Location of monitoring	Timing

For Handlers without Respiratory Protection: (check here if section is not applicable ☐)

If sensory irritation is experienced: ☐ **Intend to cease operations** ☐ **Intend to continue operations with respiratory protection**
If intend to continue operations with respiratory protection, complete section for Handlers with Respiratory Protection below.

	Monitoring equipment:

For Handlers with Respiratory Protection: (check here if section is not applicable ☐)

Representative Handler Tasks to be Monitored	Monitoring Equipment	Timing

Air Monitoring Plan for Methyl Bromide Formulation with < 20% Chloropicrin

For Buffer Zone Monitoring: (check here if section is not applicable ☐)

Name, address, and phone number of person(s) to perform sampling:

Area or Structure to be Monitored Before Reentry is Permitted	Monitoring Equipment	Timing

For Handlers with Respiratory Protection:

Representative Handler Tasks to be Monitored	Monitoring Equipment	Timing

Methyl Bromide FMP Check List

General Site Information	
A map, aerial photo, or detailed sketch is attached to this FMP that shows each of the following with distances from the application site labeled: field location, application block dimensions, buffer zones, property lines, roads, bus stops, water bodies, wells, rights-of-ways, nearby application blocks, surrounding structures, and sites requiring ⅛ and ¼ mile buffer zones.	☐
Supervision of Handlers	
An on site certified applicator will directly supervise the handlers 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.	☐
After the application is complete, and before leaving the application block, the certified applicator has provided the owner/operator and handlers with written information necessary to comply with the label and procedures outlined in the FMP.	☐
Fumigant safe handling information has been provided 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 fumigation handling tasks, at least 2 WPS-trained handlers must be present.	☐
Weather Conditions	
Wind speed at the application site is a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application.	☐
A shallow, compressed (low-level) temperature inversion is not forecast to persist for more than 18 consecutive hours during the 48-hour period after the application.	☐
An air-stagnation advisory is not in effect for the area where the application site is located.	☐
If air temperatures have been above 100 degrees F in any of the 3 days prior to application, then soil temperature will be measured and recorded in the post application summary report.	☐
Soil Conditions	
The soil has been properly prepared and the surface has been checked to ensure that it is free of clods that are golf ball size or larger.	☐
The area to be fumigated has been tilled to a depth of 5 to 8 inches.	☐
Field trash has been properly managed (e.g., residue from a previous crop has been worked into the soil to allow for decomposition prior to fumigation, little or no crop residue is present on the soil surface, and crop residue that is present does not interfere with the soil seal).	☐
The soil temperature at the depth of injection ≤ 90 degrees F at the beginning of the application.	☐
The soil moisture at 9 inches below the surface is sufficient (field capacity is 50 to 80 percent).	☐
Trash pulled by the shanks to the ends of the field will be covered with tarp or soil before making the turn for the next pass.	☐
Shank Applications (check here if section is not applicable ☐)	
For tarped-broadcast and -bedded applications, injection points will be at least 8 inches from the nearest final soil/air interface.	☐
For tarped-bedded applications, the injection depth will not be as deep as the lowest point of the tarp (i.e., the lowest point of the tuck).	☐
For untarped-bedded applications, the injection points will be at least 12 inches from the nearest final soil/air interface.	☐
For untarped-broadcast applications, the injection points will be at least 18 inches from the nearest final soil/air interface.	☐
For broadcast untarped applications, a disc or similar equipment will be used to uniformly mix the soil to at least a depth of 3 to 4 inches to eliminate the chisel or plow traces and will following elimination of the chisel trace, the soil surface will be compacted with a cultipacker, ring roller, and roller in combination with tillage equipment.	☐
For performed bed applications, the soil will be sealed by disruption of the chisel trace using press sealers, bed shapers, cultipackers, or by re-shaping (e.g., relisting, lifting, replacing) the beds immediately following injection.	☐
For beds formed at the time of application, the soil will be sealed by disrupting the chisel trace using press sealers, or bed shapers.	☐
For shanked bedded and broadcast applications, tarps will be installed immediately after fumigant is injected into the soil.	☐
Applicators have been trained and instructed not to apply or allow fumigant to drain onto the soil surface.	☐
For each injection line a check valve been located as close as possible to the final injection point, or applicators will drain/purge the line of any remaining fumigant prior to lifting injection shanks from the ground.	☐
