transmissions and that have not yet filed initial notices are encouraged to file their initial notices prior to promulgation of the final rule and in no event later than December 1, 1999.

Regulatory Flexibility Act

Although the Copyright Office, located in the Library of Congress which is part of the legislative branch, is not an ''agency'' subject to the Regulatory Flexibility Act, 5 U.S.C. 601–612, the Register of Copyrights considers the effect of a proposed amendment on small businesses. For that reason, the Register is seeking to amend yet again 37 CFR 201.35(f) in order to allow small business entities that are eligible for the statutory license to make a timely filing of its initial notice of digital transmissions. The Register is seeking the amendment at the request of the NAB, an organization that represents the interests of numerous small broadcasters who were heretofore unaware of the filing requirement, and with the expectation that the NAB will make its members aware of the filing requirement and the proposed new deadline.

List of Subjects in 37 CFR Part 201

Copyright.

Proposed Regulation

For the reasons set forth in the preamble, it is proposed that part 201 of title 37 of the Code of Federal Regulations be amended as follows:

PART 201—GENERAL PROVISIONS

1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

2. Section 201.35(f) is amended by removing the date ''October 15'' and inserting in its place ''December 1''.

Dated: October 27, 1999.

David O. Carson,

General Counsel.

[FR Doc. 99–28509 Filed 11–1–99; 8:45 am]

BILLING CODE 1410–31–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6467–7]

RIN 2060–AI73

Protection of Stratospheric Ozone: Allocation of 2000 Essential Use Allowances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: With this action, EPA is proposing the allocation of essential-use allowances for ozone depleting substances (ODS) for the 2000 control period. The United States nominated specific uses of controlled ozone-depleting substances (ODS) as essential for 2000 under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Protocol). The Parties to the Protocol subsequently authorized specific quantities of ODS for 2000 for the uses nominated by the United States. Essential use allowances permit a person to obtain controlled ozone-depleting substances as an exemption to the January 1, 1996 regulatory phaseout of production and import. EPA allocates essential use allowances to a person for exempted production or importation of a specific quantity of a controlled substance solely for the designated essential purpose.

DATES: Written comments on this proposed rule must be received on or before December 2, 1999, 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 12, 1999. If a hearing is held, EPA will publish a document in the **Federal Register** announcing the hearing information.

ADDRESSES: Comments on this rulemaking should be submitted in duplicate (two copies) to: Air Docket No. A–92–13, U.S. Environmental Protection Agency, 401 M Street, SW., Room M–1500, Washington, DC 20460. Inquiries regarding a public hearing should be directed to the Stratospheric Ozone Protection Hotline at 1–800–269–1996.

Materials relevant to this rulemaking are contained in Docket No. A–92–13. The Docket is located in room M–1500, First Floor, Waterside Mall at the address above. 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, 401 M Street, SW., Washington, DC, 20460, 202–564–9079.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

How Are Essential Use Exemptions for Ozone-Depleting Substances Approved at the International Level?

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

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

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

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

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

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

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

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

countries' need for controlled substances.''

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.

What Are the Essential Uses That EPA Has Nominated in the Past?

Decision IV/25 was implemented initially in the context of halons which were phased out of production at the end of 1993. At that time, nominations for halons were separated from those for other ozone-depleting substances. EPA issued a **Federal Register** notice requesting nominations for essential uses of halons (February 2, 1993; 58 FR 06786). In response, the Agency received over ten nominations, but was able to work with applicants to resolve their near-term requirements. As a result, the U.S. did not nominate any uses for continued halon production in 1994. About a dozen other nations put forth nominations which were reviewed by the Panel, which determined that in each case alternatives existed or that the existing supply of banked halons was adequate to meet near-term needs. The Panel, therefore, did not recommend approval for any of the nominations. In November of 1993, at the Fifth Meeting, the Parties unanimously adopted the Panel's recommendation not to approve any essential uses for production and consumption of halons in 1994.

EPA issued a second notice requesting applications for essential use applications for halons for the 1995 control period on October 18, 1993 (58 FR 53722). In response to this inquiry, EPA received no applications. The TEAP received only one nomination (from France) for essential use exemptions for halons for production and consumption of halons for an essential use in 1995. The TEAP did not recommend approval of this nomination.

