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United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

May 2009

Amended Reregistration Eligibility Decision for Dazomet

Amended Dazomet RED

List B

Case No. 2135

Approved by: Richard P Keigwin, Jr

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

Date: 5/27/09

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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
MOA	Mode of Action
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

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

Table of Contents

Abstract **9**
I. Introduction **10**
II. Chemical Overview **14**
A. Chemical Identity 14
B. Use and Usage Profile 15
C. Regulatory History 17
III. Dazomet Risk Assessments **17**
A. General Overview of Soil Fumigants 17
1. Human Health Risk 17
2. Environmental Fate, Ecological Effects and Risks 20
3. Benefits 23
4. 2008 RED Mitigation Impacts 24
B. Antimicrobial Risk 26
IV. Risk Management and Reregistration Decision **27**
A. Determination of Reregistration Eligibility 27
B. Public Comments and Responses 28
C. Regulatory Position 29
1. Regulatory Rationale 30
a. Dazomet Soil Uses 30
i. Rate Reduction and Use Sites 30
ii. Human Health Risk Management 30
aa. Bystander Risk Mitigation 32
1. Buffer Zones 32
2. Restriction for Schools and Other Difficult to Evacuate Sites 53
3. Posting 54
bb. Occupational Risk Mitigation 56
1. Handler Definition 56
2. Handler Requirements 57
3. Dermal Protection for Handlers 59
4. Respiratory Protection for Handlers 59
5. Tarp perforation and removal 67
6. Entry Prohibitions 70
cc. Other Risk Mitigation 75
1. Restricted Use Classification 75
2. Good Agricultural Practices 77
3. Fumigant Management Plans (FMPs) 80
4. Site Specific Response and Management 87
5. Notice to State Lead Agencies 94
6. Soil Fumigation Training for Applicators and Training Information for Other Handlers 95
7. Community Outreach and Education Programs 100
iii. Environmental Risk Management 105
2. Endocrine Disruptor Effects 108
3. Endangered Species Considerations 109

D. Conclusion 109
V. What Registrants Need to Do 109
A. Manufacturing Use Products 110
1. Additional Generic Data Requirements 110
2. Labeling for Manufacturing-Use Products 116
B. End-Use Products 116
1. Additional Product-Specific Data Requirements 117
2. Labeling for End-Use Products 117
Appendix A(1). Dazomet (PC Code 035602) Soil Fumigant Uses Eligible for Reregistration 118
Appendix A(2). Dazomet (PC Code 035602) Antimicrobial Uses Eligible for Reregistration 119
Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision 128
Appendix C. Technical Support Documents 129
Appendix D. Bibliography 132
Appendix E. FMP Template 133

US EPA ARCHIVE DOCUMENT

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US EPA ARCHIVE DOCUMENT

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US EPA ARCHIVE DOCUMENT

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Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) amended decision regarding the reregistration eligibility of the registered soil and antimicrobial uses of dazomet. This follows the 105-day public comment period on the Reregistration Eligibility Decision provided for stakeholders to have the opportunity to review and provide comments on issues related to the implementation of the risk mitigation measures. The Agency's risk conclusions for dazomet have not changed. In addition, all measures established in the July 2008 RED to reduce risks to bystanders and workers will still be required. However, the Agency has determined that certain modifications in how and when some measures will be implemented are appropriate. Products containing dazomet 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 dazomet uses fall into two basic categories, soil fumigation or antimicrobial use. Soil fumigation includes use on golf greens and tees, nonbearing crops, turf sites, ornamental sites, field nurseries, compost piles, potting soils, and strawberries and tomatoes in California only. Antimicrobial uses include: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment paper coatings, non-food adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

Concurrent to EPA's review of the soil fumigant uses of dazomet, EPA assessed the risks and developed risk management decisions for four other soil fumigant pesticides, including: chloropicrin, metam sodium/potassium, 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 potential economic impacts 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 dazomet from acute inhalation exposure to handlers, bystanders, and workers. To reduce these exposures and to address risks of concern, EPA is requiring a number of mitigation measures, such as buffer zones, posting, handler protection, restrictions on the timing of tarp perforation and removal operations, extending the entry prohibitions, restricted use classification (for soil uses only), mandatory good agricultural practices (GAPs), site-specific fumigant management plans (FMPs), emergency preparedness and response, notice to state and tribal lead agencies, training for applicators and handlers, and required community outreach and education programs. In addition the registrants have agreed to reduce the maximum rate from 530 lbs ai/A to 425 lbs ai/A for incorporated applications except golf course greens/tees and turf

renovation (which will remain at 530 lbs ai/A) which will directly reduce the potential risks to both humans and non-target organisms. The ecological risk assessment identified potential acute risks of concern for birds and mammals that could be exposed to unincorporated dazomet granules.

The Agency also has identified potential human health risks of concern associated with the registered antimicrobial uses of dazomet. To reduce these exposures, the Agency is requiring a number of mitigation measures, including additional PPE for handlers engaged in these applications: pulp and paper use, cooling tower use, and metering pumps. For the epoxy flooring uses, the labels must be amended to reduce the amount of dazomet formulated in end use products.

I. Introduction

This amends and supersedes the document, "Reregistration Eligibility Decision for Dazomet," published by the U.S. Environmental Protection Agency (hereafter, EPA) on July 16, 2008. That day EPA opened a 60-day public comment period on the implementation aspects of the risk mitigation measures that were required as conditions of reregistration eligibility under FIFRA. EPA received requests to extend the comment period from the Methyl Bromide Industry Panel (MBIP), California Specialty Crops Council, the Chloropicrin Manufacturers' Task Force (CMTF), the National Association of Manufacturers (NAM), the American Nursery and Landscape Association (ANLA), the California Strawberry Nurserymen's Association, the Agricultural Retailers Association, the American Forest and Paper Association, and McDermott, Will, and Emery LLP, on behalf of the Minor Crop Farmer Alliance (MCFA). In response to these requests, on August 29, 2008, EPA published a notice in the Federal Register extending the comment period for an additional 45 days. The comment period closed on October 30, 2008. EPA has completed its review of public comments as well as new scientific data and other information provided and determined that all measures established in the July 2008 RED to reduce risks to bystanders and workers will still be required. The Agency has determined that certain modifications in how and when some measures will be implemented are appropriate. The public comments and EPA's responses, as well as other supporting documents, may be found in the public docket for dazomet at EPA-HQ-2005-0128. EPA has determined that the modifications described herein will achieve the same protection goals for persons potentially exposed to dazomet but with a greater likelihood of compliance, fewer impacts on the benefits of dazomet use, and with less uncertainty regarding the protectiveness of the required measures. Please see table 1 for modifications from the 2008 RED to the 2009 amended soil fumigant REDs.

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

	2008 REDs	2009 Amended REDs
Buffer Zones	Buffer zones based on available data	New chloropicrin data support smaller buffers and increased confidence in safety New dazomet data support larger buffers

US EPA ARCHIVE DOCUMENT

	2008 REDs	2009 Amended REDs
Buffer Credits	Credits allowed based on available data; capped at 50%	New data support additional credits and an increase in the cap to 80% for chloropicrin and methyl bromide, 80% for metam sodium and metam potassium, and 40% for dazomet.
Structures within Buffer Zones	Monitor with devices before reentry	Monitor for sensory irritation before reentry
Rights of Way	Permission from local authorities must be granted if buffers extend onto rights of way	Permission from local authorities is only required when a sidewalk or permanent walkway is present
Buffer Overlap	Buffers may not overlap	Buffers may overlap; separate applications by 12 hours and increase emergency preparedness and response measures
Restriction for Difficult to Evacuate Sites	1/4 mile restriction around hard to evacuate areas including day care centers, nursing homes, schools; was to be in effect for the duration of the buffer zone period	Maintain 1/4 mile restriction but allow a reduced restricted area of 1/8 mile for applications with smaller buffers (300 feet or less); is to be in effect during the application for 36 hours following the application
Posting	Posting required at buffer zones points of entry, where people are likely to approach, and areas between these locations	The posting requirement is retained but no longer requires areas between the entry areas to be posted Information required on the signs has been simplified to encourage reuse of signs
Handler Protection	Described tasks that may only be performed by handlers and situations when 2 handlers were required to be present while in the buffer zone	Tasks that may only be performed by handlers have been updated and clarified The situations have been clarified requiring one handler supervised by a certified applicator to be present based on the chemical properties of the different soil fumigants, and current label statements
Respiratory Protection	Required monitoring devices to trigger additional measures	Allow sensory irritation properties to trigger additional measures for MITC and chloropicrin Monitoring with devices is still required to remove respirators Monitoring with devices required for methyl bromide formulations with <20% chloropicrin
Tarp perforation and removal	Perforating tarps restricted to mechanical means only	Perforating tarps by hand is allowed for areas less than 1 acre in size and for flood prevention activities
Entry Prohibitions	Entry for non-handlers is prohibited for the duration	No major changes

US EPA ARCHIVE DOCUMENT

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

US EPA ARCHIVE DOCUMENT

With regard to implementation timing, EPA has determined that most measures can be efficiently implemented via revised product labels by the 2010 use season. Other measures, in particular those related to buffer zones, will present greater compliance challenges and will require additional time for EPA to conduct the necessary outreach, and communication activities with states, tribes, other regulatory partners, fumigant users, and other stakeholders to facilitate transition. EPA has determined that these measures will be implemented via revised product labels by the 2011 use season. As a result, all measures described in this amended RED that are necessary for reregistration eligibility will appear on product labels by 2011. The table below shows the measures that will be implemented in 2010 and the additional measures that will be implemented in 2011.

Table 2. Implementation Schedule for Soil Fumigant Risk Mitigation Measures

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

○ = under development
● = adopt completely

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

US EPA ARCHIVE DOCUMENT

and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

Dazomet is used as a non-selective soil fumigant with fungicidal, herbicidal, and nematicidal properties. It is also used as an algaecide, bacteriostat, fungicide, microbiocide, mildewcide in a number of antimicrobial use sites. When dazomet is applied, it is quickly broken down into several degradates; the major degradate being methyl isothiocyanate (MITC). The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of dazomet are eligible for reregistration provided the mitigation and labeling outlined in this amended RED are implemented.

This document presents the Agency's reregistration eligibility decision for the supported soil and antimicrobial uses of dazomet. The document consists of five sections. Section I contains the regulatory framework for reregistration and a synopsis of modifications from the July 2008 RED. Section II provides a profile of the use and usage of the chemical. Section III provides a general fumigant overview and also summarizes dazomet's risk assessments as well as benefit and impact assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Unless otherwise noted, all Agency references in this document are available for review in the dazomet docket (EPA-HQ-OPP-2005-0128) at www.Regulations.gov**.**

II. Chemical Overview

A. Chemical Identity

When dazomet is applied to soil, either to the surface or incorporated, it quickly breaks down. The major degradate is MITC, but formaldehyde, monomethylamine, hydrogen sulfide and (in acid soils) carbon disulfide, are also formed. All of these degradates are gases or volatile liquids which diffuse through the spaces in the soil, killing living organisms with which they come in contact. This reregistration eligibility decision considers risks of exposure of dazomet and the major degradate, MITC, as a result of dazomet applications. Table 3 provides a summary of the dazomet and MITC nomenclature.

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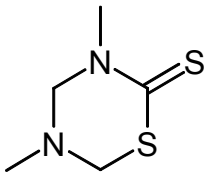
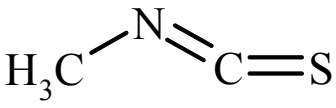
Table 3: Dazomet and MITC Nomenclature		
Properties	**Dazomet**	**MITC**
Chemical Structure		
Chemical Group	Dithiocarbamate	Isothiocyanate
Common Name	Dazomet	Methyl isothiocyanate
Molecular formula	$C_5H_{10}N_2S_2$	C_2H_3NS
Molecular Weight	162.28	73.12
CAS No.	533-74-4	556-61-6
PC Code	035602	068103
Case Number	2135	Not Applicable

B. Use and Usage Profile

Soil Uses

Pesticide Type: Broad spectrum soil fumigant with herbicidal, nematicidal, and fungicidal properties

Target pests: Weeds, nematodes and various soil-borne pathogens

Use patterns: Golf greens/tees, nonbearing crops (such as orchard crops, berries, and flower bulbs), turf sites (establishing or renovating), ornamental sites (establishing or renovating), field nurseries (establishing or renovating), greenhouses, compost piles, potting soils, and strawberries and tomatoes in California only

Formulations: Granular

Methods of Application: Tractor drawn spreaders and handheld equipment such as belly grinders and push-type spreaders

Application Rates: Maximum application rate for incorporated applications is 530 lbs ai/acre and for surface applications is 265 lbs ai/acre

US EPA ARCHIVE DOCUMENT

Technical registrant:	Certis USA, LLC
Annual Usage:	Approximately 15,000 pounds of dazomet are used annually[1] as a soil fumigant.

Antimicrobial Uses

Pesticide Type:	Algaecide, bacteriostat, fungicide, microbiocide, mildewcide
Target pests:	Fungi, bacteria, mildew, algae
Use patterns:	Dazomet may be used in a variety of ways including: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for paper coatings, non-food adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.
Formulations:	Pelleted/tableted, liquid (soluble concentrate and flowable concentrate) solutions, water soluble packaged solids, ready to use solutions
Methods of Application:	Open pour (for both solid and liquid formulations), metering pump, and water-soluble packaged solid mixing
Application Rates:	Rates vary by application use site and method. Maximum rates are included in Table 4.1 of the Revised Occupational and Residential Antimicrobial Exposure Assessment (Walls, C. 2/14/08)
Technical registrant:	BASF

[1] USDA Agricultural Chemical Usage 2003 Nursery and Floriculture Summary, September 2004, http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1001.

US EPA ARCHIVE DOCUMENT

C. Regulatory History

Dazomet, (PC code 035602) and the sodium salt, tetrahydro-3,5-dimethyl-2H-1,3,5-thiadiazine-2-thione (PC Code 035607) are included in pesticide reregistration case number 2135. Currently, there are 22 products registered containing dazomet and there are no active products registered containing the sodium salt.

Dazomet has both agricultural and antimicrobial uses. Dazomet was first registered in the United States in 1967 as an algaecide, a bacteriostat, and a microbiocide in a variety of commercial and industrial applications such as pulp and paper mills, cooling tower waters, and non-food adhesives.

In the late 1980s pre-plant soil uses of dazomet were registered. Dazomet is registered for use on non-bearing orchard crops, ornamentals, and turf to control plant pathogens, nematodes, and weeds. Unlike other soil fumigants, dazomet is applied as a dry granule and incorporated into the soil or applied to the soil surface and watered into the soil to activate it.

A Phase IV data call-in (DCI) was issued for dazomet in January 1991 and included data requirements for ecotoxicity, toxicology, and environment fate. A follow-up DCI was issued in May of 1992 that included data requirements for neurotoxicity and the nature of residue in plants. Dazomet was also included in the October 1995 agricultural reentry data call-in.

III. Dazomet 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

When dazomet is applied and mixes with moist soil, it is quickly broken down into several products. One of these products is MITC that accounts for most of the fumigant activity. The main risk of concern for handlers, workers, and bystanders associated with the soil uses of dazomet is from acute inhalation exposure to MITC as a result of fumigant off-gassing. Dazomet handlers also are at risk from direct fumigant exposure during applications. The term *handler* refers to persons involved in the application of dazomet. 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.

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In addition to soil use, dazomet is also used as an antimicrobial pesticide in the following ways: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for coatings, adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

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

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

The human health risk assessment indicates that acute inhalation exposures to MITC concentrations of 22 ppb or greater for a 1 to 8 hour time period for non-occupational (residential) bystanders and occupational handlers could 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 exposures to MITC, the standard 10X for animal to human extrapolation is not needed. 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 without eye irritation. Compared to eye irritation, the systemic and respiratory effects are more serious in nature. Unfortunately, the available toxicity data in animals or humans do not allow a quantitative

US EPA ARCHIVE DOCUMENT

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

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

In assessing risks from dazomet, 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 dazomet and the other soil fumigants within the group, several field-scale monitoring studies were considered. These studies quantify dazomet 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 dazomet use at a broad range of distances from treated fields. However, these data are limited in their utility because they provide results only for the specific conditions under which the study was conducted.

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

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

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

Based on these lines of evidence and as described in more detail in the risk assessments, EPA has determined that dazomet 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 where dazomet fumigations occur have the potential to exceed the Agency's LOC without additional mitigation measures. There are also risks of concern for occupational handlers involved in dazomet applications and for workers who may re-enter treated area shortly after fumigation or tarp perforation has been completed.

For more information about the specific information in the Agency's human health risk analysis for dazomet, refer to the documents listed below, all of which can be found in the dazomet docket # EPA-HQ-OPP-2005-0128 at http://www.regulations.gov:

- *Dazomet: Updated Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). (*Shelat, S. et al., Dated April 30, 2009)
- *Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits* (Dated May 14, 2009)
- *MITC 10X placeholder*
- *Dazomet: Updated Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED).* (Smith, C. et al., Dated June 2008)
- *Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC.* (Lowit, A. and Reaves, E., Dated June 25, 2008)

2. Environmental Fate, Ecological Effects and Risks

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The Agency's environmental fate and ecological effects risk assessments indicate that there are some concerns for non-target organisms that may be exposed to fumigants. Exposure to terrestrial organism such as birds and mammals could occur two ways, as either oral exposure to dazomet granules or by the inhalation route of exposure to the breakdown product MITC. Potential exposure to aquatic organisms may occur from surface runoff/leaching and/or volatilization and deposition of MITC in water bodies.

Hazard

Dazomet is considered moderately toxic on an acute oral basis to both birds (LD_{50} = 424 mg/kg) and mammals (LD_{50} = 415 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 oral and inhalation toxicity data with MITC are needed 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 (Dazomet and MITC)

Direct exposure of mammals and birds to dazomet granules was estimated using the model T-REX, Version 1.2.3 (T-REX, 2005). T-REX was run for tomato and strawberry crops (also applicable to turf, ornamental and other pre-plant incorporated uses) for a single application of dazomet applied at the maximum rate of 530 lb a.i./A. In addition, exposure of terrestrial animals to the volatile degradation product MITC was evaluated using a preliminary LD_{50}/square foot risk screening method. The Industrial Source Complex Short Term (ISCST3) model together with information about MITC emissions from a treated field was used to evaluate 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 (MITC)

For 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.

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 dazomet, multiple scenarios were selected representing proposed dazomet usage areas based on geography and weather. PRZM and EXAMS models and relevant scenarios were used to estimate MITC estimated exposure concentrations (EECs) in surface water based on label information for dazomet application to tomatoes, strawberries, turf and ornamental trees at the highest application rate. The scenario with the highest concentration of MITC from dazomet applications was the California strawberry scenario.

Risk

Terrestrial Risk (Dazomet and MITC)

Available dazomet toxicity studies allow the assessment of acute oral exposure of birds and mammals. Inhalation toxicity studies for MITC are only available for mammals. There are currently no studies available to estimate chronic terrestrial risks.

The Agency's levels of concern are exceeded for acute oral consumption of dazomet granular product for both mammal and bird species that are not Federally-listed as endangered or threatened as well as for 'listed' species. However, for mammal inhalation exposure to MITC all of the estimated risks are below the Agency's LOC for both listed and non-listed species. The inhalation effects observed at levels higher than would be expected under normal use and assessed in mammals included both metaplasia of respiratory epithelium and lethality. There were no data available to assess inhalation risk to birds, and additional data is required. At the present time there are no registrant-submitted toxicity studies, or studies published in the open literature, that evaluate the toxicity of dazomet or MITC to terrestrial plants.

Aquatic Risk (MITC)

None of the estimated acute fish or aquatic invertebrate risks were above the Agency's LOC for freshwater non-listed or listed species. However, no MITC studies are available for marine/estuarine organisms. For chronic risk from MITC the only data available to evaluate chronic effects on aquatic organisms are for freshwater invertebrates, which predict risks below the Agency's LOC. However, no MITC data are available to evaluate the chronic effects on freshwater and estuarine/marine fish, or estuarine/marine invertebrates. All of the estimated risks for aquatic plants were below the Agency's levels of concern.

Due to the current data gaps for dazomet and 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:

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- *Revised Environmental Fate and Ecological Risk Assessment For Dazomet.* (Khan. F. and Felkel, J., Dated April 8, 2008)

3. Benefits

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

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

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

US EPA ARCHIVE DOCUMENT

- EPA-HQ-OPP-2005-0123-0331, *Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium In Strawberry Production*
- EPA-HQ-OPP-2005-0123-0332, *Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production*
- EPA-HQ-OPP-2005-0123-0333, *Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium In Sweet Potato Production*
- EPA-HQ-OPP-2005-0123-0334, *Assessment of the Benefits of Soil Fumigation with Chloropicrin In Tobacco Production*
- EPA-HQ-OPP-2005-0123-0335, *Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium in Tomato Production*
- EPA-HQ-OPP-2005-0123-0336, *Assessment of the Benefits of Soil Fumigation with Metam Sodium in Carrot Production*
- EPA-HQ-OPP-2005-0123-0337, *Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production*
- EPA-HQ-OPP-2005-0123-0338, *Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production*
- EPA-HQ-OPP-2005-0123-0339, *Summary of the Benefits of Soil Fumigation with Methyl Bromide in Crop Production*
- EPA-HQ-OPP-2005-0123-0340, *BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants*

4. 2008 RED Mitigation Impacts

Requirements in the July 2008 RED

The July 2008 RED acknowledged that even with the use of credits, there could be significant economic impacts to some growers who may not be able to accommodate large buffers based on their current application practices. However, the Agency believed that the options provided in the scalable buffer approach in the fumigant REDs would allow growers the flexibility to modify their practices to achieve smaller buffers; for example, by treating smaller application blocks, switching to a lower emission application method, or by switching to an alternative fumigant that would require smaller buffers. Therefore, the Agency concluded that growers would be able to alter their fumigation applications, given the flexibility designed into the system, in a manner that would enable growers to minimize the impact on production. The Agency noted, however, that the buffers would significantly impact some growers by delays in planting due to longer fumigation operations, additional planning, and more trips to the field for planting and other operations if fumigating in smaller blocks resulted in staggered operations. It was determined that some of these costs could be substantial in some production scenarios.

