ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7140–5]

RIN 2060–AJ81

Protection of Stratospheric Ozone: Allocation of Essential-use Allowances for Calendar Year 2002; and Extension of the *De Minimis* Exemption for Essential Laboratory and Analytical Uses through Calendar Year 2005

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 2002. Essential-use allowances permit a person to obtain controlled class I 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. Today EPA is finalizing the proposed regulations published in the **Federal Register** on November 1, 2001. With this action, EPA is allocating essential-use allowances for production and import of class I ODSs for use in medical devices and the Space Shuttle and Titan Rockets, and extending the general exemption for class I ODSs for use in essential laboratory and analytical applications through the year 2005 as consistent with the Montreal Protocol. EPA is also finalizing regulatory changes to ensure consistency with Decisions XI/15 and XII/2 of the Montreal Protocol. Decision XI/15 states that use of class I ODS for the testing of ''oil and grease,'' and ''total petroleum hydrocarbons'' in water; testing of tar in road-paving materials; and forensic finger printing are not considered essential under the exemption for laboratory and analytical uses beginning January 1, 2002. Decision XII/2 states that any CFC MDIs approved after December 31, 2000, are not essential unless the product meets the criteria for essentiality set out in paragraph 1(a) of Decision IV/25. Decision XII/2 also authorizes Parties to the Montreal Protocol to allow transfers of CFCs produced with essential-use allowances among MDI companies. Finally, EPA is adding a regulatory language to clarify that clarifies that it is a violation of the CAA if unused class I ODS produced under the authority of essential-use allowances or the exemption for laboratory and analytical uses are used in applications other than the stated essential purposes.

DATES: This final rulemaking is effective February 11, 2002.

ADDRESSES: Materials relevant to this rulemaking are contained in Docket No. A–93–39. The Docket is located in Waterside Mall Room M–1500, 401 M Street, SW., 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.

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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 [1] 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 most class I ODSs [2] were phased out in 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 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.''

II. Allocation of Essential-Use Allowances for Medical Devices and the Space Shuttle and Titan Rockets

With today's action, EPA is implementing the statutory exemption for continued import and production of CFCs beyond the phase-out for use in medical devices. Section 604(d)(2) of the CAA states that ''notwithstanding the phase-out, EPA shall, to the extent consistent with the Montreal Protocol,

[1] ''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) essential-use 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.

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

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 [3]''. In implementing this exemption, FDA sent EPA a letter on August 9, 2001, indicating the amount of CFCs each company should receive as essential-use exemptions and their determination that a total of 3,388 metric tons of CFC were ''necessary'' for use in medical devices for the year 2002 [4]. The allocations for CFCs in the proposal reflected FDA's determination, and were based on the assumption that the Parties would approve the U.S. essential-use supplemental request for the year 2002. The Parties did approve the U.S. supplemental request by taking Decision XIII/8 at their meeting in October 2001. After publication of the proposal, one company determined that their need for CFCs for 2002 was less than originally anticipated, and voluntarily requested that EPA reduce their essential-use allowances by 356 metric tons. Thus, the total amount of CFCs allocated in this final rule is reduced from 3,388 metric tons to 3,032 metric tons. There are no changes to any other company's essential-use allowances from the proposed rule. EPA received one comment on the allocation, which is discussed in the following section.

EPA is also allocating methyl chloroform (MCF) for use in solid rocket motor assemblies. Today's allocation is authorized under Decision X/6 of the Parties to the Protocol, and section 604(d)(1) of the CAA. Essential-use allowance holders should be aware that the exemption for MCF under the CAA expires on December 31, 2004. After that date, EPA will not have statutory authority to allocate essential-use allowances for MCF. EPA did not receive comments on our proposed allocation for essential-use allowances for methyl chloroform.

EPA is allocating essential-use allowances for calendar year 2002 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 2002

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	343
Aventis	CFC–11 or CFC–12 or CFC–114	150
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	743
Glaxo SmithKline	CFC–11 or CFC–12 or CFC–114	660
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	949
Sidmak Laboratories Inc.	CFC–11 or CFC–12 or CFC–114	67
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	120
(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	47
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

III. Implementation of Decision XII/2 of the Parties to the Montreal Protocol

A. Eligible Products

Decision XII/2, titled ''Measures to facilitate the transition to chlorofluorocarbon-free metered dose inhalers,'' taken at the Meeting of the Parties in December 2000, has two provisions that are being implemented with today's action. Paragraph 2 of Decision XII/2 states ''that any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2000 for treatment of asthma and/or chronic obstructive pulmonary disease 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.''

In the past, EPA has allocated essential-use allowances for all CFC MDIs containing active moieties used for the treatment of asthma and COPD, without distinguishing among individual products. However, Decision XII/2 raises the bar for MDI products approved after December 31, 2000. In order for an MDI product in the research and development phase [5] to be considered essential, the individual MDI product must meet the criteria in Decision IV/25 paragraph 1(a). Decision IV/25 1(a) states that ''use of a controlled substance should qualify as essential only if it is necessary for the health, safety or critical for the functioning of society (encompassing cultural and intellectual aspects); and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.'' Based on Decision XII/2, EPA after consultation with FDA, has determined that CFC MDI products are no longer essential if they are still in research and development and contain active moieties already commercially available in other MDI products. This is because the new MDI products would not provide additional therapy to patients, and are not themselves necessary for the health, safety or functioning of society as specified by paragraph 1(a) of Decision IV/25. Therefore, EPA is allocating essential-use allowances to companies only for production of CFC MDIs for the treatment of asthma and COPD that were approved by FDA prior to December 31, 2000. EPA is also amending the language at 40 CFR 82.4(t)(1)(i) to state that EPA is only allocating essential-use allowances for MDI products approved by FDA before January 1, 2000. It is possible that EPA, after consultation with FDA, could allocate essential-use allowances for research and development of novel drug therapies that meet the criteria of paragraph 1(a) of Decision IV/25.

