

17th Street, NW., Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:**

Richard Naylor, Drinking Water Protection Division, Office of Ground Water and Drinking Water (4606M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202.564.3847; fax number: 202.564.3755; e-mail address: [naylor.richard@epa.gov](mailto:naylor.richard@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On June 6, 2008 (73 FR 32323), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OW-2008-0438, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC 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 Reading Room is 202-566-1744, and the telephone number for the Water Docket is 202-566-2426.

Use EPA's electronic docket and comment system at <http://www.regulations.gov>, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at <http://www.regulations.gov> as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to <http://www.regulations.gov>.

*Title:* Microbial Rules (Renewal).

*ICR numbers:* EPA ICR No. 1895.04, OMB Control No. 2040-0205.

*ICR Status:* This ICR is scheduled to expire on December 31, 2008. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this

submission is pending at OMB. 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 in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

*Abstract:* The Microbial Rules Renewal ICR examines public water system (PWS), primacy agency and EPA burden and costs for recordkeeping and reporting requirements in support of the microbial drinking water regulations. These recordkeeping and reporting requirements are mandatory for compliance with 40 CFR parts 141 and 142. The following microbial regulations are included: Surface Water Treatment Rule, Total Coliform Rule, Interim Enhanced Surface Water Treatment Rule, Filter Backwash Recycling Rule, Long Term 1 Enhanced Surface Water Treatment Rule, Long Term 2 Enhanced Surface Water Treatment Rule, and Ground Water Rule. Future microbial-related rulemakings will be added to this consolidated ICR after the regulations are finalized and the initial, rule-specific, ICRs are due to expire.

*Burden Statement:* The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.88 hours per response. 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 which have subsequently changed; 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.

*Respondents/Affected Entities:* New and existing public water systems (PWS) and primacy agencies.

*Estimated Number of Respondents:* 155,750.

*Frequency of Response:* varies by requirement (i.e., on occasion, monthly, quarterly, semi-annually, annually).

*Estimated Total Annual Hour Burden:* 10,669,916.

*Estimated Total Annual Cost:* \$554.0 million includes \$197.2 million annualized capital or O&M costs.

*Changes in the Estimates:* There is an increase of 2,045,051 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is primarily due to adjustments to burden based on consultations with drinking water associations and to restructuring adjustments (i.e., incorporation of the burden hours for the Long Term 2 Enhanced Surface Water Treatment Rule and the Ground Water Rule).

Dated: November 24, 2008.

**John Moses,**

*Acting Director, Collection Strategies Division.*

[FR Doc. E8-28451 Filed 11-28-08; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8747-3]

### Protection of Stratospheric Ozone: Request for Applications for Essential Use Allowances for 2010 and 2011

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is requesting applications for essential use allowances for calendar years 2010 and 2011. Essential use allowances provide exemptions from the phaseout on production and import of ozone-depleting substances (ODSs). Essential use allowances must be authorized by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer (the Protocol). The U.S. Government will use the applications received in response to this notice as the basis for its nomination of essential uses at the 21st Meeting of the Parties to the Protocol, to be held in 2009.

**DATES:** Applications for essential use allowances must be submitted to EPA no later than December 31, 2008 in order for the U.S. Government to complete its review and to submit nominations to the United Nations Environment Programme and the Protocol Parties in a timely manner.

**ADDRESSES:** Send two copies of application materials to: Jennifer Bohman, Stratospheric Protection Division (6205), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. For applications sent via courier service, use the following direct mailing address: 1310 L Street, NW., Washington, DC, 20005, room 1047A.

**Confidentiality:** Application materials that are confidential should be submitted under separate cover and be clearly identified as “trade secret,” “proprietary,” or “company confidential.” 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. Please note that data will be presented in aggregate form by the United States as part of the nomination to the Parties. 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:** Jennifer Bohman at the above address, or by telephone at (202) 343-9548, by fax at (202) 343-2363, or by e-mail at [bohman.jennifer@epa.gov](mailto:bohman.jennifer@epa.gov). General information may be obtained from EPA’s stratospheric protection Web site at <http://www.epa.gov/ozone/strathome.html>.

