

meet this commitment because the State has proposed RACT rules for all 13 source categories and has recently adopted a rule for one of these source categories.

EPA is proposing to conditionally approve the RACT analysis based on a commitment submitted by New Jersey. Under section 110(k)(4) of the Act, EPA may conditionally approve a plan based on a commitment from the State to adopt specific enforceable measures by a date certain, but not later than 1 year from the date of approval. If EPA conditionally approves the commitment in a final rulemaking action, the State must meet its commitment to adopt the identified regulations. If the State fails to do so, this action will become a disapproval upon the State's failure to meet its commitment. EPA will notify the State by letter that this action has occurred. If the conditional approval converts to a disapproval, the commitment will no longer be a part of the approved New Jersey SIP. Upon notification of the State that the conditional approval has converted to a disapproval, EPA will publish a notice in the **Federal Register** notifying the public that the conditional approval automatically converted to a disapproval. If the State meets its commitment, within the applicable time frame, the conditionally approved submission will remain a part of the SIP until EPA takes final action approving or disapproving the new SIP revision. If EPA disapproves the RACT SIP submittal, such action will start a sanctions and FIP clock. If EPA approves the submittal, the RACT analysis will be fully approved in its entirety and will replace the RACT conditionally approved into the SIP.

EPA is not taking action at this time on New Jersey's attainment demonstrations for the New York-Northern New Jersey-Long Island, NY-NJ-CT and the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE 8-hour ozone moderate nonattainment areas, but will do so in a future rulemaking.

## VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not

impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

## List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 29, 2008.

Alan J. Steinberg,

Regional Administrator, Region 2.

[FR Doc. E9-944 Filed 1-15-09; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 82

[EPA-HQ-OAR-2008-0503; FRL-8763-2]

RIN-2060-AO77

### Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2009

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to allocate essential use allowances for import and production of Class I ozone-depleting substances (ODSs) for calendar year 2009. Essential use allowances enable a person to obtain controlled Class I ODSs as part of an exemption to the regulatory ban on the production and import of these chemicals, which became effective as of January 1, 1996. EPA allocates essential use allowances for exempted production or import of a specific quantity of Class I substances solely for the designated essential purpose. The proposed allocation in this action is 63.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2009.

**DATES:** Written comments on this proposed rule must be received by the EPA Docket on or before February 17, 2009, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the contact listed below under **FOR FURTHER INFORMATION CONTACT** by 5 p.m. Eastern Standard Time on January 21, 2009. If a hearing is held, it will take place on February 2, 2009 at EPA headquarters in Washington DC. EPA will post a notice on our Web site (<http://www.epa.gov/ozone>) announcing further information on the hearing if it is requested.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2008-0503, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- E-mail: [A-and-R-docket@epa.gov](mailto:A-and-R-docket@epa.gov)
- Fax: 202-566-9744
- Mail: Air Docket, Environmental Protection Agency, Mailcode 2822T,

1200 Pennsylvania Ave., NW.,  
Washington, DC 20460.

• *Hand Delivery or Courier.* Deliver your comments to: EPA Air Docket, EPA West 1301 Constitution Avenue, NW., Room 3334, Mail Code 2822T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-OAR-2008-0503. EPA's policy is that all comments received by the docket will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through [www.regulations.gov](http://www.regulations.gov) or e-mail that you consider to be CBI or otherwise protected. If you would like the Agency to consider comments that include CBI, EPA recommends that you submit the comments to the docket that exclude the CBI portion but that you provide a complete version of your comments, including the CBI, to the person listed under **FOR FURTHER INFORMATION CONTACT** below. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov) your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet.