[3] The term ''medical device'' is defined in section 601(8) of the Clean Air Act. 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).

[4] For a detailed discussion of how FDA and EPA determined the amount of CFCs necessary for 2002 please refer to the proposed rule (66 FR 55145).

[5] EPA is unaware of any CFC MDI product that has been approved by the FDA since December 31, 2000.

EPA recieved two comments regarding our decision to not allocate essential-use allowances for CFC MDI products that are still in the research and development phase. The first commenter supported EPA's implementation of Decision XII/2 noting that under section 614 of the Clean Air Act, EPA must fully implement provisions of the Montreal Protocol, and that under section 604(d)(2), EPA may allocate essential-use allowances only ''to the extent such action is consistent with the Montreal Protocol.'' This commenter also states that implementation of Decision XII/2 is a good policy decision, because manufacture of MDI products approved after December 31, 2000 would send the wrong message to patients, physicians and manufacturers, encourage companies to begin development of new CFC MDI products, and impede companies' efforts to transition patients to CFC-free alternatives. Finally, the commenter states that any backsliding on the U.S. international commitments to the CFC phase-out could jeopardize future essential-use allowances for U.S. manufacturers.

The second commenter states that EPA's proposal to not allocate CFC allowances for MDI products approved by the FDA after December 31, 2000 prevents the development of less costly generic versions of presently available CFC MDIs. The commenter also states that approval of the proposal would not result in a decrease in CFC production and use in the U.S. since the reported use of CFCs for exempted MDIs has remained relatively constant each year even after the introduction of generic versions of albuterol MDIs.[6] Finally, the commenter states that the CFC phase-out in MDIs should be done over a known time period with adequate notice given to all interested parties, and that EPA's proposal to no longer consider MDI products in the research and development phase, or those approved after December 31, 2000 amounts to promulgating a regulation with retroactive effect.

As noted by the first commenter, EPA is obligated by section 614 of the CAA to fully implement decisions of the Montreal Protocol, except where the CAA contains more stringent, conflicting provisions. In addition, under section 604(d)(2), EPA is to authorize production of CFCs for use in medical devices only ''to the extent such action is consistent with the Montreal Protocol.'' If EPA were to continue to allocate essential-use allowances for MDIs that are no longer considered essential, the U.S. would be in violation of the Montreal Protocol. The effect of this would be to jeopardize not only the U.S. ability to obtain sufficient essential-use allowances of CFCs for life-saving MDIs from the Parties, but could also could weaken the Protocol as a whole. EPA and the Parties to the Protocol have made clear over the years that essential-use allowances for CFCs for MDIs are not meant to be permanent, and that when adequate alternatives are available for patients that need them, EPA will no longer allocate essential-use allowances for the MDIs. Decision XII/2, was taken by the international community and supported by a broad range of patient and physician groups[7] who were concerned that the U.S. engage in a transition that provides predictability and assurance to patients and their healthcare providers. EPA believes that introduction of new products that do not meet the criteria of paragraph 1(a) of Decision IV/25 would complicate the overall transition by giving a false impression to patients and physicians that there is no need to transition to CFC-free formulations.

Finally, EPA notes that although the cut-off date for approval of CFC MDIs is in the past, it does not mean that this regulation is retroactive. EPA is not attaching any new legal consequence to any past action of the commenter. Nor is EPA depriving the commenter of something to which it had previously been entitled. Production and import of CFCs have been prohibited since January 1, 1996, and exemptions are granted according to the criteria agreed to by the Parties to the Protocol and consistent with the provisions of the CAA.

B. Transfers of Essential-use Allowances and ''Essential-use CFCs''

With today's final rule, EPA is implementing paragraph 8 of Decision XII/2 which states that ''* * * as a means of avoiding unnecessary production of new chlorofluorocarbons, and provided that the conditions set out in paragraphs (a)–(d) of Decision IX/20 are met, a Party may allow a MDI company to transfer: (a) All or part of its essential-use authorization to another existing MDI company; or (b) CFCs to another MDI company provided that the transfer complies with national/regional license or other authorization requirements.''

Paragraphs (a)–(d) of Decision IX/20 provide the following conditions for transfers between Parties: the transfer applies only up to the maximum level that has previously been authorized for the calendar year in which the next Meeting of the Parties is to be held; both Parties agree to the transfer; the aggregate annual level of authorizations for all Parties for essential-uses of MDIs does not increase as a result of the transfer; the transfer or receipt is reported by each Party involved on the essential-use quantity-accounting format approved by the Eighth Meeting of the Parties by paragraph 9 of Decision VIII/9.

EPA is implementing Decision XII/2 by finalizing a mechanism to allow metered dose inhaler companies to transfer essential-use allowances internationally and to allow transfer of essential-use allowances to companies that do not currently hold essential-use allowances from the U.S. To accomplish this, EPA is amending the regulations in the following manner:

1. Amending the language at 82.12(a)(1) to allow essential-use allowances for CFCs to be transferred to another MDI company, and not just to another essential-use allowance holder. This will allow an MDI company that currently does not have essential-use allowances to receive them through a trade provided that the allowances are used to produce essential MDIs.

2. Adding paragraphs 82.9(c)(1)(viii) and 82.12(a)(1)(i)(I) so that the transferee engaged in a transfer of essential-use allowances must identify the specific CFC MDI products to be manufactured using the essential-use allowances. This will enable EPA to confirm that these products are in fact ''essential''.