Comments on the July 2008 RED

The July 2008 RED requested commenters to submit a description of fumigation practices and provide maps of their property illustrating locations of fields, offices, residences,

US EPA ARCHIVE DOCUMENT

roads, and property lines so that the Agency could better understand the impacts of the mitigation plan. In response, various stakeholders, including several forest seedling nursery operations, submitted detailed information. From an analysis of the information submitted, including an analysis of a nursery and options they would have for compliance, the Agency concludes that it had overestimated the ease with which many growers and fumigators would be able to comply with the buffer requirements as presented in the July 2008 RED, and that potential impacts would be much greater than previously anticipated for some types of production.

From the Agency's analysis, the primary driver of the impacts is the size of the buffer zones, which will require many growers to divide their fields into smaller fumigation blocks to achieve smaller buffer zone distances. Two other contributing factors are the prohibition on buffers overlapping in space and time and the duration of the buffer zone. As discussed above, the Agency has provided flexibility on overlapping buffers. Nevertheless, the analysis indicates that the buffer system identified in the July 2008 RED can be less flexible than expected for certain scenarios and the associated field topography, field infrastructure, and need for a consistent orientation in the application of a fumigant, which constrain how a field may be divided. Together, these requirements could result in the loss of part of a grower's field that can be effectively fumigated. Further, there may be substantial delays in completing fumigations and multiple trips to a field with fumigation equipment may often be necessary. Not only could there be delays in production activities in these instances, but it may also be difficult to maintain proper soil moisture over the period that multiple blocks would be fumigated. Soil moisture has been identified as a critical element in controlling emissions. Some growers will face numerous scheduling conflicts if they rely on commercial applicators, and the Agency estimates that growers would be more likely to conduct their own fumigations. In addition, repeated trips to the field to fumigate small blocks will increase costs, a further incentive for growers to conduct their own fumigations.

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

In addition to these impacts, if emergency preparedness and response requirements were triggered due to proximity of neighbors, for example, the requirement in the July 2008 RED to monitor the buffer zone for its duration was estimated to impose the highest direct costs. The Agency estimates that the cost of sampling tubes alone could range from $1000 to over $3000 for a field or enterprise, not including the cost of labor. These costs would fall disproportionately on growers with small acreage. As an alternative, growers could notify their neighbors of their intent to fumigate. However, the Agency understands and appreciates the many comments indicating that notification may not be an attractive option due to the potential for neighbors to attempt to impede or block fumigant applications.

US EPA ARCHIVE DOCUMENT

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

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

B. Antimicrobial Risk

In addition to the use of fumigants to sterilize soil before planting, there are a number of antimicrobial uses that the Agency has assessed in this RED. Dazomet may be used as an antimicrobial chemical in the following ways: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for paper coatings, non-food adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

All of the occupational handler risks were below the Agency's LOC except for some scenarios with the following uses: preservation of epoxy flooring compounds, pulp and paper slimicide use, and microbe control in large water cooling systems.

For more information on these antimicrobial uses:

- *Dazomet Antimicrobial Risk Mitigation Paper.* (Garvie, H., Dated June 2008)
- *Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document.* (Walls, C., Dated June 2008)
- *Dazomet: Dietary Risk Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document.* (Walls, C., Dated March 2007)
- *Environmental Fate and Ecological Risk Assessment for the Reregistration of Dazomet (035602) and MITC (068103) – Antimicrobial Uses.* (Petrie, R., Dated April 2007)

Please refer to the RED Appendix for the complete document citations, which are also available in the dazomet docket (OPP-2005-0128) at www.regulation.gov.

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products 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 dazomet. The Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient dazomet.

In Phase 5, the Agency published a risk mitigation options paper.[2] This document detailed potential mitigation options and sought public comment on these options. The following is the list of mitigation options discussed in the Agency's paper:

- Buffer zones;
- Sealing methods;
- Timing of applications;
- Application block size limitations;
- Respiratory protection;
- Tarp perforation/removal procedures;
- Entry-restricted period;
- Application method/practice restrictions;
- Fumigant management plans (FMPs);
- FMP certification;
- Responsible parties;
- Record keeping/reporting/tracking;
- Restricted Use Pesticide Classification;
- Notification and posting;
- Good agricultural practices;
- Fumigant manuals; and
- Stewardship programs.

Based on a review of the dazomet database and public comments on the Agency's assessments for dazomet, the Agency had sufficient information on the human health and ecological effects of dazomet to make decisions as part of the reregistration process under FIFRA in July 2008. The Agency determined in the 2008 Dazomet RED that dazomet products are eligible for reregistration provided that (i) required product specific data are submitted, (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments

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

are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of dazomet that are eligible for reregistration.

The Agency's decision takes into account the best available information on the potential risks and benefits of dazomet use. In reaching its reregistration decision and developing the dazomet mitigation proposal, EPA considered a range of factors, including: characteristics of bystander and other populations exposed to dazomet; hazard characteristics of dazomet 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.

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

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

B. Public Comments and Responses

The Phase 3 public comment period on the preliminary risk assessments and related documents for dazomet lasted from July 13 through October 12, 2005. EPA-HQ-OPP-2005-0128-0062 contains the Agency responses to Phase 3 public comments related to dazomet uses.

EPA revised its risk assessments and developed benefits and risk mitigation options during Phase 4. The Phase 5 public comment period on revised risk assessments, benefits analysis, and risk management options took place from May 2 to November 3, 2007. Comments on issues which were significant to many stakeholders and directly influenced EPA's decisions are highlighted in this document as well as EPA's responses to those comments. The following documents include EPA's responses to comments related to dazomet which may be found in the dazomet docket.

- *The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Dazomet.* (Smith, C., Dated June 2008)
- *Response to Phase 5 Public Comments on the Phase 4 Dazomet Environmental Fate and Ecological Risk Assessment.* (Khan, F., and Felkel, J., Dated April 2, 2008)

US EPA ARCHIVE DOCUMENT

- *Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide.* (Donaldson, D. et al., Dated June 2008)
- *Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants.* (Wyatt, T., et al, Dated June 2008)
- *Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision (RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin.* (Walls, C., Dated February 14, 2008)
- *SRRD's Response to Phase 5 Public Comments for the Soil Fumigants.* (Dated July 2008)

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

- *Further Response to Public Comments on the 7/9/08 Completed Dazomet RED.* (Dated March 3, 2009)
- *Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents* (Dated May 14, 2009)
- *Response to BEAD Related Public Comments Received on the Reregistration Eligibility Decision for Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide* (DP# 363545; Dated May 14., 2009)
- *Analysis of Soil Fumigant Risk Management Requirements using Geographic Information Systems: Case Studies based on a Forest Seedling Nursery* (DP# 363546; Dated May 13, 2009)
- SRRD's Response to Post-RED Comments for the Soil Fumigants (Dated May 20, 2009)

C. Regulatory Position

US EPA ARCHIVE DOCUMENT

1. Regulatory Rationale

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

a. Dazomet Soil Uses

i. Rate Reduction and Use Sites

Rate

The current maximum application rates for dazomet are 530 lbs ai/A for incorporated applications and 265 lbs ai/A for surface applications. According to the dazomet soil use registrant, Certis, USA LLC, the actual use rate of dazomet is usually much lower for most uses of dazomet. The turf and ornamental use rarely requires the maximum rate, except for golf course or turf renovation. For crop uses, the rate generally ranges from 200-300 lbs ai/A, although there are some cases where an application up to 400 lbs ai/A is needed. Therefore, the registrant has agreed to lower the maximum use rate of dazomet to 425 lbs ai/A for all registered uses except for golf course/turf renovation. The maximum rate for golf course/turf renovation will remain at 530 lbs ai/A.

Use Sites

Although current labels include instructions for dazomet's use in greenhouses, the Agency was not aware of greenhouse use occurring prior to the 2008 RED and prohibited all dazomet use in greenhouses. The Agency received a comment citing dazomet's use in greenhouses, and in light of this additional information, use in greenhouses is being retained provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. Please refer to Table 6 for information regarding greenhouse buffer zones.

ii. Human Health Risk Management

For details on the dazomet human health risk assessment for soil uses, please refer to the Human Health Risk Assessments referenced in Section III of this document. These documents are also available in the public docket EPA-HQ-OPP-2005-00128, located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

US EPA ARCHIVE DOCUMENT

Dietary Risk

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

Bystanders, Workers, and Handlers

The human health risk assessments indicate that inhalation exposure to bystanders who live and work near agricultural fields, nurseries, golf courses, and other areas where dazomet fumigations occur, and to handlers involved in the application of dazomet have the potential to exceed the Agency's LOC without additional mitigation measures.

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

- Reducing maximum application rates;
- Clarifying use sites;
- Buffer zones;
- Dermal protection for handlers;
- Respiratory protection for handlers;
- Restrictions on the timing of perforation and removing of tarps;
- Posting;
- Good agricultural practices;
- Fumigant management plans;
- Site specific response and management; and
- Notice to state lead agencies.

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

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

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MOEs. However, EPA has determined that these measures, working together, will prevent unreasonable adverse effects to 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 site specific response and management, notice to state lead agencies, training, and community outreach and education, as well as labeling changes.

1. Buffer Zones

The human health risk assessments indicate bystanders may be exposed to MITC air concentrations, following dazomet applications, which exceed the Agency's level of concern based on current label requirements. In general, the risk from inhalation exposures decreases as the distance from the field where bystanders are located increases. Because of this relationship, the Agency has determined that a buffer zone must be established around the perimeter of each application block where dazomet is applied. The Agency acknowledges that buffer zones alone will not mitigate all risks or eliminate incidents caused by equipment failure, human error, adverse weather (e.g., temperature inversions), or other events. The Agency however does

US EPA ARCHIVE DOCUMENT

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.

Buffer Zone Requirements

General Requirements in the July 2008 RED

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

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

Comments on the July 2008 RED

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

The Agency also received numerous comments that buffer zone duration will present severe hardship for growers. Many commenters expressed concern that the buffer zone overlap restriction would have the unintended consequence of forcing some applications to occur during less-than-optimal weather and soil conditions, because the restriction could preclude nearby application blocks from being treated when weather and soil conditions would be optimal for reducing emissions. Hence, subsequent fumigations in adjacent fields would have an increased chance of occurring when weather and soil conditions are more conducive to off-gassing. Examples cited by commenters where this situation could occur include the Southeast and Pacific Northwest where optimal soil moisture conditions occur during a limited time period. The commenters felt that while the buffer zone is in effect, properly trained and equipped handlers should be allowed to enter adjacent application blocks to make applications. Several commenters felt that providing an exception to this prohibition would make buffers more

US EPA ARCHIVE DOCUMENT

workable, reduce delays, allow a more efficient use of equipment and labor, allow growers additional flexibility to achieve compliance with buffer requirements, and potentially reduce risk if applications could be made under more favorable soil and weather conditions. In addition, some comments suggested that allowing adjacent application blocks to be treated would not increase risk to bystanders since the Agency's mitigation measures encourage users to split application blocks into smaller treatment areas which result in less fumigant being applied, less exposure, and less potential risk.

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

Based on EPA's review of the comments, and new data and information, the Agency has determined that certain amendments to the buffer zone requirements are appropriate. EPA believes these amendments will maintain the important protections for bystanders but will increase the feasibility of compliance with buffers and will reduce potential impacts of buffers on the beneficial uses of soil fumigants. The Agency does agree that compliance with buffer zone requirements as outlined in the July 2008 RED would be a significant challenge for applicators and growers. However, field flux studies, monitoring data, modeling analyses, and information from incidents involving fumigants continue to support a conclusion that dazomet off-gasses and moves away from treated fields at concentrations that have the potential to cause adverse effects. Therefore, the Agency still believes that buffer zones that exclude bystanders are a critical aspect of mitigating risks from the use of dazomet. The Agency believes the modifications to the buffer requirements, specified below, will increase compliance feasibility and encourage further adoption of emission reduction application techniques, while still protecting human health and the environment.

Amended RED Requirements

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

- the definition and duration of a buffer zone;
- the requirement to exclude field workers, nearby residents, pedestrians, and other bystanders from the buffer zone during the buffer zone period (except for transit);
- the definition of the application block;
- the minimum buffer of 25 feet and maximum buffer of ½ mile.
- the requirement limiting entry into buffer zones to handlers who have been properly trained and equipped according to EPA's Worker Protection Standard;
- the exemption for transit through buffer zones;

US EPA ARCHIVE DOCUMENT

- the prohibition on including in buffer zones bus stops or other locations where persons wait for public transit;
- the prohibition against including in buffer zones buildings under the control of the owner/operator of the application block used for storage such as sheds, barns, garages, etc., unless the storage buildings are not occupied during the buffer zone period, and the storage buildings do not share a common wall with an occupied structure;
- the prohibition against including in buffer zones residential areas that are not under the control of the owner/operator unless occupants agree in writing that they will voluntarily vacate the buffer zone until the buffer zone period expires;
- the prohibition against including in buffer zones agricultural areas that are not under the control of the owner/operator unless the owner/operator of the other area provides written agreement that they, their employees, and other persons will not enter the buffer zone; and
- the prohibition against including in buffer zones publicly owned and/or operated areas such as parks, sidewalks, walking paths, playgrounds, and athletic fields without first obtaining written permission from local authorities.

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

Buffer Zone Proximity - Exception to Allow Buffer Zone Overlap

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

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

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

US EPA ARCHIVE DOCUMENT

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

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

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

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

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

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

In summary, areas of a buffer zone not under the control of the owner/operator of the application block, may not include residential areas (including employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas) unless the occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period. The Agency determined that the concentrations of the fumigants 48 hours after completion of the application were likely to be below the Agency's level of concern, and that the warning properties of MITC would alert persons reentering these sites if concentrations had not yet

US EPA ARCHIVE DOCUMENT

dissipated were of concern. Therefore, monitoring of buildings and outdoor areas after termination of the buffer zone is not necessary and will no longer be required.

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

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

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

Buffer zone distances

The Agency has received additional flux studies from the California Department of Pesticide Regulation, and the dazomet buffer zones have been revised to reflect this new data as well as other information received during Phase 5 comment period. Buffer zones have increased for surface applications of between 132 lbs ai/A and 265 lbs ai/A only.

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

PERFUM Model Inputs

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

Rates

The maximum rates for soil applications of dazomet are 425 lbs ai/A for incorporated applications and 265 lbs ai/A for surface applications. Since there is limited use information on typical dazomet rates, a range of rates was modeled. The rates used in the model included the maximum, along with rates at 75%, 50%, and 25% of the maximum for both surface and incorporated applications.

Rates for bedded or strip applications (lb ai per treated area) were converted to broadcast equivalent application rate 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 untreated portion of the field. Assuming both fields are 10 acres, and only 50% of field in Figure 2 is fumigated, the *rate per treated acre* is 400 lbs ai/A for both Figure 1 and 2. The *broadcast rate* for Figure 1 is 400 lb ai/A but the *effective broadcast equivalent rate* for Figure 2 is 200 lbs ai/A. Labels may express rates as lbs per treated acre under the application instructions but they must identify buffer zone distances based on the broadcast or effective broadcast equivalent rates.

Figure 1. Broadcast Application

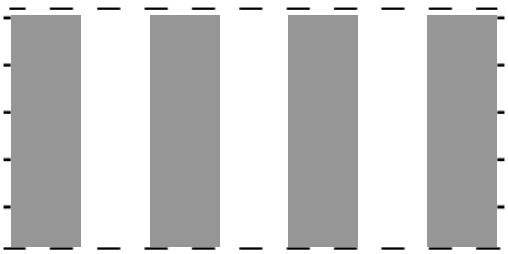

Figure 2. Bedded Application

Block Sizes

The Agency has limited information available on the size of application blocks treated in a given day but according to the registrants, dazomet is generally applied to a smaller number of acres than other fumigants, typically from 5 to 20 acres. The modeling did consider block sizes up to 40 acres per day for dazomet, and so based on the registrant comment the application block size will be limited to 40 acres for dazomet.

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

During the post-RED comment period, the Agency received comments requesting buffer zone distances for additional acreage increments for small fields. In response, the Agency determined buffer distances for smaller block sizes (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 acres). Although the Agency added additional acreage and rate increments, not all increments may be captured by the tables presented. If the tables do not capture a specific acreage or rate, round up to the nearest acre or rate. For example, when applying to a 9.5 acre field, round up to 10 acres.

In the 2008 RED, the Agency had calculated all dazomet buffer zones based on a square application block. The Agency received comments regarding the buffer zone calculations for the use of dazomet on golf course fairways, as a rectangular applicator block is more representative of how fairways are treated. The Agency agrees that fairways should be calculated using a rectangular application block because it is more representative of the typical treatment for specific use-site. The Agency has thus calculated the buffer zones for golf course fairways taking into account this additional information, and more information on these buffers is located in the section on buffer zone distances.

Emission Studies

The Agency's risk assessment for the RED includes modeling of the two main ways that dazomet is applied, surface or soil-incorporated. Details of these emission studies can be found in Appendix D of the *Dazomet: Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED dated April 2009).*

Weather

It is estimated that the major use of dazomet is in California and Washington. Some use in Michigan and Florida (or elsewhere in those regions) is also estimated. As a result, weather data for the following locations were included in this assessment: Bakersfield, CA; Ventura, CA; Flint, MI; Tallahassee, FL; Bradenton, FL; and Yakima, WA. Each modeling run used five years of weather (i.e., 1,825 potential application days) for each weather data set. Generally, Ventura, and Bradenton weather data result in the largest buffer zone distances, Bakersfield, Tallahassee, and Yakima data fall in the middle, and Flint data resulted in the smallest buffers.

Target Air Concentration

As described in the Human Health Risks section of Chapter 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

US EPA ARCHIVE DOCUMENT

concentration (HC) based on the no observable adverse effect level (NOAEL) from this study is 220 ppb.

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

An analysis based on a variety of PERFUM outputs was used in the buffer distance determinations. This involved consideration of 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 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., MOEs) at predefined buffer distances and varied percentiles of exposure.

This overall approach allowed the Agency to utilize more of the information available from PERFUM so that a more comprehensive view of the risks could be considered. Buffer distances indicated by this type of analysis along with information from monitoring studies and incidents were valuable in determining buffer distances to manage potential risks from dazomet use when coupled with other mitigation measures.

Buffer Zone Distances

The Agency has developed buffer zones distances based on application rate and application block size (rounding up to nearest rate and block size). These distances are summarized in Tables 4, 5, 6, and 7.

For each of the soil emission studies, distances were first chosen for the rates identified in the risk assessment as the 100%, 75%, 50%, and 25% of the maximum rates for each application method, as shown by the bolded red font in the table. For example, for surface applications the rates were 265 lbs ai/A, 200 lbs ai/A, 132 lbs ai/A, and 66 lbs ai/A; and for incorporated applications the rates were 530 lbs ai/A, 400 lbs ai/A, 265 lbs ai/A, and 132 lbs ai/A. For golf

US EPA ARCHIVE DOCUMENT

course fairways, buffers were calculated for rectangular application blocks of 1 and 5 acres. For greenhouse applications, buffers were calculated for structures sizes between 5,000 and 50,000 square feet. For all other applications, application block sizes of 5, 20, and 40 acres were used in the buffer zone calculations. Distances for the other rates in the buffer zone tables were scaled by assuming a linear relationship between the 100%, 75%, 50%, and 25%, and maximum rates (e.g., distance at 37.5% rate = [distance at 25% rate + distance at 50% rate]/2) with some adjustments for whole numbers. 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 used for their development.

Minimum and Maximum Buffer Zone Distances

For dazomet, the largest buffer distance is 1140 for applications of 265 lbs ai/A for greenhouses of 50,000 square feet. Applications to larger block sizes and higher rates will be prohibited for dazomet. Comments from the registrants indicate that dazomet users do not apply to large areas at the very highest rates on current labels. 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.

Additional buffer tables for use of dazomet in greenhouses and for golf course use have been added below since the 2008 RED.

