ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6881–8]

RIN 2060–AJ33

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2001

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: With this action, EPA is proposing to allocate essential-use allowances for stratospheric ozone depleting substances for the year 2001 control period. EPA allocates essential use allowances to an applicant for exempted production or import of a specific quantity of class I ozone depleting substances (ODS) solely for the designated essential purpose. Essential use allowances permit a person to obtain controlled ODS as an exemption to the January 1, 1996 regulatory phase-out of production and import of these substances. Today, EPA is proposing essential-use allowances (EUAs) for the production and/or import of ODSs for use in medical devices and for use in the Space Shuttle Rockets and Titan Rockets for calendar year 2001. EPA is also proposing a regulatory change which would allow EUAs for CFCs to be transferred among essential use recipients.

DATES: Written comments on this proposed rule must be received on or before November 6, 2000, 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 October 16, 2000. 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 to: Erin Birgfeld, Essential Use Program Manager, U.S. Environmental Protection Agency (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. All comments will be filed in EPA Air docket number A–93–39. Comments that contain business confidential information should be submitted in two versions, one clearly marked ''Public'' to be filed in the docket, and the other marked ''Confidential'' to be reviewed by authorized government personnel only.

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 4 p.m. Monday through Friday. A reasonable fee may be charged by EPA 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, Stratospheric Protection Division, Office of Atmospheric Programs, 6205J, 1200 Pennsylvania Avenue, Washington, DC 20460; 202–564–9079.

SUPPLEMENTARY INFORMATION:

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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 of all stratospheric ozone depleting substances. (''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.) The elimination of production and consumption is accomplished through adherence to phase-out schedules for the production and consumption of specific ODSs including chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform, hydrochlorofluorocarbons, and methyl bromide. As of January 1996, production and import of class I ODSs 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 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 Decision IV/25 are the following:

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

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

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

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

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

The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential uses. The Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on essential use nominations at their annual meeting.

The CAA provides exemptions to the phase-out of class I ODSs for which these controlled substances may continue to be produced and/or imported. EPA is responsible for allocating essential use allowances at the domestic level through rulemaking in accordance with provisions in the CAA. Today's action proposes to allocate essential use allowances for the use of CFCs in metered dose inhalers (MDIs), and methyl chloroform for use in the Space Shuttle and Titan Rocket solid rocket motor assemblies for calendar year 2001. Today's action also proposes changes to regulations at 40 CFR 82.12 which would allow transfer of CFC allowances among MDI manufacturers that hold EUAs.

What Was the International Procedure for Approving Essential Use Exemptions for the Year 2001?

The international process for nominating and approving essential use allowances for the year 2001 occurred in the same way as in prior years. The companies in Table III submitted

applications either on their own or as a part of the International Pharmaceutical Aerosol Consortium (IPAC) requesting class I controlled substances for essential uses in response to the August 10,1998 **Federal Register** notice (63 FR 42629). Their applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phase-out, 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.'' EPA reviewed the applications and nominated these uses to the Protocol Secretariat for consideration by the Technical and Economic Assessment Panel (TEAP) and its Technical Options Committees (TOCs). MDI producers requested a total of 3,101 metric tons of CFCs for use in 2001. The Parties to the Montreal Protocol approved this amount as essential for the U.S. for 2001 at the Eleventh Meeting in 1999 (Decision XI/14). On September 15, 1999, EPA issued another notice requesting applications for essential use allowances for the year 2001 and beyond (64 FR 50083). No company requested a supplemental amount of CFCs for the year 2001 at that time.

How Does the Clean Air Act Authorize Essential Use Allowances?

The CAA provides standing exemptions to the phase-out of class I ODSs found at section 604(d) of the Act. 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
>
> (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].

The preamble to FDA's September 1, 1999, notice of proposed rulemaking on essential use determinations (64 FR 47735) discusses FDA's approach to determining whether ''safe and effective alternative[s]'' have been developed. It states that ''A non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product. FDA's approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a safe and effective alternative for any other product. That requires a separate and distinct analysis.'' Although FDA has approved one CFC-free MDI for market, it has not yet determined that any non-CFC product is a safe and effective alternative to any CFC MDI. Accordingly, part (A) of the definition of medical device has not affected today's proposed allocation.