3. Adding essential-use allowances to the list of allowances that may be traded internationally under paragraph 82.9(c). The international transfer of essential-use allowances would occur in the same manner as international transfers of Article 5 allowances and production allowances that are currently traded, which would ensure compliance with section 616 of the CAA governing international trades. After receiving a transfer request, the Administrator can, at her discretion, consider the following factors in deciding whether to approve a transfer:

[6] Albuterol MDIs are the only CFC MDI product where generic versions have been developed.

[7] The following patient and physician groups sent a letter dated July 7, 2000 to the Department of State, The Environmental Protection Agency, and the Food and Drug Administration supporting the ''Draft Decision by the European Community on MDIs'' which was subsequently titled Decision XII/2 after adoption by the Parties in December 2000: The American Lung Association; American Academy of Allergy, Asthma and Immunology; American Academy of Pediatrics; American Association for Respiratory Care; American College of Allergy; Asthma and Immunology; American Thoracic Society; Asthma and Allergy Foundation of America; and the Joint Council on Allergy, Asthma and Immunology.

• Possible creation of economic hardship;
• Possible effects on trade;
• Potential environmental implications;
• The total amount of unexpended allowances held by United States entities;
• Whether the essential-use allowances will be used in metered dose inhalers considered essential by the Parties.

One commenter stated that two of these discretionary criteria; possible creation of economic hardship, and possible effects on trade, are not relevant to essential-use allowance transfers where volumes are likely to be minimal relative to economic activity and international trade. EPA does not agree with this comment. The Agency believes that it is important to ensure that the U.S. continues to be supplied with sufficient amounts of MDIs for patients with asthma and chronic obstructive pulmonary disease. If for example, a U.S. company requested a trade of essential-use allowances to another company who would not be supplying the U.S. with MDIs, this could cause a shortage of a specific MDI in the U.S., and potential economic hardship for MDI consumers. EPA believes that it is important to retain the right to deny a transfer of essential-use allowances if the transfer would result in a shortage of MDIs for the U.S. patients.

This commenter also states that although they generally support the specific parameters proposed by EPA for implementing transfers, they are concerned that Decision XII/2's transfer provisions not override other standards set under Protocol decisions relating to the essential-use process. The commenter suggests that companies receiving essential-use allowances through a transfer should be required to submit a complete essential-use application (based on the 2001 TEAP Handbook on Essential-use Nominations) in order to demonstrate that the requirements set forth in Decisions VII/10 and Decision IV/25 paragraph 1(b) are met.

EPA believes that requiring companies to submit a complete essential-use application as part of their transfer request would place an unnecessary burden on regulated entities. EPA notes that Decision VIII/10 states that ''Parties not operating under Article 5 will request companies applying for MDI essential-use exemptions to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts * * *''. While EPA does solicit this information from companies in their essential-use application packages, the use of the word ''request'' in Decision VIII/10 does not provide EPA with authority to deny an essential-use allowance request based on whether a company is involved in research and development of CFC-free alternatives or education alone. In fact, the information on research and development and education that EPA gathers as a part of the essential-use application process is used primarily to gauge progress of the U.S. transition, and has never been used to deny essential-use allowances for any company. Thus, EPA believes it would be inappropriate to require an essential-use application from companies to ensure that they are engaged in research and development and/or education since EPA cannot use this information as a basis for denying a transfer request. EPA could however, deny a transfer request based on whether the transferred allowances are to be used for essential MDIs. Therefore, with this final action EPA is amending the proposal by adding paragraphs 82.9(c)(1)(viii) and 82.12(a)(1)(i)(I) which require MDI companies engaged in a transfer of essential-use allowances to identify the specific CFC MDIs to be produced so that EPA can confirm that these products are ''essential''. This provision only applies if the transferee is a U.S. entity.

EPA believes that the scarcity and potentially high cost of transferred essential-use allowances provides adequate financial incentives for manufacturers to minimize fugitive emissions to ensure that ''all economically feasible steps have been taken to minimize the essential-use and any associated emission of the controlled substance'' as required by paragraph 1(b)(i) of Decision IV/25. Therefore, EPA does not believe that it is necessary to require companies to submit an essential-use application stating how emissions are reduced in their particular manufacturing plant. Finally, EPA believes that paragraph 1(b)(ii) is not relevant to transfers of essential-use allowances.

Today, EPA is also instituting a mechanism to allow MDI companies to transfer CFCs already produced under the authority of essential-use allowances to other MDI companies, as specified by paragraph 8 of Decision XII/2, by finalizing the following changes to the regulations:

1. Amending section 82.3 to define the term ''essential-use CFC.'' EPA proposed to define this term to mean ''the CFCs . . . produced under the authority of essential-use allowances and not the allowances themselves. Essential-use CFCs include CFCs imported or produced by U.S. entities under the authority of essential-use allowances for use in metered dose inhalers, as well as CFCs imported or produced by non-U.S. entities under the authority of privileges granted by the Parties and the national authority of another country for use in metered dose inhalers.'' EPA received one comment stating that this definition might be clarified if the word ''essential'' were inserted in front of the phrase ''metered dose inhalers''. EPA agrees and has made the appropriate changes to the regulatory text.

2. Modifying the parenthetical in paragraph 82.4(d) so that import of ''essential-use CFCs'' will no longer count against the U.S. MDI company's essential-use allowances for that year. This allows an MDI company to procure ''essential-use CFCs'' beyond the amount of essential-use allowances allocated to them in a particular control period if the transfer is approved by EPA.

