# US Environmental Protection Agency
# Office of Pesticide Programs

# Reregistration Eligibility Decision (RED) for Methyldithiocarbamate Salts - Metam Sodium/Potassium and MITC

**July 9, 2008**

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-08-006
July 2008

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

# 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: _____
Steven Bradbury, Director
Special Review and Reregistration Division

Date: 7/09/08

**Glossary of Terms and Abbreviations**

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

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

**Table of Contents**

**Methyldithiocarbamate Salts and Methyl Isothiocyanate Team**

Health Effects Risk Assessment
Ruth Allen
Judy Facey
Sherry Kinard
Anna Lowit
Charles Smith

Biological and Economic Analysis Assessment
Jonathan Becker
Angel Chiri
Bill Chism
Colwell Cook
David Donaldson
John Faulkner
Monisha Kaul
Andrew Lee
Nikhil Mallampalli
William Phillips, II
Sunil Ratnayake
Elisa Rim
Stephen Smearman
TJ Wyatt
Leonard Yourman
Nicole Zinn

Environmental Fate and Effects Risk Assessment
James Felkel
Faruque Khan
Gabriel Rothman

Registration Support
Tamue Gibson
Mary Waller

Risk Management – Antimicrobial Uses
Timothy Dole
Heather Garvie
Diane Isbell
Timothy Leighton
Tim McMahon
Kathryn Montague
Rick Petrie
Cassi Walls

Office of General Council
Andrea Medici

Office of Enforcement and Compliance
David Stangel

Risk Management
Dirk Helder
Veronique LaCapra
John Leahy
Nikhil Mallampalli
Cathryn OConnell
Karen Santora

## Abstract

This document presents EPA's (hereafter referred to as EPA or the Agency) 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). The Agency has determined that products containing metam-sodium, metam-potassium, and MITC for certain of 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 five basic categories that include: (1) as an agricultural soil fumigant for use on all food, feed, and fiber crops; (2) for use on golf course turf and for application to small areas of turf and soil; (3) as a root-control agent in drains and sewers; and (4) 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 restricted use.

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 PPE, including 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 decision document for metam-sodium, metam-potassium, and MITC, as announced in a Notice of Availability published in the *Federal Register*. There will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on the implementation of this decision.

## I. Introduction

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

This document presents the Agency's decision regarding the reregistration eligibility for all the registered uses of metam-sodium, metam-potassium, and methyl isothiocyanate (MITC). 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 a separate section of this RED.

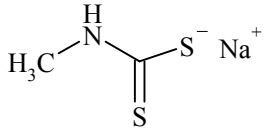
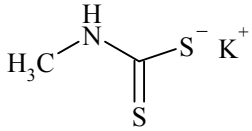
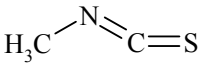
As a result of this review, the Agency has determined that certain uses of (1) metam-sodium (including use as a pre-plant soil fumigant in certain crops, specified later in this document, and as a root control agent in sewers and drains, and as an antimicrobial agent to treat wood poles and timbers and sewage sludge and animal waste); (2) metam-potassium (including 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 (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. page 99), 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. Section II provides a profile of the use and usage of the chemical. Section III provides summaries of the metam-sodium, metam-potassium, and MITC human health and ecological risk 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 docket (**EPA-HQ-OPP-2005-0125**) at www.regulations.gov.

## II. Chemical Overview

### A. Chemical Identity

Both metam-sodium and metam-potassium (see Table 1) 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 (see Table 1).

| **Table 1. 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 Chemical Co.; Loveland Products, Inc.; Taminco Inc.; BASF Sparks LLC; Tessenderlo Kerley, Inc.; Sewer Sciences, Inc.; Osmose Utilities Services, Inc. | Buckman Laboratories Inc.; Athea Laboratories Inc.; Taminco Inc.; Tessenderlo Kerley, Inc. | MLP International (Landis International, Inc.); Osmose Utilities Services, Inc. |

## B. Use Profiles

| | |
|---|---|
| Pesticide Type: | Metam-sodium and metam-potassium are broad spectrum fumigants with fungicidal, bactericidal, algaecide, 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). 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; (2) for use on golf course turf and for application to small areas of turf and soil; (3) as a root-control agent in drains and sewers |
| 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." 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 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 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, 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.<br>• 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.<br>• 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 & 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 there are 16 registered products containing metam-potassium. Metam-sodium and metam-potassium are broad spectrum fumigants with fungicidal, herbicidal, insecticidal, bactericidal, algaecide 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 1991and 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 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.

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

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

When metam-sodium and metam-potassium are applied and mixes 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.

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 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 uncertainty factor for intraspecies variability 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, while some are 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 at the exact doses 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.

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 from incidents.

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

Based on these lines of evidence and as described in more detail in the risk assessments, EPA has determined that 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 sol 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 (all are available through the metam-sodium docket at www.regulations.gov):

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

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

- EPA-HQ-OPP-2005-0125-0085, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Metam-Sodium, and Methyl Bromide in Eggplant Production
- EPA-HQ-OPP-2005-0125-0086, Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries
- EPA-HQ-OPP-2005-0125-0087, 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-2005-0125-0088, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam-sodium In Onion Production
- EPA-HQ-OPP-2005-0125-0089, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Grape Production
- EPA-HQ-OPP-2005-0125-0090, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Tree Nut Production
- EPA-HQ-OPP-2005-0125-0091, Assessment of the Benefits of Soil Fumigation with Chloropicrin, and Methyl Bromide In Pome Fruit Production
- EPA-HQ-OPP-2005-0125-0092, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium In Stone Fruit Production
- EPA-HQ-OPP-2005-0125-0093, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-Sodium in Bell Pepper Production
- EPA-HQ-OPP-2005-0125-0094, Assessment of the Benefits of Soil Fumigation with Metam-sodium in Potato Production
- EPA-HQ-OPP-2005-0125-0095, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium In Strawberry Production

- EPA-HQ-OPP-2005-0125-0096, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production
- EPA-HQ-OPP-2005-0125-0097, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium In Sweet Potato Production
- EPA-HQ-OPP-2005-0125-0079, Assessment of the Benefits of Soil Fumigation with Chloropicrin In Tobacco Production
- EPA-HQ-OPP-2005-0125-0099, 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-2005-0125-0337, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production
- EPA-HQ-OPP-2005-0125-0338, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production
- EPA-HQ-OPP-2005-0125-0339, Summary of the Benefits of Soil Fumigation with Methyl Bromide in Crop Production
- EPA-HQ-OPP-2005-0125-0340, BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants

**B. 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 concert 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):

- 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 cutting/removal procedures;
- Entry-restricted period;
- Application method/practice restrictions;
- Fumigant management plans (FMPs);
- Responsible parties;

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

- 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 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 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 (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 (See the Label Table, page 99, for a summary of amendments), and data are developed to assess intermediate- and long-term risk to bystanders. Also see Appendix A for a summary of all uses 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 and 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.

**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), (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.

- Response to Public Comments: The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Metam Sodium (OPP Docket# OPP-2005-0125). June 18, 2008. DP Barcode 293355.
- 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.
- 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. February, 14, 2008.
- SRRD's Response to Phase 5 Public Comments for the Soil Fumigants, July 2008.

## C. Regulatory Position

### 1. Regulatory Rationale

The Agency has determined that 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. 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

##### Rates

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.

**Use sites eligible for reregistration**

EPA has determined that the following uses are 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; turf (including golf courses).

The list of crops above 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/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 must be deleted, unless additional information to support a compelling case for the economic benefits of metam-sodium/metam-potassium is provided. This decision is based on potentially high risk to bystanders from metam-sodium or metam-potassium, coupled with a lack of indication of high economic benefits for crops not included in the group described above. Labels must be amended to reflect use only on the crops specified as eligible for reregistration.

## 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.

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.

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/metam-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:

- 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;
- Emergency preparedness and response plans;
- Notice to state lead agencies.

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

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

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

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

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 human health risk assessments, (in the metam-sodium docket, EPA-HQ-OPP-2005-0125, in

www.regulations.gov), 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 also available upon request from the OPP Docket Office.

### (a) General Buffer Zone Requirements

The following describes the general buffer zone requirements for metam-sodium/metam-potassium and other soil fumigants currently going through the reregistration process:

- "Buffer zone" is an area established around the perimeter of each application block or greenhouse where a soil fumigant is applied. The buffer zone must extend from the edge of the application block or greenhouse perimeter equally in all directions.
- All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the buffer zone period except for transit (see exemptions section below, page 29).
- An "application block" is a field or portion of a field treated with a fumigant in any 24-hour period. For chemigation it is the total acres of a field treated without a 48 hour interruption (see Figures 1 and 2 below for further explanation).
- The "buffer zone period" starts at the moment when any fumigant is delivered/dispensed to the soil within the application block and lasts for a minimum of 48 hours after the fumigant has stopped being delivered/dispensed to the soil.

Buffer zone distances

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

Authorized entry to buffer zones

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

Buffer zone proximity

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

Exemptions for transit through buffer zones

- Vehicular and bicycle traffic on public and private roadways through the buffer zone is permitted. "Roadway" means that portion of a street or highway improved, designed or ordinarily used for vehicular travel, exclusive of the sidewalk or shoulder even though such

sidewalk or shoulder is used by persons riding bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately. (This definition is based on the definition of roadway in the Uniform Vehicle Code prepared by the National Committee on Uniform Traffic Laws and Ordinances. See http://www.ncutlo.org/ for more details)

- Bus stops or other locations where persons wait for public transit are not permitted within the buffer zone.
- See posting section (page 48) for additional requirements that may apply.

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

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

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

- Buffer zones may not include residential areas (including yards), employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy **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 does not occur until air monitoring after the buffer zone periods end indicates that the air concentrations within the structure/space is less than the acceptable air concentration on the label, as determined by air monitoring requirements described on product labels.
- Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, **UNLESS**
  1. The owner/operator of the application block can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, and
  2. The owner/operator of the areas that are not under the control of the application provides written agreement to the applicator that they, their employees, and other persons will stay out of the buffer zone during the entire buffer zone period.
- Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields, etc), **UNLESS,**
  1. The area is not occupied during the buffer zone period,
  2. Entry by non-handlers is prohibited during the buffer zone period, and
  3. Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.
- See posting section (page 48) for additional requirements that apply.

### (b) PERFUM Model Inputs

The major input parameters for the modeling are: application rates, application block sizes, application method emission profiles, weather conditions, and the target air concentration

(based on acute inhalation endpoint and uncertainty factors). The following summarizes the key points for each of these *input* parameters.

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.

Emission Studies

The Agency's Phase 5 risk assessment includes 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 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); (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 rotary tiller and spray blade injection applications were derived from the shank injection emission study profile with intermittent water seal. 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. EPA is aware of data currently being developed by both AMVAC and researchers at Washington State University. Some of this data will quantify the flux rates from the use of standard center-pivot application equipment, both with and without the use of endguns, as well as the use of center-pivot equipment using drift-reduction technology (i.e., center pivot irrigation equipment in which the release height and maximum spray height is lowered and a solid stream or drizzle nozzle is used). The Agency will include the results of this research in its final labeling decisions, if possible.

---

[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.

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., 1825 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 uncertainty factor for intraspecies extrapolation. 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 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 not only 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 2 to 7 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 2 to 7).

- **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 is 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 which included consideration of the hazard profile of metam-sodium and metam-potassium, information from incident reports, monitoring data, stakeholder comments along with comprehensive analysis of results from PERFUM modeling and consideration of results using other models (e.g., Industrial Source Complex Model). The analysis of PERFUM results considered distances at various percentiles of the whole field and maximum distance distributions, and predicted MOEs for various distances. The risk assessment characterizes additional types of analysis that were performed. The following characterizes the risks associated with the buffer zone distances summarized in Tables 2 to 7.

The buffer zone distances at the 90$^{th}$ 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 percent chance of exposure below the Level of Concern. The buffer zone distances at the 90 $^{th}$ 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 percent 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.

| Table 2. Center Pivot Irrigation Application (High Release) 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 |
| 80 | 200 | 300 | 400 | 500 | 600 | 700 | 800 | 950 | 1100 | 1250 | 1400 | 1500 | 1600 | 1700 | 1800 |
| 100 | 300 | 400 | 500 | 600 | 700 | 800 | 900 | 1050 | 1200 | 1350 | 1500 | 1625 | 1750 | 1875 | 2000 |
| 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 or 2) the maximum spray height is greater than 6 feet, with or without end-guns.

| Table 3. Center Pivot Irrigation Application (Low Release) 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 |
| 80 | 75 | 138 | 200 | 300 | 400 | 500 | 600 | 750 | 900 | 1050 | 1200 | 1300 | 1400 | 1500 | 1600 |
| 100 | 100 | 200 | 300 | 400 | 500 | 600 | 700 | 850 | 1000 | 1150 | 1300 | 1425 | 1550 | 1675 | 1800 |
| 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 is less than 6 feet, and 2) the maximum spray height is less than 6 feet, without endguns.

| Table 4. Center Pivot Irrigation Application (Low Drift) 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 |
| 80 | 75 | 125 | 175 | 232 | 288 | 344 | 400 | 475 | 550 | 625 | 700 | 775 | 850 | 925 | 1000 |
| 100 | 100 | 150 | 200 | 275 | 350 | 425 | 500 | 588 | 675 | 763 | 850 | 938 | 1025 | 1113 | 1200 |
| 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 is less than 2 feet, and 2) maximum spray height is less than 2 feet, and 3) uses solid stream or drizzle nozzle, without endguns..

| Table 5. Chemigation (All 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 |
| 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 |
| 80 | 75 | 138 | 200 | 300 | 400 | 500 | 600 | 750 | 900 | 1050 | 1200 | 1300 | 1400 | 1500 | 1600 |
| 100 | 100 | 200 | 300 | 400 | 500 | 600 | 700 | 850 | 1000 | 1150 | 1300 | 1425 | 1550 | 1675 | 1800 |
| 120 | 200 | 300 | 400 | 500 | 600 | 700 | 800 | 950 | 1100 | 1250 | 1400 | 1550 | 1700 | 1850 | 2000 |

| Table 6. Tractor Drawn Applications-Tarped and Untarped (i.e., Shank Injection, Rotary Tiller, and Spray Blade) 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 | 32 | 38 | 44 | 50 | 56 | 63 | 69 | 75 |
| 5 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 63 | 75 | 88 | 100 |
| 10 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 63 | 75 | 88 | 100 | 125 | 150 | 175 | 200 |
| 20 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 69 | 88 | 132 | 175 | 207 | 238 | 269 | 300 |
| 30 | 25 | 38 | 50 | 57 | 63 | 69 | 75 | 113 | 150 | 188 | 225 | 257 | 288 | 319 | 350 |
| 40 | 25 | 38 | 50 | 57 | 63 | 69 | 75 | 119 | 163 | 207 | 250 | 288 | 325 | 363 | 400 |
| 50 | 25 | 50 | 75 | 82 | 88 | 94 | 100 | 150 | 200 | 250 | 300 | 350 | 400 | 450 | 500 |
| 60 | 25 | 50 | 75 | 82 | 88 | 94 | 100 | 163 | 225 | 288 | 350 | 413 | 475 | 538 | 600 |
| 80 | 50 | 75 | 100 | 125 | 150 | 175 | 200 | 250 | 300 | 350 | 400 | 475 | 550 | 625 | 700 |
| 100 | 75 | 100 | 125 | 150 | 175 | 200 | 225 | 282 | 338 | 394 | 450 | 525 | 600 | 675 | 750 |
| 120 | 75 | 113 | 150 | 175 | 200 | 225 | 250 | 313 | 375 | 438 | 500 | 575 | 650 | 725 | 800 |

| Table 7. 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 |
| 5 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 50 | 50 | 50 | 50 |
| 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 |
| 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 zones 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., deleting low-benefit, potentially high-risk use sites; requiring GAPs and FMPs; posting and emergency preparedness requirements; soil fumigant training requirements for applicators and handlers; 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 8) 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 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 97 percent, and the max percentiles range from <5 to 90 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 62 and 67 respectively).

*Example*

Consider the use scenario listed below (in Table 8) for potatoes grown in the Pacific Northwest using a center pivot with low release height (i.e., maximum spray height less than 6 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 95$^{th}$ air concentration from the PERFUM modeling data at this buffer distance is 4.
- The risk level corresponding to this buffer zone distance at the 95$^{th}$ 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 percent chance of having of exposure below the Level of Concern. (i.e., MOE ≥ 10).
- The risk level corresponding to the buffer zone distances at the 95$^{th}$ 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 percent chance of exposure below the Level of Concern. (i.e., MOE ≥ 10) for these typical use scenarios.

| Table 8. 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 w/ end gun | 140 | 120-160 | 900-1300 | n/a | n/a | n/a |
| | | Center Pivot – low release height w/o end gun | 140 | 120 | 700 | 75 | 15 | 4 |
| | | Center Pivot - w/ low drift technology | 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 w/ end gun | 140 | 160 | 1300 | n/a | n/a | n/a |
| | | Center Pivot – low release height w/o end gun | 140 | 120 | 700 | 75 | 15 | 4 |
| | | Center Pivot - w/ low drift technology | 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 |
| 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 |

| Table 8. Buffer Zone Distances and Risk Characterization for Key Metam Use Scenarios | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Whole Field and Max Distance Percentiles | | |
| | | | | 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 |

***Range of whole field and maximum distance percentiles and MOE values represents the standard water seal (lower value) and intermittent water seal (higher value) emissions data.**

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

### (d) Buffer Zone Reduction Credits

The Agency has undertaken a significant effort to evaluate available empirical data, modeling, and literature regarding the factors and control methods that may reduce emissions from soil fumigants. For details on the Agency's analysis please see the June 9, 2008 memo "Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach,"[4] in the metam docket. The Agency has also coordinated and led forums to discuss this issue at the 2006 and 2007 Methyl Bromide Alternatives Outreach (MBAO) Conferences with leading researchers and other stakeholders. A general description of the MBAO sessions can be found at http://mbao.org.