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

Table 4: Buffer zone distances (in feet) for all dazomet soil applications except golf course fairways and greenhouses

Application Rates for incorporated applications (lbs ai/acre)																			
Block Size (acres)	425	400	390	380	370	360	350	340	330	320	310	300	290	280	270	265	260	250	240
40	864	770	750	730	710	690	670	650	630	610	590	565	545	524	505	500	490	471	452
30	692	605	588	571	554	537	520	503	487	470	454	435	417	400	383	375	368	353	338
20	520	440	426	412	398	384	370	356	343	330	317	305	288	275	260	250	245	234	223
15	400	343	333	323	312	302	292	281	271	261	251	242	229	219	208	200	193	182	171
10	280	247	240	233	227	220	213	207	200	193	186	179	171	164	156	150	141	130	119
9	256	230	222	215	210	204	198	192	186	180	173	167	159	153	146	140	130	120	109
8	232	210	204	197	193	188	182	177	171	167	160	155	147	142	136	130	119	109	98
7	208	190	186	179	176	172	166	162	157	153	147	142	135	131	125	120	110	99	89
6	184	170	168	161	159	156	151	147	143	139	134	129	123	119	115	110	99	89	78
5	160	150	147	144	141	138	135	132	128	124	120	116	112	108	104	100	89	78	67
4	150	135	130	127	123	120	117	113	109	105	101	97	93	89	85	82	72	64	55
3	140	117	113	110	106	102	99	95	91	87	82	78	75	70	66	64	56	50	43
2	120	100	96	92	88	84	80	76	72	68	64	60	56	52	48	44	40	36	32
1 or less	110	75	72	69	66	63	60	57	54	51	48	45	42	39	36	33	30	25	25
Application Rates for incorporated applications (lbs ai/acre)																			
Block Size (acres)	230	220	210	200	190	180	170	160	150	140	132	130	120	110	100	90	80	70	66
40	433	414	395	375	357	339	321	303	285	267	250	250	218	186	154	122	90	58	25
30	323	308	293	281	268	255	242	229	215	202	188	188	164	141	117	94	70	47	25
20	212	201	190	187	179	171	163	154	145	136	125	125	110	95	80	65	50	35	25
15	160	149	138	133	127.7	122	117	111	105	99	92	92	82	72	62	52	42	32	25
10	108	97	86	79	76.33	73.7	71	68	65	62	58	58	53	48	43	38	33	28	25
9	99	89	76	68	65	63	61	59	56	54	51	49	45	41	38	34	31	28	25
8	88	78	65	57	55	53	51	49	47	45	44	41	38	35	33	30	28	27	25

US EPA ARCHIVE DOCUMENT

7	78	68	54	46	44	43	42	41	39	38	37	35	33	31	30	28	27	26	25	
6	67	57	44	38	35	34	33	32	31	31	30	30	29	28	28	27	26	26	25	
5	56	45	34	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	
4	47	39	31	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	
3	38	32	29	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	
2	28	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	
1 or less	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	

Table 5: Buffer zone distances (in feet) for all dazomet soil applications except golf course fairways and greenhouses

	Application Rates for surface applications (lbs ai/acre)																						
Block Size (acres)	265	260	250	240	230	220	210	200	190	180	170	160	150	140	132	130	120	110	100	90	80	70	66
40	675	669	663	657	651	645	639	630	576	522	467	414	360	306	250	250	218	186	154	122	90	58	25
30	560	546	532	518	504	490	477	465	425	385	345	305	265	225	188	188	164	141	117	94	70	47	25
20	450	429	408	387	366	345	323	300	275	250	225	200	175	150	125	125	110	95	80	65	50	35	25
15	420	400	379	359	338	318	297	274	248	222	196	170	144	118	92	92	81.67	72	62	52	42	32	25
10	390	371	350	331	310	291	271	248	221	194	167	140	113	86	58	58	53.33	48	43	38	33	28	25
9	360	342	321	303	282	264	245	222	197	172	147	122	97	72	51	51	47	43	41	36	31	27	25
8	330	313	292	275	254	237	219	196	172	148	124	100	76	52	44	44	41	38	38	33	29	27	25
7	300	284	263	247	226	210	193	170	151	132	113	94	75	56	38	38	35	34	33	30	28	26	25
6	270	255	234	219	198	183	167	144	127	110	93	76	59	42	31	31	30	29	29	27	26	26	25
5	240	223	206	189	172	155	138	120	106	92	78	64	50	36	25	25	25	25	25	25	25	25	25
4	176	164	152	140	128	116	104	91	82	73	64	55	46	37	25	25	25	25	25	25	25	25	25
3	112	105	98	91	84	77	70	62	57	51	46	40	35	30	25	25	25	25	25	25	25	25	25
2	47	45	42	41	39	38	36	35	33	32	29	28	27	26	25	25	25	25	25	25	25	25	25
1 or less	35	34	34	33	32	31	31	31	29	28	27	27	26	26	25	25	25	25	25	25	25	25	25

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Table 6: Buffer zone distances (in feet) for dazomet greenhouse applications

Structure Size	265 lbs ai/A (100%)	200 lbs ai/A (75%)	132 lbs ai/A (50%)	66 lbs ai/A (25%)
5000 square feet	240	180	120	45
10000 square feet	360	300	210	90
15000 square feet	450	330	270	110
20000 square feet	540	450	330	170
25000 square feet	630	540	390	210
30000 square feet	720	570	450	240
35000 square feet	810	650	585	270
40000 square feet	855	720	540	300
45000 square feet	900	760	600	330
50000 square feet	1140	810	630	360

Table 7: Buffer zone distances (in feet) for dazomet golf course fairways applications

	Application Rates for incorporated applications (lbs ai/acre)																		
Block Size (acres)	530	400	390	380	370	360	350	340	330	320	310	300	290	280	270	265	260	250	240
5	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
4	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
3	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
2	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
1 or less	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25

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The buffer zone distances shown in Table 7 are based on PERFUM modeling runs that are representative of golf course fairways where the width of the application block is 15% of the length of the application block. This ratio was proposed by the dazomet registrants as a typical representation of golf course fairways. The Agency understands that golf course fairway width to length ratios can vary significantly. Given these potential variations, the Agency believes that applicators can use the rectangular buffer zones shown in Table 6 if the width of the application block is less than or equal to 20% of the length of the application block. Examples have been provided below:

For an application block 550 feet long by 110 feet wide:
110 feet / 550 feet = 0.20 x 100 = 20%, so the buffers in table 6 can be used

For an application block 700 feet long by 175 feet wide:
700 feet / 175 feet = .25 x 100 = 25%, so the buffers in table 6 cannot be used;
The buffers in table 4 must be used instead.

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 MITC, 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., the **F**umigant **E**missions **M**odeling **S**ystem or FEMS). Each model was reviewed by the FIFRA Scientific Advisory Panel (SAP) in 2004 during the August and September meetings (http://www.epa.gov/oscpmont/sap/meetings/2004/index.htm). The analysis of PERFUM results considered distances at various percentiles of the whole field and maximum distance distributions, and predicted MOEs for various distances. The risk assessment characterizes additional types of analysis that were performed. EPA's goal for risk management was to achieve buffer distances where associated risks were at or above target concentration levels at high percentiles of exposure. The following characterizes the risks associated with the buffer zone distances summarized in Table 8:

- This table shows the various buffer distances for each rate and block size. It also shows the percentile for the whole and maximum distribution for each distance, as well as the MOE at the 95th percentile air concentration of PERFUM2.
- The target MOE for dazomet is 10, and the MOEs at these distances range from about 7 up to 20. Although the target air concentration is not below our LOC at all the distances, at the lowest MOE of 7, the predicted air concentration would be 28 times lower than the lowest observable adverse effect level (LOAEL) that is the level where the eye irritation effects were first observed in the human study.
- Two registrant-submitted studies were used to calculate the buffers in the RED, and this data indicated little apparent difference in risk between the surface and incorporated application methods when similar rates were compared.
- Flux data for surface applications was submitted by CDPR during the comment period, and the Agency has incorporated this new data in calculating the surface application

buffer distances. The new surface application buffer zone distances were calculated using the CDPR data because it is more conservative, and the buffer zones for the higher surface application rates have changed as a result. Since the Agency did not receive any new data for the incorporated application method, buffer zone distances for this method have not changed since the RED.

- The use of GAPs, FMPs, and other mitigation measures required by this decision will contribute to an additional decrease in risk (see GAP and FMP sections).

Example

Table 8 shows the required buffer zone distances and corresponding PERFUM modeling results for the soil uses of dazomet (excluding fairway and greenhouse applications) using both the maximum distribution and the whole field distribution to the target concentration based on an MOE of 10, as well as the MOE from the air concentration outputs from PERFUM at the 95th percentile. The weather data selected here are from Ventura, CA, since only California has agricultural uses registered which typically involve larger application blocks than dazomet's other soil uses.

Focusing on the incorporated application method in the top row, using a 265 lbs ai/A rate on a 40 Acre block size, the buffer zone required for that application is 500 feet. The blocks referenced in this example are shaded in gray in Table 8.

- At this distance using the PERFUM model to predict both the whole field and maximum distributions the results indicate 91st percentile for whole field and 57th percentile for maximum, as shown in the next two columns in the table.
    - The risk level corresponding to this buffer zone distance at the 91st percentile whole field distribution is equivalent to saying a person at any location on the perimeter of the buffer zone during the 24 hour period following the fumigation of a specific field during a 5-year period would have at least a 91 percent chance of having of an exposure below the LOC (i.e., MOE of ≥10).
    - The risk level corresponding to the buffer zone distances at the 57th 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 57 percent chance of having of an exposure below the LOC (i.e., MOE of ≥ 10) for these typical use scenarios.
- Using the PERFUM 2 model outputs of air concentrations to predict MOEs at the 95th percentile, at 500 feet for these application parameters, the MOE is about 9 which is not significantly below the target MOE of 10.

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Table 8: Dazomet's Buffers and Risk Estimates

Incorporated applications																
	530 lbs ai/A (100%) Max incorporated rate				400 lbs ai/A (75%)				265 lbs ai/A (50%)				132 lbs ai/A (25%)			
Block Size (acres)	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2
		Whole	Max			Whole	Max			Whole	Max			Whole	Max	
40	1080	93	46	7	770	93	50	7	**500**	**91**	**57**	**9**	250	96	72	11
20	650	93	43	7	440	93	49	7	250	91	53	8	125	98	73	12
5	200	92	44	7	150	92	74	8	100	96	63	11	25	99	98	19
Surface applications																
	265 lbs ai/A (100%) Max surface rate				200 lbs ai/A (75%)				132 lbs ai/A (50%)				66 lbs ai/A (25%)			
Block Size (acres)	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2
		Whole	Max			Whole	Max			Whole	Max			Whole	Max	
40	675	90	23	7	630	93	45	7	250	89	38	7	25	90	61	8
20	450	90	25	7	300	90	30	7	125	88	33	7	25	93	72	10
5	240	93	38	7	120	90	30	7	25	87	37	7	25	99	91	14

- Ventura Weather Data is used to calculate all the numbers in this table since it was one of the worst weather scenarios and for the agricultural uses of dazomet there is more use in California than Florida.
- Shaded areas represent the numbers explained in the example above.
- All values are approximate.

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

Amended General Buffer Zone Requirements

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

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

Buffer zone proximity

- To reduce the potential for off-site movement from multiple fumigated fields, buffer zones from multiple dazomet application blocks may not overlap UNLESS:
    - A minimum of 12 hours have elapsed from the time the earlier application(s) for which a buffer is in place end(s) until the latter application begins, and
    - Emergency preparedness and response measures specified later in this document have been implemented if there are any homes, businesses, or property not within the control of the fumigator within 300 feet of each buffer zone.

Buffer zone distances

- Buffer zone distances must be based on look-up tables on product labels. Twenty-five feet is the minimum buffer distance regardless of site-specific application parameters.
- For selective replant fumigation in an orchard using hand held application methods (e.g., deep injection auger probes), the minimum buffer zone will be 25 feet measured from the center of each injection site (i.e., tree hole).

Authorized entry to buffer zones

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

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Exemptions for transit through buffer zones

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

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

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

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

- Buffer zones may not include residential areas (including employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas) **UNLESS,**
  1. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and
  2. Reentry by occupants and other non-handlers must not occur until,
     - The buffer zone period has ended, and;
     - Sensory irritation is not experienced
- Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, **UNLESS,**
  1. The owner/operator of the application block can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, except as provided for above, and
  2. The owner/operator of the adjacent areas (i.e., areas that are not under the control of the owner/operator of the application block) provides written agreement to the applicator that they, their employees, and other persons will stay out of the buffer zone during the entire buffer zone period.
- Buffer zones must not include roads and rights of way **UNLESS,**
  1. The area is not occupied during the buffer zone period, and
  2. Entry by non-handlers is prohibited during the buffer zone period.

3. Applicators must comply with all local laws and regulations.

- For all other publicly owned and/or operated areas such as parks, side walks, walking paths, playgrounds, and athletic fields, buffer zones must not include these areas **UNLESS,**
  1. The area is not occupied during the buffer zone period,
  2. Entry by non-handlers is prohibited during the buffer zone period, and
  3. Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.
  4. Applicators must comply with all local laws and regulations..

Restriction for Schools and Other Difficult-to-Evacuate Sites

- "Difficult-to-evacuate" sites include schools (preschool to grade 12), state licensed day care centers, nursing homes, assisted living facilities, hospitals, in-patient clinics, and prisons.
- No fumigant application with a buffer zone greater than 300 feet is permitted within ¼ mile (1320 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the application.
- No fumigant application with a buffer zone of 300 feet or less is permitted within 1/8 mile (660 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the application.

Buffer Zone Reduction Credits

In preparing for the July 2008 RED, the Agency undertook a significant effort to evaluate available empirical data results, modeling, and scientific studies reported in the literature regarding the factors and control methods that may reduce emissions from soil fumigants. For details on the Agency's analysis, please see the June 9, 2008 memo, "Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach,"[3] in the dazomet docket. The Agency also coordinated and led a discussion on this issue at the 2006 and 2007 Methyl Bromide Alternatives Outreach (MBAO) Conferences with leading researchers and other stakeholders. A general description of the MBAO sessions can be found at http://mbao.org.

Based on the Agency's analysis of the current data, the Agency developed dazomet buffer zone reduction credits for: soils with high organic matter, and for soils with high clay content. The Agency believes that in addition to reducing bystander risk and the size of buffer zones, these credits have the potential to also decrease application rates. Applicators will be required to document any information about buffer zone credits that apply in the Fumigant Management Plan (FMP).

Soil Conditions

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

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

The Agency's factors document not only reviews available literature regarding soil conditions, but also describes modeling exercises that estimate the impact of organic matter and soil type using Chain_2D. Chain_2D is a first principles model that takes into consideration factors such as boundary layers or moisture that could impact fumigant emissions. The Agency used Chain_2D as modified by Dow AgroSciences' Steve Cryer and Ian van Wesenbeek in the sensitivity analysis[4]. 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[5]. See the Agency's factors analysis for further details about the CHAIN_2D model[6].

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

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

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

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

[5] 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.

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

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Since the 2008 RED, information from the Chloropicrin Task Force has been submitted and has allowed the Agency to reevaluate credits for soil organic matter. From these studies the Agency has determined that soils with between 1% and 2% organic matter will get a 10% credit, soils with between 2% and 3% organic matter will get a 20% credit, and greater than 3%, a 30% credit. No credit will be given for soils with less than 1% organic matter. The credit for clay content of greater than 27% will remain at 10%.

Dazomet buffer zone credits are additive and as since only the organic content and clay content credits apply for dazomet, buffer zone credits will not exceed 40 percent (e.g., 40 percent credit would apply for using > 3 percent organic content and >27 percent clay content).

For example, if an application block is 10 acres and the applicator is planning to make an incorporated application of 230 lbs of dazomet per acre, the buffer distance from the look up tables is 108 feet. If after the applicator tests the soil and determines the soil contains greater than 27 percent clay content, then the buffer zone may be reduced by 10 percent. By calculating 10 percent of 108 feet (108 feet x 10% = 10.8 feet buffer credit) and then subtracting the original buffer distance by the credit (108 feet – 10.8 feet = about 97 feet) the final buffer distance required is 97 feet.

Other Buffer Zone Credits Considered

Currently the dazomet label allows for use of tarps when making applications, but there is little information to suggest that growers are currently using tarps with dazomet. Since there is no information available about how dazomet reacts with tarps, and since other data for metam sodium suggests that standard tarps may not be very effective in trapping MITC vapors, there is no tarp credit for dazomet at this time. If additional tarps or other emission factor data become available to show the emissions from dazomet applications are decreased, the Agency will consider adding those to the dazomet label. More information on the type of data the Agency is looking for can be found in the *Health Effects Division Recommendations for Fumigant Data Requirements* (J. Dawson, C. Smith, dated June 2008).

EPA (through OPP's Environmental Stewardship Branch) has co-funded a grant with USDA-ARS for several flux studies in the southeastern U.S. These studies would provide (1) field data on the emission reduction potential of certain low permeability barrier films to support possible, additional, buffer reduction credits as well as to (2) help develop an affordable and reliable hybrid field/lab test to evaluate the many barrier films available to growers. EPA has also prepared a document to describe possible research and study designs to reduce uncertainties in understanding emission factors in the context of different films and seals, agricultural practices, and environmental conditions.[7] These studies are scheduled to be completed in 2009 and data from these studies will be submitted to the Agency for review.

Other factors such as soil moisture content, field preparation, water sealing, and application depth could not be used to justify credits based on the available data. However, EPA

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

has established mandatory good agricultural practices (GAPs) for these conditions. See the GAP section of this document for further discussion. If additional data on such emission reduction methods becomes available, EPA will consider developing further credits.

2. Restriction for Schools and Other Difficult to Evacuate Sites

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

Based on a review of the comments, the Agency has retained this mitigation measure to ensure the protection goals are still achieved and encourage lower-emission application methods. This mitigation measure has been refined such that compliance is more effective in achieving the protection goal. Modifications to this requirement include: shortening the duration of the restriction so weekends may be used to fumigate near schools and day care centers; clarifying the types of schools that are covered by this requirement; removing the term "elder care facilities" from the list since many of the same facilities are included in the terms, " assisted living facilities, nursing homes, and in-patient clinics;" and reducing the restricted area from 1/4 mile to 1/8 mile for application blocks with less than 300 foot buffers. The 1/8 mile (660 feet) distance is more than twice the required buffer distance and remains protective of people who may be difficult to evacuate while reducing the potential challenges of complying with the restrictions for some users who may be fumigating in close proximity to these types of institutions. EPA has determined that these modifications achieve the same protection goals as the 2008 RED but provide additional clarity and flexibility that will enhance users' ability to practically and effectively comply with the requirements. EPA also believes that reducing the restricted area for blocks with buffers less than 300 feet will provide an incentive for some users to adopt lower-emission application methods or practices. The revised measures are summarized below.

- "Difficult-to-evacuate" sites include schools (preschool to grade 12), state licensed day care centers, nursing homes, assisted living facilities, hospitals, in-patient clinics, and prisons.
- No fumigant application with a buffer zone greater than 300 feet is permitted within 1/4 mile (1320 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the start of application.

US EPA ARCHIVE DOCUMENT

- No fumigant application with a buffer zone of 300 feet or less is permitted within 1/8 mile (660 feet) of the sites listed above unless the site is not occupied during the application and the 36-hour period following the start of application.

3. Posting

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

In addition to alerting bystanders, posting a buffer zone will help handlers determine where and when they are required to use PPE. As described in the Handler Section, handlers working in treated areas or buffers during the buffer zone period must use label-specified PPE and meet other requirements under the Worker Protection Standard (WPS). Therefore, EPA has determined that to ensure the protectiveness of buffer zones for bystanders and handlers, the perimeter of the fumigant buffer zones must be posted.

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

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

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

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

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

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

Requirements

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

- Buffer zone posting signs must:
  - Be placed at all usual points of entry and along likely routes of approach from areas where people not under the land operator's control may approach the buffer zone.
  - Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.
  - Some examples of likely routes of approach are the area between a buffer zone and a roadway, or the area between a buffer zone and a housing development.

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

US EPA ARCHIVE DOCUMENT

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

Additional requirements for treated-area posting:

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

Contents of Signs

The **treated area** sign (currently required for fumigants) must state the following:	The **buffer zone** sign must include the following:
-- Skull and crossbones symbol  -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "Dazomet fumigant in USE," -- the date and time of fumigation, -- the date and time entry prohibition is lifted -- Name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation.	-- Do not walk sign  -- "DO NOT ENTER/NO ENTRE," -- "Dazomet OR [Name of product] Fumigant BUFFER ZONE," -- contact information for the certified applicator in charge of the fumigation

bb. Occupational Risk Mitigation

1. Handler Definition

Based on stakeholder comments provided during the Phase 5 comment period, the July 2008 RED clarified fumigation tasks that meet EPA's definition of *handler* activities, as currently defined in the Worker Protection Standard (WPS) and on fumigant labels. During the post-RED comment period the Agency received some comments from stakeholders who were concerned that the Agency was redefining *handlers*. It was not the Agency's intention to change

US EPA ARCHIVE DOCUMENT

the current definition. As a result, the Agency has slightly changed the language from the July 2008 RED so it is clear that the Agency is just clarifying the existing definition and not writing a new definition. Below is the revised language.