Applicators have been trained and instructed not to 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.	☐
Brass, carbon steel, or stainless steel fittings must be used throughout application rigs.	☐
Polyethylene tubing, polypropylene tubing, Teflon® tubing or Teflon® -lined steel braided tubing have been used for all low pressure lines, drain lines, and compressed gas or air pressure lines and is all other tubing Teflon® -lined steel braided.	☐
Application equipment been inspected to ensure that application rigs do not contain galvanized, PVC, nylon, or aluminum pipe fittings.	☐
All rigs 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.	☐
All rigs include a flowmeter or a constant pressure system with orifice plates to insure the proper amount of fumigant is applied.	☐
Applicators have been trained and instructed to 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).	☐
Application rigs are equipped with properly functioning check valves between the compressed gas cylinder or compressed air system and the fumigant cylinder.	☐
Applicators have been trained and instructed to 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, applicators have been trained and instructed to: ° 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.	☐
Applicators have been trained and instructed to: ° 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. ° Calibrate all application equipment and ensure that all control systems must be working properly.	☐
Hot Gas Applications (check here if section is not applicable ☐)	
Tarps have been installed prior to starting the application.	☐
All delivery tubes have been placed under the tarp in such a way that they do not move during the application of methyl bromide.	☐
The fumigant will be introduced from outside of the greenhouse.	☐
All fittings, connections, and valves have been checked for leaks prior to fumigation and if cylinders are replaced during the fumigation process, the connections and valves were checked for leaks prior to continuing the job.	☐
Tree Replant (non-shank) Application (check here if section is not applicable ☐)	
For each individual tree-site, the tree stump and primary root system have been removed and the tree hole has been backfilled with soil before application.	☐
The fumigant will be injected at a depth of at least 18 inches into the soil.	☐
The wand will be cleared using nitrogen or compressed air before removing it from the soil and after the wand is cleared and removed from the soil, the injection hole will be covered with soil and tamp or the soil will be compacted over the injection hole.	☐
Buffer Zones	
There are no difficult to evacuate sites within ¼ (or ⅛) miles of the application block that will be occupied during the buffer zone period.	☐
There are no bus stops or other locations where persons wait for public transit within the buffer zone.	☐
There are no buildings used for storage such as sheds, barns, garages, within the buffer zone that are occupied or that share a common wall with an occupied structure.	☐
For areas in the buffer zone that are not under the control of owner/operator of the application block, written agreement has been obtained from occupants that they will voluntarily vacate the buffer zone during the entire buffer zone period.	☐
For nearby agricultural areas that are in the buffer zone the owner/operator of that property provided written agreement that they, their employees, or other persons will stay out of the buffer zone during the entire buffer zone period.	☐
For publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields) written permission has been given to include the public area in the buffer zone from the appropriate local and/or state officials.	
Buffer Zones Overlap (check here if section is not applicable ☐)	☐
A minimum of 12 hours has elapsed from the time the 1st application ends until the 2nd application begins.	☐
If a structure exists within 300 feet of the buffer zone, appropriate emergency preparedness and response procedures are followed.	☐
Certified applicator has informed handlers of the overlapping buffers and associated health protection requirements.	☐
Personal Protective Equipment for Handlers	
At least 1 air rescue device (e.g., SCBA) is on-site in case of an emergency.	☐
All of the handler's PPE has been cleaned and maintained as required by the WPS for Agricultural Pesticides.	☐
Hazard Communication	
The application area buffer zone has been posted in accordance with the label.	☐
Pesticide product labels and material safety data sheets are on-site and readily available for employees to review.	☐
Recordkeeping	
The owner/operator of the application block has been informed that he/she as well as the certified applicator must keep a signed copy of the site-specific FMPs and the post-application summary record for 2 years from the date of application.	☐

I have verified that this site-specific FMP reflects current site conditions and product label directions before beginning the fumigation.

_____ _____

Signature of certified applicator supervising the fumigation **Date**

Post-Application Summary

General Application Information		
		Size of application block:

Weather Conditions

Summary of the weather on the day of the application:

Summary of the weather during the 48-hour period following the fumigant application:

Soil Conditions (check here if section is not applicable ☐)

Soil temperature if air temperatures were above 100 degrees F in any of the 3 days prior to the application:

Tarp Damage and Repair (check here if section is not applicable ☐)

Location and size of tarp damage:

Description of tarp/tarp seal/tarp equipment failure:

Date and time of tarp repair:

Additional comments or other deviations from FMP (if applicable):

Tarp Removal (check here if section is not applicable ☐)

Description of tarp removal (if different than in the FMP):

	Date tarps were removed:

Complaints (check here if section is not applicable ☐)

Person filing complaint: ☐ On-site handler ☐ Person off-site	If off-site person, name, address, and phone number of person filing complaints:

Description of control measures or emergency procedures followed after complaint:

Additional comments:

Description of Incidents (check here if section is not applicable ☐)	
	Date and time:
Description of emergency procedures followed:	
Additional comments:	

Elevated Air Concentration Levels (check here if section is not applicable ☐)		
☐ On-site ☐ Outside buffer zone	Location of elevated air concentration levels:	Date and time:
Description of elevated air concentration levels: (provide air monitoring results on next page)		
Description of control measures or emergency procedures followed:		
Description of deviations from FMP (if applicable):		

Posting Signs
Date of sign removal:
Description of deviations from FMP (if applicable):

Other
Additional comments/notes:

Air Monitoring Results

When Respiratory Protection is Not in Use – Sensory Irritation Experienced (check here if section is not applicable ☐)				
Date and Time	**Handler Task/Activity**	**Handler Location Where Irritation Was Observed**	**Resulting Action**	**Comments**
			☐ Cease operations ☐ Respiratory protection	
			☐ Cease operations ☐ Respiratory protection	
			☐ Cease operations ☐ Respiratory protection	
			☐ Cease operations ☐ Respiratory protection	
			☐ Cease operations ☐ Respiratory protection	

When Respiratory Protection is in Use – Direct Read Instrument Air Monitoring (check here if section is not applicable ☐)							
Sample Type	**Sample Number**	**Sample Date/Time**	**Handler Task/Activity (not applicable for structural monitoring)**	**Handler Location/ Structure Location**	**Air Concentration**	**Sampling Method**	**Comments (e.g., sensory irritation experienced while wearing respirator)**
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							
☐Area ☐Breathing Zone ☐Structure							

I have verified that this post application summary reflects the actual site conditions during the fumigation and an accurate description of deviations from the FMP (if applicable).

____ ____________________________________

Signature of certified applicator supervising the fumigation **Date**

APPENDIX D
Technical Support Documents

Appendix D. 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.
36. Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery (DP#363546). May 13, 2009.

37. Process for Defining High-Use Fumigation Areas at the State and County Levels (DP#364647) May 14, 2009.
38. Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 &039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits. May 14, 2009.

Response to Comments

39. HED Component of Response To Comments Document On Methyl Bromide Phase 5 Fumigant Risk Assessment (DP Barcode 353907).
40. 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).
41. 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).
42. SRRD's Response to Phase 5 Public Comments for the Soil Fumigants (July 2008).
43. BEAD Response to Stakeholder Comments on Non-CUE Uses of Methyl Bromide and Methyl Bromide Rate Reductions (DP# 363545) (May 7, 2009).
44. Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents (Date May 14, 2009).
45. Response to Public Comments on the 7/9/08 Completed Methyl Bromide RED. (Rothman, G. and Felkel, J. March 3, 2009).
46. Response to BEAD Related Public Comments Received on the Reregistration Eligibility Decision for Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide (DP# 363545) May 14, 2009.
47. SRRD's Response to Post-RED Comments for the Soil Fumigants (May 27, 2009).