6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2020-0084; FRL-10011-84-OAR]

RIN 2060-AU80

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: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise regulations governing the production and import of class I ozone-depleting substances in the United States to extend indefinitely the global essential laboratory and analytical use exemption. This exemption currently expires on December 31, 2021. This change would allow for continued production and import of class I substances in the United States solely for laboratory and analytical uses that have not been identified by the EPA as nonessential. This action is proposed under the Clean Air Act and is consistent with a decision by the Parties to the *Montreal Protocol on Substances that Deplete the Ozone Layer* to extend the global laboratory and analytical use exemption indefinitely beyond 2021.

DATES: Comments on this notice of proposed rulemaking must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER].** Any party requesting a public hearing must notify the contact listed below under "**FOR**

FURTHER INFORMATION CONTACT" by 5 p.m. Eastern Daylight Time on **[INSERT DATE 5 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].** If a public hearing is requested, the EPA would hold a virtual hearing on **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].** If a hearing is requested, the date, time, and other relevant information for a hearing will be available at https://www.epa.gov/ods-phaseout/phaseout-exemptions-laboratory-and-analytical-uses.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2020-0084, to the Federal eRulemaking Portal: http://www.regulations.gov. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov or email, as there may be a delay in processing mail, and hand deliveries may not be accepted. For further information on EPA Docket Center services and the current status, please visit us online at https://www.epa.gov/dockets.

Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider

comments or comment contents located outside of the primary submission (e.g., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit https://www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202-564-7716; or email address: sleasman.katherine@epa.gov. You may also visit the EPA's Web site at https://www.epa.gov/ods-phaseout/phaseout-exemptions-laboratory-and-analytical-uses for further information.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Proposed Action Apply to Me?

You may be potentially affected by this proposal if you manufacture, process, import, or distribute into commerce certain ozone-depleting substances (ODS) and mixtures. Potentially affected entities may include but are not limited to:

- Basic chemical manufacturing (NAICS code 3251)
- Pharmaceutical preparations manufacturing businesses (NAICS code 325412)
- Other chemical and allied production merchant wholesalers (NAICS code 424690)
- Environmental consulting services (NAICS code 541620)
- Research and development in the physical, engineering, and life sciences (NAICS code 54171)
- Medical laboratories (NAICS code 621511)

This list is not intended to be exhaustive, but rather provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this section could also be affected. The North American Industrial Classification System (NAICS)

codes have been provided to assist in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under "**FOR FURTHER INFORMATION CONTACT"**.

B. What Action Is the Agency Proposing?

The EPA is proposing to revise regulations governing the production and import of class I[1] ozone-depleting substances (ODS) in the United States to extend indefinitely the global essential laboratory and analytical use exemption (referred to hereafter as the "L&A exemption"). Laboratory distributors currently supply around 1,000 laboratories, and consumption[2] for laboratory use was approximately 4.4 ODP-weighted metric tons in 2018 under the L&A exemption.[3] The EPA is proposing this action under the Clean Air Act (CAA) following a recent decision by the Parties to the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol) to extend the global L&A exemption indefinitely.[4] The global exemption is implemented domestically through the EPA's regulations at 40 CFR part 82 subpart A and is currently in effect in the United States through December 31, 2021. The change proposed in this notice would allow for continued production and import of class I ODS in the United States, after that date, for laboratory and analytical uses that have not been identified by the EPA as nonessential.

C. What Is the Agency's Authority for this Proposed Action?

The CAA grants the EPA the authority to implement the Montreal Protocol's

[1] Under the CAA, certain ODS are classified as "class I" substances. Class I substances are listed in Appendix A to 40 CFR part 82, subpart A. This includes Groups I, II, III, IV, and V under the Montreal Protocol.
[2] Consumption is defined in §82.3 as production plus imports minus exports of a controlled substance (other than transshipments or used controlled substances).
[3] These data are available in the docket to this rule as well as on the Montreal Protocol's Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table.
[4] *Decision XXXI/5: Laboratory and Analytical Use*

phaseout schedules in the United States. CAA section 604 requires the EPA to issue regulations phasing out production and consumption of class I ODS according to a prescribed schedule. The EPA's phaseout regulations for class I ODS are codified at 40 CFR part 82, subpart A.

II. Background of the Laboratory and Analytical Use Exemption

The United States was one of the original signatories to the 1987 Montreal Protocol and ratified it on April 12, 1988. After ratification, Congress enacted, and President George H.W. Bush signed into law, the CAA Amendments of 1990, which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure, among other things, that the United States could satisfy its obligations under the Montreal Protocol.

