ADDRESSES: Comments are to be mailed to Makeba Morris, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103 and the Allegheny County Health Department Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Linda Miller, Permits and Technical Assessment Branch at (215) 814–2068 or by e-mail at miller.linda@.epa.gov. Please note that comments on this proposed rule must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: October 17, 2001.

James W. Newsom,

Acting Regional Administrator, Region III.

[FR Doc. 01–27282 Filed 10–31–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7096–8]

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: Notice of proposed rulemaking.

SUMMARY: With this action, EPA is proposing to allocate essential-use allowances for import and production of class I stratospheric ozone depleting substances (ODSs) for calendar year 2002. Essential use allowances permit a person to obtain controlled ODSs as an exemption to the January 1, 1996 regulatory phase-out of production and import of these chemicals. EPA allocates essential-use allowances for exempted production or import of a specific quantity of class I ODS solely for the designated essential purpose. Today, EPA is proposing to allocate essential-use allowances for production and import of ODSs for use in medical devices and the Space Shuttle and Titan Rockets, and to extend the general exemption for laboratory and analytical applications through the year 2005 as consistent with the Montreal Protocol. EPA is also proposing 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 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 proposing to add a prohibition to the regulations at 82.4 that would clarify that using virgin class I ODS produced under the authority of essential-use allowances or the exemption for laboratory and analytical uses for non-essential purposes is a violation of the CAA.

DATES: Written comments on this proposed rule must be received on or before December 3, 2001, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the Stratospheric Ozone Protection Hotline listed below by 5 p.m. Eastern Standard Time on November 13, 2001. If a hearing is held, EPA will publish a document in the **Federal Register** announcing the hearing information. Inquiries regarding a public hearing should be directed to the Stratospheric Ozone Protection Hotline at 1–800–269–1996.

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

Materials relevant to this rulemaking are contained in Docket No. A–93–39. The Docket is located 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.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at 1–800–296–1996 or Erin Birgfeld, U.S. Environmental Protection Agency, Global Programs Division, Office of Atmospheric Programs, 6205J, 1200 Pennsylvania Avenue, Washington, DC 20460, 202–564–9079.

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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 class I ODSs [2] were phased out in all developed countries including the United States. However, the Protocol and the Clean Air Act (CAA or Act) provide exemptions which allow for the continued import and/or production of class I ODS for specific uses. Under the Montreal Protocol, exemptions are granted for uses that are determined by the Parties to be ''essential.'' Decision IV/25, taken by the Parties in 1992, established criteria for determining whether a specific use should be approved as essential, and set forth the international process for making determinations of essentiality. The criteria for an essential-use as set forth in paragraph 1 of Decision IV/25 are the following:

''(a) that a use of a controlled substance should qualify as ''essential'' only if:

(i) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health; (b) that production and consumption, if any, of a controlled substance for essential-uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential-use and any associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.''

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

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

II. Essential Use Allowances for Medical Devices

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

On September 15, 1999, EPA issued a **Federal Register** notice (64 FR 50083) requesting applications for essential-use allowances for the year 2002. The applications EPA received requested exemptions for the production and import of specific quantities of CFCs (CFC–11, CFC–12, and CFC–114) for use in MDIs, and provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the ''1997 Handbook on Essential Use Nominations.'' Based on the information provided in these applications, and after consultation with the Food and Drug Administration (FDA), the U.S. forwarded a request for 2,900 metric tons of CFCs for use in metered dose inhalers to the Ozone Secretariat for consideration by the Technical and Economic Assessment Panel (TEAP) and the Aerosol Technical Options Committees (ATOC). The Parties approved the U.S. request for 2,900 metric tons of CFCs for essential-uses in Decision XII/9 taken at the December 2000 Meeting of the Parties.

On November 1, 2000, EPA issued a notice in the **Federal Register** that requested applications for supplemental essential-use allowances for the year 2002. Based on the information received as a part of these applications, EPA and FDA determined that a supplemental quantity of CFCs would be necessary to provide the U.S. with sufficient CFCs for the manufacture of MDIs to meet patient needs in the year 2002. As a result, the U.S. forwarded a supplemental request of 550 metric tons of CFCs for the year 2002 to the Ozone Secretariat for consideration by the TEAP and the Aerosol Technical Options Committee (ATOC) bringing the total quantity requested to 3,450 metric tons for calendar year 2002. The ATOC reviewed the U.S. supplemental request at their meeting in April of this year, and recommended that the Parties approve the U.S. supplemental request at the meeting of the Parties to be held in October 2001.

