Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because it establishes a safety zone. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A temporary section in 165.T13–031 is added to read as follows:

§ 165.T13–031 Safety Zone; Richland Regatta Hydroplane Races Howard Amon Park, Richland, Washington.

(a) Location. The following area is a safety zone:

(1) The waters of the Columbia River from bank to bank in the vicinity of Howard Amon Park on the Columbia River in Richland, Washington commencing at the Interstate 182 Bridge and continuing up river Northward 3.0 miles and terminating at the Columbia River Mile 339.

(b) Enforcement period. This rule will be in effect from 9 a.m. to approximately 5 p.m. on June 14, 2008 and June 15, 2008, in the described waters of the Columbia River in Richland, Washington.

(c) Regulations. In accordance with the general regulations in Section 165.23 of this part, no person or vessel not participating in the actual hydroplane race may enter or remain in this zone unless authorized by the Captain of the Port or his designated representatives. Vessels and persons granted authorization to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or his designated representatives.

(d) Vessels wishing to request permission to enter the safety zone may contact the official patrol on VHF Channel 16 or by calling 503–240–9311.

Dated: May 23, 2008.

F.G. Myer,

Captain, U.S. Coast Guard, Captain of the Port Portland.

[FR Doc. E8–13092 Filed 6–10–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2007–0297; FRL–8577–9]

RIN 2060–AO44

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2008

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 stratospheric ozone-depleting substances (ODSs) for calendar year 2008. 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 ODSs solely for the designated essential purpose. The allocation in this action is 27.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2008.

DATES: This final rule is effective June 11, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2007–0297. All documents in the docket are listed on the *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: Kirsten Cappel, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Ave., NW., Washington, DC 20460; by courier service or overnight express: 1310 L Street, NW., Room 1047C, Washington, DC 20005; by telephone: (202) 343–9556; by fax: (202) 343–2338; or by e-mail: cappel.kirsten@epa.gov.

SUPPLEMENTARY INFORMATION

Table of Contents

I. Basis for Allocating Essential Use Allowances

A. What are essential use allowances?

Essential use allowances are allowances to produce or import certain ODSs in the United States 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 an international agreement aimed at reducing and eliminating the production and consumption [1] of ODSs. The elimination of production and consumption of Class I ODSs has been accomplished through adherence to phase-out schedules for specific Class I ODSs,[2] 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. 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 the Act, this exemption was available only until January 1, 2005. Prior to that date, EPA issued essential use allowances for methyl chloroform 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 essential use allowances to manufacturers of metered dose inhalers (MDIs) that use CFCs as propellant for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

(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 in most cases alternatives are available and 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

[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.

XV/8 of the Parties to the Protocol. In a notice of proposed rulemaking published in the **Federal Register** on September 13, 2007 (72 FR 52332), EPA proposed to extend the global laboratory and analytical use exemption beyond December 31, 2007 contingent upon and consistent with future anticipated action by the Parties to the Montreal 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 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?

Before EPA will allocate an essential use allowance, the Parties to the Montreal Protocol must first authorize the United States' request to produce or import essential Class I ODSs. 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 Montreal 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 at their annual meeting on whether to authorize a Party's essential use nomination. This nomination-and-authorization cycle begins approximately two years before the year in which the allowances would be in effect. The allowances allocated through this action were nominated by the United States in January 2006.

Once the Parties authorize the U.S. nomination, EPA allocates essential use allowances to specific entities through notice-and-comment rulemaking in a manner consistent with the Act. 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 for MDIs in the coming calendar year that are necessary to protect public health. Based on FDA's determination, EPA proposes allocations for each eligible entity. Under the Act and the Montreal Protocol, EPA allocates essential use allowances in quantities that together are below or equal to the total amount authorized by the Parties. EPA will not allocate essential use allowances in amounts higher than the total authorized by the Parties. For 2008, the Parties authorized the United States to allocate up to 385 MT of CFCs for essential uses. In the nomination for 2008 essential use allowances, the United States did not request CFCs for use in MDIs where the sole active ingredient is albuterol. In a notice of proposed rulemaking published in the **Federal Register** on June 12, 2007 (72 FR 32269), EPA proposed to allocate 27.0 MT of CFC–114 for the production of epinephrine MDIs for the calendar year 2008. In this final rule, EPA is allocating 27.0 MT of CFC–114 for the production of epinephrine MDIs for 2008.

II. Response to Comments

EPA received comments from four entities on the proposed rule.

One commenter opposed EPA's proposed allocation and opposed allowing MDI manufacturers to produce any MDIs that damage the ozone layer. The commenter further stated that MDI manufacturers should research and adopt alternatives that are healthful for all.