With respect to part (B) of the definition of medical device (section 601(8)(B)), and in particular the use of the word ''essential'' in that part of the definition, EPA is relying on current FDA regulations (21 CFR 2.125) which contain a list of categories of CFC-containing medical devices, as that term is used in the CAA, that FDA, in consultation with EPA, has found to be essential. This list includes, among others, metered-dose steroids, metered-dose adrenergic bronchodilators, metered-dose cromolyn sodium, metered-dose ipratropium bromide, and metered-dose nedocromil sodium; all drugs for oral inhalation in humans for the treatment of asthma and chronic obstructive pulmonary disease. The companies for which EPA is proposing to grant essential use allowances produce CFC MDIs that fall within one of these categories. Thus, the products for which EPA is proposing to grant essential use allowances are ''determined to be essential'' by FDA.

Also with respect to part (B) of the definition of ''medical device'', EPA and FDA considered how to interpret the language regarding approval by FDA of the ''device, product, drug, or drug delivery system.'' The complete phrase reads as follows: ''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 in consultation with the Administrator.'' EPA and FDA determined that in light of the surrounding language, this phrase refers to FDA's approval of an essential use, and not the approval of the specific product in question through approval of the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for that product. Since approval of an NDA or ANDA under the Food, Drug, and Cosmetic Act (FDCA) involves unilateral action by FDA without notice-and-comment rulemaking or consultation with EPA, it is reasonable to conclude that section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Therefore, FDA and EPA read section 601(8)(B) to refer to FDA's approval of an essential use which does require notice-and comment rulemaking in consultation with EPA. This means that an MDI is ''approved and determined to be essential'' if the MDI is included within the list of categories of CFC-MDIs on FDA's essential use list. All of the MDIs for which we are proposing to allocate CFCs today meet this qualification.

With this action EPA is also proposing to allocate methyl chloroform (MCF) for use in solid rocket motor assemblies. Because the original phase-out date of methyl chloroform is 2002, EPA is not required to implement the exemption at 604(d)(1) until that time. Instead, EPA is proposing to allocate methyl chloroform under the authority of the original phase-out schedule at section 604(a) which provides that MCF may be produced at up to 20 percent of the baseline. EPA is proposing to allocate a total of 60.1 metric tons of MCF, an amount well below 20% of the MCF baseline production allowance of 315,169 metric tons (defined at 40 CFR 82.6).

II. Allocation Process for CFCs for Use in Medical Devices for the Year 2001

How Were the Essential Use Allowances for Medical Devices Determined for the Year 2001?

As explained above, section 604(d)(2) of the Act provides that EPA shall authorize production and import of limited quantities of class I substances for use in medical devices if FDA, in consultation with EPA, determines such authorization to be necessary. The following is a step-by-step list of actions EPA and FDA have taken thus far to implement the exemption for medical devices under the Act.

1. EPA worked closely with FDA to define what information would be

required from companies in order that FDA in consultation with EPA could make a determination on the amount of CFCs necessary for use in MDIs. EPA and FDA determined that the following data were needed to make a decision on the amount of CFCs necessary for use in MDIs for 2001:

- The specific MDI products to be produced in 2001
- The number of units each product produced each year since 1996
- Number of units produced in the first quarter of 2000
- Number of units anticipated to be produced in 2001
- Gross target fill weight per unit (grams)
- Total amount of CFC to be contained in product for 2001 (metric tons)
- Additional amounts of CFCs necessary for production of MDIs
- Total CFC request per product for 2001

2. On May 24, 2000, EPA sent letters to MDI manufacturers requesting the information outlined in paragraph 1. EPA also requested information on the amount of CFCs held in inventory as of January 1, 2000. The letters that EPA sent each company are available for review in the docket. The company's responses however, are considered confidential business information and are not publicly available. Tables I and II are reproductions of the reporting forms EPA asked companies to fill out in response to our letters requesting information under section 114 of the Act (114 letters).

TABLE I.—YEAR 2001 ESSENTIAL USE ALLOCATION: CFC REPORTING FORM

A Product	B Number of Units produced from 1/1/96 to 12/31/96	C Number of Units produced from 1/1/97 to 12/31/97	D Number of Units produced from 1/1/98 to 12/31/98	E Number of Units produced from 1/1/99 to 12/31/99	F Number of Units produced from 1/1/00 to 3/31/00	G Number of Units anticipated to be produced in 2001	H Gross Target fill weight per unit (grams) [1]	I Total CFC to be contained in product for 2001 (metric tons) [2]	J Additional amount necessary for production [3]	K Total request per product for 2001 [4]
Example Product	1,112,569	1,010,526	1,215,452	1,327,456	352,101	1,500,000	22	30.42	5.20	35.62

[1] If significant numbers of different canister sizes are produced, this target fill number should either be the weighted average for that product (i.e., the sum of the gross target fill times the percentage of canisters produced in that size divided by the total number of canisters) or each size may be contained in a separate row of the report.

[2] Column I= (Column G) (Column H).

[3] Provide details regarding your 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] Total request per product for 2001 (metric tons) = Sum of Columns I+J.

Note: The data presented in columns B through E will be compared to data provided in annual reports to FDA. Any significant differences in these numbers should be explained in detail.

TABLE II.—YEAR 2000 CFC STOCKPILE ANALYSIS

Chemical	On 1/1/2000: Quantity (in metric tons) of chemical stored at your facility	On 1/1/2000: Total quantity (in metric tons) of chemical available to your company [5]	On January 1, 2000: Amount of chemical produced prior to January 1, 1996 [6] available to your company	Total quantity of chemical acquired using 1999 essential use allowances
CFC–11				
CFC–12				
CFC–114				

[5] This includes amounts stored at your facility, other facilities, or an order with the chemical manufacturers.

[6] This amount refers to your company's stockpile (on 1/1/2000) of CFCs produced prior to the 1996 ban on import and production.

3. In a letter to FDA, dated August 3, 2000, Paul Stolpman, Director of EPA's Office of Atmospheric Programs, requested that FDA provide EPA with a determination regarding the amount of CFCs necessary for use in MDIs for calendar year 2001. We attached the information provided in response to 114 letters from MDI manufacturers for FDA's review. FDA verified the data against the annual reports companies file with FDA, and used the information from the companies' response to our section 114 letters as a basis for their determination.

4. On September 6, 2000, FDA Commissioner Jane Henney sent a letter to EPA with the FDA determination on the amount of CFCs necessary for use in MDIs for calendar year 2001. The quantity of CFCs to be allocated for production of MDIs in this proposed rule reflect FDA's determination made in consultation with EPA.

5. In accordance with the determinations made by FDA, in consultation with EPA, specified in their letter of September 6, 2000, today's proposal would allocate a total of 3098.67 metric tons of CFCs for use in MDIs for calendar year 2001.

6. EPA plans to issue a final allocation rule by the end of the calendar year to provide adequate time for companies to replenish their supply of CFCs for MDI production in the year 2001.

How Were the Decisions on the Amounts of EUAs for CFCs for Each Company Made?

FDA states in their letter to EPA that "* * * we have examined the information you 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 regulation at 21 CFR 2.125(e).''

In response to EPA's request for information under section 114 of the Act, two companies stated that they required CFCs to produce the same products leading to double counting and an inflated request of CFCs to manufacture these particular MDI products. This is because one company is a New Drug Application (NDA) holder who produces some of its own products, and the other is a contract filler for the NDA holder who produces the remainder of the NDA holder's products. At the time we gathered information via 114 letters, the companies had not reached an agreement on the amount of MDIs to be produced by the contract filler and the amount to be produced by the NDA holder. With this action, EPA is proposing to allocate CFCs to these two companies in the amount requested by the NDA holder. Because we are also proposing to allow EUAs to be transferrable, the NDA holder will have the opportunity to transfer some of its EUAs to the contract filler if necessary. This transfer can be accomplished by adhering to the requirements in the regulations at 40 CFR 82.12 which will be explained in detail in section IV. In the event that the change to 40 CFR 82.12 proposed in this rule which allow the transfer of EUAs is not finalized, EPA and FDA will consult with the both contract filler and the NDA holder to determine the proper allocation. Please note that EPA and FDA took into account that the contract filler also manufactures products for yet another company along with its own brand of MDIs and allocated the entire amount requested to manufacture these other MDI products.

Can the Allocation Listed in This Proposed Rulemaking Be Changed in the Final Rule?

The allocation amounts listed in this proposal are subject to additional review by EPA and FDA if new information demonstrates that the allocations are either too high or too low. Commenters requesting increases or decreases of EUAs should provide detailed information supporting their claim for additional or fewer CFCs. Any company that determines that they no longer need the full amount allocated under this proposal should notify EPA of the actual amount needed. Please note that EPA is only authorized to allocate a total of 3,101 metric tons of CFC, the amount requested by U.S. pharmaceutical companies and subsequently approved by the Parties to the Montreal Protocol for 2001.

