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# Report of Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses

**Report of Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses**

**List A**

**Case No. 0355**

Approved by: \_\_\_\_\_

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Director

Special Review and Reregistration Division

Date: \_\_\_\_\_

## 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 <sub>50</sub>	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 <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.

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

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## Abstract

This document presents EPA's decision regarding the Food Quality Protection Act (FQPA) tolerance reassessment for methyl bromide (MeBr) and reregistration eligibility of the commodity uses of the active ingredient methyl bromide. The Agency has conducted human health and environmental fate and effects risk assessments for methyl bromide and has made tolerance reassessment decisions for 140 tolerances related to all registered methyl bromide uses. The Agency has determined that, with label amendments and changes as specified in this document, there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other population subgroups, from methyl bromide's food commodity uses.

Generally, registered methyl bromide application/fumigation uses fall into four basic categories that include: (1) pre-plant soil fumigations; (2) structural, industrial, and residential uses; (3) post-harvest food commodity uses; and (4) other specialized fumigations. This decision document covers methyl bromide uses that have accompanying food residue tolerances for post-harvest fumigation of food commodities in chambers at ports or specialized structural fumigations at food processing facilities. Although some methyl bromide uses such as fumigation of timber, wood products, and industrial equipment do not require a food residue tolerance, the Agency has included them in this reregistration decision since they are performed in similar facilities and were assessed with a similar risk assessment methodology. Hereafter, these methyl bromide uses will be referred to as "methyl bromide's commodity uses."

EPA is currently assessing risks and will be developing risk management decisions for five soil fumigant pesticides: chloropicrin, dazomet, metam sodium, methyl bromide, and a new active ingredient, iodomethane. Risks of a sixth soil fumigant, 1,3-D (Telone), are also being analyzed along with the 5 soil fumigants for comparative purposes (see website link below); its risk management decision was completed in 1998. The Agency is evaluating these soil fumigants concurrently to ensure that human health risk assessment approaches are consistent, and that risk tradeoffs and economic outcomes can be 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. A decision on the reregistration of methyl bromide's non-commodity uses that do not have food tolerances (e.g., structural and pre-plant soil uses) is scheduled to be completed in 2007 with the other soil fumigants. For further details on the reregistration of the soil fumigants see [http://www.epa.gov/oppsrrd1/reregistration/soil\\_fumigants/](http://www.epa.gov/oppsrrd1/reregistration/soil_fumigants/).

The completion of the methyl bromide RED for food commodity uses results in the reassessment of 128 existing tolerances. As of April 26, 2006, the Agency considered the existing 12 tolerances from soil fumigation reassessed (see April 26, 2006, memo, "Completion of Tolerance Reassessment for Inorganic Bromides Resulting from Soil Treatment," from D. Edwards, Special Review and Reregistration Division Director to J. Jones, Office of Pesticides Program Director). The Agency's reregistration decision on methyl bromide's soil uses will not impact this RED since soil uses no longer have related food tolerances and have a negligible contribution to drinking water risks.



EPA has identified potential human health risks of concern associated with the currently registered commodity uses of MeBr from acute inhalation exposure to workers and bystanders. In this document the term “worker” refers to persons involved in applications of methyl bromide. Since methyl bromide is a restricted-use pesticide (RUP), fumigation workers must be certified applicators, or be working under the direct supervision of a certified applicator. The term “bystander” in this document refers to any other person who lives or works in the vicinity of a fumigation site. To reduce these exposures and to address subsequent risks of concern, EPA is requiring a number of mitigation measures such as site-specific fumigant management plans (FMPs), respiratory protection, buffer zones, posting and notification. The focus of the Agency’s mitigation measures is on direct acute exposure to methyl bromide from commodity uses. However, the Agency has concluded that many of these measures, combined with the MeBr phase-out mandated by the Montreal Protocol, will further reduce the potential health effects from ozone depletion that may be attributed to methyl bromide’s commodity uses, such as skin cancer. The Agency has determined that MeBr’s commodity uses are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

The Agency is issuing this decision document for MeBr, as announced in a Notice of Availability published in the *Federal Register*. There will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on this decision.

## I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency (hereafter referred to as EPA or the Agency). 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 each pesticide chemical. This document presents EPA’s assessment and risk management decisions for methyl bromide's uses in enclosures, chambers and structural food processing/storage facilities (hereafter referred to as commodity uses) to determine the need for additional data on health and environmental effects, and to determine whether or not these uses of the pesticide meet the "no unreasonable adverse effects" criteria of FIFRA and the “reasonable certainty of no harm” criteria of the Food Quality Protection Act (FQPA). Risks summarized in this document are those that result only from the commodity uses of methyl bromide. However, EPA has considered potential dietary (food + drinking water) risks associated with all methyl bromide uses, including pre-plant soil uses. As a result of this review, the Agency has determined that all products registered for commodity uses containing the active ingredient methyl bromide are eligible for reregistration provided that the risk mitigation measures indicated in this document are adopted.

The completion of the methyl bromide RED for commodity uses results in the reassessment of all 140 existing tolerances (i.e., 128 post-harvest uses + 12 tolerances from pre-plant soil applications that were already re-assessed by the Agency). A decision on the reregistration of methyl bromide's pre-plant soil uses will be completed in 2007 with the other soil fumigants. For further details on the reregistration of the soil fumigants see [http://www.epa.gov/oppsrrd1/reregistration/soil\\_fumigants/](http://www.epa.gov/oppsrrd1/reregistration/soil_fumigants/). The Agency's reregistration decision on methyl bromide's soil uses will not impact this TRED/RED since soil uses no longer have related food tolerances and have a negligible contribution to drinking water.

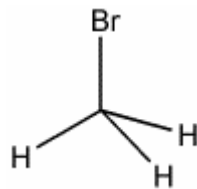
The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to methyl bromide, and methyl bromide does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of reregistration, EPA has not assumed that methyl bromide shares a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

Unless otherwise noted, all Agency references in this document are available for review in the methyl bromide docket (EPA-HQ-OPP-2005-0123) at [www.Regulations.gov](http://www.Regulations.gov).

## II. Chemical Overview

### A. Chemical Identity

Chemical Structure:



Empirical Formula:

CH<sub>3</sub>Br

Common Name:

Methyl bromide

CAS Registry Number:

74-83-9

OPP Chemical Code:

053201

Case Number: 0335

Technical or Manufacturing-Use Registrants: Albemarle Corporation, Ameribrom, Inc., Great Lakes Chemical Corporation (a Chemtura Company), and TriCal

Regulatory History:

- Introduced as pesticide in 1932
- First registered in the U.S. in 1961
- Under the Clean Air Act and the Montreal Protocol on Substances that Deplete the Ozone Layer, as of January 1, 2005, U.S. production and import of methyl bromide is banned, except for uses that qualify for (1) a critical use exemption, (2) a quarantine and preshipment exemption, or (3) an emergency exemption.

### B. Use and Usage Profile

Pesticide Type: Methyl bromide is a broad-spectrum fumigant chemical that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent.

Target pests: A wide range of pests including spiders, mites, fungi, plants, insects, nematodes, rodents, and snakes.

Use patterns: The most prevalent use pattern is as a soil fumigant; however, it is also used as a structural fumigant and for post harvest treatment of commodities.

Formulations: Pressurized gas (PrG) formulations for commodity fumigation are marketed under the trade names Meth-O-Gas and Metabrom. All methyl bromide products are classified as restricted use pesticides (RUP). The "Restricted Use" classification restricts a product, or its uses, to use by certified pesticide applicators or those working under the direct supervision of a certified applicator.

Methods of Application: MeBr gas is injected into an enclosure, chamber, structure, or under a tarp remotely using flexible tubing connected to PrG tanks.

Application Rates: Application rates for commodity fumigations can range from 1 to 20 lb ai/1000 ft<sup>3</sup>, but most perishable goods with established food tolerances under 40 CFR have application rates in the range of 1 to 4 lb ai/1000 ft<sup>3</sup> (e.g., grapes). Likewise, structural fumigation application rates are in the 1 to 9 lb ai/1000 ft<sup>3</sup> range.

Annual Usage in the U.S.:

There were a total of 23 million pounds of methyl bromide used in the U.S. in 2004 with 3 million pounds used on commodities, food processing facilities, and for food quarantine uses, and 20 million pounds used on all other sites.

Tolerances:

There are currently 140 tolerances related to registered methyl bromide uses in 40 CFR 180.123, 180.199, and 180.522.

<u># of Tolerances</u>	<u>Citation</u>
90	180.123(a)(1)
3	180.123(a)(2)(i)(A)
2	180.123(a)(2)(i)(B)
2	180.123(a)(2)(i)(C)
18	180.123(a)(2)(i)(D)
1	180.123(a)(2)(ii)
1	180.123(a)(3)(i)
7	180.123(a)(3)(ii)
1	180.123(c)
12	180.199
1	180.521
2	180.522

Methyl bromide's commodity uses encompass a wide range of enclosure types (tarps, vacuum chambers, tractor trailers, sea vans, drop-down enclosures, flour mills, etc.), enclosure volumes (less than 1,000 ft<sup>3</sup> to more than 1,000,000 ft<sup>3</sup>), and locations (urban, rural, and industrial). Most flour mills and other food processing plants are fumigated no more than once per year, while other facilities perform fumigations with methyl bromide on a daily basis (e.g., for quarantine uses). Additional summary and analysis of methyl bromide's use and usage is included in the following Agency's memos which are available in the docket:

- Qualitative Assessment of the Impact of Changes in the Use of Methyl Bromide for Quarantine Purposes in Support of the Reregistration Eligibility Decision (August 1, 2006)
- Qualitative Assessment of the Impact of Changes in the Use of Methyl Bromide on Non-Quarantine Commodities in Support of the Reregistration Eligibility Decision (August 1, 2006)
- Qualitative Assessment of the Impact of Changes in Use of Methyl Bromide on Dry Cured Pork Product Facilities in Support of the Reregistration Eligibility Decision (August 1, 2006)
- Qualitative Assessment of the Impact of Changes in the Use of Methyl Bromide in Structural Food Processing/Storage Facilities in Support of the Reregistration Eligibility Decision (August 1, 2006)

### III. Methyl Bromide Risk Assessments

For details on the human health risks associated with methyl bromide's commodity uses, please refer to Appendices J and K for the following documents:

- Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Commodity Uses. PC Code: 053201, DP Barcode: D304623 (March 10, 2006)
- Addendum To Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses. PC Code: 053201, DP Barcode: D304619 (July 12, 2006)

The Agency does not conduct ecological risk assessments for most indoor uses, such as an enclosed container or perimeter treated with MeBr. EPA has assessed risks associated with the outdoor soil uses of MeBr which are expected to result in higher environmental exposures. For the latest ecological risk assessment of methyl bromide's pre-plant soil fumigant uses, see the June 6, 2005, document "Environmental Fate and Ecological Risk Assessment for the Reregistration of Methyl Bromide."

For details on the Agency's assessment of methyl bromide's impact on stratospheric ozone depletion, as well as the health effects expressed as incremental number of skin cancer mortality and incidence for U.S. residents that would result under various methyl bromide use scenarios, please refer to the March 17, 2006, document "Methyl Bromide: Science of Ozone Depletion and Health Effects Estimates."

#### IV. Risk Management, Reregistration, and Tolerance Reassessment 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 required to support reregistration of products for commodity fumigation containing methyl bromide as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing methyl bromide registered for commodity uses provided the label changes detailed below are implemented. Additional data are required to confirm this determination.