The Parties grant essential use exemptions contingent on a finding that the use for which an exemption is being requested is essential for health, safety, or the functioning of society, and that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of health or the environment. FDA regulations at 21 CFR 2.125 provide criteria for removing ODS-containing medical devices from the list of essential uses (see also FDA's July 24, 2002 final rule at 67 FR 48370). 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 decreased from 3,136.3 MT in 2000 to 167.0 MT in 2007. FDA, in consultation with EPA, has determined that 27.0 MT of CFC–114 is necessary in 2008 for the production of epinephrine MDIs. As therapeutic alternatives become available, FDA will, consistent with its regulations, continue to initiate rulemakings for removal of essential use designations for certain MDIs in a manner that is protective of public health.

With respect to the comment that MDI manufacturers should research alternatives to replace CFC MDIs, EPA agrees that companies applying for essential use allocations to manufacture essential use MDIs should demonstrate ongoing research and development of alternatives to CFC MDIs. EPA honors commitments under the Montreal Protocol to demonstrate progress in the transition to alternatives by considering this information in the application and nomination phase of the essential use process. 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. EPA will continue to consider companies' progress in the transition to CFC-free inhalers as a factor in the essential use nomination process.

A second commenter observed that for the 2008 proposed allocation EPA used a ''new criterion'' under which allowances would be made available only to companies that held less than one year's stockpile of essential use CFCs. The commenter observed that if its allocation for 2009—as well as its allocation for 2008—were zero, it would most likely not have sufficient CFC supplies to meet anticipated patient demand for other moieties during 2009. (The commenter noted that FDA has proposed, and not yet finalized, a rule to remove the essential use designation for those moieties as of December 31, 2009, but that it would need an allocation for 2009 regardless.)

The commenter also noted that it is a contract manufacturer that makes products for clients. As a result, according to the commenter, although it could purchase CFCs from the pre-1996 stockpile to supplement its CFC supply, such action is not reasonable. The commenter explained that the price of pre-1996 CFCs is not regulated and that as a result, the material is available, if at all, only at higher prices than CFCs manufactured with essential use allowances. The commenter stated that it cannot absorb the higher cost of the pre-1996 material because the prices of its finished products are fixed.

With respect to the comment that EPA used a new approach for the 2008 proposal, EPA responds that EPA and FDA used the same procedure for 2008 as for prior years to determine the essential use allocation for each requesting MDI company. That is, to assess the amount of new CFC production required to satisfy 2008 essential uses, EPA and FDA applied the terms of Decision XVII/5, including the provision that Parties should allocate such that manufacturers of

MDIs maintain no more than one-year operational supply of CFCs for essential uses. FDA articulated to EPA that in making its determination for 2008, FDA calculated the quantity of CFCs that a manufacturer needed to produce essential use MDIs for the year and subtracted from that quantity any CFC stocks owned by the MDI manufacturer exceeding a one-year operational supply. The remainder, if more than zero, was the quantity of newly produced or imported CFCs needed by that manufacturer. In addition, FDA informed EPA that consistent with the language of Decision XVII/5, FDA evaluated each company on an individual basis, rather than the aggregate CFC supplies owned by all entities. The use of this approach has been previously described in EPA's 2006 and 2007 final rulemakings for allocating essential use allowances, 71 FR 58504 and 72 FR 32212, respectively.

With respect to the comment about not being able to meet patient demand in 2009 if its allocation in 2009 is zero, EPA and FDA will assess 2009 allocations beginning in 2008 once more current information is available regarding the medical need for CFCs in MDIs. However, EPA expects that it and FDA will follow an approach for 2009 that is similar to that used for 2008 and previous control periods.

Under this approach, FDA, in close collaboration with EPA, will undertake a thorough and comprehensive analysis of a number of factors to determine the amount of CFCs necessary for the manufacture of essential use MDIs for the 2009 control period. First, FDA would evaluate the medical necessity by assessing the number of CFC MDIs necessary to protect public health in the U.S. (including the consideration of current data on the prevalence of asthma and COPD) and the quantity of CFCs necessary to ensure the manufacture and continuous availability of those MDIs. Second, FDA would analyze the most current data available regarding the existing inventory of CFCs held by each MDI manufacturer. Third, FDA would account for the implementation of the terms of Decision XVII/5, including the provision that FDA allocate such that manufacturers maintain no more than a one-year operational supply. Finally, FDA would consider how manufacturers' existing CFC supplies would be drawn down as they manufacture essential use MDIs throughout the year.

In response to the comment regarding potential outcomes of the FDA rulemaking that is now in the proposal stage, EPA asserts that concerns about the potential need for additional allowances would be best addressed in its essential use rulemaking for the 2009 control period.

With respect to the commenter's assertion that it cannot afford the cost of pre-January 1, 1996 CFCs, EPA and FDA do not regulate the price of CFCs, whether in the pre-January 1, 1996 stockpile or produced or imported post-January 1, 1996 with essential use allowances. Rather, market mechanisms determine the price of CFCs. As discussed above, if FDA determines that there is a medical need for new production of CFCs for the manufacture of essential use MDIs, then FDA will recommend allocation of the necessary amount to the requesting MDI manufacturer to make those MDIs. That MDI manufacturer is permitted to purchase newly produced and/or imported CFCs up to the amount that it has been allocated. EPA and FDA would not expect a MDI manufacturer to need pre-January 1, 1996 CFCs when FDA has determined that that manufacturer should be allocated essential use allowances.

To supplement its CFC allocation for a particular year, an MDI manufacturer may purchase any pre-January 1, 1996 CFCs that are available in the marketplace, or it may acquire essential use CFCs through a transfer with another manufacturer (subject to EPA regulations for such transfers). However, EPA notes that in making determinations for annual essential use allocations for MDI manufacturers, FDA takes into account the entirety of each MDI manufacturer's stocks of CFCs, including pre- and post-January 1, 1996 stocks and CFCs acquired through transfers.

A third commenter supported EPA's proposed allocation and stated that it is sufficient to protect human health and provide a smooth transition to non-CFC alternatives, consistent with the principles and obligations of the Montreal Protocol, and that it conforms with the Clean Air Act and other U.S. law. The commenter stated that according to publicly available information, the quantity of pharmaceutical-grade CFCs in the United States is sufficient to meet patient needs and that EPA's proposed amount will provide a smooth transition to CFC-free alternatives. In particular, the commenter stated that the zero allocation for CFC-albuterol, which started with the 2007 allocation, will allow for the gradual phase-down of CFC albuterol on the market, and is optimal for patient care. The commenter also noted that the proposal will foster a smooth transition by not allocating CFCs to other CFC MDI products where there are CFC-free therapeutic alternatives available.

A fourth commenter, who submitted comments claimed as CBI, opposed EPA's proposed allocation as too low and requested additional essential use allowances for calendar year 2008. A redacted version of these comments has been placed in the docket. In the public version of the comments, the commenter stated that based on an internal assessment of its current stockpile, it would not be able to meet production needs of Primatene Mist® if EPA did not grant it essential use allowances for calendar year 2008. To further evaluate the needs of the commenter, on August 8, 2007, EPA sent a letter to the commenter requesting additional information about its current and projected stockpile of CFCs, as well as current and projected production of Primatene Mist®. A copy of this letter is available in the docket. On August 21, 2007, the commenter sent a letter to EPA withdrawing its comments on the 2008 proposed rulemaking. In that letter the commenter noted that its withdrawal of its 2008 comments on the proposed rulemaking should not affect its request for essential use allowances in future years. A copy of this letter is also available in the docket.

III. Allocation of Essential Use Allowances for Calendar Year 2008

With this action, EPA is allocating essential use allowances for calendar year 2008 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 1.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2008

Company	Chemical	2008 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	27.0

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 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.

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 Part 82, Subpart 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 are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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 this rule on small entities, small entities are defined as: (1) A small business that is primarily engaged in pharmaceutical preparations manufacturing (NAICS code 325412) and that has fewer than 750 employees (based on Small Business Administration size standards); (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 that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this 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 proposed rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may conclude 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 rule provides an otherwise unavailable benefit to those companies that are receiving essential use allowances. We have therefore concluded that this final rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative, if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, since it merely provides exemptions from the 1996 phase-out of Class I ODSs. Similarly, EPA has determined that this rule 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, entitled ''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 final 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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. This rule affects only the companies that requested essential use allowances. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045, ''Protection of Children from Environmental Health risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on 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 Executive Order 13045 because it implements the phaseout schedule and exemptions established by Congress in Title VI of the Clean Air Act.

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

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (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. The rule affects only the pharmaceutical companies that requested essential use allowances of CFCs.

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, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in 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 12898 (59 FR 7629 (February 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 final 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 stratospheric ozone depletion that results from this final 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 in the U.S.

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 11, 2008.

V. Judicial Review

Under section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of the action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of the action in the **Federal Register**. Under section 307(b)(2), the requirements of this rule may not be challenged later in judicial proceedings brought to enforce those requirements.

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 states, ''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.'' Thus, section 553(d) of the APA does not apply to this rule. EPA nevertheless is acting consistently with the policies underlying APA section 553(d) in making this rule effective June 11, 2008. 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, Exports, Imports, Ozone, Reporting and recordkeeping requirements.

Dated: June 5, 2008.

Stephen L. Johnson,

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 Grants of essential use allowances and critical use allowances.

(a) * * *

TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2008

Company	Chemical	2008 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	27.0

* * * * *

[FR Doc. E8–13088 Filed 6–10–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1021; FRL–8365–6]

Flutolanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for indirect or inadvertent residues of flutolanil in or on wheat and soybeans. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 11, 2008. Objections and requests for hearings must be received on or before August 11, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1021. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Lisa Jones, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9424; e-mail address: *jones.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions