providing assistance in obtaining evidence for a claim if the substantially complete application for benefits indicates that there is no reasonable possibility that any assistance VA would provide to the claimant would substantiate the claim. VA will discontinue providing assistance in obtaining evidence for a claim if the evidence obtained indicates that there is no reasonable possibility that further assistance would substantiate the claim. Circumstances in which VA will refrain from or discontinue providing assistance in obtaining evidence include, but are not limited to:

(1) The claimant's ineligibility for the benefit sought because of lack of qualifying service or other lack of legal eligibility;

(2) Claims that are inherently incredible or clearly lack merit; and

(3) An application requesting a benefit to which the claimant is not entitled as a matter of law.

(Authority: 38 U.S.C. 5103A(a)(2))

(d) *Duty to notify claimant of inability to obtain records.*

(1) If VA makes reasonable efforts to obtain relevant non-Federal records but is unable to obtain them, or after continued efforts to obtain Federal records concludes that it is reasonably certain they do not exist or further efforts to obtain them would be futile, VA will provide the claimant with oral or written notice of that fact. VA will make a record of any oral notice conveyed to the claimant. For non-Federal records requests, VA may provide the notice at the same time it makes its final attempt to obtain the relevant records. In either case, the notice must contain the following information:

(i) The identity of the records VA was unable to obtain;

(ii) An explanation of the efforts VA made to obtain the records;

(iii) A description of any further action VA will take regarding the claim, including, but not limited to, notice that VA will decide the claim based on the evidence of record unless the claimant submits the records VA was unable to obtain; and

(iv) A notice that the claimant is ultimately responsible for providing the evidence.

(2) If VA becomes aware of the existence of relevant records before deciding the claim, VA will notify the claimant of the records and request that the claimant provide a release for the records. If the claimant does not provide any necessary release of the relevant records that VA is unable to obtain, VA will request that the claimant obtain the records and provide them to VA.

(Authority: 38 U.S.C. 5103A(b)(2))

(e) The authority recognized in subsection (g) of 38 U.S.C. 5103A is reserved to the sole discretion of the Secretary and will be implemented, when deemed appropriate by the Secretary, through the promulgation of regulations.

(Authority: 38 U.S.C. 5103A(g))

[FR Doc. E9–29459 Filed 12–10–09; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2009–0566; FRL–9091–6]

RIN–2060–AP59

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to allocate essential use allowances for import and production of Class I ozone-depleting substances (ODSs) for calendar year 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 proposed allocation in this action is 30.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2010.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before January 11, 2010, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the contact listed below under **FOR FURTHER INFORMATION CONTACT** by 5 p.m. Eastern Standard Time on December 16, 2009. If a hearing is held, it will take place on December 28, 2009 at EPA headquarters in Washington, DC. EPA will post a notice on our Web site (*http://www.epa.gov/ozone/strathome.html*) announcing further information on the hearing if it is requested.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2009–0566, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: A-and-R-docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Air Docket, Environmental Protection Agency, Mailcode 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery or Courier:* Deliver your comments to: EPA Air Docket, EPA West, 1301 Constitution Avenue, NW., Room 3334, Mail Code 2822T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2009–0566. EPA's policy is that all comments received by the docket will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through *http://www.regulations.gov* or e-mail that you consider to be CBI or otherwise protected. If you would like the Agency to consider comments that include CBI, EPA recommends that you submit the comments to the docket that exclude the CBI portion but that you provide a complete version of your comments, including the CBI, to the person listed under **FOR FURTHER INFORMATION CONTACT** below. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of

special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Jennifer Bohman, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by courier service or overnight express: 1301 L Street, NW., Room 1047A, Washington, DC 20005; by telephone: (202) 343–9548; or by e-mail: *bohman.jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. What should I consider when preparing my comments?

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

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

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

II. Basis for Allocating Essential Use Allowances

A. What are essential use allowances?

Essential use allowances are allowances to produce or import certain ozone depleting substances (ODSs) in the U.S. for purposes that have been deemed ''essential'' by the U.S. Government and by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol).

The Montreal Protocol is the international agreement aimed at reducing and eliminating the production and consumption [1] of ODSs. The elimination of production and consumption of Class I ODSs is accomplished through adherence to phaseout 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

[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.

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.[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 MDIs that use CFCs as propellant for the treatment of asthma and chronic obstructive pulmonary disease.

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

An additional essential use exemption under the Montreal Protocol, as agreed in Decision X/19, is the general exemption for laboratory and analytical uses. This exemption is reflected in EPA's regulations at 40 CFR part 82, subpart A. While the Act does not specifically provide for this exemption, EPA has determined that an exemption for essential laboratory and analytical uses is allowable under the Act as a *de minimis* exemption. The *de minimis* exemption is addressed in EPA's final rule of March 13, 2001 (66 FR 14760–14770). The Parties to the Protocol subsequently agreed (Decision XI/15) that the general exemption does not apply to the following uses: testing of oil and grease, and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exemption at Appendix G to Subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352). In a December 29, 2005, final rule, EPA extended the general exemption for laboratory and analytical uses through December 31, 2007 (70 FR 77048), in accordance with Decision XV/8 of the Parties to the Protocol. At the 19th Meeting of the Parties in September 2007, the Parties agreed to extend the global laboratory and analytical use exemption through December 31, 2011, in Decision XIX/18. In a December 27, 2007, final rulemaking EPA took action to (1) extend the laboratory and analytical use exemption from December 31, 2007, to December 31, 2011, for specific laboratory uses, (2) apply the laboratory and analytical use exemption to the production and import of methyl bromide, and (3) eliminate the testing of organic matter in coal from the laboratory and analytical use exemption (72 FR 73264).