The Agency has completed its review of submitted data and its assessment of the dietary, residential, and occupational risks associated with the commodity uses of pesticide products containing the active ingredient methyl bromide. Based on these data, the Agency has sufficient information on the human health and ecological effects of methyl bromide to make its decision as part of the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing methyl bromide registered for commodity fumigation will be 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 are made to reflect these measures. Needed label changes and language are listed in Section V. Appendix A is a detailed table listing all methyl bromide uses that are eligible for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of methyl bromide's commodity uses, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data or additional data necessary to confirm the decision presented here.

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

## B. Public Comments and Responses

Through the Agency's use of a 6-phase public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for methyl bromide's commodity uses. The 6-phase process included two 60-day comment periods.

For the first comment period (Phase 3), the Agency solicited and received comments on the Agency's methyl bromide risk assessments and supporting documents. The Agency's response to comments received during this period was included in the Agency's March 21, 2006 document, "Agency Responses to Phase 3 Public Comments Related to Methyl Bromide's Uses in Enclosures, Chambers, and Structural Food Processing/Storage Facilities."

For the second comment period (Phase 5), the Agency solicited and received comments on the revised methyl bromide risk assessment and a risk mitigation options document. During the second public comment period, the Agency received comments from 18 sources: California Department of Pesticide Regulation; Value Recovery, Inc; Dow AgroSciences, LLC; The Royal Group; USA Rice Federation; Western Industries-North, Inc; ASOEX; Natural Resources Defense Council; Fumigation Service & Supply, Inc.; Pet Food Institute; North American Millers' Association (NAMA); Methyl Bromide Industry Panel (MBIP); National Pest Management Association (NPMA); Industrial Fumigant Company (IFC); US Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS); and a citizen. Most of the comments received were related to feasibility, cost, and impact of risk mitigation options document.

The comments in their entirety from both comment periods are available in the public docket (EPA-HQ-OPP-2005-0123) at <http://www.regulations.gov>. Detailed response to comments documents for both comment periods are also available in the public docket.

### C. Regulatory Position

#### 1. Food Quality Protection Act Findings

##### a. “Risk Cup” Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with methyl bromide’s commodity uses. EPA has determined that risk from dietary (food + drinking water) exposure is within its own “risk cup.” EPA considered aggregate risks for methyl bromide’s commodity uses for exposures through dietary and residential sources. In the case of MeBr, these residential exposures are to any person who lives or works in the vicinity of a fumigation site. The Agency has determined that the human health risks from these combined exposures are within acceptable levels provided the mitigation measures outlined in this document are adopted. In other words, EPA has concluded that the tolerances for methyl bromide meet FQPA safety standards provided the mitigation measures outlined in this document are adopted. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from dietary (food + drinking water) and residential sources.

##### b. Determination of Safety to U.S. Population

The Agency has determined that the 140 established tolerances for methyl bromide, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to Section 408(b)(2)(D) of the FFDCA, as amended by FQPA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the commodity uses of methyl bromide. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of methyl bromide. The risks from food, drinking water, and residential exposures related commodity uses do not exceed the Agency’s levels of concern, with the risk mitigation specified in this document.

#### 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 endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone

system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCa authority to require the wildlife evaluations. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on methyl bromide, there was no evidence of endocrine disruption effects. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, methyl bromide may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

### 3. Cumulative Risks

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to methyl bromide, or its metabolites, and any other substances. For the purposes of this reregistration decision, therefore, EPA has not assumed that methyl bromide has a common mechanism of toxicity with any other substances.

### 4. Tolerance Reassessment Summary

#### a. Commodity Uses

Table 1 provides a summary of the methyl bromide tolerance reassessment decision for 128 tolerances associated with commodity uses. The other 12 tolerances for soil uses were reassessed and are discussed below in section b. Further explanation of the tolerance reassessment decision is provided in Appendix K. There are no established or proposed Codex maximum residue limits for methyl bromide.

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
<b>Tolerances listed under 40 CFR §180.123 (a)(1):</b>			
Alfalfa, hay (POST-H)	50.0	Revoke	The MBIP is not supporting this use.
Almonds (POST-H)	200.0	150.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Tree Nuts Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Apples (POST-H)	5.0	8.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Pome Fruits Group. Commodity fumigation trials support an increased tolerance level for methyl bromide.



<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Apricots (POST-H)	20.0	5.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Stone Fruits Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Artichokes, Jerusalem (POST-H)	30.0	3.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Root and Tuber Vegetables Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Asparagus (POST-H)	100.0	0.05	Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Avocados (POST-H)	75.0	5.0	No registered use or MBIP is not supporting. However, APHIS has requested to retain this tolerance.
Barley (POST-H)	50.0	8.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Cereal Grains Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Beans (POST-H)	50.0	3.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Legume Vegetables Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Beans, green (POST-H)	50.0		
Beans, lima (POST-H)	50.0		
Beans, snap (POST-H)	50.0		
Beets, garden, roots (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Beets, sugar, roots (POST-H)	30.0		
Blueberries (POST-H)	20.0	0.5 <sup>a</sup>	Reassign to crop group tolerance for residues in/on Berries Crop Group. Commodity fumigation trials support a decreased tolerance level for methyl bromide.
Brazil nuts (POST-H)	200.0	150.0 <sup>a</sup>	See comment under almonds.
Bush nuts (POST-H)	200.0		
Butternuts (POST-H)	200.0		
Cabbage (POST-H)	50.0	1.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Brassica Leafy Vegetables Group. Commodity fumigation trials support a decreased tolerance level.
Cantaloupes (POST-H)	20.0	5.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Cucurbit Vegetables Group. Commodity fumigation trials support a decreased tolerance level.
Carrots (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Cashews (POST-H)	200.0	150.0 <sup>a</sup>	See comments under almonds.
Cherries (POST-H)	20.0	5.0 <sup>a</sup>	See comments under apricots.
Chestnuts (POST-H)	200.0	150.0 <sup>a</sup>	See comments under almonds.
Cippolini, bulbs (POST-H)	50.0	2.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Bulb Vegetables Group. Commodity fumigation trials support a decreased tolerance level.
Citrus citron (POST-H)	30.0	2.0 <sup>a</sup>	Reassign to crop tolerance for residues in/on Citrus Fruits Group. Commodity fumigation trials support a decreased tolerance level.
Cocoa beans (POST-H)	50.0	8.0	Commodity fumigation trials support a decreased tolerance level.
Coffee beans (POST-H)	75.0	Revoke	The MBIP is not supporting these uses.
Copra (POST-H)	100.0	8.0	The MBIP is not supporting this use. However, APHIS has requested to retain this tolerance.
Corn (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
Corn, pop (POST-H)	240.0		
Corn, sweet (K+CWHR)(POST-H)	50.0		
Cottonseed (POST-H)	200.0	Revoke	The MBIP is not supporting this use.
Cucumbers (POST-H)	30.0	5.0 <sup>a</sup>	See comments under cantaloupe.
Cumin, seed (POST-H)	100.0	Revoke	Covered by tolerance for residues in herbs and spices.
Eggplant (POST-H)	20.0	7.0 <sup>a</sup>	Reassign to crop group tolerance for residues in/on the Fruiting Vegetables Group. Commodity fumigation trials support a decreased tolerance level.
Filberts (Hazelnuts) (POST-H)	200.0	150.0 <sup>a</sup>	See comments under almonds.
Garlic (POST-H)	50.0	2.0 <sup>a</sup>	See comments under Cippolini bulbs.
Ginger, roots (POST-H)	100.0	3.0 <sup>a</sup>	See comments under artichoke, Jerusalem.
Grapefruit (POST-H)	30.0	2.0 <sup>a</sup>	See comments under citrus citron.
Grape (POST-H)	20.0	4.0	Commodity fumigation trials support a decreased tolerance level.
Hickory nuts (POST-H)	200.0	150.0 <sup>a</sup>	See comments under almond.
Honeydew melons (POST-H)	20.0	5.0 <sup>a</sup>	See comments under cantaloupe.
Horseradish (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Kumquats (POST-H)	30.0	2.0 <sup>a</sup>	See comments under citrus citron.

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Lemons (POST-H)	30.0		
Limes (POST-H)	30.0		
Mangoes (POST-H)	20.0	Revoke	No registered use or MBIP is not supporting.
Muskmelons (POST-H)	20.0	5.0 <sup>a</sup>	See comments under cantaloupe.
Nectarines (POST-H)	20.0	5.0 <sup>a</sup>	See comments under apricot.
Oats (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
Okra (POST-H)	30.0	7.0	The MBIP is not supporting this use. However, APHIS has requested to retain this tolerance.
Onions (POST-H)	20.0	2.0 <sup>a</sup>	See comments under Cippolini bulbs.
Oranges (POST-H)	30.0	2.0 <sup>a</sup>	See comments under citrus citron.
Papayas (POST-H)	20.0	Revoke	No registered use or MBIP is not supporting.
Parsnips (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichoke, Jerusalem.
Peaches (POST-H)	20.0	5.0 <sup>a</sup>	See comments under apricot.
Peanuts (POST-H)	200.0	150.0	No registered use or MBIP is not supporting. However, APHIS has requested to retain this tolerance.
Pears (POST-H)	5.0	8.0 <sup>a</sup>	See comment under apples.
Peas (POST-H)	50.0	3.0 <sup>a</sup>	See comments under beans.
Peas, black-eyed (POST-H)	50.0		
Pecans (POST-H)	200.0	150.0 <sup>a</sup>	See comment under almonds.
Peppers (POST-H)	30.0	7.0 <sup>a</sup>	See comment under eggplants.
Pimentos (POST-H)	30.0		
Pineapples (POST-H)	20.0	5.0	Commodity fumigation trials support a decreased tolerance level.
Pistachio nuts (POST-H)	200.0	150.0 <sup>a</sup>	See comment under almonds.
Plums (POST-H)	20.0	5.0 <sup>a</sup>	See comment under apricots.
Pomegranates	100.0	Revoke	No registered use or MBIP is not supporting
Potatoes (POST-H)	75.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Pumpkins (POST-H)	20.0	5.0 <sup>a</sup>	See comments under cantaloupes.
Quinces (POST-H)	5.0	8.0 <sup>a</sup>	See comments under apples.
Radishes (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Rice (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
Rutabagas (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Rye (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
Salsify, roots (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Sorghum, grain (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
Soybeans (POST-H)	200.0	3.0 <sup>a</sup>	See comments under beans.
Squash, summer (POST-H)	20.0	5.0 <sup>a</sup>	See comments under cantaloupes.
Squash, winter (POST-H)	20.0		
Squash, zucchini (POST-H)	20.0		
Strawberries (PRE- and POST-H)	60.0	0.05	Commodity fumigation trials support a decreased tolerance level.
Sweet potatoes (POST-H)	75.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Tangerines (POST-H)	30.0	2.0 <sup>a</sup>	See comments under citrus citron.
Timothy, hay (POST-H)	50.0	Revoke	No registered use or MBIP is not supporting
Tomatoes (POST-H)	20.0	7.0 <sup>a</sup>	See comments under eggplants.
Turnips, roots (POST-H)	30.0	3.0 <sup>a</sup>	See comments under artichokes, Jerusalem.
Walnuts (POST-H)	200.0	150.0 <sup>a</sup>	See comments under almonds.
Watermelons (POST-H)	20.0	5.0 <sup>a</sup>	See comments under cantaloupes.
Wheat (POST-H)	50.0	8.0 <sup>a</sup>	See comments under barley.
<b>Tolerances listed under 40 CFR §185.123 (a)(2):</b>			
Dried eggs	400	10.0	Reassign to “processed foods, excluding chocolate” under §180.123 (a)(2).
Parmesan cheese	325		
Roquefort cheese	325		
Tomatoes, concentrated products	250		
Figs, dried	250		
<sup>b</sup> Processed foods, excluding chocolate, other than those listed above	125	10.0	<i>Processed foods, excluding chocolate</i> Tolerance level can be lowered to cover levels of methyl bromide detected in processed food fumigation trials.
Herbs, processed	400	35.0	This tolerance can be lowered to cover levels of methyl bromide detected in processed herb and spice fumigation trials.
Spices, processed	400	35.0	
Fermented malt beverages	25	Revoke	No registered use
<b>Tolerances listed under 40 CFR §185.123 (a)(3):</b>			
Dog food	400	Revoke	This is not considered a human food use and therefore the tolerance is not required.
Barley, milled fractions	125	10.0	Reassign to “processed feeds” under §180.123 (a)(3).
Corn, milled fractions	125		