If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. 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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility 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 Docket is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:**  
Jennifer Bohman, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by courier service or overnight express: 1301 L Street, NW., Room 1013K, Washington, DC 20005; by telephone: (202) 343-9548; or by e-mail: [bohman.jennifer@epa.gov](mailto:bohman.jennifer@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

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#### **I. General Information**

*A. What should I consider when preparing my comments?*

- 1. *Confidential Business Information.* Do not submit this information to EPA

through [www.regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

#### **II. Basis for Allocating Essential Use Allowances**

##### *A. What are essential use allowances?*

Essential use allowances are allowances to produce or import certain ozone depleting substances (ODSs) in the U.S. for purposes that have been deemed "essential" by the U.S. Government and by the Parties to 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<sup>1</sup> of ODSs. The elimination of production and consumption of Class I ODSs is accomplished through adherence to phaseout schedules for specific Class I ODSs,<sup>2</sup> which include CFCs, halons, carbon tetrachloride, and methyl chloroform. As of January 1, 1996, production and import of most Class I ODSs were phased out in developed countries, including the United States.

However, the Montreal Protocol and the Clean Air Act (the Act) provide exemptions that allow for the continued import and/or production of Class I ODSs for specific uses. Under the Montreal Protocol, exemptions may be granted for uses that are determined by the Parties to be "essential." Decision IV/25, taken by the Parties to the Protocol in 1992, established criteria for determining whether a specific use should be approved as essential, and set forth the international process for making determinations of essentiality. The criteria for an essential use, as set forth in paragraph 1 of Decision IV/25, are the following:

"(a) That a use of a controlled substance should qualify as 'essential' only if:

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

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

(b) That production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) All economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(ii) The controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances."

#### *B. Under what authority does EPA allocate essential use allowances?*

Title VI of the Act implements the Montreal Protocol for the United

States.<sup>3</sup> Section 604(d) of the Act authorizes EPA to allow the production of limited quantities of Class I ODSs after the phaseout date for the following essential uses:

(1) Methyl Chloroform, "solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane parts susceptible to metal fatigue) for which no safe and effective substitute is available." Under section 604(d)(1) of the Act, this exemption was available only until January 1, 2005. Prior to that date, EPA issued methyl chloroform allowances to the U.S. Space Shuttle and Titan Rocket programs.

(2) Medical devices (as defined in section 601(8) of the Act), "if such authorization is determined by the Commissioner [of the Food and Drug Administration], in consultation with the Administrator [of EPA] to be necessary for use in medical devices." EPA issues allowances to manufacturers of MDIs that use CFCs as propellant for the treatment of asthma and chronic obstructive pulmonary disease.

(3) Aviation safety, for which limited quantities of halon-1211, halon-1301, and halon-2402 may be produced "if the Administrator of the Federal Aviation Administration, in consultation with the Administrator [of EPA] determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes." Neither EPA nor the Parties have ever granted a request for essential use allowances for halon, because alternatives are available or because existing quantities of this substance are large enough to provide for any needs for which alternatives have not yet been developed.

An additional essential use exemption under the Montreal Protocol, as agreed in Decision X/19, is the general exemption for laboratory and analytical uses. This exemption is reflected in EPA's regulations at 40 CFR part 82, subpart A. While the Act does not specifically provide for this exemption, EPA has determined that an exemption for essential laboratory and analytical uses is allowable under the Act as a *de minimis* exemption. The *de minimis* exemption is addressed in EPA's final rule of March 13, 2001 (66 FR 14760–14770). The Parties to the Protocol subsequently agreed (Decision XI/15) that the general exemption does not apply to the following uses: testing of oil and grease, and total petroleum

hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exemption at Appendix G to Subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352). In a December 29, 2005 final rule, EPA extended the general exemption for laboratory and analytical uses through December 31, 2007 (70 FR 77048), in accordance with Decision XV/8 of the Parties to the Protocol. At the 19th Meeting of the Parties in September 2007, the Parties agreed to extend the global laboratory and analytical use exemption through December 31, 2011, in Decision XIX/18. In a December 27, 2007 final rulemaking EPA took action to (1) extend the laboratory and analytical use exemption from December 31, 2007 to December 31, 2011 for specific laboratory uses, (2) apply the laboratory and analytical use exemption to the production and import of methyl bromide, and (3) eliminate the testing of organic matter in coal from the laboratory and analytical use exemption (72 FR 73264).