The Montreal Protocol is a multinational environmental agreement to protect Earth's ozone layer by phasing out the consumption and the production of most chemicals that deplete it. The Montreal Protocol provides a set of schedules to phase out ODS and also provides for mechanisms to establish certain specific and limited exemptions. For most class I ODS, the Parties may agree to grant exemptions to the ban on production and import of ODS for uses that they determine to be "essential." For example, with respect to chlorofluorocarbons (CFCs), Article 2A(4) of the Montreal Protocol 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 other ODS, such as halons (Article 2B), carbon tetrachloride (Article 2D), and methyl chloroform (Article 2E). As defined by Decision IV/25 of the Parties, "use of a controlled substance should qualify as 'essential'

only if: it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health." In addition, Annex II of the report of the Sixth Meeting of the Parties (MOP) from Decision VI/9 describes conditions applied to the exemption for laboratory and analytical uses such as purity, quantity, and specification for cylinders and handling for these controlled substances.

Decision X/19 under the Montreal Protocol extended the global exemption for essential laboratory and analytical uses through December 31, 2005. Consistent with the flexibility allowed for by the Parties, in 2001, the EPA codified a L&A exemption at 40 CFR 82.4 (see 66 FR 14760, March 13, 2001). In the preamble to that rule, the EPA determined that the statutory language in section 604 of the CAA provided grounds for the creation of a *de minimis* exemption for essential laboratory and analytical uses of certain class I ODS. Id. at 14764. The 2001 rule explains 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 under 40 CFR Part 82, subpart A 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, as per Appendix G. Since issuing the original exemption, the EPA has not received information that would suggest otherwise. As discussed later in this notice, the quantities of class I ODS used for this exemption have declined substantially since the exemption was initially created.

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

At the 18th MOP, the Parties acknowledged the need to use methyl bromide for laboratory and analytical procedures and added methyl bromide to the ODS covered by the L&A exemption in Appendix G. Decision XVIII/15 outlined specific uses and exclusions for methyl bromide under the exemption (see 72 FR 73264, December 27, 2007).

In November 2009, at the 21st MOP, the Parties in Decision XXI/6 extended the global L&A exemption through December 31, 2014. Based on this Decision, the EPA amended the regulation at 40 CFR 82.8(b) to extend the L&A exemption domestically through December 31, 2014 (see 76 FR 77909, December 15, 2011). Decision XXI/6 lists 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 additional 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.

Under Decision XXVI/5 at the 26th MOP, the Parties extended the L&A exemption until December 31, 2021, which the EPA implemented domestically through a rulemaking in 2015 (see 80 FR 3885, January 26, 2015). This Decision also requested the TEAP provide a report on the development and availability of laboratory and analytical uses that can be performed without using ODS, and Parties were encouraged to continue to investigate replacements to ODS for laboratory and analytical uses.

In 2018, the TEAP and its Medical and Chemicals Technical Options Committee (MCTOC) provided a report on alternatives to ODS for laboratory and analytical uses, available in the docket. The report noted that annual data reported to the Ozone Secretariat under Article 7 of the Montreal Protocol show a downward trend with global production of ODS for these uses of only 151 metric tons in 2016.

Most recently, in November 2019, at the 31st MOP, the Parties agreed in Decision XXXI/5 to "extend the global laboratory and analytical-use exemption indefinitely beyond 2021, without prejudice to the parties deciding to review the exemption at a future meeting." The Decision also encourages parties to further reduce their production and consumption of ODS for laboratory and analytical uses and to facilitate the introduction of laboratory standards that do not require such substances.

III. Proposed Rule

The EPA is proposing to indefinitely extend the L&A exemption for class I ODS in 40 CFR 82.8(b). This proposal would make the regulatory exemption indefinite unless or until it is limited or eliminated through future rulemaking. If the Agency finalizes this action as proposed, the Agency would still have authority to review the scope of and need for the exemption at a future date; however, the regulations would no longer contain an

expiration date for the exemption. The EPA could also change the list of uses in Appendix G, as alternatives are identified through new standards.

This proposed action is consistent with the Montreal Protocol's Decision XXXI/5. Non-ODS replacements for class I ODS may not be identified for all uses given the effort required to establish new analytical procedures for such small quantities of material. While some analytical procedures have transitioned, many ASTM and ISO standards still require small amounts of ODS, and it could take years for standards organizations to develop alternatives and for laboratories to adopt the new standards.

The Agency is also proposing to add clarifying text to explain that the L&A exemption allows for the production and import of class I ODS that have been phased out in the United States, subject to certain restrictions as described in Appendix G. The text in 40 CFR 82.8(b) establishes the exemption for essential laboratory and analytical uses but does not explicitly state that the exemption is from the prohibitions on production and import of class I ODS, although that is clear from context and the explanation in the 2001 rule (see 66 FR 14760, March 13, 2001).

Making the L&A exemption indefinite will have little effect on the stratospheric ozone layer. Exempted production and consumption of ODS for laboratory and analytical uses in the United States is on a general decline. Consumption peaked in 2004 at 55 ODP-weighted metric tons and was only 4.4 ODP-weighted metric tons in 2018, which is a negligible amount.[5] This indicates that many users, primarily laboratories, have been able to transition from ODS even with this exemption available to them. However, certain laboratory and analytical procedures continue to require the use of class I ODS in the

[5] These data are available in the docket to this rule as well as on the Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table.

United States. There are currently ten laboratory distributors that supply around 1,000 laboratories with primarily carbon tetrachloride but also small quantities of chlorobromomethane, CFCs, methyl chloroform, and methyl bromide. Maintaining this exemption would provide laboratories with essential class I ODS for which no alternatives are currently available, with negligible environmental impacts.

The EPA requests comment on the proposal to indefinitely extend the L&A exemption. The EPA is also seeking comment from standards organizations that either continue to use ODS in their standards or who have developed new standards. For instance, the EPA is seeking comment on which standards still exist that use ODS, if there are any plans or actions underway to replace those existing standards, and whether there are alternatives to using ODS. Likewise, the EPA seeks comment from laboratories that continue to use ODS or that have transitioned to ozone-safe alternatives. The EPA is seeking comments from laboratories on whether they use ODS or have transitioned to alternatives and, if they have not transitioned, which methods are still being employed that require the use of ODS. The EPA encourages laboratories to continue ongoing efforts to transition to methods that do not require the use of ODS, and information provided by commenters could be aggregated and shared to assist others.

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

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 deregulatory action. This proposed rule is expected to provide meaningful burden reduction because it allows for the continued use of ODS for laboratory and analytical use.

C. 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. The laboratory and analytical use exemption currently expires on December 31, 2021, and this action would allow for continued production and import of class I substances in the United States solely for laboratory and analytical uses that have not been identified by the EPA as nonessential, and therefore there are no PRA implications. This action proposes to indefinitely remove the expiration date for the existing exemption from the prohibitions in production and import of class I ODS.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action does not modify the recordkeeping and reporting requirements that apply to laboratory distributors who utilize the exemption. These requirements will continue to apply to distributors who use the exemption; however, the requirements are minimal and impose no significant burden. Further, nothing in this rule compels any entity to use the exemption. The Agency thus assumes that the burden reduction provided by the exemption from the phaseout on production and import of class I ODS outweighs the limited cost associated with recordkeeping and reporting. Otherwise,

laboratory distributors could choose not to use the exemption, removing the need for relevant recordkeeping and reporting.

E. Unfunded Mandates Reform Act (UMRA)

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.

F. 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.

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

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. The EPA periodically updates tribal officials on air regulations through the monthly meetings of the National Tribal Air Association and will share information on this rulemaking through this and other fora.

H. 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 the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. Depletion of stratospheric ozone results in greater transmission of the sun's ultraviolet (UV) radiation to the earth's surface. The following studies describe the effects of excessive exposure to UV radiation on children: (1) Westerdahl J, Olsson H, Ingvar C. "At what age do sunburn episodes play a crucial role for the development of malignant melanoma," Eur J Cancer 1994: 30A: 1647-54; (2) Elwood JM Japson J. "Melanoma and sun exposure: an overview of published studies," Int J Cancer 1997; 73:198-203; (3) Armstrong BK, "Melanoma: childhood or lifelong sun exposure," In: Grobb JJ, Stern RS Mackie RM, Weinstock WA, eds. "Epidemiology, causes and prevention of skin diseases," 1st ed. London, England: Blackwell Science, 1997: 63-6; (4) Whiteman D., Green A. "Melanoma and Sunburn," Cancer Causes Control, 1994: 5:564-72; (5) Heenan, PJ. "Does intermittent sun exposure cause basal cell carcinoma? A case control study in Western Australia," Int J Cancer 1995; 60: 489-94; (6) Gallagher, RP, Hill, GB, Bajdik, CD, et al. "Sunlight exposure, pigmentary factors, and risk of nonmelanocytic skin cancer I, Basal cell carcinoma," Arch Dermatol 1995; 131: 157-63; (7) Armstrong, DK. "How sun exposure causes skin cancer: an epidemiological perspective," Prevention of Skin Cancer. 2004. 89-116. However, because maintaining the laboratory and analytical exemption would have negligible environmental impacts (as discussed in sections II and III of the preamble), the EPA does not expect any additional risks to children.

I. 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.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that it is not feasible to quantify any disproportionately high and adverse human health or environmental effects from this action on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

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

Andrew Wheeler,
Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

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

Authority: 42 U.S.C. 7671c.

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) There is a global exemption for the production and import of class I controlled substances for essential laboratory and analytical uses, 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.