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>				
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>	
Sorghum (milo), grain, milled fractions	125			
Oats, milled fractions	125			
Rice, milled fractions	125			
Rye, milled fractions	125			
Wheat, milled fractions	125			
<b>Tolerance listed under 40 CFR §180.123 (c):</b>				
Ginger, roots (PRE- and POST-H)	100	Revoke	Use will be covered by tolerance for residues in/on the Root and Tuber Vegetables Group.	
<b>Tolerance listed under 40 CFR §180.521(a)(3):</b>				
Cereal grain, milled fraction	125	Revoke	Residues for the milled fractions would be no higher than that of the raw agricultural commodity and are therefore this tolerance is not needed.	
<b>Tolerance listed under 40 CFR §180.522(a):</b>				
Cereal grains	125	Revoke	There are no registered fumigation uses of methyl bromide on these products.	
Fermented malt beverages	125	Revoke		
<b>Tolerances needed under 40 CFR §180.123 (a)(1):</b>				
Vegetable, root and tuber, group 1	None	3.0	Crop group tolerance recommendations are based on maximum methyl bromide residues in/on representative commodities of each group in commodity fumigation trials.	
Vegetable, bulb, group 3	None	2.0		
Vegetable, leafy, group 4	None	0.5		
Vegetable, Brassica leafy, group 5	None	1.0		
Vegetable, legume, group 6	None	3.0		
Vegetable, fruiting, group 8	None	7.0		
Vegetable, cucurbit, group 9	None	5.0		
Fruit, citrus, group 10	None	2.0		
Fruit, pome, group 11	None	8.0		
Fruit, stone, group 12	None	5.0		
Berry group 13	None	0.5		
Nut, tree, group 14	None	150.0		
Grain, cereal, group 15	None	8.0		
Kiwifruit	None	5.0		The available data would support a tolerance of 5.0 ppm if a registrant intends to include a use on kiwifruit on MeBr labels.
<b>Tolerances needed under 40 CFR §180.123 (a)(2):</b>				

<b>Table 1. Revised Tolerance Reassessment Summary for Methyl bromide</b>			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Chocolate products	None	55.0	The available residue data on processed foods support a separate tolerance for “chocolate, products” at 55.0 ppm.
Processed foods, excluding chocolate	None	10.0	The available residue data on processed foods support a tolerance for “processed foods, excluding chocolate” at 10.0 ppm.
<b>Tolerances needed under 40 CFR §180.123 (a)(3):</b>			
Processed feeds	None	10.0	The available residue data on processed foods also supports at 10 ppm tolerance for “processed feeds”.

<sup>a</sup> Reassessed tolerance for the associated crop group.

<sup>b</sup> For tolerance reassessment purposes, this one term accounts for 18 reassessments because after the enactment of FQPA, this term was entered as 18 separate items in the Tolerance Index System (TIS). The 18 items include barley, flour; biscuit mixes; bread mixes; breeding; cake mixes; cookie mixes; flours, cereal and related products; macaroni products; noodle products; oats, flour; pie mixes; processed food; rice, cracked; rice, flours; rye flour; sorghum, milo, flours; soya, flour; vegetables, dried.

#### b. Pre-Plant Soil Uses

There are 12 tolerances currently established for residues of inorganic bromide resulting from methyl bromide soil fumigation (40 CFR 180.199). However, EPA has classified methyl bromide as a non-food use pesticide with regard to its soil fumigant uses and has proposed to revoke tolerances for soil fumigation related inorganic bromide. The Agency stated that although methyl bromide is used as an agricultural pesticide, it is considered a non-food use chemical for soil fumigation uses since it is quickly degraded or metabolized in the soil, and subsequently incorporated into natural plant constituents. Methyl bromide is also emitted to the atmosphere. Residues of the parent compound are not likely to be found in foods as a result of prior treatment of fields. While residues of inorganic bromide may be present, these residues are indistinguishable from background levels of inorganic bromide because of its ubiquity in the environment. Therefore, tolerances are not required for soil fumigant uses of methyl bromide, and tolerances currently established for residues of inorganic bromide resulting from methyl bromide soil fumigation have been proposed for revocation by the Agency. On May 31, 2006, EPA issued a proposed rule to revoke the twelve tolerances for residues of inorganic bromide from pre-plant soil uses (71 FR 30845) and accepted comments for 60 days. The Agency anticipates issuing a final rule that revokes the 12 tolerances in August 2006, after the Agency has completed its review of any comments received.

The rationale for why tolerances are not needed for pre-plant soil uses is provided in the Agency’s February 8, 2006, memo, “Methyl Bromide: Tolerance Revocation of Inorganic Bromides. PC Code: 053201, DP Barcode: D304618.”

As of April 26, 2006, the Agency considered the existing 12 tolerances from soil fumigation reassessed (see April 26, 2006, memo “Completion of Tolerance Reassessment For Inorganic Bromides Resulting from Soil Treatment” from D. Edwards, Special Review & Reregistration Division Director to J. Jones, Office of Pesticides Program Director).

#### D. Regulatory Rationale

##### 1. Dietary (food + drinking water) Risk

The Agency’s assessment of dietary risk from food plus drinking water exposure does not exceed the Agency’s level of concern. Based on conservative estimates of exposure through food and drinking water, dietary risks are below EPA’s level of concern for the general population and all population sub-groups. The following sections describe the details of the Agency’s food and water exposure estimates.

###### a. Food

For all included commodities, the acute and chronic risks do not exceed the Agency’s level of concern for the general U.S. population and all population subgroups. The acute dietary food exposure estimate for females 13-49 years old, the population subgroup with the highest acute risk, is at 2.4% of the aPAD. The chronic dietary food exposure estimate for children (3 to 5 years old), the most highly exposed population subgroup, is 10% of the cPAD. The acute and chronic exposure estimates are considered to be very conservative since it was assumed that 100% of the crops were treated with methyl bromide. This is likely to be an overestimate of the percent that is treated. Therefore, no mitigation is necessary to address the risks associated with food.

###### b. Drinking Water

The Agency typically does not estimate transport of pesticides from indoor uses such as methyl bromide’s commodity uses to surface or ground water. However estimated drinking water concentrations (EDWCs) for methyl bromide’s soil uses were developed for surface and ground water and were determined to be below EPA’s level of concern.

For pre-plant soil uses, Florida strawberries resulted in the highest modeled surface water concentration of 357 µg/L for acute exposure, and 1.0 µg/L for the chronic exposure. The surface water EDWCs are considered conservative, upper-bound estimates of potential concentrations of methyl bromide in drinking water, and EPA believes actual concentrations are likely to be much lower. This is due to several factors which including:

- Methyl bromide is a highly volatile compound and rapid volatilization from soil and surface water is expected to significantly reduce the potential concentrations of methyl bromide in drinking water.

- Modeled EDWCs represent potential methyl bromide concentrations in raw (i.e., untreated) drinking water. EPA expects additional volatilization and degradation to occur between the reservoir and the point of consumption.
- The EDWCs are based on applications to the most sensitive surface water/crop scenario (Florida strawberries) at the maximum application rate. Further, the assessment assumes that 87% of a watershed is planted in strawberries, and all strawberries in the watershed are treated with methyl bromide at the same time.
- The PRZM/EXAMS models have limited capability to capture the effect of using tarps to contain methyl bromide, which is the standard application method for strawberries in Florida.
- The EDWCs are 1-in-10 year maximum concentrations.

Groundwater concentrations were not estimated for methyl bromide because the model used for estimating groundwater concentration, SCIGROW, has limited capability to model vapor phase transport of methyl bromide to groundwater. Therefore, EPA used monitoring data to estimate potential exposure to MeBr in ground water. Based on a database of pesticides in groundwater, two wells in California (out of 20,429 wells monitored in Florida, California, and Hawaii) had detections of methyl bromide at levels from 2.5 - 6.4 µg/L. Given the concentrations detected, that two of the three states monitored account for the vast majority of MeBr use in the U.S., and the number high of samples with non-detects, the Agency has concluded that the potential exposure to methyl bromide in ground water is negligible.

The Agency has determined that the drinking water risk from methyl bromide from commodity uses is much lower than for soil uses and the potential for MeBr exposure through drinking water is negligible since essentially all of the methyl bromide applied during commodity fumigation is emitted to the atmosphere and does not readily transport to drinking water sources. For further details on the Agency's drinking water exposure analysis, see the June 6, 2005, document "Environmental Fate and Ecological Risk Assessment for the Reregistration of Methyl Bromide."

## 2. Residential Risks

The human health risk assessment indicates that acute inhalation exposures to methyl bromide concentrations of 1 ppm or greater for an 8-hour time weighted average (TWA) pose risks of concern for residential bystanders. The 1 ppm 8-hour TWA is based on the 8-hour TWA human equivalent concentration (HEC) of 30 ppm from a developmental rabbit inhalation study where the fetal effects are presumed to occur after one exposure and an uncertainty factor (UF) of 30 with a 3x for interspecies extrapolation and 10x for intraspecies variation (i.e. 30 ppm/30 UF = 1 ppm). For further details on the HEC and UF, see the Agency's March 10, 2006, memo, "Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Commodity Uses. PC Code: 053201, DP Barcode: D304623." In the case of MeBr, these residential bystander exposures are to any person who lives or works in the vicinity of a fumigation site. The mitigation measures described below are expected to ensure that acute exposures do not exceed this level. The Agency has concluded that measures to ensure that



acute risks are below EPA's level of concern will also mitigate risks for other exposure durations (i.e. short-term, intermediate-term, and chronic) to levels below EPA's level of concern. In addition, many of the mitigation measures are expected to indirectly reduce the amount of methyl bromide used or emitted into the atmosphere and therefore will reduce the potential risks associated with stratospheric ozone depletion resulting from methyl bromide commodity uses.

The Agency believes that a comprehensive approach that requires mitigation measures such as fumigation management plans (FMPs), buffer zones, air monitoring, posting and notification, and record keeping, will ensure that acute risks from inhalation exposure to both workers involved in the fumigation process and bystanders in areas around enclosures do not exceed EPA's level of concern. California established permit conditions for methyl bromide commodity fumigations in 1994 that included the use of buffer zones and other measures that are similar to what EPA is now requiring. A recent analysis conducted by the California Department of Pesticide Regulation (CDPR) indicates a major reduction of injury and illnesses associated with methyl bromide commodity fumigations since permits were required. CDPR attributes this reduction in large part to the conditions under which permits are granted. Further details regarding California's permit conditions for MeBr commodity fumigations are available on CDPR's website (<http://www.cdpr.ca.gov/docs/enfcmpli/penfltrs/penf2001/2001048.htm>).