> The following activities are prohibited from being performed in the fumigant application block or surrounding buffer zone during the buffer zone period by anyone other than persons who have been appropriately trained and equipped as handlers in accordance with the requirements in the WPS (40 CFR Part 170), from the start of the application until the entry-restricted period ends. Those activities include those persons:
>
> - Participating in the application as supervisors, loaders, drivers, co-pilots, shovelers, shovel ditchers, or as other direct application participants (note: the application starts when the fumigant is first introduced into the soil and ends after the fumigant has stopped being delivered/dispensed to the soil);
> - Using devices to take air samples to monitor fumigant air concentrations;
> - Persons cleaning up fumigant spills (this does not include emergency personnel not associated with the fumigation application);
> - Handling or disposing of fumigant containers;
> - Cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues;
> - Installing, repairing, or operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period;
> - Entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;
> - Installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps:
>   - until 14 days after application is complete if tarps are not perforated and removed during those 14 days, or
>   - until tarp removal is complete if tarps are **both** perforated **and** removed less than 14 days after application; or
>   - until 48 hours after tarp perforation is complete if they will not be removed within 14 days after application.
> - In addition to the above, persons outside the perimeter of the buffer zone who monitor fumigant air concentrations must also be trained and equipped as handlers in accordance with the requirements in the Worker Protection Standard (40 CFR Part 170).

2. Handler Requirements

Since many incidents are caused by human error and equipment failure, EPA believes the presence of on-site trained personnel would help to reduce these risks. To address these risks, the July 2008 RED required that (1) a certified applicator must supervise all fumigant handlers during the entire period that the person is performing a fumigant handling task within the treated field or within the buffer zone, (2) the person monitoring another handler could also be engaged

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in fumigant handling tasks during the monitoring period, and (3) the certified applicator supervising dazomet applications could perform all tasks without anyone supervising them.

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

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

The Agency has considered the comments and has revised the certified applicator requirement by specifying different requirements for different applications. EPA believes that these revisions accomplish the same goal as the July 2008 RED mitigation while reducing the burden on users. The revised language is:

- For ground-rig applications (e.g., shank, rototiller, and spray blade), from the start of the application until the fumigant has stopped being delivered/dispensed into the soil (e.g., soil is sealed) the certified applicator must be at the fumigation site and must directly supervise all persons performing handling activities.
- For fumigant handling activities that take place after the fumigant has been delivered/dispensed into the soil until the entry restricted period expires, the certified applicator must communicate in writing to the site owner/operator and other handlers information necessary to comply with the label and the FMP (e.g., emergency response plans and procedures).

The July 2008 RED also required that certified applicators supervising the application completed a registrant administered dazomet training program within the preceding 12 months before they applied a dazomet product. The Agency is still requiring certified applicators to complete the registrant training; however, the Agency is now requiring the certified applicators successfully complete the training every three years. Please see the *Soil Fumigation Training for Applicators and Other Handlers* section for further.

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3. Dermal Protection for Handlers

The dazomet dermal risk assessment indicated potential risks of concern for handlers for some scenarios. For handlers loading and applying dazomet for tractor drawn spreaders, there were potential risks for short term exposures assuming applications to 80 acres per day. According to information from the registrant in the phase 3 comments, dazomet is not typically applied to large acreages, but more typically applied to blocks 5-20 acres in size. The Agency is prohibiting applications to block sizes over 40 acres, so the short term concerns for dermal risk to handlers loading and applying with tractor drawn spreaders does not present unreasonable adverse effects.

For intermediate term dermal risk, there are potential risk concerns for loaders and applicators, with MOEs below 100, the intermediate dermal LOC. MOEs for loaders range from 13 for handlers wearing baseline PPE, up to 650 for handlers using closed systems. For applicators, there is only data for handlers applying with closed cabs, and the MOE is 52 for a 40 acre field. Due to the amount of dazomet applied, and the small area it is typically applied to, it is not likely a single handler will be exposed to the amount assumed in the risk assessment over the intermediate time frame of 1 to 6 months. Current dazomet labels require handlers to wear double layers (coveralls over short-sleeved shirt and short pants) and chemicals resistant gloves to protect from dermal exposures. The Agency does not calculate risks with this level of PPE since there is no data to assess coveralls over short-sleeved shirt and short pants. However, since the current labels require this level of protection, the short-term risks were acceptable and the amount of dazomet exposure assumed in the intermediate term assessment are higher than would be expected based on dazomet's use patterns, the Agency is requiring all handlers to wear double layers consisting of coveralls over short-sleeved shirt and short pants with gloves. In addition, handlers will have an option to reduce the dermal protection if application equipment (i.e., enclosed cabs) that provides dermal protection is used.

For hand held applications there are potential dermal risks of concern when making applications with baseline PPE. The registrants have indicated that they will not be continuing to support applications with hand held equipment, and labels will be amended to prohibit hand held equipment.

4. Respiratory Protection for Handlers

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

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

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

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

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

EPA does believe, however, that monitoring devices that are currently available will generally be reliable at higher concentrations of MITC and that there is high value in air monitoring using currently available devices in certain situations. As a result, EPA is maintaining the requirement for colorimetric tube monitoring once use of respirators has been triggered and respirators are being worn. This will enable handlers to detect concentrations that would exceed the upper working limit of the respirator. Additionally monitoring will still be required to help enable handlers to determine if concentrations have decreased and whether it is

US EPA ARCHIVE DOCUMENT

safe to either remove respirators or to resume the application if the fumigator has opted to cease the application rather than wear respirators.

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

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

Respiratory Requirements

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

- If at any time any handler experiences sensory irritation (tearing, burning of the eyes or nose) then either:
    - An air-purifying respirator (APR) must be worn by all handlers who remain in the application block and surrounding buffer zone, or
    - Operations must cease and handlers not wearing respiratory protection must leave the application block and surrounding buffer zone.
- Handlers can remove respirators or resume operations if two consecutive breathing-zone samples taken at the handling site at least 15 minutes apart show that levels of MITC have decreased to less than 600 ppb, provided that handlers do not experience sensory irritation. Samples must be taken where the irritation is first experienced.
- When respirators are worn, then air monitoring samples must be collected at least every 2 hours in the breathing zone of a handler performing a representative handling task.
- If at any time: (1) a handler experiences any sensory irritation when wearing a respirator, or (2) an air sample is greater than or equal to 6000 ppb, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone. If operations cease the emergency plan detailed in the FMP must be implemented.

US EPA ARCHIVE DOCUMENT

- Handlers can resume work activities without respiratory protection if two consecutive breathing-zone samples taken at the handling site at least 15 minutes apart show levels of MITC have decreased to less than 6000 ppb, provided that handlers do not experience sensory irritation.
- During the collection of air samples an air-purifying respirator must be worn by the handler taking the air samples. Samples must be taken where the irritation is first experienced.
- Work activities may resume if the following conditions exist provided that the appropriate respiratory protection is worn:
    - Two consecutive breathing zone samples for MITC taken at the handling site at least 15 minutes apart must be less than 600 ppb,
    - Handlers do not experience sensory irritation while wearing the APR, and
    - Cartridges have been changed.
    - During the collection of air samples an air-purifying respirator must be worn by the handler taking the air samples. Samples must be taken where the irritation is first experienced.

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

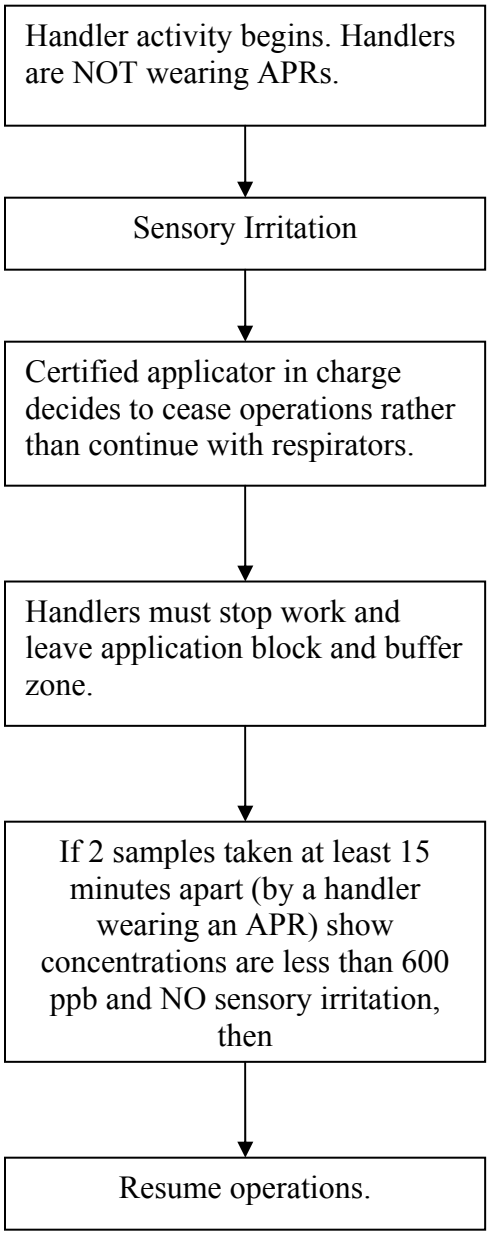

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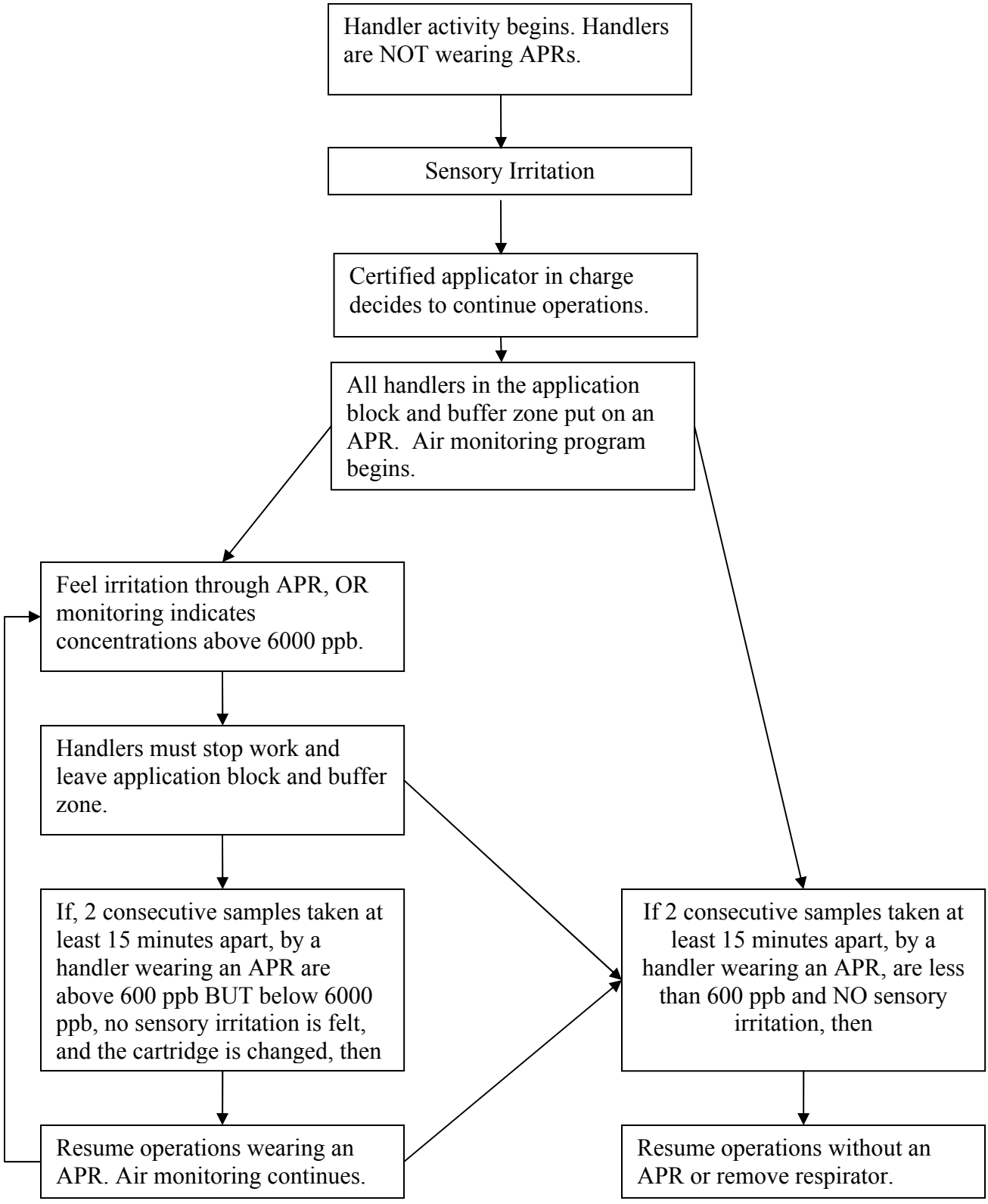
Figure 4 provides an illustration of the requirements when handlers put on a respirator.



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Respiratory Protection Equipment

In the July 2008 RED, the Agency required handlers to wear an air purifying respirator approved for MITC with a protection factor (PF) of 10. For additional clarity, even though currently there are no air-purifying respirator cartridges certified by the Mine Safety and Health Administration-National Institute for Occupational Safety and Health (MSHA-NIOSH) for protection against MITC, NIOSH/OSHA does recommend respirators with organic vapor cartridges for MITC use, and the Agency is requiring half-face respirators with organic-cartridges be used when a respirator is necessary; the Agency will consider other APR-cartridges combinations provided written certification of their efficacy against MITC is provided to the Agency. The EPA assumes that half-face respirators have a protection factor of 10, therefore, the respiratory protection will only be protective up to MITC concentrations of 6000 ppb, and if concentrations exceed 6000 ppb (or if eye irritation occurs), operations must cease. At air concentrations greater than 6000 ppb, the respirator is not designed to protect handlers from inhaling more than 600 ppb of MITC. Therefore, the handler must continue to monitor once respirators are donned. If concentrations of MITC exceed 6000 ppb or if eye irritation occurs, then the operations must cease until levels of MITC are measured to be below 600 ppb from consecutive air samples.

The Agency did receive comments regarding the cartridge recommendations, the recommended equipment, and the assumed respirator protection factor. All of these comments are addressed in detail in the following document located in the dazomet docket: *Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents* (Dated May 14, 2009). The Agency would like to clarify issues regarding the respiratory protection cartridges and respirators. Comments suggested that the Agency require organic-vapor cartridges. This was the Agency's intention in the July 2008 RED. Others commented on the use of full-face respirators and goggles. The Agency is still recommending the use of organic-vapor cartridges when protection is required.

Respirator fit testing, training, and medical qualification

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

During the post-RED comment period, the Agency received a variety of comments ranging from full support of the requirement, to comments about the cost and time burden associated with the requirement. The Agency also received several comments regarding the details of this requirement, for example who conducts the fit-testing and medical exam and what the medical exam entails. Detailed responses to the general requirements are included in the

following document: *SRRD's Response to Post-RED Comments for the Soil Fumigants*, dated May 20, 2009 located in the dazomet docket.

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

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

- Fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134)
- Trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134)
- Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner at least annually or if their health status or respirator style or use-conditions change."

Respirator availability

The handler employer must confirm and document in the FMP that enough air-purifying respirators and cartridges are available for each handler that wears an air-purifying respirator. The Agency is requiring that at minimum two handlers have the appropriate respirator and cartridges available and that these handlers are fit-tested, trained, and medically examined.

Tarp Repair

The July 2008 RED required handlers to wear APRs if they perform tarp repair operations before the entry-restricted period has ended. The requirements were different from other handling activities because the duration of tarp repair activities was believed to be shorter than other handling tasks and therefore tarp repair activities would not trigger the initial monitoring requirement. Upon consideration of comments the Agency received on this requirement, EPA has determined that respiratory protection for tarp repair activities should be handled consistently with other handler activities, i.e., handlers repairing tarps are not required to wear respirators unless sensory irritation is experienced. Additionally, the Agency believes that tarp repair like other handling activities described above would benefit from the development of

US EPA ARCHIVE DOCUMENT

sensitive monitoring devices to reliably inform handlers if and when concentrations are above the action level for respiratory protection. EPA will reevaluate this measure during Registration Review or sooner if such devices are available in the short term.

5. Tarp perforation and removal

The Agency's risk assessment indicates that there is a risk concern for handlers during the perforation (cutting, poking, punching, or slicing) and removal of tarps, and notes potential for increased risk when high barrier tarps are used. To address these risks EPA required the following mitigation in the July 2008 RED:

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

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

There is some uncertainty regarding potential risks if high barrier tarps are perforated after 5 days. This is because worker exposure data used in the risk assessments are generally based on what has been the industry standard tarping technology, i.e., low or high density polyethylene tarps, typically with higher application rates and no significant emphasis on using the GAPs as defined in the RED. Data indicate that high barrier tarps are effective measures to reduce fumigant emissions (see *Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 & 039002), MITC (PC Code 068103), Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits* located in the dazomet docket). While this reduction decreases the risk to bystanders, it could increase the risk to handlers

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perforating or removing tarps because more fumigant could be trapped between the soil surface and the tarp—currently California Department of Pesticide Regulation (CDPR) prohibits the use of methyl bromide with certain high barrier tarps due to worker concerns.

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

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

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

During earlier comment periods EPA heard from various stakeholders that windy conditions sometimes caused tarps to blow off fields and create other hazards, e.g., to motorists on nearby roadways. As a result, in the July 2008 RED the Agency provided an exception to allow tarps to be removed after 48 hours under adverse weather conditions. During the post-RED comment period EPA received comments that this exception did not fully address the issue since the mitigation required waiting a minimum of 48 hours after fumigation but tarps could blow of fields sooner than that. Commenters also said waiting 24 hours between tarp perforation and removal and the requirement to cut every broadcast tarp panel added to the potential for tarps to blow off fields and create other hazards: once tarps are cut they are prone to blowing off when windy conditions occur. To decrease the potential of tarps blowing off, commenters also suggested that the Agency add flexibility to the 24 hour requirement by giving tarp removers the option to remove tarps 2 hours after tarp perforation if monitoring indicated levels below the Agency's LOC. Commenters also suggested that every 1-3 tarp panels should be cut based on the professional judgment of the handler.

Upon review of the comments the Agency agrees that the mitigation should be revised somewhat to allow for tarp removal at any time if the tarp is no longer performing its intended function and it is creating other types of risk. Therefore, EPA is revising the exception outlined in the RED to address these comments. EPA notes that handlers undertaking these tasks must follow the respiratory protection procedures detailed in Section 4 (Respiratory Protection for

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Handlers); this change still provides handler protection while reducing the unintended consequences of tarps creating other hazards.

The Agency believes cutting every panel allows the fumigant trapped beneath each panel to off-gas before the tarp is removed. If each panel is not cut, it is not likely that necessary off-gassing can take place to reduce risks to handlers removing tarps. The Agency understands that the main concern for not cutting every panel is due to the potential for tarps to blow off and has determined that this concern is best addressed by modifying the 24-hour wait period. Tarps may be removed 2 hours after tarp perforation is complete provided that tarp removers follow the procedures set forth in the (cite respiratory protection section); therefore the risk to handlers will not increase as a result of this modification. EPA considered the suggestion to monitor before tarp removal begins; however, because of technical limitations with current technology the Agency did not include monitoring as part of the mitigation. As with the respiratory protection section, the Agency sees the value in a monitoring program if reliable and accurate devices are available and will consider monitoring during Registration Review or sooner if information becomes available.

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

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

- As described in the Handler Definition section of this document, tarp perforators and removers are considered handlers for a specified duration and every handler must adhere to the respiratory protection procedures outlined in the Respiratory Protection section of this document.
- Tarps must not be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after injection of the fumigant product and tarps have been laid or after drip lines have been purged and tarps have been laid), unless a weather condition exists which necessitates the need for early perforation or removal See *Early Tarp Removal for Broadcast Applications Only* and *Early Tarp Perforation for Flood Prevention Activities* sections below.
- If tarps will be removed before planting, tarp removal must not begin until at least 2 hours after tarp perforation is complete.

US EPA ARCHIVE DOCUMENT

- If tarps will not be removed before planting, planting or transplanting must not begin until at least 48 hours after the tarp perforation is complete.
- If tarps are left intact for a minimum of 14 days after fumigant injection into the soil is complete, planting or transplanting may take place while the tarps are being perforated.
- Each tarp panel used for broadcast fumigation must be perforated.
- Tarps used for fumigations may be perforated manually ONLY for the following situations:
    - At the beginning of each row when a coulter blade (or other device which performs similarly) is used on a motorized vehicle such as an ATV.
    - In fields that are 1 acre or less.
    - During flood prevention activities
- In all other instances tarps must be perforated (cut, punched, poked, or sliced) only by mechanical methods.
- Tarp perforation for broadcast fumigations must be completed before noon. (seepage irrigation exception)
- For broadcast fumigations tarps must not be perforated if rainfall is expected within 12 hours.
- Early Tarp Removal for Broadcast Applications Only:
    - Tarps may be removed before the required 5 days (120 hours) if adverse weather conditions have compromised the integrity of the tarp, provided that the compromised tarp poses a safety hazard. *Adverse weather* includes high wind, hail, or storms that blow tarps off the field and create a hazard, e.g., tarps blowing into power lines and onto roads. A *compromised tarp* is a tarp that due to an adverse weather condition is no longer performing its intended function and is creating a hazard.
    - If tarps are removed before the required 5 days have elapsed due to adverse weather, the events must be documented in the post fumigation summary section of the FMP.
- Early Tarp Perforation for Flood Prevention Activities
    - Tarp perforation is allowed before the 5 days (120 hours) have elapsed if rain necessitates field drainage.
    - Tarps must be immediately retucked and packed after soil removal.

