

## 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.*

[FR Doc. E8-28452 Filed 11-28-08; 8:45 am]

BILLING CODE 6560-50-P

## 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

Agency's schedule and process for National Ambient Air Quality Standards (NAAQS) review of criteria pollutants with EPA's Office of Air and Radiation and Office (OAR) and Office of Research and Development (ORD).

**DATES:** The public teleconference will be held on Friday, December 19, 2008 from 12 p.m. to 3 p.m. (Eastern Time).

*Location:* The public teleconference will be conducted by telephone only.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public who wants further information concerning the teleconference meeting may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9867; fax (202) 233-0643; or e-mail at [stallworth.holly@epa.gov](mailto:stallworth.holly@epa.gov). General information concerning the CASAC can be found on the EPA Web site at <http://www.epa.gov/casac>.

**SUPPLEMENTARY INFORMATION:**

*Background:* The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and national ambient air quality standards (NAAQS) under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six "criteria" air pollutants, including Nitrogen Oxide (NO<sub>x</sub>) and Sulfur Oxides (SO<sub>x</sub>). EPA is in the process of reviewing the secondary NAAQS for NO<sub>x</sub> and SO<sub>x</sub>. Welfare effects as defined in the CAA include, but are not limited to, effects on soils, water, wildlife, vegetation, visibility, weather, and climate, as well as effects on materials, economic values, and personal comfort and well-being. As part of that process, EPA's OAR completed the *Risk and Exposure Assessment (REA) for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur: First Draft (August 2008)*. The CASAC NO<sub>x</sub> and SO<sub>x</sub> Secondary National Ambient Air Quality Standards (NAAQS) Review

Panel held a public meeting on October 1-2, 2008 to conduct a peer review of EPA's first draft REA. The panel discussed its draft letter report on November 19, 2008. The purpose of this conference call is for the chartered CASAC to review and approve the Panel's draft letter. In addition, CASAC will also publicly discuss the entire NAAQS schedule and process with EPA's Office OAR and ORD.

*Technical Contacts:* Any questions concerning 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* should be directed to Dr. Anne Rea, OAR, at (919) 541-0053 or [rea.anna@epa.gov](mailto:rea.anna@epa.gov).

*Availability of Meeting Materials:* EPA-*Risk and Exposure Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur: First Draft* can be accessed at [http://www.epa.gov/ttn/naaqs/standards/no2so2sec/cr\\_rea.html](http://www.epa.gov/ttn/naaqs/standards/no2so2sec/cr_rea.html). The Panel's draft letter and the CASAC agenda for the teleconference will be posted in advance of the meeting on the SAB Web site at <http://www.epa.gov/casac>.

*Procedures for Providing Public Input:* Interested members of the public may submit relevant written or oral information for consideration on the topics included in this advisory activity.

*Oral Statements:* To be placed on the public speaker list for the December 19, 2008 teleconference, interested parties should notify Dr. Holly Stallworth, DFO, by e-mail no later than December 12, 2008. Individuals making oral statements will be limited to three minutes per speaker. *Written Statements:* Written statements for the December 19, 2008 teleconference should be received in the SAB Staff Office by December 12, 2008, so that the information may be made available to the CASAC Panel for its consideration prior to this meeting. Written statements should be supplied to the DFO in the following formats: One hard copy with original signature and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

*Accessibility:* For information on access or services for individuals with disabilities, please contact Dr. Stallworth at the phone number or e-mail address noted above, preferably at least ten days prior to the face-to-face meeting, to give EPA as much time as possible to process your request.

Dated: November 24, 2008.

**Anthony F. Maciorowski,**

*Deputy Director, EPA Science Advisory Board Staff Office.*

[FR Doc. E8-28453 Filed 11-28-08; 8:45 am]

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## EXPORT-IMPORT BANK OF THE UNITED STATES

### Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank)

**SUMMARY:** The Advisory Committee was established by Pub. L. 98-181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank of the United States to Congress.

*Time and Place:* Wednesday, December 10, 2008 from 9:30 a.m. to 12 p.m. The meeting will be held at Ex-Im Bank in the Main Conference Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

*Agenda:* Agenda items include a briefing of the Advisory Committee members on challenges for 2009, their roles and responsibilities and an ethics briefing.

*Public Participation:* The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If you plan to attend, a photo ID must be presented at the guard's desk as part of the clearance process into the building, and you may contact Susan Houser to be placed on an attendee list. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to December 5, 2008, Susan Houser, Room 1273, 811 Vermont Avenue, NW., Washington, DC 20571, Voice: (202) 565-3232 or TDD (202) 565-3377.

**FOR FURTHER INFORMATION:** For further information, contact Susan Houser, Room 1273, 811 Vermont Avenue, NW., Washington, DC 20571, (202) 565-3232.

**Kamil P. Cook,**

*Deputy General Counsel.*

[FR Doc. E8-28228 Filed 11-28-08; 8:45 am]

BILLING CODE 6690-01-M