

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 7. In § 522.313c, revise paragraphs (b), (e)(2)(ii), (e)(3)(ii), (e)(4)(ii), and (e)(8)(i) to read as follows:

§ 522.313c Ceftiofur sodium.

(b) *Sponsors.* See Nos. 000009, 000409, and 068330 in § 510.600(c) of this chapter.

(e) * * *
(2) * * *

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(3) * * *

(ii) *Indications for use.* For treatment of sheep respiratory disease (sheep pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(4) * * *

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(8) * * *

(i) *Amount.* 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 8. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 9. In § 558.363, revise paragraph (d)(1)(i) introductory text to read as follows:

§ 558.363 Narasin.

(d) * * *
(1) * * *

(i) *Amount per ton.* Narasin, 54 to 90 grams.

Dated: May 7, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2009-0277; FRL-9668-3]

RIN 2060-AQ83

Protection of Stratospheric Ozone: The 2012 Critical Use Exemption From the Phaseout of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is authorizing uses that qualify for the 2012 critical use exemption and the amount of methyl bromide that may be produced, imported, or supplied from existing pre-phaseout inventory for those uses in 2012. EPA is taking this action under the authority of the Clean Air Act to reflect a recent consensus decision by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer at the Twenty-Second Meeting of the Parties.

DATES: This rule is effective on May 17, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2009-0277. All documents in the docket are listed on the www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For further information about this rule, contact Jeremy Arling by telephone at

(202) 343-9055, or by email at arling.jeremy@epa.gov or by mail at U.S. Environmental Protection Agency, Stratospheric Protection Division, Stratospheric Program Implementation Branch (6205J), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may also visit the methyl bromide section of the ozone layer protection Web site at www.epa.gov/ozone/mbr for further information about the methyl bromide critical use exemption, other stratospheric ozone protection regulations, the science of ozone layer depletion, and related topics.

SUPPLEMENTARY INFORMATION: This rule concerns Clean Air Act (CAA) restrictions on the consumption, production, and use of methyl bromide (a Class I, Group VI controlled substance) for critical uses during calendar year 2012. Under the Clean Air Act, methyl bromide consumption and production were phased out on January 1, 2005, apart from allowable exemptions, such as the critical use exemption and the quarantine and preshipment (QPS) exemption. Consumption is defined under the CAA as production plus imports minus exports. With this action, EPA is authorizing the uses that qualify for the 2012 critical use exemption as well as specific amounts of methyl bromide that may be produced and imported, or sold from pre-phaseout inventory (also referred to as “stocks”) for critical uses in 2012.

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. Chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. EPA is issuing this final rule under section 307(d)(1) of the Clean Air Act, which states: “The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this section, apply to actions to which this subsection applies.” Thus, section 553(d) of the APA does not apply to this rule. EPA is nevertheless acting consistently with the policies underlying APA section 553(d) in making this rule effective on May 17, 2012. APA section 553(d) allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” Section 5 U.S.C. 553(d)(1) allows an effective date less than 30 days after publication for a rule that “that grants or recognizes an exemption or relieves a restriction.” 5 U.S.C. 553(d)(1). Since today’s action can be considered to either grant an exemption for limited critical uses during 2012 from the general

prohibition on production or import of methyl bromide after the phaseout date of January 1, 2005, or relieve a restriction that would otherwise prevent production or import of methyl bromide, EPA is making this action effective immediately upon publication.

Table of Contents

- I. General Information
 - A. Regulated entities
- II. What is methyl bromide?
- III. What is the background to the phaseout regulations for ozone-depleting substances?
- IV. What is the legal authority for exempting the production and import of methyl bromide for critical uses authorized by the parties to the Montreal Protocol?
- V. What is the critical use exemption process?
 - A. A. Background of the Process
 - B. How does this rule relate to previous critical use exemption rules?
 - C. Stocks of Methyl Bromide
 - D. Critical Uses
 - E. Critical Use Amounts
 - F. Critical Use Allowance Allocations
 - G. Critical Stock Allowance Allocations
 - H. The Criteria in Decisions IX/6 and Ex. 1/4
 - I. Emissions Minimization
- VI. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer and Advancement Act
 - J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
 - K. Congressional Review Act

I. General Information

A. Regulated Entities

Entities and categories of entities potentially regulated by this action include producers, importers, and exporters of methyl bromide; applicators and distributors of methyl bromide; and users of methyl bromide that applied for the 2012 critical use exemption including growers of vegetable crops, fruits, and nursery stock, and owners of stored food commodities and structures such as grain mills and processors. This

rulemaking does not affect applicants for future control periods.

This list is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility, company, business, or organization could be regulated by this action, you should carefully examine the regulations promulgated at 40 CFR part 82, subpart A. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section.

II. What is methyl bromide?

Methyl bromide is an odorless, colorless, toxic gas which is used as a broad-spectrum pesticide and is controlled under the CAA as a Class I ozone-depleting substance (ODS). Methyl bromide was once widely used as a fumigant to control a variety of pests such as insects, weeds, rodents, pathogens, and nematodes. Information on methyl bromide can be found at <http://www.epa.gov/ozone/mbr>.

Methyl bromide is also regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and other statutes and regulatory authority, as well as by States under their own statutes and regulatory authority. Under FIFRA, methyl bromide is a restricted use pesticide. Restricted use pesticides are subject to Federal and State requirements governing their sale, distribution, and use. Nothing in this rule implementing Title VI of the Clean Air Act is intended to derogate from provisions in any other Federal, State, or local laws or regulations governing actions including, but not limited to, the sale, distribution, transfer, and use of methyl bromide. Entities affected by this rule must comply with FIFRA and other pertinent statutory and regulatory requirements for pesticides (including, but not limited to, requirements pertaining to restricted use pesticides) when producing, importing, exporting, acquiring, selling, distributing, transferring, or using methyl bromide. The provisions in this action are intended only to implement the CAA restrictions on the production, consumption, and use of methyl bromide for critical uses exempted from the phaseout of methyl bromide.

III. What is the background to the phaseout regulations for ozone-depleting substances?

The regulatory requirements of the stratospheric ozone protection program that limit production and consumption of ozone-depleting substances are in 40 CFR part 82, subpart A. The regulatory

program was originally published in the **Federal Register** on August 12, 1988 (53 FR 30566), in response to the 1987 signing and subsequent ratification of the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol). The Montreal Protocol is the international agreement aimed at reducing and eliminating the production and consumption of stratospheric ozone-depleting substances. The United States was one of the original signatories to the 1987 Montreal Protocol and the United States ratified the Protocol on April 12, 1988. Congress then enacted, and President George H.W. Bush signed into law, the Clean Air Act Amendments of 1990 (CAAA of 1990) which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure that the U.S. could satisfy its obligations under the Montreal Protocol. EPA issued regulations to implement this legislation and has since amended the regulations as needed.

Methyl bromide was added to the Montreal Protocol as an ozone-depleting substance in 1992 through the Copenhagen Amendment. The Parties to the Montreal Protocol (Parties) agreed that each industrialized country's level of methyl bromide production and consumption in 1991 should be the baseline for establishing a freeze in the level of methyl bromide production and consumption for industrialized countries. EPA published a rule in the **Federal Register** on December 10, 1993 (58 FR 65018), listing methyl bromide as a Class I, Group VI controlled substance, freezing U.S. production and consumption at the 1991 baseline level of 25,528,270 kilograms, and setting forth the percentage of baseline allowances for methyl bromide granted to companies in each control period (each calendar year) until 2001, when the complete phaseout would occur. This phaseout date was established in response to a petition filed in 1991 under sections 602(c)(3) and 606(b) of the CAAA of 1990, requesting that EPA list methyl bromide as a Class I substance and phase out its production and consumption. This date was consistent with section 602(d) of the CAAA of 1990, which for newly listed Class I ozone-depleting substances provides that "no extension [of the phaseout schedule in section 604] under this subsection may extend the date for termination of production of any class I substance to a date more than 7 years after January 1 of the year after the year in which the substance is added to the list of class I substances."

At the Seventh Meeting of the Parties (MOP) in 1995, the Parties agreed to adjustments to the methyl bromide control measures and agreed to reduction steps and a 2010 phaseout date for industrialized countries with exemptions for critical uses. At that time, the U.S. continued to have a 2001 phaseout date in accordance with section 602(d) of the CAAA of 1990. At the Ninth MOP in 1997, the Parties agreed to further adjustments to the phaseout schedule for methyl bromide in industrialized countries, with reduction steps leading to a 2005 phaseout. The Parties also established a phaseout date of 2015 for developing (Article 5) countries.

IV. What is the legal authority for exempting the production and import of methyl bromide for critical uses authorized by the parties to the Montreal Protocol?

In October 1998, the U.S. Congress amended the Clean Air Act to prohibit the termination of production of methyl bromide prior to January 1, 2005, to require EPA to align the U.S. phaseout of methyl bromide with the schedule specified under the Protocol, and to authorize EPA to provide certain exemptions. These amendments were contained in Section 764 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. 105-277, October 21, 1998) and were codified in section 604 of the CAA, 42 U.S.C. 7671c. The amendment that specifically addresses the critical use exemption appears at section 604(d)(6), 42 U.S.C. 7671c(d)(6). EPA revised the phaseout schedule for methyl bromide production and consumption in a final rulemaking on November 28, 2000 (65 FR 70795), which allowed for the phased reduction in methyl bromide consumption specified under the Protocol and extended the phaseout to 2005 while creating a placeholder for critical use exemptions. EPA again amended the regulations to allow for an exemption for quarantine and preshipment (QPS) purposes on July 19, 2001 (66 FR 37751), with an interim final rule and with a final rule on January 2, 2003 (68 FR 238).

On December 23, 2004 (69 FR 76982), EPA published a rule (the "Framework Rule") that established the framework for the critical use exemption; set forth a list of approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from stocks and new production or import to meet the needs of approved critical uses. EPA has subsequently published rules applying the critical use exemption framework for each of the

control periods from 2006 to 2011. Under the authority of section 604(d)(6) of the CAA, this action authorizes the uses that qualify as approved critical uses in 2012 and the amount of methyl bromide that may be produced, imported, or supplied from inventory to satisfy those uses.

This action reflects Decision XXII/6, taken at the Twenty-Second Meeting of the Parties in November 2010. In accordance with Article 2H(5) of the Montreal Protocol, the Parties have issued several Decisions pertaining to the critical use exemption. These include Decisions IX/6 and Ex. I/4, which set forth criteria for review of critical uses. The status of Decisions is addressed in *NRDC v. EPA*, (464 F.3d 1, DC Cir. 2006) and in EPA's "Supplemental Brief for the Respondent," filed in *NRDC v. EPA* and available in the docket for this action. In this rule on critical uses for 2012, EPA is honoring commitments made by the United States in the Montreal Protocol context.

V. What is the critical use exemption process?

A. Background of the Process

Article 2H of the Montreal Protocol established the critical use exemption provision. At the Ninth Meeting of the Parties in 1997 the Parties agreed to criteria for the exemption, as contained in Decision IX/6. In that Decision, the Parties agreed that "a use of methyl bromide should qualify as 'critical' only if the nominating Party determines that: (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and (ii) there are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and public health and are suitable to the crops and circumstances of the nomination." EPA promulgated these criteria in the definition of "critical use" at 40 CFR 82.3.

In response to EPA's request for critical use exemption applications published in the **Federal Register** on May 20, 2009 (74 FR 23705), applicants provided data on the technical and economic feasibility of using alternatives to methyl bromide. Applicants also submitted data on their use of methyl bromide, research programs into the use of alternatives, and efforts to minimize use and emissions.

EPA's Office of Pesticide Programs reviews the data submitted by applicants, as well as data from

governmental and academic sources, to establish whether there are technically and economically feasible alternatives available for a particular use of methyl bromide, and whether there would be a significant market disruption if no exemption were available. In addition, EPA reviews other parameters of the exemption applications such as dosage and emissions minimization techniques and applicants' research or transition plans. This assessment process culminates in the development of the U.S. Government's critical use nomination (CUN). The U.S. Department of State has submitted a CUN annually to the United Nations Environment Programme (UNEP) Ozone Secretariat. The Methyl Bromide Technical Options Committee (MBTOC) and the Technology and Economic Assessment Panel (TEAP), which are advisory bodies to Parties to the Montreal Protocol, review the CUNs of the Parties and make recommendations to the Parties on the nominations. The Parties then take Decisions to authorize critical use exemptions for particular Parties, including how much methyl bromide may be supplied for the exempted critical uses. As required in section 604(d)(6) of the CAA, for each exemption period, EPA consults with the United States Department of Agriculture (USDA) and other departments and institutions of the Federal government that have regulatory authority related to methyl bromide. EPA also provides an opportunity for public comment on the amounts of methyl bromide that the agency is proposing to exempt for critical uses and the uses that the agency is proposing as approved critical uses.

Additional information on the domestic review process and methodology employed by the Office of Pesticide Programs is available in a detailed memorandum titled "Development of 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America," contained in the docket for this rulemaking. While the particulars of the data continue to evolve and administrative matters are further streamlined, the technical review itself remains rigorous with careful consideration of new technical and economic conditions.

On January 22, 2010, the U.S. Government (USG) submitted the eighth CUN to the Ozone Secretariat of the UNEP. This nomination contained the request for 2012 critical uses. In February 2010, MBTOC sent questions to the USG concerning technical and economic issues in the 2012 nomination. The USG transmitted

responses to MBTOC in March, 2010. These documents, together with reports by the advisory bodies noted above, are in the public docket for this rulemaking. The critical uses and allocation amounts reflect the analysis contained in those documents.

B. How does this rule relate to previous critical use exemption rules?

The December 23, 2004, Framework Rule (69 FR 76982) established the framework for the critical use exemption program in the U.S., including definitions, prohibitions, trading provisions, and recordkeeping and reporting obligations. The preamble to the Framework Rule included EPA's determinations on key issues for the critical use exemption program.

An approved critical user may purchase methyl bromide produced or imported with critical use allowances (CUAs) as well as limited inventories of pre-phaseout methyl bromide, the combination of which constitute the supply of "critical use methyl bromide" intended to meet the needs of agreed critical uses. Since publishing the Framework Rule, EPA has annually promulgated regulations to exempt from the phaseout of methyl bromide specific quantities of production and import for each control period (each calendar year), to determine the amounts that may be supplied from pre-phaseout inventory, and to indicate which uses meet the criteria for the exemption program for that year. See 71 FR 5985 (calendar year 2006), 71 FR 75386 (calendar year 2007), 72 FR 74118 (calendar year 2008), 74 FR 19878 (calendar year 2009), 75 FR 23167 (calendar year 2010), and 76 FR 60736 (calendar year 2011).

Today's action uses the existing regulatory framework to determine critical uses for 2012 and the amounts of critical use allowances (CUAs) and critical stock allowances (CSAs) to be allocated for those uses. A CUA is the privilege granted through 40 CFR part 82 to produce or import 1 kilogram (kg) of methyl bromide for an approved critical use during the specified control period. These allowances expire at the end of the control period and, as explained in the Framework Rule, are not bankable from one year to the next. A CSA is the right granted through 40 CFR part 82 to sell 1 kg of methyl bromide from the remaining inventory of material produced or imported prior to the January 1, 2005, phaseout date for an approved critical use during the specified control period.

C. Stocks of Methyl Bromide

The Framework Rule established provisions governing the sale of pre-phaseout inventories for critical uses, including the concept of CSAs and a prohibition on the sale of pre-phaseout inventories for critical uses in excess of the amount of CSAs held by the seller. It also established trading provisions that allow CUAs to be converted into CSAs.

The aggregate amount of pre-phaseout methyl bromide reported as being in inventory at the beginning of 2011 was 1,802,715 kg. As in prior years, the Agency continues to closely monitor CUA and CSA data. As stated in the final 2006 CUE Rule, if an inventory shortage occurs, EPA may consider various options including authorizing the conversion of a limited number of CSAs to CUAs through a rulemaking, bearing in mind the upper limit on U.S. production/import for critical uses.

As explained in the 2008 CUE Rule, EPA intends to continue releasing the aggregate methyl bromide stockpile data reported under the requirements at 40 CFR 82.13 for the end of each control period. If the number of competitors in the industry were to decline appreciably, EPA may revisit the question of whether the aggregate is entitled to treatment as confidential business information and whether to release the aggregate without notice. EPA did not propose to change the treatment of submitted information but welcomes relevant information concerning the composition of the industry. EPA did not receive any information suggesting that the number of companies has declined to the point that EPA should consider treating the aggregate as confidential information. The aggregate information for 2003 through 2011 is available in the docket for this rulemaking.

D. Critical Uses

In Decision XXII/6, taken in November 2010, the Parties to the Protocol agreed "to permit, for the agreed critical-use categories for 2012 set forth in table C of the annex to the present decision for each party, subject to the conditions set forth in the present decision and in decision Ex.I/4 to the extent that those conditions are applicable, the levels of production and consumption for 2012 set forth in table D of the annex to the present decision which are necessary to satisfy critical uses * * *" The following uses are those set forth in table C of the annex to Decision XXII/6 for the United States:

- Commodities

- National Pest Management Association food processing structures
- Mills and processors
- Dried cured pork
- Cucurbits
- Eggplant—field
- Forest nursery seedlings
- Nursery stock—fruits, nuts, flowers
- Orchard replants
- Ornamentals
- Peppers—field
- Strawberry—field
- Strawberry runners
- Tomatoes—field
- Sweet potato slips

EPA sought comment on the technical analysis contained in the U.S. nomination (available for public review in the docket to this rulemaking), and information regarding any changes to the registration (including cancellation or new registrations), use, or efficacy of alternatives that have transpired after the 2012 U.S. nomination was written. Such information has the potential to alter the technical or economic feasibility of an alternative and could thus cause EPA to modify the analysis that underpins EPA's determination as to which uses and what amounts of methyl bromide qualify for the CUE.

EPA recognizes that as the market for alternatives evolves, the thresholds for what constitutes "significant market disruption" or "technical and economic feasibility" change. EPA received one comment urging the agency to consider greater use of 1,3-D and sulfuryl fluoride than contained in the technical analysis. This comment repeats a comment submitted by the same commenter on the 2010 CUE Rule but does not provide any new data. EPA has considered the commenter's concerns and believes that response contained in the 2010 CUE Rule response to comments, which is available in the docket to this rule, still appropriately addresses this comment.

EPA proposed to modify the table in 40 CFR part 82, subpart A, appendix L to reflect the agreed critical use categories identified in Decision XXII/6. EPA is finalizing the lists of critical uses and critical users as proposed. First, EPA is removing from the list of approved critical users two users that did not submit applications for 2012 and therefore were not included in the U.S. nomination. These users are International Paper and Weyerhaeuser Company in the forest nursery seedlings sector and beans in the commodities sector.

Second, EPA is removing North Carolina and Tennessee strawberry nurseries from the list of approved

critical users. Southeast strawberry growers applied for a critical use in 2012. The U.S. did not submit a nomination to UNEP for this use in this geographical location because EPA's technical review found that there are alternatives to methyl bromide for Southeast strawberry nurseries.

Third, EPA is limiting the scope of the approved critical use for the National Pest Management Association's (NPMA) post harvest fumigations. In past control periods, the scope of the NPMA food processing critical use included "processed food, cheese, herbs and spices, and spaces and equipment in associated processing and storage facilities." MBTOC found that the nomination for food processing facilities was inadequately justified and recommended only cheese storage facilities for consideration by the Parties as a critical use. MBTOC's comments can be found in the May 2010 TEAP Progress Report in the docket to this rule. The Parties' Decision reflects the MBTOC recommendation. EPA is modifying the NPMA critical use to include only "Members of the National Pest Management Association treating cheese storage facilities."

EPA did not receive any comments objecting to the proposed modifications to the table in 40 CFR part 82, subpart A, appendix L. EPA received three comments agreeing that the proposed critical uses have a continuing need for access to methyl bromide under a 2012 CUE. One commenter stated that the strict application and review process properly limits the use of methyl bromide, given its effect on the stratospheric ozone layer. EPA also received comment that there should be no uses of methyl bromide given its toxicity and effect on the stratospheric ozone layer. EPA disagrees that all methyl bromide use should stop. The CUN addresses the need for methyl bromide for the 2012 critical uses. In addition, the 2012 critical uses were reviewed by the technical bodies to the Ozone Secretariat and authorized by the Parties to the Montreal Protocol. Concerns about the toxicity of methyl bromide are addressed through the pesticide registration program under FIFRA, as well as other authorities, and are outside the scope of this rulemaking. EPA also received one comment questioning some of the limiting critical conditions. This commenter has raised the same points in past CUE rulemakings and EPA believes our responses from past rulemakings, which are included in the docket for this rule, remain appropriate.

EPA is repeating the following clarifications made in previous years for

ease of reference. The "local township limits prohibiting 1,3-dichloropropene" are prohibitions on the use of 1,3-dichloropropene products in cases where local township limits on use of this alternative have been reached. In addition, "pet food" under subsection B of Food Processing refers to food for domesticated dogs and cats. Finally, "rapid fumigation" for commodities is when a buyer provides short (two working days or fewer) notification for a purchase or there is a short period after harvest in which to fumigate and there is limited silo availability for using alternatives.

E. Critical Use Amounts

Table C of the annex to Decision XXII/6 lists critical uses and amounts agreed to by the Parties to the Montreal Protocol. When added together, the total authorization for 2012 is 1,022,826 kg, which is equivalent to 4.0% of the U.S. 1991 methyl bromide consumption baseline. The maximum amount of new production or import authorized by the Parties is 922,826 kg (3.6% of baseline) as set forth in Table D of the annex to Decision XXII/6. The difference between the total authorization and the authorized amount of new production is 100,000 kg (0.4% of baseline), which is the minimum that the Parties expect the U.S. to use from pre-phaseout inventory on critical uses.

EPA is finalizing the amount of new production and import discussed in the proposed rule. With this final rule, EPA is allocating 759,744 kg (3.0% of baseline) of new production and import of methyl bromide for critical uses for 2012. EPA is also allocating 263,082 kg (1.0% of baseline) in the form of critical stock allowances for sale of pre-phaseout inventory for critical uses in 2012.

In the proposed rule, EPA used the methodology established in the 2008 CUE Rule to determine the level of "available stocks," from which the CSAs are calculated. At the time of the proposed rule, EPA estimated that 263,082 kg of pre-phaseout inventory would be "available" for use in 2012. Therefore, EPA proposed allocating 263,082 kg of critical stock allowances for 2012. Using the calculation described in the proposed rule, EPA then proposed a CUA amount of 759,744 kg.

Due to the timing of the 2012 CUE rulemaking, EPA issued a No Action Assurance letter December 21, 2011. This letter allowed critical use allowance holders to continue producing and importing methyl bromide beyond December 31, 2011, in the absence of allowances, subject to

certain conditions. The No Action Assurance allows for the production and import of 379,872 kg and the sale of 131,541 kg from pre-phaseout inventory for critical uses. The No Action Assurance levels were half the amounts contained in the proposed rule to allow for changes to the final rule after new inventory data were received.

At the end of February, distributors reported to EPA the amount of pre-phaseout inventory that was still under their ownership as of December 31, 2011. These data show that the pre-phaseout inventory was greater than the estimates that formed the basis of the CSA and CUA amounts in the proposed rule. In the proposed rule, EPA estimated that the inventory would decline to 692,082 kg at the end of 2011. The reported data show that the remaining inventory was actually 1,248,876 kg.

The amount of inventory drawdown was so low compared to EPA's estimates in the proposed rule that if EPA were to apply the framework calculation detailed in the proposed rule to the new data, the new production levels would be less than what is allowed under the No Action Assurance (these calculations are available in the docket for this rulemaking). The No Action Assurance allows for the production and import of 379,872 kg and the sale of 131,541 kg from pre-phaseout inventory for critical uses. Under the framework calculation based on new inventory data, the allocation would be 202,950 kg of new production/import and 819,876 kg of inventory.

Hence, EPA is not finalizing a critical use allocation of 202,950 kg for 2012. This amount would be below what is currently allowed for production/import in the No Action Assurance letter. Regulated entities have been acting on the amounts in the No Action Assurance letter in good faith, and may have already produced up to the allowed level. In addition, EPA never determined that the No Action Assurance levels for CUAs and CSAs would be sufficient for an entire year. When this situation occurred during the development of the 2011 CUE Rule, EPA finalized the new production amount allowed under the No Action Assurance and allocated CSAs up to the full level authorized by the Parties. Were EPA to follow this approach in this 2012 Rule, EPA would finalize 379,872 kg of new production and import and 819,876 kg of critical stock allowances. For the reasons discussed below, EPA is not following this approach but rather is finalizing the amounts discussed in the proposed rule.

An allocation of 202,950 kg, or even 379,872 kg (i.e., an amount consistent with the No Action Assurance) for new production and import would be substantially less than the amount proposed, which was 759,744 kg. These circumstances are substantially different from the 2011 rule, when EPA proposed to authorize 1,500,000 kg of new production, and issued a No Action Assurance for that same amount of new production. While EPA provided the public with an explanation of how it calculated its proposed authorization for CUE, and noted that it might adjust those calculations with new data, EPA believes the results of the methodology using the updated data now available are sufficiently different that additional notice and the opportunity to comment would be warranted before using that data as the basis for a final CUE authorization. At the same time, EPA recognizes that regulated entities, including manufacturers and critical users of methyl bromide, are in need of a final CUE rule for calendar year 2012. EPA did not propose, and is not considering, a total authorization of less than 1,022,826 kg for critical uses in 2012. EPA has weighed the benefit of re-opening for comment the allocation of the total authorization between critical use allowances and critical stock allowances against the time-sensitive need for a CUE authorization for the current calendar year and concluded that re-opening the allocation for comment is not warranted. Accordingly, EPA is finalizing its proposed allocations of 759,744 kg of critical use allowances and 263,082 kg of critical stock allowances for 2012.

EPA received a comment that the calculation mistakenly used the CSA allocation amount from the proposed 2011 CUE rule, not the final rule. When EPA was developing the proposed 2012 rule, the 2011 rule was still not finalized. EPA assumed that the final 2011 rule would allocate 482,333 kg but it actually allocated 555,200 kg of CSAs. The commenter requests that the estimated drawdown calculation be updated. EPA agrees with the commenter that EPA would have used the value from the final 2011 rule, had it been available when EPA was developing the proposed 2012 rule. EPA has used the updated CSA value from the final 2011 rule, as well as updated inventory information, in calculating how the formula used in the proposal would allocate the CUE authorization. However, as noted above, EPA is not basing the allocation in this final rule on that formula.

One commenter objected to EPA's proposal to allocate 759,744 kg for new

production or import. The commenter stated that the Parties authorized 922,826 kg for new production and import and that it is arbitrary and capricious for the agency to allocate any amount less than that level of new production. EPA disagrees with the commenter's interpretation of Decision XXII/6. In Table D of Decision XXII/6, the Parties authorized 922,826 kg for new production and import "minus available stocks." Thus, EPA does not believe it would be consistent with Decision XXII/6 to authorize 922,826 kg for new production and import without considering available stocks. Furthermore, EPA notes, consistent with our position in prior rulemakings, that the Agency is not required to allocate the full amount of authorized new production and consumption. The Parties only agree to "permit" a particular level of production and consumption; they do not—and cannot—mandate that the U.S. authorize this level of production and consumption domestically. Nor does the CAA require EPA to allow the full amount permitted by the Parties. Section 604(d)(6) of the CAA does not require EPA to exempt any amount of production and consumption from the phaseout, but instead specifies that the Agency "may" create an exemption for critical uses, providing EPA with substantial discretion.

When determining the CSA amount for a year, EPA considers what portion of existing stocks is "available" for critical uses. As discussed in prior CUE rulemakings, the Parties to the Protocol recognized in their Decisions that the level of existing stocks may differ from the level of available stocks. Decision XXII/6 states that "production and consumption of methyl bromide for critical uses should be permitted only if methyl bromide is not available in sufficient quantity and quality from existing stocks." In addition, earlier decisions refer to the use of "quantities of methyl bromide from stocks that the Party has recognized to be available." Thus, it is clear that individual Parties have the ability to determine their level of available stocks. Decision XXII/6 further reinforces this concept by including the phrase "minus available stocks" as a footnote to the United States' authorized level of production and consumption in Table D. Section 604(d)(6) of the CAA does not require EPA to adjust the amount of new production and import to reflect the availability of stocks; however, as explained in previous rulemakings, making such an adjustment is a

reasonable exercise of EPA's discretion under this provision.

One commenter objects to the use of a supply chain factor in determining an amount of "available stocks" that can be used by critical users and requests that EPA require that the inventory be exhausted before allowing any additional new production. The commenter also states that the calculation of the supply chain factor is overly conservative because it assumes a catastrophic loss when production is at the peak. EPA has addressed this comment in prior rulemakings; those responses are available in the docket for this rulemaking.

Another commenter stated that the CSA allocation failed to consider the effect that drawing down the pre-phaseout inventory would have if there is a catastrophic failure in the domestic supply of methyl bromide in future years. EPA believes that the calculation of the supply chain factor (which reflects the level of authorized CUE use as it declines) was adequate consideration of the possibility of a future catastrophic interruption in the domestic supply of methyl bromide. Although EPA is not relying on calculation of a supply chain factor and the formula it proposed to use to allocate CSAs in this final rule, EPA notes that the CSA allocation is lower under this final rule than if EPA had relied on that formula, because more methyl bromide remains in pre-phaseout inventory than anticipated.

