United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508P)

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Amended Reregistration Eligibility Decision (RED) for the Methyldithiocarbamate Salts (Metam-sodium, Metam-potassium) and Methyl Isothiocyanate (MITC)

Amended Reregistration Eligibility Decision (RED) Document

for

Methyldithiocarbamate Salts (Metam-sodium, Metam-potassium) and Methyl Isothiocyanate (MITC)

List B

Case Nos. 2390 and 2405

Approved by: Richard P Keigwin, Jr

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Date: 5/27/09

Glossary of Terms and Abbreviations

1,3-D	1,3-dichloropropene
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARS	Agricultural Research Service
BCF	Bioconcentration Factor
BEAD	Biological and Economic Analysis Division
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
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
GAP	Good Agricultural Practice
GLN	Guideline Number
ha	Hectare
HC	Human Concentration
IR	Index Reservoir
ISCST3	Industrial Source Complex Short Term (model)
K_d	Dissociation Constant
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern

LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
MAT	Maximum Air Temperature
MBAO	Methyl Bromide Alternatives Outreach
MITC	Methyl Isothiocyanate
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MST	Maximum Soil Temperature
MOA	Mode of Action
MOE	Margin of Exposure
mph	Miles Per Hour
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MSDS	Material Safety Data Sheet
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OECD	
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product-Specific Data Call-in
PDP	USDA Pesticide Data Program
PERFUM	**P**robabilistic **E**xposure and **R**isk Model for **Fum**igants
PF	Protection Factor
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Pesticide Root Zone Model/Exposure Analysis Modeling System (Tier II Surface Water Computer Model)
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture

USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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Abstract

This document presents EPA's amended decision regarding the reregistration eligibility of the currently registered soil, sewer root control, and antimicrobial uses of metam-sodium, the soil and antimicrobial uses of metam-potassium, and the antimicrobial uses of methyl isothiocyanate (MITC). 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 metam-sodium and metam-potassium have not changed. In addition, all measures established in the July 2008 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 metam-sodium and metam-potassium for these 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.

Generally, registered metam-sodium and metam-potassium application/fumigation uses fall into four basic categories that include: (1) use as an agricultural soil fumigant for all food, feed, and fiber crops; (2) use on golf course turf and for application to small areas of turf and soil; (3) use as a root-control agent in drains and sewers; and (4) use for a number of antimicrobial and industrial uses, including treatments for sugar (raw beets and cane sugar) processing facilities; leather; sewage, sludge, and animal waste; cooling water facilities; industrial water purification facilities; paints and coatings; petroleum operations; and remedial wood treatment. MITC is registered as an active ingredient for only one use, as an antimicrobial agent for remedial wood treatment.

Concurrent to EPA's review of the soil fumigant uses of metam-sodium and metam-potassium, EPA assessed the risks and developed risk management decisions for four other soil fumigant pesticides, including: chloropicrin, dazomet, methyl bromide, 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; its risk management decision 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.

EPA has identified potential human health risks of concern associated with the registered soil fumigant uses of metam-sodium and metam-potassium from acute inhalation exposure to handlers, bystanders, and re-entry workers. To reduce these exposures and to address subsequent risks of concern, EPA is requiring a number of mitigation measures, such as classifying some metam-sodium and metam-potassium products as restricted use, use-site restrictions, buffer zones, posting, emergency preparedness and response, monitoring and respiratory protection, restrictions on the timing of tarp perforation and removal operations, entry prohibitions,

mandatory good agricultural practices (GAPs), fumigant management plans (FMPs), and training and outreach programs. Please note that only metam-sodium and metam-potassium soil and sewer use products and the MITC use for remedial treatment of wood poles and timbers will be classified as restricted use pesticides.

The Agency has identified slight exceedance of the cancer level of concern to applicators associated with the registered sewer root control use of metam-sodium. The Agency also has identified concerns due to potentially harmful downstream effects of metam-sodium on denitrifying bacteria and the associated disruption to downstream sewage treatment facilities. To reduce applicator exposures, the Agency is requiring additional personal protective equipment (PPE), including chemical-resistant gloves, double layer clothing, and a 90% protection factor respirator approved for MITC. To reduce the potentially harmful effects of metam-sodium on denitrifying bacteria at downstream sewage treatment facilities, the Agency will be requiring additional label language requiring notification of downstream wastewater facilities before a metam application takes place.

The Agency also has identified potential human health risks of concern associated with the registered antimicrobial uses of metam-sodium, metam-potassium, and MITC. To reduce these exposures, the Agency is requiring a number of mitigation measures, such as additional labeling language for remedial wood treatment and amended labeling for the cooling tower and sewage sludge/animal waste uses. In addition, the Agency will be calling in air concentration monitoring data for all enclosed facilities that use metam-sodium and metam-potassium.

The Agency is issuing this amended decision document for metam-sodium, metam-potassium, and MITC, as announced in a Notice of Availability published in the *Federal Register*.

I. Introduction

This amends and supersedes the document, "Reregistration Eligibility Decision for Methyldithiocarbamate Salts (Metam-sodium, Metam-potassium) and Methyl Isothiocyanate (MITC)," 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 FIFRA. EPA received requests to extend the comment period from the Methyl Bromide Industry Panel (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 metam-sodium and metam-potassium (EPA-HQ-OPP-2005-0125) at www.regulations.gov. EPA has determined that the modifications described herein will achieve the same protection goals for persons potentially exposed to metam-sodium and metam-potassium and MITC but with a greater likelihood of compliance, fewer impacts on the benefits of metam-sodium and metam-potassium and MITC use, and with less uncertainty regarding the protectiveness of the required measures. Please see table 1 for modification from the 2008 RED to the 2009 amended soil fumigant REDs.

Note: Washington State University has submitted studies to quantify the flux rate for metam-sodium and metam-potassium from shank injection applications and from center pivot applications using a drizzle boom in the Pacific Northwest. These studies were submitted in April, 2009, and are currently in review. If these studies indicate that the buffer zones for these types of applications should be modified, the Agency will update the buffer tables prior to implementation of new labeling related to buffers for metam sodium in 2011. The results of these studies have not been included in this amended document.

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

Mitigation	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% for chloropicrin and methyl bromide, metam-sodium and metam-potassium, and 40% for dazomet
Structures within Buffer Zones	Monitor with devices before reentry	Monitor for sensory irritation before reentry
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
Restriction for Difficult to Evacuate Sites	1/4 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 1/4 mile restriction but allow a reduced restricted area of 1/8 mile for applications with smaller buffers (300 feet or less); is to be in effect during the application for 36 hours following the application
Posting	Posting required at buffer zones points of entry,	The posting requirement is retained but no longer requires areas between the entry

Mitigation	2008 REDs	2009 Amended REDs
	where people are likely to approach, and areas between these locations	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 required to remove respirators Monitoring with devices 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
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 soil fumigant uses of metam-sodium and metam potassium, and MITC use for remedial treatment of wood poles and timbers are required to be classified as restricted use	No change
Good Agricultural Practices (GAPs)	Certain GAPs required for all fumigant applications	Some clarifications and refinements have been made based on stakeholder comments
Fumigant Management Plans (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	Same basic measures Monitoring required only during peak emission times of the day; irritation detection acceptable for MITC and

Mitigation	2008 REDs	2009 Amended REDs
	monitored every 1-2 hours over 48 hours with monitoring devices	chloropicrin in lieu of devices; methyl bromide requires devices
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 & 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 for the antimicrobial uses and the soil fumigant uses. 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. The table 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 (for soil uses of metam-sodium and metam-potassium, and MITC use for remedial treatment of wood poles and timbers only)		●	●
New Good Agricultural Practices		●	●
Rate reductions		●	●
Use site limitations		●	●
New handler protections		●	●
Tarp cutting and removal restrictions		●	●
Extended worker reentry restrictions		●	●

Risk Mitigation Measure	Currently	2010	2011
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

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

This document presents the Agency's amended reregistration eligibility decision for all the registered uses of metam-sodium, metam-potassium, and methyl isothiocyanate. Metam-potassium and metam-sodium are non-selective fumigants with fungicidal, herbicidal, insecticidal, and nematicidal properties. Metam-sodium and metam-potassium are converted to MITC in the environment, particularly in the presence of moisture (such as in soil after application). It is MITC that performs the fumigating activity. Metam-sodium and metam-potassium have soil fumigant and antimicrobial uses, metam-sodium is also used as a root control agent in sewers and drains, and MITC is registered as an antimicrobial agent for treating wood poles and pilings. Separate risk assessments and analyses were developed for the soil fumigant, sewer root control, and antimicrobial uses of metam-sodium, metam-potassium, and MITC. To clearly present EPA's decision regarding these uses, each use will be discussed in separate sections of this reregistration eligibility decision (RED).

As a result of this review, the Agency has determined that certain uses of (1) metam-sodium (including use as a pre-plant soil fumigant in certain crops, specified later in this document, and as a root control agent in sewers and drains, and as an antimicrobial agent to treat wood poles and timbers and sewage sludge and animal waste); (2) metam-potassium (including use as a pre-plant soil fumigant in certain crops, specified later in this document, and as an

antimicrobial agent for treatment of pulp and paper, tanning drum leather applications, recirculating cooling water systems, and industrial water purification systems); and (3) MITC (for use as an antimicrobial agent to treat wood poles and pilings) are eligible for reregistration (see Appendix A), provided the risk mitigation measures outlined in this document are adopted, label amendments are made to reflect these measures (see the label table in Section V of this document), and data are developed to assess intermediate- and long-term risk to bystanders.

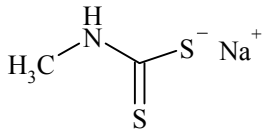
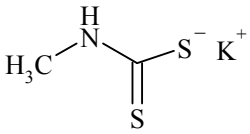
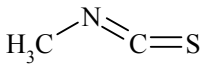
This document consists of five sections. Section I contains the regulatory framework for reregistration and a synopsis of modifications from the July 2008 RED. Section II provides a profile of the use and usage of the chemical. Section III provides a general fumigant overview and also the metam-sodium, metam-potassium, and MITC 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 metam-sodium and metam-potassium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

II. Chemical Overview

A. Chemical Identity

Both metam-sodium and metam-potassium are the active ingredients that make up reregistration case 2390 for the methyldithiocarbamate salts. The primary degradate of both metam-sodium and potassium is methyl isothycyanate (MITC), which is the active ingredient that makes up reregistration case 2405.

Table 3. Methyldithiocarbamate Salts & Methyl Isothiocyanate Nomenclature

Chemical Structure:			
Empirical Formula:	$C_2H_4NS_2Na$	$C_2H_4NS_2K$	C_2H_3NS
Common Name:	Metam-sodium	Metam-potassium	Methyl isothiocyanate
CAS Registry Number:	137-42-8	137-41-7	556-61-6
OPP Chemical Code:	039003	039002	068103
Case Number:	2390	2390	2405
Technical or Manufacturing-Use Registrants	Douglas Products and Packing Company; IBC Manufacturing Co.; Buckman Laboratories Inc.; AMVAC Chemical Corporation; Drexel	Buckman Laboratories Inc.; Athea Laboratories Inc.; Taminco Inc.; Tessenderlo Kerley, Inc.	MLP International (Landis International, Inc.); Osmose Utilities Services, Inc.

	Chemical Co.; Loveland Products, Inc.; Taminco Inc.; BASF Sparks LLC; Tessenderlo Kerley, Inc.; Sewer Sciences, Inc.; Osmose Utilities Services, Inc.		

B. Use Profiles

Pesticide Type: Metam-sodium and metam-potassium are broad-spectrum fumigants with fungicidal, bactericidal, algicidal, herbicidal, insecticidal, nematicidal, and antimicrobial properties. They are dithiocarbamate salts that break down quickly in the environment to the primary toxic degradate, methyl isothiocyanate. MITC is highly volatile and is responsible for the fumigant properties of metam-sodium and metam-potassium.

1. Soil Use

Target pests: Metam-sodium and metam-potassium are used on a wide range of pests including fungi, plants, insects, and nematodes.

Use patterns: Metam-sodium and metam-potassium are registered: (1) as an agricultural soil fumigant for use on all food, feed, and fiber crops and (2) for use on golf course turf and for application to small areas of turf and soil.

Formulations: Three formulation classes—liquid, soluble concentrate, and ready-to-use—are registered for metam-sodium and metam-potassium. Most metam-sodium products are registered for general use. Only the metam-sodium products registered specifically for use on golf courses and for use on small areas of turf and soil are classified as "restricted use." 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. No metam-sodium products are intended for use by homeowners.

Methods of Application: In agricultural settings, metam-sodium and metam-potassium are applied through chemigation or with tractor-drawn equipment. Chemigation methods include sprinkler irrigation (which accounts for 90% of irrigation applications), drip irrigation, flood irrigation, and furrow irrigation. Tractor-drawn applications are carried out with various types of shank soil injection, rotary tiller, and spray blade injection equipment. Drip/trickle irrigation and tractor-drawn applications can be either tarped or untarped. Applications to smaller areas can be made with handheld equipment, including sprinkler cans,

	hose proportioners (hose-end sprayers), or power sprayers (handgun sprayers). Metam-sodium/potassium applications to potting soil may be made by adding the chemical to soil in a cement mixer or by spraying it onto a soil stream as soil is ejected from a shredder
Application Rates:	The maximum application rate listed on most product labels for application to ornamentals; turf; and food, feed, and fiber crops is 320 pounds of active ingredient per acre (lbs ai/A). Tobacco plant beds have a maximum application rate of 387 lbs ai/A on most product labels, but at least one product lists a rate as high as 412 lbs ai/A. For small areas of ornamentals, food and fiber crops, seed beds, plant beds, and lawns, the maximum application rate is 12 lbs ai/1000 square feet.
Annual Usage in the U.S.:	Approximately 51-55 million pounds of metam-sodium and 1-2 million pounds of metam-potassium used in the U.S. in 2002.

2. Sewer Use

Target pests:	Metam-sodium is used as a root control agent for use in sewers and drains.
Use patterns:	Metam-sodium is classified as a restricted use product as a root-control agent in drains and sewers.
Formulations:	Three formulation classes—liquid, soluble concentrate, ready-to-use—are registered for metam-sodium. All metam-sodium products for sewer use are classified as restricted use pesticides. 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:	In sewer use applications, metam-sodium is applied using a foam applicator.
Application Rates:	For sewers and drains, the maximum application rate is 0.212 lbs ai/gallon of solution.

3. Antimicrobial Use

Target pests:	The antimicrobial uses of metam-sodium, metam-potassium, and MITC are used to control a number of microbiological pests, including bacteria and fungi.
Use patterns:	• Metam-sodium is registered as an antimicrobial agent for: (1) wood poles/timbers, (2) leather processing (e.g., brine-cured hides and skins), (3) raw cane and beet sugar processing facilities, and (4) sewage sludge/animal wastes. • Metam-potassium is registered as an antimicrobial agent for: (1) pulp and paper production, (2) leather processing, (3) raw cane and beet sugar processing facilities, (4) coatings (protective colloids, emulsion resins, and water-thinned paints), (5) metalworking cutting fluids and oils, (6)

petroleum operations, (7) water cooling tower systems, and (8) industrial water purification systems.

- MITC is registered as an antimicrobial agent for wood poles and pilings.

Formulations: Two formulation classes—soluble concentrate and ready-to-use—are registered for metam-sodium and metam-potassium. MITC is formulated as a solidified-melt, where it is a solid at ambient conditions and melts and vaporizes at elevated temperatures found within the pole being treated.

Methods of Application: The antimicrobial uses of metam-sodium, metam-potassium, and MITC have a number of application methods, including open pour and manual application of pre-filled tubes of solidified-melt product for treatment of wood poles and pilings; metering pump for pulp and paper, leather, cooling water towers, and industrial water purification; and metered injection for animal waste and sewage sludge treatment.

C. Regulatory History

Metam-sodium (PC Code 039003) and metam-potassium (PC code 039002) are included in pesticide reregistration case number 2390. Currently, there are 39 registered products containing metam-sodium and 16 registered products containing metam-potassium. Metam-sodium and metam-potassium are broad-spectrum fumigants with fungicidal, herbicidal, insecticidal, bactericidal, algicidal, and nematicidal properties.

Metam-potassium was first registered in the United States in 1973 as a fungicide, a bacteriostat, and a microbicide in a variety of commercial and industrial applications, such as pulp and paper mills, cooling tower waters, metalworking cutting fluids, and adhesives. In 1994, the use of metam-potassium expanded to include food and feed uses when used as a soil fumigant.

Metam-sodium was first registered in the United States in 1975. Metam-sodium is one of the most widely used agricultural pesticides in the United States and is presently registered on a wide variety of food and feed crops. Metam-sodium is also registered for a variety of antimicrobial and industrial uses.

Metam-sodium and metam-potassium are converted to MITC in the environment, particularly in the presence of moisture. It is MITC that performs the fumigating activity. It is the volatility of metam-sodium in the environment and the results of metabolism studies in plants that allow the Agency to conclude that there is no reasonable expectation of finite residues to be incurred in/on any raw agricultural commodity when these products are applied according to label directions. Therefore, this fumigant does not require the establishment of food tolerances.

A Phase IV data call-in (DCI) was issued for metam-sodium and metam-potassium in September 1991 and included data requirements for ecotoxicity, toxicology, environment fate,

and residue chemistry. Metam-sodium also was included in the October 1995 agricultural reentry DCI.

Since metam-sodium and metam-potassium are converted to MITC in the environment, this RED will also include MITC. MITC (PC code 068103) is in case number 2405. Products containing MITC were first registered in 1984 as a soil fumigant with food and non-food uses.

A Phase IV DCI was issued for MITC in July 1991 and included data requirements for ecotoxicity, toxicology, environment fate, and residue chemistry. In response to this DCI, the registrants canceled all remaining food uses in 1992. Currently, the only two remaining products containing MITC are for use on wood pilings, utility poles, and timbers for control of wood rot and decay due to fungal activity. Both products are classified as restricted use.

III. Metam-sodium and Metam-potassium Risk Assessments

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).

1. Human Health Risk

The main risk of concern for handlers, workers, and bystanders associated with the soil uses of metam-sodium and metam-potassium is from acute inhalation exposure as a result of fumigant off-gassing. Metam-sodium and metam-potassium handlers also are at risk from direct fumigant exposure during applications. The term *handler* refers to persons involved in the application. 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.

In addition to the soil use of metam-sodium and metam-potassium, there are other uses that the Agency has assessed and included in this RED: (1) metam-sodium as a root control agent in sewers and drains and as an antimicrobial agent to treat wooden poles, timbers, sewage sludge, and animal waste; (2) metam-potassium as an antimicrobial agent for treatment of pulp and paper, leather tanning drum, recirculating cooling water systems, and industrial water purification systems; and (3) MITC as an antimicrobial agent to treat wood poles and pilings.

When metam-sodium and metam-potassium are applied and mixed with moist soil or water, they are quickly broken down into several strong irritant products. One of these products

is MITC, which accounts for most of the fumigant activity. Based on monitoring data, it is clear that bystander exposures to concentrations of MITC in the air after a metam-sodium/potassium application are possible. Therefore, the focus in assessing inhalation bystander and occupational exposures resulting from metam-sodium/potassium applications is on concentrations of MITC.

Estimating exposure to fumigants is different from non-fumigant pesticides due to fumigants' volatility and thus, 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.

The human health risk assessment indicates that acute inhalation exposures to MITC of 22 ppb or greater for a 1 to 8 hour time period for non-occupational (residential) bystanders and occupational handlers could potentially pose risks of concern. The 22 ppb concentration is based on a reversible endpoint from a human eye irritation and odor threshold study for acute exposures to MITC. The lowest observable adverse effect level (LOAEL) was 800 ppb, and the human concentration (HC) based on the No Observable Adverse Effect Level (NOAEL) from this study is 220 ppb. The NOAEL of 220 ppb being used by EPA is similar to a benchmark concentration level of 200 ppb submitted by the group Toxicology Excellence in Risk Assessment (TERA) on behalf of the metam-sodium and metam-potassium registrants. The benchmark concentration analysis thus supports the Agency's toxicity endpoint. Since the study is a human exposure study for acute eye exposure to MITC, the standard 10X for animal to human extrapolation is not needed. However, a 10X human variability uncertainty factor for MITC was included, which when applied to the HC, results in the target concentration for acute inhalation exposures of 22 ppb.

California Pesticide Illness Surveillance Program data from 1992-2003 confirm that eye effects from MITC exposure as seen in this human study provide a sensitive endpoint for regulating acute inhalation exposures. In many incident cases, people complain of eye effects. However, many reported cases also report systemic or respiratory effects, and a few have effects without eye irritation. Compared to eye irritation, the systemic and respiratory effects are more adverse in nature. Unfortunately, the available toxicity data in animals or humans do not allow a

quantitative comparison of the dose response curves of the eye, systemic, and respiratory effects to determine the exact doses at which those effects occur. However, the Agency believes eye irritation provides a surrogate for other toxic effects and thus makes this the appropriate endpoint to regulate. To ensure that this endpoint is protective of any effects from repeated and longer-term exposures, EPA is requiring data to evaluate developmental, reproductive, chronic, and cancer hazards and has encouraged the registrants to pursue additional studies to characterize the dose response curves of different target organs.

The Agency has not revised the 10X human variability uncertainty factor for MITC and the MITC-generating compounds. Agency scientists have carefully reviewed comments provided by the Metam Alliance and TERA that claim a mode of action (MOA) evaluation for MITC and the relative sensitivities of the eyes and lungs to MITC, support an uncertainty factor less than 10X. Upon request by the Metam Alliance, Agency scientists have evaluated the registrant's scientific position [see www.regulations.gov, docket number: EPA-HQ-OPP-2005-0125]. While Agency scientists acknowledge that data are available to formulate a hypothesis for a MOA, currently available data are insufficient to support the key events of the proposed MOA and also to refute other scientifically plausible hypotheses (a step critical in a MOA framework analysis). Moreover, there remains uncertainty with respect to the dose response relationship for sensitive measures of respiratory effects. Thus, given gaps in the existing data for MITC, the Agency is unable to determine, according to existing guidance, that the uncertainty factor can be reduced. If, in the future, additional data are provided, the Agency will re-evaluate the scientific basis for MITC's human variability uncertainty factor.

In assessing risks from metam-sodium and metam-potassium, the Agency considered multiple lines of evidence, using the best available information from monitoring studies, modeling tools, and incident data.

- Monitoring: For the human health risk assessments completed for metam-sodium and metam-potassium 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 metam-sodium and metam-potassium 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 metam-sodium and metam-potassium use at a broad range of distances from treated fields. However, these data are limited in their utility because they provide results only for the specific conditions under which the study was conducted.

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

model and users manual are public domain and can be downloaded at http://www.exponent.com/perfum/.

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

Reconstructing incidents to examine the exact factors that 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 metam-sodium and metam-potassium 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 metam-sodium and metam-potassium soil 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 metam-sodium and metam-potassium applications and tarp perforation/removal activities and for workers who may re-enter the 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, the documents listed below are relevant and available in the metam-potassium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

- 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. May 14, 2009.
- EPA-HQ-OPP-2005-0125-0269, Metam-sodium: Final Revised Chapter of the Registration Eligibility Decision Document (RED); DP Barcode: D293354, Metam-sodium PC Code: 039003, Metam-potassium PC Code: 039002, MITC PC Code 068103. June 24, 2008.
- EPA-HQ-OPP-2005-0125-0261, Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC. (Lowit, A. and Reaves, E.). May 27, 2008.
- EPA-HQ-OPP-2005-0125-0074, Review of Fumigants Group Incident Reports
- EPA-HQ-OPP-2005-0125-0075, Summary Fumigants Group Incident Reports

- EPA-HQ-OPP-2005-0125-0103, Summary of Fumigants Group Incident and Other Data
- EPA-HQ-OPP-2005-0125-0005, Metam-sodium Bystander Risk Assessment Report
- EPA-HQ-OPP-2004-0159-0106, Revised Metam-sodium: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document. (PC Codes 039003 and 068103; DP Barcode D293328)

2. Environmental Fate, Ecological Effects and Risks

The Agency's environmental fate and ecological effects risk assessments indicate that there may be some concerns for non-target organisms that may be exposed to metam-sodium and potassium.

Metam-sodium and potassium degrade rapidly in soil to generate MITC, the volatile biocidal active product. Once MITC volatilizes into the atmosphere, it degrades rapidly due to direct photolysis. The primary concern for metam-sodium is the potential for acute exposure of terrestrial and aquatic organisms to MITC. Exposure to terrestrial organism such as birds and mammals to MITC would likely occur by the inhalation route. Potential exposure to aquatic organisms may occur from surface runoff/leaching and drift (wind) of MITC.

Hazard

Metam-sodium is considered moderately toxic on an acute oral basis to birds (LD_{50} = 211 mg/kg). MITC is considered highly toxic on an acute oral basis to mammals (LD_{50} = 55 mg/kg), and moderately toxic via the inhalation route. Acute inhalation toxicity data with MITC are not available for birds.

MITC is considered very highly toxic to both fish (lowest LC_{50} = 51.2 ppb) and aquatic invertebrates (lowest LC_{50} = 55 ppb).

Exposure

Terrestrial

Exposure of MITC to terrestrial animals was evaluated using the Industrial Source Complex Short Term (ISCST3) model together with information about MITC emissions from a treated field, taking into account the range of MITC concentrations which might be found under different conditions of application rate, weather, source size and shape (e.g., field size in acres) and distance from the treated field.

Aquatic

For MITC exposure to fish and aquatic invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. The aquatic exposure assessment

for MITC relied on Tier II aquatic models. The Pesticide Root Zone Model (PRZM version 3.1.2 beta) simulates fate and transport on the agricultural field, while the water body is simulated with Exposure Analysis Modeling System (EXAMS version 2.98.04). Simulations are run for multiple (usually 30) years and the reported estimated environmental concentrations (EECs) represent the values that are expected once every ten years based on the thirty years of daily values generated during the simulation for selected scenarios.

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 MITC in surface water bodies may be upper bound.

To simulate field application of metam-sodium, multiple scenarios were selected representing metam usage areas based on geography and weather. PRZM and EXAMS models are relevant scenarios were used to estimate MITC EECs in surface water based on label information for metam-sodium application to onions, turf, tomatoes, and potatoes at the highest application rate.

Risk

Terrestrial Risk

A refined analysis using mammal inhalation data and both monitoring and modeling data for air concentrations of MITC do not indicate an acute risk of concern for wild mammals. Avian acute toxicity data via the inhalation route are needed to evaluate risk to birds.

Risk to Plants

There is some uncertainty associated with risk of MITC to non-target plants, given the data gaps for guideline terrestrial plant toxicity data and an incomplete aquatic plant toxicity database. However based on the labeled phytotoxicity of MITC and some incidents, it is expected that at lease some non-target terrestrial plants off site may be at risk from off-gassed MITC.

Aquatic Risk

Acute aquatic levels of concern (LOCs) are slightly exceeded for MITC for both aquatic invertebrates [risk quotients (RQs) range from 0.15 to 0.64] and fish (RQs range 0.16 to 0.69). However, chronic exposure to MITC is expected to be low because of its high potential to volatilize from surface water bodies.

Due to the current data gaps for MITC, the Agency is requiring additional eco-toxicity studies for both terrestrial and aquatic organisms.

For more information on the Agency's environmental fate and ecological effects risk analysis, refer to the document listed below:

- EPA-HQ-OPP-2004-0159-0118, Revised Environmental Fate and Ecological Effects Risk Assessment for Metam-sodium and Metam-potassium. (PC Codes 039003 and 039002; DP Barcode D293339).

3. 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 domestically year-round because severe pest problems can be efficiently controlled. Benefits to crop production from metam-sodium/potassium use accrue either from superior pest control (e.g., tomatoes) or lower production costs (e.g., carrots, onions, peanuts), or both (e.g., cucurbits, peppers, potatoes), as compared to the next best alternative. Commercially feasible alternatives frequently include other soil fumigants such as chloropicrin and 1,3-dichloropropene (or mixtures of both). However, feasibility of using 1,3-dichloropropene as an alternative is limited in California, a major usage region for metam-sodium/potassium, due to local township caps on annual amounts permitted for use across all crops. Alternatives that may become commercially viable in the longer term include dimethyl disulfide (DMDS) and iodomethane, both in combination with chloropicrin. However, in the context of high metam-use sites, these materials are relevant only to cucurbits, peppers, and tomatoes, since these are the only metam-using crops for which registration of either chemical has been approved or is currently under consideration.

The table below (Table 4) summarizes some aspects of the importance of metam-sodium and metam-potassium to crop production in all crops for which benefits assessments were conducted by the Agency and these have not changed from the assessments included as part of the July 2008 RED. For further details, the reader is referred to the impact assessments, carried out by the Biological and Economic Assessment Division (BEAD), which are available in the metam-sodium and metam-potassium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

The economic benefits provided by metam-sodium and metam-potassium use in many of the crops are estimated to be substantial. For example, in potatoes, without metam, growers would likely switch to fumigation with 1,3-dichloropropene and chloropicrin, which is less effective at controlling key soil pests and more costly. BEAD estimates that net operating revenue, the difference between gross revenue and operating costs, would drop about 20% in California and by about 85% in the Pacific Northwest. Net operating revenue is a rough measure of grower income; it does not account for fixed costs of production. The annual regional

economic value of metam-sodium and metam-potassium fumigation is estimated to be about $8 million per year in California and about $48 million per year in the Pacific Northwest.