Today's action proposes to allocate essential-use allowances assuming that the Parties approve the U.S. supplemental request of 550 metric tons of CFCs for 2002. In the event that the Parties break with the ATOC recommendation, and do not approve the supplemental request, EPA would issue a final rule, in consultation with FDA, which would allocate essential-use allowances to U.S. companies based on the total amount approved by the Parties.

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

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

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

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

[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). 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.

(B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner [of FDA] in consultation with the Administrator [of EPA].''

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

C. What Was the Allocation Process for Essential-Use Allowances for Medical Devices?

The following is a step-by-step list of actions EPA and FDA have taken thus far to implement the exemption for medical devices found at section 604(d)(2) of the Act for the 2002 control period.

1. EPA collaborated with FDA to identify what information would be required from companies in order for FDA to make a determination, in consultation with EPA, on the amount of CFCs necessary for use in MDIs. EPA and FDA determined that the following data were needed to make this determination:

- The specific MDI products to be produced in 2002
- The number of units of each product produced in the year 2000
- Number of units produced in the first quarter of 2001
- Number of units anticipated to be produced in 2002
- Gross target fill weight per unit (grams)
- Total amount of CFC to be contained in product for 2002 (metric tons)
- Additional amounts of CFCs necessary for production of MDIs in 2002
- Total CFC request per product for 2002

2. On April 12, 2002, EPA sent letters to MDI manufacturers requesting the information outlined above. The letters that EPA sent each company are available for review in the Air Docket No. A–93–39. The company's responses, however, are considered confidential business information and are not publicly available. Table Ia is an example of the reporting form EPA asked companies to fill out under the authority of section 114 of the Act (114 letters).

TABLE IA.—YEAR 2002 ESSENTIAL USE ALLOCATION: CFC REPORTING FORM

Product	Number of units produced from 1/1/00 to 12/31/00	Number of units produced from 1/1/01 to 3/31/01	Number of units anticipated to be produced in 2002	Gross Target fill weight per unit (grams)	Total CFC to be contained in product for 2002 (metric tons)	Additional amount necessary for production [3]	Total request per product for 2002
A	B	C	D	E	F	G	H
Example Product	1,327,456	352,101	1,500,000	22	33.00	3.3	36.30

3. In a letter dated June 14, 2001, EPA requested that FDA make a determination regarding the amount of CFCs necessary for use in MDIs for calendar year 2002. With this request, we attached the information MDI manufacturers provided in response to the 114 letters. FDA compared the information from the companies' responses to EPA's section 114 letters with the annual reports companies file with FDA and used this information as a basis for their determination.

4. On August 9, 2001, FDA sent a letter to EPA stating the amount of CFCs necessary for use in MDIs for calendar year 2002. The FDA determination was based on the assumption that the total U.S. request of 3,450 metric tons of CFCs will be approved at the next Meeting of the Parties in October 2001. In accordance with the determination made by FDA, specified in their letter of August 9, 2001, today's action proposes to allocate essential-use allowances for a total of 3,388 metric tons of CFCs for use in MDIs for the year 2002 calendar year.

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

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

''With these definitions in mind, we [FDA] have examined the information you [EPA] obtained from individual sponsors regarding their historical and intended use of CFCs in specific products. We compared this information to the information filed with us by sponsors in previous annual reports. In listing the amounts we believe to be necessary for use in medical devices, we referred to this information, eliminated any double-counting we found, considered changes in the prevalence of asthma and COPD, and eliminated allocations for uses not considered essential by the Parties to the Montreal Protocol, even if those uses are currently listed in our regulations at 21 CFR 2.125(e).''

[3] EPA requested that respondents provide details of the additional amount needed, e.g., canisters produced but not distributed, CFCs lost in processing, CFCs remaining at end of batch run, CFCs used in line cleaning.

[4] Use of Ozone-Depleting Substances; Essential Use Determinations, September 1, 1999. (64 FR 47719)

[5] An FDA regulation at 21 CFR 108(a) defines active moiety as ''the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a pharmacological action of the drug substance.''

