ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7430–7]

RIN 2060–AK48

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

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 2003. Essential use allowances enable a person to obtain controlled class I ODSs as an exemption to the regulatory ban of production and import of these chemicals, which became effective on January 1, 1996. EPA allocates essential use allowances for exempted production or import of a specific quantity of class I ODS solely for the designated essential purpose. Today EPA is finalizing the allocations proposed in the **Federal Register** on November 6, 2002 (67 FR 67581). These allocations total 3,270 metric tons of chlorofluorocarbons for use in metered dose inhalers, and 13.2 metric tons of methyl chloroform for use in the U.S. Space Shuttle and Titan Rocket programs.

DATES: This final rulemaking is effective December 27, 2002.

ADDRESSES: Materials relevant to this rulemaking are contained in EPA Air Docket No. A–93–39. The Air Docket is located at EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC, 20460. The Air Docket is open from 8:30 a.m. until 4:30 p.m. Monday through Friday. EPA may charge a reasonable fee for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Scott Monroe, by regular mail: U.S. Environmental Protection Agency, Global Programs Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; by telephone: (202) 564–9712; or by email: *monroe.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Basis for Allocating Essential Use Allowances
A. What Are Essential Use Allowances?
B. Under What Authority Does EPA Allocate Essential Use Allowances?
C. What Is the Process for Allocating Essential Use Allowances?
II. Response to Comments
III. Allocation of Essential Use Allowances for Calendar Year 2003
IV. Administrative Requirements
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Congressional Review Act
V. Judicial Review

I. Basis for Allocating Essential use Allowances

A. What Are Essential Use Allowances?

Essential use allowances are allowances to produce or import certain ozone-depleting chemicals in the U.S. for purposes that have been deemed ''essential'' by the Parties to the Montreal Protocol and the U.S. Government.

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate the production and consumption [1] of all stratospheric ozone depleting substances (ODSs). The elimination of production and consumption of class I ODSs is accomplished through adherence to phase-out schedules for specific class I ODSs,[2] including: chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform, and methyl bromide. 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 Protocol and the Clean Air Act (Act) provide exemptions that allow for the continued import and/or production of class I ODS for specific uses. Under the 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 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 phase out 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.'' EPA issues methyl chloroform allowances to the U.S. Space Shuttle and Titan Rocket programs.

(2) Medical Devices (as defined in section 601(8) of the Act), ''if such authorization is determined by the Commissioner [of the Food and Drug Administration], in consultation with the Administrator [of EPA] to be necessary for use in medical devices.'' EPA issues allowances to manufacturers of metered-dose inhalers, which use CFCs as propellant for the treatment of

[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). Stockpiles of class I ODSs produced or imported prior to the 1996 phase out may be used for purposes not expressly banned at 40 CFR part 82.

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

[3] According to section 614(b) of the Act, Title VI ''shall be construed, interpreted, and applied as a supplement to the terms and conditions of the Montreal Protocol * * * and shall not be construed, interpreted, or applied to abrogate the responsibilities or obligations of the United States to implement fully the provisions of the Montreal Protocol. In the case of conflict between any provision of this title and any provision of the Montreal Protocol, the more stringent provision shall govern.'' EPA's regulations implementing the essential use provisions of the Act and the Protocol are located in 40 CFR part 82.

asthma and chronic obstructive pulmonary diseases.

(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.

The Protocol, under Decision X/19, additionally allows a general exemption for laboratory and analytical uses through December 31, 2005. 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 allowance 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 exclusion at appendix G to subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

C. What Is the Process for Allocating Essential Use Allowances?

Before EPA may allocate essential use allowances, the Parties to the Protocol must first approve 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 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. This nomination cycle occurs approximately two years before the year in which the allowances would be in effect. The allowances allocated through today's action were first nominated by the United States in January 2001.

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 Act. For medical devices, EPA requests information from manufacturers about the number and type of devices 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 metered-dose inhalers in the coming calendar year. Based on FDA's assessment, EPA proposes allocations to each eligible entity. Under the Act and the Protocol, EPA may allocate essential use allowances in quantities that together are below or equal to the total amount approved by the Parties. EPA may not allocate essential use allowances in amounts higher than the total approved by the Parties.

For methyl chloroform, Decision X/6 by the Parties to the Protocol established 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.'' Section 604(d)(1) of the Act terminates the exemption period for methyl chloroform on January 1, 2005. Therefore, between 1999 and 2004 EPA may allow production or import up to a total of 176.4 metric tons of methyl chloroform for authorized essential uses. According to EPA's tracking system, the total amount of methyl chloroform produced or imported by essential use allowance holders in the years 1999–2001 was 28.3 metric tons. With today's allocation totaling 13.2 tons, the U.S. remains well below the established cap on allowances for methyl choloroform.

II. Response to Comments

EPA received one comment in response to the proposed rule. The commenter supported the proposed allocations.

III. Allocation of Essential Use Allowances for Calendar Year 2003

With today's action, EPA is allocating essential use allowances for calendar year 2003 to entities listed in Table 1. These allowances are for the production or import of the specified quantity of class I controlled substances solely for the specified essential use.

TABLE I.—ESSENTIAL USE 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
Glaxo SmithKline	CFC–11 or CFC–12 or CFC–114	535
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	937
Sidmak Laboratories [4]	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

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

Company	Chemical	Quantity (metric tons)
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

[4] EPA proposed to allocate allowances to Sidmak Laboratories, Inc. for 136 metric tons for use in 2003. Following publication of the proposal, Sidmak was purchased by the pharmaceutical firm PLIVA d.d. In 2003, a subsidiary of PLIVA d.d. reportedly will replace Sidmak Laboratories, thereby acquiring Sidmak's essential use allowances. A letter to EPA describing the purchase and PLIVA's commitment to execute essential use allowances in accordance with EPA regulations and Sidmak's application for allowances has been filed in Air Docket A–93–39, Category XII–A.

IV. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) 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 entitlements, 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 action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

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.* 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 instruction; 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.

C. Regulatory Flexibility Act

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. For purposes of assessing the impact of today's rule on small entities, small entities are 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 that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, EPA has concluded 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 today's 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), Pub. L. 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.

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 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. Today's 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 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.

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

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.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA), Pub. L. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in this 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. 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 December 27, 2002.

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.

List of Subjects in 40 CFR Part 82

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

Dated: December 19, 2002.

Christine Todd Whitman,

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 82.4 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

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
Sidmak Laboratories	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

* * * * *

[FR Doc. 02–32719 Filed 12–26–02; 8:45 am]

BILLING CODE 6560–50–P