ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6952–1]

RIN 2060–AJ15

Protection of the Stratospheric Ozone: *De Minimis* Exemption for Laboratory Essential Uses for Calendar Year 2001

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to provide an exemption for laboratory and analytical essential uses for calendar year 2001. EPA has determined that an allowance for laboratory and analytical essential uses, which allows for the production and import of class I stratospheric ozone depleting substances (ODSs) beyond the phase-out of these substances, is allowable under the Clean Air Act as a *de minimis* exemption. Based on specific findings, EPA is amending the regulations on import and production of ODSs to reflect this determination and allocating a general global exemption for class I ODSs for laboratory and analytical essential uses for the year 2001. This action allows for the continued import and production of class I ODSs for essential laboratory uses necessary for protecting public health and the environment. EPA is issuing a companion proposal to this direct final rule elsewhere in this issue of the **Federal Register**.

DATES: This rule is effective on May 14, 2001 without further notice, unless EPA receives adverse comment by April 12, 2001. If we receive significant adverse comment on this rule, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Should you have any comments on this direct final rule submit them to: Margaret Sheppard, U.S. Environmental Protection Agency (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. If you send your comments via overnight express mail, send them to: Margaret Sheppard; 4th floor, 501 3rd Street NW; Washington, DC 20001. All comments will be filed in EPA Air docket number A–93–39. If your comments contain confidential business information, submit them directly to Margaret Sheppard in two versions: one clearly marked ''Public'' to be filed in the public 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. The materials may be inspected from 8 a.m. until 5:30 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 (800) 296–1996 or Margaret Sheppard, U.S. Environmental Protection Agency, Global Programs Division, Office of Air and Radiation (6205J), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; *sheppard.margaret@epa.gov;* (202) 564–9163 phone and (202) 565–2141 fax.

SUPPLEMENTARY INFORMATION: EPA is publishing this rule without specific prior proposal for calendar year 2001; we view this as a noncontroversial amendment and anticipate no adverse comment since we have already received comment on this issue in response to the proposed rule allocating essential use allowances for the year 2000 (64 FR 59144, November 2, 1999). With this action, EPA is taking the comments received on the proposed rule allocating essential use allowances for the year 2000 and applying them to a rulemaking determining a *de minimis* exemption for laboratory and analytical uses (''laboratory uses'') for the year 2001. This direct final amends 40 CFR 82.4. We are publishing a separate document that will serve as the proposal to this *de minimis* exemption for laboratory and analytical uses. This rule will be effective on May 14, 2001. If EPA receives adverse comment on this rule, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address any significant adverse comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

You may claim that information in your comments is confidential business information, as allowed by 40 CFR part 2. If you submit comments and include information that you claim as confidential business information, we request that you submit them directly to Margaret Sheppard in two versions: one clearly marked ''Public'' to be filed in the public docket, and the other marked ''Confidential'' to be reviewed by authorized government personnel only.

The regulated categories affected by this action include:

Category	SIC	NAICS
1. Medical and Diagnostic Laboratories	8071	6215
2. Research and Development in the Physical, Engineering, and Life Sciences	8731 and 8733	54171
3. Environmental Consulting Services	8999	54162

This table is not intended to be exhaustive but, rather, provides a guide for readers likely to be interested in this direct final rule. If you have any questions regarding the applicability of this direct final rule please consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Table of Contents

I. Notice of Proposed Rulemaking Summary
II. Overview of Comments
III. *De Minimis* Exemption for Essential Laboratory and Analytical Uses of Class I ODSs in 2001
IV. Criteria for Exempting Laboratory and Analytical Uses after December 31, 2001
V. Administrative Requirements
VI. Judicial Review
VII. Submittal to Congress and General Accounting Office

I. Notice of Proposed Rulemaking Summary

The Notice of Proposed Rulemaking (NPRM) published on November 2, 1999 (64 FR 59141), proposed the allocation of essential use allowances for class I stratospheric ozone depleting substances (ODSs) for specific uses agreed to by the Parties to the Montreal Protocol.[1] The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is an international

[1] This proposal addressed a number of ''essential uses'' of ODSs allowed under the Montreal Protocol, including ODSs used in metered dose inhalers, in the Space Shuttle and Titan Rockets, and laboratory and analytical methods. EPA issued an interim final rule for allowance allocations for the year 2000 for metered dose inhalers, the Space Shuttle, and Titan Rockets on January 6, 2000 (65 FR 716) and later finalized that rule on June 30, 2000 (65 FR 40524). In those final rules, we stated that we would address laboratory and analytical uses of ODSs in a separate final rule.

agreement to reduce and eventually eliminate production and consumption [2] of all stratospheric ozone depleting substances. Under both the Protocol and the Clean Air Act (''the Act''), 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. Under the Montreal Protocol and the Act, there was an original schedule for phasing out class I ODSs by January 1, 2000. (Table 2 in section 604(a) of the Act sets the amounts of class I ODSs that were allowed to be produced under the original schedule.) Later actions by the Parties, including the United States, accelerated the phase out of production and import of class I ODSs so that all developed countries had phased them out by January 1996. However, the Protocol and the 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 such determinations. Decision IV/25 states 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.

For the year 2001, the parties to the Montreal Protocol granted the U.S. essential use allowances for CFCs for use in metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease, methyl chloroform for use in the Space Shuttle and Titan Rockets, and a *global* essential use exemption for laboratory and analytical uses. Each Party nominates or requests essential use allowances for specific quantities of class I ODSs for medical devices and other essential uses. For laboratory uses, the Protocol allows for a ''global exemption''—that is, a general exemption for all laboratory and analytical uses meeting established criteria [3]—rather than requiring countries to nominate an amount to be used for laboratory and analytical uses. This ''global exemption'' for laboratory essential uses allows flexibility since it can be difficult to predict a nation's needs for laboratory research in advance. In today's rulemaking, EPA is implementing this ''global exemption'' as a general exemption for laboratory and analytical uses in the U.S.