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

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

EPA will only be authorized to allocate a total of 3,450 metric tons of CFCs if the Parties approve the U.S. supplemental request at the October 2001 meeting. As stated earlier, in the event that the Parties do not approve the U.S. supplemental request for the year 2002 in its entirety, EPA, in consultation with FDA, will allocate CFCs based on the total amount authorized by the Parties.

F. How Does Decision XII/2 of the Parties to the Montreal Protocol Affect This Year's Regulation?

(1) Eligible Products

Decision XII/2, titled ''Measures to facilitate the transition to chlorofluorocarbon-free metered dose inhalers'', taken at the last Meeting of the Parties in December 2000 has two provisions that are being implemented with today's action. First, as noted in the FDA letter, 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[6] to be considered essential, the MDI product must individually 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 believes that CFC MDI that are still in research and development, and that contain active moieties already commercially available in other MDI products are no longer ''essential''. This is because the new MDI products would not provide additional therapy to patients, and thus are not themselves necessary for the health, safety or functioning of society as specified by paragraph 1(a) of Decision IV/25.

Decision XII/2 allows for the possibility that a CFC MDI product containing an active moiety not currently available as an MDI might be considered essential if the product met the requirements of paragraph 1 of Decision IV/25. If the FDA, in consultation with EPA, determined that the new product was ''essential'' and the product met the criteria in Decision XII/2, the U.S. would forward a nomination to the Parties. Consistent with our current practice, EPA and FDA would only allocate essential-use allowances for MDIs considered to be essential by the Parties to the Protocol.

EPA, in consultation with FDA, is implementing paragraph 2 of Decision XII/2 by allocating essential-use allowances to companies only for production of CFC MDIs for the treatment of asthma and COPD, and approved by FDA prior to December 31, 2000. EPA is also proposing to amend the language at 40 CFR 82.4(t) to reflect this. One company had in prior years received essential-use allowances for research and development of CFC MDIs containing active moieties that are already available to patients in MDI form. Due to Decision XII/2, EPA and FDA cannot allocate essential-use allowances to this company for research and development of MDIs now considered to be non-essential.

(2) Transfers of Essential-Use Allowances and ''Essential-Use CFCs''

With today's proposal, 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 licence 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.

As the transition progresses, and more CFC-free MDIs become available, fewer CFC MDIs will be produced globally. While many pharmaceutical companies have production lines for CFC MDIs in more than one country, this is likely to change as demand for CFC MDIs decreases. With last year's allocation rule, EPA amended its regulations to allow transfer of essential-use allowances for CFC among essential-use allowance holders domestically (66 FR 1462). As a result of Decision XII/2, EPA is proposing 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 proposing to change the regulations 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. EPA is also 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 are currently traded. This ensures compliance with section 616 of the CAA which governs international trades. For approval of an international trade for essential-use allowances the transferor must submit the following information:

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

• The identity of the Party (i.e. the country other than the U.S. that is participating in the transfer);
• The names and telephone number of contact person for the company where the allowances are being transferred to (transferee) and names and contact person for that country's government representative;
• The type of allowances being transferred (essential-use allowances), the type of chemical being transferred (CFC–11, CFC–12, or CFC–114);
• The control period (i.e., calendar year) to which the transfer applies.

After receiving a transfer request, the Administrator may at her discretion consider the following factors in deciding whether to approve a transfer:
• 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 inhaler considered essential by the Parties.

EPA is proposing 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. EPA believes that other Parties to the Protocol are implementing this portion of Decision XII/2 in a similar manner which will allow free flow of CFCs produced with essential-use allowances between Parties and between MDI companies. EPA believes that this additional flexibility will result in a decrease in the total amount of CFCs produced for essential-uses globally.

First, we are amending section 82.3 to define the term ''essential-use CFC'' to mean CFCs already produced using essential-use allowances. Second, we are 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 will allow 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 (see next paragraph). Third, we are defining the term ''essential MDIs'' in section 82.3 as the following, ''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. 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).'' By defining essential MDIs as such, we ensure that transferred ''essential-use CFCs'' would be used solely for production of MDIs considered essential by the Parties and the country where they are being ultimately sold.

EPA is 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. Under the proposed changes to 82.12 the transferee would submit to EPA the following information before EPA would approve a transfer of essential-use CFCs.
• The identities and addresses of the transferor and the transferee;
• The name and telephone numbers of contact persons for the transferor and the transferee;
• The amount of each controlled substance (CFC–11, CFC–12, or CFC–114) being transferred;
• The specific metered dose inhaler products (i.e. the MDI drug product or active moiety) that the company plans to produce with the transferred CFCs;
• 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;
• Certification that the essential-use CFCs will be used in the production of essential MDIs. If the metered dose inhalers are to be sold in the United States, the certification must state that metered dose inhalers produced with the transferred essential-use CFCs are listed as essential at 21 CFR 2.125. If the metered dose inhalers 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.

The transferor must submit to EPA a letter concurring with the terms of the transferees request before the application is complete. For international transfers under section 82.9, EPA would require the same information requested at 82.12 and listed above, and a letter from the embassy of the Party involved in the transfer stating that the transfer is approved by the government of the Party.

If EPA approves the transfer, EPA would issue letters to the transferor and the transferee indicating that the transfer may proceed. If EPA objects to the transfer, EPA would issue letters to the transferor and transferee stating the basis for disallowing the transfer. The burden of proof is placed on the transferee (if the transferee is a U.S. company) to retain sufficient records to prove that the transferred essential-use CFCs are used only for production of essential MDIs. If the MDIs are produced in the U.S. and are to be exported to another country the transferee must ensure that the MDIs produced are considered essential by the national authority of the importing country. If EPA ultimately found that the transferee did not use the essential-use CFCs in essential MDIs, then the transferee would be in violation of the CAA.

Finally, EPA is proposing to revise the definition of ''essential-use allowances'' under section 82.3 to ensure consistency with the Montreal Protocol and section 82.4. Under the Montreal Protocol, essential-use exemptions were granted for the years 1996–2003. EPA has already granted essential-use allowances for calendar year 2001, and is proposing to allocate essential-use allowances for calendar year 2002. Further, EPA anticipates that the Parties will continue to grant essential-use exemptions until the transition from class I ODS in essential applications is complete. Therefore, EPA is proposing to change the definition of essential-use allowance by omitting a specific end date for the program.

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

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

(1) Essential Uses of Methyl Chloroform.—Notwithstanding the termination of production required by subsection (b), during the period beginning on January 1, 2002, and ending on January 1, 2005, the Administrator [of EPA], after notice and opportunity for public comment, may, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane parts susceptible to metal fatigue) for which no safe and effective substitute is available. Notwithstanding this paragraph, the authority to produce methyl chloroform

for use in medical devices shall be provided in accordance with paragraph (2).

Decision X/6 states that ''* * * the remaining quantity of methyl chloroform authorized for the United States at previous meetings of the Parties [will] be made available for use in manufacturing solid rocket motors until such time as the 1999–2001 quantity of 176.4 tons (17.6 ODP-weighted tons) allowance is depleted, or until such time as safe alternatives are implemented for remaining essential-uses.'' According to the EPA tracking system, the total amount of MCF produced or imported by essential-use allowance holders was 15.2 metric tons in the calendar year 1999, and 3.3 metric tons in the calendar year 2000. EPA is proposing to allocate 50.4 metric tons of MCF for 2002 for use in the Space Shuttle and Titan Rockets, which is the amount requested by essential-use applicants for 2002. Essential-use allowance holders should be aware that the exemption for MCF under section 604(d)(1) of the CAA expires in the year 2005. Thus, EPA will not have statutory authority to allocate essential-use allowances for MCF after that date.

IV. Allocation of Essential-Use Allowances for Medical Devices and the Space Shuttle and Titan Rockets for Calendar Year 2002

EPA is proposing to allocate 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	1016
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

V. General Laboratory Exemption for Class I ODSs

On March 13, 2001, EPA issued a direct final rule that implemented a *de minimis* exemption under the Clean Air Act for continued production and import of class I ODS for laboratory essential-uses (66 FR 14760). With the direct final rule, EPA allocated essential-use allowances for laboratory uses for the year 2001 only. Under the Montreal Protocol, the Parties have approved a global (i.e., general) exemption for laboratory and analytical uses for set periods of time. At their tenth meeting in 1998, the Parties, in Decision X/19, extended the global laboratory and analytical essential-use exemption until December 31, 2005, under the conditions set out in Annex II of the report of the Sixth Meeting of the Parties. Today's action proposes to extend EPA's regulatory *de minimis* exemption for essential laboratory and analytical uses through 2005 as consistent with the Montreal Protocol.

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.

With today's action, EPA is proposing to amend Part 82 subpart A, appendix G to define the above laboratory methods as non-essential pursuant to Decision XI/15. Under this proposed change to appendix G, production or import of class I ODSs for these specific laboratory methods will be prohibited beginning January 1, 2002.

In the U.S., class I ODSs are not used for testing of tar in road-paving materials and forensic finger-printing. Thus, we expect that the major impact of Decision XI/15 will be upon testing of oil and grease, and total petroleum hydrocarbons in water. EPA requires testing for the these conventional pollutants 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. Pursuant to Decision XI/15, methods for testing for oil and grease in water using class I ODSs will no longer be considered essential in the year 2002. Thus, new production or importation of CFC–113 for those EPA test methods will be prohibited. This should not cause a problem for laboratories since there are alternative methods available for testing of oil and grease that do not rely on class I ODS, and EPA recommends that laboratories switch to these alternative methods.[7] You may

[7] 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

use stockpiled CFC–113 that was imported for production before January 1, 2001 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.

Pursuant to Decision X/19, the TEAP will continue to make recommendations for laboratory uses which no longer require class I ODSs. The Parties to the Protocol may remove additional methods or uses from the global laboratory exemption in the future. Currently, there are no recommendations by the TEAP to remove any additional laboratory uses beyond those listed in Decision XI/15. If the Parties decide to remove any other laboratory uses from the exemption, EPA will propose appropriate regulations. EPA reserves the right to determine that a particular test method is non-essential in the United States, even if it continues to be considered essential by the Parties.

The current regulations require annual certifications from laboratory customers stating that the class I ODSs produced and/or imported under the laboratory exemption will not be resold or used in manufacturing. EPA is proposing to amend the recordkeeping and reporting requirements at 40 CFR 82.13 so that these certifications also state that the class I ODSs obtained under the laboratory exemption will be used for essential laboratory uses as defined by appendix G. EPA believes that these additional requirements will not impose additional paperwork burden on the regulated entities since annual certifications are already required.

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

EPA is proposing to add paragraph (t)(4) to section 82.4 in order to clarify that virgin 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 paragraphs (t)(2), (t)(3), and appendix G of subpart A). The regulations at section 82.4 establish limited exceptions to the production and import bans for class I ODS. The use or sale of virgin 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 general 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 section 82.4(t)(4) by stating that ''It is a violation of this subpart to obtain virgin class I ODSs under the general laboratory exemption 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.

EPA is aware that certain companies extract and recycle CFCs from MDIs that are ''off-specification'' and are thus not marketable. These recycled CFCs are often sold for use in non-essential applications. The addition of paragraph (t)(4) would not prevent this practice from continuing since the CFCs contained in off-specification MDIs are not considered virgin material. EPA is unaware of any virgin essential-use material that is being sold or used for non-essential purposes at this time, and therefore does not anticipate that this clarification will have any economic impact.

VII. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector.

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures 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:

required under the Clean Water Act, call the Office of Water Resource Center at (202) 260–7786.

(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 proposed 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 will be prepared by EPA and sent to OMB. Once the ICR in completed, EPA will issue a notice soliciting public comment on the ICR.

The information required in today's proposed rule, and that 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 also 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. 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 proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Today's rule does not affect the communities of Indian tribal governments since the only entities directly affected by this rule are the companies that requested essential-use allowances or make use of the general exemption for laboratory uses. Thus, Executive Order 13175 does not apply to this rule. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

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

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's rule on small entities, small entities is defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have less than 750 employees; 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 its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. We have determined that the one pharmaceutical company that is not receiving essential-use allowances for use in CFC MDIs could 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 in that beginning in the year 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 method available, and that stockpiled and recycled CFC–113 can continue to be used for this testing if necessary, that the economic impact of this regulation on small environmental testing laboratories is minimal. Further, alternative methods to test oil and grease that do not use ODSs are available.

Although this proposed 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. We continue to be interested in the potential impact of the proposed rule on small entities and welcome comments related to these issues.

F. Applicability of Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant'' as defined under 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. EPA interprets E.O. 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 E.O. 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 No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in this regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rule does not involve technical standards. Therefore, EPA did not considering the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. With today's action EPA is proposing 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. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

I. Executive Order 13211 (Energy Effects)

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

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Imports, Laboratory and analytical uses, Methyl chloroform, Ozone layer, Reporting and recordkeeping requirements.

Dated: October 24, 2001.

Christine Todd Whitman,

Administrator

40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.3 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. 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 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.

* * * * *

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 virgin 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) 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
Boehinger Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	743
Glaxo SmithKline	CFC–11 or CFC–12 or CFC–114	1016
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 using virgin class I ODSs produced under the authority of essential-use allowances or the essential-use exemption in paragraph (t)(3) of this section for 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 virgin 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 virgin 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 virgin 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 virgin class I ODSs under the general laboratory exemption 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), and (c)(4).

c. By adding paragraphs (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, or its essential-use allowances for CFCs for use in essential MDIs, by trading with another Party to the Protocol according to the provision 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 produced 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 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 that is 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 amount of allowances being transferred;

* * * * *

(2) * * *

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

(3) * * *

(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 transferee 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 paragraph (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.

* * * * *

(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;

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

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

(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.

(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.

(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.

* * * * *

(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.

* * * * *

(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:

* * * * *

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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DEPARTMENT OF DEFENSE

48 CFR Part 203

[DFARS Case 99–D028]

Defense Federal Acquisition Regulation Supplement; Anticompetitive Teaming

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to add policy addressing exclusive teaming arrangements. The proposed amendments specify that certain exclusive teaming arrangements may evidence violations of the antitrust laws.

DATES: Comments on the proposed rule should be submitted in writing to the address specified below on or before December 31, 2001, to be considered in the formation of the final rule.

ADDRESSES: Respondents may submit comments directly on the World Wide Web at *http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm.* As an alternative, respondents may e-mail comments to: http:dfars@acq.osd.mil. Please cite DFARS Case 99–D028 in the subject line of e-mailed comments.

Respondents that cannot submit comments using either of the above methods may submit comments to: Defense Acquisition Regulations Council, Attn: Ms. Susan Schneider, OUSD(AT&L)DP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062; facsimile (703) 602–0350. Please cite DFARS Case 99–D028.

At the end of the comment period, interested parties may view public comments on the World Wide Web at http://emissary.acq.osd.mil/dar/dfars.nsf.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Schneider, (703) 602–0326. Please cite DFARS Case 99–D028.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule amends DFARS Subpart 203.3 to add a definition of ''exclusive teaming arrangement'' and to specify that certain exclusive teaming arrangements may evidence violations of the antitrust laws. DoD previously published a proposed rule on this subject at 64 FR 63002, November 18, 1999. As a result of public comments received on the previous proposed rule, DoD is publishing this revised proposed rule to clarify that not all exclusive teaming arrangements evidence violations of the antitrust laws.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because DoD does not expect frequent use of anticompetitive teaming arrangements by contractors or subcontractors. Therefore, DoD has not performed an initial regulatory flexibility analysis. DoD invites comments from small businesses and other interested parties. DoD also will consider comments from small entities concerning the affected DFARS subpart in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 99–D028.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 203

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, DoD proposes to amend 48 CFR part 203 as follows:

1. The authority citation for 48 CFR part 203 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

2. Sections 203.302 and 203.303 are added to read as follows:

203.302 Definitions.

Exclusive teaming arrangement means that two or more companies agree, in writing, through understandings, or by any other means, to team together on a procurement and further agree not to team with any other competitors on that procurement.

203.303 Reporting suspected antitrust violations.

(c)(i) Practices or events that may evidence violations of the antitrust laws also include exclusive teaming arrangements when all of the following conditions exist:

(A) One or a combination of the companies participating on the team is the sole provider of a product or service that is essential for contract performance;

(B) The teaming arrangement impairs competition; and

(C) Government efforts to eliminate the teaming arrangement are not successful.

(ii) This policy applies only to exclusive teaming arrangements that meet all three of the conditions in paragraph (c)(i) of this section and should not be misconstrued to imply that all exclusive teaming arrangements evidence violations of the antitrust laws.

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