Based on the Agency's analysis of the current data, the Agency has developed buffer zone reduction credits for: high-barrier tarps, soils with high organic matter, soils with high clay content, and low-temperature soils. These credits may be combined. To take advantage of the credit for high barrier tarps, and to some degree, to take advantage of the credit for reduced soil temperature, users can modify their current application practices. Organic matter and clay content are difficult to change, and this credit may only be applicable for areas where these soil characteristics already exist. Changing current practices or site conditions to utilize these credits presents a challenge, but the Agency believes that, in addition to reducing bystander risk and the size of buffer zones, these credits have the potential to decrease application rates and increase efficacy. A description of the buffer zone reduction credits for metam-sodium and metam-potassium is provided below. Applicators would determine their buffer zone distance based on application equipment, application rate, and application block size. Then, they could reduce their buffer based on the use of high-barrier tarps, based on soil temperature at the time of application, based on soil organic matter content, or clay content of their soil.

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

Metam-sodium/metam-potassium buffer zone credits are additive and cannot exceed 40 % in total (i.e., if all of the above factors applied to a particular fumigation).

- **High-Barrier Tarps**

A 10% buffer credit (i.e., a 10 % reduction in the buffer distances specified in Tables 3-8 above) will be 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), are used for either a shank injection or drip metam-sodium/potassium application. Because current study data do not demonstrate significant reductions in MITC emissions using standard polyethelyne tarps, no credit will be provided for "standard" tarped metam applications. The credit is 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 have shown that MITC and chloropicrin pass through standard tarps at similar rates, the Agency has decided to allow emissions credits for the Hytibar tarp as well as the other high-barrier tarps that are being given an emissions reduction credit. The Agency believes that the actual reduction for tarps could be higher for certain conditions but that a 10% credit is appropriate based on uncertainties in the available data. The use of high barrier films is limited to shank injection and drip irrigation applications and may not be feasible or applicable to all situations where metam is currently used.

Tarp emission reduction data reviewed by EPA show that tarps have varying degrees of effectiveness. There is no current standard to evaluate tarps, and in the absence of a standard, EPA has established conservative buffer reduction factors based on available data. EPA requested assistance from USDA's Agricultural Research Service (ARS) in this effort to identify those films that have demonstrated low permeability and reduced emissions under field conditions (see EPA-HQ-OPP-2005-0123-0459 in www.regulations.gov). USDA's research includes a hybrid field-lab performance test where tarps are stretched out over beds, subjected to atmospheric and soil conditions, and then tested in the lab. The Agency believes that this approach to evaluating the permeability of agricultural tarps could simulate more realistic field conditions. EPA requested the results of film permeability testing currently being conducted in support USDA's Area-wide Pest Management Projects for both the Pacific Region and the South Atlantic Regions.

In a response to EPA's request (EPA-HQ-OPP-2005-0123-0460), USDA indicated that at least several months are needed for data review, and that it was not able to provide the data in a timeframe useful for EPA's current decisions. USDA did offer to provide samples of film taken from its ARS experiments for testing in EPA laboratories. EPA is looking into the feasibility of this option.

EPA plans to work with USDA, registrants, and other stakeholders to develop protocols for measuring the performance of tarp materials (i.e., using the mass transfer coefficient for each fumigant) that could be used for regulatory purposes. Although there are several protocols being evaluated, there is no consensus on a method. The Agency's document titled "Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit

Factor Approach," discusses these and other methods. Guidelines for conducting flux studies in the field to use as point of comparison for performance testing are already well established.

EPA (through OPP's Environmental Stewardship Branch) has proposed to co-fund a grant with USDA's ARS 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[5]. During the 60-day comment period the Agency anticipates learning more about ongoing and planned research from the scientific community that will address these uncertainties to help the Agency identify potential studies that would help refine the current risk-based mitigation decisions. The EPA will defer decisions regarding calling-in any data to address uncertainties identified with regard to these and other factors until comments provided during the 60-day comment period have been reviewed.

- **Soil Conditions**

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

The Agency's factors document not only reviews available literature regarding soil conditions, but also models 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[6.] 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[7]. See the Agency's factors document for details about the model.

---

[5] Health Effects Division Recommendations for Fumigant Data Requirements. June 2008. DP Barcode 353724
[6] Cryer, S.A. (2007) Air/Soil Boundary Conditions For Coupling Soil Physics and Air Dispersion Modeling. Unpublished report of Dow AgroSciences LLC (Report # DN241493)

7 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.

*Organic Matter*

The Agency's CHAIN_2D sensitivity analysis suggests that organic matter can have a small impact on emissions. Increasing the dissociation constant ($K_d$) value by 10 or 25% generally reduced emissions by 10 or 20%. Decreasing the $K_d$ value by 10 or 25% increased emissions by 10 or 20%. Additional information can be found on page 127-130 of the Emission Factors document cited above. Based on the review of available literature and modeling with the CHAIN_2D model, EPA believes a 10 % buffer zone credit is appropriate if the application block contains soil with organic matter of greater than 3 percent.

*Clay Content*

The Agency's CHAIN_2D sensitivity analysis suggests that soil type can have a significant impact on emissions. Generally, clay loam and sandy clay loam soils tended to show significantly lower emissions than other soil types; sometimes showing 50% reductions. Conversely, loamy sand and loam soils tended to show higher emissions than other soil types. Additional information can be found on page Pages 134 to 137 of the Emission Factors document cited above.

Based on the review of available literature and modeling with the CHAIN_2D model, EPA believes a 10 % buffer zone credit is appropriate if the application block contains soil with clay content of at least 27 %.

*Soil Temperature*

A 10% credit will be given 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. Study data show that increased soil temperature corresponds to increased fumigant emissions rates. 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). Given that lower soil temperatures lead to lower fumigant emission rates, a credit is being provided for these scenarios. 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 will not be provided to reduce the buffers for these application methods.

- **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. See the GAP section (page

62) for further discussion. If additional data confirming these measures effectively reduce emissions becomes available, EPA will consider developing further credits.

### (e) Buffer Zone Impacts

The Agency has used the best available data to estimate potential metam-sodium and metam-potassium bystander risks and has both quantitatively and qualitatively evaluated the impact of potential emission control measures on bystander risk. The Agency recognizes that there is substantial research being conducted by stakeholders to further quantify the reduction of emissions for site-specific conditions that currently exist in places where soil fumigations take place (e.g., soil conditions) and for methods that growers may be able to implement (e.g., high-barrier tarps, soil amendments, alternate application methods, etc.) and will consider such data in future decisions as new data become available. Such data may also support the Agency's decisions on additional emission credits in the future.

Table 9 **(**below**)** shows examples for buffer zone distances in selected crops with high metam-sodium use, based on typical application rates and typical application block sizes (derived from information identified in BEAD's benefits assessments). For key crops grown under typical conditions in the Pacific Northwest using center pivot irrigation, the buffer zone distances for treating 120-acre application blocks without credits are approximately 900 feet (with use of an end gun), 700 feet (without use of an end gun), and 525 feet (without use of an end gun and with use of low drift technology, e.g., a drizzle boom). For key crops grown in California on 40-acre plots under typical conditions, the buffer zone distances range from 25 to 363 feet for shank injection applications, from 319 to 700 feet for chemigation and flood irrigation, and from 107 to 150 feet for drip applications without credits. The scalable buffer approach provides growers with the flexibility to reduce the size of treated fields and/or split applications into different application blocks to reduce their buffer distance, and the emission reduction credits provide additional opportunities for growers to potentially reduce buffer zone distances.

EPA acknowledges that even with the option to reduce buffer zones distances by splitting application blocks and/or the use of credits for emission reduction conditions, the distances required by this decision could have significant economic impacts to some growers who may not be able to accommodate large buffers based on their current application practices. This decision allows growers the flexibility to continue using current practices if they can accommodate the required buffers that correspond to their current practices, or to modify their practices to achieve smaller buffers which are workable.

EPA believes that for most growers this flexible buffer system will result in workable buffers, but costs associated with achieving workable buffers will vary from site to site. Recently, EPA further examined potential impacts of buffer zones and possible adaptations growers might undertake. This analysis is available in the memo titled "Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants, (DP# 353940)", dated June 25, 2008. It will be made available in the metam-sodium docket (EPA-HQ-OPP-2005-0125 at www.regulations.gov). EPA also acknowledges that for some growers, such as those with fields bordered by residential structures,

the cost of modifying production practices may be substantial. However, EPA believes that protecting bystanders and residents in such areas is also important and the growers' benefits from using metam-sodium and metam-potassium in these areas would not outweigh the risks to bystanders.

| Table 9. Examples of Buffer Zone Distances For Selected Crops Based on Current Typical Application Rates With and Without Buffer Reduction Credits Incorporated | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Crop** | **Region** | **Application Method** | **Broadcast Equivalent Rate (lb ai/A)** | **Block Size (acres)** | **Buffer Zone Distance (ft)** | | **Maximum % Credits *** |
| | | | | | **Without buffer credits** | **With maximum buffer credit** | |
| Potatoes | PNW | Center Pivot – high release height with end gun | 140 | 120-160 | 900-1300 | 630-910 | 30% |
| | | Center Pivot – low release height without end gun | 140 | 120 | 700 | 490 | 30% |
| | | Center Pivot - low drift technology | 140 | 120 | 525 | 368 | 30% |
| | Upper Midwest | Chemigation | 150 | 30 | 200 | 140 | 30% |
| | | | | 50 | 304 | 213 | 30% |
| | PNW | Shank Injection | 140 | 80 | 175 | 122 | 30% |
| | | | | 120 | 225 | 157 | 30% |
| Carrots | CA | Shank (Broadcast) | 170 | 80 | 225 | 157 | 40% |
| | | Chemigation | 170 | 40 | 319 | 223 | 30% |
| | | | | 60 | 463 | 324 | 30% |
| | | Flood | 170 | 40 | 319 | 255 | 20% |
| | | | | 60 | 463 | 370 | 20% |
| | | Drip | 170 | 40 | 107 | 75 | 30% |
| | | | | 60 | 163 | 114 | 30% |
| | WA | Center Pivot – high release height w/ end gun | 140 | 160 | 1300 | 910 | 30% |
| | | Center Pivot – low release height w/o end gun | 140 | 125 | 700 | 490 | 30% |
| | | Center Pivot - w/ low drift technology | 140 | 125 | 525 | 368 | 30% |
| Cucurbits | AZ & CA | Shank (Strip, Tarped) | 210 | 10 | 82 | 49 | 40% |
| | | | | 40 | 185 | 111 | 40% |
| | Southeast | Shank (Strip, Tarped) | 320 | 10 | 200 | 120 | 40% |
| | | | | 40 | 400 | 240 | 40% |
| Tomatoes (Processed) | CA | Shank (Strip, Tarped) | 40 | 10 | 25 | 25 | 40% |
| | | | 60 | 40 | 38 | 23 | 40% |
| | | Drip (Tarped) | 40 | 10 | 25 | 25 | 30% |
| | | | 60 | 40 | 38 | 27 | 30% |
| Tomatoes (Fresh) | Southeast | Shank (Strip, Tarped) | 320 | 10 | 200 | 120 | 40% |
| | | | | 40 | 400 | 240 | 40% |
| Onions | OR & WA | Shank Strip (Tarped) | 210 | 30 | 169 | 101 | 40% |
| | | | | 40 | 185 | 111 | 40% |
| | CA | Shank Strip (Tarped) | 110 | 30 | 60 | 36 | 40% |
| | | | 150 | 40 | 72 | 43 | 40% |

* Note: The maximum credits are assumed to vary depending on the likely circumstances of fumigant use in a specific crop. For example, tarps are not feasible for use with chemigation, so a credit for this factor was not used in the Table for this application method, but credits for lower soil temperature, soil organic matter, and clay content are reasonably applicable (thus resulting in a maximum of 30 % credits in this scenario). Similarly, for drip application in California, since low soil temperatures are unlikely during application, but all other credit factors are potentially applicable, a maximum of 30 % credits is depicted.

## 2. Posting

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

In addition to alerting bystanders, posting a buffer zone will help handlers determine where and when they are required to use PPE. As described below, handlers working in buffers during the buffer zone period must use label-specified PPE and meet other requirements under the 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 as described below and in the example that follows.

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

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

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

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

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

Additional requirements for treated area posting:

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

**Contents of Signs**

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

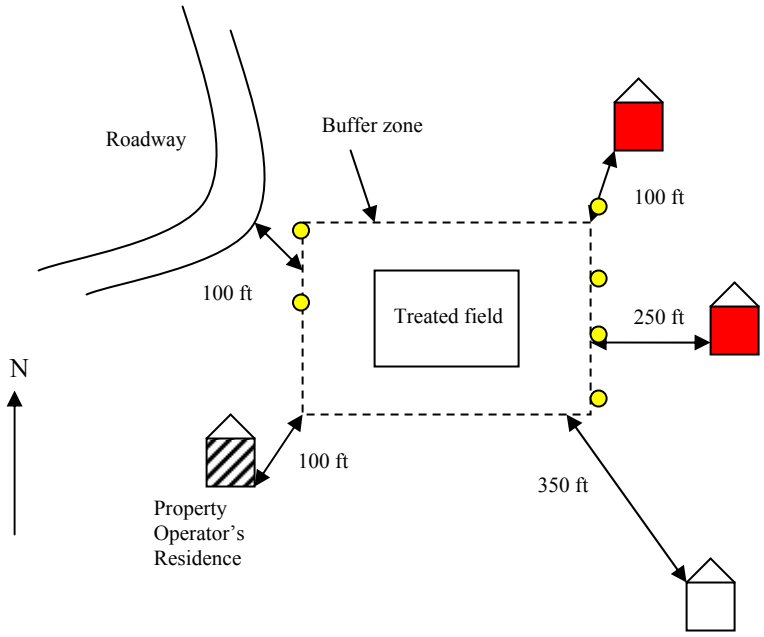
-- "DANGER/PELIGRO,"
-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"
-- "[*Name of fumigant*] Fumigant in USE,"
-- the date and time of fumigation,
-- the date and time entry prohibition is lifted
-- Name of this product, and
-- name, address, and telephone number of the certified applicator in charge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

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

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

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

**Figure 3.** Posting Example




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

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

*Buffer Zone Posting Considerations*

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

## 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

Persons engaged in any of the following activities will be defined as *handlers* on product labels. In addition, if the person is in the treated area or buffer during the application, or enters the treated area or buffer zone during the application, or enters the treated area or buffer zone for 48 hours after the application has ended, they are considered handlers and must wear the appropriate PPE:

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

### 2. Handler Requirements

All handlers involved in a metam-sodium/potassium application must be under the supervision of a certified applicator that remains on-site. Since many incidents are caused by human error and equipment failure, EPA believes the presence of onsite trained personnel would help to reduce these risks. The 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. The person monitoring another handler may also be engaged in fumigant handling tasks during the monitoring period. The certified applicator supervising metam-sodium/potassium applications can perform all tasks without anyone supervising them.

Before applying this product the certified applicator supervising that application must have, within the preceding 12 months, successfully completed a metam-sodium/metam-potassium training program made available by the registrant. The Fumigant Management Plan (FMP) must document when and where the training program was completed.

For cases when the certified applicator leaves the site such as chemigation, the certified applicator must periodically monitor the application equipment (see the label table for specific requirements) and for all applications, once the fumigation process is complete and other parties will be performing handler tasks (e.g., tarp cutting/removal, water application, etc.), the certified applicator must communicate in writing to the site owner/operator and other handlers key information needed to comply with label requirements (e.g. PPE requirements, location of buffers, when buffer zone ends, reentry restrictions, minimum times for cutting tarps, etc.).

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

### 3. Dermal Protection for Handlers

The Agency has concerns for handlers involved in metam-sodium and metam-potassium applications for dermal exposure. The Agency's human health risk assessment for metam-sodium/potassium indicates that dermal risks for many handler tasks exceed the Agency's level of concern for acute exposure to the parent metam-sodium/potassium. For handlers loading metam products at higher application rates for large acreage applications, margins of exposure (MOEs) 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. But, for many of the handler scenarios, when loading metam products for more typical acreage applications at typical application rates, margins of exposure (MOEs) are below the Agency's level of concern with additional PPE and/or when 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. The Agency has developed mitigation that is protective of the majority of handler and applicator scenarios and encourages engineering controls such as closed cabs in lieu of additional PPE to reduce dermal protection for loaders and applicators. In addition, the Agency recognizes that additional PPE creates heat stress to handlers and applicators that could lead to significant health concerns. Therefore, the Agency is requiring additional PPE where warranted, but has attempted to reduce PPE requirements where warranted and encourage engineering controls that further reduce handler and applicator exposures. The Agency has evaluated the metam-sodium/potassium labels and many of the Agency's PPE requirements are already on existing labels. As a result of this RED, the labels will be clarified to insure all products have the appropriate PPE to reduce dermal risk to handlers and applicators.

