



THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

July 16, 2012

TO: Members, Subcommittee on Energy and Power

FROM: Committee Staff

RE: Hearing on H.R. ___, "U.S. Agricultural Sector Relief Act of 2012," and H.R. ___, "Asthma Inhalers Relief Act of 2012"

On Wednesday, July 18, 2012, at 10:15 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Energy and Power will hold a legislative hearing on H.R. ___, the "U.S. Agricultural Sector Relief Act of 2012," and H.R. ___, the "Asthma Inhalers Relief Act of 2012." Discussion drafts of these bills were circulated on July 11, 2012.

I. WITNESSES

Panel 1

Mark Murai
President
California Strawberry Commission

Michelle Castellano Keeler
Vice President
Mellano & Company

Russell Costanza
Owner
Russell Costanza Farms

Scott M. Dimare
Vice President & Director of Farm Operations
Dimare Ruskin, Inc.

David Doniger
Policy Director, Climate & Clean Air Program
Natural Resources Defense Council

Panel 2

Jason Shandell
General Counsel & Secretary
Amphastar Pharmaceuticals, Inc.

Edward M. Kerwin, MD
Senior Medical Director
Allergy & Asthma Center of Southern Oregon

Monica Kraft, MD
Professor of Medicine, Duke University
President, The American Thoracic Society
Director, Duke Asthma, Allergy and Airway
Center

Chris Ward
Former Chairman
Board of Directors of the Asthma and Allergy
Foundation of America

II. BACKGROUND

The Montreal Protocol on Substances That Deplete the Ozone Layer ([Montreal Protocol](#)) is an international environmental treaty designed to reduce the production and consumption of ozone depleting substances. The treaty entered into force in 1989.¹ To implement the treaty, Congress amended the Clean Air Act in 1990 and 1998 to add [Title VI](#) of the Clean Air Act (CAA), which is administered by the U.S. Environmental Protection Agency (EPA).²

III. H.R. __, “U.S. AGRICULTURAL SECTOR RELIEF ACT OF 2012”

A. Background

For decades, methyl bromide was widely used as a fumigant for the cultivation of a variety of crops, including strawberries, tomatoes, peppers, eggplant, flowers, tree and vine crops, and at mills, and food storage and processing facilities. The U.S. [phased out](#) the use of methyl bromide, except for certain allowable exemptions and critical uses under the Montreal Protocol and Title VI of the Clean Air Act.³

To allow for critical uses, the Parties to the Montreal Protocol issued a decision in 1997 addressing such uses,⁴ and EPA published a [regulation](#) in 2004 establishing a [Critical Use Exemption](#) (CUE) process. Under that process, EPA each year solicits applications from American growers, considers whether potential [methyl bromide alternatives](#) are available, and in consultation with other Federal agencies develops a critical use nomination which is submitted to the Parties to the Montreal Protocol for approval.

As of January 1, 2005, use of methyl bromide has been phased out in the U.S., except for allowable exemptions. Since 2005, the quantities nominated for critical uses by the U.S. have decreased by over 90 percent (*see* Appendix). While the U.S. government has worked with the agricultural community to identify and develop potential alternatives, methyl bromide continues to be needed for some applications to address plant pest and disease pressures, declining nominations and the absence of effective alternatives for certain uses has raised significant

¹See [United Nations Environment Program \(UNEP\) Ozone Secretariat](#) and [EPA](#) websites.

²EPA has published regulations targeting the following compounds for phaseout: chlorofluorocabons (CFCs), chlorofluorocarbons (HCFCs), carbon tetrachloride, methyl chloroform, methyl bromide, and halons.

³See [Montreal Protocol](#), Article 2H(5); CAA Section 604(d)(6); [EPA Critical Use Exemption Information](#). Under the Protocol, there is also an allowable exemption for the production and consumption of methyl bromide for quarantine and preshipment (QPS) purposes. That QPS exemption is not addressed by H.R. __, “U.S. Agricultural Sector Relief Act.”