**SUPPLEMENTARY INFORMATION:**

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- I. Background on the Essential Use Nomination Process
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**I. Background on the Essential Use Nomination Process**

The Parties to the Protocol agreed during the Fourth Meeting in Copenhagen on November 23–25, 1992, that non-Article 5 Parties (developed countries) would phase out the production and consumption of halons by January 1, 1994, and the production and consumption of other class I substances (under 40 CFR part 82, subpart A), except methyl bromide, by January 1, 1996. The Parties also reached decisions and adopted resolutions on a variety of other matters, including 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.

Decision IV/25, paragraph 1(a), states 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.” In addition, the Parties agreed “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 \* \* \*” Decision XII/2 of the Twelfth Meeting of the Parties states that any CFC metered dose inhaler (MDI) product approved after December 31, 2000, is nonessential unless the product meets the criteria in Decision IV/25, paragraph 1(a).

The first step in obtaining essential use allowances is for the user to consider whether the use of the controlled substance meets the criteria of Decision IV/25. If the essential use request is for an MDI product, the user should also consider whether the product meets the criteria of Decision XII/2. In addition, the user should consult recent and ongoing rulemakings by the Food and Drug Administration (FDA) concerning the essential use determination of various MDI moieties. In particular, users should consider FDA’s November 19, 2008 final rulemaking that removes the essential use designation for epinephrine used in MDIs as of December 31, 2011 (73 FR 69532) and FDA’s June 11, 2007 proposed rulemaking that proposes removing the essential use designations for flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil used in MDIs as of December 31, 2009 (72 FR 32030).

Users requesting essential use allowances for calendar years 2010 and 2011 should send a completed application to EPA on the candidate use. The application 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.

Upon receipt of application, EPA reviews the information and works with other interested Federal agencies to determine whether the candidate use meets the essential use criteria and warrants nomination by the United States for an exemption. In the case of multiple exemption requests for a single use, such as for MDIs, EPA aggregates exemption requests received from individual entities into a single U.S. request. An important part of the EPA review is to ensure that the aggregate request for a particular future year adequately reflects the total market need for CFC MDIs and expected availability of CFC substitutes by that point in time. If the sum of individual requests does not account for such factors, the U.S. Government may adjust the aggregate request to better reflect true market needs.

Nominations submitted by the United States and other Parties are forwarded by the United Nations Ozone Secretariat to the Montreal Protocol’s Technical and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC), which reviews the submissions and make recommendations to the Parties for essential use exemptions. Those recommendations are then considered by the Parties at their annual meeting for final decision. If the Parties declare a specified use of a controlled substance as essential, and authorize an exemption from the Protocol’s production and consumption phaseout, EPA may propose regulatory changes to reflect the decisions by the Parties, but only to the extent such action is consistent with the Clean Air Act. Applicants should be aware that essential use exemptions granted to the United States under the Protocol in recent years have been limited to CFCs for MDIs to treat asthma and chronic obstructive pulmonary disease.

The Parties review nominations for essential use exemptions for the following year and subsequent years. This means that, if nominated, applications submitted in response to today’s notice for an exemption in 2010 and 2011 will be considered by the Parties in 2009 for final action. The quantities of controlled substances that are requested in response to this notice, if approved by the Parties to the Montreal Protocol, will then be allocated as essential use allowances to the specific U.S. companies through notice-and-comment rulemaking, to the extent that such allocations are consistent with the Clean Air Act.

## II. Information Required for Essential Use Applications for Production or Import of Class I Substances in 2010 and 2011

Through this action, EPA requests applications for essential use exemptions for all class I substances, except methyl bromide, for calendar years 2010 and 2011. This notice is the last opportunity to submit new or revised applications for 2010. This notice is also the first opportunity to submit requests for 2011. Companies will have an opportunity in 2009 to submit new, supplemental, or amended applications for 2011. All requests for exemptions submitted to EPA should present information as requested in the current version of the TEAP *Handbook on Essential Use Nominations*, which was updated in 2005. The handbook is available electronically on the Web at [http://ozone.unep.org/teap/Reports/TEAP\\_Reports/EUN-Handbook2005.pdf](http://ozone.unep.org/teap/Reports/TEAP_Reports/EUN-Handbook2005.pdf).