Taken together, benefits analyses indicate that metam-sodium and metam-potassium use is generally important in a variety of crops, and that if these fumigants could not be used, there would likely be significant negative economic impacts.

Table 4. Summary of benefits to crop production from metam-sodium & metam-potassium

Crop	Likely Alternatives to Metam	Predicted impacts of loss of Metam-sodium/Metam-potassium use
Carrots	1,3-D (with and without chloropicrin), plus various herbicides and fungicides to a much lower extent.	BEAD estimates the benefit of metam-sodium in California carrot production to be about $3.5 million annually resulting from reduced production costs compared to fumigation with 1,3-dichloropropene and applications of other herbicides and fungicides. However, 1,3-dichloropropene is subject to regulatory restrictions in California that may limit its availability for use by carrot growers. If 1,3-dichloropropene were not available to California growers, the benefits of metam-sodium could be as much as $140 million. In California, net operating revenue (NOR) could drop by 17 % if the likely alternative replaces metam-sodium. In Washington, the drop in NOR is estimated at 26%.
Cucurbits	1,3-D (with and without chloropicrin), plus various herbicides and fungicides	Use of metam-sodium to control fungi and nematodes leads to improved yields over fumigation with 1,3-dichloropropene and chloropicrin and substantially reduces production costs, which makes cucurbit production viable in infested areas. The total benefit of fumigating with metam-sodium is about $100 million annually in gross production. NOR for California growers drops by as much as 177% if metam is replaced with the likely alternatives.
Eggplant	1,3-D (with and without chloropicrin)	The benefits of metam-sodium include higher yields and lower costs compared to fumigation with 1,3-dichloropropene and chloropicrin. Benefits range from $290-1,080/acre. The total contribution of metam-sodium to California eggplant production is between $72,500 and $270,000 annually.
Grapes – vineyard replant	1,3-D (with and without chloropicrin),	Metam-sodium appears to be the preferred fumigant for vineyards in Washington and Oregon, saving growers $25-50/acre over fumigation with 1,3-dichloropropene and chloropicrin. For the region, savings range from $16,500-33,000 annually. Metam-sodium may also benefit producers through improved yields over 1,3-dichloropropene alone.
Nursery stock (fruit seedlings and roses)		Metam-sodium is used in nursery stock production throughout the U.S., however, few data are available to permit reliable estimates of area treated or quantity of fumigant used. Soil fumigation in nursery production controls diseases, nematodes and weeds and results in higher yields, higher quality plant production, and lower costs of production. Because of the great diversity of plants and production conditions and a general lack of data, BEAD has not been able to quantify the benefits, but they extend beyond producers to include consumers of nursery products and multiply considerably throughout the various production chains.
Onions	1,3-D (with and without chloropicrin), plus various herbicides and fungicides	Metam-sodium is about $34/acre less expensive than 1,3-dichloropropene and chloropicrin in the production of storage onions in Washington and Oregon, providing costs savings for the region ranging from $393,000 to $537,000 annually.

Crop	Likely Alternatives to Metam	Predicted impacts of loss of Metam-sodium/Metam-potassium use
Ornamentals (floriculture only)	Methyl bromide + chloropicrin, 1,3-D (with and without chloropicrin), plus various herbicides and fungicides	There is ample evidence of that fumigant use increases yield and quality and lowers production costs. Variations in pests and conditions suggest that yield and quality differences would be significant and that metam-sodium plays a critical role. This is especially significant for the propagative sector because changes in the supply of seedling stock would result in magnified changes to future supplies of mature plants and their products.
Peanuts	1,3-D (with and without chloropicrin), aldicarb	The benefits of metam-sodium in peanut production are largely seen in the North Carolina and Virginia areas. NOR for these growers drops by 7% if 1,3D+Chloropicrin replaces metam; NOR drops by about 60% if aldicarb is the replacement.
Peppers	1,3-D (with and without chloropicrin), plus various herbicides and fungicides	Metam-Sodium, and to a lesser extent metam-potassium, improves yields and saves on production costs compared to fumigation with 1,3-dichloropropene and chloropicrin. Use of metam-sodium makes pepper production viable on much of the 1,500 acres in pepper production in California. Total benefits range from $0.5-33.1 million annually. NOR for California growers drops by 15 to 51% if metam is replaced with the likely alternatives.
Pome fruit (apples and pears) – orchard replant	1,3-D (with and without chloropicrin),	Orchards are fumigated at replanting to decrease mortality of young trees, improve growth and speed maturation, and increase yields throughout the lifespan of orchards. While 1,3-dichloropropene and chloropicrin are used more often, on appropriate soils, metam-sodium is often less expensive. In the absence of chloropicrin, metam-sodium would result in improved yields, valued at $92.8 million/year, over use of 1,3-dichloropropene alone. Some portion of the estimated benefits is passed along to consumers.
Potatoes	1,3-D (+ chloropicrin). Approx. 13 % yield loss expected with 1,3-D+Chloropricrin his alternative	The benefits of metam-sodium include yield increases and lower production costs. Overall, the annual benefits of metam-sodium are estimated to be about $800 per acre in California, and about $250 per acre in the PNW, which translates to benefits of about $8 million per year in California, and about $48 million per year in the Pacific Northwest. At the farm level, in California, NOR would drop by 20% and in the PNW, by 85% if metam is replaced by the likely alternatives.
Stone fruit (apricot, cherry, nectarine, peach, plum and prune)	1,3-D (with and without chloropicrin), probably to a lesser extent methyl bromide + chloropicrin	As with pome fruit, orchards are fumigated prior to replanting to better establish new trees, increase survival rates, improve growth and enhance maturity, and increase yields throughout the lifespan of the orchard. On appropriate soils, metam-sodium provides cost savings of about $60/acre over 1,3-dichloropropene and chloropicrin.
Sweet potatoes	1,3-D (with and without chloropicrin), plus various herbicides and fungicides	Without metam-sodium, production of sweet potato would not be viable on nearly 10% of California fields. The benefits of metam-sodium amount to about $5.9 million in sweet potato production annually
Tomatoes	1,3-D (with and without chloropicrin), plus various herbicides and fungicides; methyl bromide + chloropicrin (fresh tomatoes only)	Metam-sodium provides more complete control of pests than does 1,3-dichloropropene and chloropicrin, which results in improved yields and increased revenue of nearly $130/acre. This represents an annual value for metam-sodium of about $7.3 million in California. Major use is in processed tomato production in California. NOR for these growers drops by about 13% if likely alternatives replace metam-sodium.

Note: As part of the response to public comments received on the REDs, the Agency reviewed the need for metam registration in the context of certain specialized situations (such as cover crops), and for specific minor crops (such as seed crops) and concluded that benefits of metam use there were important enough to warrant re-registration. This review is available in the BEAD memo titled "Response to comments on use site restrictions included in the Reregistration Eligibility Decision (RED) for Metam-Sodium and Metam-Potassium (DP # 363544)". This topic is also discussed earlier in this document in the section titled "Rate reduction and Use Sites".

There are a number of benefits assessments that have been completed by the Agency to estimate the value of these chemicals to various industries, which are listed below.

- 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
- Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery (DP# 363546)

4. 2008 RED Mitigation Impacts

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. 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 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.

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. As discussed above, the Agency has provided flexibility on overlapping buffers. Nevertheless, 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, constrain how a field may be divided. 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 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 continues to support a conclusion that metam-sodium and metam-potassium 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 metam-sodium and metam-potassium.

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 duration was estimated to impose the highest direct costs. The Agency estimates that the cost of sampling tubes alone could range from $1000 to over $3000 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. Although many aspects of the RED mitigation will appear on labels in 2010, the Agency will not require buffers until the 2011 growing season.

B. Overview of Sewer Use Risk

Because metam-sodium degrades rather quickly to MITC, short-term, intermediate-term, and chronic inhalation exposures to metam-sodium by workers are expected to be negligible when compared with MITC exposures. To address the short- and intermediate-term MITC inhalation risks from MITC, in the July 2008 metam-sodium metam-potassium RED, the Agency required that any person(s) engaged in any activities that are likely to involve direct contact with metam-sodium (including, but not limited to, mixing, loading, and/or applying metam-sodium; equipment calibration; cleaning and repair of application equipment; entering into treated areas; sampling cleanup spills; and rinsate disposal) wear a half-face respirator with organic vapor cartridge approved for MITC.

While there is insufficient toxicological data to characterize the inhalation cancer risk of MITC, due to limitations in the rat and mouse MITC oral carcinogenicity studies, the Agency anticipates that these new respiratory requirements will adequately address this risk. However, the Agency is requiring additional study data for MITC.

The Agency revised the non-cancer, short- and intermediate-term occupational handler dermal exposure assessments based on the additional usage and occupational exposure information provided by the metam-sodium sewer use registrants. The results of the revised non-cancer, short-term occupational handler dermal exposure assessments for the sewer use of metam-sodium indicate that the MOEs for the dermal risk to handlers with engineering controls (e.g., closed mixing and loading systems) were above or just below the target MOE of 100, and the MOEs for the dermal risk to handlers with full dermal PPE (i.e., chemical resistant gloves and double layer clothing) were above 49, even at the highest daily rates of amount of product handled. In the case of the intermediate-term exposures with full dermal PPE, MOEs were below the target MOE of 100, even with engineering controls. Although not all short- and intermediate-term dermal exposure MOEs reached the target MOE of 100 with the required dermal protection and engineering controls, the occupational handler dermal exposure assessments are considered to be very conservative.

EPA revised its occupational handler dermal cancer assessment for handlers engaged in sewer applications of metam-sodium to control roots in sewer systems based on the additional usage and occupational exposure information provided by the metam-sodium sewer use registrants during the post-RED comment period. The results of the revised cancer occupational handler dermal exposure assessment for the sewer use of metam-sodium indicate that cancer risks for workers in full dermal PPE requirements (i.e., chemical resistant gloves and double layer clothing) and/or those using engineering control technologies (i.e., closed mixing and loading systems) are below the target cancer risk level of between $1x10^{-4}$ to $1x10^{-6}$ for exposed handlers.

Based on the short- and intermediate-term dermal exposure risks to workers, coupled with the worker risks associated with MITC inhalation exposures, the Agency is requiring that any person(s) engaged in any activities that are likely to involve direct contact with metam-sodium, including but not limited to mixing, loading, and/or applying metam-sodium; equipment calibration; cleaning and repair of application equipment; entering into treated areas; sampling cleanup of spills; and rinsate disposal, to wear double-layer clothing, chemical resistant gloves, and a 90% protection factor respirator approved for MITC. To help mitigate these risks, the Agency is also adding a requirement that closed engineering systems for all mixing and loading activities be used.

For more information on the Agency's sewer use risk analysis, refer to the documents listed below (all are available in the metam-sodium docket at www.regulations.gov):

- "Metam Sodium: Third Revision of the HED Human Health Risk Assessment;" May 2009; Charles Smith; Health Effects Division, U.S. EPA.

C. Overview of Antimicrobial Risk

Due to the short loading and/or application durations (i.e., minutes), handlers (i.e., mixers/loaders) are not expected to be exposed to the metam-sodium degradate, MITC. However, the Agency has concerns for potential post-application inhalation exposures to MITC after metam-sodium applications in the leather and/or sugar processing industries and also workers in the vicinity of sewage sludge treatments. The Agency also has concerns for potential post-application inhalation exposures to MITC for workers in the vicinity of metam-potassium applications in the leather, pulp/paper, and sugar processing industries as well as in coatings and metal working fluid manufacturing, oil-field operations, cooling water towers, and industrial water purification facilities because MITC is a highly volatile organic chemical (vapor pressure = 150 mmHg). Furthermore, since metam-sodium and metam-potassium convert to MITC in aqueous media, the Agency also has concerns for the potential MITC inhalation exposures for the machinist who works with metal-working fluids that were preserved with metam-potassium.

For more information on the Agency's antimicrobial use and industrial risk analysis, refer to the documents listed below (all are available in the metam-sodium docket at www.regulations.gov):

- EPA-HQ-OPP-2005-0125-0264, Revised Occupational and Residential/Bystander Assessment of the Antimicrobial Use (Remedial Wood Treatment) of Chloropicrin for the Reregistration Eligibility Decision (RED) Document (Phase 3 Comment Period). PC Code 081501, DP Barcode D314399. February 14, 2008.
- EPA-HQ-OPP-2005-0125-0076, Occupational and Residential/Bystander Assessment of the Antimicrobial Use (Remedial Wood Treatment) of Methyl Isothiocyanate (MITC) for the Reregistration Eligibility Decision (RED) Document
- EPA-HQ-OPP-2005-0125-0077, Metam-potassium: Dietary Risk Assessment of Antimicrobial Uses in Sugar Processing for the Reregistration Eligibility Decision Document
- EPA-HQ-OPP-2005-0125-0078, Metam-potassium: Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document
- EPA-HQ-OPP-2004-0159-0119, Metam-sodium: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document. (PC Codes 039003 and 068103)
- EPA-HQ-OPP-2004-0159-0006, Ecological Risk from Antimicrobial Uses of Metam-sodium to be Considered in the RED
- EPA-HQ-OPP-2004-0159-0017, Metam-sodium: Dietary Risk Assessment of Antimicrobial Uses for the RED

IV. Risk Management and Reregistration Eligibility Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (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 to support reregistration of products containing metam-sodium, metam-potassium, and MITC.

In Phase 5, the Agency published a risk mitigation options paper.[1] This document detailed potential mitigation options and sought public comment on these options. The following is the list of mitigation options discussed in the Agency's paper:

- Buffer zones;
- Sealing methods;
- Timing of applications;
- Application block size limitations;
- Respiratory protection;
- Tarp perforation/removal procedures;

[1] EPA-HQ-OPP-2005-0128-0031, Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications

- Entry-restricted period;
- Application method/practice restrictions;
- Fumigant management plans (FMPs);
- FMP certification;
- Responsible parties;
- Record keeping/reporting/tracking;
- Restricted Use Pesticide Classification;
- Notification and posting;
- Good agricultural practices;
- Fumigant manuals; and
- Stewardship programs.

Based on a review of the metam-sodium, metam-potassium, and MITC databases and public comments on the Agency's assessments for these active ingredients, the Agency has sufficient information on the human health and ecological effects of metam-sodium, metam-potassium, and MITC to make decisions as part of the reregistration process under FIFRA. Further, based on the volatility of metam-sodium, metam-potassium, and MITC and metabolism studies in plants, EPA has concluded that there is a reasonable expectation that no residue on food or feed items will occur with the use of these fumigants. Therefore, no tolerances have been established.

As a result of this review, the Agency has determined that certain uses of (1) metam-sodium (including use as a pre-plant soil fumigant in certain crops, as a root control agent in sewers and drains, and as an antimicrobial agent to treat wood poles and timbers and sewage sludge and animal waste); (2) metam-potassium (including use as a pre-plant soil fumigant in certain crops and as an antimicrobial agent for treatment of pulp and paper, tanning drum leather applications, recirculating cooling water systems, and industrial water purification systems); and (3) MITC (for use as an antimicrobial agent to treat wood poles and pilings) are eligible for reregistration, provided that the risk mitigation measures outlined in this document are adopted, label amendments are made to reflect these measures (as outlines in Section V), and data are developed to assess intermediate- and long-term risk to bystanders. Appendix A summarizes the uses of metam-sodium, metam-potassium, and MITC that are eligible for reregistration.

The Agency's decision takes into account the best available information on the potential risks and benefits of metam use. In reaching its reregistration decision and developing the metam mitigation proposal, EPA considered a range of factors, including: characteristics of bystander and other populations exposed to metam; hazard characteristics of metam-sodium, metam-potassium, and MITC; available information on levels of exposure, feasibility, cost, and effectiveness of various risk mitigation options; incident information; public comments; potential impacts of mitigation on growers ability to produce crops; availability of efficacious alternatives; comparative risks of alternative control methods; and the uncertainties and assumptions underlying the risk and benefit assessments.

Some uncertainty remains associated with intermediate- and long-term exposure and risk to bystanders. To address these uncertainties, EPA is requiring additional data related to both toxicity and exposure. Notwithstanding these uncertainties, the Agency has decided to proceed with its reregistration decision and implementation of mitigation at this time because mitigation implemented to address acute bystander risk will also serve to address intermediate- and long-term bystander risk.

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. To ensure that data are developed and reviewed expeditiously, 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 review.

Voluntary Cancellation of Antimicrobial Uses

On May 15, 2008, the Agency received letters voluntarily cancelling several antimicrobial uses for metam-sodium and metam-potassium. The antimicrobial uses of metam-sodium that were cancelled included: (1) treatment of process waters during the production of sugar (i.e., raw cane and beet sugars) and (2) treatment of brine-cured hides and skins (i.e., leather) during processing, and (3) treatment of sewage sludge and animal waste. The antimicrobial uses of metam-potassium that were cancelled included: (1) the sugar beet and sugar cane use; (2) all leather uses, with the exception of the tanning drum leather use; (3) all paint uses (including the preservation of protective colloids and emulsion resins); (4) all water-based drilling, completion, and packer fluid uses; (5) all petroleum secondary recovery operation uses; (6) all once-through cooling water applications, and (7) all cutting fluids (metalworking fluids) uses. As a result of these cancellations, these uses have not been evaluated in the RED.

The Agency has determined that the remaining registered antimicrobial uses for metam-sodium (i.e., remedial treatment of wooden poles and timbers and treatment of sewage sludge and animal waste), metam-potassium (i.e., use in tanning drum leather, pulp and paper, recirculating cooling water systems, and industrial water purification systems), and MITC (i.e., remedial treatment of wooden poles and timbers) will not pose unreasonable risks or adverse effects to humans or the environment, provided that the risk mitigation measures and label changes outlined in this RED are implemented and, therefore, products containing metam-sodium, metam-potassium, and MITC for these uses are eligible for reregistration.

Based on its evaluation of metam-sodium, metam-potassium, and MITC, the Agency has determined that products containing these chemicals, 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 these chemicals. If all changes

outlined in this document are incorporated into the product labels, then current risks for metam-sodium, metam-potassium, and MITC will be adequately mitigated for the purposes of this determination under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations 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. The Agency responses to Phase 3 public comments related to metam-sodium and metam-potassium soil uses, metam-sodium sewer use, and antimicrobial uses for metam-sodium, metam-potassium, and MITC can be found in the metam-sodium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

EPA revised its risk assessments and developed benefits and risk mitigation options during Phase 4. The Phase 5 public comment period, for revised risk assessments, benefits analysis, and risk management options, lasted from May 2 to November 3, 2007. The Agency responses to Phase 5 public comments related to metam-sodium and metam-potassium soil uses, metam-sodium sewer use, and antimicrobial uses for metam-sodium, metam-potassium, and MITC can be found in the following documents, available in the metam-sodium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

- *The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Dazomet.* (Smith, C., Dated June 2008).
- *Response to Phase 5 Public Comments on the Phase 4 Dazomet Environmental Fate and Ecological Risk Assessment.* (Khan, F., and Felkel, J., Dated April 2, 2008).
- *Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide.* (Donaldson, D. et al., Dated June 2008).
- *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.* (Wyatt, T., et al, Dated June 2008).
- *Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision (RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin.* (Walls, C., Dated February 14, 2008).
- *SRRD's Response to Phase 5 Public Comments for the Soil Fumigants.* (Dated July 2008).

The Agency also opened a 60-day public comment period following the publication of the Metam-Sodium and Metam-Potassium 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 July 2008 RED which may be found in the metam-sodium and metam-potassium docket:

- *Further Response to Public Comments on the 7/9/08 Completed Dazomet RED.* (Dated March 3, 2009).
- *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* (Dated May 14, 2009).
- *Response to BEAD Related Public Comments Received on the Reregistration Eligibility Decision for Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide* (DP# 363545; Dated May 14., 2009).
- *Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery* (DP# 363546; Dated May 13, 2009).
- SRRD's Response to Post-RED Comments for the Soil Fumigants (Dated May 20, 2009).

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that products containing metam-sodium, metam-potassium, and MITC are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. EPA has determined that the modifications to the measures outlined in the July 2008 RED, described herein, will achieve the same protection goals for persons potential exposted to metam-sodium and metam-potassium but with a greater likelihood of compliance, fewer inpacts on the benefits of metam use, and with less uncertainty regarding the protectiveness of the required measures. The following is a description of the rationale for managing risks associated with the use of these fumigants. Where labeling revisions are warranted, specific language is set forth in the label table in Section V of this document.

a. Soil Fumigant Uses of Metam-sodium and Metam-potassium

i. Rate Reduction and Use Sites

While most current labels for metam-sodium and metam-potassium state that 320 lb ai/A is the maximum allowed rate, there are some labels which suggest that calculated rates may be

higher than 320 lb ai/A. To consistently clarify the maximum application rates for pre-plant soil fumigation, label language will be required to specifically state 320 lb ai/A as the upper limit for all application methods. No other rate changes for soil fumigation uses are required in this decision.

1. Use Sites Eligible for Reregistration

In the July 2008 Metam-Sodium and Metam-Potassium RED, the Agency determined the following uses to be eligible for reregistration: asparagus (nursery production only), artichokes, broccoli, brussels sprouts, cabbage, carrot, cauliflower, celery, cucurbits (cucumber, cantaloupe, honeydew, pumpkin, squash, and watermelon), eggplant, forest seedlings, grape (vineyard replant only), lettuce, mint, nursery stock (fruit seedlings and rose bushes only), oranges, onion, pome fruit (apples and pears; orchard replant only), stone fruit (apricot, cherry, nectarine, peach, plum and prune; orchard replant only), ornamentals (floriculture only), peanut, pepper, potato, spinach, strawberries, sweet potato, tobacco, tomatoes, and turf (including golf courses).

This list of crops was based on one or more of the following criteria: (1) the crop showed significant usage of metam-sodium and metam-potassium, as indicated by BEAD usage data, and/or (2) stakeholders for the crop submitted compelling benefits information for metam-sodium and metam-potassium use during the Phase 5 comment period, and/or (3) removal of metam-sodium and metam-potassium use appeared likely to increase use of methyl bromide, which is being phased out under the Montréal Protocol. "Significant usage" was defined as a crop that has more than 5% crop treated annually or more than 1,000,000 lb of metam sodium or metam potassium applied annually.

All other pre-plant uses were to be deleted, unless additional information to support a compelling case for the economic benefits of metam-sodium and metam-potassium was provided. This decision was based on potentially high risk to bystanders from metam-sodium and metam-potassium, coupled with a lack of indication of high economic benefits for crops not included in the group described above.

During the post-RED comment period, the Agency received comments from various stakeholders asking that the Agency consider the eligibility of additional use sites. Key considerations identified during the post-RED comment period included:

- Crops that are typically included as part of a rotational schedule or cover crop regimen. The Agency agrees that limiting the use metam-sodium and metam-potassium may have some unintended consequences. These include preventing good soil erosion management (with cover crops), and magnifying the negative economic impact on growers who have to alter their crop rotation scheme unexpectedly due to, for example, changes in weather conditions or economic considerations, such as contractual agreements with processors. As a result, the following crops, which have been reported to be part of typical rotational schedules for metam users, will be added as eligible use sites: alfalfa, barley, rye, sugar beets, corn, and wheat. In addition, the Agency will add "cover crops," i.e., crops planted between periods of

regular crop production to prevent soil erosion, control weeds, and improve soil quality that are incorporated into the soil before the next crop is planted and may not be harvested for food or feed, to the list of eligible use sites for metam-sodium and metam-potassium.

- Use of metam-sodium and metam-potassium as a potential alternative to methyl bromide for orchard replant of tree nuts, berry crops, ginger, and pineapple. The Agency analyzed the use of soil fumigants for orchard replant of tree nut crops, berry crops (i.e., blueberry, blackberry, raspberry, etc.), ginger, and pineapple and determined that restriction of these uses of metam-sodium and metam-potassium are likely to lead to an increased reliance on methyl bromide. As a result, orchard replant of tree nuts, berry crops, ginger, and pineapple have been added as eligible use sites for metam-sodium and metam-potassium.

- Metam-sodium and metam-potassium use on minor crops. The Agency received comments from stakeholders asking that several minor uses (e.g., arugula, wild rocket, and parsley; grapefruit) of metam-sodium and metam-potassium be considered eligible. While such minor crop uses might not reach the threshold of "significant usage," in cases where the crops mentioned were likely to be similar to others that were retained for reregistration, in terms of the pest management needs and crop production benefits, the Agency made sure to evaluate those uses for eligibility in the RED addendum. Specifically, the Agency is including several of the EPA crop group listings as eligible use sites to provide growers additional flexibility with regard to use site eligibility [for a description of these crop groups, see "Pesticide Tolerances; Revision of Crop Groups, Final Rule, Federal Register Notice, May 17, 1995 (Volume 60, Number 95); http://www.epa.gov/fedrgstr/EPA-PEST/1995/May/Day-17/pr-266.html]. As an example, by including "EPA Crop Group 4, Leafy Vegetables" as an eligible use site, arugula, wild rocket, parsley and a number of other potential minor uses, which are similar to lettuce and spinach in terms of the pest management needs and crop production benefits, become eligible use sites. Further, the Agency is adding "crops grown solely for seed" to the list of eligible use sites, because information from growers and extension agents indicates that, while a minor use, use of soil fumigants on seed crops is important for control of weeds and disease.

- California Department of Pesticide Regulation usage data. In responding to the post-RED comments, the Agency examined the California Department of Pesticides (CDPR) pesticide usage data for recent years (2003-2006), since the state generally is a significant user of metam-sodium and metam-potassium products and is a major producer of a diverse array of crops that may rely on soil fumigation, to ensure that it did not miss any important uses of metam. Based on these data, it appears that there are few crops not already deemed eligible for reregistration that do not meet the criterion of 5% or more of the crop acreage treated annually. Only seven additional crops, including sweet basil, Chinese greens (often a synonym for bok choy), celeriac (a member of the celery family), collard, dill, leeks, and Swiss chard, were identified as having 5% or more of the crop treated in at least one year during the time period studied. Based on this analysis, the Agency is adding these seven additional to the list of eligible use sites for metam-sodium and metam-potassium.

Based on the original criteria for determining eligible use sites (see above) as well as the comments and additional information received during the post-RED comment period, the EPA has determined that the following expanded list of metam-sodium and metam-potassium use sites are eligible for reregistration. All other pre-plant uses are to be deleted, and product labels must be amended to reflect use only on the crops specified as eligible for reregistration.

