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 by 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, these rules do not have tribal implications as specified by Title 43, Section 1 of the Code of Federal Regulations. EPA has determined that before a rule may take effect, the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today’s Federal Register, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: April 1, 2010.

Jared Blumenfeld,
Regional Administrator, Region IX.

■ Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52 [AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

Subpart F—California

■ 2. Section 52.220, is amended by adding paragraph (c)(377) (i)(B) to read as follows:

§52.220 Identification of plan.
- * * * * * * * * *
(c) * * * * * * * * *
(377) * * * * * * * * *
(i) * * * * * * * * *
(B) Yolo Solano Air Quality Management District.

- * * * * * * * * *
[FR Doc. 2010–10943 Filed 5–7–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82


RIN–2060–AP59

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2010

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 (ODSs) for calendar year 2010. Essential use allowances enable a person to obtain controlled Class I ODSs through 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 production or import of a specific quantity of Class I substances solely for the designated essential purpose. The allocation in this action is 30.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2010.

DATES: This final rule is effective May 10, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2009–0566. All documents in the docket are listed on the http://www.regulations.gov Website. 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 http://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: Jeremy Arling, 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) 343–9055; or by e-mail: arling.jeremy@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Basis for Allocating Essential Use Allowances
A. What are essential use allowances?
B. Under what authority does EPA allocate essential use allowances?
C. What is the process for allocating essential use allowances?
II. Essential Use Allowances for Medical Devices
III. Response to Comments
I. Basis for Allocating Essential Use Allowances
A. What are essential use allowances?
Essential use allowances are allowances to produce or import certain substances. They are the U.S. allowance to the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol).

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

A. What are essential use allowances?

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

SUPPLEMENTARY INFORMATION:

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 United States for certain uses. The U.S. allowances to the Montreal Protocol under the Clean Air Act are available in sufficient quantity and quality to meet essential applications. The elimination of production and consumption of Class I ODSs is accomplished through adherence to the Montreal Protocol, which in turn is reflected in the annual report to Congress of the U.S. government on the implementation of the Montreal Protocol. The Montreal Protocol is the international agreement that recognized the need to protect the ozone layer by eliminating the use of ozone-depleting substances and is the first international agreement aimed at reducing and eliminating the production and consumption of ODSs. The elimination of production and consumption of Class I ODSs is accomplished through adherence to the Montreal Protocol and the Clean Air Act (40 CFR part 82, subpart A, appendix A).

SUPPLEMENTARY INFORMATION:

II. Essential Use Allowances for Medical Devices

In a December 27, 2007, final rule, EPA extended the general exemption for laboratory and analytical uses. This exemption is reflected in EPA’s regulations at 40 CFR part 82. The Act and the Montreal Protocol are located in 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/19) 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 general laboratory and analytical use exemption through December 31, 2011, in Decision XIX/18. In a December 27, 2007, final
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 2010 were first nominated by the United States in January 2008.

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 2010, the Parties authorized the United States to allocate up to 92 MT of CFCs for essential uses.

II. 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 2010 calendar year.

1. On January 7, 2009, EPA sent letters to MDI manufacturers requesting the following information under section 114 of the Act (“114 letters”):
   - The MDI product in which CFCs will be used.
   - The number of units of each MDI product produced from 1/1/08 to 12/31/08.
   - The number of units anticipated to be produced in 2009.
   - The number of units anticipated to be produced in 2010.
   - The gross target fill weight per unit (grams).
   - Total amount of CFCs to be contained in the MDI product for 2010.
   - The additional amount of CFCs necessary for production.
   - The total CFC request per MDI product for 2010.

The 114 letters are available for review in the Air Docket ID No. EPA–HQ–OAR–2009–0566. 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 2009, 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–2009–0566. 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 April 1, 2009, 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 2010. This letter is available for review in Air Docket ID No. EPA–HQ–OAR–2009–0566.

4. On July 10, 2009, FDA sent a letter to EPA stating the amount of CFCs determined by the Commissioner to be necessary for each MDI company in 2010. This letter is available for review in the Air Docket ID No. EPA–HQ–OAR–2009–0566. FDA’s letter informed EPA that it had determined that 30.0 MT of CFCs were necessary for use in medical devices in the year 2010.

With respect to the 2010 determination, FDA stated, “Our determination for the allocation of CFCs is lower than the total amount requested by manufacturers. In reaching this estimate, we took into account the sponsors’ production of MDIs that used CFCs as a propellant in 2008, their estimated production in 2009, their estimated production in 2010, their anticipated essential-use allocations in 2009, and their current (as of December 31, 2008) stockpile levels. Our determination took into account any transferred CFCs as well as pre-1996 CFC amounts. Finally, we based our determination for 2010 on an estimate of the quantity of CFCs that would allow manufacturers to have adequate stockpiles at the end of 2010 consistent with the principles in 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 2009 (74 FR 2954, January 16, 2009);
- All manufacturers will procure the full quantity of CFCs allocated to them for 2009; and
- No bulk CFCs currently held by, or donated 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 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.

5. In accordance with FDA’s determination, EPA proposed to allocate 30.0 MT of CFCs for the production of MDIs for the calendar year 2010 in a proposed rulemaking published on December 11, 2009 (74 FR 65719).

6. In this final rule, EPA is allocating 30.0 MT of CFCs for the production of MDIs for calendar year 2010.

III. Response to Comments

EPA received one significant comment on the proposed rule. The commenter opposed exemptions from the regulatory phaseout of CFCs. The commenter stated that five years should be the maximum number of years for granting exemptions.

Under section 604(d) of the Act, “to the extent such action is consistent with the Montreal Protocol,” EPA is authorized to allow the production of limited quantities of Class I ODSs for use in medical devices “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.” The Act does not specify or limit the number of years for which EPA might grant essential use allowances for the production or import of CFCs for use in medical devices. [Does the Protocol have a time limit on this point? Should address that here too.]

EPA describes above the actions and decision factors used to allocate essential use allowances. EPA believes the research and analysis supporting this final action is sound and that the allocation of CFCs for the continued manufacture of MDIs is necessary. EPA notes that the Montreal Protocol’s Medical Technical Options Committee also recognized the necessity of allocating essential use allowances for CFCs for use in MDIs in 2010 by supporting the U.S. nomination.

IV. Allocation of Essential Use Allowances for Calendar Year 2010

With this action, EPA is allocating essential use allowances for calendar year 2010 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>
<thead>
<tr>
<th>Company</th>
<th>Chemical</th>
<th>2010 Quantity (metric tons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armstrong ...</td>
<td>CFC–11 or CFC–12 or CFC–114</td>
<td>30.0</td>
</tr>
</tbody>
</table>

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a “significant regulatory action” under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

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. 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 final 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 final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives “which minimize any significant economic impact of the 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 final 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. EPA therefore concluded that today’s final 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 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 allowances to entities under an exemption to the ban on production and import of Class I ODSs.

E. Executive Order 13132: Federalism

This action 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. This action merely allocates essential use allowances to entities under an exemption to the ban on production and import of Class I ODSs. Thus, Executive Order 13132 does not apply to this rule.
In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed action from State and local officials.

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

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action merely allocates essential use allowances to entities under an exemption to the ban on production and import of Class I ODSs. This action does not impose substantial direct compliance costs on Indian Tribal governments. Thus, Executive Order 13175 does not apply to this action.

**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 final 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 action merely allocates essential use allowances to entities under 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 final 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 determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it affects the level of environmental protection equally for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any ozone depletion that results from this rule will impact all affected populations equally because ozone depletion is a global environmental problem with environmental and human effects that are, in general, equally distributed across geographical regions.

**K. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. A major rule cannot take effect until 60 days after it is published in the *Federal Register*. This action not a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective May 10, 2010.

**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:** April 29, 2010.

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 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 2010**

(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease

<table>
<thead>
<tr>
<th>Company</th>
<th>Chemical</th>
<th>2010 Quantity (metric tons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armstrong</td>
<td>CFC–11</td>
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<tr>
<td></td>
<td>CFC–12</td>
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<td>CFC–114</td>
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[FR Doc. 2010–10926 Filed 5–7–10; 8:45 am]