

relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

**DATES:** Comments on this proposed action must be received in writing by December 6, 2002.

**ADDRESSES:** Comments may be mailed to Royan Teter, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

**FOR FURTHER INFORMATION CONTACT:** Royan Teter at (913) 551-7609.

**SUPPLEMENTARY INFORMATION:** See the information provided in the direct final rule which is located in the rules section of the **Federal Register**.

Dated: October 23, 2002.

**William W. Rice,**

*Acting Regional Administrator, Region 7.*

[FR Doc. 02-27839 Filed 11-5-02; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 82

[FRL-7407-8]

RIN 2060-AK48

### Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2003

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** With this action, EPA is proposing to allocate essential-use allowances for import and production of class I stratospheric ozone depleting substances (ODSs) for calendar year 2003. Essential use allowances permit a person to obtain controlled ODSs as an exemption to the January 1, 1996 regulatory phase-out of production and import of these chemicals. EPA allocates essential-use allowances for exempted production or import of a specific quantity of class I ODS solely for the designated essential purpose. EPA is proposing to allocate essential-use allowances for production and import of

ODSs for use in medical devices and the Space Shuttle and Titan Rockets.

**DATES:** Written comments on this proposed rule must be received on or before December 6, 2002, 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 by 5 p.m. Eastern Standard Time on November 16, 2002. If a hearing is held, EPA will publish a document in the **Federal Register** announcing the hearing information.

**ADDRESSES:** Comments on this rulemaking should be submitted in duplicate to: Erin Birgfeld, Essential Use Program Manager, Global Programs Division, U.S. Environmental Protection Agency (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. If you send comments using courier services or overnight express, please address comments to 501 3rd Street NW., Washington, DC 20001. Comments will be filed in EPA Air docket number A-93-39. Comments that contain confidential business information should be submitted in two versions, one clearly marked "Public", to be filed in the public docket, and the other clearly marked "Confidential" to be reviewed by authorized government personnel only. If the comments are not marked, EPA will assume they are public and contain no confidential information.

Materials relevant to this rulemaking are contained in Docket No. A-93-39. The Docket is located at 1301 Constitution Avenue, NW., Room B108; *Mail Code:* 6102T Washington, DC 20460. The materials may be inspected from 8 a.m. until 5:30 p.m. Monday through Friday. EPA may charge a reasonable fee for copying docket materials.

**FOR FURTHER INFORMATION CONTACT:** Erin Birgfeld, U.S. Environmental Protection Agency, Global Programs Division, Office of Atmospheric Programs, 6205J, 1200 Pennsylvania Avenue, Washington, DC, 20460; (202) 564-9079; *birgfeld.erin@epa.gov*.

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#### I. Background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate production and consumption<sup>1</sup> of all stratospheric ozone depleting substances (ODSs). The elimination of production and consumption is accomplished through adherence to phase-out schedules for production and consumption of specific class I ODSs including chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform, hydrochlorofluorocarbons, and methyl bromide. As of January 1996, production and import of class I ODSs<sup>2</sup> were phased out in all developed countries including the United States. However, the Protocol and the Clean Air Act (CAA or Act) provide exemptions which allow for the continued import and/or production of class I ODS for specific uses. Under the Montreal Protocol, exemptions are granted for uses that are determined by the Parties to be "essential." Decision IV/25, taken by the Parties in 1992, established criteria for determining

<sup>1</sup> "Consumption" is defined as the amount of a substance produced in the United States, plus the amount imported, minus the amount exported to Parties to the Montreal Protocol (*see* Section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced or imported prior to the 1996 phaseout can continue to be used for purposes not expressly banned at 40 CFR part 82.

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

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.”

The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential-uses, and the amount of ODS needed for that essential-use on an annual basis. The Protocol's Technology and Economic Assessment Panel evaluates the nominated essential-uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on whether to approve a Party's essential-use nomination at their annual meeting.

Once the U.S. nomination is approved by the Parties, EPA allocates essential-use exemptions to specific entities through notice-and-comment rulemaking in a manner consistent with the CAA. Under the CAA and the Montreal Protocol, EPA is authorized to allocate essential-use allowances in quantities below or equal to the amounts approved by the Parties. EPA cannot allocate essential-use allowances in amounts higher than is approved by the Parties.

## II. Essential Use Allowances for Medical Devices.

### *A. How Were Essential-Use Allowances for Medical Devices Nominated and Approved by the Parties to the Montreal Protocol?*

On November 1, 2000, EPA issued a **Federal Register** notice (65 FR 65311) requesting applications for essential-use allowances for the year 2003. The applications EPA received requested exemptions for the production and import of specific quantities of CFCs (CFC-11, CFC-12, and CFC-114) for use in metered dose inhalers (MDIs), and provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the “1997 Handbook on Essential Use Nominations.” Based on the information provided in these applications, and after consultation with the Food and Drug Administration (FDA), the U.S. forwarded a request for 3,270 metric tons of CFCs for use in metered dose inhalers to the Ozone Secretariat for consideration by the Technical and Economic Assessment Panel (TEAP) and the Aerosol Technical Options Committees (ATOC). The Parties approved the U.S. request for 3,270 metric tons of CFCs for essential-uses in Decision XIII/8 taken at the 2001 Meeting of the Parties.

### *B. How Does the Clean Air Act Authorize Essential-Use Allowances?*

The CAA provides exemptions under section 604(d) to the phase-out of class I ODSs. With today's action, EPA is proposing to implement the exemption at 604(d)(2) of the Act which states that “notwithstanding the phase-out, EPA shall, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of class I ODSs for use in medical devices, if FDA, in consultation with EPA, determines that such production is necessary for use in medical devices”. The term “medical device” is defined in section 601(8) of the Clean Air Act as follows:

“[A]ny device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system

(A) If such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of FDA]; and

(B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be

essential by the Commissioner [of FDA] in consultation with the Administrator [of EPA].”

With today's action, EPA is proposing to allocate essential-use allowances for use in MDIs that have previously been determined to fit the definition of medical device above. For a full discussion of the definition of “medical device”, and how it has been interpreted and applied in today's rulemaking please, refer to the interim final rule for the year 2000 allocation of essential-use allowances (65 FR 716).

### *C. What Was the Allocation Process for 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 2003 control period.

1. On March 4, 2002, 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 1/1/02 to 12/31/01;
- c. The number of units anticipated to be produced in 2003;
- d. The gross target fill weight per unit (grams);
- e. Total amount of CFCs to be contained in the MDI product for 2003;
- f. The additional amount of CFCs necessary for production;
- g. The total CFC request per MDI product for 2003.

The letters requesting information that EPA sent each company are available for review in the Air Docket No. A-93-39. The company's responses, however, are considered confidential business information and are not publicly available.

2. On May 24, 2002, EPA sent FDA the information MDI manufacturers provided in response to the 114 letters along with a letter requesting that FDA make a determination regarding the amount of CFCs necessary for MDIs for calendar year 2003.

3. On July 3, 2002, FDA sent a letter to EPA stating the amount of CFCs necessary for each MDI company in 2003. This letter is available in the public docket. In accordance with the determination made by FDA, today's action proposes to allocate essential-use allowances for a total of 3,270 metric tons of CFCs for use in MDIs for the year 2003 calendar year.

*D. How Were the Decisions on the Amounts of Essential-Use Allowances for Each Company Made?*

In their July 3, 2003 determination letter, FDA describes how the amount of CFCs necessary for use in MDIs was determined. They state the following: "Under our existing regulations and our proposed rule<sup>3</sup>, we have interpreted the CAA definition of medical device to refer to any product that contains an active moiety<sup>4</sup> that appears on the essential-use list found at 21 CFR 2.125. We further understand that under the Montreal Protocol, and therefore under the CAA, only products for the treatment of asthma or chronic obstructive pulmonary disease (COPD) are eligible for essential-use nominations and allocations. Under this definition, the sponsor of any drug product produced under an approved new drug application, abbreviated new drug application, or valid investigational new drug application, approved for the treatment of asthma or COPD, and containing an active moiety on our essential use list may obtain CFCs. We also understand that under Decision XII/2 of the 12th Meeting of the Parties to the Montreal Protocol, any CFC metered-dose inhaler product (MDI) for the treatment of asthma and/or COPD approved after December 31, 2000, in a non-Article 5(1) Party is not an essential-use, unless the product meets the criteria set out in paragraph 1(a) of Decision IV/25.

"With these definitions in mind, we [FDA] have examined the information you [EPA] obtained from individual sponsors regarding their historical and intended use of CFCs in specific products. We compared this information to the number of CFC MDIS necessary to ensure the public health of the United States and the quantities of CFCs needed to ensure the manufacture and continuous availability of those necessary MDIs. In listing the amounts

we believe to be necessary for use in medical devices, we referred to this information, eliminated any double-counting or redundancy we found, considered changes in the prevalence of asthma and COPD, and eliminated allocations for uses not considered essential by the Parties to the Montreal Protocol, even if those uses are currently listed in our regulations at 21 CFR 2.125(e)."