Unlike past control periods, all critical use methyl bromide that companies reported to be produced or imported in 2010 was sold to end users. The information reported to EPA is that 1,954,610 kg of critical use methyl bromide was produced or imported. A slightly higher amount than the amount produced or imported was actually sold to end-users in 2010. This additional amount was from distributors selling amounts that were carried over from the 2009 control period. Thus, EPA did not propose to apply any carryover deduction to the new production amount for 2012.

One commenter suggested that the lack of a carryover demonstrates excess demand and that EPA should therefore increase the amount of newly produced or imported material. EPA responds that the agency expects material produced or imported for use in a particular control period to be used in that control period and that there typically should not be a carryover. EPA established the carryover reduction to account for an over allocation or underuse of allowances in a particular control period and avoid any stockpiling of critical use material.

The absence of a carryover does not mean that the agency should increase the allocation. EPA's carryover calculation is consistent with the method used in previous CUE rules, and with the method agreed to by the Parties in Decision XVI/6 for calculating column L of the U.S. Accounting Framework. All past U.S. Accounting Frameworks for the methyl bromide critical use exemption are available in the public docket for this rulemaking.

EPA considers new data about alternatives that were not available at the time the U.S. Government submitted the CUN to the Parties and adjusts the allocation for new production and import accordingly. Two alternatives not considered in the 2012 CUN, which was submitted to UNEP in January 2010, may be used in limited quantities in 2012. EPA proposed to not adjust the allocation considering that the uptake of these two alternatives (iodomethane and DMDS) is expected to be minimal in 2012. One commenter agreed that the uptake will be practically nonexistent.

In July 2010, EPA registered Dimethyl Disulfide (DMDS) to control nematodes, weeds, and pathogens in tomatoes, peppers, eggplants, curcubits, strawberries, ornamentals, forest nursery seedlings, and onions. Twenty-four states have now registered DMDS and registrations are pending in four other states. Even though DMDS is registered in states that grow critical use crops, EPA believes that the uptake of this alternative will be minimal in 2012. Use in the 2011 growing season was small because the product was either not registered in the state or the distribution system was still under development. Furthermore, the manufacturer of DMDS, Arkema, has stated that they are limiting the roll-out of this alternative to ensure proper applicator training and use of odor mitigation practices. As stated in the proposed rule, EPA continues to anticipate that growers will use the 2012 growing season to test the fumigant on limited acreage. Therefore, EPA is not reducing the allocation of allowances based on the uptake of DMDS in 2012.

Second, California registered iodomethane in December of 2010. EPA is unable to estimate uptake of iodomethane in California during 2012 due to uncertainties created by the California label. Specifically, the California label has larger buffer zones and lower use rates than the federal label. EPA does not have efficacy studies at the California label's lower use rates and is uncertain how widely it will be adopted without that data. In addition to the state registration, County Agricultural Commissioners must

permit each iodomethane application that occurs within their jurisdiction.

One commenter stated that EPA should not be allocating fewer CUEs than the amount authorized by the Parties given EPA's January 19, 2011, proposal to revoke the tolerances established for sulfuryl fluoride under section 408 of the Federal Food, Drug, and Cosmetic Act (76 FR 3422). This rule is based on the current status of alternatives and is limited to 2012. The proposed tolerance revocation rule includes a staggered implementation scheme so that it is unlikely that any specific revocation will be effective as soon as 2012 (76 FR 3447). Therefore, EPA has not based the allocation amounts for 2012 on any anticipated impacts of that proposal on methyl bromide use.

EPA did not propose to take any other reductions because the 2012 CUN properly applied transition rates for all other alternatives. The TEAP report of October 2010 included reductions in its recommendations for critical use categories based on the transition rates in the 2012 CUN. The TEAP's recommendations were then considered in the Parties' 2012 authorization amounts, as listed in Decision XXII/6. Therefore, transition rates, which account for the uptake of alternatives, have already been applied for authorized 2012 critical use amounts. EPA continues to gather information about methyl bromide alternatives through the CUE application process, and by other means. EPA also continues to support research and adoption of methyl bromide alternatives, and to request information about the economic and technical feasibility of all existing and potential alternatives.

EPA also took comment on an issue raised in the proposed 2011 CUE rule. In that rulemaking, EPA proposed a critical-use allowance allocation of 1,500,000 kg for 2011, given that regulated entities had been acting in good faith on statements made by the agency in a No Action Assurance letter that producers and importers could assume the final allocation would be at least that much. While the total allocation was not affected, the amount of new production was 128,382 kg more than what EPA would have allocated for 2011 had the CSA and CUA amounts been based on the "available stocks" calculation using end of year inventory data. It also means that the critical stock allocation was 128,382 kg less than the amount of "available stocks." EPA stated in the 2011 proposed rule that the Agency could reduce critical-use allowances for new production and

import in the 2012 allocation rule to account for this difference.

EPA took comment on an alternative approach in which EPA would allocate 631,362 kg (2.5% of baseline) of CUAs for 2012. This amount is 128,382 kg less than the proposed CUA amount. The CSA amount could remain either at 263,082 kg or be increased to 391,464 kg to reflect the lower CSA allocation in 2011. The total allocation for 2012 would be 894,444 kg or 1,022,826 kg depending on how many CSAs are issued under this alternative. EPA did not propose this alternative as the lead approach because the number of CUAs in the 2011 rule did not exceed the Parties' production authorization for 2011 and the total CUE amount for 2011 was unaffected. EPA received one comment in opposition to this approach. The commenter states that the 2011 CUA allocation was proper because it maintained consistency with the No Action Assurance letter and that any "over allocation" in 2011 will self-correct in future rules. First, any additional new production would reduce the need to use CSAs, which will result in more "available stocks" in next year's CUE calculation and therefore a higher CSA allocation. Second, any unused allocation will be captured in EPA's calculation of carryover. After considering this issue, EPA is not finalizing the alternative allocation approach in the final rule.

EPA received one comment that the rulemaking process typically is not completed in a timely manner. Methyl bromide producers, importers, and distributors need advance notice of their allowances to ensure material can be manufactured or imported and ultimately distributed to growers to meet spring fumigation schedules. The commenter requests that EPA develop a more efficient process to promulgate the critical use rule so that it is in effect before the control period begins. EPA notes that the Parties to the Montreal Protocol take their decision to authorize critical uses typically a year before the control period at issue. This schedule, coupled with the Clean Air Act section 604(d)(6) requirement to provide notice and the opportunity for public comment, makes it difficult for EPA to complete the rule in advance of the control period, since the Decisions of the Parties are central to the development of the rule. However, EPA acknowledges that promulgating the rule after the start of the control period is not ideal. EPA will consider means of streamlining the Critical Use Exemption rulemaking in the future so that the rule can be issued prior to the start of the control period.

F. Critical Use Allowance Allocations

EPA is allocating critical use allowances for new production or import of methyl bromide up to the amount of 759,744 kg (3.0% of baseline) as shown in the table in 40 CFR 82.8(c)(1). These allowances expire at the end of the control period and, as explained in the Framework Rule, are not bankable from one year to the next. The CUA allocation is subject to the trading provisions at 40 CFR 82.12, which are discussed in section V.G. of the preamble to the Framework Rule (69 FR 76982).

Paragraph 3 of Decision XXII/6 states “that Parties shall endeavor to license, permit, authorize or allocate quantities of critical-use methyl bromide as listed in tables A and C of the annex to the present decision.” This is similar to language in prior Decisions authorizing critical uses. The language from these Decisions calls on Parties to endeavor to allocate critical use methyl bromide on a sector basis. EPA’s Framework Rule proposed several options for allocating critical use allowances, including a sector-by-sector approach. The agency evaluated the various options based on their economic, environmental, and practical effects. After receiving comments, EPA determined that a lump-sum, or universal, allocation, modified to include distinct caps for pre-plant and post-harvest uses, was the most efficient and least burdensome approach that would achieve the desired environmental results, and that a sector-by-sector approach would pose significant administrative and practical difficulties.

One commenter states that EPA should allocate specifically to each of the Critical Use Categories as authorized by the Parties. The EPA’s “lump sum” approach, the commenter asserts, does not guarantee that critical users have access to methyl bromide and it instead allows those with the greatest ability to pay to garner methyl bromide away from other users with approved critical needs. Furthermore, developers of methyl bromide alternatives need assurance that methyl bromide will eventually exit a particular use segment. Allowing an open market for methyl bromide allocation is an economic disincentive for anyone developing alternatives. At a minimum, this commenter supports distinguishing between pre-plant and post-harvest sectors as EPA currently does. EPA received a separate comment favoring the universal allocation approach over a sector-specific allocation. The commenter states that by allocating up to 14 types of allowances the sector

specific approach would be overly complex to administer, would create problems for distributors, and would spread allowances among too many producer/importers and distributors. EPA has addressed these comments in prior rulemakings; those responses are available in the docket for this rulemaking.

For the reasons discussed in the preamble to the 2009 CUE rule (74 FR 19894), the agency believes that under the universal allocation approach adopted in the Framework Rule, the actual critical use will closely follow the sector breakout listed in the Parties’ decisions.

G. Critical Stock Allowance Allocations

The 2004 Framework Rule (69 FR 52366) established the provisions governing the sale of pre-phaseout inventories for critical uses, including the concept of CSAs and a prohibition on the sale of pre-phaseout inventories for critical uses in excess of the amount of CSAs held by the seller. In addition, the Framework Rule further took pre-phaseout inventories into account through the trading provisions that allow CUAs to be converted into CSAs.

A preambular paragraph to Decision XXII/6 states “that parties should reduce their stocks of methyl bromide retained for employment in critical-use exemptions to a minimum in as short a time period as possible.” EPA notes that the U.S. Government does not retain pre-phaseout inventory. Pre-phaseout inventory is held by private companies that may sell or distribute it for any use that meets the labeling under FIFRA, whether critical or not. EPA believes it is responsibly managing the stocks of pre-phaseout inventory through the CUE authorization process. Prior rulemakings have generally allocated higher amounts from stocks than the minimum set forth in the Parties’ decisions. Through the careful management, aggregate amounts have been reduced by 93% since the end of 2003. In addition, EPA has undertaken a broader use of its regulatory authorities under FIFRA to progressively limit U.S. domestic use of stocks to critical uses. While it is not possible to predict the exact date by which all remaining pre-2005 inventory will be exhausted, under the FIFRA process any small remaining quantities in 2015 will likely be entirely devoted to uses that have been identified as critical under the process developed since 2005 to address critical needs of developed countries. EPA is allocating CSAs for the 2012 control period in the amount of 263,082 kg (1.0% of baseline). This is more than the difference between the total U.S. CUE

amount approved by the Parties and the permitted level of U.S. production and consumption. For 2012, that difference is 100,000 kg (0.4% of baseline).

One commenter stated that the Agency is incorrect to assume that 263,082 kg of pre-phaseout inventory will be available for critical uses in 2012. Instead, the commenter stated that EPA should allocate only 100,000 kg from stocks. The commenter says that the distributors that own stocks are free to sell them for any purpose, including for non-CUE uses, and that EPA cannot control how or whether inventory is sold. EPA agrees that the allocation system allows distributors of inventory to respond to market conditions instead of requiring them to sell inventory to critical users. EPA issues CSAs as a mechanism to track the use of stocks for critical uses. Under section 82.4(p), stocks may not be sold for use on critical uses if the seller does not hold the corresponding amount of CSAs. Critical users may purchase either newly produced or imported critical use methyl bromide or stocks sold through the expenditure of CSAs. EPA chose this approach, at least in part, to promote market flexibility and efficiency. EPA’s formula for calculating the amount of “available stocks” contains a variable representing the drawdown of pre-phaseout inventory prior to the beginning of the relevant control period. EPA has attempted to estimate the amounts of pre-phaseout inventory expected to be sold to critical and non-critical users. EPA recognizes that its estimates have become increasingly inexact in characterizing actual drawdown of pre-phaseout inventory, as the amounts in inventory have declined over time. EPA intends to consider the adequacy of using this formula to assess “available stocks” in a future action. However, the fact that distributors can choose to sell to non-critical users does not necessarily mean that the inventory is largely unavailable to critical users. In fact, regulatory changes under the FIFRA labeling requirements discussed above will likely mean that remaining stocks are increasingly only available to U.S. critical uses. End of year reported data show that the inventory on December 31, 2011, was 1,248,876 kg. EPA expects that holders of pre-phaseout inventory will be able to expend the full amount of CSA allocations to satisfy the needs of critical users.

One commenter also stated that inventory was disproportionately distributed among fewer distributors and thus is unavailable to critical users. EPA collects information annually on the number of companies that hold

inventory. These data support the comment that some companies no longer maintain any pre-phaseout inventory. Recent mergers have also resulted in fewer companies holding pre-phaseout inventory. However, there has not been a significant change in the overall geographic distribution of inventory. It is still held by companies in large amounts in both California and the Southeast, the two largest markets for critical use methyl bromide. EPA will continue to consider the question of availability of stocks in light of declining inventory and distributors in future actions. However, as noted above EPA believes that holders of pre-phaseout inventory will be able to expend the full amount of CSA allocations in 2012 to satisfy the needs of critical users.

EPA's allocation of CSAs is based on each company's proportionate share of the aggregate inventory. In 2006, the United States District Court for the District of Columbia upheld EPA's treatment of company-specific methyl bromide inventory information as confidential. *NRDC v. Leavitt*, 2006 WL 667327 (D.D.C. March 14, 2006). Therefore, the documentation regarding company-specific allocation of CSAs is in the confidential portion of the rulemaking docket and the individual CSA allocations are not listed in the table in 40 CFR 82.8(c)(2). EPA notes that it is modifying the table in 40 CFR 82.8(c)(2) to reflect the recent merger of three methyl bromide distributors who are also critical stock allowance holders. The revised table removes the individual entries for Hendrix & Dail, Hy-Yield Products, and Reddick Fumigants and adds an entry for TriEst Ag Group, Inc. EPA will inform the listed companies of their CSA allocations in a letter following publication of the rule.

H. The Criteria in Decisions IX/6 and Ex. I/4

Paragraphs 2 and 5 of Decision XXII/6 request Parties to ensure that the conditions or criteria listed in Decisions Ex. I/4 and IX/6, paragraph 1, are applied to exempted critical uses for the 2012 control period. A discussion of the agency's application of the criteria in paragraph 1 of Decision IX/6 appears in sections V.A., V.D., V.E., and V.G. of this preamble. EPA has solicited comments on the technical and economic basis for determining that the uses listed in this rule meet the criteria of the critical use exemption. The CUNs detail how each proposed critical use meets the criteria listed in paragraph 1 of Decision IX/6, apart from the criterion located at (b)(ii), as well as the

criteria in paragraphs 5 and 6 of Decision Ex. I/4.

The criterion in Decision IX/6(1)(b)(ii), which refers to the use of available stocks of methyl bromide, is addressed in sections V.E., V.F., and V.G. of this preamble. The agency has previously provided its interpretation of the criterion in Decision IX/6(1)(a)(i) regarding the presence of significant market disruption in the absence of an exemption, and EPA refers readers to the 2006 CUE rule (71 FR 5989) as well as to the memo in the docket titled "Development of 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America" for further elaboration.

The remaining considerations are addressed in the nomination documents including: the lack of available technically and economically feasible alternatives under the circumstance of the nomination; efforts to minimize use and emissions of methyl bromide where technically and economically feasible; the development of research and transition plans; and the requests in Decision Ex. I/4(5) and (6) that Parties consider and implement MBTOC recommendations, where feasible, on reductions in the critical use of methyl bromide and include information on the methodology they use to determine economic feasibility.

Some of these criteria are evaluated in other documents as well. For example, the U.S. has considered the adoption of alternatives and research into methyl bromide alternatives, criterion (1)(b)(iii) in Decision IX/6, in the development of the National Management Strategy submitted to the Ozone Secretariat in December 2005, and updated in October 2009. The National Management Strategy addresses all of the aims specified in Decision Ex. I/4(3) to the extent feasible and is available in the docket for this rulemaking.

EPA received one comment that the Agency should adjust production and import levels in the 2012 CUE Rule to account for research amounts. EPA received a similar comment on the 2011 CUE Rule. The commenter implied that EPA had a previous policy of adjusting the production and import level upward to provide an allocation for research. This is not an accurate characterization of EPA's policy. Prior to 2010, the U.S. Nomination did contain a separate amount for research. While the Parties approved research as a critical use, their decisions encouraged the use of inventory to meet critical research needs. In the corresponding CUE rules, EPA responded to the Parties' decisions by reducing the new production/import amounts by the research amount,

leaving the research portion of the total critical use exemption to be met through the use of CSAs.

In the proposed rule, EPA discussed a supplemental critical use nomination of 2,576 kg for research activities in 2012. This nomination was to have been discussed at the Meeting of the Parties in November 2011. EPA proposed to increase the final CSA allocation by up to 2,576 kg after consideration of the action taken by the Parties in November 2011 and comments on research needs. However, prior to the Meeting of the Parties, the U.S. Government withdrew the supplemental nomination. Therefore, EPA is not increasing the final CSA allocation. Nonetheless, the 2012 nomination and the decision the Parties took in 2010 are broad enough to cover both research and non-research uses. As discussed in the preamble to the 2010 CUE rule (75 FR 23179), research is a key element of the critical use process. Research on the crops shown in the table in Appendix L to subpart A remains a critical use of methyl bromide. While researchers may continue to use newly produced material for field, post-harvest, and emission minimization studies requiring the use of methyl bromide, EPA encourages researchers to use pre-phaseout inventory purchased through the expenditure of CSAs. EPA also encourages distributors to make inventory available to researchers, to promote the continuing effort to assist growers to transition critical use crops to alternatives.

I. Emissions Minimization

Previous decisions have stated that Parties shall request critical users to employ emission minimization techniques such as virtually impermeable films, barrier film technologies, deep shank injection and/or other techniques that promote environmental protection, whenever technically and economically feasible. One commenter asks EPA to require emissions minimization techniques rather than simply encourage them. EPA notes that, although EPA considers application rates in determining CUAs, requiring specific emissions minimization techniques would be outside the scope of the proposed rule. EPA developed a comprehensive strategy for risk mitigation through the 2006 Reregistration Eligibility Decision (RED) for methyl bromide, which is implemented through restrictions on how methyl bromide products can be used. This approach does require that methyl bromide labels include directions that treated sites be tarped except for California orchard replant

where EPA instead requires deep (18 inches or greater) shank applications. The RED also incorporated incentives for applicators to use high-barrier tarps, such as virtually impermeable film (VIF), by allowing smaller buffer zones around those sites. In addition to minimizing emissions, use of high-barrier tarps has the benefit of providing pest control at lower application rates. The amount of methyl bromide nominated by the United States reflects the lower application rates necessary when using high-barrier tarps, where such tarps are allowed.

EPA will continue to work with the U.S. Department of Agriculture—Agricultural Research Service (USDA–ARS) to promote emission reduction techniques. The federal government has invested substantial resources into best practices for methyl bromide use, including emission reduction practices. USDA–ARS has a national outreach effort to publicize the best practices.

Users of methyl bromide should continue to make every effort to minimize overall emissions of methyl bromide to the extent consistent with State and local laws and regulations. EPA also encourages researchers and users who are successfully utilizing such techniques to inform EPA of their experiences and to provide such information with their critical use applications.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this final rule is a “significant regulatory action” because it was deemed to raise novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to interagency recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. The application, recordkeeping, and reporting requirements have already been established under previous critical use exemption rulemakings and this action does not change any of those existing requirements. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR part 82 under the provisions of the Paperwork

Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0482. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration’s regulations at 13 CFR 121.201 (see Table below); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Category	NAICS code	SIC code	NAICS Small business size standard (in number of employees or millions of dollars)
Agricultural production ..	1112—Vegetable and Melon farming 1113—Fruit and Nut Tree Farming 1114—Greenhouse, Nursery, and Floriculture Production.	0171—Berry Crops 0172—Grapes. 0173—Tree Nuts. 0175—Deciduous Tree Fruits (except apple orchards and farms). 0179—Fruit and Tree Nuts, NEC. 0181—Ornamental Floriculture and Nursery Products. 0831—Forest Nurseries and Gathering of Forest Products.	\$0.75 million.
Storage Uses	115114—Postharvest Crop activities (except Cotton Ginning). 311211—Flour Milling	2041—Flour and Other Grain Mill Products 500 employees. 2044—Rice Milling	\$7 million.
Distributors and Applicators. Producers and Importers.	31121—Rice Milling 493110—General Warehousing and Storage 493130—Farm Product Warehousing and Storage. 115112—Soil Preparation, Planting and Cultivating. 325320—Pesticide and Other Agricultural Chemical Manufacturing.	4225—General Warehousing and Storage 4221—Farm Product Warehousing and Storage. 0721—Crop Planting, Cultivation, and Protection. 2879—Pesticides and Agricultural Chemicals, NEC.	500 employees \$25.5 million \$25.5 million. \$7 million. 500 employees

Agricultural producers of minor crops and entities that store agricultural commodities are categories of affected entities that contain small entities. This

rule only affects entities that applied to EPA for an exemption to the phaseout of methyl bromide for 2012. In most cases, EPA received aggregated requests

for exemptions from industry consortia. On the exemption application, EPA asked consortia to describe the number and size distribution of entities their

application covered. EPA estimated that 3,218 entities petitioned EPA for an exemption for the 2005 control period. EPA revised this estimate in 2011 down to 1,800 end users of critical use methyl bromide. EPA believes that the number will continue to decline as growers stop applying for critical uses. Since many applicants did not provide information on the distribution of sizes of entities covered in their applications, EPA estimated that, based on the above definition, between one-fourth and one-third of the entities may be small businesses. In addition, other categories of affected entities do not contain small businesses based on the above description.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." (5 U.S.C. 603–604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves a regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. Since this rule exempts methyl bromide for approved critical uses after the phaseout date of January 1, 2005, this action confers a benefit to users of methyl bromide. EPA estimates in the Regulatory Impact Assessment found in the docket to this rule that the reduced costs resulting from the de-regulatory creation of the exemption are approximately \$22 million to \$31 million on an annual basis (using a 3% or 7% discount rate respectively). These reduced costs are dramatic due to the high value of methyl bromide for crop production and agriculture related activities. We have therefore concluded that this rule would relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or

the private sector. Instead, this action provides an exemption for the manufacture and use of a phased out compound and would not impose any new requirements on any entities. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule is expected to affect producers, suppliers, importers, and exporters and users of methyl bromide. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on this action from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rule does not significantly or uniquely affect the communities of Indian tribal governments nor does it impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicited additional comment on this action from tribal officials.

