6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9911-77-OAR]

Protection of Stratospheric Ozone: Request for Applications for Essential Use Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In this notice, the Environmental Protection Agency (EPA) is providing information about the process for submitting applications for essential use exemptions. Essential use exemptions are exceptions to the phaseout of production and import of controlled class I ozone-depleting substances (ODS). Essential use exemptions must be authorized by the Parties to *the Montreal Protocol on Substances that Deplete the Ozone Layer* and must be in accordance with the Clean Air Act. Applications received in accordance with this notice will be considered as the basis for submitting potential nominations for essential use exemptions to future Meetings of the Parties to the Montreal Protocol.

DATES: Applications for essential use exemptions must be submitted to EPA no later than September 30 of each year, in order for the U.S. Government to complete its consideration for nomination to the United Nations Environment Programme and the Parties to the Montreal Protocol in a timely manner.

ADDRESSES: Send application materials to: Essential Use Exemption Coordinator, Stratospheric Protection Division (6205J), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

Confidentiality: Application materials that are confidential should be submitted under separate cover and be clearly identified as "confidential business information." Information covered by a claim of business confidentiality will be treated in accordance with the procedures

for handling information claimed as confidential under 40 CFR part 2, subpart B, and will be disclosed only to the extent and by means of the procedures set forth in that subpart. If no claim of confidentiality accompanies the information when it is received by EPA, the information may be made available to the public by EPA without further notice to the company (40 CFR 2.203).

FOR FURTHER INFORMATION CONTACT: Jeremy Arling at the addresses above, by telephone at (202) 343-9055, or by email at arling.jeremy@epa.gov. Information about essential uses may be obtained from EPA's stratospheric protection website at www.epa.gov/ozone/title6/exemptions/essential.html.

SUPPLEMENTARY INFORMATION:

I. Background on the Essential Use Exemption

The Parties to the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol) agreed during the Fourth Meeting in Copenhagen in 1992 that non-Article 5 Parties (developed countries) would phase out the production and consumption of halons by January 1, 1994, and phase out the production and consumption of other substances referred to under the Clean Air Act as class I substances, except methyl bromide, by January 1, 1996. The control measures for many of these substances, however, allow exemptions from the phaseout "to the extent the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential." *See, e.g.* art. 2A para 4. The Parties also decided on the criteria to be used for allowing "essential use" exemptions from the phaseout of production and import of controlled substances. Decision IV/25 of the Fourth Meeting of the Parties details the specific criteria and review process for granting essential use exemptions.

Paragraph 1(a) of Decision IV/25 states that "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." In addition, Paragraph 1(b) of Decision IV/25 states 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 the existing stocks of banked or recycled controlled substances. . ."

The Clean Air Act in section 604 contemplates exemptions from the phaseout of Class I controlled substances in the United States, including exemptions for essential uses.[1] The Clean Air Act sets sunset dates for three of these uses that are now in the past: 1) methyl chloroform use generally (ending January 1, 2005); 2) halons for fire suppression and explosion prevention generally (ending December 31, 1999); and 3) halons for fire suppression and explosion prevention for oil production on the North Slope of Alaska (ending December 31, 2004). Two other uses do not have statutory sunset dates: 1) Class I substances for medical devices (section 604(d)(2)), and 2) halons for aviation safety (section 604(d)(3)). Each of these provisions has its own criteria and process that must be followed; no exceptions are automatic.

Prior essential use applications were typically for chlorofluorocarbons (CFCs) for metered dose inhalers (MDIs). The Parties last authorized an essential use exemption for the United States allowing the production of CFCs for MDIs in 2008 for the 2010 calendar year. Effective December 31, 2013, all CFC-containing MDIs have been removed from the Food and Drug Administration's (FDA's) list of essential uses found at 21 CFR 2.125(e). The United States has not nominated halons for aviation safety as an essential use. If EPA were to receive an

[1] This notice does not address all exemptions in section 604 such as the exemptions for critical uses, sanitation and food protection, or national security.

application for halons for aviation safety, EPA would work with other relevant Federal agencies to establish the process for reviewing applications for this use.

