PART 80–REGULATION OF FUEL AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7542, 7545, and 7601(a).

■ 2. Section 80.1129 is amended as follows:
■ a. By revising paragraph (b)(1).
■ b. By revising paragraph (b)(4).
■ c. By revising paragraph (b)(5)(ii).
■ d. By adding paragraph (b)(8).

§ 80.1129 Requirements for separating RINs from volumes of renewable fuel.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(6) and (b)(8) of this section, a party that is an obligated party according to § 80.1106 must separate any RINs that have been assigned to a volume of renewable fuel if they own that volume.

* * * * *

(4) Any party that produces, imports, owns, sells or uses a volume of neat renewable fuel may separate any RINs that have been assigned to that volume of neat renewable fuel if the party designates the neat renewable fuel as motor vehicle fuel, and the neat renewable fuel is used as a motor vehicle fuel.

(5) * * *

(ii) This paragraph (b)(5) shall not apply to any party meeting the requirements of paragraph (b)(4) of this section.

* * * * *

(8) For a party that has received a small refinery exemption under § 80.1141 or a small refiner exemption under § 80.1142, and who is not otherwise an obligated party, during the period of time that the small refinery or small refiner exemption is in effect the party may only separate RINs that have been assigned to volumes of renewable fuel that the party blends into motor vehicle fuel in accordance with paragraph (b)(2) of this section.

* * * * *

3. Section 80.1131 is amended by adding paragraph (a)(8) and removing paragraph (b)(4) to read as follows:

§ 80.1131 Treatment of invalid RINs.

(a) * * *

(8) In the event that the same RIN is transferred to two or more parties, all such RINs will be deemed to be invalid, unless EPA in its sole discretion determines that some portion of these RINs is valid.

* * * * *

4. Section 80.1151 is amended by revising paragraph (b)(5) to read as follows:

§ 80.1151 What are the recordkeeping requirements under the RFS program?

* * * * *

(b) * * *

(5) Records related to the production, importation, ownership, sale or use of any volume of neat renewable fuel that any party designates as motor vehicle fuel and uses as motor vehicle fuel.

* * * * *

[FR Doc. E9–14849 Filed 6–23–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2008–0503; FRL–8922–7]

RIN–2060–AO77

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This final rule is effective June 24, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2008–0503. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be 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 Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. 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 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 1047A, Washington DC, 20005; by telephone: (202) 343–9548; or by e-mail: *bohman.jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. 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 [1] of ODSs. Eliminating the production and consumption of Class I ODSs is accomplished through adherence to phaseout schedules for specific Class I ODSs [2] which include chlorofluorocarbons (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.''

[1] ''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).

[2] Class I ozone-depleting substances are listed at 40 CFR part 82, subpart A, appendix A.

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

Title VI of the Act implements the Montreal Protocol for the United States.[3] 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 metered dose inhalers (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 laboratory and analytical use 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).

[3] *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.

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 take the final decisions on whether to approve a Party's essential use nomination at their annual Meeting of the Parties. This nomination process occurs approximately two years before the year in which the allowances would be in effect. The allowances allocated for 2009 in this final rule 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 less than 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 the United States to allocate up to 282 metric tons (MT) of CFCs for essential uses. In a notice of proposed rulemaking published in the **Federal Register** on January 16, 2009 (74 FR 2954), EPA proposed to allocate 63.0 MT of CFCs for the production of MDIs for the calendar year 2009. In this final rule, EPA is allocating 63.0 MT of CFCs for the production of MDIs for calendar year 2009.

II. Essential Use Allowances for Medical Devices

The following is a step-by-step list of actions EPA and FDA have taken 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 letters from EPA 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 annual reporting 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. 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. This letter is available for review in the Air Docket ID No. EPA–HQ–OAR–2008–0503.

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 that ''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.''

6. In accordance with FDA's determination, EPA proposed to allocate 63.0 MT of CFCs for the production of MDIs for the calendar year 2009 in a proposed rulemaking published on January 16, 2009 (74 FR 2954).

7. In this final rule, EPA is allocating 63.0 MT of CFCs for the production of MDIs for calendar year 2009.

III. Response to Comments

EPA received comments from two entities on the proposed rule.

One commenter supported the proposed rule and opposed limiting the use of ODSs in MDIs. The commenter noted that lower cost CFC MDIs are a benefit for low-income individuals.

EPA believes that only a limited amount of production or import of CFCs for use in MDIs is necessary in 2009. Section 604 of the Clean Air Act directs EPA to authorize the production of CFCs for essential MDIs if FDA, in consultation with EPA, determines such production to be necessary. FDA, in consultation with EPA, has determined that 63.0 MT of CFCs are necessary to meet the demand for 2009 MDI manufacturing. Therefore, this action allocates 63.0 MT of CFCs for use in MDIs in 2009.