- Alfalfa,
- Asparagus (nursery production only),
- Artichokes,
- Barley,
- Basil,
- Beet,
- Berries, [includes all EPA Crop Group 13, Berries Group, i.e., blackberry (*Rubus eubatus*); bingleberry; black satin berry; boysenberry; Cherokee blackberry; chesterberry; Cheyenne blackberry; coryberry; darrowberry; dewberry; Dirksen thornless berry; Himalayaberry; hullberry; lavacaberry; lowberry; lucretiaberry; mammoth blackberry; marionberry; nectarberry; olallieberry; Oregon evergreen berry; phenomenalberry; rangeberry; ravenberry; rossberry; Shawnee blackberry; youngberry, and varieties and/or hybrids of these; blueberry (*Vaccinium spp.*); currant (*Ribes spp.*); elderberry (*Sambucus spp.*); gooseberry (*Ribes spp.*); huckleberry (*Gaylussacia spp.*); loganberry (*Rubus loganobaccus*); raspberry-black and red (*Rubus occidentalis*, *Rubus strigosus*, *Rubus idaeus*)],
- Broccoli,
- Brussels sprouts,
- Cabbage,
- Carrot,
- Cauliflower,
- Celeriac,
- Chineese greens or bok choy,
- Cilantro,
- Citrus (orchard replant only), [includes all of EPA Crop Group 10, Citrus Fruits, i.e., calamondin (*Citrus mitis* X *Citrofortunella mitis*); citrus citron (*Citrus medica*); citrus hybrids (*Citrus spp.*) (includes: chironja, tangelo, tangor); grapefruit (*Citrus paradisi*); kumquat (*Fortunella spp.*); lemon (*Citrus jambhiri*, *Citrus limon*); lime (*Citrus aurantiifolia*); mandarin (tangerine) (*Citrus reticulata*); orange, sour (*Citrus aurantium*); orange, sweet (*Citrus sinensis*); pummelo (*Citrus grandis*, *Citrus maxima*); satsuma mandarin (*Citrus unshiu*)],
- Collard,
- Corn,
- Cover crops (i.e., crops planted between periods of regular crop production to prevent soil erosion, control weeds, and improve soil quality that are incorporated into the soil before the next crop is planted and may not be harvested for food or feed),
- Crops grown solely for seed,
- Cucurbits [includes all of EPA Crop Group 9, Cucurbit Vegetables Group, i.e., chayote (fruit) (*Sechium edule*); Chinese waxgourd (Chinese preserving melon) (*Benincasa hispida*); citron melon (*Citrullus lanatus* var. citroides); cucumber (*Cucumis sativus*); gherkin (*Cucumis anguria*); gourd, edible (*Lagenaria spp.*) [includes: hyotan, cucuzza (*Luffa acutangula*, *L. cylindrical;* includes hechima, Chinese okra)]; *Momordica spp.* (includes balsam apple, balsam pear, bitter melon, Chinese cucumber); muskmelon [hybrids and/or cultivars of *Cucumis melo* (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango

melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon)]; pumpkin (*Cucurbita spp.*); squash, summer (*Cucurbita pepo* var. melopepo) (includes: crookneck squash, scallop squash, straightneck squash, vegetable marrow, and zucchini); squash, winter (*Cucurbita maxima*; *C. moschata*) (includes: butternut squash, calabaza, hubbard squash) and (*C. mixta*; *C. pepo*) (includes acorn squash, spaghetti squash); and watermelon (includes hybrids and/or varieties of *Citrullus lanatus*)],

- Dill,
- Eggplant,
- Forest seedlings,
- Ginger,
- Grape (vineyard replant only),
- Kale,
- Kohlrabi,
- Leafy greens [includes all of EPA Crop Group 4, Leafy Vegetables (Except Brassica Vegetables), i.e., amaranth (leafy amaranth, Chinese spinach, tampala) (*Amaranthus spp.*); arugula (roquette) (*Eruca sativa*); cardoon (Cynara cardunculus); celery (*Apium graveolens* var. dulce); celery, Chinese (*Apium graveolens* var. secalinum); celtuce (*Lactuca sativa* var. angustana); chervil (*Anthriscus cerefolium*); chrysanthemum, edible-leaved (*Chrysanthemum coronarium* var. coronarium); chrysanthemum; garland (*Chrysanthemum coronarium* var. spatiosum); corn salad (*Valerianella locusta*); cress, garden (*Lepidium sativum*); cress, upland (yellow rocket, winter cress) (*Barbarea vulgaris*); dandelion (*Taraxacum officinale*); dock (sorrel) (*Rumex spp.*); endive (escarole) (*Cichorium endivia*); fennel, Florence (finochio) (*Foeniculum vulgare* Azoricum Group); lettuce, head and leaf (*Lactuca sativa*); orach (*Atriplex hortensis*); parsley (*Petroselinum crispum*); purslane, garden (*Portulaca oleracea*); purslane, winter (*Montia perfoliata*); radicchio (red chicory) (*Cichorium intybus*); rhubarb (*Rheum rhabarbarum*); spinach (*Spinacia oleracea*); spinach, New Zealand (*Tetragonia tetragonioides*, *T. expansa*); spinach, vine (Malabar spinach, Indian spinach) (*Basella alba*); and swiss chard (*Beta vulgaris* var. cicla)],
- Leek,
- Mint,
- Mustard,
- Nursery stock (fruit seedlings and rose bushes only),
- Onion,
- Ornamentals (floriculture only),
- Pome fruit (orchard replant only), [includes all of EPA Crop Group 11, Pome Fruits Group — Commodities, i.e., apple (*Malus domestica*); crabapple (*Malus spp.*); loquat (*Eriobotrya japonica*); mayhaw (*Crataegus aestivalis*, *C. opaca*, and *C. rufula*); pear (*Pyrus communis*); pear, oriental (*Pyrus pyrifolia*); and quince (*Cydonia oblonga*)],
- Peanut,
- Pepper,
- Potato,
- Radish,
- Rye,
- Sugar beet,
- Soybean,
- Stone fruit (orchard replant only), [includes all of EPA Crop Group 12, Stone Fruits Group— Commodities, i.e., apricot (*Prunus armeniaca*); cherry, sweet (*Prunus avium*); cherry, tart (*Prunus cerasus*); nectarine (*Prunus persica*); peach (*Prunus persica*); plum (*Prunus domestica*, *Prunus spp.*);

plum, Chickasaw (*Prunus angustifolia*); plum, Damson (*Prunus domestica spp. insititia*); plum, Japanese (*Prunus salicina*); plumcot (*Prunus. armeniaca X P. domestica*); prune (fresh) (*Prunus domestica, Prunus spp.*)],

- Strawberries,
- Sugar beet,
- Sweet potato,
- Swiss Chard,
- Tobacco,
- Tomatoes,
- Tree nuts (orchard replant only), [includes all of EPA Crop Group 14, Tree Nuts Group (i.e., almond (*Prunus dulcis*); beech nut (*Fagus spp.*); Brazil nut (*Bertholletia excelsa*); butternut (*Juglans cinerea*); cashew (*Anacardium occidentale*); chestnut (*Castanea spp.*); chinquapin (*Castanea pumila*); filbert (hazelnut) (*Corylus spp.*); hickory nut (*Carya spp.*); macadamia nut (bush nut) (*Macadamia spp.*); pecan (*Carya illinoensis*); and walnut, black and English (Persian) (*Juglans spp.*) as well as pistachio],
- Turnip,
- Turf (including golf courses), and
- Wheat

ii. Human Health Risk Management

For details on the metam-sodium and metam-potassium human health risk assessment, please refer to the human health risk assessments and addenda. These documents are also available in the public docket EPA-HQ-OPP-2005-0125, located on-line in the Federal Docket Management System (FDMS) at www.regulations.gov.

Dietary Risk

Based on the currently registered use patterns for metam-sodium and metam-potassium, dietary exposure, including exposure from drinking water, is not expected and no dietary risk mitigation is warranted for metam-sodium and metam-potassium at this time.

Bystanders, Workers, and Handlers

The human health risk assessments indicate that inhalation exposures to bystanders, handlers, and workers who live and work near agricultural fields and greenhouses where metam-sodium/potassium fumigations occur have the potential to exceed the Agency's level of concern without additional mitigation measures. To reduce the potential for metam-sodium and metam-potassium exposure to bystanders, handlers, and workers and to address associated risks of concern, EPA is requiring a number of mitigation measures which include:

- Clarifying maximum application rates
- Clarifying use sites;
- Buffer zones;
- Dermal protection for handlers;

- Respiratory protection and air monitoring for handlers;
- Restrictions on the timing of perforation and removing of tarps;
- Posting;
- Good agricultural practices;
- Fumigant management plans;
- Site specific response and management; and
- Notice to state lead agencies.

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

Some of the required mitigation measures only address one group of potentially exposed individuals (i.e., bystanders, handlers, or workers), while other measures will help reduce risk to more than one group. All mitigation measures are designed to work together to reduce exposures, enhance safety, and facilitate compliance and enforcement. The Agency has based its risk mitigation decision on a flexible approach, which EPA believes will be protective and allow users to make site-specific choices to reduce potential impacts on benefits of the use. While some of these measures, buffer zones for example, can be used to estimate margins of exposure (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.

aa. Bystander Risk Mitigation

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

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

drinking water expect to be safe from possible adverse effects associated with pesticide residues that could be present in their food and drinking water.

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

The mitigation measures for bystander risks resulting from soil fumigation are described further in the following sections.

1. Buffer Zones

The human health risk assessments indicate bystanders may be exposed to MITC air concentrations following metam-sodium and metam-potassium applications 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 metam-sodium and metam-potassium 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 and described below will mitigate risks so that bystanders will not experience unreasonable adverse effects.

The Agency considered various buffer zone schemes ranging from fixed buffer zones for every application to site-specific buffer zones. During the Phase 5 comment period, the Agency received input in favor of a flexible buffer approach that would allow fumigant users to determine the buffer zone distance based on site conditions and application practices. While the Agency believes that site-specific buffer zones would provide the most flexibility for users, the EPA currently does not have sufficient data to support this scheme. As a result, the Agency has developed a scalable buffer zone system that does provide flexibility by setting buffer zones for different application methods at various acreages and application rates.

Version 2.1.4 of the **P**robabilistic **E**xposure and **R**isk model for **Fum**igants (also called the PERFUM model) combined with monitoring data and incident data were used to characterize the risk for specific buffer zone distances corresponding to the range of application scenarios anticipated. Additional information on the PERFUM inputs and outputs can be found in Agency

risk assessment, (EPA-HQ-OPP-2005-0123-0285), in a June 2006 a peer-reviewed article describing the model (http://www.sciencedirect.com/science/journal/13522310), and/or the PERFUM user's guide which can be download from the internet (http://www.exponent.com/perfum/). A CD containing all of the PERFUM input/output files and files with the PERFUM MOE/air concentration analysis that were considered for this decision are available upon request at the OPP Docket Office.

(a) Buffer Zone Requirements

General Requirements in the July 2008 RED

The 2008 metam-sodium and metam-potassium RED described general buffer zone requirements for metam-sodium and metam-potassium 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 ¼ mile 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 metam-sodium and metam-potassium 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 metam-sodium and metam-potassium. 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 (except for transit);
- 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 exemption for transit through buffer zones;
- 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 and adjacent 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, as well as the requirement 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.

Metam only: Applications of metam-sodium and metam-potassium can take place on large fields, typically greater than 80 acres, and may require several days to complete (e.g., via center pivot or lateral move irrigation systems). In situations where such large field sizes are treated the offsite movement of emissions may be proportionately less, on an acre basis, than smaller fields because the fetch (i.e., area over which emissions are diluted) for certain areas of such fields would be either contained totally within the boundaries of the field or it would allow for significant dilution as the emissions move from the application block offsite into the buffer zone. As a result of the time requirements involved in treating such large areas and the reduced per acre contributions to overall emissions on large fields, EPA believes there is less potential for peak emissions from multiple large applications blocks to coincide and result in concentrations of concern outside adjacent buffers within localized areas than would be expected if the situation varied by larger numbers of smaller fields being treated that would more likely result in coincidental peak emissions (e.g., fields that take no more than one day to treat and that are smaller in acreage).

Although current modeling supports a conclusion that as application block size increases, the emissions into the buffer areas are reduced on a per acre basis, the data to support a robust analysis of this relationship is very limited at this time. Based on comments provided, EPA also recognizes that compliance with the prohibition on buffer overlap in areas such as the Pacific Northwest with large-scale production systems based on center pivot applications would be extremely challenging for metam users. EPA also understands that, due to the length of time needed to complete these applications, separating applications by 12 hours is also impractical. EPA also wishes to encourage adoption of improved application techniques such as low release center pivot systems because it believes that their use will reduce the potential for exposures of concern because they reduce droplet drift potential for those in proximity to fields and may reduce application rates as well because of more effective water delivery. Based on these considerations, the Agency has determined that buffer zones may overlap for center-pivot application blocks only if each block is treated using low release center pivot systems which will increase the feasibility of compliance with buffer zone requirements and will not demonstratively alter the protection provided to bystanders.

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.

Metam Only: For Low Release Center Pivot Applications only:

- A buffer zone may NOT overlap buffer zones from other application blocks which are already in effect UNLESS both application blocks are treated using low release center pivot systems. The 12 hour waiting period does not apply in this instance.

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.

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 they may be exposed to.

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. 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 MITC would alert persons reentering these sites if concentrations had not yet dissipated. Therefore, monitoring of buildings and outdoor areas after termination of the buffer zone is not necessary and will no longer be required.

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 measure. The Agency believes that requiring the applicator 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 those 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.

(b) PERFUM Model Inputs

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

Application Rates

The Agency modeled up to 320 lb ai/acre for all metam applications, the maximum application rate permitted on the metam product labels. However, typical application rates vary by crop and geographic region. According to EPA proprietary data for 2004-2005, approximately 94% of metam-sodium was applied at a rate of 225 lb ai/acre or less. OPP's Biological and Economic Analysis Division (BEAD) completed a series of benefits assessments by crop and region that included a more detailed analysis of use rates and are available for review in the metam-sodium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

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. As an example, assume that both fields are 10 acres, and only 50% of field in Figure 2 is fumigated, and the *rate per treated acre* is 400 lbs ai/A for both Figure 1 and 2. In this case, 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% value for proportion of field treated was used in the calculations.]

Figure 1. Broadcast Application

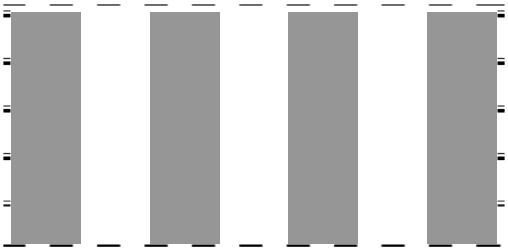


Figure 2. Bedded Application

Application Block Sizes

For all application methods, the Agency modeled up to 120 acres, which is the limit of the PERFUM model. However, typical application block sizes vary by crop and geographic region. In the Pacific Northwest, crops are typically grown in fields averaging 120-acres in size, while crops in California, the upper Midwest, and the Southeast tend to be smaller, typically 10-60 acres, 30-50 acres, and 10-40 acres respectively. OPP's Biological and Economic Analysis Division (BEAD) completed a series of benefits assessments by crop and geographic region that included a more detailed analysis of typical application block sizes, which are available for review in the metam-sodium docket (EPA-HQ-OPP-2005-0125) at www.regulations.gov.

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.

During the post-RED comment period, the Agency received comments requesting buffer zone distances for additional acreage increments for small fields. In response, the Agency determined buffer distances for smaller block sizes (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 acres. 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.

Emission Studies

The Agency's risk assessment for the July 2008 RED included modeling of four pre-plant soil application methods: (1) sprinkler irrigation (with standard[2] and intermediate[3] water seals), (2) shank injection (with standard[1] and intermediate[2] water seals, compaction, and standard

[2] A standard water seal consisted of either a ½ inch of water added immediately after an application and another ½-inch of water applied within 24 hours of the application (chemigation study) or a ½ inch of water applied within 24 hours of the application (shank injection study).

[3] An intermediate water seal consisted of a ¼ inch of water applied immediately after application, two additional ¼-inch water seals applied the same day as the application, as well as three additional ¼-inch water seals applied the day following application.

polyethylene tarps), (3) drip irrigation (with and without standard polyethylene tarps), and (4) flood irrigation. The modeling performed by EPA was based on 14 field volatility studies. The majority of these studies were conducted in California (11), with several also conducted in Florida (2) and Washington (1).

While the Agency considered the modeling data from all 14 emissions studies available, it used a subset of the most representative emissions studies to serve as the basis for developing the buffer zone distances. These studies included: (1) the Bakersfield, CA, sprinkler irrigation study with intermittent water seal (USDA CSREES Project #74; 09/02); (2) the Bakersfield, CA, shank injection study with intermittent water seal (USDA CSREES Project #74; 09/02); (3) the Citra, FL, drip irrigation study with tarps (USDA CSREES Project #74; 02/03); and (4) the Brawley, CA, flood irrigation study (MRID 473143-01). For application methods where the Agency does not currently have emissions study data available, these emissions study profiles also served as surrogate data. The buffer zone distances for all chemigation and the low-release height and low-drift center pivot applications were derived from the sprinkler irrigation emission study profile with intermittent water seal. It should be noted that the Agency does not believe that the sprinkler irrigation study emissions data are representative of the high-release height center pivot application method (which includes use of end guns). However, the Agency has selected buffer zone distances for this application method that it believes are sufficiently protective of bystander risk. Washington State University has submitted studies to quantify the flux rate for metam-sodium and metam-potassium from shank injection applications and from center pivot applications using a drizzle boom in the Pacific Northwest. These studies were submitted in April, 2009, and are currently in review. If these studies indicate that the buffer zones for these types of applications should be modified, the Agency will update the buffer tables prior to implementation of new labeling related to buffers for metam sodium in 2011. The results of these studies have not been included in this amended document and the buffer tables below. EPA is requiring the registrants to submit studies to quantify the flux rate for metam-sodium and metam-potassium from center pivot applications using low-, medium- and high-release equipment, both with and without the use of endguns. The Agency will include the results of this research in its final labeling decisions, if possible.

Based on the site characteristics (i.e., maximum air temperature, maximum soil temperature, field capacity) of the field volatility studies that served as the basis for the buffer zone distances, the profiles modeled for both the sprinkler irrigation (with intermediate water seals) and shank injection (with intermediate water seals) scenarios, were assumed to represent high-end but not necessarily the worst case for metam applications in the U.S. The profiles modeled for both the drip and flood irrigation scenarios, which served as the basis for the buffer zone distances, were assumed to represent more "typical" site characteristics. The Agency believes that several required GAPs, including mandatory soil temperature and soil moisture requirements, will greatly reduce the likelihood that worst case scenarios will occur.

Weather

The largest use of metam-sodium and metam-potassium for soil fumigation in the U.S. occurs in the Pacific Northwest and California, followed by the upper Midwest and the Southeast. Based on these high-use areas, six weather station data sets were modeled (Ventura, CA; Bakersfield, CA; Bradenton, FL; Tallahassee, FL; Flint, MI; and Yakima, WA). Each modeling run used five years of weather data (e.g., 1,825 potential application days) for each location. Generally, Ventura, and Bradenton weather data result in the largest buffer zone distances, followed by Bakersfield and Tallahassee. Flint data result in significantly smaller buffers.

Target Air Concentrations

As described in the Human Health Risks section of Section III, the 22 ppb target air concentration is based on a reversible sensitive endpoint from a human eye irritation and odor threshold study for acute exposures to MITC, with a 10X human variability uncertainty factor for intraspecies extrapolation. The lowest observable adverse effect level (LOAEL) is 800 ppb, and the human concentration (HC) based on the no observable adverse effect level (NOAEL) from this study is 220 ppb.

The Agency focused on achieving an MOE of 10 at upper percentiles of each of the distributions from the PERFUM modeling outputs. However, the buffer zone distances required to achieve this MOE would have been prohibitively large and likely would have been impossible for most growers to implement. The Agency believes that the buffer zone distances being required, in addition to the other mitigation requirements described herein (i.e., restricted use pesticide classification, posting and emergency preparedness procedures for buffer zones, mandatory good agricultural practices, required fumigant management plans, soil fumigant training requirements for applicators and handlers, and ambient air monitoring programs in high-use areas), adequately address the risk of acute fumigant exposure to bystanders and will greatly reduce the magnitude and frequency of exposure incidents.

(c) PERFUM Model Outputs

The PERFUM 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 buffer distances (i.e., the farthest downwind points) over 5 years of weather, and the whole field distribution, as described, differs because it includes all points around the perimeter for the same period. It also should be noted that another way to consider this is that maximum buffer 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 values 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 at which a target concentration of concern (i.e., the human equivalent concentration adjusted by applicable uncertainty factors) 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., margins of exposure) 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 metam-sodium and metam-potassium use when coupled with other mitigation measures.

Buffer Zone Distances

The Agency has developed required buffer zone distances based on application method, application rate, and application block size (rounding up to nearest whole units for application rate and block size). These distances are summarized in Tables 5 to 11 below.

For each of the outdoor pre-plant soil emission profiles, distances were first chosen for the rates identified in the risk assessment as the 10%, 25%, 50%, 75% and 100% of the maximum rates (i.e., 32, 80, 160, 240, and 320 lb ai/A for all metam applications), each paired with application block sizes of 5, 10, 20, 30, 40, 50, 60, 80, 100, and 120 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 label 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. It should be noted that the distances in the lookup tables are not model outputs, although the model outputs were a tool used for their development. A description of how the model outputs were used to characterize the buffer zone distances is provided immediately after the buffer zone look-up tables (Tables 5 to 11).

- **Minimum and Maximum Distances**

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

The buffer zone 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 that included consideration of the hazard profile of metam-sodium and metam-potassium, information from incident reports, monitoring data, and stakeholder comments along with comprehensive analysis of results from PERFUM modeling and consideration of results using other models (e.g., Industrial Source Complex Model). The analysis of PERFUM results considered distances at various percentiles of the whole field and maximum distance distributions as well as and predicted MOEs for various distances. The risk assessment characterizes additional types of analysis that were performed. The following characterizes the risks associated with the buffer zone distances summarized in Tables 5 to 11.

The buffer zone distances at the 90th 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 90% chance of exposure below the level of concern. The buffer zone distances at the 90th percentile whole field distribution is equivalent to saying a person somewhere on the perimeter of the buffer zone during the worst case 24-hour period following the fumigation of a specific field during a 5-year period would have at least a 90% chance of exposure below the level of concern. The risk assessment, available in the metam-sodium/potassium docket (EPA-HQ-OPP-2005-00125) at www.regulations.gov, characterizes additional types of analysis that were performed.

Note: Washington State University has submitted studies to quantify the flux rate for metam-sodium and metam-potassium from shank injection applications and from center pivot applications using a drizzle boom in the Pacific Northwest. These studies were submitted in April, 2009, and are currently in review. If these studies indicate that the buffer zones for these types of applications should be modified, the Agency will update the buffer tables prior to implementation of new labeling related to buffers for metam sodium in 2011. The results of these studies have not been included in this amended document and the buffer tables below.

Table 5. 2008 Center Pivot Irrigation Application (High Release Height*) Buffer Zone Distance in Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	50	80	125	160	185	205	220	235	250	262	275	288	300	312	325
5	50	100	150	188	225	263	300	313	325	338	350	363	375	389	400
10	50	100	150	200	250	300	350	375	400	425	450	488	525	563	600
20	75	138	200	250	300	350	400	450	500	550	600	650	700	750	800
30	75	138	200	269	338	407	475	557	638	719	800	850	900	950	1000
40	100	200	300	363	425	488	550	638	725	813	900	975	1050	1125	1200
50	100	200	300	382	463	544	625	719	813	907	1000	1100	1200	1300	1400
60	200	300	400	475	550	625	700	825	950	1075	1200	1300	1400	1500	1600
70	200	300	400	488	575	663	750	888	1025	1163	1300	1400	1500	1600	1700
80	200	300	400	500	600	700	800	950	1100	1250	1400	1500	1600	1700	1800
90	250	350	450	550	650	750	850	1000	1150	1300	1450	1563	1675	1788	1900
100	300	400	500	600	700	800	900	1050	1200	1350	1500	1625	1750	1875	2000
110	350	450	550	650	750	850	950	1100	1250	1400	1550	1688	1825	1963	2100
120	400	500	600	700	800	900	1000	1150	1300	1450	1600	1750	1900	2050	2200
140	600	700	800	900	1000	1100	1200	1350	1500	1650	1800	1950	2100	2250	2400
160	800	900	1000	1100	1200	1300	1400	1550	1700	1850	2000	2150	2300	2450	2600

* This buffer zone distance table is for center pivot irrigation equipment in which the: 1) release height greater than 8 feet, and 2) there is > 30 lbs psi at the sprinkler head.

Table 6. 2008 Center Pivot Irrigation Application (Medium Release Height**) Buffer Zone Distance in Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	25	25	37	50	62	75	87	100	112	125	138	150	162	175
5	25	38	50	63	75	88	100	113	125	138	150	263	175	188	200
10	25	50	75	94	113	132	150	175	200	225	250	288	325	363	400
20	25	50	75	107	138	169	200	250	300	350	400	450	500	550	600
30	25	50	75	125	175	225	275	357	438	519	600	650	700	750	800
40	50	75	100	163	225	288	350	438	525	613	700	775	850	925	1000
50	50	75	100	182	263	344	425	519	613	707	800	900	1000	1100	1200
60	75	138	200	275	350	425	500	625	750	875	1000	1100	1200	1300	1400
70	75	138	200	288	375	463	550	688	825	963	1100	1200	1300	1400	1500
80	75	138	200	300	400	500	600	750	900	1050	1200	1300	1400	1500	1600
90	88	169	250	350	450	550	650	800	950	1100	1250	1363	1475	1588	1700
100	100	200	300	400	500	600	700	850	1000	1150	1300	1425	1550	1675	1800
110	150	250	350	450	550	650	750	900	1050	1200	1350	1488	1625	1763	1900
120	200	300	400	500	600	700	800	950	1100	1250	1400	1550	1700	1850	2000

** This buffer zone distance table is for center pivot irrigation equipment in which the: 1) release height AND spray height is less than 8 feet, AND 2) 29lbs. or less PSI at the sprinkler head, AND 3) there are no end guns.

Table 7. 2008 Center Pivot Irrigation Application (Low Release Height***) Buffer Zone Distance in Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	25	25	30	35	40	50	60	70	85	105	125	145	165	185
5	25	25	25	35	50	63	75	94	113	132	150	163	175	188	200
10	25	38	50	63	75	88	100	125	150	175	200	225	250	275	300
20	25	38	50	70	89	107	125	157	188	438	250	288	325	363	400
30	25	38	50	75	100	125	150	188	225	263	300	350	400	450	500
40	25	50	75	107	138	169	200	238	275	313	350	413	475	538	600
50	25	50	75	119	163	207	250	294	338	382	425	494	563	632	700
60	50	75	100	150	200	250	300	363	425	488	550	613	675	738	800
70	63	100	138	192	244	297	350	419	488	557	625	694	763	832	900
80	75	125	175	232	288	344	400	475	550	625	700	775	850	925	1000
90	88	138	188	254	319	385	450	532	613	694	775	857	938	1019	1100
100	100	150	200	275	350	425	500	588	675	763	850	938	1025	1113	1200
110	125	188	250	325	400	475	550	644	738	832	925	1019	1113	1207	1300
120	150	225	300	375	450	525	600	700	800	900	1000	1100	1200	1300	1400

*** This buffer zone distance table is for center pivot irrigation equipment in which the: 1) release height AND spray height is less than 4 feet, AND 2) 29lbs. or less PSI at the sprinkler head, AND 3) solid stream nozzle (e.g. drizzle boom, Smart Drop, etc.), AND 4) there are no end guns.

Table 8. 2008 All Chemigation Except Center Pivot and Flood Applications Buffer Zone Distance In Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	38	50	55	62	68	75	80	87	93	100	115	125	137	150
2	25	38	50	57	65	73	81	88	97	104	113	152	138	150	163
3	25	38	50	58	67	78	88	97	106	116	125	189	150	163	175
4	25	38	50	60	70	83	94	105	116	127	138	226	163	175	188
5	25	38	50	63	75	88	100	113	125	138	150	263	175	188	200
6	25	40	55	69	83	97	110	125	131	155	170	268	205	223	240
7	25	43	60	75	90	106	120	138	140	173	190	273	235	258	280
8	25	45	65	81	98	114	130	150	146	190	210	278	265	293	320
9	25	48	70	87	105	123	140	163	155	208	230	283	295	328	360
10	25	50	75	94	113	132	150	175	200	225	250	288	325	363	400
20	25	50	75	107	138	169	200	250	300	350	400	450	500	550	600
30	25	50	75	125	175	225	275	357	438	519	600	650	700	750	800
40	50	75	100	163	225	288	350	438	525	613	700	775	850	925	1000
50	50	75	100	182	263	344	425	519	613	707	800	900	1000	1100	1200
60	75	138	200	275	350	425	500	625	750	875	1000	1100	1200	1300	1400
70	75	138	200	288	375	463	550	688	825	963	1100	1200	1300	1400	1500
80	75	138	200	300	400	500	600	750	900	1050	1200	1300	1400	1500	1600
90	88	169	250	350	450	550	650	800	950	1100	1100	1363	1475	1588	1700
100	100	200	300	400	500	600	700	850	1000	1150	1300	1425	1550	1675	1800
110	150	250	350	450	550	650	750	900	1050	1200	1350	1488	1625	1763	1900
120	200	300	400	500	600	700	800	950	1100	1250	1400	1550	1700	1850	2000

Table 9. 2008 Shank Injection Applications-Tarped and Untarped Buffer Zone Distance In Feet																	
	Application Rate (lb ai/A)																
Block Size (A)	**32**	**44**	**56**	**68**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	25	25	25	25	25	25	25	25	32	38	44	50	56	63	69	75
2	25	25	25	25	25	25	25	25	25	32	38	44	50	58	66	74	81
3	25	25	25	25	25	25	25	25	25	32	38	44	50	60	69	79	88
4	25	25	25	25	25	25	25	25	25	32	38	44	50	61	72	83	94
5	25	25	25	25	25	25	25	25	25	32	38	44	50	63	75	88	100
6	25	25	25	25	25	26	28	29	30	38	45	53	60	75	90	105	120
7	25	25	25	25	25	28	30	33	35	44	53	62	70	88	105	123	140
8	25	25	25	25	25	29	33	36	40	51	60	70	80	100	120	140	160
9	25	25	25	25	25	31	35	40	45	57	68	79	90	113	135	158	180
10	25	25	25	25	25	32	38	44	50	63	75	88	100	125	150	175	200
20	25	25	25	25	25	32	38	44	50	69	88	132	175	207	238	269	300
30	25	32	38	44	50	57	63	69	75	113	150	188	225	257	288	319	350
40	25	32	38	44	50	57	63	69	75	119	163	207	250	288	325	363	400
50	25	38	50	63	75	82	88	94	100	150	200	250	300	350	400	450	500
60	25	38	50	63	75	82	88	94	100	163	225	288	350	413	475	538	600
70	38	51	63	76	88	104	119	135	150	207	263	319	375	444	513	582	650
80	50	63	75	88	100	125	150	175	200	250	300	350	400	475	550	625	700
90	63	76	88	100	113	138	163	188	213	266	319	372	425	500	575	650	725
100	75	88	100	113	125	150	175	200	225	282	338	394	450	525	600	675	750
110	75	91	107	123	138	163	188	213	238	298	357	416	475	550	625	700	775
120	75	94	113	132	150	175	200	225	250	313	375	438	500	575	650	725	800

Table 10. 2008 Rotary Tiller and Spray Blade Applications Buffer Zone Distance In Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
5	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
6	25	25	25	25	25	25	25	25	25	25	25	27	29	30	32
7	25	25	25	25	25	25	25	25	25	25	25	29	32	36	39
8	25	25	25	25	25	25	25	25	25	25	25	30	36	41	46
9	25	25	25	25	25	25	25	25	25	25	25	32	39	47	53
10	25	25	25	25	25	25	25	25	25	25	25	34	43	52	60
20	25	25	25	25	25	25	25	25	25	25	25	49	73	97	120
30	25	25	25	25	25	25	25	25	25	25	25	64	103	142	180
40	25	25	25	25	25	25	25	25	25	25	25	75	125	275	225
50	25	25	25	25	25	25	25	42	58	74	90	135	180	225	270
60	25	25	25	25	25	25	25	57	88	119	150	188	225	263	300
70	25	25	25	25	25	25	25	64	103	142	180	218	255	293	330
80	25	25	25	25	25	25	25	72	118	164	210	248	285	323	360

Table 11. 2008 Drip Irrigation Applications-Tarped and Untarped Buffer Zone Distance in Feet															
	Application Rate (lb ai/A)														
Block Size (A)	**32**	**56**	**80**	**100**	**120**	**140**	**160**	**180**	**200**	**220**	**240**	**260**	**280**	**300**	**320**
1	25	25	25	25	25	25	25	25	25	25	25	32	38	44	50
2	25	25	25	25	25	25	25	27	28	30	31	37	41	46	50
3	25	25	25	25	25	25	25	29	32	35	38	41	44	47	50
4	25	25	25	25	25	25	25	30	35	39	44	46	47	49	50
5	25	25	25	25	25	25	25	32	38	44	50	50	50	50	50
6	25	25	25	26	28	29	30	37	43	49	55	56	58	59	60
7	25	25	25	28	30	33	35	42	48	54	60	63	65	68	70
8	25	25	25	29	33	36	40	47	53	59	65	69	73	76	80
9	25	25	25	31	35	40	45	52	58	64	70	76	80	85	90
10	25	25	25	32	38	44	50	57	63	69	75	82	88	94	100
20	25	38	50	57	63	69	75	82	88	94	100	125	150	175	200
30	25	38	50	57	63	69	75	94	113	132	150	188	225	263	300
40	25	50	75	82	88	94	100	113	125	138	150	200	250	300	350
50	25	50	75	82	88	94	100	125	150	175	200	250	300	350	400
60	25	63	100	113	125	138	150	175	200	225	250	300	350	400	450
70	25	76	125	140	150	163	175	207	250	269	300	350	400	450	500
80	25	88	150	163	175	188	200	238	275	313	350	400	450	500	550

For all pre-plant soil applications for metam-sodium/potassium, the buffer zone distances necessary to achieve the target MOE (an MOE of 10), for all weather station data modeled, are prohibitively large and would likely be impossible for most growers to implement. The Agency worked to balance the need to develop buffer zone distances that are sufficiently protective with the benefits that accrue from the use of metam-sodium/metam-potassium. The Agency believes that the buffer zone distances it has selected, combined with the other mitigation measures described herein (e.g., requiring GAPs and FMPs; posting and emergency preparedness requirements; soil fumigant training requirements for applicators and handlers; clarifying use sites and ambient air monitoring programs in high-use areas) will adequately address the risk of acute exposure to bystanders and will greatly reduce the magnitude and frequency of exposure incidents.