In 1993, EPA issued a **Federal Register** notice requesting essential use applications for CFCs, methyl chloroform, carbon tetrachloride, and hydrobromofluorocarbons required beyond the 1996 phaseout of consumption and production of these class I substances (May 20, 1993, 58 FR 29410). EPA received 20 applications in response to this notice. For several of these applications, EPA determined that the criteria contained in Decision IV/25 had not been satisfied. For example, EPA rejected two applications seeking CFCs for use in servicing air-conditioning equipment on the basis that adequate supplies of banked and recycled CFCs were available. However, in rejecting these nominations, the United States noted that servicing existing air-conditioning and refrigeration equipment remains a major challenge to the successful transition from ODSs and that a future nomination in this area might be necessary if a combination of retrofits, replacements, recycling, recovery at disposal, and banking do not adequately address these needs.

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

The TEAP reviewed over 200 specific uses which were submitted to the Montreal Protocol Secretariat by the Parties to the Protocol. In March 1994, the Panel issued the ''1994 Report of the Technology and Economic Assessment Panel,'' which included the Panel's recommendations for essential-use production and consumption exemptions. The Panel recommended that essential use exemptions be granted for nominations of: methyl chloroform in solvent bonding for the Space Shuttle; CFCs used in metered dose inhalers; and specific controlled substances needed for laboratory and analytical applications. For each of the other nominations submitted, the TEAP determined that one or more of the criteria for evaluating an essential use had not been satisfied. The Parties approved essential use exemptions for the uses recommended in the 1994 TEAP report. The U.S. has continued to request and receive exemptions for those same uses in subsequent years.

Have There Been Any Recent Changes to the Essential Use Process at the International Level?

At the Eighth Meeting of the Parties in 1996, a new timetable for nomination of essential uses was established in Decision VIII/9. This Decision states that Parties may nominate a controlled substance for an exemption from the production and consumption phaseout by January 31 of each year to the Ozone Secretariat. EPA has since issued **Federal Register** notices calling for essential use applications for class I controlled substances prior to the Protocol deadline for submission to the Ozone Secretariat.

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

What Does EPA Do With the Information in the Essential Use Applications?

The U.S. EPA carefully reviews all the information in each essential use application to ensure that it contains complete information in accordance with the Decisions of the Protocol Parties as reflected in the Handbook. EPA enters the information from each application into a tracking system which permits year by year comparison of quantities of ODS requested, quantities allocated, quantities of ODS received in previous years, and quantities of ODS used for the specific essential activity. The review of data enables EPA to assess whether entities are stockpiling ODS, whether there seems to be inflated requests relative to actual use, and whether there is possible double-counting between companies. For example, in 1998 we identified some double-counting in the requests for CFCs among companies. Our analysis also revealed that there were disparities between the total quantity of CFCs requested for MDIs and the actual quantity used to manufacture MDIs in previous years. To account for this inflation in the request for allocation, EPA reduced the total U.S. nomination for 1998 by 10 percent before forwarding them for consideration by the TEAP and the Parties to the Protocol.

EPA recognizes that since companies must project their need for CFCs almost two years in advance, the actual needs of a company may change in the interim. Therefore, prior to allocation, EPA consults with companies to ensure they still require the total amount of ODS requested. For example, in 1999

several essential use applicants voluntarily indicated that they would not require the total quantity of ODSs requested in their original application submitted to EPA.

Every year since 1994, EPA has reviewed applications for essential uses according to the above criteria and then forwarded the applications to the Parties. The Parties then review the recommendations by the Technology and Economic Assessment Panel and make final decisions on essential use nominations. Today's action follows decisions taken by the Parties after considering recommendations by the TEAP in 1998 and 1999.

II. Allocation of 2000 Essential Use Allowances

What Is EPA's Proposed Essential Use Allocation for the Year 2000?

In today's action, EPA is proposing allocation of essential use allowances for the 2000 control period to entities listed in Table I for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential use.

TABLE I.—ESSENTIAL USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 2000 AND ESSENTIAL USE ALLOWANCES

Company	Chemical	Quantity (metric tonnes)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC–11	588.0
	CFC–12	1516.0
	CFC–114	301.0
Medisol Laboratories, Inc.	CFC–11	70.0
	CFC–12	120.0
	CFC–114	10.0
Schering Corporation	CFC–11	330.0
	CFC–12	680.0
Sciarra Laboratories, Inc..	CFC–11	25.0
	CFC–12	75.0
	CFC–114	20.0
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket.	Methyl Chloroform	56.7
United States Air Force/Titan Rocket.	Methyl Chloroform	3.4
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply).	Class I Controlled Substances excluding CFCs, carbon tetrachloride, halons, and HBFCs (hydrobromoflouro carbons)	(1)

[1] No quantity specified.

The International Pharmaceutical Aerosol Consortium (IPAC) consolidated the essential use exemption requests of its member companies for administrative convenience. EPA will separately allocate essential-use allowances to each of IPAC's member companies.

In developing today's action, EPA considered allocating essential-use allowances in accordance with Decision X/6 of the Parties to the Montreal Protocol. Paragraph 2 of Decision X/6 states that the ''levels of production and consumption necessary to satisfy essential uses of CFC–11, CFC–12, CFC–113, and CFC–114, for metered-dose inhalers for asthma and chronic obstructive pulmonary diseases...are authorized as specified in annex I to the report of the Tenth Meeting of the Parties.'' Paragraph 5 of Decision X/6 goes on to say that ''the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group.'' Thus, EPA is considering allocating essential-use allowances for CFCs for the manufacture of metered-dose inhalers in the aggregate instead of on a compound-by-compound basis and seeks comments on this option. CFC–11, CFC–12 and CFC–114 all have an ozone depleting potential of 1.0, so an aggregate allocation of essential-use allowances for all these CFCs would add some flexibility for protecting patient health by allowing companies to better meet market demand for MDIs without causing additional damage to the stratospheric ozone layer.

How Did EPA Determine the Proposed Essential Use Allocation?

Applications submitted by the entities in Table I requested class I controlled substances for uses deemed essential for the 2000 control period. The applications provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the ''1997 Handbook on Essential Use Nominations.'' The applications requested exemptions for the production and import of specific quantities of specific class I controlled substances after the phaseout as set forth in 40 CFR 82.4. The U.S. government reviewed the applications and nominated these uses to the Protocol Secretariat for analysis by the Technical and Economic Assessment Panel (TEAP) and its Technical Option Committees (TOCs). The Parties to the Montreal Protocol approved the U.S. nominations for essential-use exemptions during the Tenth Meeting in 1998 (Decision IX/18). Today's action proposes the allocation of essential-use allowances to U.S. entities as authorized by the Parties to the Protocol and consistent with the Clean Air Act.

Does the Clean Air Act Permit Production and Import of Ozone-Depleting Substances for Essential Uses?

The Clean Air Act provides specific exemptions to the phaseout of ozone-depleting substances; unlike the Protocol, it does not provide for an open-ended essential use process. Thus, a use that is permitted under the Protocol may or may not be permitted under the Act. However, the Act's phaseout schedule for class I substances (except for methyl bromide) in Section 604 is less stringent than the Protocol phaseout schedule. For example, in 1999, three years after the phaseout of CFCs under the Protocol, the Act allows production of 15 percent of the baseline. (Note, however, that under EPA's regulations, the CFC phaseout date is the same as that under the Protocol in accordance with section 606 and 614(b) of the Act.) Thus, for the past several years, EPA has been able to authorize production and import of ozone-depleting substances for essential uses allowed under the Protocol, without regard to whether the Act contains exceptions for those uses, as long as the total authorized production does not exceed the amount permitted by the Act. However, January 1, 2000 is the phaseout date under Section 604 of the Act for all class I substances with the exception of methyl chloroform and

methyl bromide. The phaseout dates for methyl chloroform and methyl bromide are January 1, 2002 and January 1, 2005, respectively. After the phaseout date for a particular substance has passed, EPA will no longer be able to authorize production of that substance on the basis of the slower phaseout schedule under the Act.