## 4. Respiratory Protection for Handlers

The Agency's human health risk assessment for metam-sodium/potassium indicates that inhalation risks for many handler tasks exceed the Agency's level of concern for the acute exposure to the parent and MITC.

The Agency has received comments from applicators that respirators are not necessary because (1) the possibility of eye irritation and the nature of the smell of MITC (i.e., sulfur, rotten eggs) to alert handlers if there has been an unsafe exposure, (2) respirators inhibit communication which could cause an accident; and (3) in warm weather respirators can cause heat stress and other ailments. On the other hand, some stakeholders are in favor of mandatory respiratory protection because there is no economically available monitoring equipment that is sensitive enough to show that acute term occupational exposure risks have not been exceeded. These stakeholders have also stated that handlers will not be given access to respirators and other PPE unless it is required on the label.

The currently available monitoring tubes detect MITC at levels as low as 100 ppb, which is higher than the Agency's level of concern for acute exposure of 22 ppb. However, at a level of 100 ppb, handlers would be exposed to levels of MITC that are 8 times lower than effects seen at the LOAEL of 800 ppb, which is about equal to an MOE of about 2. In addition, the eye effects from MITC exposure act as a biomarker or surrogate that protects for more adverse systemic and respiratory effects. The available toxicity data in animals or humans do not allow us to compare the dose response curves of the eye, systemic, and respiratory effects, so there is uncertainty in how close the more adverse effects may be as compared to the eye irritation effect. As stated in EPA's review of the endpoint selection:

"With respect to respiratory impairment, arguably, eye irritation is less severe compared to other possible effects associated with inhalation exposure to MITC, particularly given the expected reversible nature of the eye irritation effects at lower concentrations. Nonetheless, eye (as well as nose and throat) irritation is uncomfortable and could potentially interfere with everyday tasks or activities. Due to the limitations in the existing *inhalation* toxicology database for MITC, the degree to which eye irritation predicts more serious outcomes is unclear. However, in the absence of more robust dose-response data from acute exposures, eye irritation can be considered as a biomarker and surrogate for potential respiratory effects." (D293349)

Based on (1) the reversible sensitive endpoint selected, (2) the limited monitoring technology currently available, (3) the potentially physically stressful response to respirators, and (4) the apparent fact that the current technology allows detection at levels 8 times lower than the LOAEL of 800 ppb selected, the Agency is allowing a monitoring program for MITC to 100 ppb in place of respirators for some handler tasks.

Therefore, the Agency is requiring handlers potentially exposed to MITC vapors from metam-sodium/potassium applications to either wear respirators approved for MITC or follow the monitoring program detailed below. For some handling tasks described below, respirators are required to be worn at all times due to the short duration of the task and the potential high concentration of MITC to which they could be exposed. 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.

*Continuous monitoring for tasks over a long duration*

An air purifying PF 10 respirator approved for MITC provides 10 times the inhalation protection from the air concentration in an area. Once a concentration of 100 ppb is measured in the breathing zone of the handling task, then an air purifying PF 10 respirator approved for MITC must be worn by all handlers in the treated field or buffer zone. The respirator is designed to protect the handler by reducing MITC concentrations 10 times, i.e. 1000 ppb air concentrations x 10 X respirator reduction factor = 100 ppb. At air concentrations greater than 1000 ppb the respirator is not designed to protect handlers from inhaling more than 100 ppb of MITC. Therefore, the handler must continue to monitor once respirators are donned. If concentrations of MITC exceed 1000 ppb or if eye irritation occurs, then the operations must cease until levels of MITC are measured to be below 1000 ppb from consecutive air samples.

*Additional Respiratory Requirements*

In the metam-sodium risk assessment, a respirator was considered for MITC exposure since there were inhalation risk concerns without additional protection. A protection factor (PF) of 10 for a half-face air purifying respirator was utilized. The protection factor 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 done. Without these requirements, it is unclear whether the reduction in inhalation exposure that is assumed by the protection factor is actually achieved. In order to ensure that the respiratory protection EPA is assuming is being achieved in the field, respiratory requirements for MITC generators will include fit testing, respirator training, and annual medical evaluation. In addition, respirators must be made available to all handlers that may expose them to MITC vapors. The language to be added to labels is listed below and in Table 13.

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

The employer of the fumigant handlers must make sure that all handlers in the application block and the surrounding buffer zone are provided and correctly wear the required PPE. The PPE must be cleaned and maintained as required by the Worker Protection Standard for Agricultural Pesticides."

*Long Duration Tasks*

For handlers such as applicators supervising the application, tractor drivers, tractor co-pilots, shovel men, and tarp cutters, the respiratory requirements include:

- Mandatory monitoring in the breathing zone of handlers at least once an hour, even if a respirator is worn.
- Air-purifying respirators must be put on if one of the following occurs:
  - MITC concentrations are ≥ 100 ppb, or
  - Handlers experience sensory irritation.
- All activities must cease if one of the following occurs:
  - MITC concentrations are ≥ 1000 ppb, or
  - Handlers experience sensory irritation while wearing respirators.
- In order to remove the respirator or resume work activities:
  - Two air samples for MITC must be taken in the treatment area at least 15 minutes apart.
  - The samples must be less than 100 ppb to remove the respirator and below 1000 ppb for work activity to resume with a respirator.
  - During the collection of samples an air purifying respirator must be worn.

Respirators cannot be removed until monitoring indicates that levels have decreased below the above triggers and handlers are not experiencing irritation.

*Short Duration Tasks*

Handlers that may be exposed to high concentrations of MITC and are conducting tasks that are over a short time frame, such as mixers/loaders, handlers installing/repairing irrigation systems during application, irrigation operators during application, and or tarp handlers repairing the tarp, must wear respirators at all times. No monitoring measure is required since the nature of these tasks is relatively short in duration and the monitoring would not be effective in capturing spikes in MITC. However, if a handler experiences and sensory irritation the activity must stop until corrective steps have been taken (e.g., add water to the application site, stop the mixing/loading activities, etc.) to reduce the concentration of MITC.

*Summary of Handler Dermal and Respiratory Protection Requirements*

The Agency is requiring the following mitigation measures to reduce dermal and respiratory exposures for handlers:

*Transferring Liquids*

To reduce risk to handlers who transfer liquids from any container into application equipment or delivery equipment:

- double layer clothing (baseline work clothes + coveralls), chemical resistant gloves, chemical resistant apron, chemical resistant footwear plus socks, protective eyewear and a respirator approved for MITC.

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:

- baseline work clothes, chemical resistant gloves, chemical resistant apron, protective eyewear + closed connect system.

*Driving Ground Rigs*

To reduce risk to handlers driving ground rig with a closed cab that provides dermal protection:

- baseline work clothes + respirator approved for MITC (in lieu of the respirator, the handler can follow the air monitoring program outlined above).

To reduce risk to handlers driving ground rig that does not provide dermal protection:

- double layer clothing (baseline work clothes + coveralls), chemical resistant footwear plus socks, and respirator approved for MITC (in lieu of the respirator, the handler can follow the air monitoring program outlined above).

*Set-up, Calibration, and Start Up of Chemigation Equipment*

To reduce risk to handlers who set-up and calibrate chemigation and irrigation equipment and remotely start the application from outside the buffer zone, the following is required:

- baseline work clothes.

To reduce risk to handlers who set-up and calibrate chemigation and irrigation equipment and start the application from inside the buffer zone, the following is required:

- baseline work clothes + respirator approved for MITC.

*Early Entry or Monitoring PPE*

To reduce risk to handlers entering a treated area during the application or enter the treated field for 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 enter the buffer zone for up to 48 hours after the application has ended must wear:

- baseline work clothes + respirator approved for MITC (in lieu of the respirator, the handler can follow the air monitoring program outlined above). If the handler will to be exposed to

liquid or liquid spray from the application equipment, they must wear chemical resistant coveralls or a waterproof rain suit, chemical resistant gloves, chemical resistant apron, chemical resistant footwear plus socks, and protective eyewear.

**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, particularly when high barrier tarps are used. In addition to respiratory protection requirements described above, the Agency is requiring the following to mitigate risks from inhalation exposure:

- Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after shank injection of the fumigant product and tarps (if used) have been laid or after drip lines have been purged and tarps have been laid, unless an adverse weather condition exists for broadcast applications).
- If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete.
- If tarps will not be removed after perforation, planting or transplanting cannot begin until at least 48 hours after tarp perforation is complete.
- If tarps are left intact for at least 14 days after fumigation injection into the soil is complete, planting or transplanting may occur while the tarps are being perforated.
- Adverse Weather Conditions Exemption for Broadcast Applications Only, see Figure 9: Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that:
    - At least 48 hours have passed after the fumigant injection is complete,
    - The buffer zone period is extended until 24 hours after tarp removal is complete, and
    - Subsequent fumigations of untreated areas within the application block do not occur for at least 24 hours after tarp removal is complete.
- To reduce exposure to handlers perforating tarps
    - Tarps used for fumigations must be perforated only by mechanical methods.
    - Perforation by hand or with hand-held tools is prohibited.
- Each tarp panel used for broadcast fumigations must be perforated using a lengthwise cut. This measure is to reduce the likelihood of the tarp blowing away prior to tarp removal.

**6. Entry Prohibitions**

Most of the current metam-sodium and metam-potassium labels allow reentry by workers 48 hours after application. The risk assessment indicates that risks exceed EPA's concern for workers entering fields after 48 hours. However other information in the risk assessments indicate that extending this period decreases this risk. In addition, stakeholder comments indicate that non-handler entry to perform postapplication (i.e., non-handler) tasks is generally not needed for at least 10 to 14 days following the completion of the application.

Due to the volatile nature of metam-sodium and metam-potassium and the potential for worker exposure, the Agency is prohibiting entry into the treated area or buffer zone by anyone other than a protected handler. The prohibition differs from a Restricted Entry Interval (REI)

which contains exceptions for workers doing certain tasks before the REI has expired. Workers permitted entry under the REI, are prohibited for these soil fumigants.

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

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

Figures 4,5,6,7 and 8 provide illustrations of tarp perforation/removal and entry prohibition mitigation required for various applications. The intervals depicted are the minimum that must be followed.