3. Defining the term ''essential MDIs'' in § 82.3. EPA received one comment stating that the proposed definition would be clearer if the second sentence in the definition began with ''in addition''. EPA agrees and has incorporated this into the final definition which reads as follows, ''MDIs for the treatment of asthma and chronic obstructive pulmonary disease, approved by the FDA or by another Party's analogous health authority before December 31, 2000, and considered to be essential by the Party where the MDI product will eventually be sold. In addition, if the MDI product is to be sold in the U.S., the active moiety contained in the MDI must be listed as essential at 21 CFR 2.125(e).''

4. Adding paragraph (d) to the regulations at § 82.12 to create the mechanism that EPA will use to approve transfers of essential-use CFCs between MDI companies in the U.S., and adding paragraph (g) to § 82.9 to govern transfer of essential-use CFCs between U.S. companies and companies in other Parties.

5. Revising definition of ''essential-use allowances'' under § 82.3 by omitting the specific end date to the essential-use program. For a full discussion of the transfer mechanism for essential-use CFCs please refer to the proposed rule (66 FR 55145).

IV. General Laboratory Exemption for Class I ODSs.

Under Decision X/19, the Parties approved a global (i.e., general)

exemption for laboratory and analytical uses until December 31, 2005, under the conditions set out in Annex II of the report of the Sixth Meeting of the Parties. Decision X/19 also states that at the annual Meetings of the Parties, on the basis of information reported by the Technology and Economic Assessment Panel (TEAP), the Parties may ''decide on any uses of controlled substances which should no longer be eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply.'' Subsequently, the Parties at the Eleventh Meeting of the Parties to the Protocol took Decision XI/15 which eliminated the following uses from the global exemption for laboratory and analytical uses for controlled substances from the year 2002 onward:

(a) Testing of oil and grease, and total petroleum hydrocarbons in water;

(b) Testing of tar in road-paving materials; and

(c) Forensic finger-printing.

Today's final rule extends EPA's regulatory *de minimis* exemption for essential laboratory and analytical uses through calendar year 2005, and amends part 82, subpart A, appendix G to define the above laboratory methods as non-essential pursuant to Decision XI/15. With this change to appendix G, production or import of class I ODSs for use in the laboratory methods listed above will be prohibited beginning January 1, 2002. Class I ODSs imported or manufactured prior to January 1, 2002, may continue to be used in the laboratory methods listed above. This final rule is unchanged from the proposal regarding laboratory essential-use allowances.

Please note that EPA requires testing for oil and grease, and total petroleum hydrocarbons as a part of its wastewater and hazardous waste programs. The analytical methods for measuring ''oil and grease'' include EPA methods 413.1, 413.2 and 418.1, which use CFC–113, and method 1664A, which uses n-hexane [8]. EPA received two comments from environmental testing laboratories stating that CFC–113 should continue to be allowed for EPA test methods 413.1, 413.2, and 418.1 as long as the CFC–113 was imported or manufactured before January 1, 2002. These commenters are correct. Laboratories may continue to use stockpiled CFC–113 that was imported or produced before January 1, 2002 or recycled CFC–113 as long as EPA's Office of Water and Office of Solid Waste continue to accept results from test methods using CFC–113.

Another commenter stated that EPA's Office of Solid Waste or Office of Water should not ever be allowed to discontinue the use of CFC–113 in testing of oil and grease in water, stating that changing to the hexane method is costly, flammable, and a known health hazard that is putting undue burden on laboratories. EPA's Office of Water addressed health, safety, and cost concerns in responses to comments at promulgation of EPA Method 1664A on May 14, 1999 (see 64 FR 26320). EPA believes that the n-hexane method is a viable and effective method for testing oil and grease in water, and suggests that laboratories consider transitioning to this method in the near term since beginning January 1, 2002, there will be a finite amount of CFC–113 available for testing of oil and grease and total petroleum hydrocarbons. If laboratories are not prepared to utilize the n-hexane method and CFC–113 becomes scarce, regulated entities may face being out of compliance with waste water permits. There is also a possibility that in the future the Office of Water and/or the Office of Solid Waste may remove test methods that use CFC–113 for testing of oil and grease and total petroleum hydrocarbon from their list of approved methods. Any action on this issue would be done through notice and comment rulemaking.

For more information on the laboratory exemption and testing of oil and grease and total petroleum hydrocarbons please visit our website at *www.epa.gov/ozone/mdi.*

V. Clarification Regarding Use of Material Produced Under Essential-Use Allowances for Non-Essential Uses

EPA is adding paragraph (t)(4) to § 82.4 in order to clarify that unused class I ODSs produced under the authority of essential-use allowances may not be used in applications that are not essential (i.e. those uses not listed in paragraph 82.4 (t)(1)). The regulations at § 82.4 establish limited exceptions to the production and import bans for class I ODS. The use or sale of unused class I ODS produced under these exceptions for other purposes would circumvent the production and import bans and the intent of these exceptions. We are concerned that laboratories might obtain class I ODSs in excess of their own need under the laboratory exemption with the intent of ''recycling'' the class I ODS and re-selling it into other non-laboratory markets at a profit. Therefore, we explicitly prohibit such actions in § 82.4(t)(4) by stating that ''It is a violation of this subpart to obtain unused class I ODSs under the exemption for laboratory and analytical uses in excess of actual need, and to recycle that material for sale into other markets.''

The intent of this provision is not to disallow laboratories from purchasing sufficient class I ODSs for their own use, nor is it meant to discourage laboratories from re-using or recycling class I ODSs that are legitimately used for essential laboratory methods. It is meant to discourage those that might exploit a potential loophole and purchase quantities of ODSs far in excess of what would normally be necessary for laboratory uses, nominally ''use'' the class I ODS, and then ''recycle'' the material and sell it for use in non-laboratory applications. The prohibition at § 82.4(t)(4) does not apply to companies that extract and recycle CFCs from MDIs that are not marketable since the CFCs have been introduced into a product and thus, are no longer considered unused ozone depleting material.