Quarantine fumigations supervised by USDA's Animal and Plant Health Inspection Service (APHIS) account for a large percentage of the total commodity fumigations performed in the US. The EPA has worked closely with APHIS in the development of the Agency's risk assessment and mitigation measures. Many of the fundamental elements (e.g., FMPs, buffer zones, air monitoring, record keeping, etc.) of the mitigation measures that are being required by this decision document for commodity fumigations are already required and enforced by on-site APHIS Plant Protection and Quarantine Officers (PPQOs).

The mitigation measures detailed below will require the applicator/fumigator to develop a fumigation management plan (FMP), or ensure one exists for each specific site that will be fumigated with methyl bromide. Required elements of the FMP are listed below in Section E. In developing this plan, the fumigator will determine the distance, called a buffer zone, which will protect workers and bystanders from exposure to methyl bromide that could exceed the Agency's level of concern. The Agency will provide guidance in the form of buffer zone look-up tables to enable fumigators to protect workers and bystanders. These tables will be available on the Agency internet website along with an Agency methyl bromide commodity fumigation reference manual. If, based on the current site conditions (e.g., local exhaust ventilation systems, enclosure/chamber/structure retention rates, size of treatment area, etc.), the size of the buffer zone listed in the Agency's look-up-tables is not feasible due to encroachment of occupied areas/structures, the fumigator can opt to modify the fumigation parameters or alter the site conditions so that a smaller buffer zone can be used. Examples of alternative approaches include but are not limited to:

- Reducing application rates

- Extending treatment time and allowing methyl bromide concentrations to slowly decline before starting active aeration (e.g., in California, large mills are extending treatment time from 24 to 48 hours to attain smaller buffer zones)
- Subdividing treatment areas
- Installing or modifying local exhaust ventilation systems (e.g., location/height of exhaust outlet)
- Improving the tightness or retention capacity of the enclosure/chamber/structure
- Empirically deriving retention or loss rates of the enclosure/chamber/structure (e.g., CDPR uses a one-time procedure where the low rate of 1 lb ai/1000 ft<sup>3</sup> rate is used with an empty chamber to determine loss rate)
- Installing capture recovery or destructive systems (e.g., scrubbers)

If these options do not result in feasible buffer zones for the site, there are additional alternatives detailed below that will give fumigators more flexibility but still ensure that methyl bromide levels do not exceed the Agency's level of concern (e.g., buffers based on site-specific modeling and air monitoring, with limited exceptions for traffic and other areas provided certain conditions are met). Although the Agency believes the approach outlined here offers substantial flexibility for site-specific solutions that are protective of workers and bystanders, it also recognizes that there will likely be some commodity fumigation sites where MeBr will no longer be practical to use. The mitigation measures that the Agency is requiring to protect bystanders are described further in Section E below.

### 3. Aggregate Risk

#### a. Acute

For methyl bromide, acute dietary risks are well below EPA's level of concern for the general U.S. population and all population subgroups based on conservative data and assumptions as described above in the dietary risk section of this document.

Because the acute dietary and acute inhalation endpoints for methyl bromide are based on a common effect, it would be appropriate to aggregate dietary exposures (using average, or "chronic", dietary exposure values) with acute inhalation exposures. However, because the dietary contribution to acute aggregate risk is negligible, EPA has determined that the mitigation measures EPA is requiring to protect residential bystanders will ensure that acute aggregate risks do not exceed EPA's level of concern. Therefore no additional mitigation is necessary to address acute aggregate risk.

#### b. Short-, Intermediate-Term, and Chronic Aggregate Risk

EPA did not aggregate short-, intermediate-term, or chronic dietary and inhalation exposures to methyl bromide because endpoints for dietary and inhalation exposures for these durations are not based on common toxicological effects.

#### 4. Worker Risks

The human health risk assessment indicates that acute inhalation exposures to methyl bromide concentrations of 1 ppm or greater for an 8-hour time weighted average (TWA) pose risks of concern for workers. The mitigation measures described below in Section E are designed to ensure that acute exposures for workers do not exceed this level. These measures include requiring respiratory protection for methyl bromide air concentration levels of greater than 1 ppm for an 8-hr TWA and establishing procedures for determining when the use of respiratory protection may be discontinued. The mitigation measures also specify air monitoring requirements to document the measurement of worker's potential methyl bromide inhalation exposure throughout the fumigation process. The Agency is also requiring that fumigators ensure that site-specific management plans that include the elements described in detail in Section E below are in place before initiating fumigation. EPA has determined that these requirements will protect fumigation workers as well as other onsite workers (e.g., forklift operators and other occupational bystanders).

#### 5. Stratospheric Ozone Depletion Risks

The focus of the Agency's mitigation measures as specified in section E below is to ensure protection from direct acute exposure to methyl bromide from commodity uses. The Agency concludes that many of these measures (e.g., those that reduce the total amount used or use MeBr capture/destruction systems) combined with the methyl bromide phase-out under the Montreal Protocol (i.e. all commodity uses except for pre-shipment and quarantine uses which are exempt) will further reduce the potential health effects from ozone depletion, such as skin cancer, which may result from methyl bromide's commodity uses.

#### 6. Ecological Risk

The Agency does not perform ecological risk assessments for most indoor uses, such as an enclosed container or perimeter treated with MeBr. Ecological risks from outdoor soil fumigation uses of MeBr will be addressed in the reregistration decisions for those uses in 2007.

#### E. Residential Bystander and Occupational Risk Mitigation

The following describes the rationale for the risk management decisions for bystander and worker risks associated with methyl bromide's commodity uses. Public comments and input from key stakeholders were considered in making these decisions. Where labeling revisions are warranted, specific language is set forth in summary tables of Section V of this document. It is the Agency's goal to ensure exposures are below the Agency's level of concern but allow flexibility for local, site-specific approaches, where feasible.

##### 1. Site-Specific Fumigation Management Plan (FMP)

Prior to fumigating commodities, a site-specific FMP must be developed and followed. The purpose of the FMP is to ensure the safety of the fumigators, other on-site employees, the surrounding community, and the environment. It is also designed to ensure an effective fumigation that complies with label requirements. The responsible party (i.e., the person supervising the fumigation) is responsible for ensuring FMPs are up-to-date and accurately reflect the site and current circumstances for fumigation before it takes place, and that the FMPs are followed. The Agency will provide detailed guidance for FMPs including a list of minimum elements that site-specific plans must address. This guidance will be incorporated in a methyl bromide commodity fumigation reference manual that will be available on the Agency's internet website. Product labels will require FMPs be developed based on the Agency manual. Elements that are not applicable to a given site may be so noted in the site-specific plans. The following are elements that must be included in all FMPs unless not relevant to a specific site:

- ❖ General site information (site address, site operator/owner, phone number)
  - Type of fumigation (e.g., quarantine, structural, mill, ship)
  - Description of enclosure/chamber/structure (map or sketch of the facility, volume of treatment area, enclosure materials, commodities fumigated, maximum rates and dosage times, local exhaust ventilation systems, MeBr destruction/capture systems, proximity to other structures and common walls)
  - Estimate of loss/retention rate (methods for evaluating and documenting)
  - Descriptions and locations of control rooms, storage areas, restricted areas, other work areas, and sensitive surrounding sites (such as homes, schools, hospitals, employee housing centers)
- ❖ Fumigator/applicator information (license #, address, phone, contact information for person supervising the fumigation, i.e., the responsible party)
- ❖ Treatment and aeration procedures
  - Maximum rates and dosage for each commodity
  - Location of gas introduction site (including map and description)
  - Leak testing procedures
  - Interior and perimeter air monitoring of treated areas (methods, procedures, and equipment)
- ❖ Buffer zones (see below for method to calculate treatment and aeration buffer zones based on Agency look-up tables or alternate methods)
- ❖ Authorized on-site personnel
  - Fumigators (fumigation workers must be certified applicators, or be working under the direct supervision of a certified applicator)
  - Other on-site workers
- ❖ Personal protective equipment (selection, fit-testing, maintenance, storage procedures)
- ❖ Posting and notification (plans, procedures, record of notifications)
- ❖ Record keeping
- ❖ Emergency procedures (evacuation routes, emergency utility shut-offs, locations of telephones, emergency company, local/state/federal contacts, key personnel and emergency responsibilities in case of an incident, equipment failure, or other emergency).
- ❖ Site security

- ❖ Hazard communication (product labels, material safety data sheets, etc.)
- ❖ Name, address, contact information, credentials, and signature of certifying party

The use of a comprehensive FMP will result in careful planning of all aspects of the fumigation process. While FMPs alone will not eliminate risk, they constitute a written record that provides specific logistical, performance, and contact information to help characterize the site and the fumigation process.

The responsible party (i.e. the person supervising the fumigation) must certify in writing that he/she has reviewed the FMP and that it addresses all elements required by product labels and the Agency methyl bromide commodity fumigation reference manual, and that all decisions on the treatment/aeration processes, buffer zones, and PPE are appropriate and protective. States or local governments may opt to require third-party certification (e.g., county agricultural commissioners, state pesticide enforcement officials, certified industrial hygienists, or certified safety professionals). In that case, where fumigations are supervised by a federal authority such as APHIS, the federal agency may certify the FMP. The responsible party must contact the applicable State lead agency to determine the certification requirements for that state.

For emergency fumigations that must be performed with limited advance notice, (e.g., quarantine fumigation of a ship or other container) generic plans that are not-site specific may be developed, completed, and certified as needed.

#### a. Buffer Zones

This decision requires that fumigators establish a buffer zone during the treatment and aeration periods which the responsible party has determined will protect bystanders and workers from risks posed by MeBr. EPA is preparing guidance to assist fumigators in making these decisions. Only persons supervising or performing fumigation activities are permitted within the buffer zones. All other people including workers, nearby residents, and other bystanders must be excluded from this zone except for as provided below. The buffer zone established for the treatment period must be maintained from the time MeBr is introduced until the aeration period begins. An aeration buffer zone must then be established and maintained until the methyl bromide concentration being exhausted from the enclosure is less than 5 ppm (see below for minimum aeration times). This 5 ppm level for aeration is currently required by the product label. It should be noted that the buffer zone during the aeration period in most fumigations will last only a portion of the aeration period (e.g., the air being exhausted from the treated area is less than 5 ppm but aeration is still being done until air concentration within commodity reaches 5 ppm or less).

The Agency's risk assessment provides modeled distances for treatment and aeration periods for a wide range of sites at which acute exposures have the potential to exceed the Agency's level of concern of 1 ppm for an 8-hour TWA if bystanders are present. The Agency modeled potential acute bystander exposure to methyl bromide with a distributional approach using PERFUM. The PERFUM model (V2.1.2) is available at

<http://www.sciences.com/perfum/index.html> and will eventually be placed on the Agency's website at <http://www.epa.gov/opphed01/models/fumigant/>. The PERFUM modeling framework was subjected to a Scientific Advisory Panel (SAP) review in 2004. Please refer to the SAP background documents and the SAP report (<http://www.epa.gov/scipoly/sap/2004/index.htm>). Additional characterization of the Agency's use of PERFUM in estimating acute bystander exposure to methyl bromide is also included in section 6.2 of the Agency risk assessment document.

The PERFUM model provides two types of results that include the maximum buffer distance and the whole field buffer distance. Each is reported as a distribution of distances. The whole field distance outputs represent the entire range of potential exposures, whereas maximum buffer distance outputs represent a subset of the highest daily exposure levels that were calculated. This approach provides more resolution at the highest levels of exposures. In other words, a given percentile of the whole field distance results is essentially equivalent to a corresponding percentile of maximum buffer distance results (i.e., 'x' percentile whole field distance results = 'y' percentile maximum buffer distance results). The Agency considered which PERFUM output results would adequately ensure bystander's acute exposures do not exceed 1 ppm for an 8-hour TWA.