**Figure 4.** Untarped Bed or Broadcast Applications

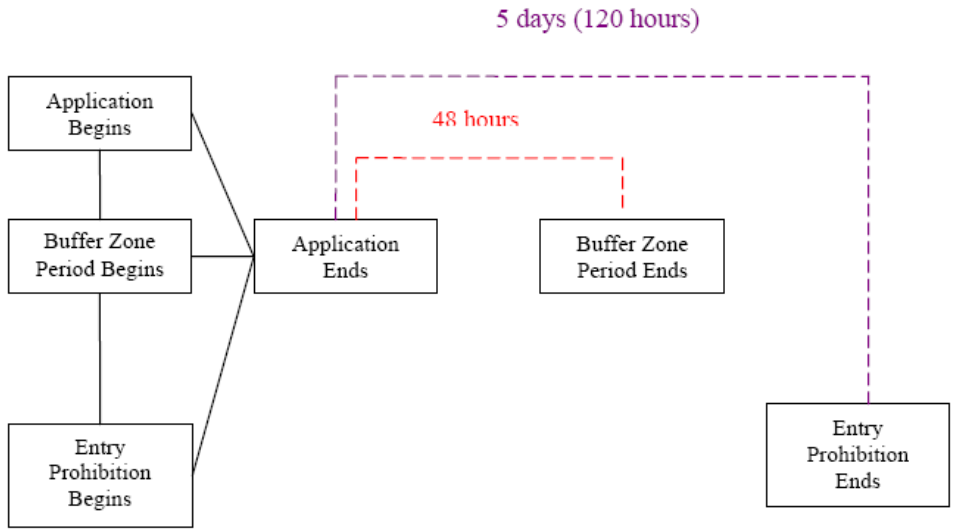


**Figure 5:** Tarps Removed Before Planting

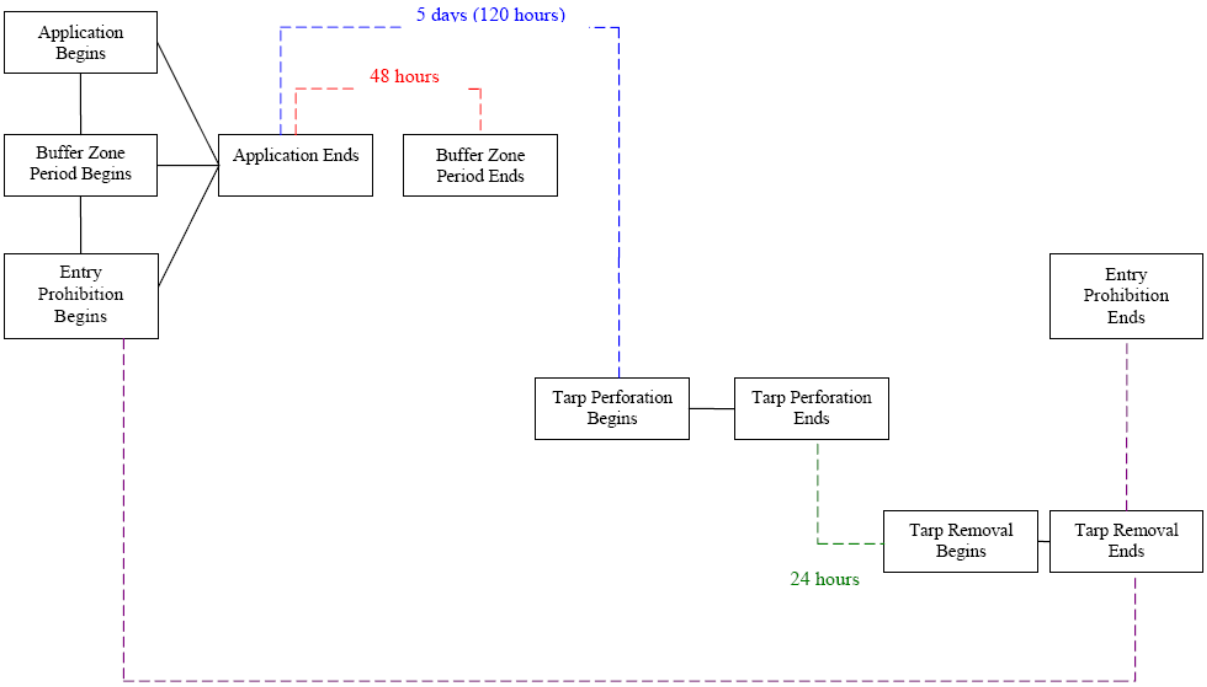



**Figure 6:** Tarps NOT Removed Before Planting

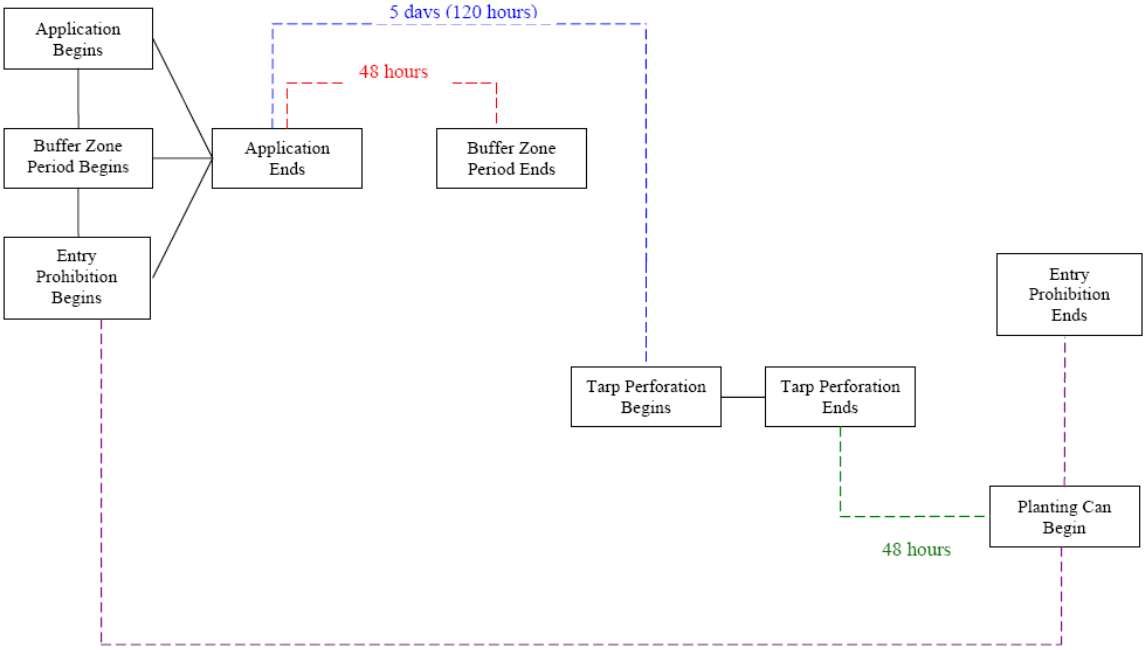


**Figure 7:** Tarps NOT Removed Before Planting and NOT Perforated Until 14 days after the application

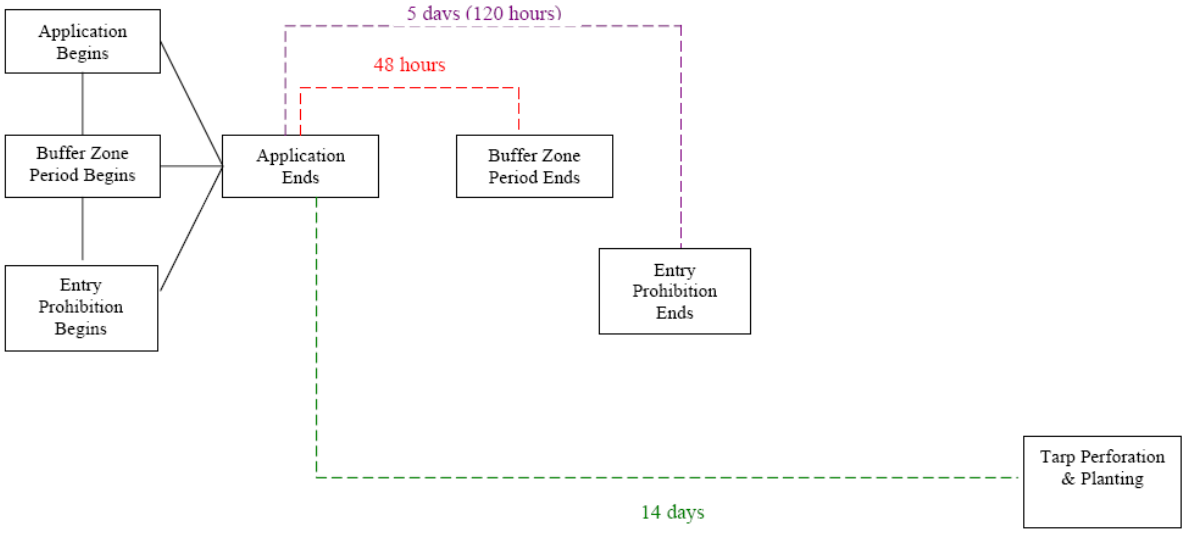
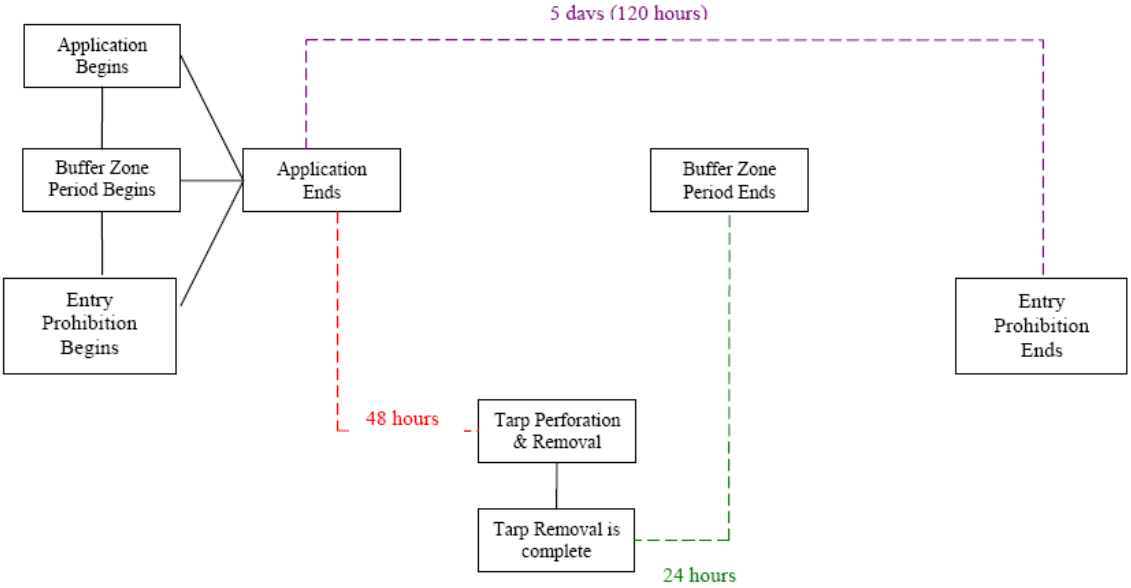



**Figure 8:** Adverse Weather Condition Exemption (Broadcast applications only)




## 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 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)) from the 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, that 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 Label Table, on page 99.

<u>Requirement on Labels</u>

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

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

*Weather conditions*

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

*Wind Speed*

- For all sprinkler and chemigation applications, maximum wind speed should not exceed 8 mph.
    - Exception: For sprinkler and chemigation applications with a release height and spray height less than 2 feet and that use a solid stream or drizzle nozzle, the maximum wind speed is 20 mph.

*Injection Depth and Soil Sealing*

- For Shank Injection Applications: The injection point for bedded and broadcast shank injection applications shall be a minimum of 3 inches from the nearest final soil/air interface. Chisel traces must be eliminated following an application. Following elimination of the chisel trace, the soil surface must be compacted with a culti-packer, ring roller, 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 application site must be sealed and compacted immediately after application using one of the following methods: a culti-packer, ring roller, bed-shaper, or other similar equipment.

*Tarps*

- When tarps are used in drip irrigation and tractor-drawn applications (i.e., shank injection, rotary till, and spray blade applications), the tarps must be installed immediately after the metam is applied to the soil.
- Only tarps mentioned previously in this document (in the subsection titled "Buffer Zone Reduction Credits", page 41) may be used for credits towards reducing the buffer.
- A written tarp plan must be developed 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.

*Soil temperature*

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

*Air temperature*

- *For All Chemigation Applications:* The maximum air temperature shall not exceed 90 degrees F during the application.

*Soil moisture*

- Prior to and throughout the duration of an application, soil moisture must be maintained at 50-80% field capacity two to six inches below the surface. The amount of moisture needed in this zone will vary according to soil type and shall be determined using standard field testing methods. Surface soil generally dries rapidly and must not be considered in this determination. Additional water treatments may be added as necessary to maintain soil moisture at the 50-80% field capacity.
- If there is insufficient moisture two to six inches below the surface, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below six inches, soil moisture can be brought to the surface by discing or plowing before or during injection. To conserve existing soil moisture, pretreatment or treatment 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.
        - For **fine textured soils** (clay loam, silty clay loam, sandy clay, silty clay, sandy clay loam and clay) there must be enough moisture so that the soil is pliable, not crumbly, but does not form a ribbon when squeezed between the thumb and forefinger.
        - For **coarse soils** (sand and loamy sand) there must be enough moisture to allow formation of a weak ball when compressed in the hand. Due to soil texture, this ball is easily broken with little disturbance.
        - In **or medium textured soils** (coarse sandy loam, sandy loam, and fine sandy loam) there must be enough moisture to allow formation of a ball which holds together with moderate disturbance, but does not stick between the thumb and forefinger.
        - For **fields with more than one soil texture**, soil moisture content in the lightest textured (most sandy) areas must comply with this soil moisture requirement. Whenever possible, the field should be divided into areas of similar soil texture and the soil moisture of each area should be adjusted as needed. Coarser textured soils can be fumigated under conditions of higher soil moisture than finer textured soils; however, if the soil moisture is too high, fumigant movement will be retarded and effectiveness of the treatment will be reduced. Previous and/or local experience with the soil to be treated or the crop to be planted can often serve as a guide to conditions that will be acceptable. If you do not know how to determine the soil moisture content of the area to be treated, consult your local extension service or soil conservation service specialist or pest control advisor (agricultural consultant) for assistance.

*Soil preparation*

- Soil shall be properly prepared and free of large clods at the surface. The area to be fumigated shall be tilled to a depth of 5 to 8 inches. The soil shall be in good tilth with no dry clods over 1.68 inches in diameter present (i.e., size of a golf ball).
- Field trash must be properly managed. Residue from a previous crop must be worked into the soil to allow for decomposition prior to fumigation. Little or no crop residue shall be

present on the soil surface. Crop residue that is present must lie flat to permit the soil to be effectively sealed.

- *For Shank Applications:* Trash pulled by the shanks to the ends of the field must be covered with tarp, soil, or other suitable material, depending on the application method before making the turn for the next pass.
- *For Drip Applications:* Till fields with known plowpans, as they lead to puddling of fumigant due to inadequate soil drainage.

*Prevention of End of Row Spillage*

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

*Flushing Drip Irrigation Lines*

- *For Drip Irrigation Applications:* After application of the fumigant, continue to irrigate the area with water to flush the irrigation system. Do not allow fumigant to remain in the irrigation system after the application is complete. The total volume of water, including the amount used for flushing the irrigation system, must be adequate to completely remove the fumigant from the lines, 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 and/or normal irrigation practices.

*Calibration, Set-up, Repair, and Maintenance of Equipment*

- <u>For All Chemigation and Center Pivot Applications:</u>
    - Properly label metam-sodium bulk 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-sodium/metam-potassium.
    - Use a single tank with capacity adequate to complete an application cycle.
    - Make sure anti-siphon devices and back-flow preventers are installed an in working order.
    - Inter-connect the pump powers supply and injector pump so that, if the center pivot stops, the injection pump shuts off.
    -
- <u>For All Tractor-Drawn Applications (i.e., Shank Injection, Spray Blade Injection, and Rotary Tiller Injection):</u>
    - Dry connect fittings (closed transfer system) must be installed on all tanks and equipment.

- Do not use fittings made from copper, brass, or zinc (coated or galvanized).
- Stainless steel impellers must be used. (Do not use pump impellers made from brass or galvanized material.)
- Each tractor saddle tank must be equipped with a minimum size #50 mesh screen for both the fill and discharge outlets.
- Main line shutoff or by-pass valves must be used to stop the flow to the distribution manifold.
- All systems must be equipped with an individual tank monitoring system to detect flow problems in each individual tank.
- Prior to applications, the applicator:
    - Must pressurize the system with nitrogen, and check all fittings, valves and connections for leaks using soap solution.
    - Must ensure that:
        - Application equipment is in good working order,
        - Hose connections are sealed and tightened,
        - There is no damage to hoses or piping,
        - Regulatory connections are sealed and tightened,
        - Sight gauges are clear and working,
        - Pressure gauges are sealed and working,
        - Nozzles and metering devices are of correct size and are sealed and unobstructed,
        - There is a secure connection between the application equipment and the power source, and
        - All shields are in place.

- <u>For All Shank Injection Applications</u>:
    - Do not apply or drain product onto the soil surface.
    - Injectors must be placed below the soil surface before product flow begins.
    - Before lifting injectors from the soil, shut off the application equipment and wait for the product to clear the lines.
    -
- <u>For All Drip Irrigation Applications:</u>
    - 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 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.

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).

### 3. Fumigant Management Plans (FMPs)

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

FMPs should aid in the proper response of the applicator or others involved in the application should an incident occur. A proper and prompt response will reduce the potential risk to bystanders from high exposure situations (e.g., readily available first responder contact information could reduce response times to impacted bystanders).

There is information from various sources that health and safety plans, which are similar to FMPs in the context of managing adverse incidents, typically reduce workplace injuries and accidents by prescribing a series of operational requirements and criteria. These plans are widely implemented in a variety of industries and are recommended as standard approaches for occupational health and safety management by groups such as American Industrial Hygiene Association[8] (i.e., through "Administrative" and "Workplace" controls). The Centers for Disease Control provides guidance for developing health and safety plans in agricultural settings.[9] 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

---

8 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)

9 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

in this process as they are required to determine whether the standards should be maintained without change, rescinded or modified. OSHA is required by Section 610 of the Regulatory Flexibility Act (5 U.S.C. 610) and Executive Order 12866 to conduct the lookback reviews. These reviews are conducted to make the subject final standards more effective or less burdensome in achieving their objectives, to bring them into better alignment with the objectives of Executive Order 12866, and to make them consistent with the objectives of the Regulatory Flexibility Act. Two examples of "lookback" reviews that support the use of FMPs for soil fumigant health and safety management include: ethylene oxide use as a fumigant/sterilant, and grain handling facilities requirements.[10]

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

Each site-specific FMP must contain the following elements:

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

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

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

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

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

Once the application begins, the certified applicator and owner/operator of the application block must provide a copy of the FMP to handlers who are involved in the fumigation, workers in areas adjacent to the application block, as well as to any Federal, State, and local enforcement personnel, upon request.

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

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

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

**4. Emergency Preparedness and Response**

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

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

To ensure that appropriate response mechanisms are in place in the event of a fumigant exposure incident, EPA is requiring that registrants provide training and information, in the context of their community outreach and education programs, to first responders in high-

fumigant use areas and areas with significant interface between communities and fumigated fields. In addition, applicators must provide on-site monitoring of buffer zone perimeters, in areas where residences and other occupied structures are present. As an alternative to on-site monitoring, applicators may provide emergency response information directly to neighbors. Each element is discussed in more detail below.

*First Responder Education*

EPA is requiring registrants through their community outreach and education programs, on page 79 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 that, in the case of a fumigant accident or incident, first responders recognize the exposure as fumigant related and respond appropriately. The information/training to be provided to first responders will include: how to recognize the early signs and symptoms of fumigant exposure, how to treat fumigant exposures, how fumigant exposure differs from other pesticide exposure, plus the material safety data sheet(s) (MSDS) for the fumigant (metam-sodium or metam-potassium) applied as well as for the active compound generated (MITC).

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

<u>Site Specific Response and Management</u>

*Fumigation Site Monitoring*

EPA has determined that monitoring of the buffer zone perimeter would be an effective approach to protect bystanders. Under this approach, if measured concentrations anywhere along the buffer perimeter reach a level of concern specified on product labels, or if the person monitoring the air concentrations experiences eye irritation, then the emergency response plan stated in the FMP (see FMP section, page 67) must be implemented. If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. Because data indicate that peak concentrations sometimes occur on the second day following applications, EPA decided that this monitoring must be done for the full buffer zone period to ensure concentrations do not exceed the action level which will be specified on product labels.

Specific requirements include:

- Monitoring must take place from the beginning of the fumigant application until the buffer zone period expires

- Monitoring must be conducted by a certified applicator or someone under his/her supervision
- Monitoring of air concentration levels of the fumigant must be in the area between the buffer zone and the residences or other occupied structure
- The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period.

- A direct reading detection device, such as a Draeger device with a sensitivity of at least 100 ppb for MITC must be used to monitor the air concentration levels of MITC.
- If at any time (1) MITC concentrations are greater than or equal to 100 ppb OR (2) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations
- If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.
- The results of the air concentration monitoring must be recorded in the FMP.

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

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

*Response Information for Neighbors*

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

- Information that must be included:
    - Location of the application block
    - Name of fumigant(s) products(s) applied including EPA Registration number
    - Applicator and property owner/operator contact information
    - Location of buffer zones
    - Time period in which the fumigation is planned to take place and the duration of buffer zone period

- Early signs and symptoms of exposure to the fumigant(s) applied, what to do, and who to call if you believe you are being exposed (911 in most cases).

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

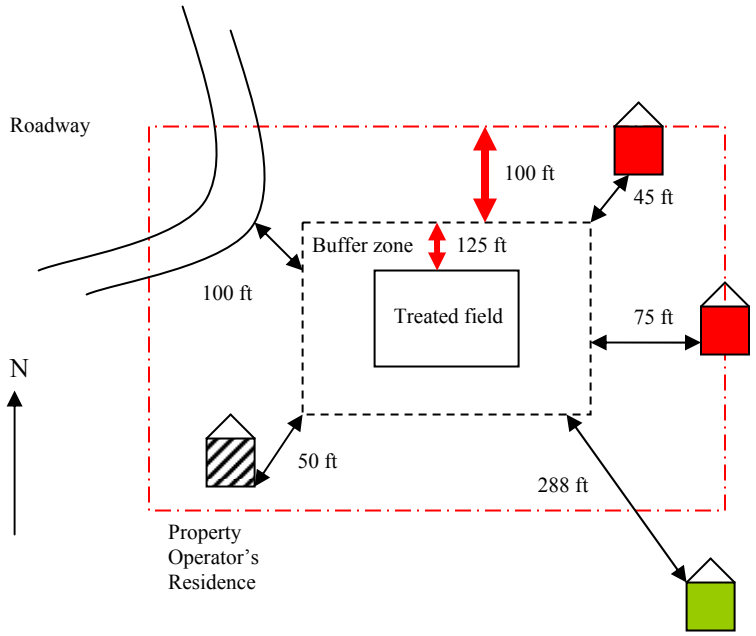
Who Needs to be Informed?:

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

To clarify this option, the following example is provided:

- IF the buffer zone is **125 feet**, people within 100 feet of the buffer zone must be provided emergency response information. So the **red** houses would need to be informed, **but** the **green** house would not.
- This requirement does not impact the roadway or the property operator's residence (striped).

**Figure 9.** Example Site Map for Informing Neighbors



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

*Emergency Preparedness and Response Considerations*

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

California currently requires notification of persons within 300 feet of a methyl bromide buffer zone. California strawberry growers consider the 300 foot notification area for methyl bromide applications in that state to be an extension of the buffer zone. In areas where a large number of people would need to be notified about planned methyl bromide fumigation, strawberry growers state that they would rather not use methyl bromide because some communities could mobilize to prevent the fumigation from taking place. Some stakeholders also commented that it would be protective and less burdensome if EPA required the user to monitor fumigant air concentrations at the edge of the buffer for 24 hours after the application to ensure the fumigant does not move beyond the buffer at concentrations that exceed EPA's level of concern. If concentrations of concern were detected, the user would be required to implement the emergency response specified in the fumigant management plan.

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

Providing communities with information about local chemical releases is an important part of emergency preparedness programs and is recognized as an effective means of addressing risk at the local level. Some states, like Florida and Wisconsin, have requirements for providing information to chemically-sensitive individuals about chemicals used nearby so they can take steps to protect themselves from potentially harmful exposures (see http://edis.ifas.ufl.edu/pi004 and http://www.legis.state.wi.us/rsb/code/atcp/atcp029.pdf). Wisconsin also requires fumigators applying metam-sodium products through chemigation to provide written notice to the county public health agency and to every individual or household within 0.25 mile of the chemigation

application site (see http://www.legis.state.wi.us/rsb/code/atcp/atcp030.pdf). EPA agrees that information about how to recognize and address exposures can help citizens reduce potential risk.

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

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

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

EPA is interested in input on the importance and usefulness of information specifying the location of the application block and buffer. EPA recognizes that such information may be difficult to convey clearly and concisely, especially if there are no easily recognizable landmarks nearby. While such information may be helpful, it may not be critical to ensuring an appropriate response to early signs and symptoms of exposure.

**5. Notice to State Lead Agencies**

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

The information that must be provided includes the following:

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

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

## 6. Soil Fumigation Training for Applicators and Other Handlers

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

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

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

*Training for Applicators Supervising Fumigations*

Registrants will be required to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and best practices for soil fumigants. EPA is

requiring registrants to submit proposals for these programs as data requirements in the Data Call-In that will accompany this RED. The training programs must address, at minimum, the following elements: how to correctly apply the fumigant; how to protect handlers and bystanders; how to determine buffer zone distances; how to develop a FMP and complete the post fumigation application summary; how to determine when weather and other site-specific factors are not favorable for fumigant application; how to comply with required GAPs and document compliance in the FMP. The training program must be made available to applicators at least annually. The registrant shall provide documentation, such as a card or certificate, to each applicator 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).

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

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

*Training Materials for Handlers*

EPA has determined that registrants must prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. EPA is requiring registrants to submit proposals for these materials as data requirements in the Data Call-Ins that will accompany this RED. The training materials must address, at minimum, the following elements: (1) what fumigants are and how they work, (2) safe application and handling of soil fumigants, (3) air monitoring and respiratory protection requirements for handlers, (4) early signs and symptoms of exposure, (5) appropriate steps to take to mitigate exposures, (6) what to do in case of an emergency, and (7) how to report incidents. Registrants must provide this training information through channels open to the public (e.g., via a website). Pesticide labels will require that applicators supervising fumigations

provide this training information to handlers under their supervision before they perform any fumigant handling task, or they must ensure that handlers have been provided the required information within the preceding 12 months. The label will also require that the training information be provided in a manner that the handler can understand. Applicators supervising fumigations must ensure the FMP includes how and when the required training information was provided to the handlers under their supervision.

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

*Soil Fumigation Training Considerations*

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

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

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

EPA stresses that registrant training programs will be separate from the state certification process and will be developed and administered by registrants in coordination with EPA. EPA will, however, work with state organizations and training experts to explore opportunities for the registrant programs to supplement state programs to provide additional training opportunities for fumigators. EPA will work with registrants in reviewing training program proposals and in developing the content for the programs and materials. EPA will also work with states to identify ways in which registrant training programs can be tailored to complement existing state programs. EPA's goal in requiring registrant training is to add to training resources. EPA is

aware of the need to coordinate carefully with states to ensure that new training does not become a burden on state agencies. EPA specifically requests comments from States on the best implementation approaches to meet these goals, and plans to meet with states during and after the public comment period to discuss options.

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

**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 within communities where soil fumigation occurs, which has raised health and safety concerns among community members. This lack of information and communication has led to inappropriate responses in cases where fumigants have moved off site and into communities. This also has led in some cases to unwarranted concern and anxiety among communities about the risks associated with the use of fumigants. The Agency believes that outreach and education to communities where soil fumigation occurs is an important component of the overall package of measures to address bystander risk. This outreach and education will address the risk of acute bystander exposure by educating community members in high-use areas about buffer zones and their characteristics and purpose; the importance of not entering these zones; how to recognize early signs of fumigant exposure, and how to respond appropriately in case of an incident. The first responder training discussed earlier (see the 'First Responder Education' subsection above) is a significant part of this program.

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

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

EPA expects registrants' proposals for the first responder programs described in the 'First Responder Education' subsection (page 71) will also be designed to integrate with existing local first-response and emergency preparedness networks.

The community outreach and education proposal and supporting materials for communities and first responders, as well as a plan for evaluating the effectiveness of the

programs, will be included as data requirements in the Data Call-In that will accompany this RED.

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

**8. Ambient Air Monitoring Program**

The Agency is requiring the registrants to develop an air monitoring program in high-use areas to evaluate whether ambient air concentrations exceed EPA's level of concern. For acute bystander exposures, the Agency's level of concern is 22 ppb. Air monitoring from South Franklin County, WA in 2005 and 2007 recorded concentrations approaching, and in some cases, exceeding 22 ppb. The Agency is also concerned about chronic exposures and is seeking additional toxicity data on the long-term effects from inhalation exposure to MITC. 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. Ambient air monitoring will 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 registrants are required to develop an air monitoring program 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 frequent metam sodium/potassium use. The registrant's proposal for developing and implementing an air monitoring program will be required as a data requirement in the Data Call-In.

## iii. Environmental Risk Management

As mentioned in Section III.2 on page 18, the Agency is concerned about both aquatic and terrestrial risks. The Agency believes that mitigation measures detailed in the Human Health Risk Mitigation Section will also reduce ecological risks. Although buffer zones and GAPs do not directly reduce the potential risk to ecological organisms, they do provide an incentive to reduce fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

For details on the metam-sodium/potassium environmental fate and ecological risk assessment, please refer to the *Environmental Fate and Ecological Assessment for the Existing Uses of Metam-sodium*, which is available in the metam-sodium docket (see EPA-HQ-OPP-2005-0125) at www.regulations.gov).

EPA has identified potential risk to terrestrial and aquatic organisms via exposure to the metam-sodium/potassium degradate MITC. Potential exposure to terrestrial organisms, such as

birds and mammals, 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 it major degradate, MITC. The Agency determined that MITC "May-Affect" this species. The Agency's assessment is currently with the Services. After the final determination has been made, the Agency may require other mitigation.

There is some 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.

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.A. 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. The Agency recognizes that managing soil moisture is important factor that may be used to reduce peak emissions, and the requirements related to soil moisture described in the GAPs section (page 62) will not result in the leaching of MITC into ground or surface water. Language is required for both tarped and non-tarped metam-sodium and metam-potassium applications to minimize potential for leaching or runoff. The specific label statements can be found in the metam-sodium/metam-potassium label table, on page 99.

### iv. Benefits of Soil Fumigation

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 10) 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. 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 10. 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 |

| Crop | Likely Alternatives to Metam | Predicted impacts of loss of Metam-sodium/Metam-potassium use |
|---|---|---|
| | | 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. |
| 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+Pic 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+Picthis 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 Pacific Northwest, 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; | 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 |

| Crop | Likely Alternatives to Metam | Predicted impacts of loss of Metam-sodium/Metam-potassium use |
|---|---|---|
| | methyl bromide + chloropicrin (fresh tomatoes only) | by about 13% if likely alternatives replace metam-sodium. |

### b. Sewer Root Control Use

**Rationale**

To assess acute and short-term risk to applicators in this use, EPA utilized two studies, conducted in Australia, which measured MITC air concentration levels during application of a metam-sodium product to sewers. Table 11 below summarizes the acute and short-term MOE estimates based on exposure levels from these studies. These estimates represent baseline conditions and do not take into account the use of gloves and respirators required by some current labeling.

**Table 11. Handler MOEs for MITC Exposure from Sewer Use**

| Study | Sample | MITC Conc. (ppm) | Acute MOE [1] | ST MOE [2] |
|---|---|---|---|---|
| Sheers R (1994) Melbourne Water - Sanafoam Vaporooter Trial, 7 November 1994 | Operator breathing zone exposure | 0.27 | 1 | 1 |
| | At point of application | 22 | <1 | na |
| | Two manholes downstream (approx. 300 m) | 0.017 | 36 | na |
| | At point of application - 24 hours post-application | 0.023 | 26 | 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 |
| | Operator breathing zone exposure | < 0.027 | 8 | 7 |
| | Operator breathing zone exposure | 0.057 | 4 | 3 |
| | At point of application - 30 mins post application | 2.6 | <1 | na |
| | At point of application - 90 mins post application | 1.3 | <1 | na |
| | At point of application - 180 mins post application | 6.8 | <1 | na |
| | At point of application - 270 mins post application | 4.4 | <1 | na |
| | At point of application - 360 mins post application | 0.87 | 1 | na |
| | At point of application - 24 hours post-application | < 0.010 | 60 | na |

[1] Acute MOEs for breathing zones samples based on NOAEL of 0.22 ppm. For other samples (less than 15 mins) acute MOEs based on 0.60 ppm.
[2] MOEs were not estimated for static measure measurements.

EPA also has revised its occupational handler cancer assessment for handlers engaged in sewer applications of metam-sodium to control invasive roots based on information submitted by Sewer Sciences, Inc. during the public comment period. The data submitted by Sewer Sciences, Inc. indicate that commercial applicators apply metam for the sewer use on a full-time basis (i.e., approximately 220 days/year) rather than the 20 days per year EPA had assumed in its previous cancer risk assessment. Revised risk estimates are given in Table 12 below.

| Table 12. Cancer Risks for Mixing/Loading/Applying Metam-sodium to Sewers with Foaming Equipment | | | | | | |
|---|---|---|---|---|---|---|
| Application Rate | Amount handled | Baseline | PPE-G | PPE-G, DL | PPE-G-OV Respirator 90% PF | PPE-G, DL-OV respirator 90% PF |
| 0.212 lb/ai/gal | 1350 gallons | 4.1e-04 | 9.8e-06 | 9.0e-06 | 3.9e-06 | 3.0e-06 |
| 0.212 lb/ai/gal | 675 gallons | 2.0e-04 | 4.9e-06 | 4.5e-06 | 1.9e-06 | 1.5e-06 |

G = gloves; DL = double layer of clothing

These estimates indicate a slight exceedance (between 1.5e-06 and 3.0e-06) of EPA's level of concern for cancer risk of 1.0e-06, assuming the use of gloves, double layer clothing, and a 90% protection factor organic vapor respirator. In assessing occupational cancer risk, EPA carefully examines uses that fall into the range between 1.0e-04 and 1.0e-06, seeking cost-effective mitigation and taking into account benefits and alternatives.

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 BEAD memo dated May 1, 2008, "Alternative Assessment on Root Control Use of Metam-sodium in Sewer Lines.", available in the metam-sodium docket at www.regulations.gov). Diquat dibromide appears to be the most likely chemical alternative. BEAD's memo also identified the added concern of metam-sodium's potentially harmful effects on denitrifying bacteria and the associated disruption to downstream sewage treatment facilities.

**Conclusion for Sewer Root Control Use**

Based on these assessments EPA 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, be required to wear double-layer clothing, chemical resistant gloves, and a 90% protection factor respirator approved for MITC. In addition, 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.

In light of the relatively slight exceedance of the cancer level of concern, the need for root control products in public sewers, EPA finds that these measures will be adequate to address the risk 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:

- Updated Label Language for the Antimicrobial Uses of Methyl Isothiocyanate (MITC) (PC Code 068103) for the Reregistration Eligibility Decision Document. May 13, 2008.
- 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.
- 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.

**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, 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 1.14E-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-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 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) 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 1.14E-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 mmHg). Furthermore, since metam-sodium and metam-potassium concert 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 Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. To analyze the potential of registered pesticide uses that may affect any particular species, the Agency uses basic toxicity and exposure data developed for the REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

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

## D. Conclusion

In this document, the Agency has described a package of mitigation measures with elements that are designed to work together to reduce risk to human health and the environment. Due to the volatility of metam-sodium, metam-potassium, and MITC, the Agency believes that all of the mitigation measures required by this decision will mitigate risks so that use of these fumigants will result in no unreasonable adverse effects.

Stakeholder comments and Agency analyses indicate that mitigation may impact the economic benefits of fumigant use. One analysis completed by the Agency quantified the potential impact of buffer zones. For details of that analysis, please see the document titled "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", posted to the metam-sodium/metam-potassium docket at www.regulations.gov.

The Agency believes that some economic impact will occur in order to protect human health and the environment from unreasonable adverse effects. However, the mitigation package described in this document incorporates flexibility which allows users to make choices that minimize potential impacts. For example, a current application practice might require a large buffer that a user is not able to implement. However, instead of setting a fixed buffer for all applications regardless of application-specific parameters, this decision allows growers the flexibility to modify their practices to achieve smaller buffers; for example treat smaller application blocks, or switch to a lower emission application method. Also, the buffer zone reduction credits allow users to take advantage of site conditions (e.g., soil conditions) or other emission reduction factors such as high barrier tarps to lessen the impact. In addition, the Agency believes that flexibility decreases the impacts associated with respiratory protection mitigation. Instead of requiring respirators for all handling tasks, the monitoring scheme specifies when respiratory protection is needed. This mitigation is protective of handlers while not increasing the burden to users by mandating respirators in such a way as to hinder communication or force users into heat stress situations.

When metam-sodium, metam-potassium, or MITC are used as antimicrobial agents for remedial wood treatments, the Agency believes that the required mitigation is protective and anticipates that it will have minimal impact on the benefits.

Taking into consideration both risk and benefit assessments as well as stakeholder comments, the Agency believes the mitigation required in this document will be protective while also minimizing impacts on fumigant users and applicators.

# V. What Registrants Need to Do

*Implementation*

The Agency has determined that the products containing metam-sodium, metam-potassium and MITC are eligible for reregistration (See Appendix A) provided that the

mitigation measures and label changes identified in this RED are implemented (See the Label Table in Section V.) EPA recognizes the extent and complexity of the mitigation needed for metam will require continued coordination among state regulatory agencies, the Agency, 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. EPA also acknowledges that certain provisions of the RED, such as the worker training program and community education, will take time to develop both the content of the program as well as a strategy for implementation.

EPA envisions the following approximate schedule for implementation of the metam RED:

| | |
|---|---|
| July, 2008 | Metam-sodium RED issued |
| Fall 2008 | Comment period closes |
| Early 2009 | EPA responds to comments, amends RED if appropriate |
| Mid 2009 | EPA issues product and generic DCIs |
| Mid 2009 | Registrants submit revised labels to EPA |
| Late 2009 | EPA reviews/approves new labeling |
| During 2009 | Registrants develop worker and community plans and submit to EPA |
| Early 2010 | Product bearing new labels enter the market; training/education programs begin. |
| 2009-2012 | Registrants develop data per DCI |
| 2013 | EPA begins Registration Review for metam and other fumigants |

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

*Labeling*

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

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 Notices (DCIs) 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 1-generation reproductive study instead of the standard 2-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 |

*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

<u>835.8100 - Field volatility from soil</u>

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.

<u>875.1100 - Dermal exposure – outdoor and 875.1300 - Inhalation exposure - outdoor</u>

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).

Special Study - Training Materials for Handlers

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

*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 (PHED) 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. The Label Table, in Section V, describes how language on the labels should be amended.

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers must be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. 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. The Label Table, page 99, describes how language on the labels should be amended.

# Label Table

**Metam Sodium and Metam Potassium and MITC Labeling Changes Summary Table**

In order to be eligible for reregistration, registrants must amend all product labels to incorporate the risk mitigation measures outlined in Section IV. Tables 13 - 19 describe how language on the labels should be amended.

| **Table 13. Summary of Labeling Changes for Metam Sodium and Metam Potassium Soil Uses** | | |
|---|---|---|
| Description | Amended Labeling Language for Manufacturing Use Products | Placement on Label |
| **Manufacturing Use Products** | | |
| For all Manufacturing Use Products | "Only for formulation into a fumigant for the following use(s): [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; turf (including golf courses)]."<br><br>"Metam sodium/metam potassium cannot be formulated into end-use products labeled for pre-plant or pre-transplant uses unless the registrant makes available to certified applicators who purchase or apply the end-use product a training program approved by EPA that provides information on how to correctly apply the fumigant including how to protect themselves, other handlers and bystanders, how to determine buffer zone distances, how to develop a Fumigant Management Plan, and how to determine when weather and other site-specific factors are not favorable for fumigant application. The training program must be made available to the certified applicators at least annually and the registrant must be able to provide, upon request, the names, addresses, and certified applicator license number of persons who successfully complete the training program."<br><br>"Metam sodium/metam potassium cannot be formulated into end-use products labeled for pre-plant or pre-transplant uses unless the registrant assures warning signs suitable for posting buffer zones are available to end-use product users at the point of sale.<br><br>The buffer zone sign must meet the following standards:<br>o Signs must remain legible during entire posting period.<br>o The size and type of the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting.<br>**Contents of Sign** | Directions for Use |

| | | |
|---|---|---|
| |  <br>-- "DO NOT ENTER/NO ENTRE,"<br>-- "[*Name of fumigant*] Fumigant BUFFER ZONE,"<br>-- a space for the date and time of fumigation,<br>-- a space for the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires)<br>-- brand name of this product, and<br>-- a space for the name, address, and telephone number of the certified applicator in charge of the fumigation | |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group | "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."<br><br>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." | Directions for Use |
| Environmental Hazards Statements Required by the RED and Agency Label Policies | "This product is toxic to mammals, birds, aquatic invertebrates and fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA." | Precautionary Statements |
| **End Use Products Intended for Occupational Use** | | |
| Restricted Use Requirement for all products that contain soil use and sewer use | "Restricted Use Pesticide due to acute inhalation toxicity to humans. For retail sale to and use by certified applicators or persons under their direct supervision and only for those used covered by the certified applicator's certification." | Top of the front panel |
| Certified applicator must complete annual training program | "The certified applicator supervising that application must successfully complete a metam-sodium/metam-potassium training program made available by the registrant within the last 12 months. The Fumigant Management Plan (see details elsewhere on this label) must document when and where the training program was completed." | |

| | | |
|---|---|---|
| Application Site Monitoring During Applications | "The certified applicator supervising the fumigant application must monitor application sites to make sure that conditions, such as changing weather conditions or equipment malfunction, do not increase the likelihood of increased off-site drift and/or increased bystander exposure. If conditions become unfavorable for continued application, the certified applicator must immediately halt the application and must permit application to resume only when the conditions are favorable for fumigant application.<br><br>For overhead, flood, or furrow irrigation or 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:<br>> once every 4 hours if the site is 20 acres or less;<br>> once every 3 hours if the site is greater than 20 acres, but less than 80 acres, and<br>> once every 2 hours if the site is 80 acres or more." | |
| Supervision of handlers | "The certified applicator must provide fumigant safe handling information to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months.<br><br>For all other fumigant handling tasks (as defined on this label), at least two WPS-trained handlers must be present to monitor one another." | Directions for Use Under the section "protection for handlers" |

| | | |
|---|---|---|
| Fumigation Handlers | "Persons engaged in any of the following activities are defined as fumigant handlers:<br>• Persons participating in the application as supervisors, loaders, chemigators, irrigation operators, installers, or repairers, tractor drivers, tractor co-pilots, shovelers, and as other direct application participants (the application starts when the fumigant is first introduced into the soil and ends after the fumigant has stopped being delivered/dispensed/injected).<br>• Persons taking air samples to monitor fumigant air concentrations;<br>• Persons cleaning up fumigant spills;<br>• Persons handling or disposing of fumigant containers;<br>• Persons cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues;<br>• Persons installing, repairing, operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period;<br>• Persons entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;<br>• Persons installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps:<br>until 14 days after application is complete if tarps are not perforated and removed during those 14 days, or<br>until tarp removal is complete if tarps are both perforated and removed less than 14 days after application; or<br>until 48 hours after tarps are perforated if they will not be removed within 14 days of application.<br><br>NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated." | In the Precautionary Use Section |
| Exclusion of Non Handlers from Application Block and Buffer Zone | "The certified applicator supervising the application and the owner/operator of the establishment where the fumigation is taking place must make sure that all persons who are not trained and PPE-equipped and who are not performing one of the handling tasks defined in this labeling are:<br>• excluded from application block during the entry prohibition period, and<br>• excluded from the buffer zone during the buffer zone period." | Directions for Use Under the section "protection for handlers" |
| Providing, cleaning, and maintaining PPE | "The employer of the fumigant handlers must make sure that all handlers in the application block and the surrounding buffer zone are provided and correctly wear the required PPE. The PPE must be cleaned and maintained as required by the Worker Protection Standard for Agricultural Pesticides." | Directions for Use Under the section "protection for handlers" |
| Respirator availability | "In case of emergency or the need for immediate respiratory protection, the fumigation handler employer must make sure that the following PPE are immediately available to all persons performing fumigant handling activities:<br>• unless an air-purifying respirator is being worn by each person performing a handling task at the site, enough air-purifying respirators and face-sealing goggles (if the respirator is a half-face style) of the type specified in the PPE section of this labeling must be immediately available at the site for each handler." | Directions for Use Under the section "protection for handlers" |

| | | |
|---|---|---|
| PPE Requirements Established by the RED for all<br>Soil Fumigants – Skin Protection | "Personal Protective Equipment (PPE) for skin protection<br>Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart."<br><br>In an emergency, such as a malfunctioning chemigation system or other equipment, handlers may be exposed to liquid spray while performing emergency tasks such as shutting off or repairing the malfunction. Such handlers must wear:<br>• chemical-resistant coveralls or a liquidproof rain suit,<br>• chemical-resistant gloves,<br>• chemical-resistant footwear plus socks,<br>• chemical-resistant headgear, and<br>• respirator and eye protection of the type specified in the eye and respiratory section in the PPE requirements on this label.<br>Handlers wearing chemical-resistant attire are limited to 15 minutes of exposure in any 30 minute period and, as required by the Worker Protection Standard for Agricultural Pesticides, employers of these handlers must take any necessary steps to avoid heat illness.<br><br>Except as required above, handlers transferring or loading liquid formulations, handlers operating motorized ground equipment with open cabs, handlers applying with hand-held application equipment, handlers repairing or inactivating irrigation or chemigation equipment during application, and handlers cleaning up spills or equipment, must wear:<br>-- coveralls over long-sleeve shirt and long pants,<br>-- chemical resistant gloves,<br>-- chemical resistant footwear plus socks,<br>-- chemical-resistant apron if transferring or loading the fumigant or cleaning up spills or equipment, and<br>-- respirator and eye protection of the type specified in the eye and respiratory section in the PPE requirements on this label.<br><br>All other handlers (see definition of fumigant handlers in this labeling) must wear:<br>-- long-sleeve shirt and long pants,<br>-- shoes plus socks,<br>-- chemical-resistant gloves, and<br>-- respirator and eye protection of the type specified in the eye and respiratory section in the PPE requirements on this label., UNLESS air monitoring indicates that eye and respiratory protection are not needed. | |

| | | |
|---|---|---|
| | All fumigant handlers who set-up and calibrate chemigation and irrigation equipment and start the application from inside the buffer zone must wear:<br>-- baseline work clothes,<br>-- respirator and eye protection of the type specified in the eye and respiratory section in the PPE requirements on this label., UNLESS air monitoring indicates that eye and respiratory protection are not needed.<br><br>See engineering controls section for more options. | |
| PPE Requirements Established by the RED for all<br>Soil Fumigants – Eye and Lung Protection | "Personal Protective Equipment (PPE) for eye and lung protection"<br><br>All handlers required on this label to wear a respirator and eye protection must wear:<br>> a NIOSH-approved half-face, full-face, or helmet/hood style respirator with either<br>• an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or<br>• a respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)., and<br>-- face-sealing goggles if a half-face respirator is worn.<br><br>Handlers must wear the required respirator and eye protection when:<br>• loading or transferring liquid fumigants, or<br>• repairing or inactivating chemigation or other irrigation equipment when exposure to liquid spray is possible, or<br>• activating chemigation or irrigation equipment when in the application block or surrounding buffer zone,<br>• handlers operating motorized ground equipment with open cabs,<br>• handlers applying with hand-held application equipment,<br>• handlers cleaning up spills or equipment, or<br>• performing a handling task that is too short-term for air monitoring (described below) at hourly intervals to be feasible, or<br>• fumigant air monitoring (described below) indicates that a respirator and eye protection are necessary..<br><br>Fumigant Air Monitoring: The following air monitoring procedures must be followed to determine whether a respirator and eye protection are required for any person performing a fumigant handling task as defined in this labeling.<br>• Air monitoring samples for MITC must be collected in the breathing zone of a handler performing a representative handling task starting approximately 30 minutes from the handler's initial exposure and at least once every 1 hour thereafter. A direct reading detection device, such as a Draeger device, with sensitivity of at least 100 ppb for MITC must be used to monitor air concentration levels of MITC.<br>• If at any time (1) MITC concentrations are greater than or equal to 100 ppb or (2) any handler experiences sensory irritation, then a respirator and eye protection as specified in this section must be worn by every handler in the application block and surrounding buffer zone,<br>• If two consecutive breathing zone samples taken at least 15 minutes apart, show levels have decreased to less than | |

| | | |
|---|---|---|
| | 100 ppb for MITC, then handlers may remove the respirators and eye protection.<br>• If at any time (1) a handler experiences any sensory irritation when wearing a respirator or (2) any air sample is greater than or equal to 1000 ppb (1 ppm) for MITC, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken.<br>• During the corrective actions a respirator and eye protection must be worn.<br>• In order to resume work activities:<br>➢ Two consecutive air samples for MITC taken at the handling site at least 15 minutes apart must be less than 1000 ppb (1 ppm) for MITC.<br>➢ During the collection of air samples a respirator and eye protection must be worn by the handler taking air samples.<br>➢ If MITC concentrations are greater than or equal to 100 ppb, then handlers resuming their handler activities must wear a respirator and eye protection.<br><br>See engineering controls section for more options. | |
| Engineering Controls | Engineering Controls for Closed Loading and/or Transfer Systems<br><br>"Handlers using a closed loading or transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] may wear reduced personal protective equipment from what is specified in the PPE section of this labeling for handlers performing loading and transferring tasks. The closed loading/transfer system must be capable of removing the pesticide from the shipping container and transferring it into 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 to no more than 2 ml per disconnect. If these requirements are met: loaders<br>-- may reduce the PPE to long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, chemical-resistant apron, and protective eyewear.<br>Handlers wearing the reduced PPE must:<br>-- be provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear, and the eye protection and respirator specified in the PPE section for respirator and eye protection.<br><br>"Engineering Controls for Motorized Ground Equipment with an Enclosed Cab:<br><br>Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may:<br>-- wear long-sleeve shirt, long pants, shoes, and socks;<br>-- *either* wear the respirator and eye protection required in the PPE section for respirator and eye protection ***or*** use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as this type of respirator; | |

| | | |
|---|---|---|
| | -- be provided, have immediately available for use, and wear in an emergency when they must exit the cab in the application block or surrounding buffer zone: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear (if overhead exposure) plus – if not already using one – the eye protection and respirator specified in the PPE section for respirator and eye protection<br>-- take off any PPE that was worn before reentering the cab, and<br>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." | |
| User Safety Recommendations | "User Safety Recommendations<br><br>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.<br><br>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.<br><br>Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing." | Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls<br><br>(Must be placed in a box.) |
| User Safety Requirements | "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."<br><br>"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." | Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements |
| PPE Requirements Established by the RED[1] For all Formulations | "Respirator fit testing, medical qualification, and training<br>Employers must ensure that all fumigant handlers are:<br>• Fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134)<br>• Trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134)<br>• 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 who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health statue or respirator style or use-conditions change." | Directions for Use Under the section "Protection for Handlers" |

| | | |
|---|---|---|
| | • | |
| Application Requirements, when tarps are used | "Tarp Perforation and/or Removal<br><br>IMPORTANT: Persons perforating, repairing, removing, and/or monitoring tarps are defined, within certain time limitations, as fumigant handlers (see definition of fumigant handlers in this labeling) and must be provided the PPE and other protections for handlers as required on this labeling and in the Worker Protection Standard for Agricultural Pesticides.<br><br>Tarps used for fumigations must be perforated (cut, punched, poked, or sliced) only by mechanical methods. Perforation by hand or with hand-held tools is prohibited.<br><br>Each tarp panel used for broadcast fumigation must be perforated using a lengthwise cut.<br><br>Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g. after shank injection of the fumigant product and tarps (if used) have been laid or after drip lines have been purged and tarps have been laid, unless an adverse weather condition exists for broadcast applications. See below.<br><br>If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete.<br><br>If tarps will NOT be removed after perforation, planting or transplanting cannot begin until at least 48 hours after the tarp perforation is complete<br><br>If tarps are left intact for a minimum of 14 days after fumigant injection into the soil is complete, planting or transplanting can take place while the tarps are being perforated.<br><br>Adverse Weather Conditions Exception for broadcast applications only:<br>Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that:<br>• At least 48 hours have passed after the fumigant injection into the soil is complete,<br>• The buffer zone period is extended until 24 hours after tarp removal is complete,<br>• Subsequent fumigations of untreated areas within the application block do not occur for at least 24-hours after tarp removal is complete, and<br>Appropriate PPE, respiratory protection, air monitoring and other requirements for the protection of handlers are met." | Direction For Use |
| Monitoring Air Concentration Levels | "MONITORING AIR CONCENTRATION LEVELS<br>Monitoring Air Concentrations in the Buffer Zone Areas: When air concentration levels must be monitored (i.e., as specified in the general buffer zone requirements section), use a direct reading detection device, such as a Draeger device, with a sensitivity of at least 100 ppb for MITC (a breakdown product of metam sodium and metam | Directions for Use under the heading "General Buffer Zone Requirements" |

| | | |
|---|---|---|
| | potassium)."" | |
| Agriculture Use Requirements box | Agricultural Use Requirements<br><br>After the standard paragraphs for the Agricultural Use Requirements box, substitute the following text for the standard restricted-entry interval and double notification requirements:<br><br>"*For entry prohibition and notification requirements, see the "Application Block Entry Prohibition and Notification" section of this labeling*." | Agricultural Use Requirements box |
| Application Block Entry Prohibitions | "Entry Prohibitions<br>Entry (including early entry that would otherwise be permitted under the WPS) by any person – other than a correctly trained and PPE-equipped handler who is performing a handling task listed on this labeling – is PROHIBITED -from the start of the application until:<br>➢ until 5 days (120 hours) after application has ended for untarped applications., or<br>➢ until 5 days (120 hours) after application is complete if tarps are not perforated and removed during those 14 days, or<br>➢ until 48 hours after tarps are perforated if they will not be removed within 14 days of application, or<br>➢ until tarp removal is complete if tarps are both perforated and removed less than 14 days after application.<br><br>NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated. " | Directions for Use under the heading "Application Block Entry Prohibition and Notification" |
| Application Block Notification Requirement | "NOTIFICATION: Notify workers of the application by warning them orally and by posting fumigant warning signs. The signs must bear the skill and crossbones symbol and state:<br>-- "DANGER/PELIGRO,"<br>-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"<br>-- "[*Name of fumigant*] Fumigant in USE,"<br>-- the date and time of fumigation,<br>-- the date and time entry prohibition period is over,<br>-- Name of this product, and<br>-- name, address, and telephone number of the certified applicator in charge of the fumigation.<br><br>Post the fumigant warning sign instead of the WPS sign for this application but follow all WPS requirements pertaining to location, legibility, size, and timing of posting and removal.<br><br>Post the fumigant warning signs at all entrances to the application block.( i.e., the field or portion of a field treated with a fumigant in any 24-hour period)" | Direction for Use under the heading "Application Block Entry Prohibition and Notification" |

| | | |
|---|---|---|
| Mandatory Good Agricultural Practices for all formulations | **Mandatory Good Agricultural Practices (GAPs)**<br><br>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).<br><br>"The following GAPs must be followed during all fumigant applications. All measurements, steps taken, and documentation to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the post application summary report.<br><br>**Weather Conditions**<br>• Prior to fumigation, the weather forecast for the 24-hour period following the fumigant application must be checked.<br>• Do not apply if the forecast, measurements, or other information shows that winds are less than 2 miles per hour.<br>• Applications should not occur during a temperature inversion or when temperature inversions are forecasted to persist for more than 6 consecutive hours in a 36 hour period after the intended application time.<br>  ▪ Visual features indicating the presence of a temperature inversion include misty conditions which occur anytime or clear skies with stars visible at night. If these conditions are observed, then fumigants must not be applied.<br>  ▪ In addition, it is anticipated that the atmosphere will routinely be stagnant early in the morning in certain regions and times of year before temperatures rise over the course of a day which will alleviate such conditions. If this cyclical atmospheric regime is forecasted, then fumigant applications may be executed. However, as under all conditions, buffer zones must be adhered to.<br>  ▪ Detailed local forecasts nationwide for sky conditions, weather conditions, and wind speed may be obtained on-line at http://www.nws.noaa.gov/ and by clicking on the region and then the county of interest. Forecasted temperature inversions may also be specifically mentioned in technical forecast discussions issued on a regional basis which are found within the same website. For further guidance, contact the local National Weather Service Forecasting Office.<br><br>**Injection Depth and Sealing**<br>For Shank Injection Applications: The injection point for bedded and broadcast shank injection applications shall be a minimum of 3 inches from the nearest final soil/air interface. The application site must be sealed immediately after application using one of the following methods:<br>• Compaction with a bed-shaper, roller, press wheel or similar device,<br>• Covering the treated soil with 3-6 inches of untreated soil, or<br>• Applying a minimum of a ½-inch of water beginning immediately after application of a set and completing the water treatment within four hours, or | Directions for Use under "Mandatory Good Agricultural Practices" |

| | | |
|---|---|---|
| | • Covering treated area with a tarp.<br><br>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 application site must be sealed immediately after application using one of the following methods:<br>• Compaction with a bed-shaper, roller, press wheel or similar device,<br>• Covering the treated soil with 3-6 inches of untreated soil, or<br>• Applying a minimum of a ½-inch of water beginning immediately after application of a set and completing the water treatment within four hours, or<br>• Covering treated area with a tarp.<br><br>**Tarps**<br>• When tarps are used in metam drip irrigation and tractor drawn applications (i.e., shank injection, rotary till, and spray blade applications), the tarps must installed immediately after the metam is applied to the soil.<br>• Only tarps tested and approved by USDA's Agricultural Research Service (ARS) may be used.<br>• A written tarp plan must be developed that includes:<br>o Schedule and procedures for checking tarpaulins for damage, tears, and other problems,<br>o Plans for determining when and how repairs to tarp will be made, and by whom,<br>o Minimum time following injection that tarp will be repaired,<br>o Minimum size of damage that will be repaired,<br>o Other factors used to determine when tarp repair will be conducted,<br>o Schedule, equipment and methods used to cut tarp,<br>o Aeration plans and procedures following cutting and /or slitting prior to tarp removal or planting, and<br>o Schedule, equipment, and procedures for tarp removal.<br><br>**Soil temperature**<br>• For all metam applications, the maximum soil temperature at three inches in depth shall not exceed 90 degrees F at the beginning of the application.<br>• If air temperatures have been above 100 degrees F for more than three hours in any of the three days prior to application, then soil temperature shall be measured and recorded in the FMP.<br><br>**Air temperature**<br>• *For All Chemigation Applications:* The maximum air temperature shall not exceed 90 degrees F during the application.<br><br>**Soil moisture**<br>• The soil moisture must be maintained at 50% to 80% of soil capacity immediately prior to, during and for 48 hours after the application.<br>• Soil must be moist two to six inches below the surface. The amount of moisture needed in this zone will vary | |

according to soil type and shall be determined using standard field testing methods. Surface soil generally dries rapidly and must not be considered in this determination.

- If there is insufficient moisture two to six inches below the surface, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below six inches, soil moisture can be brought to the surface by discing or plowing before or during injection. To conserve existing soil moisture, pretreatment or treatment tillage should be done as close to the time of application as possible.

**Soil moisture determination**

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

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

**USDA Method:** At the time of application, there must be at least 50% available soil moisture at the depth of application as determined by the USDA National Resource Conservation Service Program Aid Number 1619, "Estimating Soil Moisture by Feel and Appearance" or other USDA guidance.

**Soil preparation**

- Soil shall be properly prepared and free of large clods at the surface. The area to be fumigated shall be tilled to a depth of 5 to 8 inches. The soil shall be in good tilth with no dry clods over 1.68 inches in diameter present (i.e., size of a golf ball).
- Field trash must be properly managed. Residue from a previous crop must be worked into the soil to allow for

decomposition prior to fumigation. Little or no crop residue shall be present on the soil surface. Crop residue that is present must lie flat to permit the soil to be effectively sealed.

- *For Shank Applications:* Trash pulled by the shanks to the ends of the field must be covered with tarp, soil, or other suitable material, depending on the application method before making the turn for the next pass.
- *For Drip Applications:* Till fields with known plowpans, as they lead to puddling of fumigant due to inadequate soil drainage.

**Prevention of End of Row Spillage**

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

**Flushing Drip Irrigation Lines**

- *For Drip Irrigation Applications:* After application of the fumigant, continue to irrigate the area with water to flush the irrigation system. Do not allow fumigant to remain in the irrigation system after the application is complete. The total volume of water, including the amount used for flushing the irrigation system, must be adequate to completely remove the fumigant from the lines, but should be less than the amount that could over-saturate the beds. If common lines are used for the fumigant application and a water treatment/seal (if applied), these lines must be adequately flushed before starting the water treatment/seal and/or normal irrigation practices.

**Calibration, set-up, repair, and maintenance for application rigs**

- Brass or stainless steel fittings must be used throughout, and all tubing must be teflon or teflon-lined steel braid.
- Galvanized pipe must not be used.
- All rigs must include a filter to remove any particulates from the fumigant, and a check valve that is visible to the tractor pilot during application to prevent backflow of the fumigant into the pressurizing cylinder.
- Rigs must include a flowmeter or a constant pressure system with orifice plates to insure the proper amount of fumigant is applied.
- The pressure rating of all components of the rig must be at least 500 psi.
- To prevent the backflow of fumigant into a compressed gas cylinder, applicators must:
  - Make sure that positive pressure is maintained in the nitrogen cylinder at not less than 200 psi during the entire time it is connected to the fumigation rig.
  - Ensure that rigs are equipped with properly functioning check valves between the nitrogen cylinder and fumigant cylinder. The check valve is best placed on the outlet side of the nitrogen pressure regulator, and is oriented to only allow nitrogen to flow out of the cylinder.
  - Always pressurize the system with nitrogen before opening the fumigant cylinder valve.
- Before using a fumigation rig for the first time, or when preparing it for use after storage, the operator must check

| | | |
|---|---|---|
| | the following items carefully:<br>- Check the filter, and clean or replace the filter element as required.<br>- Check all tubes and chisels to make sure they are free of debris and obstructions.<br>- Check and clean the orifice plates.<br>- Pressurize the system with nitrogen, and check all fittings, valves, and connections for leaks using soap solution.<br>• Install the fumigant cylinder, and connect and secure all tubing. Slowly open the nitrogen valve, and increase the pressure to the desired level. Slowly open the fumigant cylinder valve, always watching for leaks.<br>• When the application is complete, close the fumigant cylinder valve and blow the residual fumigant out of the cylinder with nitrogen. At the end of the season, disconnect the fumigant cylinder, and seal all tubing openings with tape to prevent the entry of insects and dirt." | |
| Site-Specific Fumigation Management Plans for all metam sodium and metam potassium end-use products containing directions for use for soil fumigation | "Site-Specific Fumigation Management Plan (FMP)<br>Prior to the start of fumigation, the certified applicator supervising the application must verify that a site-specific fumigation management plan (FMP) exists for each application block (i.e., a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period). The FMP may be prepared by the certified applicator, the site owner/operator, registrant, or other party. The certified applicator must verify in writing the site-specific FMPs reflects current site conditions before the start of fumigation.<br><br>Each site specific FMP must contain the following elements:<br>❖ General site information<br>➢ Site address,<br>➢ Site operator/owner's name, address, and, phone number<br>➢ Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, public roads, bus stops, water bodies, wells, rights-of-ways inside buffers, nearby application blocks, surrounding structures (occupied and non-occupied), and sites requiring ¼ mile buffer zones (e.g., prisons, schools, hospitals, state licensed day care centers) with distances from the application site labeled<br>❖ Applicator information (license #, address, phone, contact information for person supervising the fumigation)<br>❖ Authorized on-site personnel (Names of all handlers and the tasks they are authorized and trained to perform)<br>❖ Application procedures<br>➢ Fumigation window (target application date, earliest and latest possible date of fumigation)<br>➢ Product information (brand name, registration number)<br>➢ Type of fumigation (e.g., shank, broadcast, drip, raised bed, strip, etc.)<br>➢ Target application rate and application block size<br>❖ Good Agricultural Practices (GAPs)<br>➢ Mandatory<br>➢ Optional (registrant may choose to develop optional GAPs)<br>➢ Measurements and other documentation planned to ensure GAPs are achieved (e.g. measurement of soil and other site conditions; tarp repair/cutting/removal plans; etc.) | In the Directions for Use for Pre-plant soil fumigation under the heading "Site-Specific Fumigation Management Plan (FMP)" |

| | | |
|---|---|---|
| | ❖ Buffer zones<br>➢ Calculations and rationale for buffer zones distances (e.g. specify table from label that distances based on, rate and block size, applicable credits applied)<br>➢ Start and stop times for buffer zones<br>❖ Respirators and other personal protective equipment (PPE) for handlers (respirator type, respirator cartridge, and other PPE selection; verification that respirator training/fit-testing/medical exams is current; and maintenance/storage procedures)<br>❖ Air monitoring<br>➢ Type of samples that will be collected (e.g., occupational, in occupied structures, outside buffer zone if fumigation site monitoring is conducted, etc.)<br>➢ When and where samples will be collected<br>➢ Duration of samples<br>➢ Sampling methods<br>➢ Name, address, and, phone number of person taking samples<br>❖ Posting (names of persons who will post signs, location of posting signs, procedures for posting and sign removal)<br>❖ Site specific response and management<br>➢ Fumigation site monitoring<br>▪ Description of who, when, where, and procedures for monitoring buffer zone perimeter<br>➢ Response information for neighbors<br>▪ List of residences and businesses informed (neighboring property owners)<br>▪ Method of sharing information<br>❖ State and tribal lead agency notification<br>▪ Include information that is sent to the lead agency<br>❖ Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (tarp cutters/removers, irrigators, etc.)<br>❖ Record keeping procedures<br>❖ 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).<br>❖ Hazard communication (product labels, material safety data sheets, etc.)<br><br>For situations where an initial FMP is developed and certain elements do not change for multiple fumigation sites (e.g. applicator information, authorized on-site personnel, record keeping procedures, emergency procedures, etc.) only elements that have changed need to be updated in the site-specific FMP provided the following:<br>• 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.<br>• Recordkeeping requirements are followed for the entire FMP (including elements that do not change) | |

| | | |
|---|---|---|
| | The employer of fumigant handlers must make the FMP available to each of their handler employees involved in the fumigation.<br><br>The certified applicator supervising the fumigation and the owner/operator of the agricultural establishment where the fumigation is taking place must, upon request, make the FMP available to any Federal, state, tribal, or local enforcement personnel.<br><br>Within 30 days of completing the application portion of the fumigation process, the certified applicator supervising the application must complete a post fumigation application summary that describes any deviations from FMP that have occurred, measurements taken to comply with GAPs as well as any complaints and/or incidents that have been reported to him/her. The summary must include the actual date of the application, application rate, and size of application block fumigated.<br><br>The certified applicator who supervised the fumigation and the owner/operator of the agricultural establishment where the fumigation took place must keep a signed copy of the site-specific FMPs and the post-application summary record for at least 2 years following the application and must make them available, upon request, to Federal, state, tribal, and/or local enforcement personnel." | |
| Information Exchange | "When the certified applicator supervising the application leaves the application site after the application portion of the fumigation process is complete and other persons will be performing handler tasks (see the handling activities listed elsewhere in this labeling), the certified applicator must communicate in writing all of the requirements on this labeling with respect to the fumigation process and protection of handlers to the owner/operator of the agricultural establishment where the fumigation is taking place.<br><br>IMPORTANT: this requirement does not override the requirements in the Worker Protection Standard for Agricultural Pesticides for information exchange between owners/operators of agricultural establishments and commercial pesticide applicators." | |
| General Buffer Zones requirements for all formulations | "General Buffer Zone Requirements<br>A "buffer zone" must be established for every fumigant application.<br>• "Buffer zone" is an area established around the perimeter of each application block where a soil fumigant is applied. The buffer zone must extend from the edge of the application block equally in all directions.<br>• All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the entire buffer zone period except for certain exemptions for certain persons transiting through the buffer zone (see transit exemptions below).<br>• An "application block" is a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period.<br>• The "buffer zone period" starts when the fumigant is first introduced into the soil within the application block and lasts for a minimum of 48 hours after injection of the fumigant product has stopped and tarps have been laid, and after any the hot gas drip lines have purged of fumigant.<br>• "Roadway" means that portion of a street or highway improved, designed, or ordinarily used for vehicular travel. "Roadway" does not include any sidewalk or shoulder even if the sidewalk or shoulder is used by persons riding | In the Directions for Use for Pre-plant soil fumigation under the heading "General Buffer Zone Requirements" |

bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately.

Buffer zone distances

- Minimum buffer zone distances must be based on look-up tables in the “Buffer Zone Distance” section of this label (25 feet is smallest buffer zone distance regardless of site-specific application parameters).

Authorized entry to buffer zones

- Only trained and PPE-equipped handlers performing a fumigant handling tasks listed in this labeling are allowed in the buffer zone during the buffer zone period.

Buffer zone proximity

- Buffer zones from multiple application blocks may not overlap (including blocks fumigated by adjacent property owners, (see below for exemptions for areas not under the control of owner/operator of application block).
- No fumigant applications will be permitted within 0.25 (one-quarter) mile of schools, state licensed daycare centers or preschools, nursing homes, assisted living facilities, elder care facilities, hospitals, in-patient clinics and prisons if these facilities will be occupied during the buffer zone period.

Exemptions for transit within buffer zones ( Posting and notification requirements in this labeling must be complied with.)

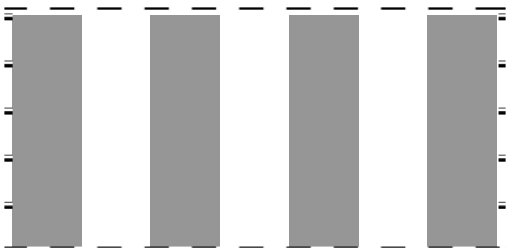
- Vehicular and bicycle traffic on public and private roadways within the buffer zone is permitted.
- Bus stops or other locations where persons wait for public transit are not permitted with in the buffer zone.

Structures under the control of owner/operator of the application block (Posting and notification requirements in this labeling must be complied with.)

- Buffer zones may not include buildings used for storage such as sheds, barns, garages, etc., **UNLESS,**
  3. The storage buildings are not occupied during the buffer zone period, and
  4. The storage buildings do not share a common wall with an occupied structure.

Areas not under the control of owner/operator of the application block (Posting and notification requirements in this labeling must be complied with.)

- 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,
  3. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and
  4. Reentry by occupants and other non-handlers must not occur until
     - The buffer zone period has ended, and
     - Two consecutive air samples for MITC taken in the structure at least 30 minutes apart indicate less than 100 ppb MITC is present.

| | | |
|---|---|---|
| | • Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, UNLESS,<br>3. The owner/operator can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, and<br>4. The owner/operator of the areas that are not under their control provides written agreement to the certified applicator supervising the application that they, their employees, and other persons under their jurisdiction will not enter or remain in the buffer zone during the entire buffer zone period.<br>• Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights-of -way, sidewalks, walking paths, playgrounds, athletic fields, etc), UNLESS,<br>b) The area is not occupied during the entire buffer zone period,<br>c) Entry by any person, except a trained and PPE-equipped handler performing a handling task listing in this labeling, is prohibited during the buffer zone period, and<br>(2) 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. | |
| Buffer Zone Distances for all formulations | "**Buffer Zone Distances**<br>Buffer zone distances must be calculated using the application rate and the size of the application block.<br>  <br>**Figure 1.** Broadcast Application<br>  <br>**Figure 2.** Bedded Application<br>In **Figures 1 and 2,** the dashed line represents the perimeter of the field, the shaded area is the portion of the field that is treated, and the un-shaded area is the area of the field that is untreated. Assuming both fields are 10 acres, and only 50% of field in figure 2 is fumigated, the *labeled rate per treated acre* is 400 lbs ai/A for both Figure 1 and 2. The *broadcast rate* for figure 1 is 400 lb ai/A but the *effective broadcast equivalent rate* for Figure 2 is 200 lbs ai/A. The minimum buffer zone distances must be based on the broadcast or effective broadcast equivalent rates."<br><br>Note to registrant: 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.<br><br>"For all metam sodium and metam potassium soil applications, the tables following this Label Table (Tables 13-17) must be used to determine the minimum buffer distances. Round-up to the nearest rate and block size, where applicable." | In the Directions for Use for Pre-plant soil fumigation under the heading "Buffer Zone Distances" |

| | | |
|---|---|---|
| Buffer Zone Credits | "**Buffer Zone Credits**<br>The buffer zone distances for metam sodium and metam potassium applications may be reduced by the percentages listed below; however the minimum buffer zone distance is 25 feet regardless of available buffer zone credits.<br>• 10% reduction in buffer zone distance, IF the organic content of soil in the application block is greater than 3%. Record the measurements taken to verify the organic content in the FMP.<br>• 10% reduction in buffer zone distance, IF the clay content of the soil in the application block is greater than 27%. Record the measurements taken to verify the clay content in the FMP.<br>• 10% reduction in buffer zone distance, IF the soil temperature in the application block is less than 70 degrees Fahrenheit.<br>• A 10% reduction in buffer zone distance IF one of the following high-barrier tarps is used for either a shank injection or drip application of metam sodium/potassium. : (1) Hytibar, (2) Hytiblock 7 Black, (3) Black Blockade, (4) Bromostop®, (5) IPM Clear VIF 1.38 mil, or (6) Eval/Mitsui 1.38 mil,<br><br>Example of credit calculation<br><br>For example, if the buffer zone is 50 feet and the application qualifies for a buffer zone reduction credit since the soil organic content is greater than 3%. Then the buffer zone can be reduced by 10%, i.e., reduced by 5 feet based on the following calculation: 50 feet – (50 feet x 10%) = 45 feet" | In the Directions for Use for Pre-plant soil fumigation under the heading "Buffer Zone Credits" |
| Posting | **"Posting Fumigant Buffer Zones**<br>• Posting all entrances to the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period) is required for all soil fumigants and use sites. The posting requirements for the application block are listed elsewhere in this labeling.<br>• Posting of the fumigation **buffer zone** is required, **<u>except</u>** when one of the following conditions exist:<br>(1) if there is a physical barrier that prevents access into the buffer zone, such as a fence or wall, that separates the edge of the buffer zone from workers or bystanders, or<br>(2) if the area within 300 feet of the edge of the buffer zone is entirely controlled by owner/operator of the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period); however this exception does not apply to any area under the control of the owner/operator that may be used as housing for workers or other employees. IMPORTANT: if there is public land or any land under someone else's control within 300 feet from the edge of the buffer zone, the buffer zone must be posted.<br>• If the buffer zone must be posted, signs must be placed at all usual points of entry and along likely routes of approach from areas where people not under the control of the application block's owner/operator may approach the buffer zone.<br>o Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.<br>o When there are no usual points of entry, signs must be posted in the corners of the buffer zone, between the corners of the buffer zone, and along sides so that one sign can be viewed (not read) from the previous one. | In the Directions for Use for Pre-plant soil fumigation under the heading "Posting" |

| | | |
|---|---|---|
| | o The buffer zone posting signs must remain posted at least until the end of the buffer zone period and must be removed within 3 days after the end of the buffer zone period.<br>▪ Contiguous Application Blocks Exception: If multiple contiguous application blocks are fumigated within a 14-day period, a buffer zone may be established starting from the outer edge of the contiguous application blocks. This buffer zone is in effect from the beginning of the first application until the buffer zone period for the last application block has expired. The periphery of the buffer zone must be posted during this entire period. Signs may remain posted until 3days after the buffer zone period for the last application block has expired.<br>• The buffer zone posting should meet the following standards:<br>o The printed side of the sign must face away from the buffer zone.<br>o Signs must remain legible during entire posting period.<br>o The signs at entrances to buffer zones must be removed by the certified applicator in charge of the fumigation (or someone under his/her supervision).<br>o The general standards for size and type of signs for the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting.<br>o The signs must remain visible and legible during the time they are posted."<br><br>**Contents of Signs**<br>The **treated area** sign must state the following:<br>-- Skull and crossbones symbol<br>  <br>-- "DANGER/PELIGRO,"<br>-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"<br>-- "[*Name of fumigant*] Fumigant in USE,"<br>-- the date and time of fumigation,<br>-- the date and time entry prohibition is lifted<br>-- brand name of this product, and<br>-- name, address, and telephone number of the certified applicator in charge of the fumigation.<br><br>The **buffer zone** sign must state the following:<br>-- Do not walk sign<br>  <br>-- "DO NOT ENTER/NO ENTRE,"<br>-- "[*Name of fumigant*] Fumigant BUFFER ZONE,"<br>-- the date and time of fumigation,<br>-- the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires)<br>-- brand name of this product, and<br>-- name, address, and telephone number of the certified applicator in charge of the fumigation | |
| Site specific response and management | <u>"Site Specific Response and Management</u><br><br>The certified applicator must either follow the directions under the "fumigant site monitoring" section or follow the | In the Directions for Use for Pre-plant soil fumigation |

| | | |
|---|---|---|
| | directions under the "response information for neighbors" section.<br><br>**Fumigation Site Monitoring**<br><br>From the beginning of the fumigant application until the buffer zone period expires, a certified applicator or someone under his/her supervision must monitor the air concentration levels of the fumigant in the area between the buffer zone and any residences or businesses that trigger the 'response information for neighbors' requirement.<br>• The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period.<br>• A direct reading detection device, such as a Draeger device with a sensitivity of at least 100 ppb for MITC must be used to monitor the air concentration levels of MITC.<br>• If at any time (1) MITC concentrations are greater than or equal to 100 ppb OR (2) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations<br>• If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.<br>• The results of the air concentration monitoring must be recorded in the FMP.<br>• Informing the appropriate federal, state or tribal lead agencies is still required.<br><br>**Response Information for Neighbors**<br><br>The certified applicator (or someone under his/her supervision) supervising the fumigation must ensure that residences and owners/operators of businesses that meet the criteria below have been provided the emergency response information at least **48 hours** before fumigation occurs. The information provided may include application dates that range for no more than **2 weeks**. After 2 weeks, the information must be delivered again.<br><br>Criteria for providing response information for neighbors:<br>• If the buffer zone is less than or equal to **100 feet**, then residences and businesses within **50 feet** from the edge of the buffer zone must be informed.<br>• If the buffer zone is greater than **100 feet** but less than or equal to **200 feet**, then residences and businesses within **100 feet** from the edge of the buffer zone must be informed.<br>• If the buffer zone is greater than **200 feet** but less than or equal to **300 feet**, then residences and businesses within **200 feet** from the edge of the buffer zone must be informed.<br>• If the buffer zone is greater than **300 feet**, then residences and businesses within **300 feet** from the edge of the buffer zone must be informed.<br><br>Information that must be included:<br>• Location of the application block and surrounding buffer zone<br>• Fumigant(s) applied including EPA Registration #<br>• Applicator and property owner/operator contact information | under the heading "Site specific response and management" |

| | | |
|---|---|---|
| | • Time period that fumigation may occur (must not range more than 2 weeks)<br>• Duration of buffer zone<br>• The information must also include:<br>  o information on what is being applied,<br>  o signs and symptoms of exposure to the fumigant,<br>  o what to do and who to call if you believe you are being exposed (911 in most cases).<br><br>• The method used to share the response information for neighbors must be described in the FMP and may be accomplished through mail, door hangers, or through other methods that will effectively inform people in residences and businesses within the required distance from the edge of the buffer zone." | |
| Notice to State and Tribal Lead Agencies | **"Notice to State and Tribal Lead Agencies**<br><br>The state and trial lead agency information must be provided to the appropriate state or tribal lead agency in a written format prior to the application.<br><br>The information that must be provided to state and trial lead agencies includes the following:<br><br>  o Location of the application block and surrounding buffer zone,<br>  o Fumigant(s) applied including EPA Registration #,<br>  o Applicator and property owner/operator contact information,<br>  o Time period that fumigation may occur (must not range more than 2 weeks),<br>  o Duration of buffer zone." | Directions for Use under "Notice to State and Tribal Lead Agencies" |
| Pre-plant Application Restrictions | Maximum application rate is 320 lbs ai/A. | In the Directions for Use for Pre-plant soil fumigation under the heading "Maximum Application Rates for Pre-Plant Soil Fumigation" within its own box |

| | | |
|---|---|---|
| Environmental Hazards | "This pesticide is toxic to mammals, birds, aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate." | Precautionary Statements immediately following the User Safety Recommendations |
| General Application Restrictions | "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."<br>"While metam-sodium and metam-potassium have certain properties and characteristics in common with chemicals that have been detected in groundwater (metam-sodium and metam-potassium are highly soluble in water and have low adsorption to soil), volatilization are these chemicals' most important route of dissipation. To reduce the potential for leaching to groundwater, especially in soils with shallow groundwater, for broadcast, tarped applications, the tarps must be perforated (cut, punched, etc.) before noon and only when rainfall is not expected within 12 hours. For raised-bed, tarped applications, rainfall are not a factor since planting occurs with the tarp in place." | Place in the Direction for Use directly above the Agricultural Use Box. |
| | Label Statements for all Metam Sewer Use | |
| PPE Requirements Established by the RED for all Sewer Fumigants<br><br>(these are all separate products) | "All fumigant handlers who mix, load, transfer, apply, or otherwise handle sewer fumigants must wear:<br>-- coveralls over long-sleeve shirt and long pants,<br>-- chemical resistant gloves,<br>-- chemical resistant footwear plus socks,<br>-- chemical-resistant apron if transferring or loading the fumigant or cleaning up spills or equipment,<br>-- a NIOSH-approved half-face, full-face, or helmet/hood style respirator with either<br>• an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or<br>• a respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)., and<br>-- face-sealing goggles if a half-face respirator is worn.<br><br>-- respirator and eye protection of the type specified in the eye and respiratory section in the PPE requirements on this label.<br><br>"All sewer fumigant support personnel who remain outside the treatment zone and who are not exposed to either liquid spray or vapors must:<br>-- wear long-sleeved shirt, long pants, shoes, and socks, and<br>-- be provided, have immediately available, and must wear in an emergency, such when they may be exposed to liquid spray or vapors, the handler PPE listed in this section. | |
| Application Restrictions | Applicators must notify downstream waste water treatment facilities prior to the start of metam-sodium applications so that they may monitor the operations of the wastewater treatment plant. | Directions for Use |

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

| Labeling Changes Summary Table for the Antimicrobial Uses of MITC, Metam Sodium and Metam Potassium | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| **MITC** | | |
| All End Use Products | For remedial treatment of wooden poles/timbers:<br><br>1. Plug the pre-drilled holes immediately after applications;<br>2. Do not treat structures/beams indoors;<br>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 2 treatment holes intersect an internal void or rot pocket, redrill the holes farther up the pole into relatively solid wood. | Directions for Use |
| **Metam Sodium** | | |
| All End Use Products | For remedial treatment of wooden poles/timbers:<br><br>1. Plug the pre-drilled holes immediately after applications;<br>2. Do not treat structures/beams indoors;<br>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 2 treatment holes intersect an internal void or rot pocket, redrill the holes farther up the pole into relatively solid wood. | Directions for Use |

| Labeling Changes Summary Table for the Antimicrobial Uses of MITC, Metam Sodium and Metam Potassium | | |
|---|---|---|
| Update language for treatment of sewage sludge/animal waste to replace current language which reads that material needs to be placed for 14-21 days or until a phytotoxicity test is done (registration 5481-477) | "Treated material must be placed in a protected storage area for 21 days." | Directions for Use |
| **Metam Potassium** | | |
| Update application method language for cooling water system use | "A metering pump system must be used when applying this product." | Directions for Use |
| Update PPE language for cooling water system use | "Appropriate PPE (long pants, long-sleeved shirts, and chemical resistant gloves) must be used when applying this product." | Personal Protective Equipment (PPE) |

| Table 14. Center Pivot Irrigation Application (High Release) 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 |
| 80 | 200 | 300 | 400 | 500 | 600 | 700 | 800 | 950 | 1100 | 1250 | 1400 | 1500 | 1600 | 1700 | 1800 |
| 100 | 300 | 400 | 500 | 600 | 700 | 800 | 900 | 1050 | 1200 | 1350 | 1500 | 1625 | 1750 | 1875 | 2000 |
| 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 or 2) the maximum spray height greater than 6 feet, including end-guns.

| Table 15. Center Pivot Irrigation Application (Low Release) 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 |
| 80 | 75 | 138 | 200 | 300 | 400 | 500 | 600 | 750 | 900 | 1050 | 1200 | 1300 | 1400 | 1500 | 1600 |
| 100 | 100 | 200 | 300 | 400 | 500 | 600 | 700 | 850 | 1000 | 1150 | 1300 | 1425 | 1550 | 1675 | 1800 |
| 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 is less than 6 feet, and 2) the maximum spray height is less than 6 feet. It does not include end-guns.

| Table 16. Center Pivot Irrigation Application (Low Drift) 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 |
| 80 | 75 | 125 | 175 | 232 | 288 | 344 | 400 | 475 | 550 | 625 | 700 | 775 | 850 | 925 | 1000 |
| 100 | 100 | 150 | 200 | 275 | 350 | 425 | 500 | 588 | 675 | 763 | 850 | 938 | 1025 | 1113 | 1200 |
| 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 is less than 2 feet, and 2) maximum spray height is less than 2 feet, and 3) uses solid stream or drizzle nozzle.

| Table 17. Chemigation (All 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 |
| 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 |
| 80 | 75 | 138 | 200 | 300 | 400 | 500 | 600 | 750 | 900 | 1050 | 1200 | 1300 | 1400 | 1500 | 1600 |
| 100 | 100 | 200 | 300 | 400 | 500 | 600 | 700 | 850 | 1000 | 1150 | 1300 | 1425 | 1550 | 1675 | 1800 |
| 120 | 200 | 300 | 400 | 500 | 600 | 700 | 800 | 950 | 1100 | 1250 | 1400 | 1550 | 1700 | 1850 | 2000 |

| Table 18. Tractor Drawn Applications-Tarped and Untarped (i.e., Shank Injection, Rotary Tiller, and Spray Blade) 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 | 32 | 38 | 44 | 50 | 56 | 63 | 69 | 75 |
| 5 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 63 | 75 | 88 | 100 |
| 10 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 63 | 75 | 88 | 100 | 125 | 150 | 175 | 200 |
| 20 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 69 | 88 | 132 | 175 | 207 | 238 | 269 | 300 |
| 30 | 25 | 38 | 50 | 57 | 63 | 69 | 75 | 113 | 150 | 188 | 225 | 257 | 288 | 319 | 350 |
| 40 | 25 | 38 | 50 | 57 | 63 | 69 | 75 | 119 | 163 | 207 | 250 | 288 | 325 | 363 | 400 |
| 50 | 25 | 50 | 75 | 82 | 88 | 94 | 100 | 150 | 200 | 250 | 300 | 350 | 400 | 450 | 500 |
| 60 | 25 | 50 | 75 | 82 | 88 | 94 | 100 | 163 | 225 | 288 | 350 | 413 | 475 | 538 | 600 |
| 80 | 50 | 75 | 100 | 125 | 150 | 175 | 200 | 250 | 300 | 350 | 400 | 475 | 550 | 625 | 700 |
| 100 | 75 | 100 | 125 | 150 | 175 | 200 | 225 | 282 | 338 | 394 | 450 | 525 | 600 | 675 | 750 |
| 120 | 75 | 113 | 150 | 175 | 200 | 225 | 250 | 313 | 375 | 438 | 500 | 575 | 650 | 725 | 800 |

| Table 19. 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 |
| 5 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 32 | 38 | 44 | 50 | 50 | 50 | 50 | 50 |
| 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 |
| 80 | 25 | 88 | 150 | 163 | 175 | 188 | 200 | 238 | 275 | 313 | 350 | 400 | 450 | 500 | 550 |

## Appendix A: Use Patterns 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** | | | |
| asparagus (nursery production only)<br>artichokes<br>broccoli, Brussels sprouts, cabbage<br>carrot<br>cauliflower, celery<br>cucurbits (cucumber, cantaloupe, honeydew, pumpkin, squash, and watermelon)<br>eggplant<br>forest seedlings<br>grape – vineyard replant only<br>lettuce<br>mint<br>nursery stock (fruit seedlings and rose bushes only)<br>oranges<br>onion<br>pome fruit (apples and pears) – orchard replant only<br>stone fruit (apricot, cherry, nectarine, peach, plum and prune) – orchard replant only<br>ornamentals (floriculture only)<br>peanut | Liquid, Soluble Concentrate | 320 lbs. a.i./Acre | See The Label Table For Specific Use Limitations. |

| Use Site | Formulation | Annual Application Rate | Use Limitations |
|---|---|---|---|
| pepper<br>potato<br>spinach<br>strawberries<br>sweet potato<br>tobacco<br>tomatoes<br>turf (including golf courses) | | | |

**<u>Metam Sodium</u> (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.<br><br>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. | |

| Use Site | Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | Subsequent Dose: 1.7 to 10.2 fluid ounces per 1000 gallons of water every 1 to 5 days or as needed; or<br><br>Initial Dose: 6.9 to 13.9 fl. Oz. of product per 1000 gallons of system water (56-115 ppm).<br><br>Subsequent Dosage: 2.3 to 9.8 fl. Oz per 1000 gallons of water (20-115 ppm); or<br><br>Initial Dose: 1.5 to 3.0 fl. Oz. of product per 1000 gallons of system water (15-30 ppm).<br><br>Subsequent Dosage: 0.5 to 3.0 fl. Oz per 1000 gallons of water (5-30 ppm); or<br><br>Initial Dose: 3.3 to 6.6 fl. Oz. of product per 1000 gallons of system water (30-60 ppm).<br><br>Subsequent Dosage: 1.1 to 6.6 fl. Oz per 1000 gallons | |

| Use Site | Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | 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.<br><br>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<br><br>5.0 to 10.0 fl. Oz per 1000 gallons of water (50-100 ppm) for 4 to 8 hours.<br><br>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<br><br>0.8-5.0 lbs of product per ton for six hours; or<br><br>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;<br><br><u>Pole Circumference in inches/No. of Tubes Installed</u> :<br><br>**35" or less -** 3 holes | Do not contaminate water, food or feed by storage or disposal.<br>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 |
|---|---|---|---|---|
| | | | beginning at ground line spaced 120 degrees apart and 6”to 8” higher than the previous hole.<br><br>**36” to 49” -** 4 holes beginning at the ground line spaced 90 degrees apart and 6” to 8” higher than the previous hole.<br><br>**50” to 59”-** 5 holes beginning at the ground line spaced 70 degrees apart and 6”to 8” higher than the previous pole.<br><br>**60” to 70” –** 6 holes beginning at ground line spaced 60 degrees apart and 4” to 6” higher than the previous hole.<br><br>**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. | |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | **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.<br><br>**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: Table of Generic Data Requirement and Studies Used to Make the Reregistration Decision

This section is currently not available.

## Appendix C: Technical Support Documents

This section is currently not available.