The Agency selected the buffer zone distances for metam-sodium/metam-potassium, such that the resulting MOEs are ≥ 3 for all application methods and all weather stations data. While this does not meet the target air concentration for the buffer zone distances, even at the lowest MOE (MOE of 3), the predicted air concentration at the edge of the buffer would be 12 times lower than the lowest observable adverse effect level (LOAEL), which is the level at which eye irritation effects begin in humans.

The table below (Table 12) shows the buffer distances and risk characterization for some key use scenarios, based on crop, region, typical application rate, and typical application block size. It also shows the percentile for the whole field and max distribution for each distance, as well as the MOE at the 95th percentile air concentration of PERFUM.

- As noted previously, the target MOE for metam-sodium/potassium is 10, and the MOEs for these key metam use scenarios range from 3 up to 26.
- For the key metam use scenarios presented below, all of the whole field percentiles range from 60 to 99.9 percent, and the max percentiles range from <5 to 99 percent.
- The use of GAPs, FMPs, and other mitigation measures required by this decision will contribute to an additional decrease in risk (see GAPs and FMPs sections below, pages 102 and 112 respectively).

Example

Consider the use scenario listed below (in Table 12) for potatoes grown in the Pacific Northwest using a center pivot with medium release height (i.e., maximum spray height less than 8 feet off the ground and no use of end guns). Here, with an application rate of 140 lb ai/acre and an application block size of 120 acres, the buffer zone distance (without emissions credits) would be 700 feet. Note that:

- The MOE at the 95th air concentration from the PERFUM modeling data at this buffer distance is 4.
- The risk level corresponding to this buffer zone distance at the 95th percentile whole field distribution is equivalent to saying a person at any location on the perimeter of the buffer zone during the worst 24-hour period following the fumigation of a specific field during a 5-year period would have at least a 75% chance of having of exposure below the level of concern (i.e., MOE $\geq$ 10).
- 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 15% chance of exposure below the level of concern (i.e., MOE $\geq$ 10 for these typical use scenarios).

Table 12. Buffer Zone Distances and Risk Characterization for Key Metam Use Scenarios

Crop	Region	Application Method	Typical Application Rates (lb ai/A)	Typical Application Block Size (A)	Buffer Zone Distances (ft) w/o Credits	Whole Field and Max Distance Percentiles		MOEs at the 95th Air Concentration from PERFUM2
						Whole Field	Max	
Potatoes	PNW	Center Pivot – high release height	140	120-160	900-1300	n/a	n/a	n/a
		Center Pivot – medium release height without end gun	140	120	700	75	15	4
		Center Pivot – low release height without end gun	140	120	525	60	15	3
	Upper Midwest	Chemigation	150	30	200	65	<5	3
				50	304	65	<5	3
	PNW	Shank Injection	140	80	175	60	<5	4
				120	225	60	<5	3
Carrots	CA	Shank (Broadcast)	170	80	225	65	<5	3
		Chemigation	170	40	319	75	15	3
				60	463	75	15	3
		Flood	170	40	319	65	<5	3
				60	463	65	<5	3
		Drip	170	40	107	70	10	4
				60	163	65	<5	4
	WA	Center Pivot – high release height	140	160	1300	n/a	n/a	n/a
		Center Pivot –medium release height without end gun	140	120	700	75	15	4
		Center Pivot – low release height without end gun	140	120	525	60	15	4
Cucurbits	AZ & CA	Shank (Strip, Tarped)	210	10	82	65	<5	3
				40	185	60	<5	3
	Southeast	Shank (Strip, Tarped)	320	10	200	75	<5	3
				40	400	70	<5	3
Tomatoes (Processed)	CA	Shank (Strip, Tarped)	40	10	25	97	80	15
			60	40	38	65	<5	9
		Drip (Tarped)	40	10	25	99.9	99	26
			60	40	38	97	80	11
Tomatoes (Fresh)	Southeast	Shank (Strip, Tarped)	320	10	200	75	<5	3
				40	400	70	<5	3
Onions	OR & WA	Shank Strip	210	30	169	60	<5	3
				40	185	60	<5	3
	CA	Shank Strip	110	30	60	65	<5	5
			150	40	72	60	<5	3
Peppers	CA	Chemigation (Strip)	240	10	250	70	<5	3
				40	700	80	10	3
		Drip (Tarped)	240	10	75	75	10	5
				40	150	65	<5	3
	Southeast	Shank (Strip, Tarped)	320	10	200	75	<5	3
				40	400	70	<5	3

Table 12. Buffer Zone Distances and Risk Characterization for Key Metam Use Scenarios								
						Whole Field and Max Distance Percentiles		
Peanuts	NC & VA	Chisel Strip (Shaped Beds)	35	50	25	85	35	12
				100	75	75	10	11
Sweet Potato	CA	Shank (Strip, Tarped)	300	10	175	65	<5	3
				40	363	65	<5	3
Tobacco	SC & VA	Shank (Strip Tarped)	90	10	25	85	40	7
			252	40	269	65	<5	3
Eggplant	CA	Shank (Strip Tarped)	160	10	50	65	<5	4
				40	75	60	<5	3
	Southeast	Shank (Strip Tarped)	320	10	200	75	<5	3
				40	400	70	<5	3

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

Amended General Buffer Zone Requirements

The following describes the general buffer zone requirements, as amended, for metam sodium:

- "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.

<u>Buffer zone proximity-Exception to Allow Buffer Zone Overlap</u>

- To reduce the potential for off-site movement from multiple fumigated fields, buffer zones from multiple metam-sodium and metam-potassium application blocks may not overlap UNLESS:
    - 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.

For Metam-Sodium and Metam-Potassium Low Release Center Pivot Applications only:

- A buffer zone may NOT overlap buffer zones from other application blocks which are already in effect UNLESS both application blocks are treated using low release center pivot systems. The 12 hour waiting period does not apply in this instance.

- 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.

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, and;
     - Sensory irritation is not experienced
- 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..

Restriction for Schools and Other Difficult-to-Evacuate Sites

- "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 (1320 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 1/8 mile (660 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the application.

(d) 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,"[4] in the metam-sodium and metam-potassium docket. The Agency also coordinated and led a discussion on this issue at the 2006 and 2007 Methyl Bromide Alternatives Outreach (MBAO) Conferences with leading researchers and other stakeholders. A general description of the MBAO sessions can be found at http://mbao.org.

Based on the Agency's analysis of the current data, the Agency developed metam-sodium and metam-potassium buffer zone reduction credits for: high-barrier tarps (10%), soils with high organic matter (10%), soils with high clay content (10%), and low-temperature soils (10%). The July 2008 RED stated that the buffer zone credits were additive, but that the total credit could not exceed 40 percent. The Agency believes that in addition to reducing bystander risk and the size of buffer zones, these credits have the potential to also decrease application rates. Applicators will be required to document any information about buffer zone credits that apply in the Fumigant Management Plan (FMP).

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 additive effect in reducing emissions when multiple factors were combined. As a result, EPA has updated the buffer reduction credits and determined that the 40% 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 D362369, Updated Health Effects Division Recommendations For Good Agricultural Practices and Associated Buffer Credits", in the metam docket.

Soil Conditions

Soil conditions like the amount of organic matter and type of soil do have an impact on fumigant emissions. However, soil conditions differ from other credits because they are

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

essentially beyond a grower's ability to change. Although a grower may not be able to manipulate organic matter or soil type, the Agency's factors document indicates that soil conditions can reduce fumigant emissions, and is offering credits for these conditions. EPA acknowledges that some variability in soil characteristics within a given field is likely. If users are unsure whether the fields they intend to treat meet the criteria for a credit, they may consult with their local agriculture extension office or soil conservation district for assistance in determining soil characteristics.

The Agency's factors document not only reviews available literature regarding soil conditions, but also describes modeling exercises that estimate the impact of organic matter and soil type using Chain_2D. Chain_2D is a first principles model that takes into consideration factors such as boundary layers or moisture that could impact fumigant emissions. The Agency used Chain_2D as modified by Dow AgroSciences' Steve Cryer and Ian van Wesenbeek in the sensitivity analysis[5]. Cryer and van Wesenbeek modified the original source code to create a more usable graphical user interface; this included incorporating a new air/soil boundary condition proposed by Wang in 1998[6]. See the Agency's factors analysis for further details about the CHAIN_2D model[7].

Based on the review of available literature and modeling with the CHAIN_2D model, EPA believes 10 percent buffer zone credits are appropriate if the application block contains soil with organic matter of greater than 3 percent and/or for clay content of at least 27 percent. CHAIN_2D that shows the impact of changes in organic content is not fumigant specific.

The Agency's Chain_2D sensitivity analysis suggests that organic matter can have a small impact on emissions. There is generally a high correlation between the organic matter content of the soils and the dissociation constant (K_d) value. Increasing K_d value by 10 or 25 percent generally reduced emissions by 10 or 20 percent. Decreasing the K_d value by 10 or 25 percent increased emissions by 10 or 20 percent (see figures 147 to 154 of the factors analysis for further details).

Generally, clay loam and sandy clay loam soils tended to show significantly lower emissions than other soil types, sometimes showing 50 percent lower reductions. Conversely, loamy sand and loam soils tended to show higher emissions than other soil types (see figures 167 to 174 of the factors analysis for further details).

Since the 2008 RED, information from the Chloropicrin Task Force has been submitted and has allowed the Agency to reevaluate credits for soil organic matter. From these studies the Agency has determined that soils with between 1% and 2% organic matter will get a 10% credit,

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[5] Cryer, S.A. (2007) Air/Soil Boundary Conditions For Coupling Soil Physics and Air Dispersion Modeling. Unpublished report of Dow AgroSciences LLC (Report # DN241493)

[6] Wang, D; Yates, S.R.; Jury, W.A. (1998) Temperature Effect on Methyl Bromide Volatilization: Permeability of Plastic Cover Films. J. Environ. Qual. 27, 821-827.

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

soils with between 2% and 3% organic matter will get a 20% credit, and greater than 3%, a 30% credit. No credit will be given for soils with less than 1% organic matter. The credit for clay content of greater than 27% will remain at 10%.

Soil Temperature

In the July 2008 RED, the Agency provided a 10% buffer zone credit for all chemigation, center pivot, and/or tractor drawn (i.e., shank injection, spray blade, and rotary tiller) application in soils with temperatures of 70°F or less when measured at a soil depth of 3 inches for all chemigation, center pivot, spray blade, and rotary tiller applications and at the injection depth for shank injection applications. The Agency's analysis of available data indicated increased soil temperature corresponds to increased fumigant emissions rates. Given that lower soil temperatures lead to lower fumigant emission rates, a credit was provided for application scenarios with lower soil temperatures. Because the emissions studies from which the buffer zones were developed for chemigation, center pivot, and tractor drawn applications all occurred at high air and soil temperatures, with maximum air temperatures (MATs) between 90-106°F and/or maximum soil temperatures (MSTs) between 90-93°F (where reported), a credit was given. Because the emissions studies used to develop buffer distances for the remaining application methods (i.e., drip and flood irrigation) occurred at lower temperatures, with MATs between 70-73°F and a MSTs of 70°F (where reported), an emission credit was not provided to reduce the buffers for these application methods.

During the post-RED comment period, the Agency reviewed all of the currently available data on the effects of soil temperature on fumigant emissions. Based on this analysis, the Agency is providing an additional soil temperature credits as described below.

Chemigation, Center Pivot, and/or Tractor Drawn Application

The emissions studies used to currently develop buffer distances for metam sodium applications performed using chemigation, center pivot, and/or tractor drawn equipment occurred at high temperatures. The average day/night air temperature in these studies ranged from 80-90°F and the maximum soil temperatures ranged from 90-93°F (where reported). A 10% emission credit is being provided to reduce the buffers for these types of applications in soils with temperatures ranging from 50-70°F when measured at a soil depth of 3 inches. In addition a 20% emission credit is being provided to reduce the buffers for these types of applications in soils with temperatures of 50°F or less when measured at a soil depth of 3 inches.

Drip and Flood Application

The emissions studies used to currently develop buffer distances for metam sodium applications performed using drip and flood irrigation equipment occurred at reasonable temperatures. The average day/night air temperature in these studies was approximately 60°F and the maximum soil temperatures around 70°F (where reported). A 10% emission credit is

being provided to reduce the buffers for these types of applications in soils with temperatures of 50°F or less when measured at a soil depth of 3 inches.

Note: Stakeholders and the registrants have proposed a laboratory soil column study examining the effect of soil temperature and soil moisture on MITC emissions. This study may provide more information around the effect on MITC emissions and the emissions for metam-sodium and metam-potassium may be revisited if necessary after review of these data.

High-Barrier Tarps

In the July 2008 RED, a 10% buffer credit was given when one of the following high-barrier tarps is used: Bromostop® (1.38 mil), IPM Clear VIF (1.38 mil), Eval/Mitsui (1.38 mil), Hytiblock 7 Black (0.00125"), XL Black Blockade (0.00125"), or Hytibar (1.5 mil) for either a shank injection or drip metam-sodium and metam-potassium application. Because current study data do not demonstrate significant reductions in MITC emissions using standard polyethelyne tarps, no credit was provided for "standard" tarped metam applications. The credit was based on a study (Papiernik 2004) that shows significant reductions in MITC emissions when using a Hytibar (a high-barrier) tarp when compared to a standard polyethylene tarp in drip irrigation experiments in both sand mesocosm and field experiments. Given that study data (Wang et al., 2006) have shown that MITC and chloropicrin pass through standard tarps at similar rates, the Agency decided to allow emissions credits for the Hytibar tarp as well as the other high-barrier tarps that were given an emissions reduction credit for chloropicrin applications. The Agency believed that the actual reduction for tarps could be higher for certain conditions but that a 10% credit was appropriate based on uncertainties in the available data.

Since the July 2008 RED was published, the Agency has looked at all of the available tarp data, in total. There is very limited data currently available that examines the ability of high-barrier tarps to reduce MITC emissions. One literature study (Papiernik et. al., 2004) showed significant reductions in MITC emissions when using a Hytibar (a high-barrier) tarp when compared to a standard polyethylene tarp in drip irrigation experiments. Also, another study (Wang et. al., 2006) showed that MITC and chloropicrin pass through standard tarps at similar rates (same order of magnitude).

As a result, the Agency has decided to allow emissions credits for all high-barrier tarps that are being given an emissions reduction credit for chloropicrin. The Agency has selected more conservative credits for MITC based on uncertainties in the available data.

- A 15% buffer credit is appropriate for the following high-barrier tarps: Canslit Heatstrip Silver and Canslit Metalized.
- A 30% buffer credit is appropriate for the following high-barrier tarps: 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).

Credit Cap

The Agency determined, in the July 2008 RED, that the buffer zone credits were additive. This meant, for example, that a 10% credit for a high barrier tarp could be added to a 10 % credit for organic matter to achieve a total credit of 20%. The Agency placed a limit, or "credit cap," of 40% on the total size of the credit allowed for metam. 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 40% cap would be a disincentive to growers considering whether to adopt emission-reducing application methods.

Upon review of the new data and public comments, the Agency has decided to raise the credits 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-40% 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.

Credit Example

If an application block is 10 acres and the applicator is planning to make a shank tarped application of 320 lbs of metam per acre, the buffer distance from the look up tables is 200 feet. If the applicator decides to use the Hytibar (1.5 mil) high barrier tarp, then the buffer zone may be reduced by 30 percent. By calculating 30 percent of 200 feet (200 feet x 30% = 60 feet buffer credit) and then subtracting the original buffer distance by the credit (200 feet – 60 feet = 140 feet) the final buffer distance required is 140 feet.

Other Buffer Zone Credits Considered

Other factors such as soil moisture content, field preparation, water sealing, and application injection depth could not be quantified as to how effectively they reduce emissions and were not used to establish buffer credits at this time. However, EPA has established mandatory good agricultural practices (GAPs) for these conditions. If additional tarps or other emission factor data become available to show the emissions from metam-sodium and metam-potassium applications are decreased, the Agency will consider adding those to the metam-sodium and metam-potassium label. More information on the type of data the Agency is looking for can be found in the *Health Effects Division Recommendations for Fumigant Data Requirements* (J. Dawson, C. Smith, dated June 2008).

EPA (through OPP's Environmental Stewardship Branch) has proposed to co-fund a grant with USDA-ARS for several flux studies in the southeastern U.S. These studies would

provide (1) field data on the emission reduction potential of certain low permeability barrier films to support possible, additional, buffer reduction credits as well as to (2) help develop an affordable and reliable hybrid field/lab test to evaluate the many barrier films available to growers. EPA has also prepared a document to describe possible research and study designs to reduce uncertainties in understanding emission factors in the context of different films and seals, agricultural practices, and environmental conditions.[8] These studies were completed in the spring of 2009 and data from these studies will be submitted to the Agency for review in the near future.

Other factors such as soil moisture content, field preparation, water sealing, and application depth could not be used to justify credits based on the available data. However, EPA has established mandatory good agricultural practices (GAPs) for these conditions. See the GAP section of this document for further discussion. If additional data on such emission reduction methods becomes available, EPA will consider developing further credits.

2. 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. The mitigation measures have 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 cares; 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 1/4 mile to 1/8 mile for application blocks with less than 300 foot buffers. The 1/8 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

[8] Health Effects Division Recommendations for Fumigant Data Requirements. June 2008. DP Barcode 353724

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 1/4 mile (1320 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.
- No fumigant application with a buffer zone of 300 feet or less is permitted within 1/8 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.

3. Posting

Posting is recognized as 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 Handler Section, handlers working in treated areas or buffers during the buffer zone period must use label-specified PPE and meet other requirements under the Worker Protection Standard (WPS). Therefore, EPA has determined that to ensure the protectiveness of buffers for bystanders and handlers, the perimeter of the fumigant buffer zones must be posted.

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, etc.), 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.

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

Additional requirements for treated-area posting:

- The treated area posted signs must remain posted for no less than the duration of the *entry restricted period* after treatment.
- Treated area signs must be removed within 3 days after the end of the entry-restricted period.
- Signs must meet the general standards in the WPS for placement, text size, and location (40 CFR §170.120).

Contents of Signs

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

-- "DANGER/PELIGRO,"
-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"
-- "Metam-sodium [or metam-potassium] 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,"
-- "Metam-sodium [or metam-potassium] [Name of product] Fumigant BUFFER ZONE,"
-- contact information for the certified applicator in charge of the fumigation

bb. Occupational Risk Mitigation for Soil Uses

The Agency has concerns for handlers involved in metam-sodium and metam-potassium applications for both dermal and inhalation exposure. In many cases with maximum personal protective equipment (PPE), exposure still exceeds the Agency's level of concern for short-term and long-term exposures. Based on stakeholder comments, there appears to be a misunderstanding as to what EPA considers to be *handler* activities.

1. 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 July 2008 RED so it is clear that the Agency is just clarifying the existing definition and not writing a new one. 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 Worker Protection Standard (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 visually monitor application equipment to ensure proper functioning and monitor fumigant air concentrations must also be trained and equipped as handlers in accordance with the requirements in the WPS (40 CFR Part 170)."

2. Handler Requirements

Since many incidents are caused by human error and equipment failure, EPA believes the presence of on-site trained personnel would help to reduce these risks. To address these risks, the July 2008 RED required that (1) a certified applicator must supervise all fumigant handlers during the entire period that the person is performing a fumigant handling task within the treated field or within the buffer zone, (2) the person monitoring another handler could also be engaged in fumigant handling tasks during the monitoring period, and (3) the certified applicator supervising metam-sodium and metam-potassium applications could perform all tasks without anyone supervising them.

The July 2008 Metam-Sodium and Metam-Potassium RED included exceptions for the on-site applicator supervision requirements in cases when the certified applicator typically leaves the site during an application. Requirements in the RED label table specified that for overhead, flood, or furrow irrigation and chemigation applications, the certified applicator supervising the fumigant application must be on site at the start of application but may leave and return for periodic monitoring of the fumigation site as long as he/she monitors the site at least once every four hours if the site is 20 acres or less; once every three hours if the site is greater than 20 acres, but less than 80 acres; and once every two hours if the site is 80 acres or more. The Agency believes that consistent monitoring of water-run applications (e.g., drip, overhead, flood, or furrow irrigation and chemigation) is needed to help reduce potential risks during an application.

In addition to certified applicator supervision, in the July 2008 RED, the Agency required that a minimum of two WPS-trained handlers remain on site when handlers are fixing tarps, moving irrigation equipment, and/or performing other handler tasks as defined above. This mitigation measure was put in place to address the possibility that handlers could be overcome with the vapors and have difficulty leaving the area while they are performing these tasks. The Agency is removing this handler requirement for the MITC generating chemicals since the hazard profiles are not the same for all the soil fumigants. With MITC-generating compounds, EPA believes eye or sensory irritation would likely be felt in sufficient time for a handler to leave the area or put on a respirator, before more serious effects occur. With chloropicrin, in contrast, as indicated by precautionary statements on current labels, a handler may be overcome more quickly, justifying the presence of another person to provide assistance if needed.

During the post-RED comment period the Agency received many comments that stressed the difficulty 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 huge burden. Other stakeholders stated that the Agency needs to modify the requirement to ensure that the certified applicator is on site while others believe 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 revised the certified applicator and WPS-trained handler requirements for different application methods. EPA believes that these revisions accomplish the same goal as the July 2008 RED mitigation while reducing the burden on users.

- For all applications, except water run, (e.g., shank, rotary tiller, etc.) 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 water-run applications (e.g., chemigation, center pivot, lateral move, drip, overhead, flood, furrow irrigation, etc.), the certified applicator must be at the fumigation site to start the application including set-up, calibration, and initiation of the application. The certified applicator may leave the site but must return at least every two hours to visually inspect the equipment to ensure proper functioning and monitor the air around the buffer zone and must supervise all WPS-trained handlers on-site until the fumigation has stopped being delivered/dispersed into the soil. WPS-trained handlers may perform the monitoring functions in place of the certified applicator but must be under the supervision of the certified applicator and able to communicate with the certified applicator at all times during monitoring activities via cell phone or other means. The results of monitoring activities must be captured in the FMP.
- 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 supervising the application completed a metam-sodium and metam-potassium registrant training program within the preceding 12 months before they applied a metam-sodium and metam-potassium product. The Agency is still requiring certified applicators complete the registrant training; however, the Agency is now requiring the certified applicators successfully complete the training every three years. Please see the *Soil Fumigation Training for Applicators and Other Handlers* section for further.

3. Dermal Protection for Handlers

The Agency's human health risk assessment for metam-sodium and metam-potassium identifies dermal risks for many handler tasks that exceed the Agency's level of concern for short-term, and intermediate-term exposures to the parent metam-sodium and metam-potassium. To address these dermal risk concerns, in the July 2008 Metam-Sodium and Metam-Potassium RED, the Agency required handlers engaged in various tasks (e.g., transferring or loading liquids; operating motorized ground application equipment with open cabs; and cleaning up spills) to wear dermal protection (e.g., double layer clothing, chemical resistant footwear plus socks) to protect against dermal exposure.

During the post-RED comment period, the Agency received a comment from the Northwest Horticultural Council indicating that the primary application method for orchard replant using metam sodium in the Pacific Northwest, a row/strip treatment of metam sodium to a future tree row using a weed sprayer while irrigation sprinklers are running, was not specifically addressed in the Agency's RED decision. Based on additional information provided by a representative for the Council in a 3/13/08 e-mail to the Agency (a copy of this e-mail has been posted to the metam sodium docket at EPA-HQ-OPP-2005-0125), EPA is including this application method, provided that handlers wear the following dermal PPE to protect them from both the product and sprinkler irrigation: long-sleeved shirt and long pants; a full waterproof, chemical-resistant suit; chemical-resistant gloves; chemical-resistant footwear plus socks; and protective eyewear. Generally, the Agency does not like to require the use of full waterproof, chemical-resistant suits for handlers, given concerns regarding heat stress for handlers, especially for handheld applications. However, based on the comments submitted by the Council indicating that this PPE is currently a standard practice and these applications are likely occurring in a cooler weather climate, the Agency is requiring such PPE in this instance.

The majority of comments relating to dermal handler protection for metam-sodium and metam-potassium that the Agency received during the post-RED comment period involved the need for additional clarification of key dermal handler mitigation and risk concerns. Specifically, clarification of the "baseline work clothes" requirement was requested. The Agency has more clearly defined this term in the dermal requirements section below to avoid any potential confusion.

Additionally, during the post-RED comment period, the Agency received comments from various stakeholders indicating that the Agency had not fully characterized the dermal risks from metam-sodium and metam-potassium, specifically short-term and intermediate-term non-cancer and cancer dermal risks in the July 2008 Metam-Sodium and Metam-Potassium RED. To address these concerns, the Agency is providing additional characterization of these risks below.

Metam-Sodium and Metam-Potassium Non-Cancer Occupational Dermal Risks: Short-Term and Intermediate-Term

The results of the non-cancer, short-term and intermediate-term handler dermal exposure assessments indicate that the MOEs for the dermal risk to handlers with both full PPE (i.e., gloves and double-layer clothing) and/or engineering controls (i.e., closed mixing and loading

systems and use of enclosed cabs) are above the Agency's level of concern (LOC) (i.e., MOE < 100) for many of the agricultural scenarios. The estimated exposures and risks are summarized in Tables 1-4 in Appendix J of the third revision of the Agency's human health risk assessment. To view, please see, "Metam Sodium: Third Revision of the HED Human Health Risk Assessment, DP# 293354 located in the metam sodium docket at: EPA-HQ-OPP-2005-0125.

For short-term hander exposure scenarios, the margins of exposure (MOEs) for handlers loading metam products at higher application rates for large acreage applications exceed the Agency's level of concern even with the addition of maximum personal protective equipment (PPE). This is also true for applicators who are applying metam products at higher application rates for large acreage applications. However, for many of the short-term handler exposure scenarios, when loading metam products for more typical acreage applications at typical application rates, MOEs are below the Agency's level of concern when additional PPE and/or engineering controls are incorporated. For applicators, when treating typical acreage at more typical application rates, MOEs are below the Agency's level of concern with additional PPE or when using a closed cab that provides dermal protection.

For intermediate-term exposures, the MOEs for handlers for the dermal risk to handlers with both full PPE (e.g., gloves and double-layer clothing) and/or engineering controls (e.g., closed mixing and loading systems) exceed the Agency's LOC (i.e., MOE < 100) for the majority of the agricultural scenarios.

Short- and intermediate-term dermal exposure MOEs for many handler scenarios are below an MOE of 100 with the required dermal protection and/or engineering controls. The occupational dermal risk assessments are based on data from the Pesticide Handler Exposure Database (PHED) and Outdoor Residential Exposure Task Force (ORETF). PHED and ORETF were designed to be used to assess nonvolatile pesticides. In the case of metam-sodium and metam-potassium, these data were used because there are no chemical-specific data available to the Agency. Since metam-sodium and metam-potassium degrades quickly to MITC, the dermal short- and intermediate-term risk assessment for metam generated by the Agency using data from PHED and ORETF can be considered to be conservative.

For the intermediate-term dermal exposures, another source of conservatism comes from the assumption that workers are exposed throughout an 8-hour workday for a 1- 6 month period. However, the Agency believes that many handlers, particularly private applicators of metam sodium, typically apply metam-sodium and metam-potassium for much shorter periods of time. In a 2004 survey of growers and applicators that use metam sodium conducted by the Metam Sodium Alliance and reviewed by the Agency, average number of days per year that growers reported potential metam exposure was 15 days, while custom applicators had an average of 50 days per year.

To address the short- and intermediate-term dermal risks from metam-sodium and metam-potassium, consistent with the mitigation required in the July 2008 RED, the Agency is requiring handlers engaged in various tasks to wear dermal protection to protect against dermal

exposure. Given the conservative nature of the non-cancer short- and intermediate-term dermal exposure assessment, coupled with the Agency's dermal PPE requirements and engineering control requirements, which are detailed below in the dermal requirements section, the Agency believes that these measures are protective of possible short-term and intermediate-term dermal risks for metam-sodium and metam-potassium.

Metam-Sodium and Metam-Potassium Cancer Occupational Risks: Dermal Exposures

The Agency's metam-sodium and metam-potassium cancer occupational handler dermal exposure assessment indicates that cancer risks for both noncommercial and commercial handlers are above the Agency's LOC (ranging from $1x10^{-4}$ to $1x10^{-6}$) for the majority of agricultural scenarios with maximum PPE in place. This assessment should be considered conservative for a number of reasons. (1) The assessments were based on data from PHED and ORETF, which are generally meant to assess non-volatile pesticides. Using this data to assess dermal exposure to metam sodium should be considered very conservative due to the volatile nature of metam sodium. (2) Closed systems are used to mix and load metam-sodium and metam-potassium, which will greatly reduce any potential exposure to metam-sodium and metam-potassium itself. (3) Much of the equipment typically used to apply metam-sodium and metam-potassium also greatly reduces any potential exposure to metam-sodium and metam-potassium itself. Tractor applications of metam sodium either immediately incorporate or directly inject metam sodium into the ground, and handlers are typically not in the field during chemigation applications.

Dermal Requirements

The Agency is requiring the mitigation measures specified below to reduce dermal exposures for handlers. Where indicated, "baseline work clothes" refers to long-sleeved shirt, long pants, and socks and shoes.

- *Transferring Liquids*
  - To reduce risk to handlers who transfer liquids from any container into application equipment or delivery equipment, the following is required:
    - Double-layer clothing (i.e., baseline work clothes and coveralls), chemical-resistant gloves, chemical-resistant apron, chemical-resistant footwear plus socks, and protective eyewear.
  - To reduce risk to handlers who transfer liquids from any container into application equipment or delivery equipment using a closed-connect system that reduces leakage to less than 2 ml of liquid per disconnect, the following is required:
    - Baseline work clothes, chemical resistant gloves, chemical resistant apron, protective eyewear, and a closed-connect system.

- *Driving Ground Rigs:*

- To reduce risk to handlers driving ground rig with a closed cab that provides dermal protection, the following is required:
  - Baseline work clothes.
- To reduce risk to handlers driving a ground rig that does not provide dermal protection, the following is required:
  - Double-layer clothing (i.e., baseline work clothes and coveralls) and chemical-resistant footwear plus socks.

- *Set-up, Calibration, and Start Up of Chemigation Equipment:*
  - To reduce risk to handlers who set-up and calibrate chemigation and irrigation equipment and either start the application from inside the buffer zone or remotely start the application from outside the buffer zone, the following is required:
    - Baseline work clothes.

- *Row/Strip Treatment Application of Metam Sodium via Weed Sprayer while Irrigation Sprinklers are Running:*
  - To reduce risk to handlers who apply metam-sodium and metam-potassium via weed sprayer while irrigation sprinklers are running for row/strip treatment for orchard replant, the following is required:
    - Long-sleeved shirt and long pants; chemical-resistant gloves; a full waterproof, chemical-resistant suit and chemical-resistant footwear plus socks; and protective eyewear.

- *Early Entry or Monitoring PPE:*
  - To reduce risk to handlers (1) entering a treated area during the application or (2) entering the treated field up to 120 hours after the application has ended for any reason (including, but not limited to, equipment repair, cleaning up spills, equipment monitoring, scouting), or (3) entering the buffer zone for up to 48 hours after the application, the following is required:
    - Baseline work clothes. If the handler will to be exposed to liquid or liquid spray from the application equipment, they must wear chemical-resistant coveralls, chemical-resistant gloves, chemical- resistant apron, chemical resistant footwear plus socks, and protective eyewear.

4. Respiratory Protection for Handlers

The Agency's human health risk assessment for metam indicates that inhalation risks for many handler tasks exceed the Agency's LOC for the acute exposure to the parent (metam) and MITC. In the 2008 Metam-Sodium and Metam-Potassium RED, the Agency required handlers potentially exposed to MITC vapors from metam-sodium and metam-potassium applications to either wear at least a half-face respirator during the handling activity, or follow the monitoring program detailed below. In addition, the Agency required that for some handling tasks, respirators were required to be worn at all times due to the short duration of the task and the potentially high concentration of MITC exposure. The certified applicator supervising the

fumigant application must ensure that any handler who enters the buffer zone (including tractor drivers, loaders, irrigators, tarp cutters, removers, etc.) is either wearing respiratory protection or is following the handler monitoring requirements, with respirators immediately available to each handler.

During the post-RED comment period, the Agency received several comments on the *Respiratory Protection for Handlers* section. For MITC, comments focused on the feasibility of using colormetric tubes, due to the current sensitivity and accuracy of the tubes; the cost of the tubes; and the Agency's trigger level of 100 ppb, which some commenters questioned, given that the Agency's level of concern for acute MITC exposures is 22 ppb. Some comments also suggested that rather than wear respirators, fumigators should have the option of ceasing the application until air concentrations of MITC are less than the action level.

After reviewing the comments, the Agency has determined that respiratory protection is still needed to mitigate risks to metam-sodium and metam-potassium handlers if concentrations of MITC reach a certain level; however, EPA is revising the required procedures for determining when respirators must be used due to technological limitations of currently available monitoring devices that are appropriate for field use. EPA believes that while colorimetric tubes are likely to be reliable at higher concentrations and when used in more static conditions (e.g., a warehouse or laboratory), under the dynamic conditions characteristic of outdoor field fumigation, currently available devices provide somewhat less reliable information about concentrations relative to EPA's action level, which is below the levels for which the devices are rated.

The Agency is aware of several commercial systems for monitoring MITC, including colormetric tubes from the following manufacturers: Sensidyne and Dragaer. While these tubes have detection limits of at least 100 ppb, based on commenters' experience and the accuracy of the tubes (e.g., some tubes have a standard deviation plus or minus 20-30%), the Agency believes it is possible that handlers will experience sensory irritation before the monitoring device shows a level of concern. As such, the Agency does not believe that initial monitoring to trigger the use of respirators significantly reduces handler risks. EPA is also concerned that monitoring with devices that are not reliable could cause handlers to believe that concentrations are below the action level despite other indications (eye irritation). As a result, the Agency is removing the initial monitoring requirement. In addition, EPA is aware that monitoring with these devices adds significant costs to fumigations. For additional details please see the following document: *Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery*, dated May 13, 2009, located in the metam docket.

EPA does believe, however, that monitoring devices that are currently available will generally be reliable at higher concentrations of MITC and that there is high value in air monitoring using currently available devices in certain situations. As a result, EPA is maintaining the requirement for colorimetric tube monitoring 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 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.

Since the Agency has removed the initial monitoring requirement, regulating at an action level of 100 ppb is no longer appropriate since that level was based on the lowest detection limit of the currently available MITC monitoring tubes. Due to the reliability issue discussed above, instead, the Agency is using an action level of 600 ppb which corresponds to early signs of exposure and effects are non-severe and reversible at this level. The Agency believes that this level is effective as a warning for handlers of when concentrations are reaching the point where steps are needed to protect fumigant handlers from inhalation exposures.

Respiratory Requirements

The following procedures must be followed for all agricultural pre-plant soil applications of metam-sodium and metam-potassium. In addition to the respiratory protection requirements, the Agency believes that GAPs, FMPs, and other mitigation measures will reduce inhalation risks from MITC to levels below the EPA's level of concern.

- 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 MITC have decreased to less than 600 ppb, provided that handlers do not experience sensory irritation. Samples must be taken where the irritation is first experienced.
- When respirators are worn, then 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) an air sample is greater than or equal to 6000 ppb, 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 MITC have decreased to less than 600 ppb, 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 MITC taken at the handling site at least 15 minutes apart must be less than 600 ppb,
    - Handlers do not experience sensory irritation while wearing the APR, and
    - Cartridges have been changed.
    - 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.

Figure 3. Provides an illustration of the requirements when handlers cease operations.

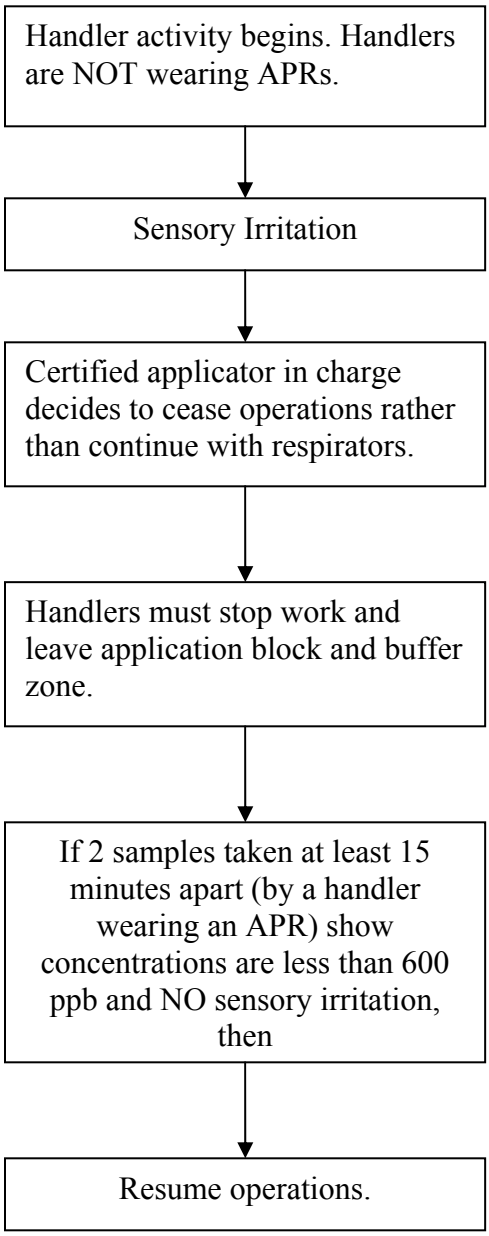
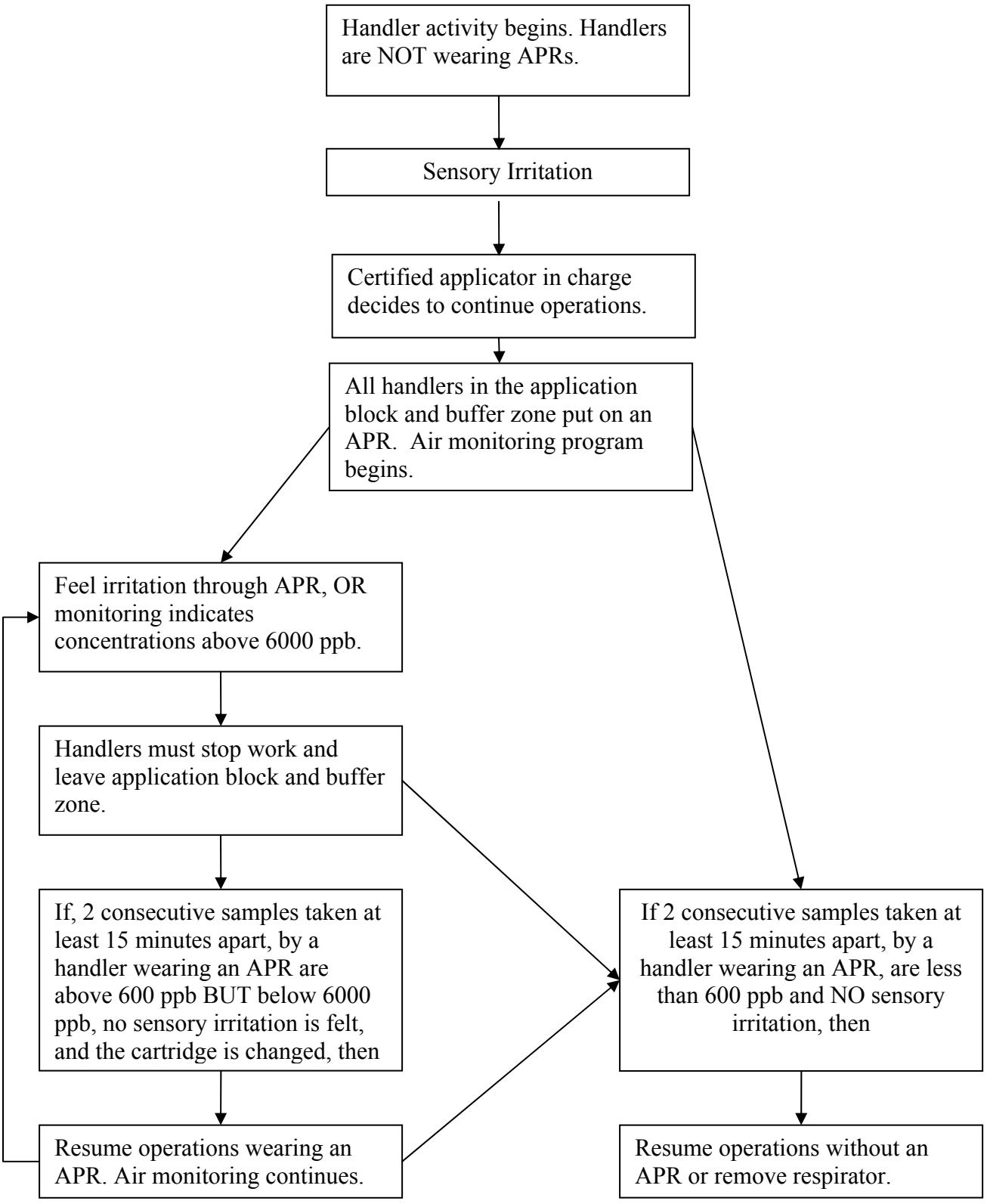


Figure 4. Provides an illustration of the requirements when handlers put on a respirator.



Respiratory Protection Equipment

In the July 2008 RED, the Agency required handlers to wear an air purifying respirator approved for MITC with a protection factor (PF) of 10. For additional clarity, even though 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 MITC, NIOSH/OSHA does recommend respirators with organic vapor cartridges for MITC use, and the Agency is requiring half-face respirators with organic-cartridges be used when a respirator is necessary; the Agency will consider other APR-cartridges combinations provided written certification of their efficacy against MITC is provided to the Agency. The EPA assumes that half-face respirators have a protection factor of 10, therefore, the respiratory protection will only be protective up to MITC concentrations of 6000 ppb, and if concentrations exceed 6000 ppb (or if eye irritation occurs), operations must cease. At air concentrations greater than 6000 ppb, the respirator is not designed to protect handlers from inhaling more than 600 ppb of MITC. Therefore, the handler must continue to monitor once respirators are donned. If concentrations of MITC exceed 6000 ppb or if eye irritation occurs, then the operations must cease until levels of MITC are measured to be below 600 ppb from consecutive air samples.

The Agency did receive comments regarding the cartridge recommendations, the recommended equipment, and the assumed respirator protection factor. All of these comments are addressed in detail in the following document located in the metam-sodium and metam-potassium docket: *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* (Dated May 14, 2009). The Agency would like to clarify issues regarding the respiratory protection cartridges and respirators. Comments suggested that the Agency require organic-vapor cartridges. This was the Agency's intention in the July 2008 RED. Others commented on the use of full-face respirators and goggles. The Agency is still recommending the use of organic-vapor cartridges when protection is required.

Respirator fit testing, training, and medical qualification

As detailed in the July 2008 RED, the respirator protection factor described above in the *Respiratory Protection Equipment* section is based on the following assumptions: 1) the respirator is fit-tested, 2) proper respirator training occurs, and 3) an annual medical evaluation and clearance is completed. Without these requirements, it is unclear whether the reduction in inhalation exposure that is assumed by the protection factor will be achieved. In order to ensure that the respiratory protection EPA is assuming is being achieved in the field, respiratory requirements will include fit testing, respirator training, and annual medical evaluation.

During the post-RED 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 the requirement. The Agency also received several comments regarding the

details of this requirement, for example who conducts the fit-testing and medical exam and what the medical exam entails.

While EPA recognizes that there is a cost associated with the fit-testing, training, and medical exam requirement the Agency still believes that respirator fit-testing, training, and medical exams are a necessary part of the mitigation package. Since the Agency is now offering a *cease operations* option where handlers can leave the application block and surrounding buffer zone in lieu of putting on an air-purifying respirator, the Agency is only requiring that handlers who wear a respirator are fit-tested, trained, and medically examined. The Agency believes that this revision will reduce the cost associated with this requirement while still keeping the same level of protection for the handlers that wear respirators. The following language must be added to product labels:

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

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

Respirator availability

The handler employer must confirm and document in the FMP that enough air-purifying respirators and cartridges are available for each handler that wears an air-purifying respirator. 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.

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, 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.

5. 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 fumigation completion, 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 difficulty implementing the 24 hour wait 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 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), Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits). 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 amount of days before high barrier tarps can be perforated.

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 broadcast 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 Section 4 (Respiratory Protection for Handlers); 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 section of this document; therefore the risk to handlers will not increase as a result of this modification. EPA considered the suggestion to monitor before tarp removal begins; however, because of technical limitations with current technology the Agency did not include monitoring as part of the mitigation. As with the respiratory protection section, the Agency sees the value in a monitoring program if reliable and accurate devices are available and will consider monitoring during Registration Review or sooner if information becomes available.

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 of this 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 of this document.
- 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 with Seepage Irrigation sections below.
- If tarps will be removed after planting, tarp removal must not begin until at least 2 hours after tarp perforation is complete.
- 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 early tarp removal in fields with seepage irrigation if rainfall necessitates draining fields
- 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. (seepage irrigation exception)
- 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 with Seepage Irrigation
    - Tarp perforation is allowed before the 5 days (120 hours) have elapsed if rain necessitates field drainage.
    - Tarps must be immediately retucked and packed after soil removal.
    - Subsequent tarp perforations must not occur until the original 5 days have elapsed.
    - The events must be documented in the post fumigation summary section of the FMP."
    -

6. Entry Prohibitions

Most of the current metam-sodium and metam-potassium labels allow reentry to the treated field by workers 48 hours after application. The risk assessment indicates that risks exceed EPA's level of concern for workers entering fields after 48 hours. However, the risk assessment indicates that extending this period decreases this risk. 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 7 to 14 days following the completion of the application and could reduce the effectiveness of the fumigation by disturbing the soil thus allowing the fumigate to escape the soil before it effectively controls pests.

Due to the volatile nature of metam-sodium and metam-potassium and the potential for worker exposure, in the July 2008 RED the Agency restricted entry into the treated area by

anyone other than a protected handler. This restriction differs from a restricted entry interval (REI), that is currently required for most conventional pesticides, which contains exceptions for workers doing certain tasks before the REI has expired (e.g., scouting). Workers permitted entry under the REI are prohibited for soil fumigants. Under the Worker Protection Standard (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 comments that indicated the opposite of the comments received in phase 5. The post-RED comments stressed that the restriction would prohibit certain activities from taking place and that the restrictions were not warranted. Based on discussions with stakeholders and the risks identified, EPA does not believe that the entry restricted period will have a substantial impact on agricultural operations, and the Agency is not making any changes to the July 2008 RED mitigation listed below.

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

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

Figures 5, 6, 7, and 8 provide illustrations of tarp perforation/removal and entry prohibition mitigation required for various metam-sodium and metam-potassium applications. The intervals depicted are the minimum that must be followed.

Figure 5. Untarped Applications

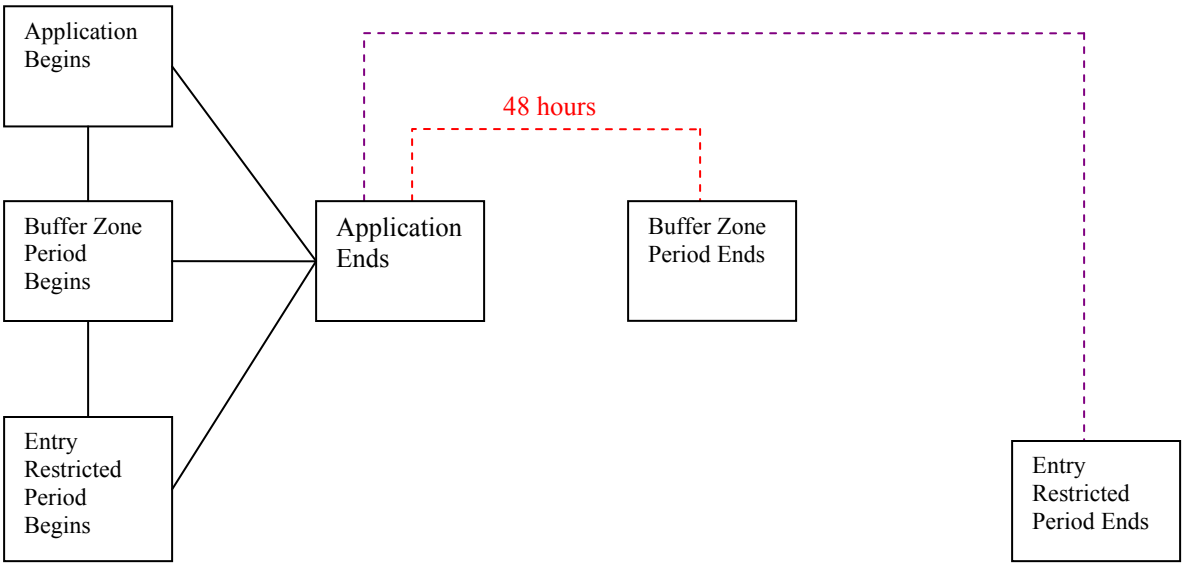


Figure 6. Tarp Broadcast Applications (tarps removed before planting)

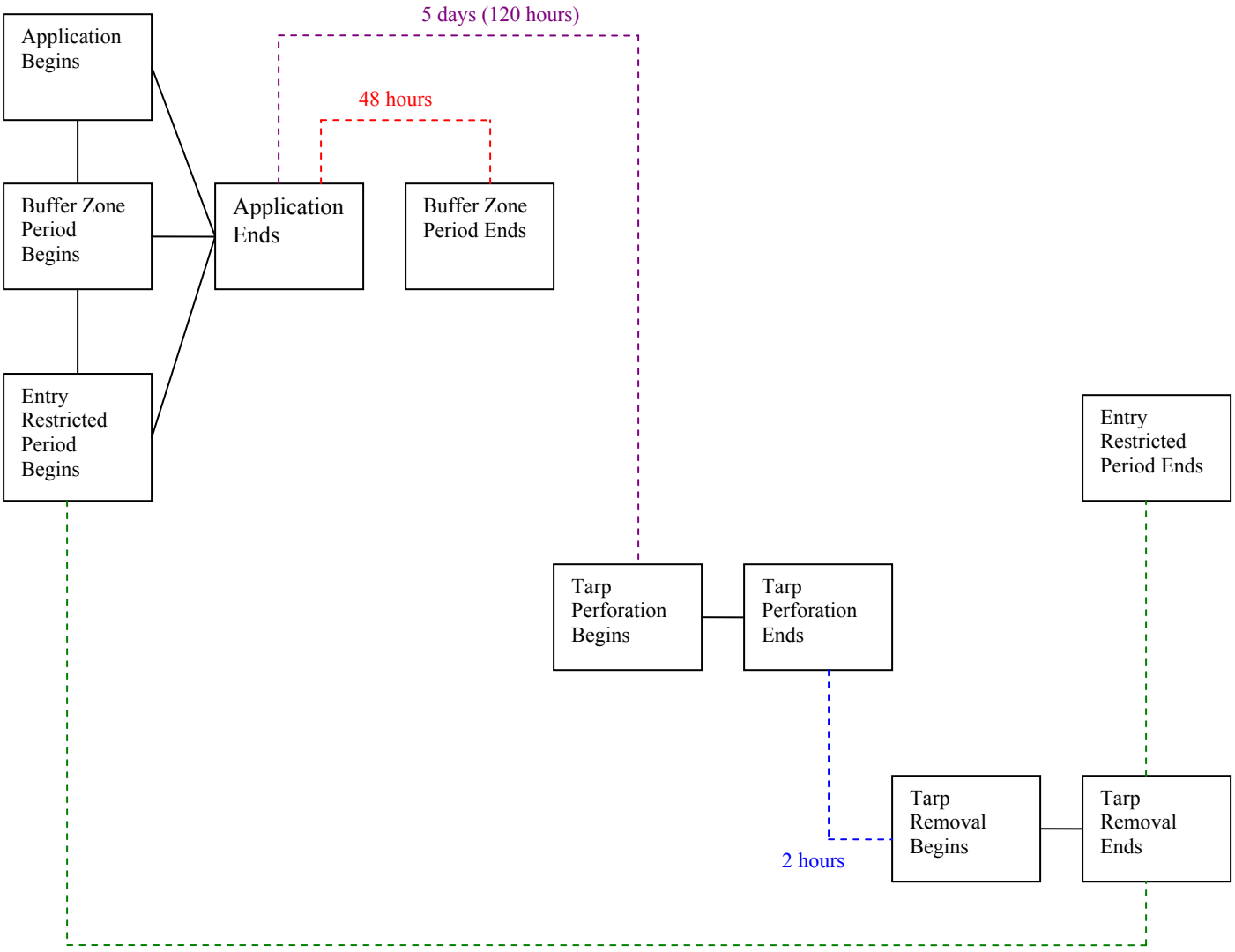


Figure 7. Tarp Bed Applications (Tarps not removed before planting)

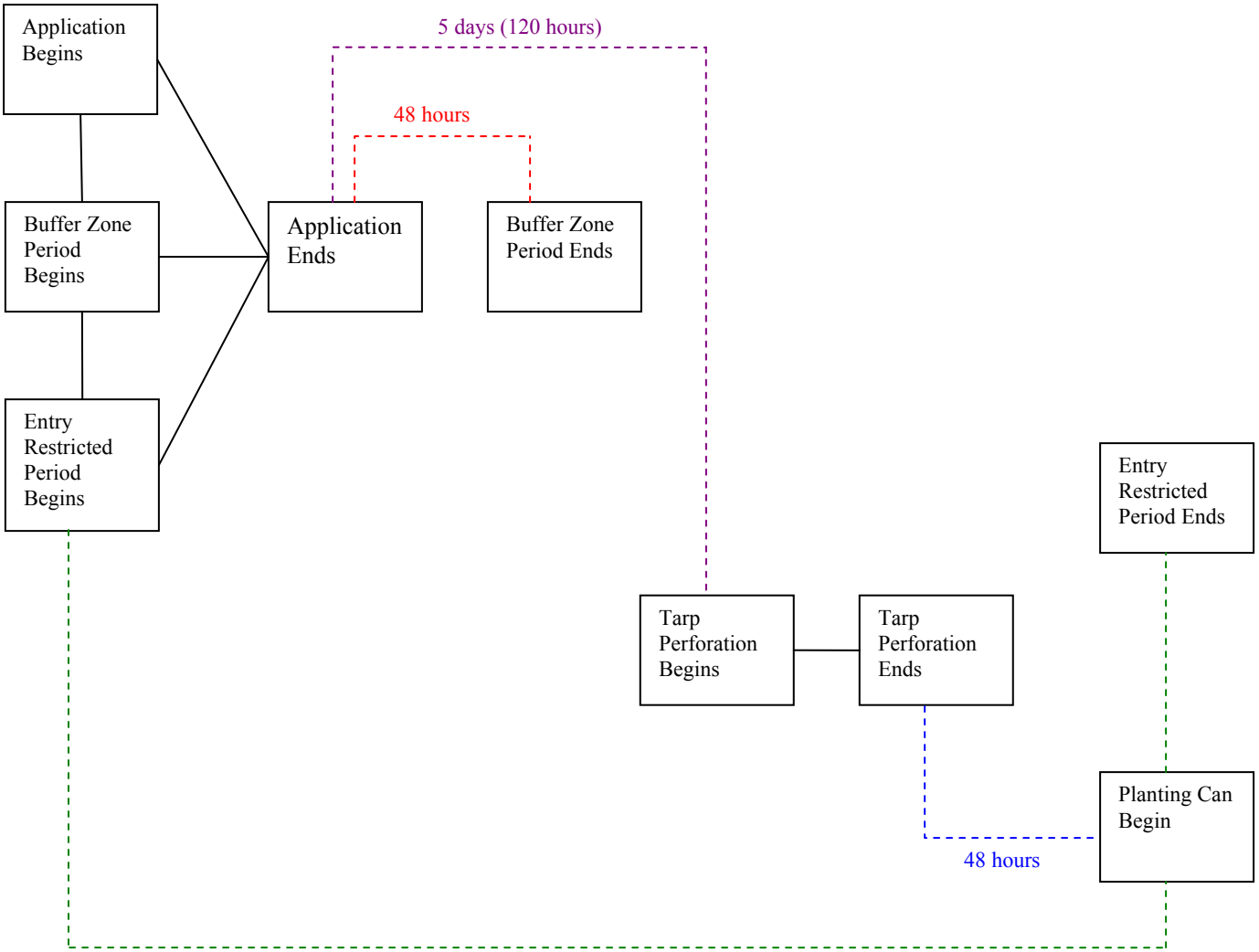
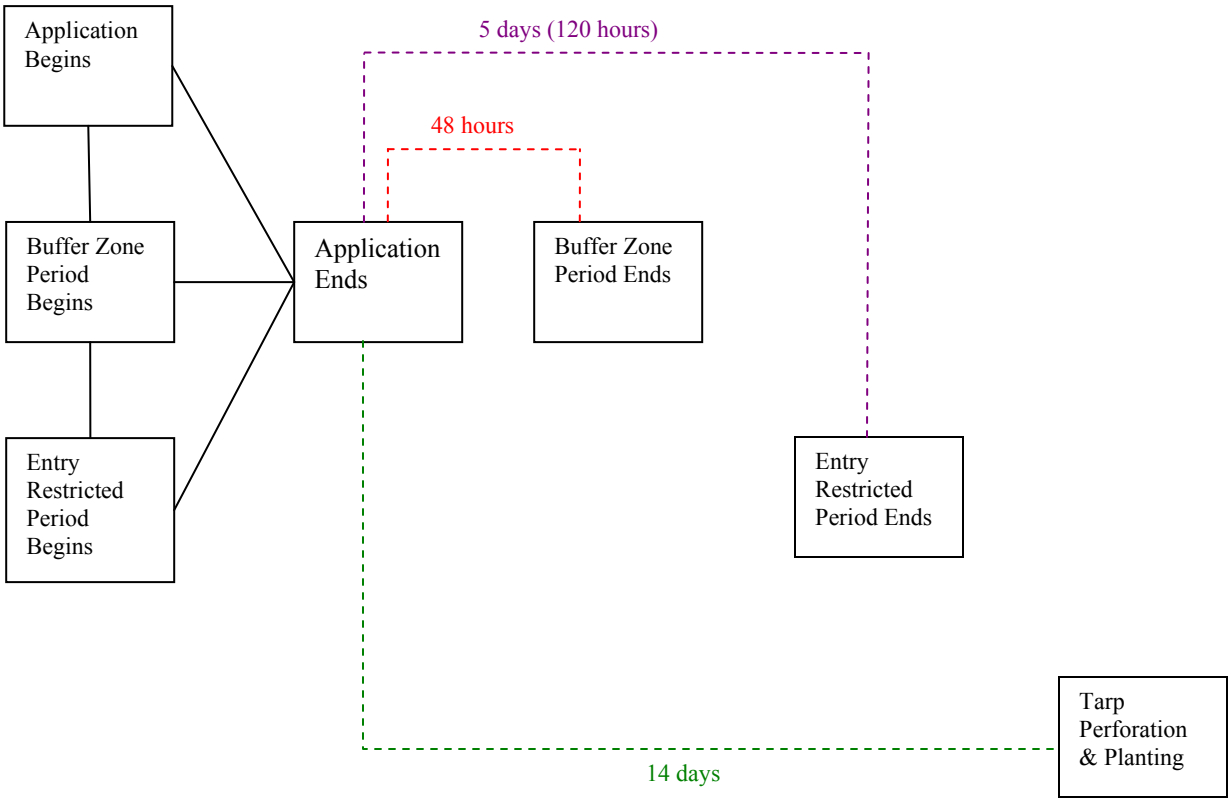


Figure 8. Tarp Bed/Broadcast Applications (Tarps are not perforated until 14 days after application)



cc. Other Risk Mitigation

1. Restricted Use Pesticide (RUP) Classification

All soil fumigant products containing methyl bromide, 1,3-dichloropropene (Telone®), iodomethane, and chloropicrin are currently classified as RUPs. Soil fumigant products containing metam-sodium and metam-potassium are currently unclassified as such. However, MITC, the byproduct of metam-sodium and metam-potassium, has characteristics that meet the criteria for restricted use for both human hazard criteria (as specified in 40 CFR 152.170(b)) and from other evidence (as specified in 40 CFR 152.170(d)) including use history and incident data from exposure to MITC.

Human Hazard Criteria

The acute toxicity profile of MITC shows it is more acutely toxic (toxicity categories are all I or II) than metam-sodium and metam-potassium (mostly toxicity categories III and IV). While the product toxicity of metam-sodium and metam-potassium do not meet the hazard criteria for classification as restricted use, the degradate product of MITC, which both handlers and bystanders can be exposed to, does meet the criteria.

Other Evidence

If any soil fumigant is not applied correctly, bystanders may be exposed to concentrations that exceed levels of concern and that could cause significant adverse effects. There is a history of incidents involving metam-sodium in which multiple bystanders experienced illness/injury despite being several hundred to several thousand feet from the treated area. The application of soil fumigants can pose hazards for several hours from the time of application to several days after application. Depending on the situation, worker and/or area air monitoring may be required to ensure that exposure limits are not exceeded. Special equipment is often needed to apply soil fumigant safely and accurately (e.g., compaction rig, tarp equipment, self-contained breathing apparatus). To apply soil fumigants safely and ensure bystanders and applicators are not adversely affected, handlers also need specialized skills and training.

In sum, metam-sodium and metam-potassium meet the standard for restricted use because:

- The application of these fumigants involves complex operations requiring specialized training and/or experience.
- Fumigant label directions call for specialized apparatus and protective equipment that is not available to the general public.
- A minor failure to follow label directions may result in severe adverse effects.
- Even if directions for use are followed, use may result in discernible adverse effects, of both direct and indirect nature, on non-target organisms.

Therefore, the Agency has determined that all metam-sodium and metam-potassium soil fumigant products must be classified as restricted use. Label requirements will include the following details, which are also contained in the attached label table.

Requirement on Labels

"Restricted Use Pesticide due to acute inhalation toxicity to humans."

"For retail sale to and use by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

In order to ensure that a certified applicator is at the application site, the label will also state, "the certified applicator supervising the application must be at the fumigant application site and able to maintain visual contact with every handler participating in the application starting when the fumigant is first introduced into the soil and ending after the fumigant has stopped being delivered/dispensed to the soil and the soil is sealed."

2. 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 good agricultural practices (GAPs) that were required for soil applications of metam-sodium and metam-potassium. 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,
- university research exemptions, and

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, and will continue to review GAPs as the Agency finalizes the soil fumigant labels.

The GAPs outlined in the RED and this RED amendment has 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.

Note: The Agency plans to work with the registrants and other stakeholders to refine the GAPa for metam-sodium and metam-potassium prior to the 2010 and 2011 growing season.

Weather Conditions

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.

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

2008 RED since they provide additional clarity that will enhance users' ability to practically comply with the requirements. The revised statements are stated below.

The following are mandatory GAPs that must be followed during all applications, as specified below. All measurements and other documentation planned to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the post application summary report.

Registrants may also include optional GAPs that reduce emission on product labels. Some of the optional GAPs may qualify for buffer zone credits (e.g., reduced soil temperature, use of high barrier tarps, increased soil organic matter, and soils with increased clay content). All measurements and other documentation planned to ensure that the optional GAPs are achieved must be recorded in the FMP and/or the post application summary report.

GAPS for Ground-rig Applications (Shank, Spray Blade, Rotary Tiller, etc.)

Wind Speed

- 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.

Weather conditions

- 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.
- 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.

Identifying 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 Conditions, Injection Depth and Soil Sealing

- Soil must be in good tilth and free of large clods at the surface. If subsurface soil compaction layers (hardpans) are present within the intended fumigation treatment zone, a deep tillage to fracture these layers must occur prior to the soil fumigant application.

- Field residue and stubble must be worked into the soil with little or no crop residue 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.

- For shank injection applications: The injection point for bedded and broadcast shank injection applications shall be a minimum of 3 inches from the post-application soil surface. Chisel traces must be eliminated following an application and the soil surface must be compacted immediately with a culti-packer, ring roller, coil packer, soil-crumbler basket, bed-shaper, or other similar equipment.

- For spray blade and rotary tiller applications: Spray or drip the product mixture on the soil immediately ahead of the bed-shaping equipment or tiller. The soil surface must be compacted immediately after application using a culti-packer, ring roller, soil-crumbler basket, bed-shaper, or other similar equipment.

Soil temperature

- For all ground-rig applications, the maximum soil temperature measured throughout the treatment area at a three-inch soil depth must be between 90-40 degrees F.

Soil Moisture

- Soil moisture, at the start of an application, must be at 60-80% field capacity two to six inches below the soil surface.

- To achieve soil moisture at 60-80% field capacity, water treatments before or during the application, or tillage before or during the application may be necessary.

- To conserve soil moisture, pretreatment water or tillage should be done as close to the time of application as possible.

- The soil shall contain at the time of application enough moisture two to six inches below the surface to meet the *Feel Method* test as appropriate for the soil texture. .

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

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

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

fine textured soils (clay, clay loam, and silty clay loam) there must be enough moisture (50 to 75 percent available soil water moisture) so the soil is moist, forms 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.

Prevention of Spillage

- Do not apply or allow fumigant to drain onto the soil surface.

Application and Equipment Considerations

- Injectors must be placed below the soil surface before product flow begins.
- Clear lines before lifting injectors from the soil.
- Each injection line must have a check valve located as close as possible to the final injection point.
- Use only tanks, hoses and fittings approved for metam.

- Dry connect fittings (closed transfer system) must be installed on all tanks and transfer hoses.

- All systems must be equipped with an individual tank monitoring system to detect flow problems in each individual tank.

- Each nozzle must be equipped with a flow monitor, e.g. mechanical, electronic, or Red-ball type monitor.

- Prior to applications, the applicator must ensure that:

    - Application equipment is in good working order,
    - All tanks, hoses, fittings, valves and connections are tightened, sealed and not leaking,
    - Tank monitoring equipment, flow monitoring equipment and check valves are functioning properly,
    - There is no damage to hoses or piping,
    - Sight gauges and pressure gauges are working,
    - Nozzles and metering devices are of correct size and are sealed and unobstructed,
    - All shields are in place.

Tarps

- When tarps are used in tractor applications, the tarps must be installed immediately after application.

- Only approved tarps identified in this document, in the section titled "Buffer Zone Reduction Credits", may be used for credits towards reducing the buffer.

- A written tarp plan must be developed and included in the FMP that includes:

    - Schedule and procedures for checking tarpaulins for damage, tears, and other problems,
    - Plans for determining when and how repairs to tarp will be made, and by whom,
    - Minimum time following injection that tarp will be repaired,
    - Minimum size of damage that will be repaired,
    - Other factors used to determine when tarp repair will be conducted,
    - Schedule, equipment and methods used to cut tarp,
    - Aeration plans and procedures following cutting and /or slitting prior to tarp removal or planting, and
    - Schedule, equipment, and procedures for tarp removal.

GAPS for Sprinkler and Chemigation Applications

Wind Speed

- For mid-release, high-release and end-gun sprinkler or chemigation applications as defined by U.S. EPA, wind speed at the application site must be a minimum of 2 mph at the start of the application or forecasted to reach 5 mph during the application and the maximum wind speed is 8 mph.

- For low-release sprinkler or chemigation applications as defined by U.S. EPA, wind speed at the application site must be a minimum of 2 mph at the start of the application or forecasted to reach 5 mph during the application and the maximum wind speed is 25 mph.

Wind Speed

- 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.

Weather conditions

- 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.
- 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.

Identifying 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 Conditions

- Soil must be in good tilth and free of large clods at the surface. If subsurface soil compaction layers (hardpans) are present within the intended fumigation treatment zone, a deep tillage to fracture these layers must occur prior to the soil fumigant application.

- Field residue and stubble must be worked into the soil with little or no crop residue 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.

Air Temperature

- The maximum air temperature is 90 degrees F.

Soil temperature

- The maximum soil temperature, measured at a three-inch soil depth, is 90 degrees F.

Soil Moisture

- Apply sufficient water before or during the application to ensure soil moisture at 60-80% field capacity at a minimum of two to six inches below the soil surface at the start of the application.

Flushing Irrigation Lines

- Do not allow fumigant to remain in the irrigation system after the application is complete. After application of the fumigant, flush the injection and irrigation system with untreated water. The flush time must be adequate to purge the fumigant from the injection and irrigation system, but should be less than the amount that could over-saturate the beds. If common lines are used for both the fumigant application and a water treatment/seal (if applied), these lines must be adequately flushed before starting the water treatment/seal.

Set-up, Repair and Maintenance of Equipment

- Anti-siphon and back-flow prevention devices must be installed and in working order.

- Storage tanks must be inspected, in good condition, and not past their life expectancy to ensure product does not spill or leak.

- Storage tanks must have proper pesticide labels on them.

- Install a shut-off valve on the tank outlet to secure the bulk storage tank when not in use.
- Use only tanks constructed with materials approved for handling metam-sodium/metam-potassium.
- Inter-connect the pump power supply and injection pump so that, if the center pivot or linear move stops, the injection pump shuts off.

GAPs for Drip Application

Wind Speed

- 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.

Weather conditions

- 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.
- 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.

Identifying 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 Conditions

- Soil must be in good tilth and free of large clods at the surface. If subsurface soil compaction layers (hardpans) are present within the intended fumigation treatment zone, a deep tillage to fracture these layers must occur prior to the soil fumigant application.

- Field residue and stubble must be worked into the soil with little or no crop residue 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 Temperature

- The maximum soil temperature is 90 degrees F, measured at three inches in depth.

Set-up, Repair and Maintenance of Equipment

- Properly label metam-sodium storage tanks.
- Install a shut-off valve to secure the bulk storage tank when not in use.
- Use only tanks constructed with materials approved for handling metam products.
- The drip irrigation system (main lines, headers, drip tape) must be thoroughly checked for leaks before the start of the application. An adequate run-time and pressure are needed to detect leaks. Look for puddling along major pipes (holes on pipes or leaky joints), at the top and ends of rows (leaky connections, open drip tape), in the furrows and on the bed surface (damaged drip tape, malfunctioning emitters).
- To inject fumigant, use a metering system, effectively designed and constructed of materials that are compatible with the fumigant and capable of being fitted with system interlocking controls.
- The system must contain a functional back-flow/check valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination and backflow.
- The fumigant injection system must contain a functional, automatic, quick-closing check valve to prevent the flow of fumigant back toward the fumigant container.
- The fumigant injection system must contain a functional, normally closed valve located on the intake side of the injection point and connected to the system interlock to prevent fumigant from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the fumigant injection when the irrigation water flow stops or decreases to the point where fumigant distribution is adversely affected.

Tarps

- When tarps are used in drip irrigation the tarps must be installed immediately after application.

- Only tarps mentioned previously in this document (in the subsection titled "Buffer Zone Reduction Credits", may be used for credits towards reducing the buffer.

- A written tarp plan must be developed and included in the FMP that that includes:

  - Schedule and procedures for checking tarpaulins for damage, tears, and other problems,
  - Plans for determining when and how repairs to tarp will be made, and by whom,
  - Minimum time following injection that tarp will be repaired,
  - Minimum size of damage that will be repaired,
  - Other factors used to determine when tarp repair will be conducted,
  - Schedule, equipment and methods used to cut tarp,
  - Aeration plans and procedures following cutting and /or slitting prior to tarp removal or planting, and
  - Schedule, equipment, and procedures for tarp removal.

Flushing Drip Irrigation Lines

- After application of the fumigant, flush the injection and irrigation system with untreated water. Do not allow fumigant to remain in the irrigation system after the application is complete. The total volume of water must be adequate to completely remove the fumigant from the irrigation system. If common lines are used for both the fumigant application and a water treatment/seal (if applied), these lines must be adequately flushed before starting the water treatment/seal.

3. 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[9] (i.e., through "Administrative" and "Workplace" controls). The Centers for Disease Control provides guidance for developing health and safety plans in agricultural settings.[10] 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

[9] 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)

[10] 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

Flexibility Act (5 U.S.C. 610) and Executive Order 12866 to conduct the "lookback" reviews. These reviews are conducted to make the subject final standards more effective or less burdensome in achieving their objectives, to bring them into better alignment with the objectives of Executive Order 12866, and to make them consistent with the objectives of the Regulatory Flexibility Act. Two examples of "lookback" reviews that support the use of FMPs for soil fumigant health and safety management include: ethylene oxide use as a fumigant/sterilant, and grain handling facilities requirements.[11]

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. Stakeholders noted that much of the information required for the site-specific FMP is already being documented by users and most industry stakeholders supported mandatory FMPs provided they are not too restrictive or complex. Several comments from industry and user stakeholders expressed concern that FMP requirements would increase paperwork burden without providing

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

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 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 metam-sodium and metam-potassium.

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 hours 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 labels.

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, 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 (preschool to grade 12), 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 than 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 label (lb ai/A)
  - Application block size from lookup table on 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, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).
- Posting procedures (name, address, and phone number of person(s) who will post signs, location of posting signs, procedures for posting and 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, address, and phone number of person doing notification
    - Method of sharing 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 when respiratory protection is required (minimum of one handler), date of medical qualification to wear a respirator and date of fit testing for respirator.

- Air monitoring
  - 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
- Good Agricultural Practices (GAPs)
  - Description of applicable mandatory GAPs (registrants may also include optional GAPs)
  - Measurements and other documentation planned to ensure GAPs are achieved (e.g., measurement of soil and other site conditions, tarp repair/perforating/removal plans)
- 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 that he/she (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. The summary must include the actual date of the application, application rate, and size of application block fumigated.

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
- 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 complaint (e.g., on-site handler, person off-site)
  - If off-site person, name, address, and phone number of person filing complaint
  - Description of control measures or emergency procedures followed after complaint
- Description of incidents, equipment failure, or other emergency and emergency procedures followed (if applicable)
- Details of elevated air concentrations monitored on-site (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:
      - Sample date and time
      - Handler task/activity
      - Handler 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 templates, 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 metam-sodium and metam-potassium 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

The Agency has provided a template located in the appendix of this document.

4. 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 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 and metam-potassium 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 or 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 requirement is not dependent on people actually being present in the nearby buildings and homes. In this respect it differs from the quarter/eighth mile buffer zone restriction on certain types of occupied structures. Rather, this measure is intended to ensure protection in places people may be found present. Whether measures are required depends on the size of the buffer zone and how close land (e.g., residential properties and businesses) 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 certain 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 may be, which 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) determine the applicable distance for implementing this requirement. When the area is scaled to the size of the buffer, small buffers which generally result from applications to small areas, at low application rates, and/or using low-emission application techniques, will have small or no areas to 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 the EPA has included an exception for

application blocks so fields with the smallest required buffers (25 feet) would not be subject to this requirement, since they are most likely using lower application rates, applying to smaller areas, and/or using better 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 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. Stakeholders felt the inherent warning properties of chloropicrin and MITC (i.e., eye irritation) were better indicators of exposure than available devices. Several of these comments noted concerns with the reliability of such devices at low concentrations. 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 above 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. 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 of technological limitations of currently available devices for MITC and chloropicrin that are not practical or 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 on how 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 three times per day during the full buffer zone period at dawn, dusk, and once 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.
- The person 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 any 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 below at least 1 week prior to the fumigant application in a specified field. If after 4 weeks, the fumigation has not yet taken place, the information must be delivered again.

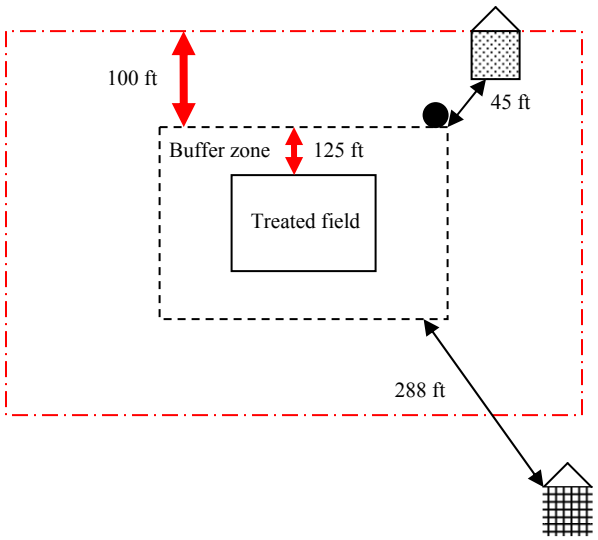
- Information that must be provided includes:
  - The general location of the application block,
  - Fumigant(s) applied including the active ingredient, name of the fumigant products(s), and the EPA Registration number,
  - Contact information for the applicator and property owner/operator,
  - Time 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 who to call if you believe you are being exposed (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:

- 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 (they must monitor where the black dot is) and the buffer zone or residents of the dotted house(?) [people within 100 feet of the buffer zone] must be provided emergency response information.
- So the **dotted** houses would need to be informed, **but** the location of the cross-hatched house would not prompt any action.

Figure 9. Example Site Map for Informing Neighbors.



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

5. 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

For states already requiring such information through an existing state process, applicators will not be required to comply with this requirement. For example, the California Department of Pesticide Regulation already obtains this information as part of their permitting process for fumigant applications.

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.

6. 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 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 failure to comply 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 the certified applicator supervising that application must have successfully completed, within the last 36 months, a metam training program made available by the registrant. The Fumigant Management Plan must document when and where the training program 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. This training would be required as a condition of use by product labeling. 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, above and 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 a required in the DCI that accompanies this amended 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. 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 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, metam-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.

7. Community Outreach and Education Program

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 the 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 MITC, (4) appropriate steps to take to mitigate exposures to MITC, (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 the 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 both the fumigant applied (e.g., metam-sodium and metam-potassium) as well as the active compound generated (e.g., MITC). 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 metam-sodium or metam-potassium fumigant exposure, (2) how to treat metam-sodium or metam-potassium fumigant exposures, and (3) how ("x" chemical) 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, including: brochures, fact sheets, CDs, videos, web-based training materials, etc., 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 metam-sodium and metam-potassium 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 metam-sodium and metam-potassium have been identified by the Agency using EPA proprietary data. [Although state-level data are available from USDA's National Agricultural Statistics Service (NASS), EPA proprietary data are more robust.] Second, the high-use counties for metam-sodium and metam-potassium 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 Metam-Soidum and Metam-Potassium: The Agency is defining states with high usage of metam-sodium and metam-potassium as those states where, on average, more than 100,000 lbs of metam-sodium and metam-potassium are applied annually. To determine those states where, on average, more than 100,000 lbs of metam-sodium and metam-potassium has been applied annually, the Agency obtained data on the average number of pounds of metam-sodium and metam-potassium 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 memo, "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 and supporting documentation located in the metam-sodium and metam-potassium docket at EPA-HQ-OPP-2005-0128.

- Step 2: Identifying Counties with High Use of Metam-Sodium and Metam-Potassium: 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 metam-sodium and metam-potassium may be high. Because county-level fumigant usage data is not publicly available and EPA proprietary data are not reliable, crop acreage should be used as a surrogate indicator for fumigant usage. Crop acreage can be obtained for major use sites of metam-sodium and metam-potassium from the publicly available 2007 USDA Census of Agriculture. Crop acreages for each of the major use sites for metam-sodium and metam-potassium should be obtained for each the major use sites for metam-sodium and metam-potassium 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 1,000,000 lb of metam-sodium and metam-potassium applied annually.

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

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

- Step 1: Identify States with High Use of Metam-Sodium and Metam-Potassium:
  - Based on its analysis of proprietary data, the Agency has identified the following high-use states for metam: 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. The same process would be applied to other high-use states.

- Step 2: Identify the Counties in California with High Use of Metam-Sodium and Metam-Potassium:

- EPA has identified the following as the major use sites of metam-soidum and metam-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 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 memo "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 which is located in the metam-sodium and metam-potassium 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 memo "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 which is located in the metam-sodium and metam-potassium 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.

8. Ambient Air Monitoring Program

In the July 2008 Metam-Sodium and Metam-Potassium RED, the Agency required the registrants to develop an air monitoring program in high-use areas to evaluate whether ambient air concentrations exceed EPA's level of concern and help the Agency to determine whether the RED mitigation measures are adequately protective of bystanders and decide whether additional risk management measures are warranted.

During the post-RED comment period, the Agency received 2008 ambient air monitoring data for MITC in Southern Franklin County, Washington, from the Washington State University (WSU) Food and Environmental Quality Lab (FEQL) ["2008 MITC Residential Community Air Assessment: Franklin County, Washington" (LePage and Goss 2008); MRID 47732802]. Agency analysis of ambient air data collected by WSU-FEQL in Southern Franklin County, Washington in 2005, 2007, and 2008 show exceedances of the Agency's level of concern for MITC (MOE < 10) at two monitoring stations in the fall of 2008. Agency analysis of ambient air data for MITC in California from 1997-2001 developed by the California Air Resources Board (CARB) identified exceedances of the Agency's short- and intermediate-term levels of concern (MOE < 30) at three sample locations (indoor and outdoor) in Bakersfield, California, in the summer of 1997. In addition, the Agency is aware of a number of on-going ambient monitoring efforts going on in certain parts of the country including California and the Pacific Northwest. (For additional information on the Agency's analysis of both the WSU-FEQL and CARB ambient air monitoring data, please see "Metam Sodium: Third Revision of the HED Human

Health Risk Assessment, DP# 293354 located in the metam–sodium and metam-potassium docket at: EPA-HQ-OPP-2005-0125.) The Agency is also concerned about chronic exposures and is seeking additional toxicity data on the long-term effects from inhalation exposure to MITC. However, none of the available ambient air studies conducted so far adequately reflects potential long-term concentrations of MITC.

As part of the RED, the Agency is implementing a number of mitigation measures designed to reduce air concentrations of MITC. To help the Agency to determine if these mitigation measures are adequately protective of bystanders and to decide whether additional risk management measures are warranted, the Agency is requiring registrants to conduct ambient air monitoring programs in six counties in the United States with the highest usage of metam-sodium and metam-potassium, as identified in EPA's analysis to identify high-use areas for implementing their community outreach and first responder training programs (see the *Community Outreach Program* and *First Responder Education* sections for details). Registrants are required to develop air monitoring programs that will enable the Agency to evaluate both: (1) potential maximum peak air concentrations in areas of high seasonal use and (2) potential community-level chronic air concentrations in areas of high metam-sodium and metam-potassium use. The air monitoring should begin in 2010 and continue thru the 2011 and 2012 application seasons. This data will allow the Agency to evaluate whether the package of mitigation measures, including buffer zones, have effectively reduced ambient air concentrations and will be included in the reevaluation for metam-sodium and metam-potassium in registration review. EPA encourages the registrants to work with existing air monitoring programs such as in CA and WA or the registrants may develop their own program. The registrant's proposal for developing and implementing an air monitoring program will be required as a data requirement in the data call-in. Proposals should identify the six high use counties where ambient air monitoring will take place. EPA will review these proposals to determine whether they adequately address the requirements specified in the DCI.

Environmental Risk Management

In the July 2008 RED, EPA addressed the concerns about both aquatic and terrestrial risks which are discussed in Section III.C. 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.

The July 2008 RED discussed exposure to terrestrial organisms, such as birds and mammals, which could occur via inhalation of MITC. Potential exposure to aquatic invertebrates and fish may occur from surface runoff/leaching and drift (wind) of MITC.

A species-specific analysis for the California Red-Legged Frog case has been conducted for metam-sodium and metam-potassium and it major degradate, MITC. The Agency determined that MITC "May-Affect" this species. The Agency's assessment is currently with the Services (i.e., the U.S. Fish and Wildlife Service and the National Marine Fisheries Service).

After the final determination has been made, the Agency may require other mitigation.

The July 2008 RED also discussed uncertainty associated with potential risk to non-target plants, given that there are no data available. Additional plant toxicity data for MITC is being required.

The July 2008 RED noted that based on the fate parameters of MITC, it should not persist in terrestrial environments because of volatilization and degradation and the available non-targeted monitoring data does not detect MITC in the ground-water samples within the U.S. However, MITC is highly soluble in water and has a low adsorption to soil which suggests that there is a potential of leaching to shallow groundwater under flooded and saturated conditions. Also, if intense rainfall or continuous irrigation occurs there is potential for MITC to move to surface water. Due to the importance of adequate soil moisture as described in the GAP section and the knowledge that volatilization is metam-sodium and metam-potassium's most important route of dissipation, EPA required the following language in the July 2008 RED taking these factors into consideration: "While metam-sodium, metam-postassium, and their major degradate MITC have certain properties and characteristics in common with chemicals that have been detected in groundwater (MITC is highly soluble in water and has low adsorption to soil), volatilization is this chemical's most important route of dissipation."