III. Allocation of Essential Use Allowances for Calendar Year 2001

What Is EPA's Proposed Essential Use Allocation for Calendar Year 2001?

EPA is proposing to allocate essential use allowances for the year 2001 control period to entities listed in Table III for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential use. The proposed allocation of CFCs for use in MDIs reflects the determination on the amount of CFCs ''necessary'' as specified under section 604(d)(2) of the Act.

TABLE III.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva, Armstrong Pharmaceuticals Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	258.00
Glaxo Wellcome Inc.	CFC–11 or CFC–12 or CFC–114	858.10
Aventis Pharmaceuticals (formerly RPR)	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	384.87
Sidmak Laboratories/Medisol Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.30
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

Why Is EPA Allocating CFC–11, CFC–12, and CFC–114 in the Aggregate to Each Company?

EPA is allocating essential-use allowances for CFC–11, CFC–12, and CFC–114 in the aggregate in accordance with Decision X/6 of the Parties to the Montreal Protocol which states that ''the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group.'' Allocating CFCs for MDI manufacture in the aggregate instead of on a compound-by-compound basis adds flexibility to the regulation without causing additional damage to the stratospheric ozone layer since CFC–11, CFC–12 and CFC–114 all have the same ozone depleting potential of 1.0.

Why Is EPA No Longer Allocating EUAs to the International Pharmaceutical Aerosol Consortium (IPAC) as a Whole, But Instead Allocating on a Company-by-Company Basis?

In the past, EPA allocated EUAs to IPAC as a whole and then sent letters to each of its member companies notifying them of their particular allocation. This inevitably resulted in minor delays in informing IPAC member companies of their allocations. This year, EPA is allocating EUAs on a company-by-company basis in order to inform the IPAC member companies directly of their specific allocations. Thus it will be clear to each company, including the IPAC members, the quantities that are being proposed for each company allowing all companies opportunity to comment on their individual allocations.

What Is EPA's Method for Allocating Methyl Chloroform (MCF) for Use in Solid Rocket Motors?

With this action, EPA is proposing to allocate 60.1 metric tons of MCF for use in solid rocket motors, the same amount allocated in the years 1999 and 2000. Please note that with this action EPA is proposing to allocate MCF in an amount

lower than would be consistent with Decision X/6 taken at the Tenth meeting of the Parties to the Protocol because EPA believes that doing so would allocate MCF in excess of the necessary amount.

Decision X/6 states that '' * * * the remaining quantity of methyl chloroform authorized for the United States at previous meetings of the Parties 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 U.S. essential use recipients in 1999 was just 12 metric tons indicating that the transition away from MCF is progressing faster than anticipated, and that allocating the unused portion of MCF in its entirety would be excessive. EPA believes that allocating the same amount allocated in 2000, 60.1 metric tons of MCF, provides a sufficient amount for use in solid rocket motors for the year 2001. Please note that in future allocations essential use allowance holders for MCF will still have access to MCF until the 1999–2001 quantity of 176.4 metric tons is depleted or until this use is no longer considered essential.

In the event that commenters provide sufficient reasons as to why EPA should allocate MCF in an amount consistent with Decision X/6, for example, EPA would allocate MCF according to the following equation:

The amount of MCF approved by the Parties for essential uses for 1999–2001 $-2\times$ The amount of MCF imported or produced by U.S. essential use holders in 1999=Allocation for 2001 (*i.e.,* 176.4 metric tons -2×12 metric tons=152.4 metric tons).

Since the amount of MCF acquired in the year 2000 is not yet known, the equation assumes that essential use holders will acquire the same amount of MCF in 2000 as they had in 1999 and provides the best possible approximation of the quantity of MCF that should be allocated if EPA is persuaded to allocate MCF in the amount consistent with Decision X/6.

What Reporting Requirements Relate to the Essential Uses of Ozone Depleting Substances?

Any person obtaining class I controlled substances after the phase-out under the essential use exemptions in today's action is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential-use allowances or persons obtaining class I controlled substances under the essential-use exemptions must comply with the record keeping and reporting requirements in 40 CFR 82.13. Instructions and forms for reporting are found in the Guidance Document for the Stratospheric Ozone Protection Program after January 1, 1996. This document can be obtained by contacting the Stratospheric Ozone Protection Hotline at (800) 296–1996 between 10:00 am and 4:00 pm Eastern Standard Time.