The Agency is basing its buffer zone distances for MeBr's commodity uses on 99th percentile whole field distance outputs from PERFUM model results. These results represent the distances within which all bystanders must be excluded to ensure that their acute exposure to methyl bromide does not exceed the Agency's level of concern. EPA believes that requiring buffers at these distances combined with other mitigation measures described in this document will ensure that exposures will not exceed the Agency's level of concern. Furthermore, an analysis by the Agency has determined that the distances for scenarios modeled using the 99th percentile whole field distance outputs are in many cases similar to the distances currently required by California's permit conditions for MeBr commodity fumigations. As previously noted above, the EPA believes that establishing buffers zones along with other elements of California's permitting system have been very effective in reducing methyl bromide exposures.

It should be noted that the Agency has modeled ground level local exhaust ventilation (i.e., the PPQ method), while CDPR prohibits this practice. The Agency will allow the use of this method in states that do not prohibit it provided all mitigation measures described in this document and on product labels are followed. The discharge location of the ground level exhaust ventilation must be at least 25 feet from the enclosure (and any building that houses the enclosure).

#### 1) Buffer Zones Based on Agency Look-Up-Tables

The Agency will provide information in the form of look-up tables for commodity fumigators to follow to ensure that workers and bystanders are protected. These tables will be available on the Agency's internet website along with a methyl bromide commodity fumigation reference manual for a full range of application rates, loss rates, local ventilation systems, and

enclosure/chamber/structure volumes which can be determined and which must be established for each site. Distinct buffer zones will be required during the treatment and aeration periods and once the aeration period is completed the buffer zones may be discontinued. The Agency has determined that establishment of these buffers will ensure that bystander exposure to methyl bromide will not exceed the Agency's level of concern. Only authorized persons with respiratory protection (as specified in respiratory protection section below) may be permitted within the buffer zones.

## 2) Buffer Zones Based on Alternate Methods

Buffer zones that are more or less than those listed in the Agency's look-up tables may be established based on site-specific modeling (using site-specific data such as weather, flux rates, empirically derived or measured retention rates, etc.). The Agency recognizes that it is not practical or feasible to capture every possible site scenario in look-up tables. Therefore buffer zones based on site-specific enclosure/chamber/structural volumes or local exhaust ventilation (LEV) system parameters may also be modeled for individual sites. Only models specified in the Agency's methyl bromide commodity fumigation reference manual may be used to determine buffer zones.

Since the number of samples needed to adequately measure maximum downwind concentration is possible but impractical, air-monitoring data alone will likely not be sufficient to reduce required buffer zones. However, the Agency will allow buffer zone distances to be determined based on site-specific air monitoring that is done in accordance with criteria that will be specified in the Agency methyl bromide commodity fumigation manual.

Air monitoring and modeling for methyl bromide destruction or capturing devices such as scrubbers may also be used to determine the use of smaller buffer zones than those listed in the Agency's look-up tables. While this mitigation method may not yet be currently economically feasible for larger sites, it is one of the few options that directly reduce the total methyl bromide released and potential ozone depletion.

## 3) Minimum Buffer Zones

While modeling results predict no risk concern for locations immediately adjacent to the discharge location for some scenarios, the Agency believes that best management practices warrant a minimum buffer for all sites. Therefore, the responsible party must determine an appropriate minimum buffer zone based on site-specific conditions. For example, APHIS may decide to maintain their currently required buffers of 30 ft and 200 ft buffers for treatment and aeration periods, respectively, as a minimum buffer zone. However, EPA believes the minimum buffers during treatment and aeration periods should never be less than 10 feet during treatment and aeration periods. These minimum distances are based on the current requirements used by California for commodity fumigation.

## 4) Exceptions

### Occupied Structures

Exceptions from buffer zones for occupied structures that are within the buffer zones may be made in a FMP if air monitoring of methyl bromide concentrations within the occupied structure and around the perimeter of the fumigated enclosure during treatment and aeration periods are less than a ceiling limit of 5 ppm or an 8-hour TWA of 1 ppm. The Agency's methyl bromide commodity fumigation reference manual will provide guidance regarding air monitoring methods for these exceptions. Exemptions may not be used for sensitive sites (such as homes, schools, hospitals, employee housing centers) or buildings that share a wall with an enclosure being fumigated. FMPs must establish emergency procedures to be followed in the event air concentrations exceed a ceiling limit of 5 ppm or an 8-hour TWA of 1 ppm at these locations (e.g., immediate evacuation or use of respirators for workers). The specified buffer zone will be required for all other areas. Prior to conducting fumigations, the responsible party must obtain written acknowledgement from occupants of any structures that are exempted from buffer zones that the occupants have received information on the hazards of methyl bromide and understand the emergency procedures specified in the FMP.

### Non-Occupied Structures

Exceptions from buffer zones for structures that have been evacuated that are within the buffer zone may be made in the FMP. Steps must be specified that will ensure that occupants do not reenter the structure until treatment and aeration periods are completed and that air concentrations within the structure do not exceed 1 ppm for an 8-hour TWA when occupants reenter the structure.

### Transit

Limited transit (e.g., use of roads) for brief durations within the buffer zone may occur be if unavoidable.

#### b. Posting and Notification

Workers who handle treated commodities after they are transported from fumigation sites have a right-to-know the potential risks related to the handling of the treated commodities. This is especially a concern for workers who handle treated commodities from which the methyl bromide desorption rate is slow (e.g., walnuts and timber). The fumigator must provide these workers access to the material safety data sheet (MSDS) for the methyl bromide end-use product before workers come in contact with the treated commodities. In addition, the exterior of containers/packaging of all treated commodities must be clearly identified as having been fumigated with methyl bromide and aerated in accordance with EPA labels before leaving fumigation facilities. Fumigators must also comply with applicable Department of Transportation and any other federal, state, and local requirements for placarding vehicles leaving fumigation sites.



The community living or working in close proximity to commodity fumigation sites must have access to information on the nature of applications taking place and potential hazards that nearby fumigations may pose. Specifically, fumigators must ensure that all residents and businesses that own or occupy properties adjacent to sites where commodity fumigations with MeBr are taking place (and those located adjacent to buffer zones specified in the FMP) have been notified and provided with information on how the community can access FMPs for that site. Once an initial notification is completed, notification must occur annually, or within 30 days after a change in the FMP. Notification may be done via mail, newspaper, radio, television, posting at public sites (e.g., library, court house, post office) or other methods which the responsible party has determined is likely to ensure adjacent residents and businesses have access to the required information.

The posting and notification requirements for the community and workers will help ensure compliance with mitigation measures required by this decision and the product label. Furthermore, EPA believes that when workers and members of the community are well informed, compliance with mitigation measures is more likely to be successful and protective.

### c. Record Keeping

#### 1) Fumigation Sites

All monitoring results, application dates, and current FMPs must be kept on-site and be made readily available to local/state/federal enforcement personnel and all workers, and be provided upon request to any interested party in the community. FMPs must be kept and be available for at least 2 years from the date of fumigations. Mobile or non-fixed sites (e.g., ship holds or sites with no fixed buildings or structures after fumigation is completed) are required to keep records on-site only during the entire fumigation process (i.e., pre-treatment, treatment, and aeration periods). Site records may be maintained and made available to the public using the Internet or other methods. On-site records will be used by local, state, and federal enforcement staff to verify compliance with EPA labels.

#### 2) Fumigators

Responsible parties supervising fumigations must also maintain records of monitoring results and application dates for all sites where they have conducted fumigations for at least two years from the date of fumigations. In addition, they must also maintain FMPs for each site fumigated for at least two years from the date of fumigations. Fumigators must also comply with any local or State record keeping requirements.

### 2. Respiratory Protection for Fumigation Workers and Other On-site Workers

Respiratory protection will be required for anyone entering any area where methyl bromide concentrations are greater than 1 ppm for an 8-hour TWA. The Mine Safety and Health

Administration-National Institute for Occupational Safety and Health (MSHA-NIOSH) certification for cartridges used with air purifying respirators has not been given for any cartridges currently on the market that are specifically designed for protection against methyl bromide. The 3M 60928 is a NIOSH-approved combination organic vapor/acid gas chemical cartridge/P100 particulate filter. While NIOSH does not have a test procedure to certify air purifying filters for protection against methyl bromide, this combination cartridge is recommended by 3M for use against radioiodine or methyl bromide at ambient concentrations up to 5 ppm and for not more than one shift. For further details on the 3M's recommendations, see February 2001 "3M Technical Data Bulletin #146 Use Recommendations for 3M 60928 Cartridge/Filter" (link to 3M website: <http://multimedia.mmm.com/mws/mediawebsserver.dyn?6666660Zjcf6lVs6EVs666BraCOrrrQ-> ). The EPA has decided that the use of 3M air purifying respirators (APRs) equipped with 3M Model 60928 Organic Vapor/Acid Gas/P100 cartridges may be used for concentrations up to 5 ppm, and not for more than one work shift per day (and any MSHA-NIOSH certified cartridge for MeBr that becomes available). Respirator APR-cartridge combinations for other manufacturers will also be considered by the Agency provided written certification of their efficiency against methyl bromide is provided. CDPH currently allows the use of the 3M 60928 Cartridge/Filter for methyl bromide concentrations up to 5 ppm for commodity fumigations. The current requirement that aeration of all treated commodities continue until methyl bromide concentrations (within the treated commodity) are 5 ppm or less will not be changed. For methyl bromide air concentrations greater than 5 ppm, supplied air (SA) respirators or self contained breathing apparatus (SCBA) must be worn by all fumigation workers and other on-site personnel.

Manufacturers of direct-read instruments commonly used during fumigations specify a limit of detection as low as 0.2 ppm (e.g., Dräger Methyl Bromide Tube, Model # 0.2/a 8103391). However, fumigators and other industry stakeholders report that direct-read instruments allow reliable measurement only as low as 2 ppm. The Agency has determined that the use of respiratory protection can be discontinued within buffer zones specified above based on either of the following two procedures:

- Procedure 1: Daily exposure to MeBr without a respirator is less than 240 minutes. If four consecutive air samples are taken at least 15 minutes apart within the treated area using direct read devices show that air concentrations of 2 ppm or less, then use of respiratory protection may be discontinued. At least two additional samples must then be taken at least 30 minutes apart. If either of these samples is greater than 2 ppm, the use of respiratory protection must be resumed, and can only be discontinued again if two sample readings taken at least 15 minutes apart are less than 2 ppm.
- Procedure 2: Daily exposure to MeBr without a respirator is less than 160 minutes. If four consecutive air samples are taken at least 15 minutes apart within the treated area using direct read devices show air concentrations of 3 ppm or less, then use of respiratory protection may be discontinued. At least two additional

samples must then be taken at least 30 minutes apart. If either of these samples is greater than 3 ppm, the use of respiratory protection must be resumed, and can only be discontinued again if two sample readings taken at least 15 minutes apart are less than 3 ppm.

Under both procedures, air samples must be collected at least hourly throughout the workday (if workers are present) after respiratory protection is discontinued to ensure concentrations do not exceed 1 ppm for an 8 hour TWA. Records of sampling must be kept (see record keeping requirements above). The Agency has determined that these measures will ensure that worker exposures will not exceed 1 ppm for an 8-hour TWA.