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

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

III. Essential Use Allowances for Medical Devices

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

a. The MDI product where CFCs will be used.

b. The number of units of each MDI product produced from 1/1/08 to 12/31/08.

c. The number of units anticipated to be produced in 2009.

d. The number of units anticipated to be produced in 2010.

e. The gross target fill weight per unit (grams).

f. Total amount of CFCs to be contained in the MDI product for 2010.

g. The additional amount of CFCs necessary for production.

h. 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

[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.

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 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.

In accordance with the FDA determination, today's action proposes to allocate essential use allowances for a total of 30.0 MT of CFCs for use in MDIs for calendar year 2010.

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

IV. Proposed Allocation of Essential Use Allowances for Calendar Year 2010

TABLE I—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2010

Company	Chemical	2010 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	30.0

EPA proposes to allocate essential use allowances for calendar year 2010 to the entity listed in Table I. These allowances are for the production or import of the specified quantity of Class I controlled substances solely for the specified essential use.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

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

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

B. Paperwork Reduction Act

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

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any

rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's proposed rule on small entities, small entity is defined as: (1) A small business that is primarily engaged in pharmaceutical preparations manufacturing as defined by NAICS code 325412 with less than 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 5 USC 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

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

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. This action 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 solicits comment on this 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. EPA specifically solicits additional comment on this proposed action from tribal officials.

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

EPA interprets EO 13045 as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not subject to EO 13045 because it implements Section 604(d)(2) of the Clean Air Act which states that the Agency shall authorize essential use exemptions should the Food and Drug Administration determine that such exemptions are necessary.

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

This action is not 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 proposed rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has concluded that it is not practicable to determine whether there would be disproportionately high and adverse human health or environmental

effects on minority and/or low income populations from this proposed rule. EPA believes, however, that this action affects the level of environmental protection equally for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any ozone depletion that results from this proposed rule will impact all affected populations equally because ozone depletion is a global environmental problem with environmental and human effects that are, in general, equally distributed across geographical regions.

List of Subjects in 40 CFR Part 82

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

Dated: December 7, 2009.

Lisa P. Jackson,

Administrator.

40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

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

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

(a) * * *

TABLE I—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2010

Company	Chemical	2010 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	30.0

* * * * *

[FR Doc. E9–29556 Filed 12–10–09; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 0808041047–9114–02]

RIN 0648–AW62

Magnuson-Stevens Act Provisions; National Standard 2—Scientific Information

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes revisions to the guidelines for National Standard 2 (NS2) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) regarding scientific information. This action is necessary to provide guidance on the use of best scientific information available (BSIA) for the effective conservation and management of the nation's marine living resources. NMFS proposes to modify the existing NS2 guidelines on BSIA and establish new guidelines for scientific peer review to ensure the reliability, credibility, and integrity of the scientific information used in fishery conservation and management measures. Further, NMFS is proposing to add language to the guidelines regarding the role of the Scientific and Statistical Committees (SSCs) of the Regional Fishery Management Councils (Councils), and the relationship of SSCs to the peer review process. The proposed NS2 guidelines will also clarify the content and purpose of the Stock Assessment and Fishery Evaluation (SAFE) Report and related documents. These actions are necessary to ensure the use of BSIA in the development of fishery management plans and plan amendments, as required by NS2 of the MSA. The intended effect of these actions is to ensure that scientific information, including its collection and analysis, has been validated through formal peer review or other appropriate review, is transparent, and is used appropriately by SSCs, Councils, and NMFS in the conservation and management of marine fisheries. These guidelines are designed to provide quality standards for the collection and provision of biological, ecological, economic, and sociological information to fishery managers, Councils, and the public, while recognizing regional differences in fisheries and their management.

DATES: Written comments must be received by March 11, 2010.

ADDRESSES: You may submit comments, identified by 0648–AW62, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic comments via the Federal eRulemaking Portal *http://www.regulations.gov.*
- *Fax:* Attn: William Michaels 301–713–1875.
- *Mail:* William Michaels, NOAA Fisheries Service, Office of Science and Technology, F/ST4, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (for example, name address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

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FOR FURTHER INFORMATION CONTACT: William Michaels, 301–713–2363 x136.

SUPPLEMENTARY INFORMATION:

I. Overview of Proposed Revisions to the Guidelines for National Standard 2

Section 301(a)(2) of the MSA specifies that fishery conservation and management measures shall be based upon the best scientific information available. Section 301(b) of the MSA states that ''the Secretary (of Commerce) shall establish advisory guidelines