It should be noted that under 40 CFR 82.3 and 82.4 (63 FR 41626, August 4, 1998), entities receiving essential-use allowances must be the importer of record for quantities of CFCs brought into the United States. This requires that the essential-use allowance holder be listed as the importer of record on Customs Form 7501. As a result, the essential-use allowance holder who imports quantities of class I controlled substances is responsible for submitting both an Importer Quarterly Report and an Essential-Use Holder Quarterly Report.

IV. Proposed Changes to 82.12 Allowing Transfer of EUAs for CFCs Among Essential Use Allowance Holders

With this document EPA is proposing to add essential use allowances to the list of allowances that can be transferred under 40 CFR 82.12. This change will enable essential use holders to transfer EUAs for CFCs to other essential use holders for the production of essential MDIs. EPA believes that allowing EUAs to be transferred among essential use allowance holders incorporates flexibility into the current regulations without increasing the amount of ODSs allocated.

Why Is EPA Proposing To Allow EUAs To Be Transferred Among EUA Holders?

Each year EPA requests applications from pharmaceutical companies for essential use allowances for use in MDIs. EPA analyzes these applications and uses them as the basis for the U.S. nomination for essential use allowances at the Meeting of the Parties to the Montreal Protocol which occurs two years prior to the year in which EUAs are allocated to companies. Because it can be difficult to forecast the amount of CFCs required for MDI production two years in advance, the Parties provide an opportunity for countries to request a supplemental amount of essential use allowances in the year following the initial request. This system allows companies two opportunities to request essential use allowances for the same year, ensuring that if the initial request is not sufficient, there is a mechanism to increase the allocation for that year. Essential use applicants had the option of requesting supplemental CFCs for 2001 in September 15, 1999, in response to the EPA document (64 FR 50083). No applicant elected to supplement their request for the year 2001 at that time.

Even in the absence of applications for supplemental CFCs from pharmaceutical companies, EPA and FDA consulted in March of this year to determine whether the total allocation of 3,101 metric tons would be sufficient to produce MDIs for the U.S. market. EPA and FDA determined, based on the amount of CFCs used for MDI production in previous years, that 3,101 metric tons would be sufficient to supply the MDI market as a whole while accounting for the projected increase in demand for MDIs. However, EPA and FDA noted that individual companies may have increased market growth compared to others and would therefore need additional CFCs. Because of the inherent uncertainty in allocating specific amounts of CFCs to individual companies engaged in a dynamic market, EPA is proposing that EUAs for CFCs become transferable among EUA holders. This will ensure that companies have the opportunity to access CFCs beyond the amount allocated to them in the year 2001 and beyond, and can better respond to market shifts that may occur.

Will I Be Able To Transfer EUAs for CFCs to Anyone I Want?

No, EUAs for CFCs would only be transferable among those companies that have applied for and received EUAs for the year 2001. In addition, companies must certify in writing to EPA that the EUAs will only be used in the production of essential medical devices as defined in the Food, Drug and Cosmetic Act at 21 CFR 2.125 and considered essential by the Parties to the Protocol.

If EUAs for CFCs Are Transferable, Can They Be Transferred From Year to Year?

No, EUAs would not be transferable from year to year. Any EUAs for CFCs not expended in 2001 will expire at the end of 2001.

Is There a Penalty for Transferring EUAs?

Yes. The CAA at section 607(a) states that rules governing transfer of allowances for the production of class I and class II substances '' * * * shall insure that the transactions under the

authority of this section will result in greater total reductions in the production in each year of class I and class II substances than would occur in that year in the absence of such transactions.'' In compliance with this section, current regulations at 40 CFR 82.12 governing transfers of production and consumption allowances require one percent of the traded amount to be deducted from the transferor's unexpended allowances. EPA is proposing to amend the regulation so that in the case of EUA transfers, one tenth of one percent of the amount traded would be deducted from the transferor's account. EPA believes that given the relatively small amount of EUAs available for use in MDIs, and that providing sufficient EUAs for MDIs is critically important for protecting public health, deducting one percent of the amount of EUAs to be traded would be too high a penalty and may create a barrier against transferring EUAs freely. EPA believes that reducing the amount deducted from the transferor's account, would overcome this potential barrier. Therefore, with today's action EPA is proposing changes to regulations at § 82.12 to require that in the case of transferring EUAs, one tenth of one percent in excess of the amount traded would be deducted from the transferor's account.