⁴Pursuant to [Decision IX/6](#), a use is deemed critical if the lack of methyl bromide would result in significant market disruption, and there is no technically and economically feasible alternative available. In 1997, the Parties also issued [Decision IX/7](#) allowing for use of methyl bromide in response to an emergency event, in an amount not exceeding 20 metric tons in response to such event.

concerns in the U.S. agricultural community about access to sufficient quantities of methyl bromide for critical uses.⁵

B. Summary of Legislation

H.R. __, the "[U.S. Agricultural Sector Relief Act of 2012](#)" seeks to ensure the viability and competitiveness of the U.S. agricultural sector and contains the following provisions.

Section 1: This section provides the short title of "U.S. Agricultural Sector Relief Act of 2012."

Section 2: This section amends section 604(h) of the Clean Air Act relating to the phase-out of methyl bromide under the Montreal Protocol treaty.

Section 2(a) directs that the EPA Administrator (i) for each calendar year, take all appropriate actions within the agency's authority to seek a critical use exemption under the treaty for the full amount of methyl bromide necessary for approved critical uses; (ii) shall not deny or reduce an application unless the Administrator has substantial evidence, provided to the applicant in writing, establishing there is a technically and economically feasible alternative; and (iii) in evaluating any potential alternatives, shall consider the cost, commercial availability, and demonstrated effectiveness of the alternative, and consider any State or local regulations that may restrict its use.

Section 2(a) also directs that the Administrator allow for the use of methyl bromide in response to emergency events, in an amount necessary up to 20 metric tons. Section 2(a) further provides that the aggregate amount of methyl bromide allowed for use in response to emergency events in the United States in a calendar year shall not exceed the total amount authorized by the Parties to the Montreal Protocol for the United States for critical uses in 2011.

Section 2(a) also provides the following definitions:

- (1) The term "approved critical use" means approved critical uses found in Appendix L to subpart A of part 82 of title 40, Code of Federal Regulations, as in effect on January 1, 2005.
- (2) The term "critical use" means a circumstance in which (i) there are no technically and economically feasible methyl bromide alternatives or substitutes acceptable from the standpoint of environment and health and suitable to the crops and circumstances involved; and (ii) the lack of methyl bromide for a particular use would result in significant market disruption.
- (3) The term "emergency event" means a situation at a farm, nursery, food processing facility, or commodities storage facility that requires the use of methyl bromide to control a pest or disease, and for which there is no critical use exemption in effect, or insufficient quantities of methyl bromide available under an existing critical use exemption, for such site.

⁵In March 2012, sales of methyl iodide, a primary pre-plant alternative, were [suspended](#) in the U.S. Additionally, EPA has [proposed](#) to phase out sulfuryl fluoride, a primary alternative for food storage and processing facilities.

Section 2(b) directs the Administrator, in consultation with the Secretary of Agriculture, to issue final regulations relating to emergency events, including in the regulations criteria for identifying an emergency event and provisions to ensure the timely approval or disapproval of emergency event applications.

IV. H.R. __, "ASTHMA INHALERS RELIEF ACT OF 2012"

A. Background

For over 40 years, epinephrine inhalers containing chlorofluorocarbons (CFCs) were available to consumers in the United States for treatment of asthma symptoms without a physician's prescription. Pursuant to the Montreal Protocol and Title VI of the Clean Air Act, the inhalers were phased out pursuant to a 2008 [regulation](#) issued by the Food and Drug Administration (FDA) in consultation with EPA. Under that regulation, the inhaler most commonly marketed as Primatene Mist is no longer manufactured and a ban on its sale went into effect on December 31, 2011. Removal of this inhaler represents less than one percent of total global CFC emissions.⁶

Alternative over-the-counter inhalers are not yet available for treatment of asthma symptoms. Today, asthma inhalers are only available by physician prescription. However, there is a remaining inventory of approximately one million epinephrine inhalers containing CFCs in storage at the manufacturer's facility. In 2011, the National Association of Chain Drugstores, the National Community Pharmacists Association, and other distributors, and the manufacturer submitted requests to EPA for a waiver from the ban on CFC-containing inhalers to allow for sale or distribution of the remaining inventories without threat of an EPA enforcement action. On December 30, 2011, EPA sent a response to the manufacturer declining its request.

B. Summary of Legislation

H.R. __, the "[Asthma Inhalers Relief Act of 2012](#)" seeks to provide relief to asthma sufferers and contains the following provisions.

Section 1: This section provides the short title of "Asthma Inhalers Relief Act of 2012."

Section 2: This section addresses the distribution, sale and consumption of remaining inventories of over-the counter chlorofluorocarbon (CFC) epinephrine inhalers.

Section 2(a) directs the Administrator of the Environmental Protection Agency to allow the distribution, sale, and consumption of remaining inventories of such inhalers, refrain from taking any enforcement action against any distributor or seller on the basis of any Federal law implementing the Montreal Protocol, and issue a No Action Assurance Letter to any requesting distributor or seller stating the agency will not initiate such an enforcement action.

⁶"[Use of Ozone-Depleting Substances; Removal of Essential-Use Designation \(Epinephrine\); Final Rule](#)" 73 Fed. Reg. 69532 (November 19, 2008). Two prescription asthma inhalers that contain CFCs continue to be sold and are not scheduled to be [phased out](#) until Dec. 31, 2013.

Section 2(b) clarifies that nothing in the legislation should be construed to limit the authority of the Food and Drug Administration, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), to ensure the safety and effectiveness of such inhalers.

Section 2(c) provides the following definitions:

- (1) “CFC epinephrine inhaler” means any epinephrine inhaler containing CFCs that was manufactured and classified as over-the-counter prior to January 2, 2012;
- (2) “Federal law implementing the Montreal Protocol” means any provision of Title VI of the Clean Air Act or other Federal law implementing the Montreal Protocol, including the regulation entitled “Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine)” published at 73 Fed. Reg. 69532 (November 19, 2008);
- (3) “Montreal Protocol” has the meaning given in section 601 of the Clean Air Act.; and,
- (4) “Over-the-counter” means not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) or otherwise not required to be dispensed only upon issuance of a prescription.

Section 2(d) provides that the Act shall cease to be effective on August 1, 2013.

V. ISSUES

The following issues are expected to be examined at the hearing:

- Current and expected future needs for methyl bromide for critical uses;
- The agricultural sector’s efforts to transition from methyl bromide to alternatives;
- Concerns relating to the availability and efficacy of methyl bromide alternatives; and
- The international critical use exemption process under the Montreal Protocol.
- Current inventories of epinephrine inhalers containing CFCs available for use;
- Over-the-counter alternatives for asthmatics; and,
- The costs and availability of prescription alternatives.

VI. STAFF CONTACT

If you have any questions regarding the hearing, please contact Mary Neumayr of the Committee staff at (202) 225-2927.