6. Entry Prohibitions

Current dazomet labels allow reentry to the treated field by workers 24 hours after application. The risk assessment indicates that risks could exceed EPA's LOC for workers entering fields at this time period. In addition, stakeholder comments prior to the July 2008 RED indicated that non-handler entry to perform post-application (i.e., non-handler) tasks is generally not needed for at least 10 to 14 days following the completion of the application.

Due to the volatile nature of MITC and the potential for exposure to unprotected workers, in the July 2008 RED the Agency restricted entry into the treated area by anyone other than a properly trained and protected handler. This restriction differs from Restricted Entry Intervals

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(REIs) that is currently required for most conventional pesticides where dermal exposure is the primary pathway of exposure. Under the Worker Protection Standard (WPS), exceptions allow certain tasks to take place before the REI has expired as long as dermal contact with treated surfaces will be limited; however for fumigants where inhalation exposure is the primary risk concern, entry to a treated area is further restricted.

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

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

- 5 days (120 hours) after application has ended for untarped applications (Figure 5), or
- After tarps are perforated and removed if tarp removal is completed less than 14 days after application (Figure 6), or
- 48 hours after tarps are perforated if they will not be removed prior to planting (Figure 7), or
- 5 days (120 hours) after application is complete if tarps are not perforated and removed until14 days after the application is complete (Figure 8).

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

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Figure 5. Untarped Applications

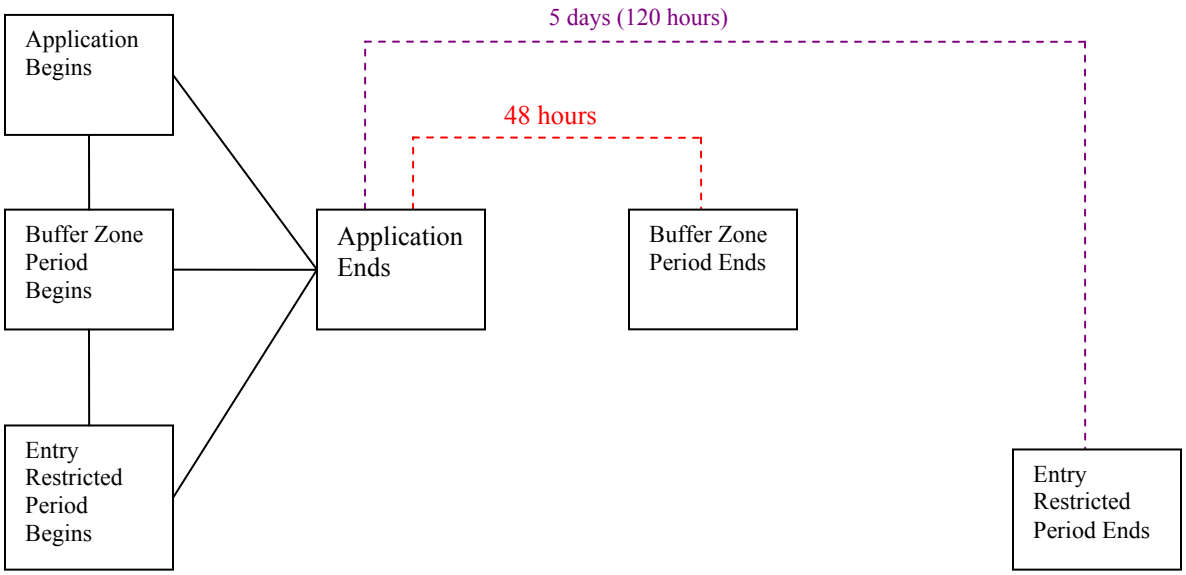

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Figure 6. Tarp Broadcast Applications (tarps removed before planting)

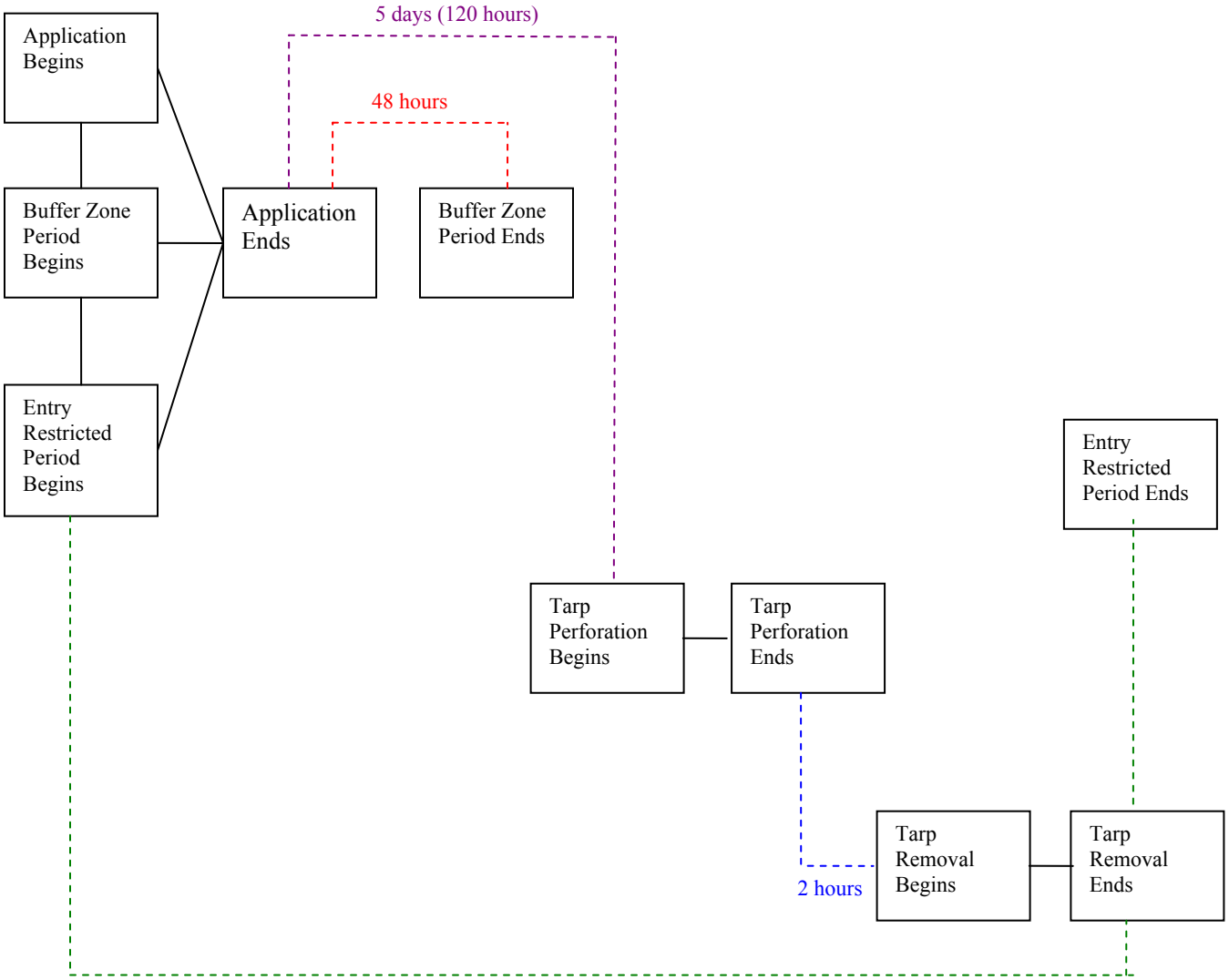

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Figure 7. Tarp Bed Applications (Tarps not removed before planting)

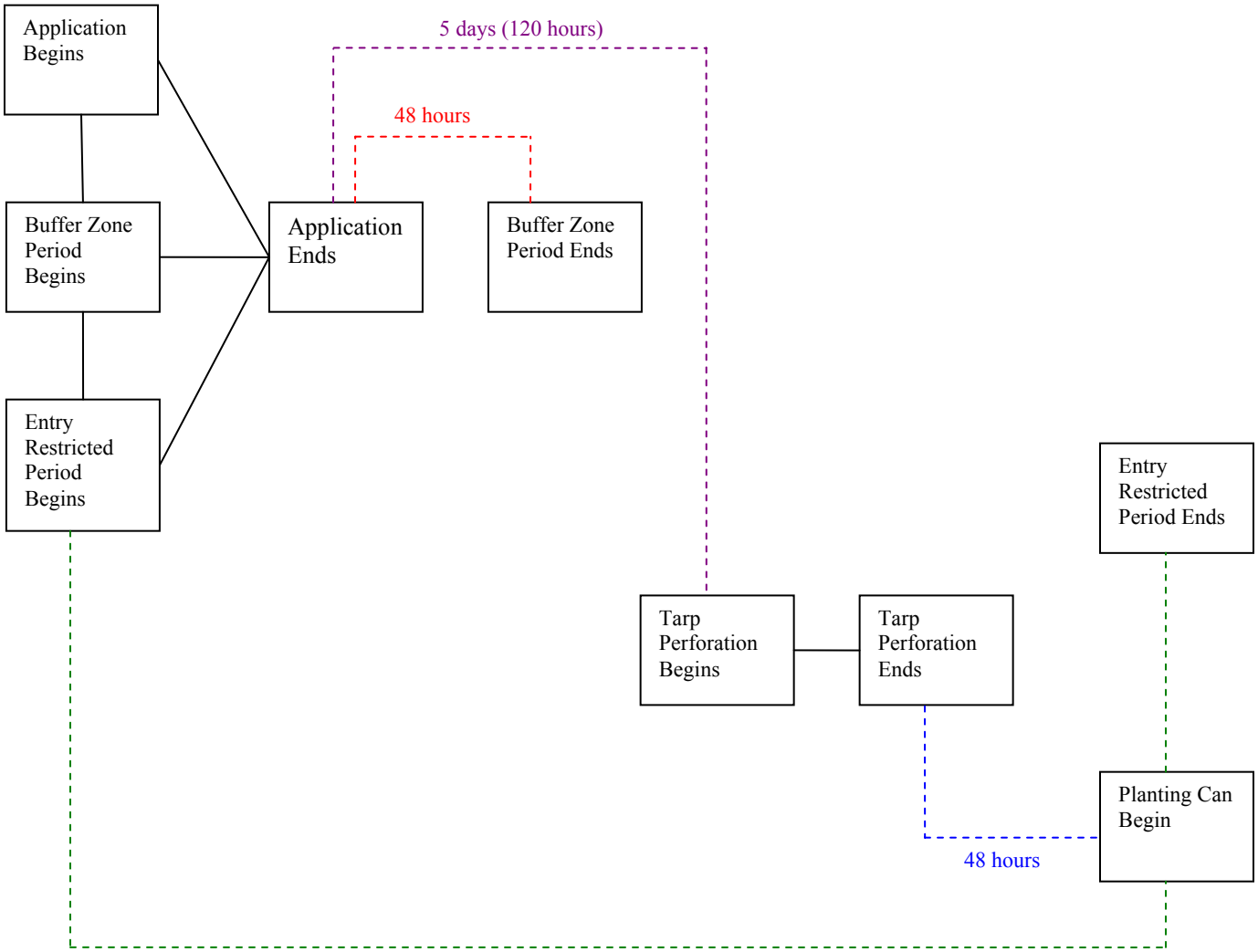

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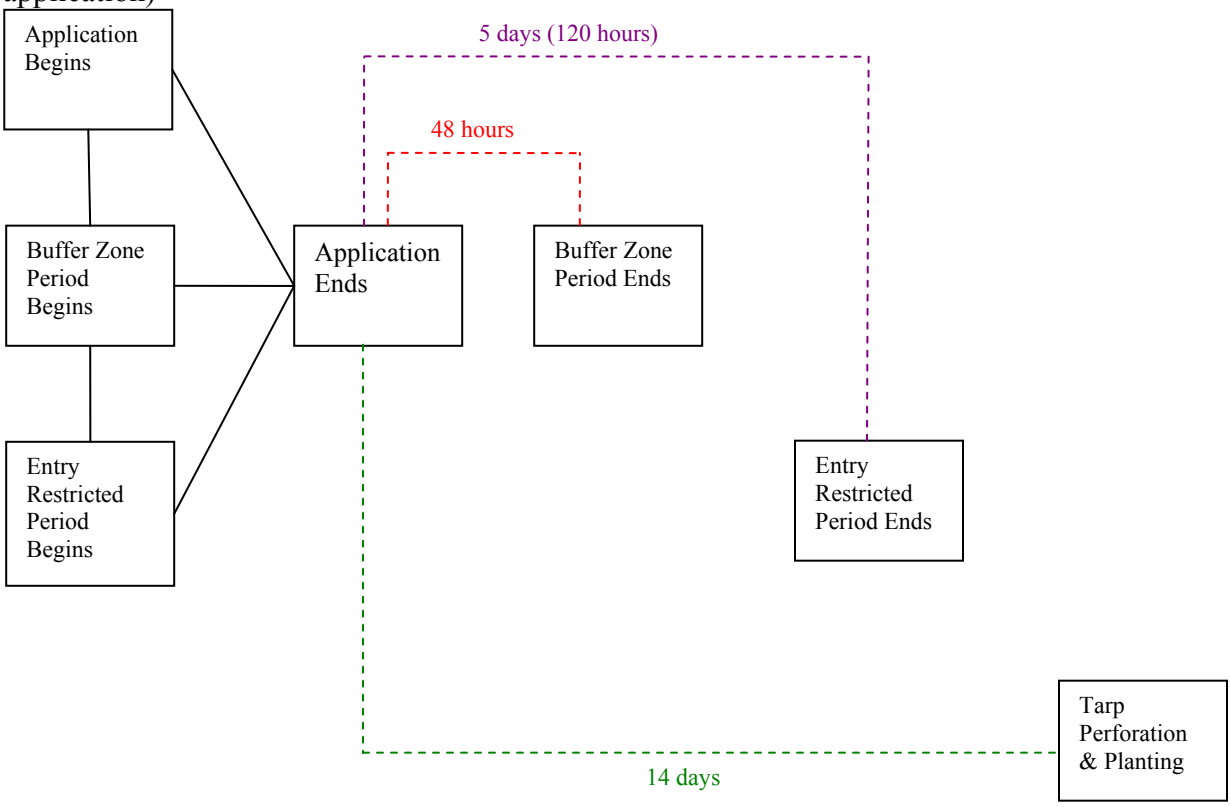
Figure 8. Tarp Bed/Broadcast Applications (Tarps are not perforated until 14 days after application)



cc. Other Risk Mitigation

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

1. Restricted Use Classification

All soil fumigant products containing methyl bromide, 1,3-dichloropropene (1,3-D), iodomethane, and chloropicrin are currently classified as RUPs. Soil fumigant products containing dazomet and metam sodium/potassium are currently unclassified. However, MITC, the byproduct of dazomet and metam sodium/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

US EPA ARCHIVE DOCUMENT

other evidence (as specified in 40 CFR 152.170(d)) including 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 dazomet (mostly toxicity categories III and IV. While the product toxicity of dazomet does 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 fumigants 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 risk 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 fumigants safely and accurately (e.g., compaction rig, tarp equipment, and self-contained breathing apparatus). To apply soil fumigants safely and ensure bystanders and applicators are not adversely affected, handlers also need specialized competencies.

In sum, dazomet meets the standard for restricted use because:

- The application of 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 dazomet soil fumigant products must be classified as restricted use. Label requirements will include the following, which is also contained in Table 9. This requirement has not changed from the July 2008 RED.

<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."

US EPA ARCHIVE DOCUMENT

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

Since the application methods and work practices of fumigators have direct impacts on the amount of fumigant applied and emitted, the Agency determined that labeling should require proven practices that will reduce risks to handlers, bystanders, and the environment. Registrants, applicators, growers, and other stakeholders have consistently reported to the Agency that GAPs are a key mitigation measure to reduce the amount of fumigants applied and fumigant emissions.

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

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

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

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

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

The Agency has clarified the language regarding inversions and wind speed requirements. The Agency agrees that erosion control is an important consideration. However,

US EPA ARCHIVE DOCUMENT

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

The following are mandatory GAPs that already appear on dazomet product labels. Some of the measures have been updated to clarify the language and be consistent among the fumigant chemical product labels.

- Do not use dazomet when the soil temperature is extremely high (over 90° F at 2"deep).
- Do not apply dazomet if ambient air temperature exceeds 103° F.
- Do not apply within 3-4 feet of growing plants or closer than the drop line of trees and large shrubs. If slopes are treated with this product, take precautions to prevent the chemical from washing downward to growing plants.
- The area intended for treatment should be in seedbed condition with a fine tilth, free of clods. Do not apply dazomet to dry or improperly tilled soil. Repeated cultivation before treating will improve control of perennial weeds. Ditching around the site will prevent weed seeds, nematodes, and fungi from washing into the treated area and contaminating it.
- For optimal effect, the soil to be fumigated must have sufficient moisture for good plant growth (at least 50% field capacity) for 5-14 days (depending on temperature) before the treatment.
- After application, the soil must be kept uniformly moist for 5-7 days. As soon as possible after incorporation, the soil must be sealed to retain the concentration of gases in the soil which can be achieved by:
  - Compacting the soil surface after incorporation with a roller attached behind the compacting implement.
  - Moistening the surface after incorporation so a crust forms.
  - Lightly moistening the soil on the third and fourth days after treatment in case the weather dries out the soil surface to avoid surface cracks.
  - In difficult situations best results may be obtained by tarping the treated area.
- Do not store dazomet in an open spreader overnight.
- Do not apply dazomet when wind may cause granules to drift from target area.
- Do not apply dazomet through any type of irrigation equipment.
- Before using dazomet be aware that the three most critical factors for a successful fumigation program are: soil preparation, soil temperature, and soil moisture.

Weather Conditions

US EPA ARCHIVE DOCUMENT

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

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

Based on these comments the Agency has revised the "weather conditions" section of the GAPs that relates to temperature inversions to clarify that parts of the weather conditions that are requirements and those that are included to help guide the applicator to identify temperature inversions. The measures have also been updated to prohibit application only if temperature inversion conditions are forecasted to persist for more than 18 of the 48 hours after the start of the application since this will filter out conditions when diurnal temperature inversions may occur, though even diurnal temperature inversions could contribute to exposures to fumigant concentrations outside buffers. As such, EPA believes that the measures described below in the emergency preparedness and response section of this document are important to address potential risks associated with shorter-term diurnal inversions. The Agency is also changing the wind speed requirement so winds may either be 2 mph at the start of application or be forecasted to reach 5 mph during the application. These changes are designed to prevent applications when inversion conditions are predicted to occur after the application has begun, since this is the time when the peak off-gassing is expected to occur. In summary, EPA has determined that applicators must (1) check the weather forecast and make a decision whether to proceed with a planned fumigation, based on conditions that are predicted, (2) only begin a fumigant application if wind speed is a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application, and (3) not fumigate if there will be a persistent low-level local inversion or an air stagnation advisory is in effect. EPA believes advisory language providing more detailed information on how to identify inversions and adverse weather conditions will increase the likelihood that applicators will proceed with applications only when weather conditions are or are forecast to be favorable for safe fumigations. See below and the label table in Section V of this document for label statements.

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

US EPA ARCHIVE DOCUMENT

Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigation *must* be checked to determine if unfavorable weather conditions exist or are predicted and whether fumigation should proceed.

Wind speed at the application site must be a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application.

Do not apply if a shallow, compressed (low-level) temperature inversion is forecast to persist for more than 18 consecutive hours for the 48-hour period after the start of application, or if there is an air-stagnation advisory in effect for the area in which the fumigation is planned.

Detailed local forecasts for weather conditions, wind speed, and air stagnation advisories may be obtained on-line at: http://www.nws.noaa.gov. For further guidance, contact your local National Weather Service Forecasting Office.

Unfavorable Weather Conditions

Unfavorable weather conditions block upward movement of air, which results in trapping fumigant vapors near the ground. The resulting air mass can move off-site in unpredictable directions and cause injury to humans, animals or property. These conditions typically exist prior to sunset and continue past sunrise and persist as late as noontime. Unfavorable conditions are common on nights with limited cloud cover and light to no wind and their presence can be indicated by ground fog or smog and can also be identified by smoke from a ground source that flattens out below a ceiling layer and moves laterally in a concentrated cloud.

All measurements and other documentation planned to ensure that the mandatory label requirements are achieved must be recorded in the FMP and/or the post application summary report.

3. Fumigant Management Plans (FMPs)

As noted elsewhere in this document, soil fumigation is a complex site-specific activity. Failure to adhere to label requirements and procedures for safe use has led to accidents affecting workers involved in fumigations as well as bystanders. Information from various sources shows that health and safety plans, FMPs in this context, typically reduce workplace injuries and accidents by prescribing a series of operational requirements and criteria. In fact plans like these are widely implemented in a variety of industries and are recommended as standard approaches for occupational health and safety management by groups such as American Industrial Hygiene

US EPA ARCHIVE DOCUMENT

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 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]

In the July 2008 RED, EPA required FMPs to be completed before a fumigant application occurs. EPA concluded that FMPs will reduce potential risks to bystanders as well as handlers by requiring that applicators have carefully planned, in writing, each major element of the fumigation. In this context, an FMP is a set of performance criteria for each application, including how the fumigator intends to comply with label requirements. As added benefits, the Agency determined that FMPs would ensure directions on the product labels were followed and that the conditions under which fumigation occurred were documented. EPA also concluded that FMPs would help ensure an appropriate response by the applicator or others involved in the application should an incident occur since a proper and prompt response would reduce the potential risk to bystanders from potential high exposure situations (e.g., readily available first responder contact information could reduce response times to impacted bystanders and carefully thought out emergency response plans can help ensure appropriate actions are taken in case of unforeseen events).