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, "Metam-sodium, metam-potassium and their major degradate MITC have certain properties and characteristics in common with chemicals that have been detected in groundwater (MITC is highly soluble in water and has low adsorption to soil)."

The July 2008 RED also included language required for both tarped and non-tarped metam-sodium and metam-potassium applications to minimize potential for leaching. During the post-RED comment period commenters stated that the following language was not clear or enforceable: "For untarped applications of metam-sodium and metam-potassium, 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."

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." The revised statement is based on information presented in a 2007 article by Zhang and Wang[12].

Please see section V of this document for the revised ground water label statements.

b. Sewer Root Control Use

12 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.

During the post-RED comment period, the Agency received additional usage and occupational exposure information from the two metam-sodium sewer use registrants, Sewer Sciences, Inc. and Douglas Products and Packaging Company, which allowed the Agency to refine the metam-sodium non-cancer (i.e., short-term and intermediate-term) and cancer sewer use risk estimates. (To view the revised metam-sodium human health risk assessment, which incorporates the revised sewer use risk estimates, please see: Metam Sodium: Third Revision of the HED Human Health Risk Assessment, 04/30/09, D357118 in the metam-sodium docket at EPA-HQ-OPP-2005-0125.) The comments specifically focused on the inputs of application rate, the amount of product handled per day, the amount of time applicators may be exposed during a work day, and the typical number of days per year that metam-sodium is used. A short summary of the information provided and an explanation of how it was used by the Agency in revising it risk assessment is summarized below.

- Application Rate: The Agency revised the application rate used in the 2008 RED calculations (0.212 lb ai/A) based on typical application rate data submitted by Douglas Products and Packaging (0.111 lb ai/A) for Sanafoam Vaporooter II (EPA Registration No. 1015-70) and the application rate information listed on Sewer Science Inc.'s product, Rout, label (EPA Registration No. 64898-4) (0.127 lb ai/A). Both application rates were considered in the revised human health risk assessment.
- Amount of Metam-Sodium Handled Daily: Sewer Sciences Inc. reported that their applicators treat between 4,500 and a maximum of 10,000 feet of sewer pipe (8" diameter) in a day, which corresponds to between 600 and 1,333 gallons of metam-sodium handled per day. Douglas Products and Packaging reported that their applicators treat between 2000 and 4000 linear feet of sewer pipe (8" diameter) daily, which corresponds to between 250 and 500 gallons of metam-sodium handled per day. The Agency utilized both exposure estimates in its revised human health risk assessment.
- Exposure – Number of Days Workers Treat Sewers Each Year: Based on an analysis of its sales data, Douglas Products reported that workers apply metam-sodium to sewers a maximum of 160 days per year. Sewer Sciences reports that applicators apply their products approximately 220 days per year. Both exposure scenarios were considered in the revised human health risk assessment.
- Exposure – Number of Hours Exposed to Metam-Sodium Each Day: Sewer Sciences Inc. has reported that commercial applicators work with metam-sodium 8 hours each day and, therefore, metam-sodium worker exposures should be estimated at 8 hours daily. The comments submitted by Douglas Products and Packaging reported that the time per day that metam-sodium exposure can occur is limited to the amount of time actually spent loading the chemical and the time when the applicator hose is removed from the sewer manhole. Most of the application time consists of the hose being unrolled into the manhole cover and then rolled out of the manhole cover. Therefore, there is no potential for exposure to metam-sodium during most of the application time. Based on the usage and exposure information submitted by Douglas Products and Packaging, the Agency believes that it is appropriate to assume two hours of exposure to metam-sodium in its cancer assessments, since the duration of exposure to metam-sodium is limited.

During the public comment period, the Agency also received information from Douglas Products indicating that closed engineering systems are employed for all mixing and loading

activities. As a result, EPA is requiring closed mixing loading systems for all metam-sodium sewer use applications to limit exposures to handlers.

In a February 2009 letter received from a representative on behalf of the registrant, Sewer Sciences Inc., the company provided data identifying the sewer use of metam-sodium as a source of N-nitrosodiumethylamine (NDMA) in wastewater and asked the Agency to consider this information in its assessment of the use of metam-sodium in sewers. In the Agency's "Revised Environmental Fate and Ecological Effects Risk Assessment for Metam-sodium and Metam-potassium" (PC Codes 039003 and 039002; DP Barcode D293339) (see the metam-sodium docket at: EPA-HQ-OPP-2004-0159-0118), the Agency acknowledged NDMA, for which there is a National Recommended Water Quality Criteria of 0.00069 µg/L (current/potential drinking water) and 3.0 µg/L (no potential for drinking water), as a reported contaminant in metam-sodium sewer use products. To further evaluate metam-sodium sewer use as a potential source for NDMA in wastewater, the Agency will require the registrants, in response to the product-specific data call-in (pDCI) that will accompany this RED addendum, to report to the Agency any concentration of NDMA in their product(s), pursuant to FIFRA Section 158.350(a)(4).

Based on comments received during the post-RED comment period the Agency is providing additional characterization or the dermal risks from metam-sodium and the inhalation risks from both metam-sodium and MITC. Additionally, comments received from Sewer Sciences, Inc. identified errors that had been made in July 2008 RED which included noncommercial handler cancer risks, representing five days of exposure, rather than the commercial handler cancer risks, which were represented by 220 days of exposure and presenting cancer risk from dermal exposures to metam-sodium when an OV respirator is worn. In their comments, Sewer Sciences Inc. correctly noted that if the cancer risks are derived from dermal exposure, a respirator would not be an effective means of mitigating these risks.

Rationale

Metam Sodium Non-Cancer Occupational Risk Concerns – Acute & Short-term Inhalation Risks from MITC Exposure

Because metam-sodium degrades rather quickly to MITC, short-term, intermediate-term, and chronic inhalation exposures to metam-sodium by workers are expected to be negligible when compared with MITC exposures. To assess acute and short-term inhalation risks to applicators, EPA utilized two studies, conducted in Australia, which measured MITC air concentration levels during application of a metam-sodium product to sewers. These studies represent the best available acute- and short-term MITC inhalation exposure data. Table 12 below summarizes the acute and short-term MOE estimates for MITC inhalation exposure to handlers based on exposure levels from these studies. Estimates represent baseline conditions as well as the use of dermal or respiratory protection, as indicated.

Table 12. Handler MOEs for MITC Inhalation Exposure from Sewer Use Application of Metam-Sodium

Study	Sample	MITC Conc. (ppm)	Baseline MOEs		PF 10 Respirator MOEs	
			Acute	ST	Acute	ST

			MOE [1]	MOE [2]	MOE [1]	MOE [2]
Sheers R (1994) Melbourne Water - Sanafoam Vaporooter Trial, 7 November 1994	Operator breathing zone exposure	0.27	1	1	10	10
	At point of application	22	<1	na	9-10	na
	Two manholes downstream (approx. 300 m)	0.017	36	na	360	na
	At point of application - 24 hours post-application	0.023	26	na	260	na
Sheers R (1995) Melbourne Water - Sanafoam Vaporooter Trial, 13-14 February 1995, ICI Australia Operations Pty Ltd.	Operator breathing zone exposure	< 0.017	13	10	130	100
	Operator breathing zone exposure	< 0.027	8	7	80	70
	Operator breathing zone exposure	0.057	4	3	40	30
	At point of application - 30 mins post application	2.6	<1	na[3]	9-10	na[3]
	At point of application - 90 mins post application	1.3	<1	na[3]	9-10	na[3]
	At point of application - 180 mins post application	6.8	<1	na[3]	9-10	na[3]
	At point of application - 270 mins post application	4.4	<1	na[3]	9-10	na[3]
	At point of application - 360 mins post application	0.87	1	na[3]	10	na[3]
	At point of application - 24 hours post-application	< 0.010	60	na[3]	600	na[3]

[1] Acute MOEs for breathing zones samples based on NOAEL of 0.22 ppm. For other samples (less than 15 minutes) acute MOEs based on 0.60 ppm. Acute target MOE = 10.
[2] MOEs were not estimated for static measure measurements. Short-term target MOE = 30.
[3] na = not available

These estimates indicate that for samples taken in the breathing zone of the applicator, the target MITC concentrations ranged from 0.27 ppm to < 0.017 ppm, with acute MOEs ranging from 1 to 13 and short-term MOEs ranging from 1 to 10. While these MOEs are below both the target MOE of 10 for acute inhalation exposures to MITC and the target MOE of 30 for short-term exposures to MITC, as noted previously, these estimates do not take into account the use of respiratory protection. Samples taken at the point of application (i.e., directly over a manhole where a metam-sodium application had taken place, both immediately after an application and at regular intervals in time after an application had taken place), were largely below an MOE of 1. To address the short- and intermediate-term MITC inhalation risks from MITC, in the July 2008 metam-sodium metam-potassium RED, the Agency required that any person(s) engaged in any activities that are likely to involve direct contact with metam-sodium (including, but not limited to, mixing, loading, and/or applying metam-sodium; equipment calibration; cleaning and repair of application equipment; entering into treated areas; sampling cleanup spills; and rinsate disposal) wear a half-face respirator with organic vapor cartridge approved for MITC.

While there is insufficient toxicological data to characterize the inhalation cancer risk of MITC, due to limitations in the rat and mouse MITC oral carcinogenicity studies, the Agency anticipates that these new respiratory requirements will adequately address this risk. However, the Agency is requiring additional study data (see Section V), including: (1) an inhalation development toxicity rat study (GLN 870.3550), (2) a two-generation inhalation reproduction study in rat (GLN 870.3800), and (3) carcinogenicity studies (i.e., rat and mouse) for MITC (GLN 870.4200). In addition, to understand the ratio of the conversion of metam-sodium to MITC, the Agency is adding a requirement for monitoring data in the breathing zone of the mixer/loader/applicator for sewer use metam-sodium applicators (GLN 875.1300) This study should measure dermal exposure to metam-sodium and inhalation exposure to MITC to determine what handlers are being exposed to and in what quantities. This MITC monitoring data, in addition to the data being requested to characterize the inhalation cancer risk of MITC, will enable the Agency to further characterize the toxicity profile of this chemical and to confirm

whether the mitigation measures being required are adequate or if additional measures are warranted. These data will be required as a part of the data call-in that will accompany this RED.

Metam-Sodium Non-Cancer Occupational Risk Concerns – Short- and Intermediate-Term Dermal Risks from Metam-Sodium Exposure

The Agency revised the non-cancer, short- and intermediate-term occupational handler dermal exposure assessments based on the additional usage and occupational exposure information provided by the metam-sodium sewer use registrants. The results of the revised non-cancer, short-term occupational handler dermal exposure assessments for the sewer use of metam-sodium indicate that the MOEs for the dermal risk to handlers with engineering controls (e.g., closed mixing and loading systems) were above or just below the target MOE of 100, and the MOEs for the dermal risk to handlers with full dermal PPE (i.e., chemical resistant gloves and double layer clothing) were above 49, even at the highest daily rates of amount of product handled. In the case of the intermediate-term exposures with full dermal PPE, MOEs were below the target MOE of 100, even with engineering controls. Revised risk estimates are given in Table 13 below.

Table 13: Metam-Sodium Non-cancer Dermal Sewer Handler Risk Estimates

Application Rate (lbs ai/gal)	Amount Handled Daily (gals)	Baseline MOE	PPE-G[1] MOE	PPE-G[1],DL[2] MOE	Eng Cont MOE[6]
Short-term Margins of Exposure [3]					
0.111	500 [5]	0.73	93	130	250
	1125 [5]	0.33	41	56	110
0.127	500 [5]	0.64	81	110	220
	1125 [5]	0.29	36	49	96
Intermediate-term Margins of Exposure [4]					
0.111	500 [5]	0.017	2.2	3	5.9
	1125 [5]	0.0077	0.97	1.3	2.6
0.127	500 [5]	0.015	1.9	2.6	5.1
	1125 [5]	0.0068	0.85	1.2	2.3

[1] G = gloves.
[2] DL = double layer of clothing.
[3] Short-term margins of exposure are calculated using a NOAEL of 4.22 mg/kg/day from a developmental rat toxicity study. Short-term target MOE = 100.
[4] Intermediate-term margins of exposure are calculated using a NOAEL of 0.1 mg/kg/day from a chronic dog toxicity study. Intermediate-term target MOE = 100.
[5] 500 and 1125 gallons handled per day equals treating 4,000 and 9,000 linear sewer feet per day.
[6] Engineering controls = mixing and loading activities, but not applications.

Although not all short- and intermediate-term dermal exposure MOEs reached the target MOE of 100 with the required dermal protection and engineering controls, the occupational handler dermal exposure assessments are considered to be very conservative. Coupled with the Agency's dermal PPE requirements (i.e., chemical resistant gloves and double layer clothing) and engineering control requirements (i.e., closed mixing and loading systems), the Agency believes that it is being protective of possible metam-sodium short-term and intermediate-term dermal risks. The occupational dermal risk assessments are based on data from the Pesticide Handler Exposure Database (PHED). PHED was designed to be used only to assess nonvolatile

pesticides. In the case of metam-sodium sewer use, PHED was used because there is no data available to the Agency to assess exposure to metam-sodium itself. Since metam-sodium degrades rather quickly to MITC, the dermal short- and intermediate-term sewer risk assessment for metam generated by the Agency using data from PHED can be considered very conservative. In addition, the mixer-loader open-pour exposure information from PHED used to estimate risk for sewer use handlers of metam-sodium mixing, loading, and applying is not necessarily a good representation of the actual sewer application activities. The PHED scenario assumes that the handler is directly mixing and pouring the chemical into the application tank, while application information provided by the registrants describes a lower-exposure practice in which the applicator unrolls a hose into the manhole cover and then rolls the hose out of the manhole cover as the chemical is being applied.

Another source of conservatism comes from the fact that both the short- and intermediate-term dermal exposure assessments assume that workers are exposed throughout an 8-hour workday. However, the Agency believes that the amount of time workers are exposed to metam-sodium each day is limited to the amount of time spent loading and applying metam-sodium, which the Agency has estimated at 2 hours per day, based upon information submitted by the registrant, Douglas Products and Packaging Company.

To address the short- and intermediate-term dermal risks from metam-sodium, consistent with the mitigation required in the July 2008 metam-sodium/potassium RED, the Agency is requiring that any person(s) engaged in any activities that are likely to involve direct contact with metam-sodium (including, but not limited to, mixing, loading, and/or applying metam-sodium; equipment calibration; cleaning and repair of application equipment; entering into treated areas; sampling cleanup spills; and rinsate disposal) be required to wear double-layer clothing and chemical-resistant gloves.

In addition to the worker PPE requirements, the Agency will also require closed engineering systems for all mixing and loading of metam-sodium for sewer use. In addition, all systems must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage. Finally, handlers will also be required to position a clean water rinse hose to continually rinse off the application hose as it is extracted from the sewer pipe. All of these mitigation measures are designed to further protect handlers from exposures. These additional requirements are a result of information that the Agency received from Douglas Products and Packaging Company during the post-RED comment period regarding typical usage scenarios, which included such practices.

To better evaluate the dermal exposure to mixer/loader/applicators of metam sewer use applications and to confirm whether the mitigation measures included in this RED are adequate and/or determine whether additional mitigation measures are warranted, the Agency also will be requiring the registrants to submit outdoor dermal exposure data (GLN 875.1100) and product use information (875.1700) as a part of the data call-in that will accompany this RED.

Metam-Sodium Cancer Occupational Risk Concerns

EPA revised its occupational handler dermal cancer assessment for handlers engaged in sewer applications of metam-sodium to control roots in sewer systems based on the additional usage and occupational exposure information provided by the metam-sodium sewer use registrants during the post-RED comment period. The results of the revised cancer occupational handler dermal exposure assessment for the sewer use of metam-sodium indicate that cancer risks for workers in full dermal PPE requirements (i.e., chemical resistant gloves and double layer clothing) and/or those using engineering control technologies (i.e., closed mixing and loading systems) are below the target cancer risk level of between $1x10^{-4}$ to $1x10^{-6}$ for exposed handlers. Revised risk estimates are given in Table 14 below.

Table 14: Metam-Sodium Cancer Sewer Risk Estimates

Application Rate (lbs ai/gal)	Amount Handled Daily (gals)	Hours per Day Exposed	Number of Days Treating per Year	Baseline Cancer Risk	PPE-G[1] Cancer Risk	PPE-G[1],DL[2] Cancer Risk	Eng Cont Cancer Risk
0.111	500 [3]	2	160	2.5E-04	2.0E-06	1.4E-06	7.3E-07
			220	1.8E-04	1.4E-06	1.1E-06	5.3E-07
0.127			160	2.8E-04	2.3E-06	1.7E-06	8.4E-07
			220	2.1E-04	1.6E-06	1.2E-06	6.1E-07

[1] G = gloves.
[2] DL = double layer of clothing.
[3] 500 gallons handled per day equals treating 4,000 linear sewer feet per day.

Potential Impacts of Metam-Sodium on Nitrifying Bacteria at Downstream Water Treatment Facilities

During the Phase 5 and post-RED comment periods, the Agency received comments from various stakeholders, including Sewer Sciences Inc. and wastewater treatment plant personnel, indicating that metam-sodium impacted downstream wastewater treatment plant operations as a result of bacterial upset. Some wastewater treatment plant personnel provided anecdotal information that the use of metam-sodium led to upsets in the microorganisms at their facilities, but specific details regarding the circumstances that led to these upsets were not provided. During this period, the Agency also received comments from Douglas Products and Packaging and other wastewater treatment plant personnel, indicating that they have observed no evidence that metam-sodium has led to impacts on downstream wastewater treatment plant operations as a result of bacterial upset.

The Agency evaluated the available literature to determine whether there is the potential concern for impacts to wastewater treatment plant microorganisms following application of pesticide products containing metam-sodium. Based on this analysis, the Agency has determined that "it appears as though there is a reasonable body of evidence to indicate that there may be circumstances in which application of pesticide products containing metam-sodium to control intrusion of roots into sewage collection pipes and storm drains could adversely affect activated sludge microorganisms in wastewater treatment plants downstream of sites where such products have been applied." For full details on the Agency's analysis, please see the 4-16-09 Antimicrobial Division memo, "*Evaluation of Potential Impacts to Wastewater Treatment Plan*

Microorganisms Following Application of Pesticide Products Containing Metam Sodium (sodium methyldithiocarbamate) as an Active Ingredient to Control Intrusions of Roots into Sewage Collection Pipes and Storm Drains, located in the metam-sodium and metam-potassium docket at EPA-HQ-OPP-2005-0125].

To mitigate the Agency's concern over potentially harmful effects of metam-sodium on denitrifying bacteria and the associated disruption to downstream sewage treatment facilities, the Agency is requiring applicators to notify downstream wastewater facilities prior to the start of metam-sodium applications so that they may monitor the operations of the wastewater treatment plant. The applicators are required to report how much product they are applying to the sewer system to operators of downstream water treatment plants and to inform these operators that high concentrations of these chemicals in wastewater may adversely affect the biological sewage breakdown process in wastewater treatment plants.

Conclusion for Sewer Root Control Use

EPA has evaluated the need for control of invasive roots in sewer systems and the available chemical, mechanical, and non-chemical alternatives to metam-sodium, concluding that each type of control has a place in effective sewer maintenance (*see Revised Alternatives Assessment on Root Control Use of Metam-Sodium in Sewer Lines (DP # 358321) and Response to Public Comments Received* dated May 8, 2009 which is available in the metam-sodium and metam-potassium docket at EPA-HQ-OPP-2005-0125.

Based on the short- and intermediate-term dermal exposure risks to workers, coupled with the worker risks associated with MITC inhalation exposures, the Agency is requiring that any person(s) engaged in any activities that are likely to involve direct contact with metam-sodium, including but not limited to mixing, loading, and/or applying metam-sodium; equipment calibration; cleaning and repair of application equipment; entering into treated areas; sampling cleanup of spills; and rinsate disposal, to wear double-layer clothing, chemical resistant gloves, and a 90% protection factor respirator approved for MITC. To help mitigate these risks, the Agency is also adding a requirement that closed engineering systems for all mixing and loading activities be used.

To mitigate potentially harmful effects of metam-sodium on denitrifying bacteria and the associated disruption to downstream sewage treatment facilities, the Agency is requiring applicators to notify downstream waste water facilities prior to the start of metam-sodium applications so that they may monitor the operations of the wastewater treatment plant.

Based on the revised occupational risk assessments, coupled with the conservative nature of the short- and intermediate-term non-cancer data, the Agency finds that these measures will be adequate to address the risks associated with the sewer use of metam-sodium.

c. Antimicrobial Uses

For details on the metam-sodium, metam-potassium, and MITC human health risk assessments, please refer to the Human Health Risk Assessments and addenda for these chemicals. The following documents are recent additions:

- EPA-HQ-OPP-2005-0125-0267, Updated Label Language for the Antimicrobial Uses of Methyl Isothiocyanate (MITC) (PC Code 068103) for the Reregistration Eligibility Decision Document. May 13, 2008.
- EPA-HQ-OPP-2005-0125-0266, Risk Mitigation Measures, Voluntary Cancellations and Updated Label Language for the Antimicrobial Uses of Metam Potassium (PC Code 039002) for the Reregistration Eligibility Decision Document. May 15, 2008.
- EPA-HQ-OPP-2005-0125-0265, Risk Mitigation Measures, Voluntary Cancellations and Updated Label Language for the Antimicrobial Uses of Metam Sodium (PC Code 039003) for the Reregistration Eligibility Decision Document. May 15, 2008.

These documents are also available in the public docket EPA-HQ-OPP-2005-00125, located on-line in the Federal Docket Management System (FDMS) at www.regulations.gov.

During the post-RED comment period, the Agency received a comment from Sewer Sciences, Inc., which identified errors on pages 86 and 88 of the RED, wherein the Agency inadvertently included a combined cancer risk value of metam sodium and metam potassium. The risk information presented in the risk assessments for the antimicrobial uses of metam sodium and metam potassium correctly state the cancer risk for antimicrobial uses of both metam sodium and metam potassium. This error has been corrected below.

MITC

The results from the occupational and potential bystander assessment indicated that the occupational and potential bystander risks to the remedial wood treatment uses of MITC (i.e., treatment of utility poles, pilings, bridge timbers, and laminated wood products located outdoors) are expected to be negligible, based on the product formulation, product packaging, method of application, and required use of PPE during the application activity.

Mitigation for Wood Pole/Piling Use:

The Agency is requiring the following label requirements, which are also contained in the label table, in Section V.

1. "Plug the pre-drilled holes immediately after applications,"
2. "Do not treat structures/beams indoors," and
3. "Do not drill an application hole through seasoning checks to apply product. If the hole intersects a check, plug the hole and drill another. If more than two treatment holes intersect an internal void or rot pocket, redrill the holes farther up the pole into relatively solid wood."

Metam-sodium

The results of the occupational assessment for most antimicrobial uses of metam-sodium (i.e., treatment of poles and pilings, leather processing, and treatment of sewage sludge) indicated that the non-cancer dermal and inhalation risks to handlers were not of concern (i.e., all MOEs are greater than the target of 100). The cancer risks for the rest of the metam-sodium uses

were in the range of 1.1e-4 to 6.8e-6, where the target cancer risk level is between 1e-4 to 1e-6 for occupationally exposed workers.

Because of the short loading and/or application durations (i.e., minutes), handlers (i.e., mixers/loaders) are not expected to be exposed to the metam-sodium degradate, MITC. Occupational post-application and potential bystander (i.e., residents) exposure to MITC after the pole treatment is considered negligible. Any migration of MITC through the wooden cap into the ambient air conditions is considered negligible. However, the Agency has concerns for potential post-application inhalation exposures to MITC after metam-sodium applications in the leather and/or sugar processing industries and also for workers in the vicinity of sewage sludge treatments. However, no data are available to estimate the air concentrations at these types of processing facilities.

The following uses have been voluntarily cancelled for metam-sodium: (1) the sugar beet/sugar cane use and (2) all leather and hide processing uses. One registrant has voluntarily cancelled the organic sludge fumigation use; however, this use is still being maintained by another registrant. Therefore, the antimicrobial uses of metam-sodium that remain include: (1) the remedial treatment of wooden poles and timbers and (2) treatment of sewage sludge and animal waste.

Mitigation for Wood Pole/Piling Use:

The Agency is requiring the following label requirements, which are included in the label table, in Section V.

1. "Plug the pre-drilled holes immediately after applications,"
2. "Do not treat structures/beams indoors," and
3. "Do not drill an application hole through seasoning checks to apply product. If the hole intersects a check, plug the hole and drill another. If more than two treatment holes intersect an internal void or rot pocket, re-drill the holes farther up the pole into relatively solid wood."

Mitigation for Use to Treat Sewage Sludge and Animal Waste:

The Agency is requiring the new label language be developed, which states that the treated material is placed in a protected storage area for 21 days. The current label language reads that the treated material needs to be paced in a protected storage area for 14-21 days or until a phytotoxicity test is completed. This new label language is contained in the Label Table, in Section V.

Metam-potassium

The results of the occupational assessment for most antimicrobial uses of metam-potassium (i.e., pulp and paper, leather, sugars, and emulsions and cutting fluids) indicated that the non-cancer dermal and inhalation risks to handlers were not of concern (i.e., all MOEs are greater than the target of 100). However, the occupational assessment results of metam-potassium used in water cooling systems exceeded the Agency's level of concern (i.e., MOEs

were less than the target of 100) for dermal and inhalation exposures of handlers during open-pouring activities. Similarly, the cancer risk for the handlers of liquid open-pour products in water cooling facilities was also of concern, and is 2.9e-3. The cancer risks for the rest of the metam-sodium and metam-potassium handlers were in the range of 1.1e-4 to 1.6e-8, where the target cancer risk level is between 1e-4 to 1e-6 for occupationally exposed workers.

Because of the short loading and/or application durations (i.e., minutes), handlers (i.e., mixers/loaders) are not expected to be exposed to the metam-potassium degradate, MITC. However, the Agency has concerns for potential post-application inhalation exposures to MITC for workers in the vicinity of metam-potassium applications in the leather, pulp/paper, and sugar processing industries, as well as in coatings and metal working fluid manufacturing, oil-field operations, cooling water towers, and industrial water purification facilities because MITC is a highly volatile organic chemical (vapor pressure = 150 mm Hg). Furthermore, since metam-sodium and metam-potassium convert to MITC in aqueous media, the Agency also has concerns for the potential MITC inhalation exposures for the machinist who works with metal-working fluids that were preserved with metam-potassium.

While industrial workers are not expected to be exposed to MITC while mixing or loading paint products containing metam-potassium, bystanders in the vicinity of freshly painted areas and occupational/professional workers and residential (do-it-yourself) applicators could have potential inhalation exposure to MITC. (It is assumed that all metam-potassium used in paint products converts to MITC.) All of the professional painter MOEs for all time durations exceeded the Agency's level of concern (target MOE of 10). At the maximum application rate, the residential painter MOEs for the 8-hour and 28-day durations also exceed the Agency's level of concern. Furthermore, at the maximum application rate, the post-application bystander MOE for all durations also exceeds the Agency's level of concern.

The technical registrants have chosen to voluntarily cancel the following uses of metam-potassium: (1) the sugar beet/sugar cane use; (2) all leather uses, with the exception of the tanning drum leather applications; (3) all paint uses (inclusive of the preservation of protective colloids and emulsion resins); (4) all water-based drilling, completion, and packer fluid uses; (5) all petroleum secondary recovery operations uses; (6) all once-through cooling water applications; and (7) all cutting fluids (metalworking fluids) uses. Those antimicrobial uses of metam-potassium that remain include: (1) the tanning drum leather use, (2) pulp and paper, (3) recirculating cooling water systems, and (4) industrial water purification systems.

Mitigation for Cooling Water Tower Use:

Both the dermal and inhalation risk and the cancer risk to occupational workers during open-pour activities for the recirculating cooling water tower use are mitigated by requiring the use of a metering pump system for the recirculating cooling tower use. Label requirements will include the following, which is also contained in the label table, in Section V.

- "This antimicrobial product may only be used in recirculating cooling water facilities."
- "This antimicrobial product can only be applied to recirculating cooling water systems via a metering pump system."

- Update PPE to be inclusive of long sleeves, long pants, chemical resistant gloves, and goggles or face shield.

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, metam-sodium, metam-potassium, and MITC 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 metam-sodium, metam-potassium and MITC 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. Conclusion

The Agency has determined that products containing metam-sodium, metam-potassium and MITC are eligible for reregistration provided the risk mitigation measures outlines 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 the document.

V. What Registrants Need to Do

EPA recognizes that the extent of the mitigation needed for metam-sodium and metam-potassium 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	Metam-sodium/potassium REDs 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- and other fumigants	EPA begins Registration Review for metam-sodium and metam-potassium

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.

The Agency has determined that, with the mitigation measures identified in this document, some metam-sodium, metam-potassium, and MITC uses are eligible for reregistration; however, additional data are required to confirm this decision. In the near future, the Agency intends to issue data call-in (DCI) notices requiring product-specific data and generic (technical grade) confirmatory data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of metam-sodium, metam-potassium, and MITC has been reviewed, and data gaps exist. The data listed below are necessary to confirm the reregistration eligibility decision documented in this RED and determine whether the mitigation measures outlined in this RED are adequate or if additional measures are warranted.

The Agency is requiring the following toxicity studies.