#### *C. What is the process for allocating essential use allowances?*

The procedure set out by Decision IV/25 calls for individual Parties to nominate essential uses and the total amount of ODSs needed for those essential uses on an annual basis. The Protocol's Technology and Economic Assessment Panel (TEAP) evaluates the nominated essential uses and makes recommendations to the Parties. The Parties make the final decisions on whether to approve a Party's essential use nomination at their annual meeting. This nomination process occurs approximately two years before the year in which the allowances would be in effect. The allowances proposed for allocation for 2009 were first nominated by the United States in January 2007.

For MDIs, EPA requests information from manufacturers about the number and type of MDIs they plan to produce, as well as the amount of CFCs necessary for production. EPA then forwards the information to the Food and Drug Administration (FDA), which determines the amount of CFCs necessary for MDIs in the coming calendar year. Based on FDA's determination, EPA proposes allocations to each eligible entity. Under the Act and the Montreal Protocol, EPA may allocate essential use allowances in quantities that together are below or equal to the total amount approved by the Parties. EPA will not allocate essential use allowances in amounts higher than the total approved by the Parties. For 2009, the Parties authorized

<sup>1</sup> "Consumption" is defined as the amount of a substance produced in the United States, plus the amount imported into the United States, minus the amount exported to Parties to the Montreal Protocol (see Section 601(6) of the Clean Air Act).

<sup>2</sup> Class I ozone depleting substances are listed at 40 CFR part 82, subpart A, appendix A.

<sup>3</sup> See Section 614(b) of the Act. EPA's regulations implementing the essential use provisions of the Act and the Protocol are located in 40 CFR part 82.

the United States to allocate up to 282 MT of CFCs for essential uses.

### III. Essential Use Allowances for Medical Devices

The following is a step-by-step list of actions EPA and FDA have taken thus far to implement the exemption for medical devices found at section 604(d)(2) of the Act for the 2009 calendar year.

1. On January 16, 2008, EPA sent letters to MDI manufacturers requesting the following information under section 114 of the Act ("114 letters"):

- a. The MDI product where CFCs will be used.
- b. The number of units of each MDI product produced from 1/1/07 to 12/31/07.
- c. The number of units anticipated to be produced in 2008.
- d. The number of units anticipated to be produced in 2009.
- e. The gross target fill weight per unit (grams).
- f. Total amount of CFCs to be contained in the MDI product for 2009.
- g. The additional amount of CFCs necessary for production.
- h. The total CFC request per MDI product for 2009.

The 114 letters are available for review in the Air Docket ID No. EPA-HQ-OAR-2008-0503. The companies requested that their responses be treated as confidential business information; for this reason, EPA has placed the responses in the confidential portion of the docket.

2. At the end of January 2008, as required by 40 CFR 82.13(u), EPA received information from MDI manufacturers that included such data as the type and quantity of CFCs held at the end of the year (i.e. stocks of pre-1996 and post-1996 CFCs). The data submitted from the MDI manufacturers is available for review in the Air Docket ID No. EPA-HQ-OAR-2008-0503. The companies requested that their individual responses be treated as confidential business information; for this reason, EPA has placed the individual responses in the confidential portion of the docket.

3. On February 13, 2008, EPA sent FDA the information MDI manufacturers provided in response to the 114 letters and information required by 40 CFR 82.13(u) with a letter requesting that FDA make a determination regarding the amount of CFCs necessary for MDIs for calendar year 2009. This letter is available for review in Air Docket ID No. EPA-HQ-OAR-2008-0503.

4. On April 28, 2008, FDA sent a letter to EPA stating the amount of CFCs

determined by the Commissioner to be necessary for each MDI company in 2009. This letter is available for review in the Air Docket ID No. EPA-HQ-OAR-2008-0503. FDA's letter informed EPA that it had determined that 88.0 MT of CFCs were necessary for use in medical devices in the year 2009.