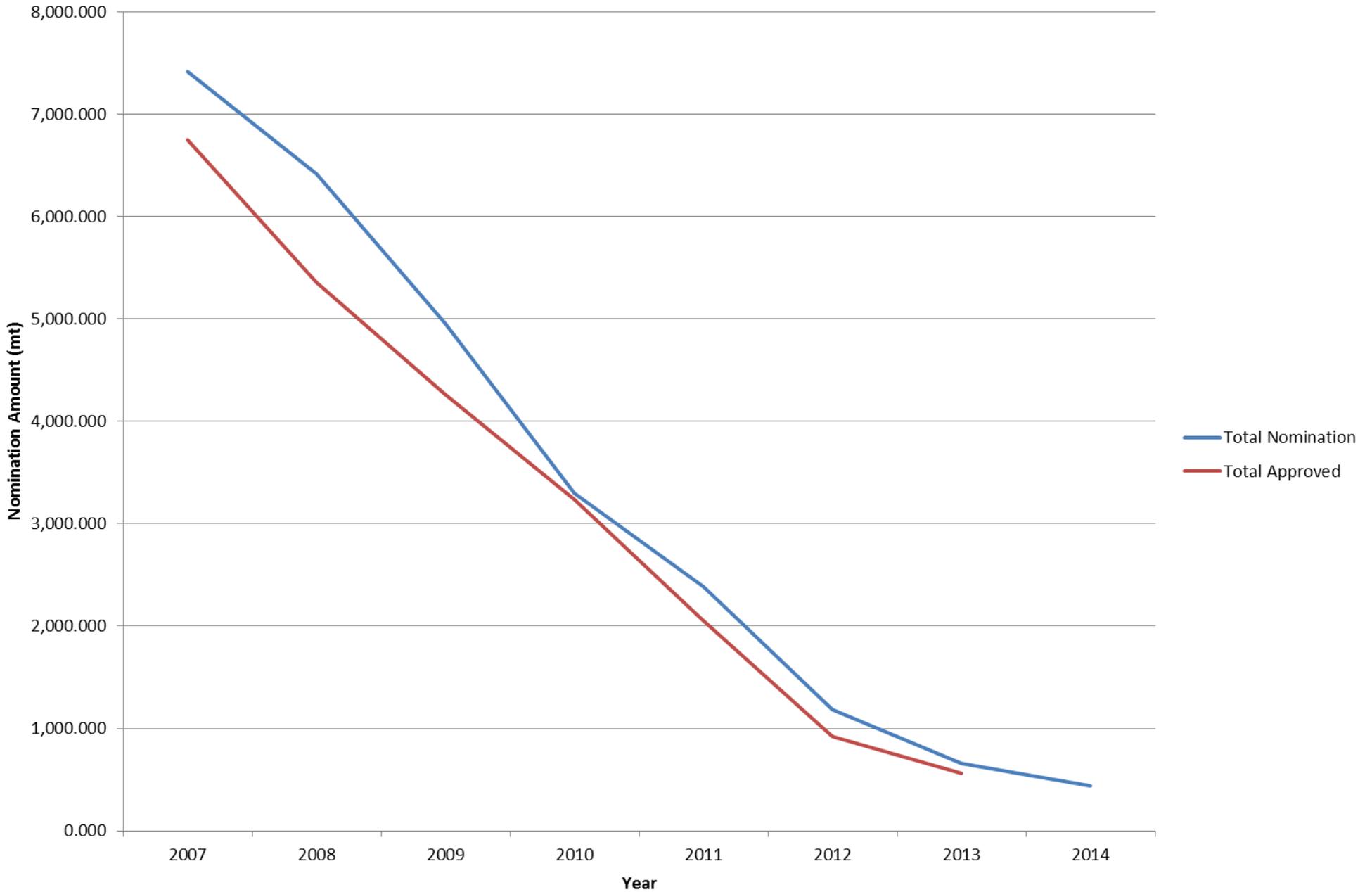
Attachment: Appendix

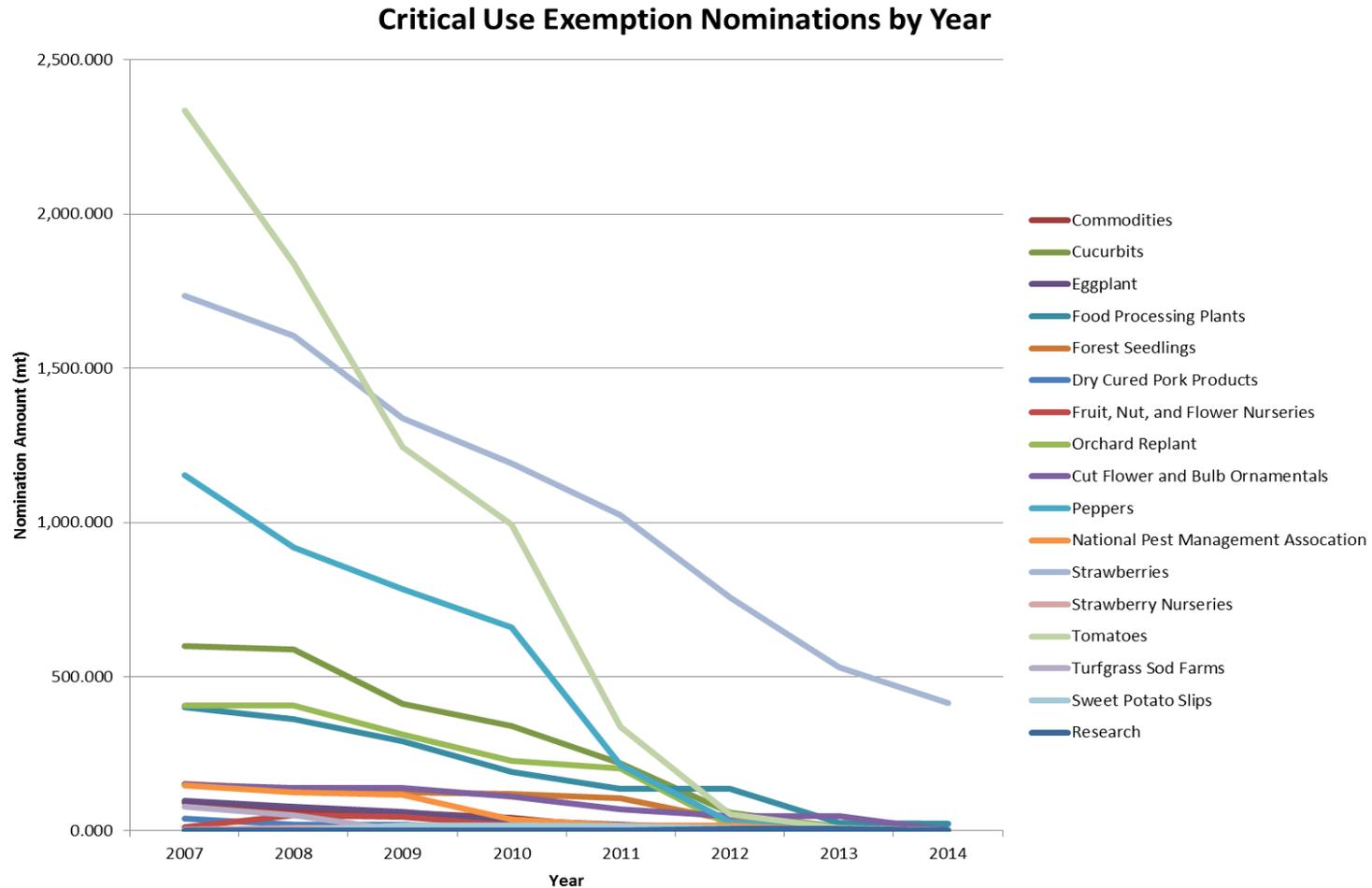
Appendix

U.S. Critical Use Exemption (CUE) Nominations in Metric Tons*

Approved Critical Uses	Applicable Year (Year Submitted)								Percentage Reduction
	2007 (2005)	2008 (2006)	2009 (2006)	2010 (2008)	2011 (2009)	2012 (2010)	2013 (2011)	2014 (2012)	
Commodities	91.299 mt	67.699 mt	58.921 mt	43.007 mt	10.041 mt	4.907 mt	.822 mt	.740 mt	99.19%
Cucurbits	598.927 mt	588.949 mt	411.765 mt	340.405 mt	218.032 mt	59.500 mt	11.899 mt	Not Included	100%
Cut Flower and Bulb Ornamentals	149.965 mt	138.538 mt	137.776 mt	111.391 mt	70.178 mt	48.164 mt	48.164 mt	Not Included	100%
Dry Cured Pork Products	40.854 mt	19.669 mt	19.669 mt	4.465 mt	3.730 mt	3.730 mt	3.730 mt	3.730 mt	90.87%
Eggplant	96.480 mt	79.546 mt	62.789 mt	34.732 mt	21.561 mt	6.904 mt	1.381 mt	Not Included	100%
Food Processing Plants	401.889 mt	362.952 mt	291.418 mt	191.993 mt	135.299 mt	135.299 mt	25.334 mt	22.800 mt	94.33%
Forest Seedlings	152.629 mt	133.140 mt	125.758 mt	120.853 mt	106.043 mt	34.230 mt	Not Included	Not Included	100%