How Can I Transfer EUAs From My Company to Another?

In order to complete a transfer of EUAs for CFCs from one essential use allowance holder to another, the transferor would have to submit to the Administrator a letter with the information requested in 40 CFR 82.12(a)(1). Under the regulations at 40 CFR 82.12 the transferor must submit to the Administrator a transfer claim with the following information:

1. The identities and addresses of the transferor and transferee.
2. The names and telephone numbers of contact persons for both the transferor and transferee.
3. The type of allowances being transferred, which in this case would always be essential use allowances.
4. The group of controlled substances being transferred, which would always be Group I.
5. The amount of allowances being transferred in kilograms.
6. The control period for which the allowances are being transferred (*e.g.* calendar year 2001).
7. The amount of unexpended essential use allowances for the current control period.
8. The amount of the 0.1% offset applied to the unweighted amount traded that will be deducted from the transferor's allowance balance.

Guidance documents and a sample letter which outlines the necessary information that a transferor must submit to EPA will be available through the Stratospheric Ozone Hotline at 1–800–296–1996.

As outlined in § 82.12, EPA will determine according to records maintained by the EPA ODS tracking system whether the transferor possesses as of the date of the transfer claim, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus one tenth of one percent of that amount). Within three working days of receiving a complete transfer claim, EPA will notify the transferor and transferee if the transferor has sufficient unexpended allowances to confer the transfer claim, and will issue a notice indicating that EPA does not object to the transfer. EPA will then reduce the transferor's balance of essential use allowances by the amount to be transferred plus one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer.

If EPA's records show that the transferor has insufficient unexpended allowances to cover the transfer claim, or that the transferor has failed to respond to one or more Agency requests to supply information needed to make a determination, EPA will issue a notice disallowing the transfer. Within 10 working days after receipt of notifications, either party may file a notice of appeal, with supporting reasons, to EPA, in which case EPA may either affirm or vacate the disallowance. If no appeal is taken by the tenth working day after notification, the disallowance shall be final on that day. (The transferor and transferee will be held liable in accordance with Title I, section 113 of the Act for any violations that occur as a result of an improper transfer.) In the event that EPA does not respond to a transfer claim within three working days of receipt of the completed claim, the transferor and transferee may proceed with the transfer and EPA will reduce the transferor's balance accordingly.

V. 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.

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

B. Executive Order 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)

This action does not impose any new information collection burden as defined by the PRA. The Office of Management and Budget's (OMB's) draft guidance on PRA states that a rule is exempt from OMB review if it ''explicitly applies to nine or fewer persons''. Since the reporting requirements in this rule are not of general applicability, and apply only to the eight entities receiving EUAs for CFCs only if a company decides to transfer EUAs to another essential use holder, we believe that this rule is exempt from the requirement of submitting an Information Collection Request and undergoing OMB review.

However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR 82.12 which set forth the process for inter-company transfers of consumption allowances under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0170 (EPA ICR No.1432.17). Copies of the ICR document(s) may be obtained from Sandy Farmer, by mail at the Office of Environmental Information, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the internet at http://www.epa.gov/icr. Include the ICR and/or OMB number in any correspondence.

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 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility

After considering the economic impacts of today's proposed rule on small entities, EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this rule. EPA has also determined that this action will not have a significant economic impact on a substantial number of small entities. This rule does not have a significant impact on a substantial number of small entities. The only entities that are directly affected by this allocation are those to which CFCs and other ODSs are being allocated. There are only ten entities which are affected by this rulemaking (see table 1 above). This rule does not have an adverse economic impact on any entity because it grants exceptions to a pre-existing ban.

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 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 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 432255, 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and theat preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This rule 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. This rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

List of Subjects in 40 CFR Part 82

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

Dated: September 29, 2000.

Carol M. Browner,

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 82.4 is amended by revising the table in paragraph (t)(2) to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva Americas, Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim	CFC–11 or CFC–12 or CFC–114	258.00
Glaxo Wellcome	CFC–11 or CFC–12 or CFC–114	858.10
Aventis	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	384.87
Sidmak Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.3
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

§ 82.12 [Amended]

* * * * *

3. Section 82.12 is amended by revising paragraphs (a) (1) introductory text, (a)(1)(i)(H), (a)(1)(ii) introductory text, (a)(1)(ii)(A), and (a)(1)(iii) to read as follows:

§ 82.12 Transfers.