EPA and FDA understand that patients may incur additional costs to purchase inhalers as the market transitions to CFC-free alternatives, such

as HFA MDIs. For example, patients covered by medical insurance may encounter higher co-payments to purchase HFA MDIs, which are brand name products. However, patient assistance programs exist to assist patients with the increased costs. For low-income patients, these programs include free and/or discounted medicines. To assist patients facing higher co-pays associated with the increased costs of the HFA MDIs, programs such as coupons and discounted HFA MDIs are being made available through physicians' offices, at pharmacies, and at individual manufacturers' Web sites.

In a related rulemaking, FDA responded to a similar comment regarding the cost of CFC-free alternatives, stating, ''Considering the availability of programs providing low-cost or free prescription drugs that would allow low-income, elderly, and uninsured individuals to purchase alternative MDIs, and the availability of physician samples, we believe that patients will be adequately served by alternative MDIs'' (73 FR 69532).

A second commenter supported the proposed rule but believes that the US Government should take actions to limit the amount of CFCs needed for use in MDIs in the future. The commenter believes that the U.S. Government should set up procedures or guidelines to encourage MDI manufacturers to develop CFC-free MDIs. The commenter also asked whether the global laboratory and analytical use exemption would extend to the future use of MDIs.

EPA notes that the transition to ozone-safe alternatives is well underway and that, for example, the allocation of essential use allowances for CFC-based MDIs significantly decreased from over 3,000 MT in 2000 to 63.0 MT in 2009. In this action, EPA is only allocating essential use allowances to one manufacturer of CFC–MDIs.

FDA has found the use of ODSs to be essential in a limited number of medical products, including certain metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease (see 21 CFR 2.125(e)(1) and (e)(2)). When a specific medical product meets the criteria for removal of the essential use designation, FDA initiates rulemakings that remove the essential use designations for MDIs in a manner that is protective of public health. Specifically, FDA published a final rule in 2008 that removes the essential use designation for epinephrine used in MDIs as of December 31, 2011 (73 FR 69532). Further, FDA published a proposed rule in 2007 that proposes removing the essential use designations for flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil used in MDIs as of December 31, 2009 (72 FR 32030).

With respect to the comment that EPA should encourage MDI manufacturers to develop CFC-free MDIs, EPA agrees that companies that apply for essential use allocations should demonstrate ongoing research and development of alternatives to CFC MDIs. Decision VIII/10, taken in 1997, provides for applicants to submit information on the status of research and development into alternatives, and Decision XIX/13, taken in September 2007, provides for applicants to submit related information describing their progress in transitioning to CFC-free formulations. Since 1997, EPA has requested that applicants provide this information with their applications for CFC essential use nominations. The MDI manufacturer that is receiving an essential use allocation has submitted information to EPA pertaining to its research and development efforts.

Finally, the global laboratory and analytical exemption allows the continued production and import of small amounts of class I ODSs for use in essential laboratory and analytical methods. 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. The use of CFCs in MDIs is not a laboratory or analytical use. Therefore, the use of CFCs in MDIs would not qualify under the global laboratory and analytical use exemption.

IV. Allocation of Essential Use Allowances for Calendar Year 2009

With this action, EPA is allocating essential use allowances for calendar year 2009 to the entity listed in Table 1. These allowances are for the production or import of the specified quantity of Class I controlled substances solely for the specified essential use.

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

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 make 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 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 in its field.

After considering the economic impacts of today's 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 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 rule will relieve regulatory burden for all small entities. EPA solicited comments on the potential impact of the proposed rule on small entities. EPA did not receive comments related to the potential impact of the proposed rule on 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. 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 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 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 have tribal implications because it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action. EPA solicited comment on the proposed rule from tribal officials. EPA did not receive any comments from tribal officials on the proposed rule.

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 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 a ''significant energy action'' as defined in Executive Order 13211 (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 have any adverse energy effects because it merely allocates essential use allowances to entities manufacturing metered dose inhalers as an exemption to the ban on production and import of Class I ODSs.

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 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 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 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.

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. Therefore, 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.** This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective June 24, 2009.

VI. Effective Date of This Final Rule

Section 553(d) of the Administrative Procedures Act (APA) generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. This final rule is issued under section 307(d) of the CAA, which does not include a 30-day effective-date period requirement, and which precludes the application of section 553(d). CAA section 307(d)(1) (''The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies.'') EPA is making this final rule effective June 24, 2009, and believes that this is consistent with the policies underlying APA section 553(d). Specifically, APA section 553(d) provides an exception for any action that grants or recognizes an exemption or relieves a restriction. Because this action grants an exemption to the phaseout of production and consumption of CFCs, EPA is making this action effective immediately to ensure continued availability of CFCs for medical devices.

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: June 18, 2009.

Lisa P. Jackson,

Administrator.

■ 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.

Subpart A—Production and Consumption Controls

■ 2. Section 82.8 is amended by revising table I 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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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 161

[EPA–HQ–OPP–2004–0387; FRL–8418–5]

Data Requirements for Antimicrobial Pesticides; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: EPA is issuing this technical amendment to clarify that the data requirements for pesticide registration in 40 CFR part 161 are applicable only to antimicrobial pesticides.

DATES: This technical amendment is effective June 24, 2009.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0387. All documents in the docket are listed in the docket index available in *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday,