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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2010-0672; FRL-9507-6]

RIN 2060-AQ39

Protection of Stratospheric Ozone: Extension of the Laboratory and Analytical Use Exemption for Essential Class I Ozone-Depleting Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is extending the laboratory and analytical use exemption for the production and import of Class I ozone-depleting substances through December 31, 2014. This action is taken under the Clean Air Act consistent with the recent actions by the Parties to the *Montreal Protocol on Substances that Deplete the Ozone Layer*. The exemption allows the production and import of controlled substances in the United States for laboratory and analytical uses that have not been already identified by EPA as nonessential.

DATES: This action is effective on **[Insert date of publication]**

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2010-0672. All documents in the docket are listed on the www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742).

FOR FURTHER INFORMATION CONTACT: Jeremy Arling by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, NW, Washington, DC, 20460; by courier service or overnight express: 1301 L Street, N.W., Washington, D.C., 20005; by telephone: 202-343-9055; or by email: arling.jeremy@epa.gov. You may also visit the EPA's Ozone Protection Web site at www.epa.gov/ozone/strathome.html for further information about EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and other related topics.

SUPPLEMENTARY INFORMATION:

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. Chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the Federal Register. EPA is issuing this final rule under section 307(d)(1) of the Clean Air Act, which states: "The provisions of section 553 through 557 . . . of Title 5 shall not, except as expressly provided in this section, apply to actions to which this subsection applies." Thus, section 553(d) of the APA does not apply to this rule. EPA is nevertheless acting consistently with the policies underlying APA section 553(d) in making this rule effective on **[Insert date of publication]**. APA section 553(d) allows an

effective date less than 30 days after publication "as otherwise provided by the agency for good cause found and published with the rule." As explained below, EPA finds that there is good cause for this rule to become effective on **[insert date of publication]**, even though this results in an effective date fewer than 30 days from the date of publication in the Federal Register. The purpose of the 30-day waiting period prescribed in APA section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. This final rule extends an exemption from the phaseout of class I ozone depleting substances for limited laboratory and analytical uses that is set to expire on December 31, 2011. A shorter effective date in such circumstances is consistent with the purposes of APA section 553(d), which provides an exception for any action that grants or recognizes an exemption or relieves a restriction. Accordingly, we find good cause exists to make this rule effective **[insert date of publication]**.

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I. Extension of the Laboratory and Analytical Use Exemption

The *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol, or Protocol) is the international agreement to reduce and eventually eliminate the global production and consumption[1] of ozone-depleting substances (ODS). This goal is accomplished through adherence by each country that is a Party to the Montreal Protocol to phaseout schedules for specific controlled substances. The Protocol established January 1, 1996, as the date by which the production and import of most Class I controlled substances – including chlorofluorocarbons (CFCs), carbon tetrachloride, and methyl chloroform[2] - were phased out in developed countries, including the United States. The Clean Air Act grants EPA the authority to implement the Protocol's phaseout schedules in the United States. Section 604 of the Clean Air Act requires EPA to promulgate regulations phasing out production and consumption of Class

[1] "Consumption" is defined as the amount of a substance produced in the United States, plus the amount imported into the United States, minus the amount exported from the United States to other Parties to the Montreal Protocol (see Section 601(6) of the Clean Air Act).

[2] Class I controlled substances are listed at 40 CFR part 82, subpart A, Appendix A.

I ODS according to a prescribed schedule. EPA's phaseout regulations for ODS are codified at 40 CFR part 82, subpart A.

The Montreal Protocol provides exemptions that allow for the continued import and/or production of ODSs for specific uses. Under the Montreal Protocol, for most Class I ODSs, the Parties may collectively grant exemptions to the ban on production and import of ODS for uses that they determine to be "essential." For example, with respect to CFCs, Article 2A(4) provides that the phaseout will apply "save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential." Similar language appears in the control provisions for halons (Art. 2B), carbon tetrachloride (Art. 2D), methyl chloroform (Art. 2E), hydrobromofluorocarbons (Art. 2G), and chlorobromomethane (Art. 2I). As defined by Decision IV/25 of the Parties, "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."