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

[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

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

US EPA ARCHIVE DOCUMENT

any problems such as complaints or incidents that occurred as a result of the fumigation. The RED also specified requirements for record keeping and that FMPs must be provided, upon request, to enforcement officials and handlers involved in the fumigation.

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

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

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

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

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

Amended FMP Requirements

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

The Agency agrees with comments that having both the applicator and the owner/operator provide copies of the FMP to handlers is unnecessarily duplicative and that providing each worker with a hardcopy of the FMP wastes paper. The Agency also agrees that it is not necessary for the FMP to be provided to the workers in areas adjacent to the application block. Workers in adjacent areas will be notified of the fumigation by buffer posting requirements and, in the case of neighbors whose land is part of a buffer zone, the adjoining neighbor has responsibility for workers in areas adjacent to the application for which permission was granted to use as part of a fumigation buffer. The Agency has revised the following requirement that was included in the 2008 RED, "Once the application begins, the certified applicator and owner/operator of the application block must provide a copy of the FMP to handlers involved in the fumigation, workers in adjacent areas to the application block, and federal/state/local enforcement personnel, upon request." The RED Amendment requires the certified applicator to make a copy of the FMP available for viewing by handlers involved in the fumigation. The certified applicator or the owner/operator of the application block must provide a copy of the FMP to any federal, state, tribal, or local enforcement personnel who request the FMP. In the case of an emergency, the FMP must be made available when requested by federal/state/local emergency response and enforcement personnel.

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

Each site-specific FMP must contain the following elements:

- Applicator information (name, phone number, license number, employer name, employer address, date of completing registrant dazomet training program)
- General site information
  - Application block location, address, or global positioning system (GPS) coordinates
  - Name, address, and, phone number of owner/operator of the application block
  - Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, roads, rights-of-ways, sidewalks, permanent walking paths, bus stops, water bodies, wells, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ or ⅛ mile buffer zones (e.g., schools, state licensed day care centers, nursing homes, assisted living facilities, hospitals, in-patient clinics and prisons) with distances from the application site labeled
- General application information (target application date/window, brand name of fumigant, EPA registration number)
- Tarp Information and procedures for repair, perforation and removal (if tarp is used)

US EPA ARCHIVE DOCUMENT

- Brand name, lot number, thickness
- Name and phone number of person responsible for repairing tarps
- Schedule for checking tarps for damage, tears, and other problems
- Maximum time following notification of damage that the person(s) responsible for tarp repair will respond
- Minimum time following application that tarp will be repaired
- Minimum size of damage that will be repaired
- Other factors used to determine when tarp repair will be conducted
- Name and phone number of person responsible for cutting and/or removing tarps (if other than certified applicator)
- Equipment/methods used to cut tarps
- Schedule and target dates for cutting tarps
- Schedule and target dates for removing tarps

- Soil conditions (description of soil texture in application block, method used to determine soil moisture)
- Weather conditions (summary of forecasted conditions for the day of the application and the 48-hour period following the fumigant application)
  - Wind speed
  - Inversion conditions (e.g., shallow, compressed (low-level) temperature inversion)
  - Air stagnation advisory
- Buffer zones
  - Application method
  - Application rate from lookup table on label (lb ai/A)
  - Application block size from lookup table on label (acres)
  - Credits applied
  - Buffer zone distance
  - Description of areas in the buffer zone that are not under the control of the owner/operator of the application block
- Respirators and other personal protective equipment (PPE) for handlers (handler task, protective clothing, respirator type, respirator cartridge type, respirator cartridge replacement schedule, eye protection, gloves, other PPE)
- Emergency procedures (evacuation routes, locations of telephones, contact information for first responders, local/state/federal contacts, key personnel and emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).
- Posting procedures (person(s) who will post signs, location of posting signs, procedures for sign removal)
- Site-specific response and management (if applicable)
  - Fumigant site monitoring
    - Description of who, when, where, and procedures for monitoring buffer zone perimeter
  - Response information for neighbors
    - List of residences, businesses, and neighboring property owners informed
    - Name, address, and phone number of person doing notification

US EPA ARCHIVE DOCUMENT

- Method of sharing information

- State and tribal lead agency notification (If state and/or tribal lead agency requires notice, provide a list of contacts that were notified and date notified.)
- Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (e.g., tarp cutters/removers, irrigators) for complying with label requirements (e.g., buffer zone location, buffer zone start/stop times, timing of tarp cutting and removal, PPE).
  - Name and phone number of persons contacted
  - Date contacted
- Authorized on-site personnel
  - Names, addresses and phone numbers of all handlers
  - Employer name, addresses, and phone numbers for all handlers
  - Tasks that each handler is authorized and trained to perform
  - Date of PPE training for each handler
  - For handlers designated to wear respirators when respiratory protection is required (minimum of one handler), date of medical qualification to wear a respirator and date of fit testing for respirator.
- Air monitoring
  - For buffer zone monitoring:
    - Name, address, and phone number of handler to perform monitoring activities
    - Location and timing of monitoring for the buffer zone
  - For handlers without respiratory protection:
    - If sensory irritation is experienced, indicate whether operations will be ceased or operations will continue with respiratory protection
    - If intend to cease operations when sensory irritation is experienced, provide the name, address, and phone number of the handler that will perform monitoring activities prior to operations resuming
  - For handlers with respiratory protection:
    - Representative handler tasks to be monitored
    - Monitoring equipment to be used and timing of monitoring
- Good Agricultural Practices (GAPs)
  - Description of applicable mandatory GAPs (registrants may also include optional GAPs)
  - Measurements and documentation to ensure GAPs are achieved (e.g., measurement of soil and other site conditions)
- Description of hazard communication. (The buffer zone around the application block has been posted in accordance with the label. Pesticide product labels and material safety data sheets are on-site and readily available for employees to review.)
- Record keeping procedures (the owner/operator of the application block as well as the certified applicator, must keep a signed copy of the site-specific FMP and the post application summary for 2 years from the date of application).

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

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

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

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

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

- Actual date of the application, application rate, and size of application block fumigated
- Summary of weather conditions on the day of the application and during the 48-hour period following the fumigant application
- Tarp damage and repair information (if applicable)
  - Location and size of tarp damage
  - Description of tarp/tarp seal/tarp equipment failure
  - Date and time of tarp repair
- Tarp removal details (if applicable)
  - Description of tarp removal (if different than in the FMP)
  - Date tarps were cut
  - Date tarps were removed
- Complaint details (if applicable)
  - Person filing complaint (e.g., on-site handler, person off-site)
  - If off-site person, name, address, and phone number of person filing complaint
  - Description of control measures or emergency procedures followed after complaint
- Description of incidents, equipment failure, or other emergency and emergency procedures followed (if applicable)
- Details of elevated air concentrations monitored on-site (if applicable)
  - Location of elevated air concentration levels
  - Description of control measures or emergency procedures followed
  - Air monitoring results

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

- When sensory irritation experienced:
  - Date and time of sensory irritation
  - Handler task/activity
  - Handler location where irritation was observed
  - Resulting action (e.g., cease operations, continue operations with respiratory protection)
- When using a direct read instrument:
  - Sample date and time
  - Handler task/activity
  - Handler location
  - Air concentration
  - Sampling method

❖ Date of sign removal
❖ Any deviations from the FMP

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

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

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

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

4. Site Specific Response and Management

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

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

To ensure that appropriate response mechanisms are in place in the event of a fumigant exposure incident, EPA is requiring that registrants provide training information, in the context of their community outreach and education programs to first responders in high-fumigant use areas and areas with significant interface between communities and fumigated fields. In addition, for situations in which people, homes, or other structures are in close proximity to buffer zones, applicators must either monitor buffer zone perimeters or, alternatively, provide emergency response information directly to neighbors. Each element is discussed in more detail below.

First Responder Education

EPA is requiring registrants through their community outreach and education programs (see the Community Outreach and Education Section), to ensure that emergency responders have the training and information that they need to effectively identify and respond to fumigant exposure incidents. EPA believes this will help ensure, in the case of a fumigant accident or incident that first responders recognize the exposure as fumigant related and respond appropriately. Additional details are included in the Community Outreach and Education Section of this document.

Emergency Preparedness and Response Considerations for the 2008 RED

Prior to the 2008 RED the EPA received comments from many stakeholders about the Agency's emergency preparedness and response option. Users have commented that notification is burdensome and that it is unnecessary if buffer zones are also required. However, community groups have commented on the importance of bystanders being informed when fumigations are occurring, since this group of pesticides, compared to other pesticides, has a greater potential to move off site and affect people not involved in the application. State regulators have different views on this requirement. Some support the sharing of information with neighbors, and some states have notification requirements for fumigations with certain products or for certain application methods. In addition, some states require notification to chemically sensitive individuals in proximity to pesticide applications. Others also had concerns about the enforceability of this type of measure and the possible burden on the states to enforce a notification requirement.

California currently requires notification of persons within 300 feet of a methyl bromide buffer zone. California strawberry growers consider the 300 foot notification area for methyl

US EPA ARCHIVE DOCUMENT

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

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

Providing communities with information about local chemical releases is an important part of emergency preparedness programs and is recognized as an effective means of addressing risk at the local level. Some states, like Florida and Wisconsin, have requirements for providing information to chemically-sensitive individuals about chemicals used nearby so they can take steps to protect themselves from potentially harmful exposures (see http://edis.ifas.ufl.edu/pi004 and http://www.legis.state.wi.us/rsb/code/atcp/atcp029.pdf). The requirements in Florida do not apply to agricultural chemical applications. Wisconsin also requires fumigators applying metam sodium products through chemigation to provide written notice to the county public health agency and to every individual or household within ¼ miles of the chemigation application site (see http://www.legis.state.wi.us/rsb/code/atcp/atcp030.pdf). EPA agrees that information about how to recognize and address exposures can help citizens reduce potential risk.

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

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

Emergency Preparedness and Response Revisions

US EPA ARCHIVE DOCUMENT

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

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

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

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

US EPA ARCHIVE DOCUMENT

concentrations of fumigant moving beyond buffers is greatest (i.e., at dawn and dusk). As a precaution, monitoring is also required once during the night and during the day.

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

While the Agency is modifying the procedures for monitoring buffer zones because of technological limitations of currently available devices for MITC and chloropicrin that are not practical or reliable for field use, the Agency does believe that quantitative air monitoring would enhance safety if the appropriate technology were available as it is for methyl bromide. Some equipment manufacturers have indicated interest in developing devices that would be more functional and reliable for field fumigation applications (e.g., badge-type monitors). EPA encourages such efforts and plans to stay abreast of developments and improvements in monitoring devices and will consider this issue again in Registration Review or sooner should such monitors become available in the short term. In the interim, buffer monitoring for the MITC generating chemicals and chloropicrin will rely on sensory indicators (e.g., eye and/or nose irritation) to trigger a response instead of using tubes. Monitoring tubes are still required for measuring products that contain more than 80% methyl bromide.

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

Emergency Preparedness and Response Requirements

US EPA ARCHIVE DOCUMENT

When are Emergency Preparedness and Response Measures Needed?

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

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

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

Fumigation Site Monitoring

EPA has determined that monitoring of the buffer zone perimeter for fumigants moving beyond buffers is an effective approach to protecting bystanders. Under this approach, if the person monitoring the buffer perimeter experiences eye or nasal irritation, an early sign of exposure to concentrations that exceed the Agency's action level, then the emergency response plan specified in the FMP must be implemented. If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. Because data indicate that peak concentrations sometimes occur on the second day following applications, and the greatest potential for concentrations outside buffers may be observed at dawn and dusk, EPA has decided that this monitoring must be done at least three times per day during the full buffer zone period at dawn, dusk, and once during the night and during the day, to ensure concentrations do not exceed the action level which will be specified on product labels.

Specific requirements include:

- Monitoring must take place beginning on the day the application begins until the buffer zone period expires.
- Monitoring must be conducted by a certified applicator or someone under his/her supervision.
- Monitoring for air concentrations above the action level for the fumigant, as determined by sensory irritation, must take place in areas between the buffer zone perimeter and residences or other occupied areas that trigger this requirement.
- The person monitoring for perceptible levels must start monitoring approximately 1 hour before sunset of the day the application begins and continue once during the night, once at 1 hour after sunrise, and once during the day until the end of the buffer zone period.

US EPA ARCHIVE DOCUMENT

- If at any time the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented.
- If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.
- The location and any results of the air monitoring must be recorded in the FMP.

While protective, this site monitoring might be burdensome for users fumigating in areas with few people. Therefore, EPA is allowing users the alternative option of providing emergency response information directly to neighbors.

Response Information for Neighbors

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

- Information that must be provided includes:
  - The general location of the application block,
  - Fumigant(s) applied including the active ingredient, name of the fumigant products(s), and the EPA Registration number,
  - Contact information for the applicator and property owner/operator,
  - Time period in which the fumigation is planned to take place (must not range more than 4 weeks),
  - Early signs and symptoms of exposure to the fumigant(s) applied, what to do, and what emergency responder phone number to call who to call if you believe you are being exposed (911 in most cases), and.
  - How to find additional information about fumigants.

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

To clarify this measure, the following example is provided:

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

Figure 9. Example Site Map for Informing Neighbors

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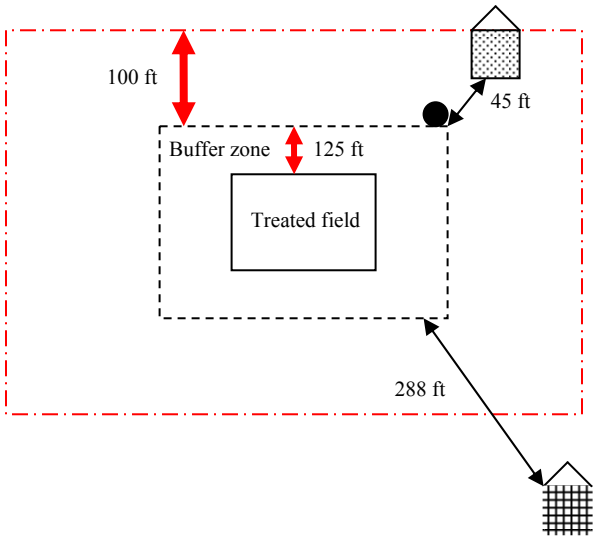

If there are no residences or other occupied structures within 300 feet of the edge of the buffer zone, or if the buffer distance is the minimum of 25 feet, neither site monitoring nor providing information to neighbors is required.

5. Notice to State Lead Agencies

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

Following publication of the July 2008 REDs, the Agency received feedback from some states that were interested in receiving the notice because it would enhance their ability to provide technical assistance and assure compliance. However, the Agency also received comments from states that were concerned about the notification requirement largely due to resource constraints. Some states also indicated that they are already well-informed about when and where fumigations take place, and receiving specific notice of applications would create a paperwork burden rather than aid their compliance assistance and assurance programs. Some states recommended that, in lieu of receiving notice of fumigations, states could modify their cooperative agreements with EPA to incorporate specific strategies for assuring compliance with the new fumigant labels. States also suggested that rather than providing notice directly to states,

US EPA ARCHIVE DOCUMENT

fumigators could enter application information into a registrant-developed and maintained database. They suggested this would be an appropriate mechanism because it would standardize and streamline the process for applicators to provide the required information, and states could access and utilize information more quickly, with greater ease, and using fewer state resources.

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

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

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

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

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

Soil fumigation is an inherently complex activity involving specialized equipment and application techniques. Additionally, the mitigation measures required as part of these decisions will introduce new requirements in the form of more detailed instructions and restrictions on soil fumigations. Failure to adequately manage fumigant applications increases risks to handlers involved in the fumigation, nearby workers, and other bystanders. Incident data show that a number of fumigant incidents are the result of misapplications, failure to follow label requirements and other safety precautions, and other errors on the part of fumigant applicators.

US EPA ARCHIVE DOCUMENT

Although states have certification programs, some of which include a specific category or subcategory for soil fumigation, there currently is not a consistent standard across states and regions where soil fumigation is done. Additionally, the federal certification program currently has no category for soil fumigation, and while EPA is considering the development of a category for soil fumigation, the potential changes to the federal certification program and worker safety regulations to include a soil fumigation category are not anticipated in the near future.

EPA believes that training is an effective way to increase applicators' skill and knowledge so they are better prepared to effectively manage the complexities and risks associated with soil fumigation. Further, training is a means of ensuring fumigators are able to understand and comply with revised fumigant labeling. Therefore, EPA determined that training designed to establish a national baseline for safe fumigant use, developed and implemented by registrants, will help enhance fumigators' ability to adequately manage the complexities of soil fumigation and enhance compliance with fumigant product labeling. EPA also determined that providing additional safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from risks of exposure.

Soil Fumigation Training Considerations

In comments on fumigant risk management options, stakeholders were broadly supportive of additional training for applicators and handlers. During the Phase 5 and post-RED comment periods, the majority of stakeholders, including growers, community groups, farm workers, states, and registrants expressed strong support for increased training for applicators and other handlers. Several comments noted that fumigant incidents affecting both fumigant workers and bystanders could have been prevented or mitigated if applicators had better training about correct practices and procedures.

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

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

US EPA ARCHIVE DOCUMENT

As noted above, several states have high-quality certification programs for fumigators that include exams to test the competency of fumigators. EPA recognized that for applicators to become certified in those states, they must acquire the knowledge and skill necessary to pass the exam. But several stakeholders commented that training opportunities are varied across the country, and the scope and detail of information provided in available training is not consistent. EPA is also concerned that information in existing programs will need to be substantially updated as a result of new requirements associated with this decision and the label changes which will implement it. Although EPA is considering revisions to the federal certification and training program in the future to include a soil fumigation category/subcategory, EPA believes that registrants have access to resources and materials to best develop and deliver training in the interim.

EPA stresses that registrant training programs will be separate from the state certification process and will be developed and administered by registrants in coordination with EPA. EPA will, however, work with state organizations and training experts to explore opportunities for the registrant programs to supplement any existing state programs to provide additional training resources for fumigators working in those states. EPA will also work with state lead agencies and extension programs to review training program proposals, the content for the programs and materials, and proposed vehicles for delivery.

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

Pesticide labels will state that the certified applicator supervising that application must have successfully completed, within the last 36 months, a dazomet training program made available by the registrant. The Fumigant Management Plan must document when and where the training program was completed. This requirement for registrant-provided applicator training does not supersede or fulfill state requirements, unless the state has expressly acknowledged that the registrant training may substitute for state requirements.

Training for Applicators Supervising Fumigations

The July 2008 RED required registrants to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and best management practices for soil fumigants. During the public comment period on the proposed mitigation measures and the post-RED comment period, stakeholders were broadly supportive of additional training for fumigators, but concerns were raised with regard to implementation of the training. The Agency also received comments from state representatives and pesticide applicator training

US EPA ARCHIVE DOCUMENT

organizations, such as the Association of American Pesticide Control Operators, American Association of Pesticide Safety Educators, and Certification & Training Assessment Group, expressing concern over EPA's decision to implement the training via labeling and raising questions over compliance and state enforcement of such a requirement and the potential for conflict or redundancy with state certification and training programs. Various stakeholders recommended that, rather than a label-mandated training requirement, the Agency, instead, should require registrants to develop and implement training for soil fumigant applicators as a condition of registration.

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

Each registrant must develop and implement training programs for applicators in charge of soil fumigations on the proper use of and best practices for soil fumigants. In addition, registrants will be required to submit proposals for these programs as data requirements that will accompany this RED. EPA will review each program and determine whether it adequately addresses the requirements specified in the DCI. The proposal must address, among other elements, both the content and the format for delivering training. The Agency acknowledges the value of hands-on training in the field, but recognizes that may not be feasible in all instances. The Agency welcomes and is actively seeking participation from state lead agencies and extension programs in the evaluation of the registrant training proposals and materials that are submitted.

The training programs must address, at a minimum, the following elements: (1) how to correctly apply the fumigant, including how to comply with new label requirements; (2) how to protect handlers and bystanders; (3) how to determine buffer zone distances; (4) how to develop a FMP and complete the post-fumigation application summary; (5) how to determine when weather and other site-specific factors are not favorable for fumigant application; and (6) how to comply with required GAPs and how to document compliance with GAPs in the FMP. In addition, based on comments received during the post-RED comment period, the Agency is

US EPA ARCHIVE DOCUMENT

adding a seventh training element—training programs must also include information on how to develop and implement emergency response plans—to ensure that applicators are prepared in the event that a problem develops during or shortly after the fumigant application. EPA is also requiring registrants to incorporate a mechanism for evaluating the effectiveness of their training programs at conveying the required information to participants and for determining whether participants have successfully completed the training program.