*E. Will the Amounts Actually Allocated in the Final Rule Be the Same as the Amounts Listed in This Proposed Rule?*

The amounts listed in this proposal are subject to additional review by EPA and FDA if new information demonstrates that the proposed allocations are either too high or too low. Commentors requesting increases or decreases of essential-use allowances should provide detailed information supporting their claim for additional or fewer CFCs. Any company that no longer needs the full amount listed in this proposal should notify EPA of the actual amount needed.

**III. Exemption for Methyl Chloroform for Use in the Space Shuttle and Titan Rockets**

EPA is proposing to allocate methyl chloroform (MCF) for use in solid rocket motor assemblies. The CAA exemption for continued production and import of methyl chloroform is found at 604(d)(1) and reads as follows:

(1) Essential Uses of Methyl Chloroform.—Notwithstanding the termination of production required by subsection (b), during the period beginning on January 1, 2002, and ending on January 1, 2005, the Administrator [of EPA], after notice and opportunity for public comment, may, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of 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. Notwithstanding this paragraph, the authority to produce methyl chloroform for use in medical devices shall be provided in accordance with paragraph (2).

Decision X/6 states that " \* \* \* the remaining quantity of methyl chloroform authorized for the United States at previous meetings of the Parties [will] be made available for use in manufacturing solid rocket motors until such time as the 1999–2001 quantity of 176.4 tons (17.6 ODP-weighted tons) allowance is depleted, or until such time as safe alternatives are implemented for remaining essential-uses." According to the EPA tracking system, the total amount of MCF produced or imported by essential-use allowance holders from 1999 through 2001 was 28.3 metric tons, well below the limit of 176.4 metric tons. Based on the need for MCF for the space shuttle and Titan Rocket, EPA is proposing to allocate 13.2 metric tons of MCF for 2003.

Essential-use allowance holders should be aware that the exemption for MCF under section 604(d)(1) of the CAA expires in the year 2005. Thus, EPA will not have statutory authority to allocate essential-use allowances for MCF after that date.

**IV. Allocation of Essential-Use Allowances for Medical Devices and the Space Shuttle and Titan Rockets for Calendar Year 2003**

EPA is proposing to allocate essential-use allowances for calendar year 2003 to entities listed in Table I for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential-use.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2003

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	574
Aventis .....	CFC-11 or CFC-12 or CFC-114 .....	48
Boehringer Ingelheim Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	907
GlaxoSmithKline .....	CFC-11 or CFC-12 or CFC-114 .....	535
Schering-Plough Corporation .....	CFC-11 or CFC-12 or CFC-114 .....	937

<sup>3</sup> Use of Ozone-Depleting Substances; Essential Use Determinations, September 1, 1999. (64 FR 47719). The final rule was published on July 24, 2002, and will take effect January 20, 2003 (67 FR 48370).

<sup>4</sup> An FDA regulation at 21 CFR 314.108(a) defines active moiety as " the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other

noncovalent derivative (such as a complex, a chelate or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance."

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2003—Continued

Company	Chemical	Quantity (metric tons)
Sidmak Laboratories Inc. ....	CFC-11 or CFC-12 or CFC-114 .....	136
3M Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	133
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket .....	Methyl Chloroform .....	9.8
United States Air Force/Titan Rocket .....	Methyl Chloroform .....	3.4

## VI. Administrative Requirements

### A. 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 under section 203 of the UMRA a small government agency plan. 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.

Today’s 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 the 1996 phaseout of class I ODSs. Similarly, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Again, this is because this rule merely allocates essential use exemptions to entities as an exemption to the ban on production and import of class I ODSs.

### B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is “significant” and therefore subject to OMB review and the requirements of the Executive Order. The Order defines “significant regulatory action” as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. It has been determined that this rule is not a “significant regulatory action” under the terms of Executive Order 12866 and is therefore not subject to OMB review.

### C. Paperwork Reduction Act (PRA)

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB

control number 2060-0170 (EPA ICR No. 1432.21).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR part 9 and 48 CFR Chapter 1.

### D. 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 6, 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.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.”

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Today's rule does not affect the communities of Indian tribal governments since the only entities directly affected by this rule are the companies that requested essential-use allowances. Thus, Executive Order 13175 does not apply to this rule. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

*E. Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.*

The 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 today's rule on small entities, small entities is defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have 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. This is because this rule provides an otherwise unavailable benefit to those companies that are receiving essential use allowances.