Decision X/19 under the Montreal Protocol (taken in 1998) allowed a general exemption for essential laboratory and analytical uses through December 31, 2005. EPA codified this exemption at 40 CFR part 82, subpart A. While the Clean Air Act does not specifically provide for this exemption, EPA determined that an exemption for essential laboratory and analytical uses was allowable under the Act as a de minimis exemption. EPA addressed the de minimis exemption in a regulation issued March 13, 2001 (66 FR 14760).

Decision X/19 also requested the Montreal Protocol's Technology and Economic Assessment Panel (TEAP), a group of technical experts from various Parties, to report annually to the Parties to the Montreal Protocol on laboratory and analytical procedures that could be performed without the use of controlled substances. It further stated that at future Meetings of the Parties (MOPs), the Parties would decide whether such procedures should no longer be eligible for exemptions. Based on the TEAP's recommendation, the Parties to the Montreal Protocol decided in 1999 (Decision XI/15) that the general exemption no longer applied to the following uses: testing of oil and grease and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated these exclusions at Appendix G to subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

At the 18th MOP, the Parties acknowledged the need for methyl bromide for laboratory and analytical procedures, and added methyl bromide to the ODSs under the essential laboratory and analytical use exemption. Decision XVIII/15 outlined specific uses and exclusions for methyl bromide under the exemption. EPA incorporated specific uses of methyl bromide in the essential laboratory and analytical use exemption at Appendix G to subpart A of 40 CFR part 82 on December 27, 2007 (72 FR 73264).

In November 2009, at the 21st MOP, the Parties in Decision XXI/6 extended the global laboratory and analytical use exemption through December 31, 2014. Decision XXI/6 also notes laboratory and analytical uses of ODSs for which the TEAP and its Chemicals Technical Options Committee (CTOC), determined that alternative procedures exist. However, the Parties did not exclude any of those procedures from the exemption

for laboratory and analytical uses. The Parties asked the TEAP and the CTOC to continue to consider possible alternatives and report back to the Parties.

EPA's regulations regarding this exemption at 40 CFR 82.8(b) currently state, "A global exemption for Class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2011, subject to the restrictions in appendix G of this subpart, and subject to the recordkeeping and reporting requirements at §82.13(u) through (x). There is no amount specified for this exemption." Because certain laboratory procedures continue to require the use of Class I substances in the United States, because non-ODS replacements for the Class I substances have not been identified for all uses, and because the Parties, via Decision XXI/6, extended this exemption through December 31, 2014, EPA proposed to revise 40 CFR 82.8(b) to reflect the extension of the exemption to December 31, 2014. The EPA received two comments in total on the proposed rule, including the proposal to adopt the Parties' extension, one from a corporation (the company commenter) and one from a laboratory. The company commenter supported the proposed extension of the global laboratory use exemption through December 31, 2014, while the other commenter supported the extension insofar as it applied to the use of carbon tetrachloride. For a more detailed discussion of the reasons for the exemption, refer to the regulation issued March 13, 2001 (66 FR 14760). That rule discusses how the controls in place for laboratory and analytical uses provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal of the small amounts of Class I ODS used in such applications, due to the Appendix G requirements for small quantity and high purity.

In the decade since EPA issued the exemption, EPA and has not received information that would suggest otherwise.

In the proposed rule, EPA also sought comment on adding to the list of procedures that are excluded from the exemption under 40 CFR part 82, appendix G. EPA did not propose to add these procedures at this time. The following uses are noted in Decision XXI/6 as being laboratory and analytical procedures for which the TEAP and its CTOC have concluded that alternatives exist:

(a) Analyses in which the ODS is used as a solvent for spectroscopic measurements:
- (i) of hydrocarbons (oil and grease) in water or soil
- (ii) of simethicone (polydimethylsiloxane)
- (iii) when recording infrared and nuclear magnetic resonance (NMR) spectra, including hydroxyl index

(b) Analyses in which the ODS is used as a solvent for electrochemical methods of analysis of:
- (i) cyanocobalamin
- (ii) bromine index

(c) Analyses involving selective solubility in the ODS of:
- (i) cascarosides
- (ii) thyroid extracts
- (iii) polymers

(d) Analyses in which the ODS is used to preconcentrate the analyte, for:
- (i) liquid chromatography (HPLC) of drugs and pesticides
- (ii) gas chromatography of organic chemicals such as steroids
- (iii) adsorption chromatography of organic chemicals