The Act's provision for specific exemptions includes the following. Section 604 (d)(2) of the Act states that notwithstanding the phaseout, EPA shall, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of class I substances for use in medical devices, if FDA, in consultation with EPA, determines that such production is necessary. Section 604(d)(3) states that EPA may, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of halon-1211, halon-1301, and halon-2402 solely for the purpose of aviation safety, if the Federal Aviation Administration, in consultation with EPA, determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes. Section 604(d)(1) provides that during the period from January 1, 1992 to January 1, 2005, EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications for which no safe and effective substitute is available. Section 604(d)(4) states that EPA cannot use any of these three exemptions to authorize any person to produce a class I substance in annual quantities greater than 10 percent of that person's baseline year as defined in Section 601(2). Section 604(g)(3) of the Act provides that EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of halon-1211, halon-1301, and halon-2402 after December 31, 1999 and before December 31, 2004 for use in fire suppression and explosion prevention in association with domestic production of crude oil and natural gas energy supplies on the North Slope of Alaska, if it is determined that no safe and effective substitute has been developed and that such authorization is necessary for fire suppression or explosion prevention purposes. EPA cannot use this exemption to authorize any person to produce any of these halons in an amount greater than 3 percent of that person's baseline. Finally, section 604(f) states that the President may, to the extent consistent with the Montreal Protocol, provide an exemption for production of CFC -114, halon-1211, halon-1301, and halon-2402 as necessary to protect U.S. national security interests, if the President finds that adequate substitutes are not available and that the production and use of the substance are necessary to protect national security interests.

How Does the Allocation for the Year 2000 Differ From 1999 and Previous Years?

Each year, the Parties to the Protocol have approved an unlimited, global essential use exemption for the production and consumption of high purity ozone depleting substances for use in laboratory and analytical techniques. EPA has implemented this exemption domestically through regulation. However, beginning January 1, 2000 EPA may no longer be able to allow laboratory essential use exemptions for most Class I substances because the Act does not specifically list laboratory and analytical uses as an exception to the phaseout. Thus, as of January 1, 2000, EPA may no longer be able to grant laboratory essential use exemptions for CFCs, halons, carbon tetrachloride, or HBFCs, because the phaseout date under the Act for these substances is January 1, 2000. It should be noted, however, that EPA believes that the ban would apply only to the import and production of these class I ODSs and would not apply to their actual use in the laboratory. Therefore, EPA believes that laboratories could continue to use stockpiles of class I ODSs that were produced or imported prior to January 1, 2000. Trade among companies of class I ODSs that were produced or imported for laboratory uses prior to January 1, 2000 would be permitted. The supply of this subset of class I ODSs (which includes CFCs and carbon tetrachloride) after this date however, would be finite, and once domestic stockpiles are depleted, laboratories would cease to have access to these chemicals. EPA solicits comment on the above interpretation and other possible interpretations of the statutory requirements related to EPA's ability to grant essential use exemptions for laboratory and analytical uses.

For the year 2000, EPA is implementing the exception for medical devices found in section 604(d)(2) of the Clean Air Act. ''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].

EPA and FDA are discussing how best to interpret the above definition of ''medical device.'' With respect to part (A) of the definition (section 601(8)(A)), which relates to ''safe and effective alternative[s]'', 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. FDA's preamble points out, and EPA agrees, 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 to any other product. That requires a separate and distinct analysis.''

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 proposes to rely on current FDA regulations (21 CFR 2.125) which contain a list of uses of CFCs 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. The companies for which EPA is proposing to grant essential use allowances produce MDIs that are covered by one of the categories on FDA's essential use list. Thus, the products for which EPA is proposing to provide essential use allowances belong to the product categories ''determined to be essential'' by FDA.

Also with respect to part (B) of the definition of ''medical device'', EPA and

FDA are discussing at least two interpretations of the language regarding approval by FDA of the ''device, product, drug, or drug delivery system.'' First, one could interpret the word ''approved'' as referring to FDA's approval of the specific product in question through approval of the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for that product. Alternatively, one could interpret it as referring to FDA's approval of the same active moiety under that or any other NDA or ANDA. (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 derivatives (such as a complex, chelate or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.'')

The implications of adopting the first interpretation described above, would require EPA to have more information regarding product approvals. The 1997 TEAP Handbook on Essential Use Nomination is the guidance document used for application for essential use exemptions. Because this Handbook does not request companies to specifically list the products for which the CFCs will be used, EPA does not have the information necessary to determine whether the products are in fact ''approved'' by FDA. Therefore, EPA has sent out formal requests for this additional information under section 114 of the Act to the pharmaceutical companies who requested CFCs for the year 2000. If the first interpretation is adopted, EPA will analyze the data received from these letters and will not allocate CFCs in the final rule for those individual products that are not approved by FDA. The allocation in this proposed rule represents the amount allocated by the Parties to the Montreal Protocol at the Tenth Meeting of the Parties, and may be reduced in the final rule.