EPA is responsible for allocating essential use allowances in the U.S. through rulemaking in accordance with provisions in the Act. From 1996 through 1999, EPA implemented the Montreal Protocol's laboratory exemption under the authority of the original phase-out schedule specified in the Act at section 604(a). Under section 604(a), Table 2, EPA could authorize production and import of carbon tetrachloride and other class I ODSs in amounts that did not exceed 15 percent of the baseline amount for each substance (the amount of CFCs and halons consumed in 1986 is the baseline amount for these chemicals, and the amount of carbon tetrachloride consumed in 1989 is the baseline amount for this chemical) through 2001 for methyl chloroform and through 1999 for all other class I ODSs. The actual amounts of class I ODSs previously supplied to laboratories under this global essential use exemption are listed in Table III below. These amounts were far below 15 percent of baseline for these substance (See Table III for the quantities of class I ODSs supplied to laboratories under this previous essential use exemption versus the baseline amount of each chemical as defined at 40 CFR 82.6.) EPA implemented the laboratory use exemption as part of the phase-out described in section 604(a) without granting a specific allocation.

The original phase-out schedule specifies that production and consumption of carbon tetrachloride and other class I substances should be zero in the year 2000. While section 604(d) does provide explicit exemptions to the ban on production and consumption of class I ODSs for use in medical devices and various other uses such as halons for aviation safety, and methyl chloroform for nondestructive testing of metal fatigue, the Act does not explicitly provide or prohibit an exemption for laboratory and analytical uses. Thus, in the November 2, 1999 proposed rule allocating essential use allowances for calendar year 2000, we identified the possibility that in the year 2000 and beyond, EPA might not be able to provide a laboratory essential use exemption under section 604(d) for most class I ODSs, including CFCs, halons, carbon tetrachloride, or hydrobromofluorocarbons (HBFCs).

We also explained in the proposal that the ban would apply only to the import and production of class I ODSs for laboratory uses and would not apply to their actual use in the laboratory. Thus, laboratories could continue to use stockpiles of class I ODSs produced or imported prior to January 1, 2000, and lab suppliers could continue to buy and sell laboratory grade class I ODSs held in stock to laboratories. We also stated that if EPA determined in the final rulemaking that essential use exemptions for laboratory uses were no longer available, the supply of this subset of class I ODSs would be finite, and once domestic stockpiles were depleted, laboratories would cease to have access to these chemicals. Finally, EPA solicited 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.

II. Overview of Comments

EPA initially received three comments concerning laboratory uses in response to the NPRM published on November 2, 1999.[4] One commenter, who represents research-based

[2] ''Consumption'' is defined as the amount of a substance produced in the United States, plus the amount imported, minus the amount exported to Parties to the Montreal Protocol (*see* section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced prior to the 1996 phase-out can continue to be used for purposes not expressly banned at 40 CFR part 82, subpart C-Ban on Nonessential Products Containing Class I Substances and Ban on Nonessential Products Containing or Manufactured with Class II Substances.

[3] EPA has previously adopted the United Nations Environment Programme's recommendations for criteria for and conditions on the exemption for laboratory and analytical uses in appendix G of subpart A of 40 CFR part 82. Under these criteria, the following laboratory purposes qualify for the exemption: equipment calibration; use as extraction solvents, diluents, or carriers for chemical analysis; biochemical research; inert solvents for chemical reactions, as a carrier or laboratory chemical; and other critical analytical and laboratory purposes.

[4] The three commenters were the Pharmaceutical Research and Manufacturers of America, Hoffmann-La Roche, Inc., and Gardner, Carton & Douglas, representing the CFC Consortium.

pharmaceutical and biotechnology companies, stated that EPA can and should continue to allow a laboratory use exemption for all ODSs in order to ensure that research on new materials is as unrestricted as is reasonably possible. The commenter said that the ability to purchase and to import small quantities of various ODSs may be necessary in early stages of research on new compounds since in synthesizing some chemicals, it may be difficult to obtain the desired reaction product if an ODS cannot be used as a reagent. According to the commenter, while companies' efforts for developing compounds may devote the time and resources necessary to redesign the approach for synthesizing a chemical in the later stages, for the early stages of developing compounds, the turnover and attrition rates are so high that an inability to purchase a critical starting material may result in leaving unexplored an entire category of potentially therapeutic molecules. According to the commenter, a verbal survey of pharmaceutical companies turned up only a few who had purchased any ODSs for laboratory use in the last two or three years. These instances were one-time purchases of a few grams of material for use in research. In at least one case during 1999, the material had to be imported, as it was not available for purchase within the United States. The commenter believes that manufacture and importation at this rate of usage represent a legitimate *de minimis* activity, especially when contrasted with the ODS released by a single refrigerant leak from a large chiller. The commenter believed that EPA should continue to allow the manufacture and importation of all ODS for laboratory and analytical use, subject to the limitations in 40 CFR part 82, subpart A, appendix G.

The second commenter is a pharmaceutical company who also opposes the deletion of EPA's previous essential use exemption for laboratory and analytical uses, and asks that EPA provide a *de minimis* exemption for class I ODSs for these uses. This commenter stated that the use of carbon tetrachloride is critical as a laboratory solvent and co-reagent in laboratory synthetic development procedures involving the reduction and dehydration of certain intermediates that lead to derivatives used in research and development programs for test drugs. They stated that although it may be possible to substitute other solvents for these uses, any transition would require a commitment of additional time and resources, and success cannot be assured. This commenter also stated that carbon tetrachloride is one of the only solvents for Nuclear Magnetic Resonance (NMR) analytical chemical procedures used to elucidate the molecular structure of certain complex organic chemicals. Finally, this commenter stated that the total quantity of carbon tetrachloride currently used in these laboratory synthetic and analytical procedures is estimated to be 16 liters annually, most of which is ultimately disposed for treatment as hazardous waste. This commenter also stated that EPA can allow the laboratory use exemption under the Act, which provides a basis for a *de minimis* exemption according to the Court in *Alabama Power Company* v. *Costle* (636 F. 2d 323, 360–61 (D.C. Cir. 1979)), when the ''burdens of regulation yield a gain of trivial or no value.''

Another commenter, a consortium that represents pharmaceutical companies who produce metered dose inhalers, urged EPA to retain the laboratory-use exemption at least for the narrow purpose of testing those CFCs which are destined for use in metered dose inhalers (MDIs). MDI manufacturers are required by the Food and Drug Administration (FDA) to test each batch of CFC propellant used in MDIs to assure that the CFCs conform to various specifications, including limits on impurity levels. The commenter stated that removing the laboratory-use exemption would substantially and unnecessarily complicate the process of acceptance testing for MDIs for companies that manufacture the MDIs in Europe and then import them to the U.S. The commenter believed that under the proposal, such companies would need to request and receive a special essential-use allowance allocation for a minuscule amount of CFCs used to test the MDIs in the U.S., rather than relying upon the laboratory use exemption.

This commenter stated that EPA is not restricted to granting exemptions to those enumerated in section 604(d) of the Act, and that the Agency could consider a *de minimis* exemption. The commenter also suggested that CFCs imported to the U.S. to be analyzed as to whether they meet the FDA specifications for use in metered dose inhalers could be exempted using the authority at 604(d) of the Act. This section of the Act provides an exemption for import and production of CFCs for use in medical devices. In particular, the commenter stated that the use of CFCs for use ''in'' a medical device, an exempt essential use under section 604(d)(2), could include the CFCs used for laboratory testing as part of the CFCs used in the manufacture of MDIs.

EPA agrees that a *de minimis* exemption for laboratory essential uses is appropriate, for the reasons described below in section III. Because we are addressing the wider issue for all laboratory uses of class I ODSs, we do not believe it is necessary at this time to decide whether CFCs (Class I ODSs) used to test MDIs fall under the medical device essential use exemption of section 604(d)(2). Companies can rely upon the laboratory use exemption to obtain CFCs for acceptance testing of MDIs.

Because of the small number of initial comments, we felt it would be important to gather additional stakeholder input on the laboratory use portion of the rule while finalizing the year 2000 allocation of essential use allowances for metered dose inhalers and the Space Shuttle and Titan Rockets. The interim final rule allocating essential use allowances for the year 2000 for use in metered dose inhalers and the Space Shuttle and Titan Rockets was published on January 6, 2000 (65 FR 716), and the final rule was published on June 30, 2000 (65 FR 50524).

EPA solicited additional stakeholder input on the laboratory essential use exemption by working with Sigma Aldrich, a major supplier of class I ODSs for laboratory uses. Sigma Aldrich posted a notice on their website stating that EPA was proposing to disallow the import and production of class I ODSs for use in laboratory and analytical uses, and that EPA would consider comments on this issue. In response to the Sigma Aldrich announcement, EPA received over 70 comments requesting that EPA continue to allow lab uses of class I ODSs in the year 2000 and beyond. (Comments are posted in docket # A–93–39.)

One group of commenters stated that an exemption for laboratory and analytical uses for class I ODSs is critical because many regulatory programs within the EPA and at the state level require that various pollutants, including class I ODSs such as carbon tetrachloride and certain CFCs, be monitored in water, air and soil. These programs include those promulgated under the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). In order to test for the presence and quantify the amount of any chemical in water, soil, or air, the testing equipment must be calibrated using high purity samples of

the chemical of interest as a standard. Then testers must analyze a sample of water, soil, or air using the specific methodology for identifying concentrations of the chemical established by various public health agencies including EPA. As explained more fully in section III below, EPA agrees that these types of monitoring tests do require the use of certain CFCs and that it is appropriate to grant an exemption for these types of essential laboratory uses.

Table I below contains EPA statutes and environmental testing regulations which require testing for various class I ODSs. As such, calibration standards of class I ODSs are necessary to determine whether the contaminant is present in the sample, and it is not possible to create an alternative test method that uses no class I ODSs.

TABLE I.—ENVIRONMENTAL TESTING AND MONITORING METHODS USING CLASS I ODSS AS CALIBRATION STANDARDS

Authority	Environmental testing programs	Test Method
Clean Water Act	Volatile organic compounds in water and surface water; National Pollutant Discharge Elimination System; National Primary Drinking Water Standards—Testing for volatile organic compounds in water.	Methods 502.2, 524.2, 551.1, 601, 624, 5035 CLP for volatile organic compounds in water.
Clean Air Act	Hazardous Air Pollutants; Air Toxics; National Ambient Air Quality Standards—Photochemical Air Monitoring Stations (PAMS) program.	Methods TO–14 and TO–15 for volatile organic compounds in air.
RCPA/CERCLA	Solid waste	Methods 8021B, 8260 for carbon tetrachloride in soil and solid waste.
Occupational Safety and Health Act.	NIOSH/OSHA National Institute for Occupational Safety and Health/Occupational Safety and Health Administration.	Method 1020: for CFC–112a and CFC–112 in air Method 1003: for halogenated hydrocarbons in air, including carbon tetrachloride Method 1018: for CFC–12 in air.

Table II below contains statutes and the environmental testing regulations which require testing methods that use class I ODSs as extractants or solvents. In the future, the Agency believes it may be possible to use alternatives to some of these testing methods that would not require class I ODSs:

TABLE II.—TESTING METHODS THAT REQUIRE CLASS I ODSS AS EXTRACTANTS OR SOLVENTS

Authority	Environmental testing program	Test method
Occupational Safety and Health Administration	NIOSH/OSHA	Method 5026: Measurement of mineral oil mist in air.
Clean Water Act	National Pollutant Discharge Elimination System.	Method 418.1 Petroleum Hydrocarbons, Total Recoverable; Method 413.1[5] and 413.2, Oil and Greast, Total Recoverable.

[5] Method 1664 Revision A does not use class I ODSs and is available as an alternative to methods 413.1. Guidance documents on this test method may be accessed at *http://www.epa.gov/ost/methods/oil.htm1*. This alternative method has been available since mid-1999, a relatively short time. EPA is still in the proces of informing testers that this alternative method is available and that methods 413.1 and 413.2 are no longer the only acceptable tests to meet EPA requirements. Testers require time to adjust to learning the new test procedures, using new equipment and using up or replacing existing stocks of CFC–113. Therefore, the Agency believes that it is appropriate to continue to allow methods 413.1 and 413.2 as essential laboratory uses for calendar year 2001. As discussed below in section IV, this may no longer be true beginning with calendar year 2002.

The second group of comments that EPA received was from researchers who utilize class I ODSs in small quantities in the laboratory for a wide variety of basic science research applications. These commenters stated that restricting the availability of carbon tetrachloride and CFCs for laboratory use would be a major impediment to scientific research, and would put U.S. academic and industrial researchers at a great disadvantage. They also stated that carbon tetrachloride and CFCs have long played central roles in a wide variety of investigations involving these compounds as gas phase samples, solutes, or solvents, and have been essential in developing a proper understanding of a broad range of chemical properties and processes whose significance extends throughout all basic and applied chemical sciences. A few commenters noted that decreased availability of CFCs and carbon tetrachloride would significantly restrict the range of compounds available for pharmaceutical design and would restrict the development of potentially life-saving therapies. Finally, many commenters stated that the amount of class I ODSs used in research settings is very small. Some commenters provided estimates of the amount of CFCs and carbon tetrachloride used in their particular laboratory uses in a year. These estimates ranged from as little as twenty-five milliliters or a few grams, from estimates of some smaller, academic laboratories, to a maximum of fifty-three liters, for a large pharmaceutical firm.

All commenters, with one exception, urged EPA to continue to provide an essential use exemption allowing continued production and import of class I ODSs for laboratory and analytical uses. Many stated that the majority of responsible researchers store the chemical waste in sealed bottles, so ODSs used in lab applications typically are not emitted into the atmosphere. One commenter estimated that only 0.4% to 10% of carbon tetrachloride, the most commonly used ODS in laboratories, was emitted to the atmosphere rather than recovered. Again, for the reasons set forth below in section III, EPA has determined that a de minimis exemption is appropriate for essential laboratory uses in 2001. Part of the rationale for this determination is that the controls in place, as noted by the commenters and as required in appendix G, provides adequate

assurances that very little, if any, environmental damage will result from the handling and disposal of the small amounts of class I ODSs used in laboratory applications.

In summary, commenters stated there are no adequate alternatives for class I ODS in the following applications:

1. Carbon tetrachloride:

(a) Liver toxicity research.

(b) Research into the functioning of enzymes related to biodehalogenation, and the study of metabolic routes leading to toxic effects.

(c) Low molecular weight halogenated compounds including some class I ODSs are transformed into synthetic ''building blocks,'' a useful strategy for the development of new medicinal and pharmacological agents.

(d) As an extractant for organic synthesis and purification, as well as unreactive solvents for carrying out fundamental chemical studies.

(e) As a medium to carry out enzymatic reactions.

(f) As a solvent for procedures such as benzylic halogenation.

(g) For use in Nuclear Magnetic Resonance Spectroscopy (NMR) (Carbon tetrachloride is critical for this use since it is necessary to use a solvent containing no hydrogen atoms for testing certain materials.)

(h) In the chemical separation of osmium for geological research which is a critical step used in determining the absolute age of rocks, minerals, and meteorites.

2. Various CFC compounds, including CFC–113:

(a) Preparation of kidney tissue for studying the pathogenesis of kidney disease.

(b) In the study of electrostrictive stimulated Rayleigh scattering using lasers.

(c) Preparation of antiproliferative glycolypids and analogs of KRN7000, both of which have potential as anti-cancer agents.

(d) Preparation of adenoviral vectors for gene therapy.

(e) Biochemical investigations into the mechanism of enzyme action.

(f) Hydrologic age dating to determine the pathway and persistence of ground water contamination by other synthetic chemicals.

The one commenter who believed no exemption was necessary stated that there are alternatives available and that CFCs and carbon tetrachloride do not need to be available for laboratory and analytical uses. EPA disagrees. For nearly all laboratory uses identified, such as class I ODSs used as calibration standards, there are no alternatives available. Because the use of class I ODSs are necessary to provide the public with important environmental and health testing, EPA believes that an essential use exemption for laboratory uses is justified for 2001. For the one testing method where we are aware of an alternative method that does not require class I ODS, the method for testing oil and grease in water, the Agency believes that users should switch to the alternative method as soon as is reasonably possible.

EPA received one comment stating that because environmental testing laboratories are required to conduct testing using methods specified by EPA using class I ODS, the taxes placed on these substances should be waived since the laboratory has no alternative method available to them. Under the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, section 7506, Congress imposed a new federal tax on CFCs and other ODSs to encourage cuts in consumption of these chemicals and to promote the development of alternatives. EPA does not have the authority to waive this or any other tax.