II. Essential Use Nomination Process

Entities requesting essential use exemptions should send a completed application to EPA on the candidate use by September 30, three years prior to the year of the intended use. Upon receipt of applications, EPA will review the information and work with other interested Federal agencies as required in section 604 of the Clean Air Act to determine whether the candidate use satisfies Clean Air Act requirements, as well as whether it meets the essential use criteria adopted by the Parties to the Montreal Protocol and warrants nomination by the United States for an exemption.

All Parties, including the United States, must transmit nominations to the UNEP Ozone Secretariat by January 31 to be considered by the Parties at their annual meeting at the end of that year. The UNEP Ozone Secretariat forwards nominations to the Montreal Protocol's Technical and Economic Assessment Panel (TEAP) and its relevant Technical Options Committee (TOC). The TOC and the TEAP review the nomination to determine whether it meets the criteria for an essential use established by Decisions IV/25, XII/2, XV/5, and XVI/12, and to make recommendations to the Parties for essential use exemptions. The Parties then consider those recommendations at their annual meeting before making a final decision.

An essential use exemption is granted to the nominating Party for a specific quantity of a specified ODS for a specific time period. If the Parties determine that a specified use of a controlled substance is essential and authorize an exemption from the Protocol's production and consumption phaseout, EPA may then take domestic action to allow the production and consumption to the extent consistent with the Clean Air Act.

III. Information Required for Essential Use Applications

In the past, EPA had annually issued a notice requesting applications for essential use exemptions. Through this action, EPA provides the opportunity to submit applications for essential use exemptions for class I substances for all future control periods (calendar years). Applications requesting essential use allowances should include information that U.S. Government agencies and the Parties to the Protocol can use to evaluate the candidate use according to the criteria in the Decisions described above. Applications that fail to include sufficient information may not be nominated.

Specifically, all applications submitted to EPA should include the information requested in the current version of the TEAP *Handbook on Essential Use Nominations*, which as of the date of this notice was last updated in 2009. The handbook is available electronically on the internet at http://ozone.unep.org/teap/Reports/TEAP_Reports/EUN-Handbook2009.pdf. EPA requests that applications contain the following information, as described in the handbook, in order for the U.S. to provide sufficient information to the Montreal Protocol's technical review bodies within the nomination:

1. A detailed description of the use that is the subject of the nomination;

2. Details of the type, quantity, and quality of the controlled substance that is requested to satisfy the use;

3. The period of time and the annual quantities of the controlled substances that are requested;

4. An explanation of why the nominated volumes and the intended use of these quantities are necessary for health and/or safety, or critical for the functioning of society;

5. An explanation of what other alternatives and substitutes are currently available and what steps are being taken to implement those alternatives and substitutes;

6. An explanation of why alternatives and substitutes are not sufficient or appropriate to eliminate the proposed use;

7. A description of the measures that are proposed to eliminate all unnecessary emissions, including design considerations and maintenance procedures;

8. An explanation of what efforts are being undertaken to employ other measures for this application in the future;

9. A description of the efforts that have been made to acquire stockpiled or recycled controlled substance for this application both domestically and internationally as well as an explanation of what efforts have been made to establish banks for the controlled substance; and

10. A description of any other barriers encountered in attempts to eliminate the use of the controlled substance for this application.

In addition, applicants should specify which exemption in CAA section 604 they are seeking: the exemption for medical devices at section 604(d)(2) or the exemption for aviation safety at section 604(d)(3). Each of these statutory exemptions has its own process and criteria that would need to be satisfied prior to any regulatory action authorizing the exemption.

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this notice under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060-0170.

Dated: May 30, 2014.

Paul Gunning, Acting Director,
Office of Atmospheric Programs.

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