

**Statement for the Record of Regina McCarthy
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**Hearing on the “U.S. Agricultural Relief Act of 2012” and the “Asthma Inhalers Relief Act
of 2012”**

**Subcommittee on Energy and Power
Committee on Energy and Commerce
July 18, 2012**

Chairman Whitfield, Ranking Member Rush, and members of the Committee, I appreciate the opportunity to provide a written statement for the record on the draft bills entitled the “U.S. Agricultural Relief Act of 2012” and the “Asthma Inhalers Relief Act of 2012,” which are presently before the Committee. These bills address the treatment of methyl bromide and Primatene Mist, respectively, which are or contain ozone-depleting substances that the United States has agreed to phase out of domestic consumption and production under the Montreal Protocol, subject to specified critical and essential use exemptions.

Although the Administration does not yet have a formal position on these draft bills, the bills could have a number of unintended adverse consequences. Since each legislative draft deals with a very different exemption process and has differing potential consequences, I will provide background and address each separately.

Background on the Montreal Protocol

The Montreal Protocol on Substances that Deplete the Ozone Layer was signed by the United States in 1987, with the personal support of President Ronald Reagan, and ratified in 1988. The Protocol, which has undergone multiple revisions over successive years, phases out the consumption and production of ozone depleting substances. Because the stratospheric ozone layer absorbs ultraviolet-B radiation that would otherwise reach the surface of the planet,

emission of ozone depleting substances results in increased exposure to UV-B radiation which may cause increased incidence of skin cancer and other health and environmental impacts. The Montreal Protocol has been ratified by the United States and 196 other countries and is widely recognized as one of the world's most successful multilateral international conventions in force.

As part of the 1990 amendments to the Clean Air Act, Congress enacted Title VI of the Act, which directs EPA to work with other federal agencies to carry out U.S. Montreal Protocol commitments for phasing out ozone depleting substances. Title VI specifies mechanisms to complement this phase-out, including a ban on nonessential products. It also provides flexibility to allow continued production of ozone depleting substances in areas where additional time might be required to identify effective alternatives.

The “U.S. Agricultural Sector Relief Act of 2012”

Methyl bromide is an odorless, colorless gas that has been used as a soil fumigant and structural fumigant to control pests across a wide range of agricultural and other sectors. Because methyl bromide depletes the stratospheric ozone layer, the amount of methyl bromide produced and imported in the United States was reduced incrementally until it was phased out on January 1, 2005, pursuant to our obligations under the Montreal Protocol and Title VI of the Clean Air Act.

Under the Protocol, the Parties to the Protocol have authority to permit exemptions from the phaseout for “critical” uses of methyl bromide that are nominated by a given country. The Parties to the Protocol have agreed to Decision IX/6 governing such exemptions, which states that:

“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 health and are suitable to the crops and circumstances of the nomination;”

The decision also establishes criteria and a process for the Parties to the Protocol to assess the quantity of production and consumption, if any, of methyl bromide that should be permitted for nominated critical uses.

EPA, in 2003, established the Critical Use Exemption process for methyl bromide in anticipation of the 2005 phaseout, to provide for growers with critical needs for continued use of the fumigant beyond the phaseout. The U.S. Government develops each annual critical use nomination for methyl bromide through a rigorous technical process involving the careful efforts of several agencies, and in close collaboration with the grower community.

Each year, EPA solicits applications from growers and grower groups. Staff of the EPA Office of Pesticide Programs and the U.S. Department of Agriculture (USDA) Office of Pest Management Policy review applications and work with growers to compile the best available information on current critical uses. EPA recognizes the vital importance of extensive interaction with the user community. Accordingly, EPA, USDA, and Department of State conducted meetings this winter with user groups to further ensure that federal agencies are able to work actively with applicants to identify information gaps. Calls and meetings were held to discuss specific crop, production, and use conditions, to enhance supporting information. EPA also provides support to, and attends, the annual Methyl Bromide Alternatives Outreach Conference.

In addition, between 1995 and 2012, USDA – through the Agricultural Research Service, the National Institute of Food and Agriculture (formerly, the Cooperative State Research Education and Extension Service), and the Interregional Research Project 4 (IR-4) programs – has provided substantial support for research and outreach related to alternatives for crops that used methyl bromide. These actions demonstrate, on the part of the U.S. Government, an understanding of the important needs of the agriculture and user community and an ongoing commitment to work effectively to help meet those needs.

All these efforts have the common goal of allowing the U.S. Government to develop technically supportable estimates for U.S. critical needs for methyl bromide. The value of this careful process has been demonstrated in the success to date in Montreal Protocol negotiations. The U.S. Government has successfully supported its nominations for critical uses of methyl bromide, securing approval of an average of 88 percent of our nominated amount for each year from 2005 through 2013.

While the current critical use exemption process has been effective and successful, the draft bill could disrupt that process in a number of respects. Most notably, the bill calls for EPA to take all appropriate action within its authority to seek a critical use exemption under the Protocol – for each and every applicant in the full amount requested by the applicant for an approved critical use – unless EPA has substantial evidence that there is a technically and economically feasible alternative available for that use. The bill appears intended to shift the burden of proof for justifying a critical use exemption from the applicant to EPA. This shift may have the unintended result of producing U.S. nominations that are less likely to secure international agreement because they are not as fully technically supported and may be viewed by other Parties as less rigorous than nominations developed under the current process. It may

also undermine the value of EPA's analysis in the interagency process to prepare and submit a critical use exemption nomination to the Montreal Protocol Parties every year. Furthermore, by requiring that the Administrator "shall" seek a critical use exemption under the Montreal Protocol, the bill would interfere with the Executive's constitutional authority to determine the time, scope, and objectives of international negotiations. Another concern raised by the bill is that, by referring to the list of critical uses set forth in the Code of Federal Regulations on January 1, 2005, it applies to an outdated universe of potential critical uses. In so doing, it excludes an array of critical users that were identified after that date. The bill also would add back some uses that need not be on the list, as many once-critical users since 2005 have adopted effective alternatives and no longer rely on methyl bromide.

The draft bill further articulates a separate "emergency events" process for methyl bromide, which we believe would be counterproductive and would ultimately undermine our ability to secure future exemptions for critical uses. In particular, the bill raises three key potential concerns. At present, the Parties have not fully defined what may qualify as an emergency event; if the United States enacts legislation defining the term expansively, this may encourage the Parties to the Protocol to pursue greater specificity with regard to allowable emergency uses, potentially limiting important existing flexibility. In addition, this bill may call into question whether the United States is attempting to create an independent exemption for critical uses that operates outside the agreed critical use exemption process. This could undermine our efforts to have our critical use exemption nomination approved through the Montreal Protocol. Further, the bill's list excludes certain very high value national security applications that are most directly applicable to the emergency uses exemption – for example,

homeland security uses that may be needed, such as use of methyl bromide to decontaminate a building after Anthrax exposure.

Finally, it is important to note that there are two substantial issues associated with the use of methyl bromide that the draft bill does not address and that, if the legislation were enacted, could very well prove to be problematic. First the availability of methyl bromide is regulated by EPA directly under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires the registration of pesticides sold or distributed in the United States. As part of the registration process, EPA approves the labeling of the pesticide product, including enforceable directions for its use. Any uses of methyl bromide as provided for under the provisions of this draft legislation would still be required to meet the FIFRA standards before they could be legally allowed. Thus EPA would still have the responsibility to regulate the use of methyl bromide under FIFRA in meeting its responsibilities for protecting public health and the environment in addition to meeting its Clean Air Act responsibilities.

Just as important, the decision to approve a critical use rests with the Parties to the Montreal Protocol in accordance with the terms of the Protocol. As such, any U.S. nominations for exemptions would still be subject to and dependent on approval under the Protocol before EPA could implement the exemptions domestically.