5. On August 12, 2008, FDA sent a letter to EPA revising its April 28, 2008 essential use determination. FDA's revised letter informed EPA that it had determined that 63.0 MT of CFCs were necessary for use in medical devices for the year 2009. In its letter FDA stated, "This letter revises our recommendations for the amount of CFCs necessary for use in medical devices in the year 2009. The amount of CFCs recommended in our April 28, 2008 letter was based on information available then, that led to assumptions that are now outdated." This letter is available for review in the Air Docket ID No. EPA-HQ-OAR-2008-0503.

With respect to the 2009 determination, FDA stated, "FDA's determination for the allocation of CFCs is lower than the total amount requested by sponsors. In reaching this determination, we took into account the sponsors' production of MDIs that used CFCs as a propellant in 2007, their estimated production in 2008, their estimated production in 2009, their anticipated essential-use allocations in 2008, their current (as of December 31, 2007) stockpile levels, and any intercompany transfers of CFCs. Finally, FDA based its determination for 2009 on an estimate of the quantity of CFCs that would allow manufacturers to have a 12-month stockpile at the end of 2009, in accordance with paragraph 3 of Decision XVI/12 and paragraph 2 of Decision XVII/5."

The letter stated that in making its determination, FDA made the following assumptions:

- All manufacturers will receive the full essential-use allocation proposed by EPA for calendar year 2008 (72 FR 32269, June 12, 2007);
- All manufacturers will procure the full quantity of CFCs allocated to them for 2008; and
- No bulk CFCs currently held by, or allocated to, any manufacturer will be exported from the United States.

EPA has confirmed with FDA that this determination is consistent with Decision XVII/5, including language on stocks that states that Parties "shall take into account pre- and post-1996 stocks of controlled substances as described in paragraph 1(b) of Decision IV/25, such that no more than a one-year operational supply is maintained by that manufacturer." Allowing manufacturers

to maintain up to a one-year operational supply accounts for unexpected variability in the demand for MDI products or other unexpected occurrences in the market and therefore ensures that MDI manufacturers are able to produce their essential use MDIs.

For calendar year 2009, FDA's determination aggregates the amounts of CFC-11, -12, or -114 being allocated to the MDI manufacturer. In its letter FDA stated, "As has generally been our practice, FDA is aggregating the amounts for CFCs, and is providing recommendations on the total amounts of CFCs necessary to protect the public health. FDA expects manufacturers to maintain an appropriate balance of CFCs necessary to produce their CFC MDIs."

In accordance with the FDA determination, today's action proposes to allocate essential use allowances for a total of 63.0 MT of CFCs for use in MDIs for calendar year 2009.

The amounts listed in this proposal are subject to additional review and revision by EPA and FDA if information demonstrates that the proposed allocations are either too high or too low. We specifically request comment on the extent to which the proposed allocation of CFCs is sufficient to protect public health and ensure the manufacture and continuous availability of CFCs necessary to meet the expected demand. We also request comment on whether the proposed allocation, when considered along with current stocks, will best protect consumers by providing a smooth transition to non-CFC alternatives. Commenters requesting increases or decreases of essential use allowances should provide detailed information supporting a claim for additional or fewer CFCs. Any company that needs less than the full amount listed in this proposal should notify EPA of the actual amount needed.

### IV. Proposed Allocation of Essential Use Allowances for Calendar Year 2009

TABLE I—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2009

Company	Chemical	2009 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong	CFC-11 or CFC-12 or CFC-114.	63.0

EPA proposes to allocate essential use allowances for calendar year 2009 to the

entity listed in Table I. These allowances are for the production or import of the specified quantity of Class I controlled substances solely for the specified essential use.

## V. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action” because it raises novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

EPA prepared an analysis of the potential costs and benefits related to this action. This analysis is contained in the Agency’s Regulatory Impact Analysis (RIA) for the entire Title VI phaseout program (U.S. Environmental Protection Agency, “Regulatory Impact Analysis: Compliance with Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals,” July 1992). A copy of the analysis is available in the docket for this action and the analysis is briefly summarized here. The RIA examined the projected economic costs of a complete phaseout of consumption of ozone-depleting substances, as well as the projected benefits of phased reductions in total emissions of CFCs and other ozone-depleting substances, including essential use CFCs used for MDIs.