### 3. Storage Areas

The Agency has concerns for when commodities are treated, aerated to 5 ppm and then moved to storage areas where air exchange rates may not be sufficient to allow for adequate dissipation of methyl bromide. This is especially a concern for commodities for which the desorption rate of methyl bromide is slow (e.g., walnuts, timber, etc.). Air monitoring of all storage areas where fumigated commodities are located must be conducted before workers without respiratory protection are allowed to enter. The procedures described in the previous section must be followed to determine when worker respiratory protection use is required and when its use may be discontinued.

### 4. Minimum Aeration Times

#### a. Mechanical and Passive Aeration

Enclosures (i.e., areas fumigated) must be aerated for a minimum of 4 hours if mechanically ventilated using fans, or 12 hours if passively ventilated. At the end of the aeration process, the concentration within the treated commodity (or space for structural fumigations) must be no greater than 5 ppm. The commodity may not be moved from the enclosure during the aeration period, except where noted below. For some commodities and enclosure types, aeration times of longer than 12 hours may be needed to achieve concentrations of 5 ppm or less.

#### b. Exceptions

Exceptions for these minimum aeration times are allowed under the following conditions:

- Vacuum Chambers - Vacuum chambers that provide at least 4 air changes per hour.
- Aeration Outside of Fumigation Enclosure - Fumigated commodity may be removed from the fumigation enclosure as soon as the concentration of methyl bromide in the air spaces between the stacked commodities is less than 5 ppm and at least ten air changes have been completed. However, the minimum aeration

time (4 or 12 hours) must be provided before anyone is permitted to handle (process, package) the treated commodity. In other words, the minimum aeration time must be provided before people can handle the treated commodity. The aeration can occur within the enclosure, a storage area, or some other holding area. The length of time for which aeration is required can be prorated between the time inside the enclosure and outside the enclosure if the method of aeration is changed. For example, if two hours of mechanical aeration are completed before the commodity is removed from the enclosure, one-half of the required aeration has been achieved. Therefore, six hours of passive aeration outside of the enclosure is still required (the second half of the required aeration).

- Air Monitoring - Various types of monitoring may indicate that the minimum aeration times can be reduced. This may involve testing the rate of desorption for a specific commodity or monitoring workers with charcoal tubes, Summa canisters, long-path infrared spectrometer, or some other sensitive method. This type of monitoring cannot be done with colorimetric detector tubes. Air monitoring must be done with devices that have a limit of detection (LOD) of 0.5 ppm or lower. Additional guidance regarding monitoring requirements will be provided in the Agency methyl bromide commodity fumigation reference manual.

The facts that support using any of these exceptions must be clearly explained in the site's FMP.

## V. What Registrants Need to Do

The Agency has determined that with the mitigation measures identified in this document, use of methyl bromide to fumigate commodities is eligible for reregistration; however, additional data are required to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) confirmatory data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are additional confirmatory generic data that the Agency intends to require for methyl bromide's commodity uses.

### A. Manufacturing Use Products

#### 1. Additional Generic Data Requirements

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

Most pertinent product chemistry requirements data have been satisfied for the Ameribrom 100% and Albemarle 99.8% T/TGAIs, and for the Albemarle 98% FI; however, additional data are required for:

- OPPTS Guideline 830.6314 and 7050 - T/TGAIs concerning oxidation/reduction and UV/vis absorption
- OPPTS 830.6314 - Albemarle 98% FI concerning oxidation/reduction

For further details regarding product chemistry please refer to “Reregistration of Methyl bromide: Product and Residue Chemistry Chapters to the Reregistration Eligibility Document (D271583, C. Olinger, 2/22/02).” This document is included in the methyl bromide docket (EPA-HQ-OPP-2005-0123).

The assessment of occupational and residential risks associated with the use of methyl bromide is complex. There was a significant amount of data available but additional data are still required to confirm the findings of this document. These include both occupational monitoring of various workers in different industry sectors and data to better assess exposures to the general population. The types of data, guideline citations, and examples of the scenarios which need to be addressed are presented below. Final selection of the scenarios must be approved by the Agency. Development of data described below may fall under the Agency's final rule for protection of human subjects (40 CFR Part 26); any such studies must comply with the requirements of this rule.

- OPPTS Guideline 875.1400 - Inhalation exposure for applicators (indoors)  
Commodity - (e.g., fumigators, material handlers, aerators)  
Industrial - (e.g., fumigators, material handlers, aerators)
- OPPTS Guideline 875.2500 - Inhalation exposure for postapplication workers  
Commodity - (e.g., forklift drivers, sorters, packagers)  
Industrial - (e.g., line workers, forklift drivers)
- Requirements for special studies -

Meteorological data for probabilistic modeling purposes product use information by major use region, frequency, application

Parameters (e.g., rate, amounts treated, data, application equipment and emission control technologies used)

Measurements of indoor methyl bromide air concentrations for residences in proximity to treated facilities

Measurement of ambient methyl bromide air concentrations in representative high-use areas of the U.S.

## 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

#### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers must be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For questions regarding the PDCI, contact Karen Jones from OPP/SRRD's Product Reregistration Branch at (703)308-8047 or by e-mail at [Jones.Karen@epa.gov](mailto:Jones.Karen@epa.gov).

## 2. Labeling for End-Use Products

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

<b>Table 2. Summary of Labeling Changes for Methyl Bromide Commodity Fumigation</b>		
<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
For all Manufacturing Use Products	<p>Methyl bromide cannot be formulated into end-use products containing directions for use for fumigation of commodities in chambers at ports or specialized structural fumigations at food processing facilities unless the end-use product labeling includes requirements for site-specific fumigant management plans, buffer zones, air concentration monitoring, aeration periods, respiratory protection requirements and contains a reference to following all of the requirements in EPA’s methyl bromide commodity fumigation manual.</p> <p>“Methyl bromide cannot be formulated into end-use products labeled for commodity use on alfalfa hay, coffee beans, cottonseed, mangoes, papayas, pomegranates, timothy hay. End-use product labels must be revised to delete all references to and use directions for these commodities.”</p>	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>"This product is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."</p>	Precautionary Statements

End Use Products Intended for Occupational Use		
Identify as a fumigant any methyl bromide end-use product containing directions for use for commodity fumigation	Prominently identify the end-use product as a <b>“Fumigant”</b>	Insert the word “fumigant” as part of the product name or close to the product name, either as part of the product-type identification or as a separate word or sentence
Add precautionary language in Spanish on any methyl bromide end-use product containing directions for use for commodity fumigation	Add the following Spanish signal word and statement:  <b>"PELIGRO</b>  Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"	On front panel of the label near the signal word DANGER.
Add acceptable air concentration language to any methyl bromide end-use product containing directions for use for commodity fumigation	<b>"AIR CONCENTRATION LEVEL</b> The acceptable air concentration level for persons exposed to methyl bromide from commodity uses is 1 ppm for an 8-hour time weighted average (TWA) (4 mg/m <sup>3</sup> ). The air concentration level must be measured by a direct reading detection device, such as a Matheson-Kitagawa, Draeger, or Sensidyne and air monitoring must be conducted as specified in the “Monitoring Air Concentrations Section of this labeling.”	In the Hazards to Humans and Domestic Animals section of the labeling immediately following the precautionary statements.
PPE Requirements Established by the RED for methyl bromide end-use products containing directions for use for commodity fumigation	<b>"PERSONAL PROTECTIVE EQUIPMENT</b>  <b>Applicators and other handlers must wear:</b> -- Loose-fitting long-sleeved shirt and long pants -- Shoes and socks -- Protective eyewear when handling liquid. -- In addition, when a respirator is required, protect the eyes from the vapors by wearing a full-face respirator or face-sealing goggles with a half-face respirator.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals



	<p><b>Respirator Requirements:</b> Once methyl bromide has been introduced into an enclosure, a person located within the treatment area, treatment buffer zone, aeration buffer zone, post-treatment commodity storage areas, and tank storage areas may only be present without a respirator when air monitoring procedures in the “Monitoring Air Concentration Levels” are followed. The certified applicator supervising the fumigation must make sure that all persons in the treatment buffer zone and the aeration buffer zone have appropriate respiratory protection or are removed from the exposure area.</p> <p><b>Air Concentrations Greater than 5 ppm:</b> If the methyl bromide air concentration level is measured to be 5 ppm or greater at anytime, each person in the exposure area must wear either  -- a supplied-air respirator (MSHA/NIOSH approval number prefix TC-19C), or  -- a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F)."</p> <p><b>Air Concentrations of 5 ppm or less:</b> If the methyl bromide air concentration level is measured to be 5 ppm or less, each person in the exposure area must wear one of the following types of respirator:  -- a supplied-air respirator (MSHA/NIOSH approval number prefix TC-19C), or  -- a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F), or  -- a NIOSH-approved half-face, full-face, or hood-style respirator with a cartridge or canister certified by the manufacturer for protection from exposure to methyl bromide at concentrations up to 5 ppm. The manufacturer must provide EPA, in writing, certification of the effectiveness of the cartridge or canister against exposures to methyl bromide and specify the length of time (such as one 8-hour work shift) that the cartridge or canister will remain effective. EPA will provide a list all certified cartridges and canisters in the Agency’s Methyl Bromide Commodity Fumigation Reference Manual</p> <p><b>Air Concentrations Less than 1 ppm for an 8-hour TWA</b> No respirator is required if the air concentration level of methyl bromide in the working area is measured to be less than 1 ppm for an 8-hour time weighted average (TWA).</p> <p><b>Transit Exception:</b> If roads or other vehicle passageways are located within the treatment buffer zone or the aeration buffer zone, occupants of vehicles are permitted to travel through the buffer zone without respiratory protection, provided the transit period is brief and the need for the transit is unavoidable.</p>	
User Safety Requirements for all methyl bromide end-use products containing directions for use for commodity fumigation	<p><b>"USER SAFETY REQUIREMENTS</b></p> <ul style="list-style-type: none"> <li>- Respirator Requirements: When a respirator is required for use with this product, the certified applicator supervising the fumigation must make sure that: <ul style="list-style-type: none"> <li>a) Respirators must be fit tested and fit checked using a program that conforms with OSHA’s</li> </ul> </li> </ul>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Personal Protective Equipment

	<p>requirements (described in 29 CFR Part 1910.134;</p> <p>b) Respirator users must be trained using a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134;</p> <p>c) Respirator users must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn;</p> <p>d) Respirators must be maintained according to a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134.</p> <p>-- Do not wear jewelry, gloves, tight clothing, rubber protective clothing, or rubber boots when handling. Methyl bromide is heavier than air and can be trapped inside clothing or objects and cause skin injury.</p> <p>-- If liquid fumigant splashes or spills on clothing, remove them at once and place them outdoors in an isolated place to aerate, because fumes will be an intolerable source of irritation.</p> <p>-- Immediately after application remove outer clothing, shoes, and socks. Do not reuse contaminated clothing or shoes until cleaned. Keep and wash the clothing and shoes separately from other laundry.</p> <p>-- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.</p> <p>-- Follow manufacturer's instructions for cleaning/maintaining protective eyewear and respirators."</p>	Requirements
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following User Safety Requirements</p> <p>(Must be placed in a box.)</p>
Site-Specific Fumigation Management Plans for all methyl bromide end-use products containing directions for use for	<p>“<b>SITE-SPECIFIC FUMIGATION MANAGEMENT PLAN (FMP)</b></p> <p>Prior to fumigating commodities, a site-specific fumigation management plan (FMP) must be developed. The certified applicator supervising the fumigation must ensure that the FMP is up-to-date and applicable to the fumigation before it takes place. The minimum elements that FMP site-specific plans</p>	<p>In the Directions for Use for Commodity Fumigation under the heading “Site-Specific Fumigation</p>

<p>commodity fumigation</p>	<p>must address, details about how to develop the FMP, and a methyl bromide commodity fumigant reference manual are available through EPA’s publication office (EPA # XXXX or at EPA’s website (<a href="http://www.epa.gov/XXXXX">www.epa.gov/XXXXX</a>))</p> <p>For emergency fumigations that must be performed with limited advance notice, (e.g., quarantine fumigation of a ship or other container) generic (non-site-specific) plans may be developed, completed, and certified as needed.</p> <p>During the two year period following a fumigation, the site-specific FMP must be made readily available to all fumigation workers and other on-site workers, and must be made available upon request to any local, state, tribal, or federal pesticide enforcement personnel, and to any interested individuals in the community.</p> <p>Before the start of any commodity fumigation, the certified applicator supervising the fumigation must certify in writing that he/she has reviewed the FMP and that it addresses all elements identified on this labeling and in EPA’s Methyl Bromide Commodity Fumigation Reference Manual. In addition, he/she must certify in writing that the elements in the FMP related to the treatment and aeration processes, appropriate buffer zones, and personal protective equipment are appropriate to that fumigation and that they will be implemented according to the FMP. The signed certification must be kept for at least two years with the FMP and application records as specified in this labeling.”</p>	<p>Management Plan (FMP)”</p>
<p>Restrictions During Fumigation and Aeration</p>	<p><b>“BUFFER ZONES</b></p> <p>The certified applicator supervising the fumigation must determine the buffer zone (the appropriate distance from the fumigation site) that must be maintained during fumigation and the buffer zone that must be maintained until the air concentration exhausted from the treatment area is 5 ppm or less. The treatment buffer zone and the aeration buffer zone must be included in the site-specific fumigation management plan. The appropriate buffer zones may be determined through one of the following methods:</p> <ul style="list-style-type: none"> <li>-- EPA’s Methyl Bromide Commodity Fumigation Buffer Zone Tables located in EPA’s Methyl Bromide Commodity Fumigation Reference Manual, which is available through EPA’s publication office (EPA # XXXX or at EPA’s website (<a href="http://www.epa.gov/XXXXX">www.epa.gov/XXXXX</a>)); or</li> <li>-- buffer zones less than those listed in EPA’s Buffer Zone Tables can be established based on site-specific modeling using only models meeting the criteria described in EPA’s Methyl Bromide Commodity Fumigation Reference Manual. The site data needed for such models includes weather, flux rates, measured or empirically derived retention rates, exhaust methods, and other site-specific information. Note that air monitoring and modeling for methyl bromide destruction or capturing devices, such as scrubbers, may be used to establish buffer zones less than those listed in EPA’s Buffer</li> </ul>	<p>Directions for Use for Commodity Fumigation under the heading “BUFFER ZONES”</p>

	<p>Zone Tables provided that it complies with criteria described in EPA Methyl Bromide Commodity Fumigation Reference Manual.</p> <p>Minimum Buffer Zones: Regardless of the method use to establish appropriate treatment buffer zone and aeration buffer zone, the minimum treatment or aeration buffer zone is 10 feet.”</p>	
<p>Buffer Zone Entry Restrictions</p>	<p><b>“BUFFER ZONE ENTRY RESTRICTIONS</b></p> <p>Entry by any person, except the certified applicator supervising the fumigation, or persons under his/her direct supervision, is prohibited in the treatment buffer zone and in the aeration buffer zone. Authorized persons who enter the treatment or aeration buffer zones must be wearing all of the personal protective equipment specified for handlers on this labeling. If a structure within the treatment buffer zone or the aeration buffer zone is not occupied (due to deliberate evacuation or other reasons), steps must be taken to ensure that persons do not enter the structure until the treatment and aeration periods are completed and until the air concentrations within the structure do not exceed 1 ppm for an 8-hour TWA when any persons are permitted to re-occupy the structure..</p> <p><b>Exceptions to Buffer Zone Entry Restrictions:</b> Two exceptions are permitted to treatment buffer zones and aeration buffer zones</p> <ol style="list-style-type: none"> <li>1. <b>Occupied Structure Exception:</b> Occupants of a structure that is within the treatment and/or aeration buffer zone may remain in the structure, <i>provided</i> continuous real-time monitoring indicates that methyl bromide concentrations are 5 ppm or less within the occupied structure. This exception only applies to structures occupied by occupational workers. It does not apply to homes, apartment buildings, schools, hospitals, nursing homes, employee housing centers, or other sensitive sites. To use this exception, the FMP must state the distance of the occupied structure to the fumigation site, the method of conducting the real time monitoring for methyl bromide during treatment and aeration, and specific procedures for immediate intervention, such as cessation of aeration, evacuation of building, or supplying all occupants with appropriate respirators if the concentration of methyl bromide exceeds 5 ppm at any time.</li> <li>2. <b>Transit Exception:</b> If roads or other vehicle passageways are located within the treatment buffer zone or the aeration buffer zone, occupants of vehicles are permitted to travel through the buffer zone without respiratory protection, provided the transit period is brief and the need for the transit is unavoidable. To use this exception, the FMP must state the distance from the fumigation site to the vehicle passageway, the estimated length of time vehicles will be in the buffer zone, and the rationale why occupants of the vehicle will not be adversely affected by the exposure methyl bromide while in transit through the buffer zone.”</li> </ol>	<p>Directions for Use for Commodity Fumigation under the heading “BUFFER ZONE ENTRY RESTRICTIONS”</p>

<p>Monitoring Air Concentration Levels</p>	<p><b>“MONITORING AIR CONCENTRATION LEVELS</b></p> <p><b>Monitoring Air Concentrations in Treatment Buffer Zones, Aeration Buffer Zones, and Commodity Storage Areas:</b> Air concentration levels must be monitored using a direct reading detection device, such as a Matheson-Kitagawa, Draeger, or Sensidyne device. If colorimetric tubes are used for air monitoring, measurements of 2 ppm or less should be considered and recorded as 2 ppm. Respiratory protection must be used by all personnel who enter and remain in a treatment buffer zone, in an aeration buffer zone, or in a commodity storage area until one of the following air concentration monitoring procedures has been completed:</p> <p>-- Procedure 1: Provided that exposure to methyl bromide by any worker who is not wearing respiratory protection is limited to a maximum of 240 minutes (4 hours) per day, respirator protection may be discontinued in the treatment buffer zone, the aeration buffer zone, and/or the commodity storage area, provided four consecutive air concentration samples taken at least 15 minutes apart indicate methyl bromide air concentration levels of 2 ppm or less <i>and</i> two additional air concentration samples taken at least 30 minutes apart also indicate methyl bromide air concentration levels of 2 ppm or less. If either of the two samples taken at least 30 minutes apart indicates a methyl bromide air concentration level greater than 2 ppm, then respiratory protection must continue until two additional air concentration samples taken at least 15 minutes apart indicate that methyl bromide air concentration levels are 2 ppm or less.</p> <p>-- Procedure 2: Provided that exposure to methyl bromide by any worker who is not wearing respiratory protection is limited to a maximum of 160 minutes (2 hours and 40 minutes) per day, respirator protection may be discontinued in the treatment buffer zone, the aeration buffer zone or the commodity storage area, provided, provided four consecutive air concentration samples taken at least 15 minutes apart indicate methyl bromide air concentration levels of 3 ppm or less <i>and</i> two additional air concentration samples taken at least 30 minutes apart also indicate methyl bromide air concentration levels of 3 ppm or less. If either of the two samples taken at least 30 minutes apart indicates a methyl bromide air concentration level greater than 2 ppm, then respiratory protection must continue until two additional air concentration samples taken at least 15 minutes apart indicate that methyl bromide air concentration levels are 3 ppm or less.</p> <p><b>Continued Air Monitoring:</b> After respiratory protection is discontinued on the day of fumigation, the certified applicator supervising the fumigation or someone under his/her supervision must continue to monitor air concentration levels of methyl bromide in the treatment buffer zone, in the aeration buffer zone, and in any area where the treated commodity is stored at least hourly throughout the remainder of</p>	<p>Directions for Use for Commodity Fumigation under the heading “MONITORING AIR CONCENTRATION LEVELS”</p>
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	<p>the workday (when any workers are present). If at any time, methyl bromide air concentration levels exceed 2 ppm or 3 ppm corresponding to for Procedures 1 and 2, respectively as described above , then respiratory protection must be resumed for all personnel in the exposure area.</p> <p><b>Recordkeeping:</b> Records must be kept of all methyl bromide air monitoring (see recordkeeping requirements elsewhere on this labeling).”</p>	
Aeration Period	<p><b>“AERATION PERIOD</b></p> <p>Aeration period is the time from the end of the treatment period until the concentration within the treated commodity or space for structural fumigations is no greater than 5 ppm. The certified applicator supervising the fumigation must determine the aeration time that is appropriate for the fumigation that will take place. The time of the aeration period must be included in the site-specific fumigation management plan.</p> <p>Except as provided below, enclosures where methyl bromide fumigation took place must be aerated for a minimum of:</p> <ul style="list-style-type: none"> <li>-- 4 hours if mechanically ventilated using fans, or</li> <li>-- 12 hours if passively ventilated using windows or doors only.</li> </ul> <p>The minimum aeration time is measured starting at the end of the fumigation period and the beginning of aeration through mechanical or passive means. At the end of the aeration period, the methyl bromide air concentration level within the treated commodity or within the space for structural fumigation must be measured. Until the air concentration level is measured to be 5 ppm or less, the commodity cannot be moved from the fumigation enclosure.</p> <p>Exceptions to minimum aeration times: Enclosures where methyl bromide fumigation took place need not be aerated for the minimum aeration times listed here, provided:</p> <ul style="list-style-type: none"> <li>-- a vacuum chamber is used that provides at least 4 air exchanges per hour. The minimum aeration time for such a vacuum chamber is the time from the start of aeration until 10 air exchanges have been completed. If this exception to the minimum aeration period is used, the site-specific fumigant management plan must explain the basis for exception, such as documentation on the designation that the enclosure is a vacuum chamber and about the number of air exchanges per hour for the fumigation enclosure. Criteria for vacuum chambers may found in the EPA’s Methyl Bromide Commodity Fumigation Reference Manual, which is available through EPA’s publication office (EPA # XXXX or at EPA’s website (<a href="http://www.epa.gov/XXXXX">www.epa.gov/XXXXX</a>));</li> <li>-- various types of air monitoring indicate that the minimum aeration times can be reduced. This may</li> </ul>	Directions for Use for Commodity Fumigation under the heading “AERATION PERIOD”