Although this proposed rule will not have significant economic impact on a substantial number of small entities, we continue to be interested in the potential impact of the proposed rule on small entities and welcome comments related to these issues.

*F. Applicability of 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 or 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 proposed rule is not subject to Executive Order 13045 because it implements the phase-out schedule and exemptions established by Congress in Title VI of the Clean Air Act.

*G. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Pub. L. No. 104-113, section 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.

*H. 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 proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule. 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 rule from State and local officials.

*I. Executive Order 13211 (Energy Effects)*

This rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

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

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Imports, Methyl chloroform, Ozone layer.

Dated: October 30, 2002.

**Christine Todd Whitman,**  
*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 82.4 is amended by revising the table in paragraph (t)(2) to read as follows:

**§ 82.4 Prohibitions.**

*	*	*	*	*
(t)	*	*	*	
(2)	*	*	*	

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2003

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(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
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Boehringer Ingelheim Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	907
GlaxoSmithKline .....	CFC-11 or CFC-12 or CFC-114 .....	535
Schering-Plough Corporation .....	CFC-11 or CFC-12 or CFC-114 .....	937
Sidmak Laboratories Inc. ....	CFC-11 or CFC-12 or CFC-114 .....	136
3M Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	133
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket ....	Methyl Chloroform .....	9.8
United States Air Force/Titan Rocket .....	Methyl Chloroform .....	3.4

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 [FR Doc. 02-28212 Filed 11-5-02; 8:45 am]  
 BILLING CODE 6560-50-P

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**RIN 1018-A111**

**Endangered and Threatened Wildlife and Plants; Listing the Beluga Sturgeon (*Huso huso*) as Endangered**

**AGENCY:** Fish and Wildlife Service, Interior.  
**ACTION:** Proposed rule; notice of public hearing and extension of comment period.

**SUMMARY:** The Fish and Wildlife Service (Service) gives notice that a public hearing will be held on the proposal to list the beluga sturgeon (*Huso huso*) under the Endangered Species Act of 1973. The proposal was published on July 31, 2002 (67 FR 49657), in response to a petition received from the Natural Resources Defense Council, the Wildlife Conservation Society, and SeaWeb. The hearing will allow all interested parties to submit additional comments regarding the proposal to list beluga sturgeon under the Endangered Species Act.

**DATES:** The comment period on the proposal is extended through December

28, 2002. The public hearing will be held from 1 to 4 p.m. on Thursday, December 5, 2002, in Arlington, Virginia.

**ADDRESSES:** The public hearing will be held in the first floor conference room of the Marymount University, Ballston Campus, 1000 North Glebe Road, Arlington, Virginia, on December 5, 2002. Written comments and materials should be sent to the Chief, Division of Scientific Authority, U.S. Fish and Wildlife Service, Room 750, 4401 N. Fairfax Drive, Arlington, Virginia 22203, or by fax, 703-358-2276, or by e-mail, [ScientificAuthority@fws.gov](mailto:ScientificAuthority@fws.gov). Comments and materials received will be available for public inspection, by appointment, from 8 a.m. to 4 p.m. at the above address.

**FOR FURTHER INFORMATION CONTACT:** Marie T. Maltese at the above address (telephone 703/358-1708).

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 4 (b)(5)(E) of the Endangered Species Act (Act) requires that a public hearing be held on the proposed regulation if any person files a request for such a hearing within 45 days after the date of publication of general notice in the **Federal Register**. Public hearing requests were received during the allotted time period from Mark Berrigan, Chairman, Sturgeon Production Working Group, Florida Department of Agriculture and Consumer Services;

Robert Ctvrtlik, Ciram Corporation; Mats Engstrom, President, Tsar Nicoulai Caviar, Inc.; and R. Sherman Wilhelm, Director, Division of Aquaculture, Florida Department of Agriculture and Consumer Services. Anyone expecting to make an oral presentation at these hearings is encouraged to provide a written copy of their statement to the hearing officer prior to the start of the hearing. In the event there is a large attendance, the time allotted for oral statements may have to be limited. Oral and written statements receive equal consideration. There are no limits to the length of written comments presented at this hearing or mailed to the Service. In order to accommodate the presently scheduled public hearing, the Service extends the public comment period. Written comments may now be submitted through December 28, 2002, to the office in the **ADDRESSES** section.

**Author**

The primary author of this notice is Marie T. Maltese (See **ADDRESSES** section).

**Authority:** The authority for this action is the Endangered Species Act (16 U.S.C. 1531-1544).

Dated: October 31, 2002.

**Steve Williams,**

*Director, Fish and Wildlife Service.*

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