Fruit, Nut, and Flower Nurseries	12.684 mt	51.102 mt	45.282 mt	17.954 mt	7.955 mt	1.591 mt	.541 mt	Not Included	100%
National Pest Management Association	147.320 mt	124.946 mt	117.779 mt	37.778 mt	17.365 mt	17.365 mt	Not Included	Not Included	100%
Orchard Replant	405.415 mt	405.666 mt	314.007 mt	226.021 mt	203.591 mt	18.324 mt	6.230 mt	Not Included	100%
Peppers	1,151.751 mt	919.006 mt	783.821 mt	658.952 mt	212.775 mt	28.366 mt	5.673 mt	Not Included	100%
Research	Not Included	Not Included	Not Included	Not Included	Not Included	7.445 mt (submitted with 2013 nomination)	7.537 mt	Not Included	100%
Strawberries	1,733.901 mt	1,604.669 mt	1,336.754 mt	1,191.815 mt	1,023.471 mt	756.515 mt	531.737 mt	415.067 mt	76.06%
Strawberry Nurseries	4.483 mt	8.838 mt	8.837 mt	7.381 mt	7.381 mt	3.752 mt	3.752 mt	Not Included	100%
Sweet Potato Slips	Not Included	Not Included	18.144 mt	18.144 mt	14.515 mt	8.709 mt	Not Included	Not Included	100%
Tomatoes	2,334.047 mt	1,840.100 mt	1,245.249 mt	994.582 mt	336.191 mt	54.423 mt	10.741 mt	Not Included	100%
Turfgrass Sod Farms	78.040 mt	52.189 mt	Not Included	Not Included	Not Included	Not Included	Not Included	Not Included	100%
Total U.S. Nomination	7,417.999 mt	6,415.153 mt	4,958.034 mt	3,299.490 mt	2,388.128 mt	1,181.779 mt	656.366 mt	442.337 mt	94.04%
Total Quantity Approved by the Parties	6,749.060 mt	5,355.976 mt	4,261.974 mt	3,232.856+2.018 mt	2,055.200 mt	922.826 mt	562.326 mt	To Be Determined	91.67% between 2007 and 2013

Nomination and Approved Quantities





*Prepared by Energy & Commerce Committee Majority staff based on data provided by the following sources:

EPA “Critical Use Exemption Information,” July 9, 2012 <<http://www.epa.gov/ozone/mbr/cueinfo.html>>.

United Nations Environment Programme, Ozone Secretariat, “Meeting of the Parties of the Montreal Protocol: Agreed Critical Use Categories for 2013,” <http://ozone.unmfs.org/new_site/en/Treaties/decisions_text.php?dec_id=1120>.

United Nations Environment Programme, Ozone Secretariat, “Summary of Critical Use Nominations/Exemptions by Countries up to MOP22,” <http://ozone.unep.org/Exemption_Information/Critical_use_nominations_for_methyl_bromide/Summary_of_Critical_Use_Nominations_after_MOP18.shtml>