



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2014-0621; FRL-9921-52-OAR]

RIN 2060-AS38

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

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rule extends the laboratory and analytical use exemption for the production and import of class I ozone-depleting substances through December 31, 2021. The Environmental Protection Agency (EPA) is taking this action under the Clean Air Act, consistent with a recent decision of 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 rule is effective [**insert date of publication in the Federal Register**].

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2014-0621. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is 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, 20004. 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 (6205T), 1200 Pennsylvania Avenue, NW, Washington, DC, 20460; 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 in the FEDERAL REGISTER]**. APA section 553(d) allows an effective date less than 30 days after publication for a rule that "that grants or recognizes an exemption or relieves a

restriction.” 5 U.S.C. § 553(d)(1). Since today’s action grants an exemption for limited laboratory and analytical uses from the general prohibition on production or import of Class I ozone depleting substances after their phaseout dates, EPA is making this action effective immediately upon publication.

I. General Information

A. Does this Action Apply to Me?

Entities potentially regulated by this action include: (1) pharmaceutical preparations manufacturing businesses (NAICS code 325412); (2) medical and diagnostic laboratories (NAICS code 621511); (3) research and development in the physical, engineering, and life sciences (NAICS code 54171); and (4) environmental consulting services (NAICS code 541620). This list is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility, company, business, or organization could be regulated by this action, you should carefully examine the regulations promulgated at 40 CFR part 82, subpart A. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section.

II. 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 consumption¹ of ozone-depleting substances (ODS). This goal is accomplished through adherence by each country that is a Party to the Protocol to phaseout schedules for specific controlled substances. The Protocol established January 1, 1996, as

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).

the date by which the production and import of most substances classified as “class I controlled substances” under the Clean Air Act (CAA or Act) – including chlorofluorocarbons (CFCs), carbon tetrachloride, and methyl chloroform² - were to be 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 issue regulations phasing out production and consumption of class 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 ODS for specific uses. For most class I ODS, 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.”

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

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 ODS 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. Based on this decision, EPA amended the regulation at 40 CFR 82.8(b) to extend the essential laboratory and analytical use exemption through December 31, 2014 (76 FR 77909, December 15, 2011). Decision XXI/6 also notes laboratory and analytical uses of ODS 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.

In November 2014, the Parties in Decision XXVI/5 extended the global laboratory and analytical use exemption through December 31, 2021. This final rule extends the laboratory and analytical use exemption found in 40 CFR 82.8(b) to match the recent international decision.

A detailed discussion of the laboratory and analytical uses of ODS can be found in the regulation issued by EPA on March 13, 2001 (66 FR 14760). That rule also 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. For example, class I ODS must be sold in cylinders three liters or smaller or in glass ampoules 10 milliliters or smaller. Since issuing the original exemption, EPA has not received information that would suggest a significant environmental effect from this exemption.

U.S. production and consumption of ODS under the laboratory and analytical use exemption is on a general decline, indicating that many users have been able to transition from ozone-depleting substances. However, 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, EPA is extending this exemption through December 31, 2021.

EPA received one substantive comment in response to the proposed rule, which was supportive of extending the exemption through December 31, 2021. The commenter, a manufacturer of ozone-depleting substances used as solvents under the exemption, agreed that non-ODS replacements for class I substances have not been identified, and stated that the low volume of usage of these chemicals and their exclusive use in professionally managed analytical laboratories means there is very low risk that environmental damage will occur.

EPA believes an extension of seven years is warranted, as it is unlikely that non-ODS replacements will be in place for all laboratory and analytical uses prior to that time. Decision XXVI/5 encourages parties to continue to investigate the possibility of replacing ozone-depleting substances in laboratory and analytical uses. EPA did not receive comments from standards organizations that continue to use ODS in their standards or from laboratories that have transitioned to ozone-safe alternatives. EPA intends to continue to work to investigate barriers to transitioning from ozone-depleting substances to alternatives for this limited use.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

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 and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060-0170. This action extends but does not modify the existing exemption from the phaseout of class I ODS.

C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. 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, has no net burden or otherwise has a positive economic effect on 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 this action will relieve regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. 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 production and consumption until December 31, 2021.

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.

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

This action does not have tribal implications as specified in Executive Order 13175. 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 extends the essential laboratory and analytical use exemption from the 1996 and 2005 phaseouts of class I ODS production and consumption until December 31, 2021. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. A discussion of this action's health and risk effects are contained in the direct

final rule establishing the *De Minimis* Exemption for Laboratory Essential Uses (66 FR 14760; March 13, 2001). 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.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

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

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations because it does 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 (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA 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 comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in the Supplementary Information section of the preamble, including the basis for that finding.

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.

Dated: January 16, 2015.

Gina McCarthy,
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. Amend § 82.8 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, 2021, 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. 2015-01295 Filed 01/23/2015 at 8:45 am; Publication Date: 01/26/2015]