federal register

Thursday
January 7, 1999

Part IV

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Allocation of 1999 Essential-Use Allowances; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6217–1]

RIN 2060–AI26

Protection of Stratospheric Ozone: Allocation of 1999 Essential-Use Allowances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this action, EPA is allocating essential-use allowances for the 1999 control period. The United States nominated specific uses of controlled ozone-depleting substances (ODS) as essential for 1999 under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Protocol). The Parties to the Protocol subsequently authorized specific quantities of ODS for 1999 for the uses nominated by the United States. 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 rule is effective January 7, 1999.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at 1–800–296–1996 or Tom Land, U.S. Environmental Protection Agency, Stratospheric Protection Division, Office of Atmospheric Programs, 6205J, 401 M Street, SW., Washington, DC, 20460, 202–564–9185.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Allocation of 1999 Essential-Use Allowances
III. Response to Comments
IV. Summary of Supporting Analysis
A. Unfunded Mandates Reform Act
B. Executive Order 12875: Enhancing the Intergovernmental Partnership
C. Executive Order 12866
D. Paperwork Reduction Act
E. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments
F. Regulatory Flexibility Act
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. National Technology Transfer and Advancement Act
I. Submission to Congress and the General Accounting Office

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** document 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 document 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** document 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 document. 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; rocket motor assembly 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 1997 and 1998.

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** document 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 on Essential-use Nominations. 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. The Handbook can also be downloaded from the TEAP website at: http://www.teap.org/html/teap__reports.html.

II. Allocation of 1999 Essential-Use Allowances

In today's action, EPA is allocating essential-use allowances for the 1999 control period 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 USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1999 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)—Armstrong Laboratories, Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, Schering Corporation, 3M.	CFC–11	899.5
	CFC–12	2157.4
	CFC–114	183.6
Medisol Laboratories, Inc	CFC–11	67.3
	CFC–12	115.3
	CFC–114	9.6
Aeropharm Technology, Inc	CFC–11	80.1
	CFC–12	160.2
Sciarra Laboratories, Inc	CFC–11	0.5
	CFC–12	1.5
	CFC–114	0.5
(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).	[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 the entities in Table I requested class I controlled substances for uses claimed to be essential during the 1999 control period. The applications provided information in accordance with the criteria set forth in Decision IV/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 the Ninth Meeting in 1997 (Decision IX/18). Today's action allocates essential-use allowances to United States entities based on nominations decided upon by the Parties to the Protocol.

The 1999 global essential-use exemption for analytical and laboratory applications published in today's rule does not alter the strict requirements both in 40 CFR 82.13 and in appendix G to 40 CFR part 82, subpart A. 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 in today's action 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 record keeping and reporting requirements in § 82.13 and the restrictions in Appendix G.

III. Response to Comments

EPA received one comment pointing out that, in accordance with the direct final rule published on August 4, 1998 (63 FR 41625) and the related subsequent notice on October 5, 1998 (63 FR 53290), the regulatory citation in the propose rule published on November 20, 1998 (63 FR 64437) should be changed from § 82.4(r)(2) to § 82.4(t)(2). With this action, EPA makes this appropriate change to the paragraph citation to be consistent with changes made in prior rules.

IV. Summary of Supporting Analysis

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 by State, local, and tribal governments, in the aggregate, or by 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. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

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. Because this rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this rule does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on State, local or tribal governments. The final rule does not impose any enforceable duties on these

entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. 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 that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

D. 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.

E. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies or matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. The final rule does not impose any enforceable duties on Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements 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 not-for-profit enterprises, and small governmental jurisdictions. This final rule would not have a significant impact on a substantial number of small entities since essential-use allocations are granted to large pharmaceutical manufacturing corporations and not small entities such as small businesses, not-for-profit enterprises or small governmental jurisdictions.

EPA concluded that this final rule would not have a significant impact on a substantial number of small entities, therefore, I hereby certify that this action will not have a significant economic impact on a substantial number of small entities. This rule, therefore, does not require a regulatory flexibility analysis.

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 E.O. 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.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 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 final rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

I. Submission to Congress and the General Accounting Office

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. 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).

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: December 31, 1998.

Carol M. Browner,

Administrator.

Accordingly, 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(t)(2) is amended by revising the table to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL-USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1999 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) [1]—Armstrong Laboratories, Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, Schering Corporation, 3M.	CFC–11	899.5
	CFC–12	2157.4
	CFC–114	183.6
Medisol Laboratories, Inc	CFC–11	67.3
	CFC–12	115.3
	CFC–114	9.6
Aeropharm Technology, Inc	CFC–11	80.1
	CFC–12	160.2
Sciarra Laboratories, Inc	CFC–11	0.5
	CFC–12	1.5
	CFC–114	0.5
(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).	([2])

[1] 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.

[2] No quantity specified.

* * * * *

[FR Doc. 99–324 Filed 1–6–99; 8:45 am]

BILLING CODE 6560–50–P