G. Executive Order No. 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets EO 13045 (62 F.R. 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Therefore, we have concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the agency decides not to use available and applicable voluntary consensus standards. This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it affects the level of environmental

protection equally for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any ozone depletion that results from this rule will impact all affected populations equally because ozone depletion is a global environmental problem with environmental and human effects that are, in general, equally distributed across geographical regions of the United States.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action not a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective May 17, 2012.

List of Subjects in 40 CFR Part 82

Environmental protection, Chemicals, Exports, Imports, Ozone depletion.

Dated: May 11, 2012.

Lisa P. Jackson,
Administrator.

For the reasons stated in the preamble, 40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

■ 2. Section 82.8 is amended as follows:

■ a. By revising the table in paragraph (c)(1);

■ b. By revising paragraph (c)(2) including the table.

§ 82.8 Grant of essential use allowances and critical use allowances.

* * * * *
(c) * * *
(1) * * *

Company	2012 Critical use allowances for pre-plant uses* (kilograms)	2012 Critical use allowances for post-harvest uses* (kilograms)
Great Lakes Chemical Corp. A Chemtura Company	425,197	36,499
Albemarle Corp	174,851	15,009
ICL-IP America	96,626	8,294
TriCal, Inc	3,009	258
<i>Total**</i>	<i>699,683</i>	<i>60,061</i>

* For production or import of Class I, Group VI controlled substance exclusively for the Pre-Plant or Post-Harvest uses specified in appendix L to this subpart.

** Due to rounding, numbers do not add exactly.

(2) Allocated critical stock allowances granted for specified control period. The following companies are allocated critical stock allowances for 2012 on a pro-rata basis in relation to the inventory held by each.

Company

Albemarle
Degesch America, Inc.
Prosource One
Bill Clark Pest Control, Inc.

Helena Chemical Co.
Trical Inc.
Burnside Services, Inc.
ICL-IP America
Trident Agricultural Products
Cardinal Professional Products
Industrial Fumigant Company
TriEst Ag Group, Inc.
Chemtura Corp.
Pacific Ag Supplies Inc.
Univar
Crop Production Services

Pest Fog Sales Corp.
Western Fumigation
TOTAL—263,082 kilograms

■ 3. Appendix L to Subpart A is revised to read as follows:

APPENDIX L TO SUBPART A OF PART 82—APPROVED CRITICAL USES AND LIMITING CRITICAL CONDITIONS FOR THOSE USES FOR THE 2012 CONTROL PERIOD

Approved critical uses	Approved critical user and location of use	Limiting critical conditions that exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation
Column A	Column B	Column C

PRE-PLANT USES

Cucurbits	(a) Growers in Delaware and Maryland	Moderate to severe soilborne disease infestation.
	(b) Growers in Georgia and Southeastern U.S. limited to growing locations in Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia.	Moderate to severe yellow or purple nutsedge infestation.
Eggplant	(a) Florida growers	Moderate to severe soilborne disease infestation. Moderate to severe root knot nematode infestation. Moderate to severe yellow or purple nutsedge infestation.
		Moderate to severe soilborne disease infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation.

Approved critical uses Column A	Approved critical user and location of use Column B	Limiting critical conditions that exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation Column C
	(b) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium collar, crown and root rot. Moderate to severe southern blight infestation. Restrictions on alternatives due to karst topographical features.
Forest Nursery Seedlings	(a) Southern Forest Nursery Management Cooperative (Growers in Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia). (b) Northeastern Forest and Conservation Nursery Association (Government-owned seedling nurseries in Illinois, Indiana, Kentucky, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, West Virginia, and Wisconsin). (c) Michigan Seedling Growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Moderate to severe weed infestation including purple and yellow nutsedge infestation. Moderate to severe Canada thistle infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Moderate to severe soilborne disease infestation. Moderate to severe Canada thistle infestation. Moderate to severe nutsedge infestation. Moderate to severe nematode infestation.
Nursery Stock (Fruit, Nut, Flower).	(a) Members of the California Association of Nursery and Garden Centers representing Deciduous Tree Fruit Growers. (b) California rose nurseries	Moderate to severe nematode infestation. Medium to heavy clay soils. Local township limits prohibiting 1,3-dichloropropene. Moderate to severe nematode infestation. Local township limits prohibiting 1,3-dichloropropene.
Orchard Replant	California stone fruit, table and raisin grape, wine grape, walnut, and almond growers.	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted orchard soils to prevent orchard replant disease. Medium to heavy soils. Local township limits prohibiting 1,3-dichloropropene.
Ornamentals	(a) California growers	Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Local township limits prohibiting 1,3-dichloropropene. Moderate to severe weed infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation.
Peppers	(a) Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers. (b) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium root, collar, crown and root rots. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation.
Strawberry Fruit	(a) California growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation, or moderate to severe pythium root and collar rots. Moderate to severe southern blight infestation, crown or root rot. Restrictions on alternatives due to karst topographical features. Moderate to severe black root rot or crown rot. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Local township limits prohibiting 1,3-dichloropropene. Time to transition to an alternative.

Approved critical uses Column A	Approved critical user and location of use Column B	Limiting critical conditions that exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation Column C
Strawberry Nurseries	(b) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Carolina geranium or cut-leaf evening primrose infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe black root and crown rot. Moderate to severe soilborne disease infestation. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation.
Sweet Potato Slips	California growers	Local township limits prohibiting 1,3-dichloropropene.
Tomatoes	(a) Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers. California growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and, in Florida, soils not supporting seepage irrigation.
	(b) Maryland growers	Moderate to severe fungal pathogen infestation.

POST-HARVEST USES

Food Processing	(a) Rice millers in the U.S. who are members of the USA Rice Millers Association. (b) Pet food manufacturing facilities in the U.S. who are members of the Pet Food Institute. (c) Members of the North American Millers' Association in the U.S. (d) Members of the National Pest Management Association treating cheese storage facilities.	Moderate to severe beetle, weevil, or moth infestation. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative. Moderate to severe beetle, moth, or cockroach infestation. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative. Moderate to severe beetle infestation. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative. Mite infestation.
Commodities	California entities storing walnuts, dried plums, figs, raisins, and dates (in Riverside county only) in California.	Rapid fumigation required to meet a critical market window, such as during the holiday season.
Dry Cured Pork Products	Members of the National Country Ham Association and the Association of Meat Processors, Nahunta Pork Center (North Carolina), and Gwaltney and Smithfield Inc.	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermestid beetle infestation. Ham mite infestation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 272

[EPA-R06-2011-0484 FRL-9652-9a]

Oklahoma: Incorporation by Reference of Approved State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Solid Waste Disposal Act, as amended, commonly referred to as the Resource Conservation and Recovery Act (RCRA), allows the Environmental Protection Agency (EPA) to authorize States to operate their hazardous waste management programs in lieu of the Federal program. The EPA uses the regulations entitled "Approved State Hazardous Waste Management Programs" to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and

regulations that will be subject to the EPA's inspection and enforcement. The rule codifies in the regulations the prior approval of Oklahoma's hazardous waste management program and incorporates by reference authorized provisions of the State's statutes and regulations.

DATES: This regulation is effective July 16, 2012, unless the EPA receives adverse written comment on this regulation by the close of business June 18, 2012. If the EPA receives such comments, it will publish a timely withdrawal of this immediate final rule