OPPTS Guideline Number	Data Requirement	Study type
870.6200	Neurotoxicity Screening Battery - Inhalation	TOX
870.3550	Developmental Toxicity Screening Test - Inhalation	TOX
870.3800	Reproduction and Fertility Effects - Inhalation	TOX
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	TOX
870.4200	Chronic/Carcinogenicity Rats - Inhalation	TOX
870.4200	Chronic/Carcinogenicity Mice - Inhalation	TOX

870.6200 - Neurotoxicity Screening Battery

An acute neurotoxicity study in rat via the inhalation route with pathological evaluation of the complete respiratory tract is being requested. The Agency is currently using single day, acute exposures in its consideration of buffer zones following applications of metam-sodium and metam-potassium. The toxicology data available to inform this decision are limited to an eye irritation study in human subjects and an acute inhalation study. The purpose of the acute study was to determine the LC50, not for use in hazard identification for human health risk assessment. The Agency cannot evaluate the dose response relationship of irritation and systemic effects to the nose and lungs using these studies. This information on the respiratory tract is critical for the risk assessment as the relative sensitivity of eye irritation and more serious health outcomes is unknown. The Agency is open to discussing MITC-specific changes to the standard neurotoxicity screening battery to ensure that the appropriate target organs are evaluated and that relevant dose-response data would be generated.

870.3550 - Developmental toxicity screening test - Inhalation

This inhalation developmental toxicity study in rat is being requested to further characterize the toxicity profile of this compound via the inhalation route. MITC has been shown to travel off fields to areas where the general public lives, works, and plays. As such, it is appropriate to evaluate the effects of MITC on pregnant females and their fetuses.

870.3800 - Reproduction and Fertility Effects

Two generation reproduction study in rat via inhalation with pathological evaluation of the complete respiratory tract in offspring is needed. This inhalation reproductive toxicity study is being requested to further characterize the toxicity profile of this compound via the inhalation

route. MITC has been shown to travel off fields to areas where the general public lives, works, and plays. As such, it is appropriate to evaluate the effects of MITC on reproductive performance and to pups directly exposed to MITC via the inhalation route. Note: the Agency would be open to discussing with the registrant the potential for performing the new enhanced one-generation reproductive study instead of the standard two-generation study.

870.5550 - Unscheduled DNA Synthesis in Mammalian Cells in Culture

This study is required to complete the genetic toxicity testing battery.

870.4200 - Chronic/Carcinogenicity Rats and Mice

Carcinogenicity studies for MITC *per se* are insufficient to characterize cancer risk; therefore, the carcinogenic potential of MITC cannot be determined at this time. Although there are not expected to be exposures of six months or longer in duration in a given year, since the same fields are often treated every year, there is potential for exposure to occur annually for many years. Moreover, metaplasia of the respiratory epithelium, a lesion often associated cancer, was observed after only 28 days of exposure in the subchronic inhalation study in rats with MITC. As such EPA is requiring inhalation carcinogenicity studies with MITC in rats and mice.

Additional data requirements for metam-sodium and metam-potassium soil uses

OPPTS Guideline Number	Data Requirement	Study type
835.8100	Field Volatility from soil	ORE
875.1100	Dermal exposure - outdoor	ORE
875.1300	Inhalation exposure - outdoor	ORE
Special	Avian acute inhalation, MITC	ECO
850.1075	Acute Marine/Estuarine Fish, MITC	ECO
850.1025	Acute Marine/Estuarine Mollusk, MITC	ECO
850.1035	Acute Marine/Estuarine Shrimp, MITC	ECO
850.4225	Seedling Emergence – Tier II, MITC.	ECO
850.4250	Vegetative Vigor – Tier II, MITC	ECO
850.4400	Aquatic Plant Growth – Tier II, MITC (3 remaining species)	ECO
850.3020	Honeybee Acute Contact	ECO
Special	Community Outreach and Education Program	Special
Special	Training for Applicators Supervising Fumigations	Special
Special	Training Materials for Handlers	Special
Special	Buffer Zone Posting Signs	Special

Data Requirements:

The Agency is requiring the following volatility and human exposure studies which will be used to confirm if bystander and worker risks are below the Agency's level of concern. They will also be used to determine if additional mitigation measures are warranted:

- GLN 835.8100 - Field volatility from soil (center pivot, spray blade, and rotary tiller)
- GLN 875.1100 - Dermal exposure - outdoor
- GLN875.1300 - Inhalation exposure - outdoor

835.8100 - Field volatility from soil

Volatility studies are required for metam-sodium and metam-potassium soil uses to determine flux for modeling purposes of the breakdown products of metam-sodium and metam-potassium, including formaldehyde. Center pivot, spray blade, and rotary tiller application methods should be included.

For center pivot applications the Agency is requiring field volatility studies for all application methods including high release, medium release and low release application methods. In addition, the field volatility study for low release applications should evaluate the cumulative flux from 2 adjacent applications that are occurring at the same time.

875.1100 - Dermal exposure – outdoor and 875.1300 - Inhalation exposure - outdoor

These studies will be used to confirm if bystander and worker risks are below the Agency's level of concern. They will also be used to determine if additional mitigation measures are warranted.

Special - Avian acute inhalation, MITC

The current estimate of avian risk is based largely on the mammal assessment. This study will enable an inhalation risk assessment specific to birds. This is critical, since avian exposure to MITC is expected to be largely via inhalation.

850.1075 - Acute Marine/Estuarine Fish, MITC

The aquatic risk assessment of metam-sodium and metam-potassium use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment for marine/estuarine species exposure.

850.1025 - Acute Marine/Estuarine Mollusk, MITC

The aquatic risk assessment of metam-sodium and metam-potassium use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment 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*.

850.1035 - Acute Marine/Estuarine Shrimp, MITC

The aquatic risk assessment of metam-sodium and metam-potassium use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment for marine/estuarine species exposure.

850.4225 - Seedling Emergence – Tier II, MITC

Metam-sodium and metam-potassium are used in part due to the phytotoxicity of MITC at the application site. This study will enable the assessment of risk to non-target terrestrial plants off site.

850.4250 - Vegetative Vigor – Tier II, MITC

Metam-sodium and metam-potassium are used in part due to the phytotoxicity of MITC at the application site. This study will enable the assessment of risk to non-target terrestrial plants off site.

850.4400 - Aquatic Plant Growth – Tier II, MITC

Only one of four tests currently available (on duckweed) is considered to be acceptable (Core) (MRID #45919422). The submission of data for remaining test species under this guideline will reduce uncertainty and improve the assessment of risk to aquatic plants. For example, the blue-green alga and green alga studies are 72-hour OECD studies that are only accepted as Tier I screening studies.

850.3020 – Honeybee acute contact, MITC

Although there is honeybee data for metam-sodium and metam-potassium indicating that it is relatively non-toxic to honey bees, there is a concern that MITC could be more toxic to bees. Therefore, honeybee acute contact data is required for MITC.

Special Study - Community Outreach and Education Program

The Agency is requiring registrants to develop and implement community outreach and education programs, including programs for first responders, to address these needs. Community outreach and education programs must include the following elements, at minimum: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident. EPA expects registrants' proposals for the first responder programs described 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 that successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion.

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

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.

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 36 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 (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," -- "Dazomet 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," -- "Dazomet 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.

Additional data requirements for metam-sodium sewer uses

Because chemical-specific exposure data were not available to assess the sewer use of metam-sodium, surrogate data for mixers and loaders from the Pesticide Handlers Exposure Database (PHED) were used in the risk assessment. To better evaluate exposure and characterize risk and to confirm that the mitigation measures included in this RED are adequate and/or determine whether additional measures are warranted, the following data will be required for metam-sodium:

- GLN 875.1100 – Dermal exposure – outdoor
- GLN 875.1700 – Product use information

Because metam-sodium degrades into MITC, the Agency also needs MITC monitoring data in the breathing zone of the mixer/loader/applicator. The following data will be required for MITC:

- GLN 875.1300 – Inhalation exposure - outdoor

Given the specialized nature of these sewer-use studies, the Agency would like to discuss the study design with the registrants before the studies are begun.

Additional data requirements for metam-sodium and metam-potassium antimicrobial uses

Because chemical-specific exposure data were not available to assess the antimicrobial uses of metam-potassium, surrogate data from both the Pesticide Handlers Exposure Database and the Chemical Manufacturers Association (CMA) were used to generate screening-level risk assessments. Therefore, the following data are needed to confirm the mitigation measures included in this RED are adequate, or if additional measures are warranted.

- GLN 875.1200 - Dermal exposure - indoor
- GLN 875.1400 - Inhalation exposure - indoor
- GLN 875.1600 - Applicator exposure monitoring data reporting
- GLN 875.1700 - Product use information

Because metam-sodium degrades into MITC, the Agency needs MITC air concentration monitoring data for all enclosed facilities that utilize metam-sodium. For metam-sodium this only includes sewage sludge and animal waste treatment facilities as the leather use and sugar cane and beet uses are being voluntarily cancelled. The guideline numbers are as follows:

- GLN 875.2500 - Inhalation exposure study
- GLN 875.2700 - Product use information
- GLN 875.2800 - Description of human activity
- GLN 875.2900 - Post-application data reporting and calculations

Residue data are needed to support the metam-potassium antimicrobial use in pulp and paper manufacturing. The purpose of this confirmatory study is to demonstrate that the paper manufacturing processes remove any residual metam-potassium and MITC.

- GLN 860.1520

Because metam-potassium degrades into MITC, the Agency needs MITC air concentration monitoring data for all enclosed facilities that utilize metam-potassium. For metam-potassium this includes pulp and paper facilities, recirculating cooling water facilities, leather processing facilities, and industrial water purification facilities. The guideline numbers are as follows:

- GLN 875.2500 - Inhalation exposure study
- GLN 875.2700 - Product use information

- GLN 875.2800 - Description of human activity
- GLN 875.2900 - Post-application data reporting and calculations.

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.

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 master record identification numbers (MRIDs) 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. For questions regarding the PDCI, contact Karen Jones from OPP/SRRD's Product Reregistration Branch at (703) 308-8047 or by e-mail at Jones.Karen@epa.gov.

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: Uses Eligible for Reregistration

Metam Sodium (PC Code 039003) and Metam Potassium (PC Code 039002) Soil Fumigant Uses Eligible For Reregistration

Use Site	Formulation	Annual Application Rate	Use Limitations
Soil Pre-Plant Alfalfa, Asparagus (nursery production only), Artichokes, Barley, Basil, Beet, Berries, [includes all EPA Crop Group 13, Berries Group, i.e., blackberry (Rubus eubatus); bingleberry; black satin berry; boysenberry; Cherokee blackberry; chesterberry; Cheyenne blackberry; coryberry; darrowberry; dewberry; Dirksen thornless berry; Himalayaberry; hullberry; lavacaberry; lowberry; lucretiaberry; mammoth blackberry; marionberry; nectarberry; olallieberry; Oregon evergreen berry; phenomenalberry; rangeberry; ravenberry; rossberry; Shawnee blackberry; youngberry, and varieties and/or hybrids of these; blueberry (Vaccinium spp.); currant (Ribes spp.); elderberry (Sambucus spp.); gooseberry (Ribes spp.); huckleberry (Gaylussacia spp.); loganberry (Rubus loganobaccus); raspberry-black and red (Rubus occidentalis, Rubus strigosus, Rubus idaeus)], Broccoli, Brussels sprouts, Cabbage, Carrot, Cauliflower, Celeriac, Chineese greens or bok choy, Cilantro, Citrus (orchard replant only), [includes all of EPA Crop Group 10, Citrus Fruits, i.e.,	Liquid, Soluble Concentrate	320 lbs. a.i./Acre	See The Label Table For Specific Use Limitations.

Use Site	Formulation	Annual Application Rate	Use Limitations
calamondin (Citrus mitis X Citrofortunella mitis); citrus citron (Citrus medica); citrus hybrids (Citrus spp.) (includes: chironja, tangelo, tangor); grapefruit (Citrus paradisi); kumquat (Fortunella spp.); lemon (Citrus jambhiri, Citrus limon); lime (Citrus aurantiifolia); mandarin (tangerine) (Citrus reticulata); orange, sour (Citrus aurantium); orange, sweet (Citrus sinensis); pummelo (Citrus grandis, Citrus maxima); satsuma mandarin (Citrus unshiu)],			
Collard,			
Corn,			
Cover crops (i.e., crops planted between periods of regular crop production to prevent soil erosion, control weeds, and improve soil quality that are incorporated into the soil before the next crop is planted and may not be harvested for food or feed),			
Crops grown solely for seed,			
Cucurbits [includes all of EPA Crop Group 9, Cucurbit Vegetables Group, i.e., chayote (fruit) (Sechium edule); Chinese waxgourd (Chinese preserving melon) (Benincasa hispida); citron melon (Citrullus lanatus var. citroides); cucumber (Cucumis sativus); gherkin (Cucumis anguria); gourd, edible (Lagenaria spp.) [includes: hyotan, cucuzza (Luffa acutangula, L. cylindrical; includes hechima, Chinese okra)]; Momordica spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber); muskmelon [hybrids and/or cultivars of Cucumis melo (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon)]; pumpkin (Cucurbita spp.); squash, summer (Cucurbita pepo var. melopepo) (includes: crookneck squash, scallop squash, straightneck squash, vegetable marrow, and zucchini); squash, winter (Cucurbita maxima; C. moschata) (includes: butternut squash, calabaza, hubbard squash) and (C. mixta; C. pepo) (includes acorn squash, spaghetti squash); and watermelon (includes hybrids and/or varieties of Citrullus lanatus)],			
Dill,			
Eggplant,			
Forest seedlings,			

Use Site	Formulation	Annual Application Rate	Use Limitations
Ginger, Grape (vineyard replant only), Kale, Kohlrabi, Leafy greens [includes all of EPA Crop Group 4, Leafy Vegetables (Except Brassica Vegetables), i.e., amaranth (leafy amaranth, Chinese spinach, tampala) (Amaranthus spp.); arugula (roquette) (Eruca sativa); cardoon (Cynara cardunculus); celery (Apium graveolens var. dulce); celery, Chinese (Apium graveolens var. secalinum); celtuce (Lactuca sativa var. angustana); chervil (Anthriscus cerefolium); chrysanthemum, edible-leaved (Chrysanthemum coronarium var. coronarium); chrysanthemum; garland (Chrysanthemum coronarium var. spatiosum); corn salad (Valerianella locusta); cress, garden (Lepidium sativum); cress, upland (yellow rocket, winter cress) (Barbarea vulgaris); dandelion (Taraxacum officinale); dock (sorrel) (Rumex spp.); endive (escarole) (Cichorium endivia); fennel, Florence (finochio) (Foeniculum vulgare Azoricum Group); lettuce, head and leaf (Lactuca sativa); orach (Atriplex hortensis); parsley (Petroselinum crispum); purslane, garden (Portulaca oleracea); purslane, winter (Montia perfoliata); radicchio (red chicory) (Cichorium intybus); rhubarb (Rheum rhabarbarum); spinach (Spinacia oleracea); spinach, New Zealand (Tetragonia tetragonioides, T. expansa); spinach, vine (Malabar spinach, Indian spinach) (Basella alba); and swiss chard (Beta vulgaris var. cicla)], Leek, Mint, Mustard, Nursery stock (fruit seedlings and rose bushes only), Onion, Ornamentals (floriculture only), Pome fruit (orchard replant only), [includes all of EPA Crop Group 11, Pome Fruits Group —Commodities, i.e., apple (Malus domestica); crabapple (Malus spp.); loquat (Eriobotrya japonica); mayhaw (Crataegus aestivalis, C. opaca, and C. rufula); pear (Pyrus communis); pear, oriental (Pyrus pyrifolia); and quince			

Use Site	Formulation	Annual Application Rate	Use Limitations
(Cydonia oblonga)], Peanut, Pepper, Potato, Radish, Rye, Sugar beet, Soybean, Stone fruit (orchard replant only), [includes all of EPA Crop Group 12, Stone Fruits Group—Commodities, i.e., apricot (Prunus armeniaca); cherry, sweet (Prunus avium); cherry, tart (Prunus cerasus); nectarine (Prunus persica); peach (Prunus persica); plum (Prunus domestica, Prunus spp.); plum, Chickasaw (Prunus angustifolia); plum, Damson (Prunus domestica spp. insititia); plum, Japanese (Prunus salicina); plumcot (Prunus. armeniaca X P. domestica); prune (fresh) (Prunus domestica, Prunus spp.)], Strawberries, Sugar beet, Sweet potato, Swiss Chard, Tobacco, Tomatoes, Tree nuts (orchard replant only), [includes all of EPA Crop Group 14, Tree Nuts Group (i.e., almond (Prunus dulcis); beech nut (Fagus spp.); Brazil nut (Bertholletia excelsa); butternut (Juglans cinerea); cashew (Anacardium occidentale); chestnut (Castanea spp.); chinquapin (Castanea pumila); filbert (hazelnut) (Corylus spp.); hickory nut (Carya spp.); macadamia nut (bush nut) (Macadamia spp.); pecan (Carya illinoensis); and walnut, black and English (Persian) (Juglans spp.) as well as pistachio], Turnip, Turf (including golf courses), and Wheat			

Metam Sodium (PC Code 039003) Uses Eligible For Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Sewer Use				
Root Control in Sewer Lines	liquid, soluble concentrate (SC), ready-to-use (RTU)	Foam application equipment	For sewers and drains, the maximum application rate is 0.212 lbs ai/gallon of solution.	Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.
Agricultural Premises & Equipment				
Sewage Sludge & Animal Waste Treatment	Sewage Sludge & Animal Waste Treatment	Sewage Sludge & Animal Waste Treatment	Sewage Sludge & Animal Waste Treatment	Sewage Sludge & Animal Waste Treatment
Wood Preservatives				

Timbers and Wood Poles/Pilings	Ready to Use Liquid	Fumigant is poured into holes that have been drilled into section of poles where decay is detected	Wood Poles: Drill holes at a 45 degree angle to a length of approximately 2 ½ times the radius of the wood. The first hole should be at the groundline and succeeding holes approximately 6-8 inches higher and 90 degrees rotated from the next lower hole. The amount of fumigant to be used per pole is based on the pole circumference at the groundline. Plug holes with treated wood plugs.	None Listed

Metam Potassium (PC Code 039002) Uses Eligible For Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Industrial Processes and Water Systems				
Recirculating Cooling Tower Water	Ready to Use	Chemical metering pumps	Initial Slug: 5.1 to 10.2 fluids ounces of product per 1000 gallons of water. Subsequent Dose: 1.7 to 10.2 fluid ounces per 1000 gallons of water every 1 to 5 days or as needed; or Initial Dose: 6.9 to 13.9 fl. Oz. of product per 1000 gallons of system water (56-115 ppm). Subsequent Dosage: 2.3 to 9.8 fl. Oz per 1000 gallons of water (20-115 ppm); or Initial Dose: 1.5 to 3.0 fl. Oz. of product per 1000 gallons of system water (15-30 ppm). Subsequent Dosage: 0.5 to 3.0 fl. Oz per 1000 gallons of water (5-30 ppm); or Initial Dose: 3.3 to 6.6 fl. Oz. of product per 1000 gallons of system water	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			(30-60 ppm). Subsequent Dosage: 1.1 to 6.6 fl. Oz per 1000 gallons of water (10-60 ppm).	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Industrial Water Purification systems (including reverse osmosis systems, filters, clarifiers and ion exchange equipment)	Ready to Use	Chemical metering pumps	24.5 to 49.0 fl. Oz per 1000 gallons of water (200-400 ppm) for 4 to 6 hours. Online Maintenance treatment: 4.9 to 9.8 fl. Oz. of product per 1000 gallons of water (40 to 80 ppm) for 6 – 12 hours, once a week or as needed; or 5.0 to 10.0 fl. Oz per 1000 gallons of water (50-100 ppm) for 4 to 8 hours. Online Maintenance treatment: 1.0 to 2.0 fl. Oz. of product per 1000 gallons of water (10 to 20 ppm) for 6 – 12 hours, once a week or as needed.	Not intended for use in potable water.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications		Use Limitations
Pulp & Paper Mills	Ready to Use	Chemical metering pumps	0.25 to 1lb.of product per short ton; or 0.8-5.0 lbs of product per ton for six hours; or 0.2 to 0.4 lb of product per ton.	None Listed	
Materials Preservatives					
Paper making (preservation)	Ready to Use	Chemical metering pumps	75 to 400 ppm depending on PH level.	None Listed	
Tanning Drum Leather	Ready to Use	Open pour	To preserve tannery glue solutions, add to glue at rates of 100-250 ppm, based on the total weight of the glue solution	None Listed	

MITC (068103) Uses Eligible For Reregistration

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Wood preservatives				
Remedial Treatment: Utility poles, piling, bridge timbers, and laminated wood products (located outdoors).	Ready to Use	Manually insert tube into pre-drilled hole	Dosage Rate: 1 tube (30 grams) per drill hole; Pole Circumference in inches/No. of Tubes Installed : **35" or less** - 3 holes beginning at ground line spaced 120 degrees apart and 6"to 8" higher than the previous hole. **36" to 49" -** 4 holes beginning at the ground line spaced 90 degrees apart and 6" to 8" higher than the previous hole. **50" to 59"-** 5 holes beginning at the ground line spaced 70 degrees apart and 6"to 8" higher than the previous pole. **60" to 70" –** 6 holes beginning at ground line spaced 60 degrees apart and 4" to 6" higher than	Do not contaminate water, food or feed by storage or disposal. Do not use, pour, spill or store near an open flame.

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			the previous hole. **70" to 80"-** 7 holes. The first 2 at ground line 160 degrees apart and the remaining 5 spaced 60 degrees apart and 4" to 6" higher than the previous hole. **80" to 90"**- 8 holes. The first 2 at ground line 180 degrees apart and the remaining 6 spaced 50 degrees apart and 4" to 6" higher than the previous hole. **Over 90"–** 9 holes. The first 2 at ground line 180 degrees apart and the remaining 7 spaced 45 degrees apart and 4" to 6" higher than the previous hole.	

Appendix B: Studies Used to Make the Reregistration Decision

This section not currently available.

Appendix C: Technical Support Documents

Additional support of this RED is maintained in the OPP docket at: http://www.regulations.gov at EPA-HQ-OPP-2005-0125. This docket may be accessed in the OPP docket room located at S-4900, One Potomac Yard 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding federal holidays, from 8:30-4:00 pm. All documents may be view in the OPP docket room or downloaded or viewed via the internet.

Health Effects Support Documents

- "Metam Sodium: Third Revision of the HED Human Health Risk Assessment;" May 2009; Charles Smith; Health Effects Division, U.S. EPA.
- 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).
- "Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC; PC Codes 053201, 029001, 081501, 035602, 039003, 039002, 068103; Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents;" May 2009; Charles Smith and Jeff Dawson; Health Effects Division; U.S. EPA.
- EPA-HQ-OPP-2007-0350-0172, MOA Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC. June 25, 2008. DP Barcode 293356.
- "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), Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits;" May 2009; Charles Smith and Jeff Dawson; Health Effects Division; U.S. EPA.
- EPA-HQ-OPP-2007-0350-0173, Factors Which Impact Soil Fumigant Emissions - Evaluation For Use In Soil Fumigant Buffer Zone Credit Factor Approach. June 9, 2008. (DP Barcode 306857).

Biological and Economical Analysis Support Documents

- Evaluation of Potential Impacts to Wastewater Treatment Plant Microorganisms…"; PC Code: 039003; DP Barcode: 364230; April 2009; Pat Jennings; Antimicrobials Division; U.S. EPA.
- Response to comments on use site restrictions included in the Reregistration Eligibility Decision (RED) for Metam-Sodium and Metam-Potassium (DP Barcode: 363544); May 2009; Nikhil Mallampalli, Chism, Becker; Biological and Economic Analysis Division; U.S. EPA.
- Revised Alternatives Assessment on Root Control Use of Metam-Sodium in Sewer Lines (DP # 358321) and Response to Public Comments Received (EPA Docket No. EPA-HQ-OPP-2005-0125);" May 2009; Sunil Ratnayake and Tara Chandgoyal; Biological and Economic Analysis Division; U.S. EPA.
- Identification of High-Use Fumigation Areas at State and County Levels (DP#364647);" May 2009; Monisha Kaul and Jenna Carter; Biological and Economic Analysis Division; U.S. EPA.

- 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.
- Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery (DP#363546). May 13, 2009.
- Process for Defining High-Use Fumigation Areas at the State and County Levels (DP#364647) May 14, 2009.
- EPA-HQ-OPP-2007-0350-0168, 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. June 25, 2008. DP Barcode 353940.
- EPA-HQ-OPP-2007-0350-0169, 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.
- EPA-HQ-OPP-2007-0350-0018, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam Sodium in Cucurbit Production.
- EPA-HQ-OPP-2007-0350-0019, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam Sodium in Eggplant Production.
- EPA-HQ-OPP-2007-0350-0020, Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries.
- EPA-HQ-OPP-2007-0350-0021, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, Dazomet, and Metam Sodium for Use in Raspberry Nurseries, Fruit and Nut Deciduous Tree Nurseries, and Rose Bush Nurseries in California.
- EPA-HQ-OPP-2007-0350-0022, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam-sodium in Onion Production.
- EPA-HQ-OPP-2007-0350-0023, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium in Grape Production.
- EPA-HQ-OPP-2007-0350-0024, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam Sodium in Tree Nut Production.
- EPA-HQ-OPP-2007-0350-0025, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam Sodium in Pome Fruits Production.
- EPA-HQ-OPP-2007-0350-0026, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium in Stone Fruit Production.
- EPA-HQ-OPP-2007-0350-0027, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam Sodium in Bell Pepper Production.
- EPA-HQ-OPP-2007-0350-0028, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Potato Production.
- EPA-HQ-OPP-2007-0350-0029, Assessment of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium in Strawberry Production.
- EPA-HQ-OPP-2007-0350-0030, Assessment of the Benefits of Chloropicrin, Methyl Bromide, Metam-sodium and Dazomet Use In Strawberry Nursery Runner Production.
- EPA-HQ-OPP-2007-0350-0031, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium on Sweet Potato Production.
- EPA-HQ-OPP-2007-0350-0032, Assessment of the Benefits of Soil Fumigation with Chloropicrin in Tobacco Production.
- EPA-HQ-OPP-2007-0350-0033, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam Sodium in Tomato Production.

- EPA-HQ-OPP-2007-0350-0034, Assessment of the Benefits of Soil Fumigation with Metam-Sodium in Carrot Production.
- EPA-HQ-OPP-2007-0350-0035, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production.
- EPA-HQ-OPP-2007-0350-0036, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production.
- EPA-HQ-OPP-2007-0350-0037, BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants (Chloropicrin, Dazomet, Methyl Bromide, Metam Potassium, and Metam Sodium.

Environmental Fate and Ecological Effects Support Documents

- EPA-HQ-OPP-2004-0159-0117 – Transmittal Memo for the Revised Environmental Fate and Ecological Effects Risk Assessment for Metam Sodium and Metam Potassium.
- EPA-HQ-OPP-2004-0159-0118 Revised Environmental Fate and Ecological Effects Risk Assessment for Metam Sodium and Metam Potassium.

Antimicrobial Assessment Support Documents

- EPA-HQ-OPP-2007-0350-1066, Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision (RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin.

Buffer Zone Credits Support 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. May 14, 2009.
- EPA-HQ-OPP-2007-0350-1073, Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach. Dawson, J. and Smith, C.; D306857; June 9, 2008.
- EPA-HQ-OPP-2007-0350-1078, Health Effects Division Recommendations for Fumigant Data to Refine Exposure Assessments. DP Barcode 353724.

Risk Management Support Documents

- EPA-HQ-OPP-2007-0350-1077, SRRD's Response to Phase 5 Public Comments for the Soil Fumigants. Rice, M. and McNally, R.; July 2008.
- EPA-HQ-OPP-2007-0350-0003, Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications.

Appendix D: FMP Template-MeBr Example

Note: The Agency plans to work with the registrants and other stakeholders to develop a metam-sodium and metam-potassium specific FMP that will serve as a template for growers and the States to use for the most common application methods prior to the 2010 and 2011 growing season.

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		
Target application date/window:	Brand name of fumigant:	EPA Registration Number:
Tarps (check here if section is not applicable ☐)		
Brand name:	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 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 contact person responsible for cutting and/or removing tarps (if other than 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 and moisture in application block:	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:	Rate from lookup table on label (lb ai/A):	Block size from lookup table on label (acres):	Credits applied:	Buffer zone distance:
☐ Bedded ☐ Broadcast ☐ Hot gas - outdoor ☐ Hot gas - greenhouse ☐ Hand held probes			☐ high barrier film _____ % ☐ organic content _____ % ☐ clay content _____ % ☐ other: _____ % Total credits _____ %	_____ 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, odor 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	
If your state and/or tribal lead agency requires notice, list contacts that were notified:	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.	
If intend to cease operations - Name, address, and phone number of handler to perform monitoring activities prior to operations resuming:	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		
Application date and time:	Application rate:	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 cut:	Date tarps were removed:

Odor Complaints (check here if section is not applicable ☐)	
Person filing odor complaint: ☐ On-site handler ☐ Person off-site	If off-site person, name, address, and phone number of person filing odor complaints:
Description of control measures or emergency procedures followed after odor complaint:	
Additional comments:	

Description of Incidents (check here if section is not applicable ☐)	
Description of incident, equipment failure, or other emergency:	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							
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☐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**