III. *De Minimis* Exemption for Essential Laboratory and Analytical Uses of Class I ODSs in 2001

With today's action, EPA is making the determination that continued import and production of class I ODSs for laboratory and analytical uses in 2001 is allowable as a *de minimis* use under the Act for the following reasons:

1. The amount produced for this use is infinitesimal and trivial when compared to the amount of class I ODSs produced prior to the regulatory ban in 1996 when baseline production allowances of class I ODS totaled 10,840 metric tons for carbon tetrachloride, and 322,558 metric tons for all CFCs. Furthermore, the amount of class I ODS used for laboratory uses is approximately two orders of magnitude smaller than the amount used for metered dose inhalers, and about the same order of magnitude as the amount of methyl chloroform used in the Space Shuttle and Titan Rockets, both of which receive an essential use exemption. (For a comparison of the amounts, see Tables III and IV below.)

2. The continued production of small amounts of class I ODSs is essential for a number of analytical tests mandated by EPA and other public health agencies as part of programs for protecting the environment and human health.

3. The nature of these laboratory and analytical applications involves extremely controlled use and disposal of all chemicals, including any ODSs. As a result, emissions of the ODSs into the atmosphere are negligible.

4. The class I ODSs, specifically carbon tetrachloride and CFCs, are used in small quantities for a myriad of uses in basic science research and medical research. Disallowing the essential use allowances for these uses would inhibit important scientific innovations with important public health benefits such as developing new drug therapies and research into liver pathogenesis.

In addition to these reasons, EPA believes that a *de minimis* essential use exemption for laboratory and analytical uses in calendar year 2001 is appropriate because:

(A) EPA recognizes the limited grounds for the creation of a *de minimis* exemption, but believes such grounds exist by the very nature of the statutory language contained in Title VI of the Act, specifically section 604. In addition to the general production phase out in section 604(a), Congress, by operation of section 604(d), also provides for exemptions where limited uses would serve an important public need. EPA believes that the laboratory uses noted today are very similar to the exemptions provided in 604(d) and serve similar public purposes. It should be noted that section 604(d) provides for specific exemptions, but by its express language it does not preclude other exemptions. Courts have consistently held that where Congress has not expressly prohibited an exemption there is likely to be a basis for the justification of *de minimis* authority to provide an exemption when the burdens of regulation yield a gain of trivial or no value. (See *Alabama Power Company* v. *Costle* (636 F.2d 323, 360–61 (D.C. Cir. 1979); *Environmental Defense Fund* v. *EPA* (82 F.3d 451, 465 (D.C. Cir. 1996)). In addition to providing essential laboratory needs as noted above, EPA also believes that the ban of ODSs for laboratory uses would produce trivial environmental benefit.

(B) As noted below in Table III of this preamble, EPA expects there to be very small quantities of ODSs actually consumed under this exemption and such quantities are well below the cap for certain exemptions contained in section 604(d). In light of the conditions already applied to the global exemption by appendix G to subpart A of 40 CFR part 82, EPA believes that any additional controls on laboratory uses would provide little, if any, benefit. Appendix G also sets forth the limited laboratory uses for the import or new production of ODSs.

(C) EPA believes a *de minimis* exemption in this circumstance is also consistent with the language and intent of section 614(b). Although this section requires EPA to implement both the

Montreal Protocol and the Clean Air Act, and in cases of conflict to implement that which is more stringent, it is believed that the guidelines set forth in Decision IV/25 and in appendix G of subpart A of 40 CFR part 82 provide stringent controls on how the categorical exemption for laboratory uses shall be applied. Therefore, EPA believes it is meeting its legal obligations and will continue to assess annually whether such laboratory uses are indeed essential.

(D) As noted above, the use of ODSs are required in many environmental and health tests mandated by the government. The requirements of these tests would go unfulfilled should EPA implement only the language contained within the Act. Therefore, EPA believes it is appropriate to use the *de minimis* ''tool'' to avoid this otherwise inherent conflict. The courts have held that the ''literal meaning of a statute need not be followed where the precise terms lead to absurd or futile results, or where failure to allow a *de minimis* exemption is contrary to the primary legislative goal.'' (See *State of Ohio* v. *EPA* (997 F.2d 1520, 1534 (D.C. Cir. 1993); *Public Citizen* v. *Young* (831 F.2d 1108 (D.C. Cir. 1987)). Given the number of environmental and health statutes with laboratory tests which require the use of ODSs it is likely that Congress did not intend for a ban on such uses by the provisions set forth in the Clean Air Act.

Based on these considerations, EPA is allocating a *de minimis* exemption for all laboratory and analytical uses for production and import of class I ODSs for the year 2001. There is no cap on the amount that may be produced or imported for the year 2001, consistent with the Montreal Protocol's treatment of laboratory uses. Laboratory and analytical uses must meet the conditions and criteria described in appendix G of subpart A of 40 CFR part 82. We will continue the same monitoring and reporting requirements for 2001 that we previously finalized on August 5, 1998 as part of the regulations for the phase out of class I ODSs at 40 CFR 82.13 (u) through (z) (63 FR 41625). These requirements are described below.

Environmental Impact of the Laboratory Essential Use Exemption

As illustrated by Table III, the quantity of class I ODSs supplied to various laboratories in the U.S. under the general essential use exemptions in the year 1996 through 1999 have been extremely small. These quantities are small even when contrasted with the relatively small quantities of class I ODSs used in the U.S. in metered dose inhalers and for the Space Shuttle and Titan Rocket, both essential uses for which the Act provides a specific exemption (see Table IV). The Act at section 604(d)(3) also provides an exemption for the use of halon-1211, halon-1301, and halon-2402 for the purposes of aviation safety.

TABLE III.—AMOUNT OF CLASS I ODSS SUPPLIED TO LABORATORIES IN THE U.S.

Chemical	Ozone depleting potential	Baseline consumption allowance (metric tons) as defined by 40 CFR 82.6	Amount of chemical supplied to labs by year [3] (metric tons)			
			1999	1998	1997	1996
CFC–11	1	91,976	0.143	0.11	0.2	0.15
CFC–12	1	148,398	< 0.001	< 0.001	< 0.001	< 0.001
CFC–112	1	5.9	< 0.001	< 0.001	< 0.001	< 0.001
CFC–113	0.8	71,072	2.761	7.052	11.478	4.478
CFC–114	1	5,171	0.007	0.002	0.006	0.007
CFC–115	.001	5,935	< 0.001	< 0.001	< 0.001	0.001
Carbon tetrachloride	1.1	10,840	9.248	6.694	9.535	10.326
Methyl Chloroform	0.1	255,991	2.413	2.269	6.695	4.591
Methyl Bromide	0.7	109	0.014	0.031	0.007	0.023
Hydrobromo-fluorocarbons (Group VII Class I ODSs)	(*)	40	0.003	0.008	0.004	0.014

[3] Data taken from U.S. EPA ODS Tracking System.
* Varies with specific chemical.

TABLE IV.—AMOUNT OF CLASS I ODSS USED FOR ESSENTIAL USES OTHER THAN LABORATORY AND ANALYTICAL USES IN THE U.S.[2]

Year	Amount of CFCs (CFC–11, CFC–12, and CFC–114) used in MDIs	Amount of methyl chloroform used in the space shuttle and Titan rockets
1999	2630 metric tons	11 metric tons.
1998	2425 metric tons	6.4 metric tons.
1997	2255 metric tons	24.5 metric tons.
1996	2368 metric tons	0 metric tons.

The amounts of class I ODSs that have been used for laboratory uses is approximately two orders of magnitude smaller than the amount used for metered dose inhalers, and about the same order of magnitude as the amount of methyl chloroform used in the Space Shuttle and Titan Rockets. The amount of class I ODS used for laboratory uses is four to six orders of magnitude smaller than the baseline amounts which represent the amount of class I ODSs used prior to the complete ban under the phase-out. EPA believes that Congress did not intend to create a conflict between enforcing programs under the Clean Water Act, the Resource Conservation and Recovery Act, the Clean Air Act, and the Comprehensive Emergency Response, Compensation and Liability Act which require the use

of class I ODSs as calibration standards, and enforcing a complete ban on production of class I ODSs under Title VI of the Act. EPA believes that preventing the use of ODSs to ensure compliance with environmental statutes uses is contrary to the public welfare and is trivial in terms of the total amount of ODS emitted into the atmosphere. In addition, the Agency believes that the public benefit of allowing the continued use of class I ODSs for basic science research far outweighs any potential environmental damage by the very small amount of ODSs emitted into the atmosphere through this use.

Environmental Benefits of Allowing a de Minimis Exemption for Laboratory and Analytical Uses

As discussed above, EPA and other public health agencies require testing for many different pollutants in the air, water, and soil, including carbon tetrachloride and other class I ODSs. Many environmental remediation and testing programs require monitoring of carbon tetrachloride, a toxic chemical which causes liver damage and which EPA classifies as a probable human carcinogen. Carbon tetrachloride and other class I ODSs are often used in laboratories to prepare standards to verify that testing and monitoring equipment reads correctly. Comparison against the standard ensures that the testing equipment accurately determines the presence of a particular class I ODS and its concentration in a sample. The use of analytical standards is critical to detecting the class I ODSs at a concentration near permit limits.

Table I lists analytical methods requiring carbon tetrachloride or other class I ODSs under wastewater discharge, waste management and air permit programs. In addition to these analytical test method requirements, identification of historical contamination sites often includes sampling of soil and groundwater and analyses for chlorinated compounds such as carbon tetrachloride or other class I ODSs. Ongoing remediation programs, where a class I ODS may be a constituent of concern, would be adversely affected by disallowing a laboratory essential use exemption. Without high purity standards, it would be impossible to analyze samples with the accuracy required to identify and implement an appropriate remedy or to correctly monitor the progress of the remediation program for these compounds.

CFCs and other class I ODSs are also required as a solvent or extractant in tests for other pollutants in environmental and worker safety programs. (See Table II for examples.) In some cases, the tests themselves mandate the use of class I ODSs. Until and unless alternative test methods can be developed and approved by the applicable governing agencies, laboratories will continue to need class I ODSs for these required test methods. It may take many years to develop some of these alternative testing methods, and in some cases, it may not be possible to find alternatives. The Technical and Economic Assessment Panel for the Montreal Protocol periodically reviews the need for specific analytical methods and seeks alternative testing methods that do not require class I ODSs. In each case where an alternative method becomes available, regulators will need time to adopt the alternative method and testers will require time to learn about and to switch to the alternative testing method. As discussed below in section IV and above in section II, footnote 5, EPA expects this to occur for one particular method used in the U.S. for testing oil and grease in water.

Current EPA and Occupational Safety and Health Administration (OSHA) regulations have put in place testing requirements to protect the environment and human health. EPA believes that it would be contrary to the public welfare to prevent testing that requires using class I ODSs when those tests protect the environment and human health unless the hazards of keeping the class I ODSs outweigh the benefits of these environmental tests. Because of the small amounts of class I ODSs required for this testing and because these uses emit little or no ODSs, we believe that the benefits of health and environmental tests significantly outweigh the potential damage to the ozone layer by allowing the use of class I ODSs in these tests. The Montreal Protocol currently allows for such testing through 2005. Also, the Agency believes that until alternative test procedures are approved that do not require class I ODSs, preventing use of the class I ODSs needed to perform required environmental testing would create an untenable situation for many laboratories and state and local environmental and public health agencies.