(e) Titration of iodine with thiosulfate (iodometric analyses) for determination of:
- (i) iodine
- (ii) copper
- (iii) arsenic
- (iv) sulphur

(f) Iodine and bromine index measurements (titrations)

(g) Miscellaneous analyses, namely
- (i) stiffness of leather
- (ii) jellification point

(iii) specific weight of cement
(iv) gas mask cartridge breakthrough

(h) Use of ODS as a solvent in organic chemical reactions
(i) O- and N-difluoromethylation

(i) General use as laboratory solvent, namely
(i) washing of NMR tubes
(ii) removal of greases from glassware

EPA sought comment on whether alternative procedures exist in the United States for each of these laboratory applications. EPA received comments from the same two commenters noted above regarding the use of carbon tetrachloride (CTC), which is an ODS, in analyses under section (a)(iii) of Decision XXI/6, which analyses are described above. Due to its unique properties (e.g. lack of carbon-hydrogen bonds, small but non-zero solubility), the commenters stated that CTC is used as a solvent in certain analytical measurements.

The company commenter stated that the procedures listed in section (a)(iii) of Decision XXI/6 are standard spectroscopic procedures for which CTC is not required. Therefore, the commenter does not oppose the exclusion of those procedures from the exemption. The commenter did describe its own current use of the chemical for a proprietary method of hydroxyl analysis that does not fall under the analysis listed in section (a)(iii) and for which CTC would still be required.

The laboratory commenter also discussed CTC's unique properties and commented that the continued use of CTC as a solvent is essential for some of the uses listed in section (a)(iii) of Decision XXI/6. It interpreted the Decision language quoted above as proposed regulatory language and requested that the following line be added to the potential exclusion that appears in paragraph (a)(iii) of the Decision: "Research

applications for which there are no effective alternate solvents for carbon tetrachloride are not prohibited."

EPA did not propose to remove any of these procedures from the list of exempted uses of ODS and is not taking action in this final rule. However, EPA continues to be interested in laboratory uses of ODS for which there are no effective alternatives since this issue continues to be discussed by the Parties to the Protocol.

II. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This action extends the existing laboratory and analytical use exemption allowing the production and import of Class I ozone-depleting substances until December 31, 2014. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR 82.8(a) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060-0170. The OMB control numbers for EPA's regulations in 40 CFR 82 are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

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

For purposes of assessing the impact of today's rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have fewer than 750 employees; (3) 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 (4) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant its field.

After considering the economic impacts of today's rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." 5 USC 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a

substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

This action provides an otherwise unavailable benefit to those companies that obtain ozone-depleting substances under the essential laboratory and analytical use exemption. We have therefore concluded that today's rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. This action merely extends the essential laboratory and analytical use exemption from the 1996 and 2005 phaseouts of Class I ODS until December 31, 2014. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action merely extends the essential laboratory and analytical use exemption from the 1996 and 2005 phaseouts of Class I ODS until December 31, 2014. Thus, Executive Order 13132 does not apply to

this action. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on this action from State and local officials.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose any enforceable duties on communities of Indian tribal governments. This action merely extends the essential laboratory and analytical use exemption from the 1996 and 2005 phaseouts of Class I ODS until December 31, 2014. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicited comment on this action from tribal officials.

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

EPA interprets EO 13045 (62 F.R. 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution,

or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Therefore, we have concluded that this rule does not have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA), Public Law No. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in 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 rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high

and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it will not affect the level of protection provided to human health or the environment. The controls in place for laboratory and analytical uses provide adequate assurance that very little, if any, environmental impact will result from the handling and disposal of the small amounts of Class I ODS used in such applications.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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. A "major rule," as defined by 5 U.S.C. 804(2), cannot take effect until 60 days after it is published in the Federal Register. This action not a "major rule." This rule will be effective January 1, 2012.

List of Subjects in 40 CFR Part 82

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

DATE: December 9, 2011.

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Lisa P. Jackson,
Administrator.

For the reasons set out in the preamble, 40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

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

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

2. Section 82.8 is amended by revising paragraph (b) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

* * * * *

(b) A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2014, subject to the restrictions in appendix G of this subpart, and subject to the recordkeeping and reporting requirements at §82.13(u) through (x). There is no amount specified for this exemption.

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[FR Doc. 2011-32179 Filed 12/14/2011 at 8:45 am; Publication Date: 12/15/2011]