In brief, the TEAP Handbook states that applicants should present information on:

- Role of use in society;
- Alternatives to use;
- Steps to minimize use;
- Recycling and stockpiling;
- Quantity of controlled substances requested; and
- Approval date and indications (for MDIs).

In addition, entities should address the following points to ensure that their applications are clear and complete. First entities that request CFCs for multiple companies should clearly state the amount of CFCs requested for each company. Second, all essential use applications for CFCs should provide a breakdown of the quantity of CFCs necessary for each MDI product to be produced. This detailed breakdown will allow EPA and FDA to make informed decisions regarding the amount of CFCs to be nominated by the U.S.

Government for the years 2010 and 2011. Third, all new drug application (NDA) holders for CFC MDI products produced in the United States should submit a complete application for essential use allowances either on their own or in conjunction with their contract filler. In the case where a contract filler produces a portion of an NDA holder's CFC MDIs, the contract filler and the NDA holder should determine the total amount of CFCs necessary to produce the NDA holder's entire product line of CFC MDIs. The NDA holder should provide an estimate of how the CFCs would be split between the contract filler and the NDA holder in the allocation year. This estimate will be used only as a basis for determining

the nomination amount, and may be adjusted prior to allocation of essential use allowances. Since the U.S. Government does not forward incomplete or inadequate nominations to the Ozone Secretariat, it is important for applicants to provide all information requested in the Handbook, including comprehensive information pertaining to the research and development of alternative CFC MDI products per Decision VIII/10, para. 1 as specified in the Supplement to Nomination Request (pg. 46). Finally, consistent with Decision XIX/13 taken in September 2007 at the 19th Meeting of the Parties, when requesting essential use CFCs for MDIs, applicants should provide the following information: (1) The company's commitment to the reformulation of the concerned products; (2) the timetable in which each reformulation process may be completed; and (3) evidence that the company is diligently seeking approval of any CFC-free alternative(s) in its domestic and export markets and transitioning those markets away from its CFC products.

The accounting framework matrix in the Handbook (Table IV) entitled "Reporting Accounting Framework for Essential Uses Other Than Laboratory and Analytical Applications" requests data for the year 2008 on the amount of ODSs exempted for an essential use, the amount acquired by production, the amount acquired by import and the country(s) of manufacture, the amount on hand at the start of the year, the amount available for use in 2008, the amount used for the essential use, the quantity contained in exported products, the amount destroyed, and the amount on hand at the end of 2008.

Because all data necessary for applicants to complete Table IV will not be available until after the control period ends on December 31, 2008, companies should not include this chart with their essential use applications in response to this notice. Instead, companies should report their data as required by 40 CFR 82.13(u)(2) in Section 5 of the report entitled "Essential Use Allowance Holders and Laboratory Supplier Quarterly Report and Essential Use Allowance Holder Annual Report." This form may be found on EPA's Web site at [http://www.epa.gov/ozone/record/downloads/EssentialUse\\_ClassI.doc](http://www.epa.gov/ozone/record/downloads/EssentialUse_ClassI.doc). EPA will then compile companies' responses and complete the U.S Accounting Framework for Essential Uses for submission to the Parties to the Montreal Protocol by the end of January 2009. EPA may also request additional

information from companies to support the U.S. nomination using its information gathering authority under Section 114 of the Act.

EPA anticipates that the Parties' review of MDI essential use requests will focus extensively on the United States' progress in phasing out CFC MDIs, including education programs to inform patients and health care providers of the CFC phaseout and the transition to alternatives. Accordingly, applicants are strongly advised to present detailed information on these educational programs, including the scope and cost of such efforts and the medical and patient organizations involved in the work. In addition, EPA expects that Parties will be interested in research and development activities being undertaken by MDI manufacturers to develop and transition to alternative, CFC-free MDI products. To this end, applicants are encouraged to provide detailed information on these efforts. Applicants should submit their exemption requests to EPA as noted in the "Addresses" section above.

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: November 24, 2008.

**Brian J. McLean,**

*Director, Office of Atmospheric Programs.*

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8747-4]

### Science Advisory Board Staff Office; Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the chartered Clean Air Scientific Advisory Committee (CASAC) to consider and approve the CASAC Panel's draft report regarding its peer review of EPA's *Risk and Exposure Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur: First Draft (August 2008)*. The CASAC will also discuss the