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Part IV

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Allocation of 1998 Essential Use Allowances; Interim Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–5953–6]

RIN 2060–AG48

Protection of Stratospheric Ozone: Allocation of 1998 Essential Use Allowances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: With this action, EPA allocates essential-use allowances for the 1998 control period. The United States nominated specific uses of ozone-depleting substances (ODS) as essential uses for 1998 under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). The Parties to the Protocol subsequently approved production and import of ODS for the uses nominated by the United States in the quantities specified. In today's action, EPA allocates essential use allowances based on the quantities approved by the Parties for the nominated uses. Essential use allowances permit a person to obtain controlled ozone-depleting substances as an exemption to the January 1, 1996 regulatory phaseout of production and import. Essential use allowances are allocated to a person for exempted production or importation of a specific quantity of a controlled substance solely for the designated essential purpose.

DATES: This action is effective January 28, 1998. EPA will consider all written comments received by February 27, 1998, to determine if any change to this action is necessary.

ADDRESSES: Comments on and materials supporting this interim final rule are collected in Air Docket No. A–92–13, U.S. Environmental Protection Agency, 401 M Street, SW., Room M–1500, Washington, DC 20460. The Docket is located in room M–1500, First Floor, Waterside Mall at the address above. The materials may be inspected from 8 am until 4 pm Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials. Those wishing to notify EPA of their intent to submit adverse comments on this action should contact Tom Land, EPA, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation (6205–J), 401 M Street, SW., Washington, DC 20460, (Docket # A–92–13), (202)–564–9185.

FOR FURTHER INFORMATION CONTACT: Tom Land, EPA, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation (6205–J), 401 M Street, SW., Washington, DC 20460, (202)–564–9185 or The Stratospheric Ozone Hotline at (800)–296–1996.

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I. Background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) sets specific deadlines for the phaseout of production and importation of ozone depleting substances (ODS). At their Fourth Meeting in 1992, the signatories to the Protocol (the Parties) amended the Protocol to allow exemptions to the phaseout for uses agreed by the Parties to be essential. At the same Meeting, the Parties also adopted Decision IV/25, which established both criteria for determining whether a specific use should be approved as essential and a process for the Parties to use in making such a determination.

The criteria for an essential use as set forth in Decision IV/25 are the following:

''(1) 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;

(2) 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.''

Decision IV/25 also sets out the procedural steps for implementing this process. It first calls for individual Parties to nominate essential uses. These nominations are then to be evaluated by the Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) which makes recommendations to representatives of all Protocol Parties. The final decision on which nominations to approve is to be taken by a meeting of the Parties.

The initial cycle of implementing this Decision has been completed in the context of halons which were phased out of production at the end of 1993. This initial timetable separated nominations for halons from those for other ozone-depleting substances. EPA issued a **Federal Register** notice requesting nominations for essential uses of halons (February 2, 1993; 58 FR 6786). In response, the Agency received over ten nominations, but was able to work with applicants to resolve their near-term requirements. As a result, the U.S. did not nominate any uses for continued halon production in 1994. About a dozen other nations put forth nominations which were reviewed by the Technical and Economic Assessment Panel. Because the Panel determined that in each case alternatives existed or that the existing supply of banked halons was adequate to meet near-term needs, it did not recommend approval of any of the nominations. In November of 1993, at the Fifth Meeting, the Parties unanimously adopted the recommendation of the Panel not to approve any essential uses for the production or consumption of halons in 1994.

EPA issued a second notice for essential use nominations for halons on October 18, 1993 (58 FR 53722). These nominations covered possible production of halons in 1995 for essential uses. In response to this inquiry, EPA received no nominations.

Only one nomination (from France) was received by the TEAP for production and consumption of halons for an essential use in 1995. The TEAP did not recommend approval of this nomination.

EPA also issued a **Federal Register** notice requesting nominations for essential use applications which would need to continue beyond the 1996 phaseout of consumption and production allowances for CFCs, methyl chloroform, carbon tetrachloride, and hydrobromofluorocarbons (May 20, 1993, 58 FR 29410). EPA received 20 applications in response to this notice. For several of these applications, EPA determined that the criteria contained in Decision IV/25 had not been satisfied. For example, two applications sought CFCs for servicing existing air-conditioning equipment. EPA rejected these applications on the basis that if all

economically feasible steps were taken prior to the 1996 phaseout, then adequate supplies of banked and recycled CFCs should be available. However, in rejecting these nominations, the United States noted that servicing existing air-conditioning and refrigeration equipment remains a major challenge to the successful transition from the use of CFCs and that a future nomination in this area might be necessary if a combination of retrofits, replacements, recycling, recovery at disposal, and banking do not adequately address these needs.

Of the responses to the **Federal Register** request for essential use applications, the United States submitted essential use nominations to the Protocol Secretariat for the following uses of CFCs: metered dose inhalers and other selected medical applications; a bonding agent for the Space Shuttle; aerosol wasp killers; limited use in a specified bonding agent and polymer application; and a generic application for laboratory uses under specified limitations. (Letter from Pomerance to UNEP, September 27, 1993).