As stated earlier, 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. EPA and FDA are now discussing appropriate approaches to implementing the essential use exemption for medical devices. EPA's final essential use allocation for the year 2000 will be based on what FDA determines is ''necessary'' under section 604(d)2 of the Act.

The phaseout date for methyl chloroform under the Act is January 1, 2002. Until that date, the Act permits production and import of methyl chloroform equivalent to 20% of baseline. The amount of methyl chloroform allocated for 2000 is well below this limit. Beginning in the year 2002, EPA will implement the exception for essential uses of methyl chloroform found in 604(d)(1) of the Act.

What Reporting Requirements Must Be Followed for the Essential Uses of Ozone Depleting Substances?

Any person obtaining class I controlled substances after the phaseout under the essential use exemptions proposed in today's action would be 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.

III. Summary of Supporting Analysis

A. Unfunded Mandates Reform Act

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

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. Because this proposed 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 proposal does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12875: Enhancing the Intergovernmental Partnership

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

regulatory proposals containing significant unfunded mandates.''

Today's proposed rule does not create a mandate on State, local or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

C. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant'' regulatory action as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

D. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.16).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

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

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies or matters that significantly or uniquely affect their communities.''

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

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule would not have a significant impact on a substantial number of small entities since the rule allocates CFC's to specific entities which have previously submitted requests.

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

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

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant'' as defined under 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 proposed rule is not subject to Executive Order 13045 because it implements the phaseout schedule established by Congress in Title VI of the Clean Air Act.

H. 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 its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs

EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

I. Federalism

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, [64 FR 43255 (August 10, 1999),] which will go into effect on November 2, 1999. In the interim, the current Executive Order 12612, [52 FR 41685 (October 30, 1987),] on federalism still applies. Under this order, this proposed rule will not have a substantial direct effect upon States, upon the relationship between the national government and the States, or upon the distribution of power and responsibilities among the various levels of government. This proposed rule will affect only the production of controlled ozone-depleting substances by private entities.

List of Subjects in 40 CFR Part 82

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

Dated: October 26, 1999.

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

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 2000 AND ESSENTIAL USE ALLOWANCES

Company	Chemical	Quantity (metric tonnes)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC–11	588.0.
	CFC–12	1,516.0.
	CFC–114	301.0.
Medisol Laboratories, Inc.	CFC–11	70.0.
	CFC–12	120.0.
	CFC–114	10.0.
Schering Corporation.	CFC–11	330.0.
	CFC–12	680.0.
Sciarra Laboratories, Inc..	CFC–11	25.0.
	CFC–12	75.0.
	CFC–114	20.0.
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket.	Methyl Chloroform	56.7.
United States Air Force/Titan Rocket.	Methyl Chloroform	3.4.
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply).	Class I Controlled Substances excluding CFCs, carbon tetrachloride, halons, and HBFCs (hydrobromofluoro carbons)	No quantity specified.

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[FR Doc. 99–28506 Filed 11–1–99; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–2276, MM Docket No. 99–315, RM–9731]

Digital Television Broadcast Service; McAllen, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Entravision Holdings, LLC, licensee of station KNVO, NTSC Channel 48, McAllen, Texas, requesting the substitution of DTV channel 49 for its assigned DTV channel 46. DTV channel 49 can be substituted and allotted to McAllen, Texas, as proposed, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 26–05–20 N. and 98–03–44 W. However, since the community of McAllen is located within 275 kilometer of the U.S.-Mexican border, concurrence by the Mexican government must obtained for this allotment. DTV Channel 49 can be allotted to McAllen with a power of 200 (kW) and a height above average terrain (HAAT) of 288 meters.

DATES: Comments must be filed on or before December 20, 1999, and reply comments on or before January 4, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W., Room TW-A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Barry A. Friedman and Andrew S. Hyman, Thompson, Hine & Flory LLP, 1920 N Street, NW, Suite 800, Washington, DC 20036 (Counsel for Entravision Holdings, LLC).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–315, adopted October 26, 1999, and released October 27, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, S.W., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.