	<p>involve testing the rate of desorption for a specific commodity or monitoring workers with charcoal tubes, Summa canisters, long-path infrared spectrometer, or some other sensitive method. This type of air monitoring cannot be done with colorimetric detector tubes. Air monitoring must be done with devices that have a limit of detection (LOD) of 0.5 ppm or lower. Additional guidance regarding monitoring requirements will be provided in the EPA Methyl Bromide Commodity Fumigation Reference Manual. If this exception to the minimum aeration period is used, the site-specific fumigant management plan must explain the basis for exception.”</p>	
<p>Moving Fumigated Commodities from the Fumigation Enclosure</p>	<p><b>“MOVING FUMIGATED COMMODITIES TO SEPARATE STORAGE AREAS</b>  Fumigated commodities may be moved from the fumigation enclosure to storage areas, <i>provided</i>  -- the concentration of methyl bromide in the air spaces among the stacked commodities is measured to be 5 ppm or less, <i>and</i>  -- at least ten air exchanges have been completed in the fumigation enclosure.</p> <p>However, the minimum aeration time must be completed in the storage area before workers are permitted to process, package, or otherwise handle the treated commodity. The total aeration time is measured from the start of aeration in the fumigation enclosure and includes aeration time in the fumigation enclosure plus any aeration that occurs in a holding area and aeration that occurs in the storage area. If a combination of aeration techniques are used, the effective aeration time can be prorated to reflect the techniques used. For example, if two hours of mechanical ventilation occur in the fumigation enclosure before the commodity is moved to a storage area, then that constitutes one-half of the required minimum aeration time (2 hours out of 4 hours for mechanical ventilation). If the storage area uses passive ventilation, then the storage area would have to be passively ventilated for at least 6 hours (one half of the 12 hours for passive ventilation) before workers would be permitted to handle the treated commodity.”</p>	<p>Directions for Use for Commodity Fumigation under the heading “MOVING FUMIGATED COMMODITIES TO SEPARATE STORAGE AREAS”</p>

<p>Onsite Notification for all methyl bromide end-use products containing directions for use for commodity fumigation</p>	<p><b>"PLACARDING OF FUMIGATED AREAS</b></p> <p>The certified applicator in charge of the fumigation (or someone under his/her supervision) must placard all entrances to the fumigated area with signs bearing:</p> <ul style="list-style-type: none"> <li>-- skull and crossbones symbol</li> <li>-- "DANGER/PELIGRO,"</li> <li>-- "Area under fumigation, DO NOT ENTER/NO ENTRE,"</li> <li>-- "Methyl Bromide Fumigant in use,"</li> <li>-- the date and time of fumigation, and</li> <li>-- name, address, and telephone number of the certified applicator in charge of the fumigation."</li> </ul> <p>"Do not enter or allow entry by unprotected persons into the fumigated area until the signs are removed. Such signs must only be removed when aeration has occurred and when the air concentration level of methyl bromide is monitored as described in this labeling and indicates that workers can enter without respiratory protection. Signs must remain legible during entire posting period."</p> <p>"The warning signs at entrances to fumigated structures may only be removed by the certified applicator in charge of the fumigation (or someone under his/her supervision)."</p> <p>"Vehicles leaving the fumigation site must be placarded with applicable U.S. Department of Transportation warning signs."</p>	<p>In the Directions for Use for Commodity Fumigation under the heading "PLACARDING FUMIGATED AREAS"</p>
<p>Treated Commodity Notification</p>	<p><b>TREATED COMMODITY NOTIFICATION</b></p> <p>"The certified applicator supervising the fumigation or someone under his/her supervision must affix a tag or label to the exterior of every container or package containing fumigated commodities that states:</p> <p>"The contents of this container have been fumigated with methyl bromide fumigant and have been aerated in accordance with EPA approved methyl bromide product labels."</p> <p>The certified applicator supervising the fumigation (or someone under his/her direct supervision) must make the Material Safety Data Sheet (MSDS) for this methyl bromide product available to workers before they handle methyl bromide fumigated commodities.</p>	<p>In the Directions for Use for Commodity Fumigation under "Treated Commodity Notification" immediately following "Placarding of Fumigated Areas:"</p>
<p>Community Notification</p>	<p><b>"COMMUNITY NOTIFICATION</b></p> <p>The certified applicator supervising the fumigation (or someone under his/her direct supervision) must ensure that residents and owners/operators of businesses within and immediately adjacent to the treatment and aeration buffer zones for the facility have been notified that commodities are being</p>	<p>In the Directions for Use for Commodity Fumigation under "COMMUNITY NOTIFICATION"</p>



	<p>fumigated with methyl bromide at the facility and how they can access the Fumigant Management Plan(s) for the facility. The notification must state that in case of an accident:</p> <ul style="list-style-type: none"> <li>-- people in the immediate area may be exposed to methyl bromide,</li> <li>-- exposure to methyl bromide may result in irritation to the skin, eyes, and respiratory tract, and</li> <li>-- persons who experience such symptoms should seek fresh air immediately.</li> </ul> <p>The notification must take place before the first fumigation begins after the FMP is completed and must be repeated annually or within 30 days of a change in the FMP, which ever occurs first. The notification method must be included in the FMP and may be accomplished through mail, newspaper, radio, television, posting at public sites, such as local library, court house, post office), or through another method that effectively notifies persons within or immediately adjacent to the treatment and aeration buffer zones for the fumigation facility.”</p>	immediately following “Treated Commodity Notification”
Recordkeeping	<p><b>“RECORDKEEPING</b></p> <p>The certified applicator supervising the fumigation or persons under his/her direct supervision must maintain records which include the dates fumigation took place and the results of air monitoring. During the two-year period following a fumigation, these records must be made readily available to all fumigation workers and other on-site workers, and must be made available upon request to any local, state, tribal, or federal pesticide enforcement personnel, and to any interested individuals in the community. The records may be provided to the public using the Internet.”</p>	Directions for Use for Commodity Fumigation under the heading “RECORDKEEPING”
Environmental Hazards Statements	<p><b>“ENVIRONMENTAL HAZARDS</b></p> <p>This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.“</p>	Precautionary Statements under Environmental Hazards
Storage and Disposal language of for all methyl bromide end-use products containing directions for use for commodity fumigation	"Persons moving, handling, or opening containers must wear the personal protective equipment (including prescribed respirators when necessary) specified in the Human Hazards section of this labeling. Store containers in a well-ventilated area."	Storage and Disposal section of the label
Spill and Leak Procedures of for all methyl bromide end-use	<b>"SPILL AND LEAK PROCEDURES</b> Evacuate everyone from the immediate area of the spill or leak. No person may enter into the spill or leak area without wearing the appropriate personal protective equipment, including prescribed	In the labeling section titled "Storage and Disposal" <b>or</b> by

<p>products containing directions for use for commodity fumigation</p>	<p>respiratory protection,(see the Hazards to Humans section of this labeling),until one of the air concentration monitoring procedures has been completed (see the Monitoring Air Concentrations section of this labeling).</p> <p>Only certified applicators or persons under their direct supervision are permitted to perform such cleanup. Move leaking or damaged containers outdoors or to an isolated location. Observe strict safety precautions. Work upwind, if possible. Allow spilled fumigant to evaporate.</p> <p>Contaminated soil, water, and other cleanup debris is a toxic hazardous waste. Report spill to the National Response Center (800-424-8802) if the reportable quantity of 1000 lbs. is exceeded."</p>	<p>themselves under the heading "Spill and Leak Procedures"</p>
<p>General Application Restrictions</p>	<p><b>"DIRECTIONS FOR USE</b> It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.</p> <p>Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation."</p>	<p>Place in the Direction for Use directly below the heading "Directions for Use"</p>
<p>Commodity-Specific Application Restrictions</p> <p>(The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.)</p>	<p>End-Use Products with directions for use for commodity fumigations must have the following maximum application rates and maximum exposure periods:</p> <p><b>Almonds:</b> maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.</p> <p><b>Apples:</b> maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Apricots:</b> maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Artichokes, Jerusalem:</b> maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Asparagus:</b> maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Avocados:</b> APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum</p>	

exposure period is 3 hours

**Barley:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Beans (succulent):** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Beans (dried):** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Beets (roots) :** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Blackberries:** APHIS only: maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Blueberries:** maximum application rate is 2.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Brazil nuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Broccoli:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Bushnuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Butternuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Cabbage:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Cantaloupes:** APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Carrots:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Cashews:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Cauliflower:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Cherries:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Chestnuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Chestnuts: use limited to vacuum chambers only.** maximum application rate is 6.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours.

**Cippolini bulbs:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours.

**Citron Citrus Fruit:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Cocoa beans:** maximum application rate is 1.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours. Maximum number of fumigations is two with a 12-day retreatment interval.

**Cocoa beans:** when used in a vacuum chamber, the maximum application rate is 1.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 12 hours.

**Copra:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Corn:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Corn, pop:** use limited to vacuum chambers only. maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

	<p><b>Corn, sweet:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Cucumbers:</b> APHIS only: maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 2.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Eggplant:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Filberts:</b> maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.</p> <p><b>Garlic:</b> APHIS only: maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Grapefruit:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Grapes:</b> APHIS only: maximum application rate is 2.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Hickory nuts:</b> maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.</p> <p><b>Honeydew melons:</b> APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours</p> <p><b>Horseradish:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Kiwi fruit:</b> APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours. Users other than APHIS: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum</p>	
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exposure period is 3 hours

**Kumquats:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Leafy vegetables:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Lemons:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Limes:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Macadamia nuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Muskmelons:** APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours

**Nectarines:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Oats:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Okra:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Onions:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours.

**Oranges:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Parsnips:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Peaches:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Peanuts:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Pears:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Peas (with pods):** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Peas (dried):** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Pecans:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Peppers:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Pimentos:** maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 3 hours.

**Pineapples:** APHIS only: maximum application rate is 2.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours. Users other than APHIS: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours

**Pistachios:** maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Plums:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Potatoes:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours.

**Pumpkins:** maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Quinces:** maximum application rate is 5.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Radishes:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Rice:** APHIS only: when using a tarp, the maximum application rate is 9.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 12 hours. APHIS only when using a vacuum chamber, the maximum application rate is 12 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 12 hours. Users other than APHIS: maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours

**Rutabagas:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 6 hours.

**Rye:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Salsify roots:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 3 hours.

**Sorghum (grain):** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.

**Squash (summer):** APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours

**Squash (winter):** APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours

**Squash, zucchini:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Strawberries:** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.

**Sugar beets (roots):** maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.

**Sweet potatoes:** maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.



	<p><b>Tangelos:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Tangerines:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours.</p> <p><b>Tomatoes:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Turnips (roots) :</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p> <p><b>Walnuts:</b> maximum application rate is 3.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.</p> <p><b>Watermelons:</b> APHIS only: maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours. Users other than APHIS: maximum application rate is 2.5 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 2 hours</p> <p><b>Wheat:</b> maximum application rate is 3.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 24 hours.</p> <p><b>Yams:</b> maximum application rate is 4.0 lb ai/1000 ft<sup>3</sup> and maximum exposure period is 4 hours.</p>	
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## C. Conclusions

The Agency is issuing this Reregistration Eligibility Decision (RED) document for commodity fumigation uses of methyl bromide, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing methyl bromide. The Agency has determined that all currently registered commodity fumigation uses of methyl bromide are eligible for reregistration provided that the mitigation measures are adopted on product labels.

The Agency has also determined that all methyl bromide tolerances are reassessed, as detailed in this document. There will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on this document.

## Appendices

Appendix A: Methyl Bromide Use Patterns Eligible For Reregistration

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision for Methyl Bromide

Appendix C: Technical Support Documents

Appendix D: Bibliography

Appendix E: Generic Data Call-In

Appendix F: Product Specific Data Call-In

Appendix G: EPA's Batching of Methyl Bromide Products for Meeting Acute Toxicity Data Requirements for Reregistration

Appendix H: List of Registrants Sent Data Call-Ins

Appendix I: List of Available Related Documents and Electronically Available Forms

Appendix J: Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Commodity Uses. PC Code: 053201, DP Barcode: D304623," (March 10, 2006)

Appendix K: Addendum To Phase 5 Health Effects Division (HED) Human Health Risk Assessment For Commodity Uses. PC Code: 053201, DP Barcode: D304619 (July 12, 2006)