Finally, calibration standards of class I ODSs are critical for enforcement of Title VI, the portion of the Act which protects stratospheric ozone. Calibration standards are necessary to calibrate the chemical identification devices that customs agents use to test whether imports of chemicals are properly labeled and are legal imports of class I ODSs. Without calibration standards available, the ability of the customs agents to properly identify class I ODSs would be compromised as would the ability of the U.S. to enforce the Act and the Montreal Protocol.

Benefits in Allowing Laboratory Essential Use Allowances for Medical and Basic Science Research

Despite the very small quantities of class I ODSs used for basic science research, the Agency believes that disallowing production and import of class I ODSs would needlessly disadvantage scientists pursuing important discoveries, for example:

(1) Investigating potential new drug therapies. A class I ODS sometimes is necessary to synthesize various compounds to investigate efficacy at an early stage of research on the new drug. Not allowing access to class I ODSs by removing the exemption for laboratory uses could slow the development of promising treatments for a variety of medical problems.

(2) Carbon tetrachloride has been used for many years to induce liver damage in rats as a model for liver disease in humans. Use of a different chemical would yield non-comparable results to previous studies, which would adversely affect research on this topic in the U.S.

(3) Carbon tetrachloride is considered the ideal solvent in analytical procedures using Nuclear Magnetic Resonance to determine the molecular structure of organic substances. Organic compounds can be potentially useful in a variety of applications, such as vitamins, dietary supplements and flavorings.

(4) Carbon tetrachloride is essential in determining the age of geologic formations. Such research is useful for understanding the geology of an area.

Laboratory and Analytical Uses of Ozone Depleting Substances Considered Essential Under the Global Exemption for 2001

The United Nations Environment Programme (UNEP) recommended criteria for and conditions on the exemption for laboratory and analytical uses. EPA adopted these recommendations in appendix G of subpart A of 40 CFR part 82 as part of the regulations for phasing out class I ODSs. Under the criteria of this appendix, the following laboratory uses qualify for the exemption: Equipment calibration; use as extraction solvents, diluents, or carriers for chemical analysis; biochemical research; inert solvents for chemical reactions, as a carrier or laboratory chemical; and other critical analytical and laboratory

purposes. Class I ODSs used in manufacture of a product in a laboratory do not qualify for this exemption.

Appendix G of subpart A of 40 CFR part 82 also specifies certain conditions for laboratory uses of class I ODSs under the exemption. The class I ODSs must meet standards of purity (at least 99.0 or 99.5 percent purity, depending on the substance). The class I ODSs may then be mixed with other chemicals as they are customarily used in the laboratory. The class I ODSs or mixtures must be supplied in particular kinds of containers (re-closable containers or high pressure cylinders smaller than three liters or in glass ampules of 10 mm or less). These containers must be marked clearly as substances that deplete the ozone layer which are restricted to laboratory use and analytical purposes. In addition, there are requirements for recycling and disposal. Finally, the Parties, including the U.S., have requirements for reporting the purity, quantity, and test procedures required for each class I ODSs, the efforts for eliminating its use, and regulations or other requirements on controlled substances.

EPA believes that appendix G of subpart A of 40 CFR part 82 clarifies the allowable, essential uses of class I ODSs under the global exemption for laboratory and analytical essential uses. We continue to require that the conditions of this appendix apply to today's exemption.

Reporting Requirements Related to Laboratory and Analytical Essential Uses of Ozone Depleting Substances

Any person obtaining class I controlled substances after the phase-out under the laboratory use exemption 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 (u) through (z). In short, these regulations require the following:

(a) Laboratory customers purchasing a controlled substances under the global laboratory essential-use exemption must provide the producer, importer or distributor with a one-time-per-year certification for each controlled substance that the substance will only be used for laboratory applications and will not be resold or used in manufacturing. The certification must also include:

(1) The identity and address of the laboratory customer;

(2) The name and phone number of a contact person for the laboratory customer; and

(3) The name and quantity of each controlled substance purchased, and the estimated percent of the controlled substance that will be used for each listed type of laboratory application (§ 82.13(y)).

(b) Any distributor of laboratory supplies receiving an essential use exemption for sale to laboratory customers must:

(1) Report quarterly the quantity received of each controlled substance from each producer or importer (§§ 82.13(v) and 82.13 (u));

(2) Report quarterly the quantity of each controlled substance purchased by each laboratory customer whose certification was previously provided to the distributor (§ 82.13(x)); and

(3) Maintain as records copies of certifications from laboratory customers provided (§ 82.13(w)).

(c) Distributors of laboratory supplies, who purchased class I controlled substances under the global laboratory essential-use exemption, and who only sell the class I substances as reference standards for calibrating laboratory analytical equipment, may be eligible to report annually instead of quarterly (§ 82.13(z)).

For guidance documents and reporting forms, please contact the Stratospheric Protection Hotline at (800) 296–1996 or (301) 614–3390.

IV. Criteria for Exempting Laboratory and Analytical Uses After December 31, 2001

Today's rule provides a *de minimis* exemption for essential laboratory uses of class I ODSs for 2001 based on the criteria mentioned in the previous section. These criteria for 2001 are consistent with the Montreal Protocol and with the requirements for laboratory uses of class I ODSs in appendix G of subpart A of 40 CFR part 82. EPA expects to make rulings on laboratory uses of class I ODSs for future years that will consider similar issues and criteria.