The “Asthma Inhaler Relief Act of 2012”

Epinephrine is a short-acting beta-adrenergic bronchodilator used for temporary relief of shortness of breath, tightness of chest, and wheezing due to asthma. Marketed as Primatene Mist, epinephrine metered-dose inhalers (MDIs) that contain chlorofluorocarbons (CFCs) are over-the-counter inhalation aerosol products used to treat the symptoms of asthma. CFCs are

ozone-depleting substances that, pursuant to the Montreal Protocol, were banned from domestic consumption and production in the United States in 1996.

Both the Montreal Protocol and Title VI allow for continued production of CFC-based metered dose inhalers through an essential use exemption provision. The Parties to the Montreal Protocol approved Decision IV/25, which provides the following criteria for assessing a proposed essential use:

“It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;”

Congress, through Title VI of the Clean Air Act, effectively established a partnership between EPA and the U.S. Food and Drug Administration (FDA) to guide a gradual, patient-safe phase-out of CFC propelled inhalation aerosols, and transition to non-CFC propellant alternate inhalation aerosols for asthma treatments when such an alternate is developed. Since the prior CFC propellants were banned in 1996, EPA has managed the essential use exemption process for these products. Under this process, EPA solicited information from pharmaceutical makers about annual CFC needs, developed essential use exemption requests in close consultation with FDA, and worked with FDA and the Department of State to secure approval of U.S. nomination amounts by the Parties to the Montreal Protocol. EPA then completed rulemakings to allow for additional production of otherwise banned CFCs in amounts authorized by the Parties to the Montreal Protocol. These amounts were determined by careful review and coordination with FDA, the agency with the responsibility for determining the medical necessity for continued essential use status for each individual active agent used to treat asthma.

This interagency partnership has been highly successful. Since the CFC phaseout in 1996, FDA has phased out nearly all CFC-propelled inhalation aerosols from the U.S. market, and has approved 19 safe and effective alternative asthma treatments. In the case of Primatene Mist, FDA conducted a thorough public process involving stakeholders, pharmaceutical manufacturers, and medical and patient advocacy groups. A 2008 FDA rule set a date for removing epinephrine from the list of essential CFC uses, stating that continued availability of epinephrine CFC inhalers are not necessary to save lives, to reduce or prevent asthma morbidity, or to significantly increase patient quality of life. Based on information gathered during the rulemaking process, FDA revised the rule's effective date from the proposed date of December 31, 2010 to December 31, 2011. Delaying the phase-out of epinephrine CFC MDIs by one year provided patients with additional time to transition to non-CFC alternatives and provided the manufacturer of Primatene Mist with the additional time it requested at a public meeting to reformulate Primatene Mist without CFCs. On January 1, 2012, Primatene Mist became subject to the Clean Air Act ban on the sale and distribution of nonessential products.

The certainty and transparency of this process allowed pharmaceutical manufacturers ample time – 20 years in the case of epinephrine – to research, develop and secure regulatory approval for patient-friendly effective alternatives. We are concerned that a bill that would require EPA to allow for the sale of remaining stocks of epinephrine inhalers would confuse patients, reduce confidence in the transition process, and send a strong signal to other pharmaceutical manufacturers that orderly engagement in public policy processes may not be rewarded. Further, the bill's language is directed at restricting EPA enforcement authority. Although Congress has the authority to legalize the sale of Primatene Mist, the proposed legislation would set an unacceptable precedent. The proposed legislation specifically directs the

Executive branch to exercise its discretion in a specific way by requiring the issuance of a No Action Assurance.

Conclusion

In summary, existing flexibilities under the Montreal Protocol and the Clean Air Act have proven adequate to address critical and essential use issues associated with ozone-depleting substances. Using these flexibilities, EPA and its federal agency partners have worked cooperatively with stakeholders to safely and effectively address issues associated with methyl bromide and Primatene Mist. EPA does not believe that the draft bills before the Committee are necessary and is concerned that their enactment could lead to a number of unintended and adverse consequences. Accordingly, I respectfully urge the Committee to carefully consider these issues as it proceeds.