EPA received one comment which strongly supports EPA's amendments to § 82.4, stating that these amendments will ensure consistency with the transfer provisions and help to prevent circumvention of the essential-use exemption.

VI. Effective Date for This Final Rule

This final rule is effective on February 11, 2002. 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) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption to the phase-out of production and consumption of CFCs, EPA is making this action effective immediately to ensure continued availability of CFCs for medical devices and class I ODSs for essential laboratory and analytical methods.

[8] On May 14, 1999, EPA published alternative analytical methods for these tests that do not require using class I ODSs: Method 1664 Revision A: N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated—Hexane Extractable Material (SGR–HEM; Nonpolar Material) by Extraction and Gravimetry. EPA promulgated method 9071B to replace method 9070 and incorporates Method 1664 for use in EPA's Resource Conservation and Recovery Act programs. For more information on method 1664, please reference EPA's Office of Water website at *www.epa.gov/ost/methods/oil.html.* For technical information regarding Resource Conservation and Recovery Act test methods and regulations please call the Office of Solid Waste Methods information and communication exchange at (703) 821–4690. For technical information regarding testing methods required under the Clean Water Act, call the office of Water Resource Center at (202) 260–7786.

VII. 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 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.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This rule imposes no enforceable duty on any State, local or tribal government. For the private sector, it clarifies existing requirements and adds recordkeeping and reporting requirements for those who wish to participate in a voluntary program. Thus, 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 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 by OMB and EPA that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

C. Paperwork Reduction Act (PRA)

The information collection requirements in this rule will be submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 2051.01) and a copy may be obtained from Sandy Farmer, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by calling (202) 260–2740. The information requirements are not effective until OMB approves them.

The information required in today's final rule, and will be outlined in the ICR is mandatory under section 603(b) of the CAA which states that all production, import, and export of class I and class II ODSs must be reported to EPA. EPA is requesting information from transferors and transferees of essential-use CFCs to ensure the conditions of Decision XII/2 and section 604(d) of the Act are met, so that only essential MDI products will be produced using essential-use CFCs. The information collected will be considered confidential, and will only be released in the aggregate to protect individual company information.

The estimated burden will be set forth in the ICR. We do not expect this cost and burden to be substantial since similar reporting requirements for transferring production, consumption, and essential-use allowances are already in place under subpart A. Further, there are only a small number of MDI companies that are able to produce CFC-MDIs in the U.S. Thus, the number of companies engaged in transferring essential-use CFC will be small as well. If EPA receives adverse comment on the ICR, we would change the information collection requirement in the year 2003 allocation rule to be published later in 2002.

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 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 final 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 or make use of the general exemption for laboratory uses. Thus, Executive Order 13175 does not apply to this rule.

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.

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; and environmental testing services (NAICS code 541380) that have annual receipts of less than $5 million dollars (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 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. Based on comments received from the one pharmaceutical company that is not receiving essential-use allowances for use in CFC MDIs, EPA has determined that this company will experience an economic impact. The direct impact of this rule is that this company will be unable to import or produce CFCs for research and development of CFC MDIs that contain active moieties already available to the public. However, the economic impact is not quantifiable since this company does not have MDI products that are approved by the FDA and can be sold in the U.S. This company has participated in the essential-use allowance process since the original phaseout of class I ODS in 1996, and is aware that the U.S. as a Party to the Montreal Protocol is bound to complete the transition to CFC-free MDIs.

Environmental testing labs are affected by this rule since beginning January 1, 2002, newly imported or produced CFC–113 cannot be used in the testing of oil and grease, and total petroleum hydrocarbons in water. EPA believes that because there is an alternative non-CFC method available, and that stockpiled and recycled CFC–113 can continue to be used for this testing if necessary, that there is no economic impact on small environmental testing laboratories. EPA did not receive any comments indicating that there would be significant economic impacts on any environmental testing laboratories as a result of this action.

Although this final rule will not have significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact on small entities. In the case of environmental testing laboratories, EPA is minimizing the reporting requirements associated with this rule by simply amending the yearly certification already required of them under existing regulations. In this case of the one pharmaceutical company that is not receiving essential-use allowances for CFCs, we believe that there is no way to reduce the impact on this small business while still complying with Decision XII/2 of the Montreal Protocol.

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 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.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in the 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.

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 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. With today's action EPA is establishing that the use of CFC–113 for testing of oil and grease is no longer considered ''essential'' as consistent with Decision XI/15 of the Parties to the Montreal Protocol. Thus, import and production of CFCs for this use will be prohibited beginning January 1, 2002. EPA believes that this will not substantially affect local and state government implementation of the Clean Water Act since stockpiles of CFC–113 produced or imported prior to the year 2002, and recycled material can continue to be used for these methods. Further, alternative methods that do not use ODSs are available. Thus, Executive Order 13132 does not apply to this rule.

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.

VIII. 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 the judicial proceedings brought to enforce those requirements.

IX. Submittal 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. 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 February 11, 2002.

List of Subjects in 40 CFR Part 82

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

Dated: February 1, 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 82.3 is amended by adding new definitions in alphabetical order for ''Essential-use chlorofluorocarbons (Essential CFCs)'', and ''Essential metered dose inhaler (Essential MDI)'', and revising the definition of ''Essential-use allowances'' to read as follows:

§ 82.3 Definitions.

* * * * *

Essential Metered Dose Inhaler (Essential MDI) means metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease, approved by the Food and Drug Administration or by another Party's analogous health authority before December 31, 2000, and considered to be essential by the Party where the MDI product will eventually be sold. In addition, if the MDI product is to be sold in the U.S., the active moiety contained in the MDI must be listed as essential at 21 CFR 2.125(e).

Essential-Use Allowances means the privileges granted by § 82.4(t) to produce class I substances, as determined by allocation decisions made by the Parties to the Montreal Protocol and in accordance with the restrictions delineated in the Clean Air Act Amendments of 1990.

Essential-Use Chlorofluorocarbons (Essential-use CFCs) are the CFCs (CFC–11, CFC–12, or CFC–114) produced under the authority of essential-use allowances and not the allowances themselves. Essential-use CFCs include CFCs imported or produced by U.S. entities under the authority of essential-use allowances for use in essential metered dose inhalers, as well as CFCs imported or produced by non-U.S. entities under the authority of privileges granted by the Parties and the national authority of another country for use in essential metered dose inhalers.

* * * * *

3. Section 82.4 is amended:

a. By revising paragraph (d).

b. By revising paragraph (k).

c. By revising paragraphs (t) introductory text, (t)(1)(i), and (t)(3).

d. By adding the table to the end of paragraph (t)(2).

e. By adding paragraphs (t)(1)(iii) and (t)(4).

The revisions and additions read as follows:

§ 82.4 Prohibitions.

* * * * *

(d) Effective January 1, 1996, for any class I , Group I, Group II, Group III, Group IV, Group V, or Group VII controlled substances, and effective January 1, 2005, for any class I, Group VI controlled substances, no person may import (except for transhipments or heels), at any time in any control period (except for controlled substances that are transformed or destroyed, or transfers of essential-use CFCs) in excess of the amount of unexpended essential-use allowances or exemptions as allocated under this section, or the amount of unexpended destruction and transformation credits obtained under § 82.9 held by that person under the authority of this subpart at that time for that control period. Every kilogram of excess importation (other than transhipments or heels) constitutes a separate violation of this subpart. It is a violation of this subpart to obtain unused class I ODSs under the general laboratory exemption in excess of actual need and to recycle that material for sale into other markets.

* * * * *

(k) Prior to January 1, 1996, for all Groups of class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, a person may not use production allowances to produce a quantity of a class I controlled substance unless that person holds under the authority of this subpart at the same time consumption allowances sufficient to cover that quantity of class I controlled substances nor may a person use consumption allowances to produce a quantity of class I controlled substances unless the person holds under authority of this subpart at the same time production allowances sufficient to cover that quantity of class I controlled substances. However, prior to January 1, 1996, for all class I controlled substances, and prior to January 1, 2005 for class I, Group VI controlled substances, only

consumption allowances are required to import, with the exception of transhipments, heels and used controlled substances. Effective January 1, 1996, for all Groups of class I controlled substances, except Group VI, only essential-use allowances or exemptions are required to import class I controlled substances, with the exception of transhipments, heels, used controlled substances, and essential-use CFCs.

* * * * *

(t) Effective January 1, 1996, essential-use allowances are apportioned to a person under paragraphs (t)(2) and (t)(3) of this section for the exempted production or importation of specified class I controlled substances solely for the purposes listed in paragraphs (t)(1)(i) through (iii) of this section.

(1) * * *

(i) Metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary disease that were approved by the Food and Drug Administration before December 31, 2000.

(ii) * * *

(iii) Essential Laboratory and Analytical Uses (Defined at appendix G of this subpart).

(2) * * *

TABLE I.—ESSENTIAL-USE ALLOCATION FOR CALENDAR YEAR 2002

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	343
Aventis	CFC–11 or, CFC–12 or, CFC–114	150
Boehringer Ingelheim Pharmaceuticals	CFC–11 or, CFC–12 or, CFC–114	743
Glaxo SmithKline	CFC–11 or, CFC–12 or, CFC–114	660
Schering-Plough Corporation	CFC–11 or, CFC–12 or, CFC–114	949
Sidmak Laboratories Inc.	CFC–11 or, CFC–12 or, CFC–114	67
3M Pharmaceuticals	CFC–11 or, CFC–12 or, CFC–114	120
(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	47
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

(3) A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2005 subject to the restrictions in appendix G of this subpart, and subject to the record keeping and reporting requirements at § 82.13(u) through (z). There is no amount specified for this exemption.

(4) Any person acquiring unused class I ODSs produced under the authority of essential-use allowances or the essential-use exemption in paragraph (t)(3) of this section for use in anything other than an essential-use (i.e. for uses other than those specifically listed in paragraph (t)(1) of this section) is in violation of this subpart. Each kilogram of unused class I ODS produced or imported under the authority of essential-use allowances or the essential-use exemption and used for a non-essential-use is a separate violation of this subpart. Any person selling unused class I material produced or imported under the authority of essential-use allowances or the essential-use exemption for uses other than an essential-use is in violation of this subpart. Each kilogram of unused class I ODS produced under the authority of essential-use allowances or the essential-use exemption and sold for a use other than an essential-use is a separate violation of this subpart. It is a violation of this subpart to obtain unused class I ODSs under the exemption for laboratory and analytical uses in excess of actual need and to recycle that material for sale into other markets.

* * * * *

4. Section 82.9 is amended:

a. By revising the section heading.

b. By revising paragraphs (c) introductory text, (c)(1) introductory text, (c)(1)(iv), (c)(2)(iv), (c)(3)(iv) and (c)(4).

c. By adding paragraphs (c)(1)(vii), (c)(3)(v) and (g).

The revisions and additions read as follows:

§ 82.9 Availability of allowances in addition to baseline production allowances for class I ozone depleting substances—International transfers of production allowances, Article 5 allowances, essential-use allowances, and essential-use CFCs.

* * * * *

(c) A company may increase or decrease its production allowances, its Article 5 allowances by trading with another Party to the Protocol according to the provision under this paragraph (c). A company may increase or decrease its essential-use allowances for CFCs for use in essential MDIs according to the provisions under this paragraph (c). A nation listed in appendix C to this subpart (Parties to the Montreal Protocol) must agree either to transfer to the person for the current control period some amount of production or import that the nation is permitted under the Montreal Protocol or to receive from the person for the current control period some amount of production or import that the person is permitted under this subpart. If the controlled substance is produced under the authority of production allowances and is to be returned to the Party from whom production allowances are received, the request for production allowances shall also be considered a request for consumption allowances under § 82.10(c). If the controlled substance is produced under the authority of production allowances and is to be sold in the United States or to another Party (not the Party from whom the allowances are received), the U.S. company must expend its consumption allowances allocated under § 82.6 and § 82.7 in order to produce with the additional production allowances.

(1) For trades from a Party, the person must obtain from the principal diplomatic representative in that nation's embassy in the United States a signed document stating that the appropriate authority within that nation has established or revised production limits or essential-use allowance limits for the nation to equal the lesser of the maximum production that the nation is allowed under the Protocol minus the amount transferred, the maximum

production or essential-use allowances that are allowed under the nation's applicable domestic law minus the amount transferred, or the average of the nation's actual national production level for the three years prior to the transfer minus the production transferred. The person must submit to the Administrator a transfer request that includes a true copy of this document and that sets forth the following:

* * * * *

(iv) The chemical type, type of allowance being transferred, and the level of allowances being transferred;

* * * * *

(vii) In the case of transferring essential-use allowances, the transferor must include a signed document from the transferee identifying the CFC MDI products that will be produced using the essential-use allowances.

(2) * * *

(iv) The chemical type, type of allowance being transferred, and the level of allowances being transferred; and

(3) * * *

(iv) The total amount of unexpended production or essential-use allowances held by a U.S. entity.

(v) In the case of transfer of essential-use allowances the Administrator may consider whether the CFCs will be used for production of essential MDIs.

* * * * *

(4) The Administrator will issue the person a notice either granting or deducting production allowances, Article 5 allowances, or essential-use allowances, and specifying the control period to which the transfer applies, provided that the request meets the requirement of paragraph (c)(1) of this sections for trades from Parties and paragraph (c)(2) of this section for trades to Parties, unless the Administrator has decided to disapprove the trade under paragraph (c)(3) of this section. For a trade from a Party, the Administrator will issue a notice that revises the allowances held by the person to equal the unexpended production, Article 5, or essential-use allowances held by the person under this subpart plus the level of allowable production transferred from the Party. For a trade to a Party, the Administrator will issue a notice that revises the production limit for the person to equal the lesser of:

(i) The unexpended production allowances, essential-use allowances, or Article 5 allowances held by the person under this subpart minus the amount transferred; or

(ii) The unexpended production allowances, essential-use allowances, or Article 5 allowances held by the person under this subpart minus the amount by which the United States average annual production of the controlled substance being traded for the three years prior to the transfer is less than the total production allowable for that substance under this subpart minus the amount transferred. The change in allowances will be effective on the date that the notice is issued.

* * * * *

(g) *International transfer of essential-use CFCs.* (1) For trades of essential-use CFCs where the transferee or the transferor is a person in another nation (Party), the persons involved in the transfer must submit the information requested in § 82.12(d)(2) and (d)(3), along with a signed document from the principal diplomatic representative in the Party's embassy in the United States stating that the appropriate authority within that nation has approved the transfer of the essential-use CFCs.

(2) If the transfer claim is complete, and EPA does not object to the transfer, then EPA will issue letters to the transferor and the transferee indicating that the transfer may proceed. EPA reserves the right to disallow a transfer if the transfer request is incomplete, or if it has reason to believe that the transferee plans to produce MDIs that are not essential MDIs. If EPA objects to the transfer, EPA will issue letters to the transferor and transferee stating the basis for disallowing the transfer. The burden of proof is placed on the transferee to retain sufficient records to prove that the transferred essential-use CFCs are used only for production of essential MDIs. If EPA ultimately finds that the transferee did not use the essential-use CFCs for production of essential MDIs then the transferee is in violation of this subpart.

* * * * *

5. Section 82.12 is amended by

a. Revising the section heading.

b. Revising paragraph (a)(1) introductory text.

c. Adding paragraphs (a)(1)(i)(I) and (d).

The revisions and additions read as follows:

§ 82.12 Domestic transfers for class I controlled substances.

(a) * * *

(1) Until January 1, 1996, for all class I controlled substances, except for Group VI, and until January 1, 2005, for Group VI, any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's consumption allowances or production allowances, and effective January 1, 1995, for all class I controlled substances any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's Article 5 allowances. After January 1, 2002 any essential-use allowance holder (including those persons that hold essential-use allowances issued by a Party other than the United States) (''transferor'') may transfer essential-use allowances for CFCs to a metered dose inhaler company solely for the manufacture of essential MDIs.

(i) * * *

(I) The transferor must include a signed document from the transferee identifying the CFC MDI products that will be produced using the essential-use allowances.

* * * * *

(d) *Transfers of essential-use CFCs.* (1) Effective January 1, 2002, any metered dose inhaler company (transferor) may transfer essential-use CFCs to another metered dose inhaler company (transferee) provided that the Administrator approves the transfer.

(2) The transferee must submit a transfer claim to the Administrator for approval before the transfer can take place. The transfer claim must set forth the following:

(i) The identities and addresses of the transferor and the transferee; and

(ii) The name and telephone numbers of contact persons for the transferor and the transferee; and

(iii) The amount of each controlled substance (CFC–11, CFC–12, or CFC–114) being transferred; and

(iv) The specific metered dose inhaler products (i.e. the MDI drug product or active moiety) that the transferee plans to produce with the transferred CFCs; and

(v) The country(ies) where the CFC metered dose inhalers produced with the transferred essential-use CFCs will be sold if other than in the United States; and

(vi) Certification that the essential-use CFCs will be used in the production of essential MDIs. If the MDIs are to be sold in the United States, the certification must state that MDIs produced with the transferred essential-use CFCs are listed as essential at 21 CFR 2.125, and were approved by the Food and Drug Administration before December 31, 2000. If the MDIs produced with the essential-use CFCs are to be sold outside the United States, the transferee must certify that the metered dose inhalers produced with the essential-use CFCs are considered essential by the importing country.

(3) The transferor must submit a letter stating that it concurs with the terms of

the transfer as requested by the transferee.

(4) Once the transfer claim is complete, and if EPA does not object to the transfer, then EPA will issue letters to the transferor and the transferee within 10 business days indicating that the transfer may proceed. EPA reserves the right to disallow a transfer if the transfer request is incomplete, or if it has reason to believe that the transferee plans use the essential-use CFCs in anything other than essential MDIs. If EPA objects to the transfer, within EPA will issue letters to the transferor and transferee stating the basis for disallowing the transfer. The burden of proof is placed on the transferee to retain sufficient records to prove that the transferred essential-use CFCs are used only for production of essential MDIs. If EPA ultimately finds that the transferee did not use the essential-use CFCs for production of essential MDIs then the transferee is in violation of this subpart.

* * * * *

6. Section 82.13 is amended:

a. By revising paragraphs (f)(2)(xv) and (f)(3)(xii).

b. By revising paragraphs (g)(1)(xvi) and (g)(4)(xiii).

c. By revising paragraph (u).

d. By revising paragraph (v).

e. By revising paragraph (y) introductory text.

The revisions read as follows:

§ 82.13 Recordkeeping and reporting requirements.

* * * * *

(f) * * *

(2) * * *

(xv) Written certifications that quantities of controlled substances, meeting the purity criteria in appendix G of this subpart, were purchased by distributors of laboratory supplies or by laboratory customers to be used only in essential laboratory and analytical uses as defined by appendix G, and not to be resold or used in manufacturing.

* * * * *

(3) * * *

(xii) In the case of laboratory essential-uses, certifications from distributors of laboratory supplies that controlled substances were purchased for sale to laboratory customers who certify that the substances will only be used for essential laboratory and analytical uses as defined by appendix G of this subpart, and will not be resold or used in manufacturing; or, if sales are made directly to laboratories, certification from laboratories that the controlled substances will only be used for essential laboratory and analytical uses (defined at appendix G of this subpart) and will not be resold or used in manufacturing.

* * * * *

(g) * * *

(1) * * *

(xvi) Copies of certifications that imported controlled substances are being purchased for essential laboratory and analytical uses (defined at appendix G of this subpart) or being purchased for eventual sale to laboratories that certify that controlled substances are for essential laboratory and analytical uses (defined at appendix G of this subpart).

* * * * *

(4) * * *

(xiii) The certifications from essential-use allowance holders stating that the controlled substances were purchased solely for specified essential-uses and will not be resold or used in manufacturing; and the certifications from distributors of laboratory supplies that the controlled substances were purchased solely for eventual sale to laboratories that certify the controlled substances are for essential laboratory and analytical uses (defined at appendix G of this subpart), or if sales are made directly to laboratories, certifications from laboratories that the controlled substances will only be used for essential laboratory and analytical uses (defined at appendix G of this subpart) and will not be resold or used in manufacturing.

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(u) Any person allocated essential-use allowances who submits an order to a producer or importer for a controlled substance must report the quarterly quantity received from each producer or importer.

(v) Any distributor of laboratory supplies receiving controlled substances under the global laboratory essential-use exemption for sale to laboratory customers must report quarterly the quantity received of each controlled substance from each producer or importer.

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(y) A laboratory customer purchasing a controlled substance under the global laboratory essential-use exemption must provide the producer, importer or distributor with a one-time-per-year certification for each controlled substance that the substance will only be used for essential laboratory and analytical uses (defined at appendix G of this subpart) and not be resold or used in manufacturing. The certification must also include:

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7. The heading and paragraph 1 of appendix G to subpart A is revised to read as follows:

Appendix G to Subpart A of Part 82—UNEP Recommendations for Conditions Applied to Exemption for Essential Laboratory and Analytical Uses

1. Essential laboratory and analytical uses are identified at this time to include equipment calibration; use as extraction solvents, diluents, or carriers for chemical analysis; biochemical research; inert solvents for chemical reactions, as a carrier or laboratory chemical and other critical analytical and laboratory purposes. Pursuant to Decision XI/15 of the Parties to the Montreal Protocol, effective January 1, 2002 the following uses of class I controlled substances are not considered essential under the global laboratory exemption:

a. Testing of oil and grease and total petroleum hydrocarbons in water;

b. Testing of tar in road-paving materials; and

c. Forensic finger printing.

Production for essential laboratory and analytical purposes is authorized provided that these laboratory and analytical chemicals shall contain only controlled substances manufactured to the following purities:

CTC (reagent grade)—99.5
1,1,1,-trichloroethane—99.5
CFC–11—99.5
CFC–13—99.5
CFC–12—99.5
CFC–113—99.5
CFC–114—99.5
Other w/ Boiling P>20 degrees C—99.5
Other w/ Boiling P<20 degrees C—99.0

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