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

In the July 2008 RED, the Agency required applicators supervising fumigations to complete the training annually. During the post-RED public comment period, the Agency received comments from various stakeholders indicating that the substance and content of training would not change significantly from year to year, and that an annual training requirement for applicators would be excessive and burdensome to both applicators and registrants and was unnecessary. As a result of these comments, the Agency has decided to require applicators supervising fumigations to have successfully completed the program within the preceding 36 months and to document when and where the training program was completed in their FMPs. This may be accomplished, for example, by simply attaching a copy of the training documentation provided by the registrant to the FMP. The registrant also must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion.

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

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Training Materials for Handlers

EPA is requiring registrants to prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. The Agency is requiring registrants to submit proposals for these materials through the data call-ins that will accompany this RED. EPA will review these materials to determine whether they adequately address the requirements specified in the DCI. The Agency welcomes and is actively seeking participation from state lead agencies and extension programs in the evaluation of these handler training materials.

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

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

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

7. Community Outreach and Education Programs

EPA understands from public comments, site visits, and stakeholder meetings, conducted as part of the soil fumigant review, that there is often a fundamental lack of information and communication about soil fumigants within communities where soil fumigation occurs, which has raised health and safety concerns among community members. This lack of information and communication has led to inappropriate responses in cases where fumigants have moved off site and into communities. This also has led, in some cases, to unwarranted concern and anxiety among communities about the risks associated with the use of fumigants. The Agency believes that outreach and education to communities where soil fumigation occurs is an important component of the overall package of measures to address bystander risk. Community outreach will address the risk of acute bystander exposure by informing community members in high-use areas about buffer zones and their characteristics and purpose, the meaning of posted warning signs, the importance of not entering buffer zones, how to recognize early signs of fumigant exposure, and how to respond appropriately in case of an incident.

In the July 2008 RED, the Agency required registrants to develop and implement community outreach and education programs to address these needs. At a minimum, these programs were to include the following elements: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident as well as a plan for evaluating the effectiveness of these programs. Few details on how the programs would be implemented were provided in the RED. Rather, during the post-RED comment period, the Agency sought feedback from the registrants and other stakeholders on how best to design and target programs to community members in high-use areas. The Agency encouraged the registrants to work with existing community resources, such as community health networks, for disseminating information and implementing community outreach programs.

During the post-RED comment period, the Agency received some comments from stakeholders that suggested that having registrants develop and implement a community outreach and education program is unnecessary and likely to needlessly raise heath and safety concerns among community members, and such a requirement could draw scarce resources from other registrant stewardship efforts. As noted previously, the Agency believes that providing basic information about soil fumigants and buffer zones as well as information on what to do in the event that an incident occurs to communities in high fumigant use areas is an important component of the overall package of risk mitigation measures to address bystander risk. EPA's community outreach requirements do not preclude other voluntary stewardship programs or activities targeted to community members or the applicator/grower community, but rather are meant to help ensure that community members in high fumigant usage areas are informed about soil fumigant safety and better able to respond appropriately if an incident were to occur.

Few recommendations and no specific proposals for these programs were received during the post-RED comment period. Therefore, the Agency is identifying minimum requirements that each registrant must fulfill when developing its community outreach programs in response to a DCI that will be issued. The Agency remains open to considering additional registrant outreach program elements that address the same needs and goals as the program requirements described

US EPA ARCHIVE DOCUMENT

below in their response to the DCI. EPA notes that registrants have suggested that programs focusing on specific target audiences, such as staff and managers of migrant health care and day care facilities, prison officials, and school nurses and principals, may be more effective in providing useful information in a meaningful way than broadcast messages to entire communities. Registrants have indicated that they will provide proposals for such programs in late May 2009. EPA looks forward to these proposals and will consider the extent to which they contribute to meeting the goals of the community outreach programs required by the RED.

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

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

Information for First Responders

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

US EPA ARCHIVE DOCUMENT

information already included in state and local training for first responders about soil fumigants specifically.

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

The Agency is willing to consider additional registrant proposals so long as they address the same needs and achieve the same goals as the program requirements described below. At a minimum, registrants will be required to develop and disseminate chemical-specific soil fumigant training materials to first responders i.e., police, fire, rescue, emergency medical services, and others who respond to "911" calls) operating in high fumigant-use areas. As a data requirement in the DCIs that will accompany the REDs, registrants must submit proposals detailing how they will (1) identify the first responder entities in high soil fumigant-use areas to which they will disseminate the training materials, and (2) provide materials to the first responders in these areas. Additionally registrants must provide draft copies of the training materials for EPA review and approval. As per the requirements included in the July 2008 RED, at a minimum, the materials must convey the following information to first responders: (1) how to recognize the early signs and symptoms of dazomet fumigant exposure, (2) how to treat dazomet fumigant exposures, and (3) how dazomet fumigant exposures differ from other pesticide exposures as well as (4) copies of material safety data sheet(s) for the fumigant applied as well as for the active compound generated, if applicable. Training materials can take a number of forms, including: brochures, fact sheets, CDs, videos, web-based training materials, etc., as long as these materials incorporate, at a minimum, the information requirements identified above.

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

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

Process for Identifying High-Use Fumigant Areas:

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

- Step 1: Identifying States with High Use of Dazomet: The Agency is defining states with high usage of dazomet as those states where, on average, more than 100,000 lbs of dazomet are applied annually. To determine those states where, on average, more than 100,000 lbs of dazomet has been applied annually, the Agency obtained data on the average number of pounds of dazomet applied in all states across a ten–year period (1999-2008) using EPA proprietary data. To view the Agency's analysis of this data, please see the Biological and Economic Analysis Division's memo, "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 and supporting documentation located in the dazomet docket at EPA-HQ-OPP-2005-0128.

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

For the purposes of this analysis, the Agency defines a "major use site" as any crop that has more than 5% crop treated annually or more than 100,000 lb of dazomet applied annually. Given the low usage rates of dazomet at this time, the requirement for community outreach and first responder training programs will not likely be triggered. However, the Agency could review this issue during registration review to determine of dazomet usage has changed, such that community outreach and first responder training programs are determined to be necessary.

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

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

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

- Step 2: Identify the Counties in California with High Use of Metam Sodium:
    - EPA has identified the following as the major use sites of metam sodium/potassium: artichokes, cabbage, cantaloupes, carrots, onions, peanuts, peppers, potatoes, spinach, squash, tomatoes, and watermelons.
    - Using the 2007 USDA Census of Agriculture, registrants will need to obtain harvested crop acreage data for each of the 12 major use sites for metam sodium identified above for each county in California. (An example of this analysis is provided as a supporting document to the Biological and Economic Analysis Division's memo "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 and supporting documentation located in the dazomet docket at EPA-HQ-OPP-2005-0128)
    - Registrants will then need to sum the total number of combined crop acres for these major use sites for each county in California and then select all the counties that make up at least the top 90% of acreage in the county. [An example of this analysis is also provided as a supporting document to the Biological and Economic Analysis Division's memo "Process for Defining High-Use Fumigant Areas at State and County Levels" dated May 14, 2009 and supporting documentation located in the dazomet docket at EPA-HQ-OPP-2005-0128)

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

iii. Environmental Risk Management

In the July 2008 RED, EPA addressed the concerns about both aquatic and terrestrial risks are discussed in Section III.C. The July 2008 RED also stated that EPA believed that mitigation measures detailed in the Human Health Risk Mitigation Section would also reduce ecological risks. The Agency stated that although buffer zones and GAPs do not directly reduce the potential risk to ecological organisms, these mitigation measures do provide an incentive to reduce fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

US EPA ARCHIVE DOCUMENT

The July 2008 RED discussed exposure to terrestrial organisms such as birds and mammals, which could occur two ways, as either oral exposure to dazomet granules or by the inhalation route of exposure to the breakdown product MITC. Potential exposure to aquatic organisms may occur from surface runoff/leaching and drift (wind) of MITC.

The risk assessment also identified potential acute risks of concern for birds and mammals, since it is assumed they could be exposed to unincorporated dazomet granules. There are uncertainties about the aquatic risks since there are no toxicity data available. Additional eco-toxicity data are required for both dazomet and MITC.

Since dazomet is applied as a granular and watering in is required in order to activate the product, the amount of dazomet granular left on the soil surface to which birds and mammals could have access is not estimated in this assessment. It is likely the amount of dazomet actually available to birds and mammals is less than assumed in the risk assessment due to watering in.

In addition, the registrants will lower the maximum rate for dazomet from 530 to 425 lbs a.i./A for all use sites, except for golf-course renovation. This rate reduction will also reduce the potential for effects on non-target organisms. In addition, the structure of the buffer zones required in this decision encourages growers to use the lowest rate and block size feasible in order to establish the smallest possible buffer zone distance for an application. Although this mitigation measure does not directly reduce the potential risk to ecological organisms, it does provide an incentive to reduce fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

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

While the Agency believes that volatilization is this chemical's most important route of dissipation, it is being removed from the groundwater statement because volatilization is addressed in other areas of the mitigation package. The new language will state, "Dazomet has certain properties and characteristics in common with chemicals that have been detected in groundwater (dazomet is highly soluble in water and has low adsorption to soil)."

US EPA ARCHIVE DOCUMENT

The July 2008 RED also included language required for both tarped and non-tarped dazomet applications to minimize potential for leaching or runoff. During the post-RED comment period commenters stated that the following language was not clear or enforceable: "For **untarped** applications of dazomet, potential leaching into groundwater and runoff into surface water can be reduced by avoiding applications when heavy rainfall is forecasted to occur within 24 hours."

EPA would like to clarify that the statement was meant to be advisory and not mandatory. However in an effort to clarify the requirement the Agency has revised the July 2008 RED language as follows, "For untarped applications, leaching and runoff may occur if there is heavy rainfall after soil fumigation." The revised statement is based on information presented in a 2007 article by Zhang and Wang[11].

b. Dazomet Antimicrobial Uses

The Agency received comments on the RED for antimicrobial uses of dazomet. A summary of the risk mitigation measures for the antimicrobial uses of dazomet is presented below; for further information on the antimicrobial risk assessment and mitigation, please see these documents in the dazomet docket:

- *Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document.* (Walls, C., Dated June 4, 2008)

- *Risk Mitigation Measures and Updated Label Language for the Antimicrobial Uses of Dazomet (PC Code 035602) for the Reregistration Eligibility Decision Document.* (Garvie, H., Dated June 2 2008)

All of the dazomet antimicrobial uses are for occupational applications. These uses include: 1) a treatment during the production of pulp and paper; 2) a materials preservative treatment for paper coatings, non-food adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) a biocide treatment used during petroleum operations; 4) a biocide treatment used in recirculating cooling water systems; and 5) a remedial wood treatment to utility poles.

Risks of Concern

All of the occupational handler inhalation, dermal and total MOEs were above the target MOE of 100 (short-term and intermediate-term) except for the following scenarios:

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

US EPA ARCHIVE DOCUMENT

- Intermediate-term dermal exposure resulting from the preservation of epoxy flooring compounds via solid open pour methods: MOE = 58
- Intermediate-term total exposure resulting from the preservation of epoxy flooring compounds via solid open pour methods: MOE = 55
- Intermediate-term dermal exposure resulting from pulp and paper slimicide use via solid open pour methods: MOE = 79
- Intermediate-term total exposure resulting from pulp and paper slimicide use via solid open pour methods: MOE = 74
- Intermediate-term inhalation exposure resulting from the maintenance dose of microbe control in large water cooling system via metering pump: MOE = 98
- Intermediate-term total exposure resulting from the maintenance dose of microbe control in large water cooling system via metering pump: MOE = 55

Risk Mitigation Measures

- For epoxy flooring open pour scenario- labeling language must state that the product is not to exceed 3,500 ppm (maximum application rate of .35%) by weight of material treated.
- For the pulp and paper solid open pour scenario – update PPE language to state that long sleeve coveralls will be required in addition to wearing long sleeved shirt, long pants, shoes, socks, goggles or face shield and chemical resistant gloves.
- For the cooling tower use: update personal protective equipment (PPE) language to state that chemical resistant gloves are necessary, in addition to goggles or face shield.
- For all scenarios that use metering pumps, chemical resistant gloves must be used.
- Additional label instructions for pole treatment use requiring that pre-drilled holes are plugged immediately after application and instructions that holes are not to be drilled through seasoning checks.

The data requirements for dazomet's antimicrobial use and label changes are found in Section V.

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

US EPA ARCHIVE DOCUMENT

developed and vetted, dazomet may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species Considerations

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

D. Conclusion

The Agency has determined that products containing dazomet are eligible for reregistration provided the risk mitigation measures outlines above are adopted and label amendments are made to reflect these measures. Where labeling revisions are warranted, specific language is set forth in Section V of this document.

V. What Registrants Need to Do

EPA recognizes that the extent of the mitigation needed for dazomet and the other soil fumigants will require continued coordination among state regulatory agencies, EPA, registrants, growers and other stakeholders to ensure that all provisions of the RED are understood, that data are developed and evaluated expeditiously, and that bystander and worker protection measures are implemented as soon as practicable.

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

July 2008	Dazomet RED issued
October 2008	Comment period closed
May 2009	EPA responds to comments, amends RED as appropriate
Mid 2009	EPA issues product and generic DCIs
September 1, 2009	**Registrants must submit revised labels to EPA**, reflecting phase one of the mitigation measures as outlined in Table 2: restricted use, GAPs, rate reductions, limitations on use sites, new handler protection measures, tarp cutting and removal restrictions, extended worker re-entry restrictions, training information for workers, and relevant portions of the FMP requirements.
December, 2009	EPA reviews/approves new labeling for 2010 use season

US EPA ARCHIVE DOCUMENT

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

Labeling

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

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dazomet for the eligible uses has been reviewed and determined to be substantially complete. However, data to characterize the hazard of MITC, the degradate of dazomet, are not available and are necessary to confirm the reregistration eligibility decision documented in this RED.

Data requirements for all dazomet uses

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

US EPA ARCHIVE DOCUMENT

	(MITC)	
870.4200	Chronic/Carcinogenicity Mice – Inhalation (MITC)	TOX

870.6200 - Neurotoxicity Screening Battery

Acute neurotoxicity study in rat via the inhalation route with pathological evaluation of the complete respiratory tract. The Agency is using single day, acute exposures in its consideration of buffer zones following applications of dazomet. The toxicology data available to inform this decision are limited to an eye irritation study in human subjects and an acute inhalation study in rats. The purpose of the acute study in rats was to determine the LC50, not for use in hazard identification for human health risk assessment. The Agency can not 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 residential areas. 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 rats via inhalation with pathological evaluation of the complete respiratory tract in offspring is needed for MITC. 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 residential areas. 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. The Agency is 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 for MITC.

870.4200 - Chronic/Carcinogenicity in Rats and Mice

US EPA ARCHIVE DOCUMENT

Carcinogenicity studies for MITC per se are not available; 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.

Data requirements for dazomet's soil uses

OPPTS Guideline Number	Data Requirement	Study type
835.8100	Field Volatility from Soil	ORE
Special	Avian Acute Inhalation, MITC	ECO
850.2300	Avian Reproduction, Dazomet (bobwhite quail and mallard)	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, MITC	ECO
Special	Community Outreach and Education Program	Special
Special	Training for Applicators Supervising Fumigations	Special
Special	Training Materials for Handlers	Special
Special	Buffer Zone Posting Signs	Special

<u>835.8100 - Field Volatility from Soil</u>

Volatility studies are required for dazomet's soil uses to determine flux for modeling purposes of the breakdown products of dazomet, including formaldehyde.

<u>Special - Avian Acute Inhalation, MITC</u>

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.

<u>850.2300 - Avian Reproduction (bobwhite quail and mallard duck), Dazomet</u>

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US EPA ARCHIVE DOCUMENT

These studies are needed to assess potential reproductive effects in birds from exposure to the parent dazomet in the granular formulation. Neither of the existing studies is able to provide an overall NOAEL/LOAEL needed for risk assessment. There were problems with mixing of the diet in both studies and the mallard study had unacceptably high embryo mortality in the controls between day 21 and hatch. The studies indicate the possibility of severe reproductive effects, particularly in the mallard study, which included effects prior to those identified in the controls.

850.1075 - Acute Marine/Estuarine Fish, MITC

The aquatic risk assessment of dazomet 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 dazomet 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 dazomet 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

Dazomet is 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. The protocol should be modified to test using air concentrations of MITC.

850.4250 - Vegetative Vigor – Tier II, MITC

Dazomet is 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. The protocol should be modified to test using air concentrations of MITC.

850.4400 - Aquatic Plant Growth – Tier II, MITC

Only one of five 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 dazomet 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 - 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 ensure compliance 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 fumigant exposure.

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

The registrant must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion. Applicators supervising fumigations must have successfully completed the program within the preceding 36 months and must document when and where the training program was completed in the FMP. The registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training and (2) make this database available to state and/or federal enforcement entities upon request. In addition, the applicator must provide to Federal, State, or local enforcement personnel, upon request, documentation that verifies completion of the appropriate training program(s).

Training programs must also include information on how to develop and implement emergency response plans to ensure that applicators are prepared in the event that a problem develops during or shortly after the fumigant application. EPA is also requiring registrants to incorporate a mechanism for evaluating the effectiveness of their training programs at conveying

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the required information to participants and for determining whether participants have successfully completed the training program.

Special Study - Training Materials for Handlers

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

Special Study – Buffer Zone Posting Signs

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

The **treated area** sign (currently required for fumigants) must state the following: -- Skull and crossbones symbol  -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "Dazomet fumigant in USE," -- the date and time of fumigation, -- the date and time entry prohibition is lifted -- Name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation.	The **buffer zone** sign must include the following: -- Do not walk sign  -- "DO NOT ENTER/NO ENTRE," -- "Dazomet OR [Name of product] Fumigant BUFFER ZONE," -- contact information for the certified applicator in charge of the fumigation

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

Data requirements for dazomet's antimicrobial uses

Chemical Manufactures Association (CMA) unit exposure data to be called in:

- GLN 875.1200 – dermal indoor exposure
- GLN 875.1400 – inhalation indoor exposure
- GLN 875.1600 – applicator exposure monitoring data reporting
- GLN 875.1700 – product use information

Because dazomet degrades into MITC, the Agency needs MITC air concentration monitoring data for all enclosed facilities that utilize dazomet. 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 dazomet antimicrobial use in pulp and paper manufacturing. The purpose of this confirmatory study is to demonstrate that the paper manufacturing processes remove any residual dazomet and MITC - GLN 860.1520

Avian acute oral LD_{50} data using technical MITC to bobwhite quail or mallard duck – GLN 850.2100

Acute estuarine fish LC_{50} data using technical MITC – GLN 850.1075

Acute mysid shrimp using technical MITC – GLN 850.1035

Acute bivalve embryo larvae using technical MITC to Eastern oyster – GLN 850.1055

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices, and applicable policies.

B. End-Use Products

US EPA ARCHIVE DOCUMENT

1. Additional Product-Specific Data Requirements

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

2. Labeling for End-Use Products

In order to be eligible for reregistration, registrants must amend all product labels to incorporate the risk mitigation measures outlined in Section IV.

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Appendix A

Appendix A(1). Dazomet (PC Code 035602) Soil Fumigant Uses Eligible for Reregistration

Use Site	Formulation	Method of Application	Maximum Application Rate	Use Limitations
Soil				
Nonbearing crops (such as orchard crops, berries, and flower bulbs), ornamental sites (establishing or renovating), field nurseries (establishing or renovating), compost piles, potting soils, and strawberries and tomatoes in California only	Granular	Tractor drawn spreader	425 lbs ai/A for incorporated applications. 265 lbs ai/A for surface applications.	Application with hand-held applications is prohibited. See the label table in Section V for additional use restrictions.
Golf greens/tees, turf sites (establishing or renovating),	Granular	Tractor drawn spreader	530 lbs ai/A for incorporated applications. 265 lbs ai/A for surface applications.	Application with hand-held applications is prohibited. See the label table in Section V for additional use restrictions.
Greenhouses	Granular	Tractor drawn spreader/ mechanical spreader	265 lbs ai/A for surface applications.	Application with hand-held applications is prohibited. See the label table in Section V for additional use restrictions.

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Appendix A(2). Dazomet (PC Code 035602) Antimicrobial Uses Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials Preservatives				
Slurries and high viscosity suspensions (starches, non-food use adhesives, clay slurries, glues, coatings for paper and resin emulsions)	Ready to use solution 1706-193	Pump or Gravity feed	Add 0.03-0.50% by weight based on the total formulation. Actual use levels should be determined by a test of the system.	
	Soluble concentrate 1448-104 33753-25	Pump or Gravity feed	Add 0.01-0.11% by weight based on the total formulation. Actual use levels should be determined by a test of the system.	
	Flowable concentrate 67869-25	Pump or Gravity feed	Add 0.5-2.5% by weight of the suspension or dispersion. Actual use levels should be determined by a test of the system.	
	Soluble concentrate 67869-46	Pump or Gravity feed	Add at concentration of 250 ppm to 5000 ppm to water	
	Formulation Intermediate 1448-98			
Slurries and high viscosity suspensions (starches, non-food use adhesives, clay slurries, and coatings for paper)	Ready to use solution 1448-103 1448-395 1706-193 9386-3	Pump or Gravity feed	Add 0.04-0.5 % by weight based on the total formulation. Actual use levels should be determined by a test of the system.	

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	9386-28			
	Ready to use solution 74655-1	Pump or Gravity feed	Add 1.67-2.5 pounds per 1000 gallons of material to be preserved. Actual use levels should be determined by a test of the system.	
	Formulation Intermediate 1448-98			
Slurries and high viscosity suspensions (starches, non-food use adhesives, clay slurries, coatings for paper, and glues)	Soluble concentrate 1706-195	Pump or Gravity feed	Add 0.04-0.1% by weight based on the total formulation. Actual use levels should be determined by a test of the system.	
Paper and pulp mill Slime control	Ready to use solution 1448-103 1448-395 9386-3 9386-28	Pump or Gravity feed	Intermittent method: Add 12-20 oz per ton (dry basis) of pulp or paper for two hours every 8 hours. Continuous method: Add 5-15 oz per ton (dry basis) of pulp or paper on a continuous basis.	Badly fouled systems may require cleaning before initial treatment.
	Ready to use solution 1706-193	Pump or Gravity feed	Add 5-36 oz per ton of finished product on a continuous basis. Actual use levels should be determined by a test of the system.	Shock dosages are to be avoided. Badly fouled systems may require cleaning before initial treatment.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Ready to use 1706-195	Pump or Gravity feed	0.083-0.415 lbs. per 1000 gallons of treated water. Actual use levels should be determined by a test of the system.	
	Flowable concentrate 67869-25	Pump or Gravity feed	Add 0.5-2.5% by weight of the suspension or dispersion. Actual use levels should be determined by a test of the system.	Badly fouled systems may require cleaning before initial treatment.
	67869-46	Pump or Gravity feed	Add concentrations of 250-4000 ppm into make up water during the grind during the manufacturing process	
	Ready to use solution 74655-1	Pump or Gravity feed	If system is noticeably fouled, add product at the rate of 0.5 to 3.0 pounds per ton of pulp or paper product. Additions to additive system should be made directly at the rate of 0.2 to 4.0 pounds (24 to 480ppm) per 1000 gallons. Add product at the rate of 0.5-2.0 pounds per ton of pulp or paper produced. Treat the system as needed to maintain control. Additions to the additive system may be reduced to 0.2 to 2.0 pounds (24 to 240 ppm) per 1000 gallons.	Badly fouled systems may require cleaning before initial treatment.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Construction Products: Caulking material, Concrete additives, concrete and masonry additives	Soluble concentrate: 67869-46	Incorporation	Can be fed at concentration of 250 to 6000 ppm either directly to the finished product or to one of the raw materials	
Coatings for paper	Soluble concentrate: 67869-46	Incorporation	Add at concentration of 250 to 4000 ppm into the makeup water during the grind during the manufacturing process	
Epoxy Flooring Compounds	Ready to use solution 1448-104	Solid open pour Water-soluble packaged solids	0.59% a.i. by weight (0.6% product by weight of material treated X 98% a.i. in product)	
	Formulation Intermediate 1448-98			
Industrial Processes and Water Systems				
Recirculating cooling water systems	Ready to use solution 1448-103 1448-395 9386-3 9386-28	Pump or Gravity feed	Add 3.25-6.5 ounces of product to 1000 gallons of water to produce a 30-60ppm concentration initially. Add 0.5-3.25 ounces of product to 1000 gallons of water to produce a 5-30ppm concentration to maintain control.	
	Soluble concentrate	Pump or Gravity feed	Add 16 ounces of product per each 5,000-16,000 gallons of	

US EPA ARCHIVE DOCUMENT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-104		water in system initially to produce a concentration of 7.5-15ppm. Add 16 ounces of product per each 15,000-96,000 gallons of water in system to produce a concentration of 1.25-7.5ppm to maintain control.	
Recirculating cooling water systems	Formulation Intermediate 1448-98			

US EPA ARCHIVE DOCUMENT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Oilfield water treatment and water floods	Ready to use solution 1448-103 1448-395 9386-3 9386-28	Open Pour	Add 2.1 pounds of product to 1000 gallons of drilling fluid to produce a 2500ppm concentration initially. Add 0.30 pounds of product to 1000 gallons of drilling fluid to produce a 350ppm concentration to maintain control.	
	Soluble concentrate 33753-25	Open Pour	Add 1.67 pounds of product to 1000 gallons of drilling fluid to produce a 200ppm concentration initially. Add 1.25 pounds of product to 1000 gallons of drilling fluid	

US EPA ARCHIVE DOCUMENT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			to produce a 150ppm concentration to maintain control.	
Soluble	concentrate 1448-104		Add 5.22 pounds of product to 1000 gallons of drilling fluid to produce a 625ppm concentration initially. Add 0.73 pounds of product to 1000 gallons of drilling fluid to produce an 88ppm concentration to maintain control. For water soluble packaging: One pound per 191 gallons initially then one pound per 1363 gallons to maintain control.	
Oilfield Drilling Muds and work over or completion fluids	Soluble concentrate 1448-104 9386-13 33753-25	Open Pour	Add 175-182 pounds of product to 1000 barrels of drilling fluid to produce a 500-520ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	
	Ready to use solution 1448-103 9386-3		Add 75 pounds of product to 1000 barrels of drilling fluid to produce a 2080-2500ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	

US EPA ARCHIVE DOCUMENT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Ready to use solution 1448-395 9386-28		Add 75 pounds of product to 1000 barrels of drilling fluid to produce a 2080ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	
Wood Preservatives				
Utility Poles, pilings, timbers, solid and laminated wood products.	Pelleted solid 7969-162 71406-5 1448-104	Applied in treatment holes drilled into wood product to be treated	Drill three 7/8 in. diameter by 14 in. long holes at a steep angle (45 deg or greater) in a spiral patter starting at ground line. Apply 70 grams of end use product into each hole. Do not overfill treatment hole. Add liquid accelerant if desired to treatment hole. Plug treatment hole with a tight fitting treated wooden dowel, removable plastic plug or other suitable cap.	For wood in ground contact, the first hole should start at or slightly below ground line and should be arranged in a spiral pattern covering the treatment zone with about 6" to 12" vertically between holes. An accelerant of a 1% solution of copper napthenate in mineral spirits may be added to treatment holes after application of the product and is designed to speed up the decomposition and release of the active fumigant inside the wood product. Keep accelerant away from product except when in treatment holes, which should be plugged immediately after they combine. Not to be used indoors or underneath indoor structures.
Technical Registrations				
	Chemical: 7969-161	N/A	N/A	For use in the formulation of dazomet end-use registrations only. For use in the formulation of microbiocides and wood protectants only.

US EPA ARCHIVE DOCUMENT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Technical chemical: 9386-10	N/A	N/A	For use in the formulation of dazomet end-use registrations only
	Technical chemical: 67869-18	N/A	N/A	For use in the formulation of dazomet end-use registrations only For use in the following Industrial Process Water Systems: pulp and paper mill systems. For Material Preservations of slurries and high viscosity suspensions (starches, non-food adhesives, clay slurries, glues, coatings for paper, and resin emulsions)

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

This section is currently not available.

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Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room S-4400, **One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202**. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov These documents include:

Health Effects Support Documents

- Methyl Bromide, 1,3-Dichloropropene, Chloropicrin, Dazomet, Metam Sodium/Potassium, MITC: Health Effects Division (HED) Component of Agency Response To Comments On 2008 Reregistration Eligibility Documents, May 14, 2009

- Dazomet: Third Revision of the HED Human Health Risk Assessment. April 30, 2009

- Dazomet: Updated Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). Smith, C. et al.; D354014; June 24, 2008.

- Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC. Lowit, A. and Reaves, E.; D293356; TXR 0054860; June 25, 2008.

- The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Dazomet. Smith, C.; D306858; June 18, 2008.

Environmental Fate and Ecological Effects Support Documents

- Further Response to Public Comments on the 7/9/08 Completed Dazomet RED, Rothman, G. and Felkel, J. March 3, 2009

- Revised Environmental Fate and Ecological Risk Assessment For Dazomet. Khan. F. and Felkel, J.; D306855; April 8, 2008.

- Response to Phase 5 Public Comments on the Phase 4 Dazomet Environmental Fate and Ecological Risk Assessment. Khan, F., and Felkel, J.; D306854; April 2, 2008.

Biological and Economical Analysis Support Documents

- Response to BEAD Related Public Comments Received on the Reregistration Eligibility Decision for Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide (DP# 363545) May 14, 2009.

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

US EPA ARCHIVE DOCUMENT

- Process for Defining High-Use Fumigation Areas at the State and County Levels (DP#364647) May 14, 2009.

- Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries. (Chiri, D. and Donaldson, D. Dated April 19, 2007) EPA-HQ-OPP-2005-0125-0044

- 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. (Faulkner, J., and Yourman, L., Dated April 20, 2007) EPA-HQ-OPP-2005-0125-0045

- Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production. (Yourman, L., and Smearman, S., Dated April 19, 2007) EPA-HQ-OPP-2005-0125-0054

- Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production. (Chiri, A., and Wyatt., T., Dated April 18, 2007) EPA-HQ-OPP-2005-0128-0060

- Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide. (Donaldson, D. et al., Dated June 2008)

- Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants. (Wyatt. T., et al, Dated June 2008)

Antimicrobial Assessment Support Documents

- Dazomet Antimicrobial Risk Mitigation Paper. Garvie, H., Dated June 2, 2008.

- Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document. Walls, C.; D Dated June 2008.

- *Dazomet: Dietary Risk Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document.* (Walls, C., Dated March 2007)

- *Environmental Fate and Ecological Risk Assessment for the Reregistration of Dazomet (035602) and MITC (068103) – Antimicrobial Uses.* (Petrie, R., Dated April 2007)

- Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision

(RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin. Walls, C.; February 14, 2008.

Buffer Zone Credits Support Document

- Methyl Bromide (PC Code 053201), Chloropicrin (PC Code 081501), Dazomet (PC Code 035602), Metam Sodium and Potassium (PC Codes 039003 &039002), MITC (PC Code 068103), DP Barcode 362369, Updated Health Effects Division Recommendations for Good Agricultural Practices and Associated Buffer Credits. May 14, 2009

- Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach. Dawson, J. and Smith, C.; D306857; June 9, 2008.

Risk Management Support Documents

- SRRD's Response to Post-RED Comments for the Soil Fumigants. Rice, M. and McNally, R; May 2009.

- SRRD's Response to Phase 5 Public Comments for the Soil Fumigants. Rice, M. and McNally, R.; July 2008.

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

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Appendix D. Bibliography

This section is not currently available.

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Appendix E. FMP Template (template uses MeBr soil applications as an example)

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

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

General Application Information		
		EPA Registration Number:

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

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

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

Buffer Zones				
Application method: ☐ Bedded ☐ Broadcast ☐ Hot gas - outdoor ☐ Hot gas - greenhouse ☐ Hand held probes		Block size from lookup table on label (acres):	_____	Buffer zone distance: _____ ft
List and describe areas in the buffer zone that are not under the control of owner/operator of the application block:				

Personal Protective Equipment for Handlers					
Handler Task	Clothing	Respirator Type, Filter Cartridge Type and Change-out Schedule	Eye Protection	Gloves	Other

Emergency Response Plan		
Description of evacuation routes:		
Locations of telephones:		
Contact information for first responders:	Local/state/federal contacts:	Other contact information for emergencies:
Emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).		

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Posting Signs

Name and phone number of person that is doing posting:

Location of posting signs:

Procedures for posting and sign removal:

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

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

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

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

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

Method used to provide information:

Notice to State Lead Tribal Agencies

	Date notified:

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

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

Names and phone numbers of persons contacted:	Date contacted:

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Comments/notes:	

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Site Map

Location of application block: _____

Map Legend

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

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Handler Information

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

Air Monitoring Plan

For Buffer Zone Monitoring: (check here if section is not applicable ☐)				
Name of handler performing monitoring activities	**Handler address**	**Handler phone number**	**Location of monitoring**	**Timing**

For Handlers without Respiratory Protection: (check here if section is not applicable ☐)	
If sensory irritation is experienced: ☐ **Intend to cease operations** ☐ **Intend to continue operations with respiratory protection** If intend to continue operations with respiratory protection, complete section for Handlers with Respiratory Protection below.	
	Monitoring equipment:

For Handlers with Respiratory Protection: (check here if section is not applicable ☐)		
Representative Handler Tasks to be Monitored	**Monitoring Equipment**	**Timing**

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

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

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

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

For Handlers with Respiratory Protection:

Representative Handler Tasks to be Monitored	Monitoring Equipment	Timing

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Methyl Bromide FMP Check List

General Site Information	
A map, aerial photo, or detailed sketch is attached to this FMP that shows each of the following with distances from the application site labeled: field location, application block dimensions, buffer zones, property lines, roads, bus stops, water bodies, wells, rights-of-ways, nearby application blocks, surrounding structures, and sites requiring ⅛ and ¼ mile buffer zones.	☐
Supervision of Handlers	
An on site certified applicator will directly supervise the handlers participating in the application starting when the fumigant is first introduced into the soil and ending after the fumigant has stopped being delivered/dispensed to the soil and the soil is sealed.	☐
After the application is complete, and before leaving the application block, the certified applicator has provided the owner/operator and handlers with written information necessary to comply with the label and procedures outlined in the FMP.	☐
Fumigant safe handling information has been provided to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months.	☐
For all fumigation handling tasks, at least 2 WPS-trained handlers must be present.	☐
Weather Conditions	
Wind speed at the application site is a minimum of 2 mph at the start of the application or forecasted to reach at least 5 mph during the application.	☐
A shallow, compressed (low-level) temperature inversion is not forecast to persist for more than 18 consecutive hours during the 48-hour period after the application.	☐
An air-stagnation advisory is not in effect for the area where the application site is located.	☐
If air temperatures have been above 100 degrees F in any of the 3 days prior to application, then soil temperature will be measured and recorded in the post application summary report.	☐
Soil Conditions	
The soil has been properly prepared and the surface has been checked to ensure that it is free of clods that are golf ball size or larger.	☐
The area to be fumigated has been tilled to a depth of 5 to 8 inches.	☐
Field trash has been properly managed (e.g., residue from a previous crop has been worked into the soil to allow for decomposition prior to fumigation, little or no crop residue is present on the soil surface, and crop residue that is present does not interfere with the soil seal).	☐
The soil temperature at the depth of injection ≤ 90 degrees F at the beginning of the application.	☐
The soil moisture at 9 inches below the surface is sufficient (field capacity is 50 to 80 percent).	☐
Trash pulled by the shanks to the ends of the field will be covered with tarp or soil before making the turn for the next pass.	☐
Shank Applications (check here if section is not applicable ☐)	
For tarped-broadcast and -bedded applications, injection points will be at least 8 inches from the nearest final soil/air interface.	☐
For tarped-bedded applications, the injection depth will not be as deep as the lowest point of the tarp (i.e., the lowest point of the tuck).	☐
For untarped-bedded applications, the injection points will be at least 12 inches from the nearest final soil/air interface.	☐
For untarped-broadcast applications, the injection points will be at least 18 inches from the nearest final soil/air interface.	☐
For broadcast untarped applications, a disc or similar equipment will be used to uniformly mix the soil to at least a depth of 3 to 4 inches to eliminate the chisel or plow traces and will following elimination of the chisel trace, the soil surface will be compacted with a cultipacker, ring roller, and roller in combination with tillage equipment.	☐
For performed bed applications, the soil will be sealed by disruption of the chisel trace using press sealers, bed shapers, cultipackers, or by re-shaping (e.g., relisting, lifting, replacing) the beds immediately following injection.	☐
For beds formed at the time of application, the soil will be sealed by disrupting the chisel trace using press sealers, or bed shapers.	☐
For shanked bedded and broadcast applications, tarps will be installed immediately after fumigant is injected into the soil.	☐
Applicators have been trained and instructed not to apply or allow fumigant to drain onto the soil surface.	☐
For each injection line a check valve been located as close as possible to the final injection point, or applicators will drain/purge the line of any remaining fumigant prior to lifting injection shanks from the ground.	☐
Applicators have been trained and instructed not to lift injection shanks from the soil until the shut-off valve has been closed and the fumigant has been depressurized (passively drained) or purged (actively forced out via air compressor) from the system.	☐
Brass, carbon steel, or stainless steel fittings must be used throughout application rigs.	☐
Polyethylene tubing, polypropylene tubing, Teflon® tubing or Teflon® -lined steel braided tubing have been used for all low pressure lines, drain lines, and compressed gas or air pressure lines and is all other tubing Teflon® -lined steel braided.	☐
Application equipment been inspected to ensure that application rigs do not contain galvanized, PVC, nylon, or aluminum pipe fittings.	☐
All rigs include a filter to remove any particulates from the fumigant, and a check valve to prevent backflow of the fumigant into the pressurizing cylinder or the compressed air system.	☐
All rigs include a flowmeter or a constant pressure system with orifice plates to insure the proper amount of fumigant is applied.	☐
Applicators have been trained and instructed to ensure that positive pressure is maintained in the cylinder at not less than 200 psi during the entire time it is connected to the application rig, if a compressed gas cylinder is used. (This is not required for a compressed air system that is part of the application rig because if the compressor system fails the application rig will not be operable).	☐
Application rigs are equipped with properly functioning check valves between the compressed gas cylinder or compressed air system and the fumigant cylinder.	☐
Applicators have been trained and instructed to always pressurize the system with compressed gas or by use of a compressed air system before opening the fumigant cylinder valve.	☐

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Before using a fumigation rig for the first time, or when preparing it for use after storage, applicators have been trained and instructed to: ° Check the filter, and clean or replace the filter element as required. ° Check all tubes and chisels to make sure they are free of debris and obstructions. ° Check and clean the orifice plates and screen checks, if installed. ° Pressurize the system with compressed gas or compressed air, and check all fittings, valves, and connections for leaks using soap solution.	☐
Applicators have been trained and instructed to: ° Install the fumigant cylinder, and connect and secure all tubing. Slowly open the compressed gas or compressed air valve, and increase the pressure to the desired level. Slowly open the fumigant cylinder valve, always watching for leaks. ° When the application is complete, close the fumigant cylinder valve and blow residual fumigant out of the fumigant lines into the soil using compressed gas or compressed air. At the end of the application, disconnect all fumigant cylinders from the application rig. At the end of the season, seal all tubing openings with tape to prevent the entry of insects and dirt. ° Calibrate all application equipment and ensure that all control systems must be working properly.	☐
Hot Gas Applications (check here if section is not applicable ☐)	
Tarps have been installed prior to starting the application.	☐
All delivery tubes have been placed under the tarp in such a way that they do not move during the application of methyl bromide.	☐
The fumigant will be introduced from outside of the greenhouse.	☐
All fittings, connections, and valves have been checked for leaks prior to fumigation and if cylinders are replaced during the fumigation process, the connections and valves were checked for leaks prior to continuing the job.	☐
Tree Replant (non-shank) Application (check here if section is not applicable ☐)	
For each individual tree-site, the tree stump and primary root system have been removed and the tree hole has been backfilled with soil before application.	☐
The fumigant will be injected at a depth of at least 18 inches into the soil.	☐
The wand will be cleared using nitrogen or compressed air before removing it from the soil and after the wand is cleared and removed from the soil, the injection hole will be covered with soil and tamp or the soil will be compacted over the injection hole.	☐
Buffer Zones	
There are no difficult to evacuate sites within ¼ (or ⅛) miles of the application block that will be occupied during the buffer zone period.	☐
There are no bus stops or other locations where persons wait for public transit within the buffer zone.	☐
There are no buildings used for storage such as sheds, barns, garages, within the buffer zone that are occupied or that share a common wall with an occupied structure.	☐
For areas in the buffer zone that are not under the control of owner/operator of the application block, written agreement has been obtained from occupants that they will voluntarily vacate the buffer zone during the entire buffer zone period.	☐
For nearby agricultural areas that are in the buffer zone the owner/operator of that property provided written agreement that they, their employees, or other persons will stay out of the buffer zone during the entire buffer zone period.	☐
For publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields) written permission has been given to include the public area in the buffer zone from the appropriate local and/or state officials.	
Buffer Zones Overlap (check here if section is not applicable ☐)	☐
A minimum of 12 hours has elapsed from the time the 1st application ends until the 2nd application begins.	☐
If a structure exists within 300 feet of the buffer zone, appropriate emergency preparedness and response procedures are followed.	☐
Certified applicator has informed handlers of the overlapping buffers and associated health protection requirements.	☐
Personal Protective Equipment for Handlers	
At least 1 air rescue device (e.g., SCBA) is on-site in case of an emergency.	☐
All of the handler's PPE has been cleaned and maintained as required by the WPS for Agricultural Pesticides.	☐
Hazard Communication	
The application area buffer zone has been posted in accordance with the label.	☐
Pesticide product labels and material safety data sheets are on-site and readily available for employees to review.	☐
Recordkeeping	
The owner/operator of the application block has been informed that he/she as well as the certified applicator must keep a signed copy of the site-specific FMPs and the post-application summary record for 2 years from the date of application.	☐

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

_____ _____

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

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Post-Application Summary

General Application Information		
		Size of application block:

Weather Conditions

Summary of the weather on the day of the application:

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

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

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

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

Location and size of tarp damage:

Description of tarp/tarp seal/tarp equipment failure:

Date and time of tarp repair:

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

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

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

	Date tarps were removed:

Odor Complaints (check here if section is not applicable ☐)

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

Description of control measures or emergency procedures followed after odor complaint:

Additional comments:

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

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

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

Other
Additional comments/notes:

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Air Monitoring Results

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

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

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

____ ______________________________

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

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