### B. Paperwork Reduction Act

This action does not impose any new information collection burden. The recordkeeping and reporting requirements included in this action are already included in an existing information collection burden and this action does not propose any changes that would affect the burden. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR 82.8(a) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2060–0170. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act 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 impact of today’s proposed rule on small entities, small entity is defined as: (1) A small business that is primarily engaged in pharmaceutical preparations manufacturing as defined by NAICS code 325412 with less than 750 employees; (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 its field.

After considering the economic impacts of today’s proposed 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 rule on small entities.” 5 U.S.C. 603 and 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 regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

This proposed action will provide an otherwise unavailable benefit to those companies that are receiving essential use allowances by creating an exemption to the regulatory phaseout of chlorofluorocarbons. We have therefore concluded that today’s proposed rule will relieve regulatory burden for all small entities. We continue to be interested in the potential impact of the proposed rule on small entities and welcome comments on issues related to such impacts.

### 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. This action is deregulatory and does not impose any new requirements on any entities. Therefore, this action is not subject to the requirements of sections 202 and 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 because this rule merely allocates essential use exemptions to entities as an exemption to the ban on production and import of Class I ODSs.

### E. Executive Order 13132: Federalism

Executive Order 13132, titled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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.”

This proposed rule does not have federalism implications. It will 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. Thus, Executive Order 13132 does not apply to this rule.

### 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 action does not impose substantial direct compliance costs on Indian tribal governments. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicits additional comment on this proposed action from tribal officials.

### G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets EO 13045 as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not

subject to EO 13045 because it implements Section 604(d)(2) of the Clean Air Act which states that the Agency shall authorize essential use exemptions should the Food and Drug Administration determine that such exemptions are necessary.

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

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

*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. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rule 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 (EO) 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 concluded that it is not practicable to determine whether there would be disproportionately high and adverse human health or environmental effects on minority and/or low income populations from this proposed rule. EPA believes, however, that this action 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 proposed 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.

**List of Subjects in 40 CFR Part 82**

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Imports, Methyl Chloroform, Ozone, Reporting and recordkeeping requirements.

Dated: January 12, 2009.

**Stephen L. Johnson,**  
*Administrator.*

40 CFR Part 82 is proposed to be 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.

**Subpart A—Production and Consumption Controls**

2. Section 82.8 is amended by revising the table in paragraph (a) to read as follows:

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

(a) \* \* \*

**TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2009**

Company	Chemical	2009 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong	CFC-11 or CFC-12 or CFC-114.	63.0

\* \* \* \* \*

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 648**

[Docket No. 080521698–8699–01]

**RIN 0648-AW87**

**Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Secretarial Interim Action**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comment.

**SUMMARY:** NMFS proposes a temporary Secretarial interim action under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to implement measures intended to immediately reduce overfishing in the Northeast (NE) multispecies fishery, while addressing the need to help sustain fishing communities, without compromising rebuilding objectives. Measures proposed for the commercial fishery include the following: A differential days-at-sea (DAS) area north of 41°30' N. lat., whereby a vessel would be charged 2 days for every day fished; a large Southern New England (SNE) Closure Area; and modified groundfish trip limits. This action does not change the scheduled DAS reduction in the NE Multispecies Fishery Management Plan (FMP), which would result in an approximate 18-percent reduction in DAS. For private recreational vessels fishing in the Exclusive Economic Zone (EEZ) and for federally permitted charter/party vessels, this action would extend in time a seasonal prohibition on the possession of Gulf of Maine (GOM) cod, and prohibit the possession of SNE winter flounder. For federally permitted charter/party vessels, this action would implement a trip limit for Georges Bank (GB) cod. In addition, this action proposes to mitigate some of the negative short-term economic impacts of the FMP by making modifications to the DAS Leasing Program, the Regular B DAS Program, and the DAS Transfer Program; continuing the Eastern U.S./Canada Haddock Special Access Program (SAP); and implementing a reduction in the haddock minimum size to 18 inches (45 cm). Finally, this action would specify management measures for the U.S./Canada Management Area for fishing year (FY) 2009.