While EPA is making the determination that a *de minimis* exemption applies to laboratory essential use allowances for the year 2001, it should be noted that the Parties to the Montreal Protocol have not extended the global laboratory and analytical essential-use exemptions indefinitely. Decision X/19 taken at the tenth meeting of the Parties in 1998 states that the global laboratory and analytical essential-use exemption lasts until December 31, 2005 under the conditions set out in annex II of the report of the Sixth Meeting of the Parties. Decision X/19 also states that at the annual Meetings of the Parties, on the basis of information reported by the Technology and Economic Assessment Panel (TEAP), the Parties may decide on any uses of controlled substances which should no longer be eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply. (The full text Decision X/19 is posted in docket A–93–39, and may also be reviewed at the UNEP website at http://www.unep.org/ozone/)

The Parties at the Eleventh Meeting of the Parties to the Protocol took Decision XI/15. This decision eliminated the following uses from the global exemption for laboratory and analytical uses for controlled substances from the year 2002:

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

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

(c) Forensic finger-printing.

EPA plans to issue a rule through notice and comment rulemaking that would allocate a global exemption for essential laboratory uses for the year 2002 in accordance with Decision XI/15. This means that for the year 2002, EPA would provide a global exemption to the ban on production and import of class I ODSs for laboratory uses, except for use in those laboratory applications considered non-essential by the Parties pursuant to Decision XI/15. Therefore, new production or import of class I ODSs for non-essential uses would be prohibited beginning January 1, 2002.

EPA notes that in the U.S., class I ODSs generally are not used for testing of tar in road-paving materials and forensic finger-printing. Thus, we expect that the major impact of decision XI/15 will be upon testing of oil, grease and total petroleum hydrocarbons in water. The Clean Water Act requires testing for the conventional pollutant ''oil and greases'' in water. The analytical methods for measuring ''oil and greases'' include EPA methods 413.1, 413.2 and 418.1, which use CFC–113. Pursuant to Decision XI/15, EPA will however propose that methods for testing oil and grease using class I ODSs will no longer be considered ''essential'' in the year 2002 and thus newly produced CFC–113 will not be available for those EPA test methods. However, this should not cause a problem for laboratories. On May 14, 1999, EPA published an alternative analytical method for these tests that does not require using class I ODSs: Method 1664 Revision A: N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated—Hexane Extractable

Material (SGR–HEM; Nonpolar Material) by Extraction and Gravimetry. EPA promulgated method 9071B to replace method 9070 and incorporates Method 1664 for use in EPA's Resource Conservation and Recovery Act programs. For more information on method 1664, please reference EPA's Office of Water website at http://www.epa.gov/ost/methods/oil.html. For technical information regarding Resource Conservation and Recovery Act test methods and regulations please call the Office of Solid Waste Methods information and communication exchange at (703) 821–4690. For technical information regarding testing methods required under the Clean Water Act, call the Office of Water Resource Center at (202) 260–7786.

Pursuant to decision X/19, the TEAP will continue to make recommendations for laboratory uses which no longer require class I ODSs in the future. The Parties to the Protocol may disallow additional uses from the global ban on essential use exemptions in the future. Currently, there are no recommendations by the TEAP to disallow any additional laboratory uses beyond those listed in decision XI/15. If the Parties decide to disallow any other laboratory uses, EPA will issue regulations to enforce those decisions. Further, EPA reserves the right to determine that a particular test method is non-essential in the United States, even if it continues to be considered essential by the Parties.

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

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). The information collection requirements were revised in a direct final rule on August 4, 1998 (EPA ICR No. 1432.17).

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 Orders 13084 and 13175: Consultation and Coordination With Indian Tribal Governments

On January 1, 2001, Executive Order 13084 was superseded by Executive Order 13175. However, this rule was developed during the period when Executive Order 13084 was still in force,

and so tribal considerations were addressed under Executive Order 13084.

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 Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. For purposes of assessing the impact of today's rule on small entities, small entities are defined as (1) a small business that manufactures or sells chemicals and has 500 or fewer employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. Without today's direct final, manufacturers of ODSs for laboratory uses would be subject to the general ban on the production and import of class I ozone depleting substances under the Clean Air Act. This action reduces regulatory burden by providing an exemption to the ban for the production and import of class I ozone depleting substances specifically for laboratory and analytic uses.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. The rule itself is an exemption which reduces the burden of the phase out of ozone depleting substances. We requested comment from laboratory users, some of whom work in small research laboratories, in the development of today's rule and have issued an exemption from a ban otherwise applicable.

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, section12(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 changing any 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 that 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 final 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 final rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances for use in laboratory and analytical applications. Thus, the requirements of section 6 of the Executive Order to not apply to this rule.

VI. Judicial Review

Under section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of the action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of the action in the **Federal Register**. Under section 307(b)(2), the requirements of this rule may not be challenged later in the judicial proceedings brought to enforce those requirements.

VII. Submittal To Congress and General Accounting Office

The Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. EPA has determined that this regulation will become effective on May 14, 2001 and thus no good cause finding is necessary. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 82

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

Dated: March 5, 2001.

Christine Todd Whitman,

Administrator.

40 CFR Part 82 is to be amended as follows:

PART 82—[AMENDED]

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 introductory text of paragraph (t), by removing paragraph (t)(1)(iii), and by adding paragraph (t)(3) to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) Effective January 1, 1996, essential-use allowances are apportioned to a person under paragraph (t)(2) of this section for the exempted production or importation of specified class I controlled substances solely for the purposes listed in paragraphs (t)(1)(i) and (ii) of this section. From October 5, 1998 through December 31, 1999 production and importation of class I controlled substances for laboratory and analytical applications are exempted as an essential use if conducted in accordance with requirements in § 82.13 (u) through (z) and appendix G to subpart A.

(1) * * *

(2) * * *

(3) A global exemption for class I ozone depleting substances for laboratory and analytical uses shall be in effect for the year 2001 subject to the restrictions in appendix G of this subpart.

Laboratory and analytical applications are exempted as essential uses for the year 2001 if conducted in accordance with the requirements at § 82.13(u) through (z) and appendix G of this subpart and in accordance with the Montreal Protocol. There is no amount specified for this exemption.

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