Nominations from the U.S. and other countries for over 200 specific uses were submitted to the Montreal Protocol Secretariat and provided to the Technical and Economic Assessment Panel for review. In March 1994, the Panel issued the ''1994 Report of the Technology and Economic Assessment Panel.'' The Report includes the Panel's recommendations for essential-use production and consumption exemptions. The Panel recommended that essential use exemptions be granted for nominations of: Methyl chloroform in solvent bonding for the Space Shuttle; CFCs used in metered dose inhalers; and specific controlled substances needed for laboratory and analytical applications. For each of the other nominations submitted, the TEAP determined that one or more of the criteria for evaluating an essential use had not been satisfied. For example, in the case of several of the U.S. nominations, the report states that alternatives are available and therefore the essential use exemption is not warranted.

In every year since 1994, the Parties have reviewed recommendations by the Technology and Economic Assessment Panel and made final decisions on essential use authorizations. Today's action follows decisions taken by the Parties after considering recommendations by the TEAP in 1996 and 1997.

In 1993, the Parties to the Protocol modified the timetable for submission of essential use nominations to combine both halons and all the other class I controlled substances (except methyl bromide) and to reduce the overall length of time between nomination and decision. According to Decision V/18, essential use nominations for halon consumption and production for 1995 and beyond, and essential use nominations for all the other class I controlled substances (except methyl bromide) for 1997 and beyond, must be submitted to the Secretariat prior to January 1st of the year prior to the year for which production and consumption is being sought. The Parties again revised the timetable for essential use nominations in Decision VIII/9 requiring submission by 31 January in the year in which decisions would be taken for subsequent years. EPA revised the domestic schedule accordingly so a **Federal Register** notice calling for essential use applications for class I controlled substances for future years is published prior to the Protocol deadline for submission to the Ozone Secretariat.

Decision V/18 directed the Technology and Economic Assessment Panel to develop a ''handbook on essential use nominations'' (Handbook). The July 1994 Handbook contained forms and instructions for how to apply for an essential-use exemption. Subsequent decisions by the Parties to the Protocol created additional criteria for essential use authorizations now reflected in the August 1997 Handbook. The Handbook may be obtained from the Stratospheric Protection Division, U.S. Environmental Protection Agency or the Ozone Secretariat of the Montreal Protocol in Nairobi.

II. Allocation of 1998 Essential Use Allowances

In today's action, EPA is allocating essential use allowances for the 1998 control period to the 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 USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1998 AND ESSENTIAL USE ALLOWANCES

Company/entity	Class I controlled substance	Quantity (metric tonnes)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Abbott Laboratories, Armstrong Laboratories, Boehringer Ingelheim, Glaxo Wellcome, 3M, Rhone Poulenc Rorer, Schering-Plough Corporation.	CFC–11	1043.6
	CFC–12	2512.2
	CFC–114	338.0
Medisol	CFC–11	78.0
	CFC–12	132.0
	CFC–114	11.0
Aeropharm	CFC–11	83.0
	CFC–12	166.7
(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	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply)	All Class I Controlled Substances (except Group VI).	No [1]

[1] No quantity specified.

The International Pharmaceutical Aerosol Consortium (IPAC) consolidated requests for an essential use exemption to be nominated to the Protocol as an agent of its member companies for administrative convenience. By means of a confidential letter to each of the companies listed above, EPA will allocate essential-use allowances separately to each company in the amount requested by it for the nomination.

Applications submitted by these companies requested class I controlled substances for uses claimed to be essential during the 1998 control period. The applications provided information in accordance with the criteria set forth in Decision VI/25 of the Protocol and the procedures outlined in the ''Handbook on Essential Use Nominations.'' The applications request exemptions for the production and import of specific quantities of specific class I controlled substances after the phaseout as set forth in 40 CFR 82.4. The applications were reviewed by the U.S. government and nominated to the Protocol Secretariat for analysis by the Technical and Economic Assessment Panel (TEAP) and its Technical Option Committees (TOCs). The Parties to the Montreal Protocol approved the U.S. nominations for essential-use exemptions during meetings in 1995 and 1996. In today's action essential-use allowances are allocated to United States entities based on nominations decided upon by the Parties to the Protocol.

The 1998 global essential use exemption for analytical and laboratory applications published in today's rule imposes strict requirements both in § 82.13 and in Appendix G of this subpart. The restrictions for the global laboratory and analytical essential use exemption listed in Appendix G include requirements regarding purity of the class I controlled substances and the size of the containers. In addition, there are detailed reporting requirements in § 82.13 for persons that take advantage of the global laboratory and analytical essential-use exemption for class I controlled substances. The strict requirements are established because the Parties to the Protocol, and today's rule, do not specify a quantity of essential use allowances permitted for analytical and laboratory applications, but establish a global essential-use exemption, without a named recipient.

Any person obtaining class I controlled substances after the phaseout under the essential use exemptions published in today's rule is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential-use allowances or persons obtaining class I controlled substances under the essential-use exemptions must comply with the recordkeeping and reporting requirements in § 82.13 of this subpart and the restrictions in Appendix G of this subpart.

Section 307(d) of the Clean Air Act Amendments of 1990 (CAA or the Act) states that in the case of any rule to which section 307(d) applies, notice of proposed rulemaking must be published in the **Federal Register** (CAA 307(d)(3)). The promulgation or revision of regulations under title VI of the CAA (relating to stratospheric ozone protection) is generally subject to section 307(d). However, section 307(d) does not apply to any rule referred to in subparagraphs (A) or (B) of section 553(b) of the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq.

APA section 553(b) requires that any rule to which it applies be issued only after the public has received notice of, and an opportunity to comment on, the rule. However, APA section 553(b)(B) exempts from those requirements any rule for which the issuing agency for good cause finds that providing prior notice-and-comment would be impracticable, unnecessary or contrary to the public interest. Thus, any rule for which EPA makes such a finding is exempt from the notice-and-comment requirements of both APA section 553(b) and CAA section 307(d).

EPA believes that the circumstances presented here provide good cause to take this action without prior notice and comment. EPA finds that providing prior notice and comment would be impracticable and contrary to the public interest because the ozone-depleting substances need to be available to the listed entities in 1998 for the health and safety of society as defined in the Protocol essential use criteria. The allocation of essential-use allowances for CFCs to the manufacturers of metered-dose inhalers will ensure the availability of treatment in order to protect the health of U.S. patients with asthma and chronic obstructive pulmonary disease. The allocation of essential-use allowances for methyl chloroform for the manufacture of the Thiokol/Space Shuttle Rockets and the Titan Rockets will provide a guarantee of safety from explosions that are unacceptable risks to both national programs.

Nonetheless, EPA is providing 30 days for submission of public comments following today's action. EPA will consider all written comments submitted in the allotted time period to determine if any change to this action is necessary.

Section 553(d) of the APA generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. However, APA section 553(d)(1) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption from the phaseout of production and consumption of most class I ozone-depleting substances, EPA is making this action immediately effective to ensure the availability of ozone-depleting substances for essential uses during the 1998 control period.

III. Additional Changes in the Essential Use Process To Be Published in Subsequent Proposed Rulemaking

EPA will be publishing a Notice of Proposed Rulemaking that includes changes to the essential-use provisions published in the **Federal Register** on May 10, 1995. One of the proposals will be a simplification of the process for allocating essential-use allowances by providing that allowances will be allocated through a Notice published in the **Federal Register** rather than through a Final Rulemaking. EPA will propose allocating essential-use allowances according to the quantities approved by the Parties to the Protocol for which applications were submitted to the U.S. government. EPA will be seeking comments on a simplification of the current allocation process.

EPA will also be proposing changes to the reporting requirements for holders of essential-use allowances in the subsequent Notice of Proposed Rulemaking. EPA will propose changes to the reporting requirements to allow the U.S. to gather information in accordance with Decision VIII/9, paragraph 9. Under the reporting format associated with Decision VIII/9, paragraph 9, Parties to the Protocol are requested to report data regarding essential uses, including inventories of CFCs, quantities of CFCs imported and produced for essential uses, the amount of CFCs that are actually filled into metered-dose inhalers, and stockpiles of CFCs remaining at the end of a control period.

IV. Summary of Supporting Analysis

A. Unfunded Mandates Reform Act and Regulatory Flexibility Act

Since this action is not subject to notice-and-comment rulemaking requirements under the APA or any other law, it is also not subject to sections 202, 204 or 205 of the

Unfunded Mandates Reform Act (UMRA). In addition, since this action does not impose annual costs of $100 million or more on small governments or uniquely affect small governments, the Agency has no obligations under section 203 of UMRA. Moreover, since this action is not subject to notice-and-comment requirements under the APA or any other statute as stated above, it is not subject to section 603 or 604 of the Regulatory Flexibility Act.

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 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 by EPA that this rule is not a ''significant regulatory action'' within the meaning of the Executive Order.

C. 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.* 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. 1432.16).

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 15.

D. Executive Order 12875

Today's action does not impose any unfunded mandate upon any State, local, or tribal government; therefore, Executive Order 12875 does not apply to this rulemaking.

E. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and recordkeeping requirements.

Dated: January 16, 1998.

Carol M. Browner,

Administrator.

40 CFR part 82 is 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(r)(2) is amended by revising the table to read as follows:

§ 82.4 Prohibitions.

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(r) * * *

(2) * * *

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TABLE I.—ESSENTIAL USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1998 AND ESSENTIAL USE ALLOWANCES—Continued

Company/entity	Class I controlled substance	Quantity (metric tonnes)
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply)	All Class I Controlled Substances (except Group VI).	([2])

[1] IPAC consolidated requests for an essential use exemption to be nominated to the Protocol as an agent of its member companies for administrative convenience. By means of a confidential letter to each of the companies listed above, EPA will allocate essential-use allowances separately to each company in the amount requested by it for the nomination.
[2] No quantity specified.

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