(a) * * *

(1) Until January 1, 1996, for all class I controlled substances, except for Group VI, and until January 1, 2001, 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, and after January 1, 2001 any essential use allowance holder (''transferor'') may transfer essential use allowances for CFCs to any other essential use allowance holder for CFCs (''transferee'') solely for the production of essential products (defined at 21 CFR 2.125) as follows:

(i) * * *

(H) The amount of the one percent offset applied to the unweighted amount traded that will be deducted from the transferor's production or consumption allowance balance (except for trades from transformers and destroyers to producers or importers for the purpose of allowance reimbursement) In the case of transferring essential use allowances, the amount of one tenth of one percent of the amount traded will be deducted from the transferor's allowance balance.

(ii) The Administrator will determine whether the records maintained by EPA, taking into account any previous transfers and any production, allowable imports and exports of controlled substances reported by the transferor, indicate that the transferor possesses, as of the date the transfer claim is processed, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus, in the case of transferors of essential use allowances, one tenth of one percent of that amount, and in the case of transferors of production or consumption allowances, one percent of that amount). Within three working days of receiving a complete transfer claim, the Administrator will take action to notify the transferor and transferee as follows:

(A) If EPA's records show that the transferor has sufficient unexpended allowances to cover the transfer claim, the Administrator will issue a notice indicating that EPA does not object to the transfer and will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, or in the case of transfers of essential use allowances, one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer. However, if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

* * * * *

(iii) In the event that the Administrator does not respond to a transfer claim within the three working days specified in paragraph (a)(1)(ii) of this section, the transferor and transferee may proceed with the transfer. EPA will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, or in the case of essential use allowances, one tenth of one percent of that amount. However, if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

* * * * *

[FR Doc. 00–25745 Filed 10–5–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 403

[FRL–6883–1]

RIN 2090–AA16

Pretreatment Program Reinvention Pilot Projects Under Project XL

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Today EPA is proposing changes to the National Pretreatment Program regulations to allow Publicly Owned Treatment Works (POTWs) that have completed the Project eXcellence and Leadership (Project XL) selection process, including Final Project Agreement (FPA) development, to modify their approved local Pretreatment Programs. These POTWs would be allowed to modify their programs following the procedures in 40 CFR 403.18, and implement the new local programs as described in their FPAs.

In today's proposed rule, EPA recognizes that many POTWs with approved Pretreatment Programs have mastered the administrative and procedural requirements of the National Pretreatment regulations (40 CFR Part 403). Several of these POTWs want the opportunity to implement local pretreatment programs with effectiveness measured against environmental results rather than strict adherence to programmatic and administrative measures. These POTWs have expressed an interest in Project XL to test new pilot ideas that focus resources on activities that they believe would provide greater environmental benefits than are achieved by complying with current regulatory requirements. This rule is intended to provide the regulatory flexibility that will enable these test programs to move forward. Currently, five POTWs are actively involved in this Project XL process.

DATES: Public Comments: All public comments on the proposed rule must be received on or before November 6, 2000. Comments provided electronically will be considered timely if they are submitted electronically by 11:59 p.m. (Eastern time) November 6, 2000.

ADDRESSES: Comments should be addressed to ''Project XL/CWA Pretreatment,'' Water Docket MC–4101; United States Environmental Protection Agency, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Commenters are also requested to submit an original and 3 copies of their written comments as well as an original and 3 copies of any attachments, enclosures, or other documents referenced in the comments. Commenters who would like EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

EPA will also accept comments electronically. Comments should be addressed to the following Internet address: ow-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII, WordPerfect 5.1/6.1/8 format file and avoid the use of special characters or any form of encryption. Electronic comments will be transferred into a paper version for the official record. EPA will attempt to clarify electronic comments if there is an apparent error in transmission.

Supporting materials are also available for inspection and copying at U.S. EPA, Headquarters, 401 M Street, SW., Room 445 West Tower, Washington, DC 20460 during normal business hours. Persons wishing to view the materials at the Washington, DC location are encouraged to contact Mr. Chad Carbone in advance by telephoning (202) 260–4296.

FOR FURTHER INFORMATION CONTACT: Mr. Brian Frazer, (202) 260–0101, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania