

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 taken at the thirteenth 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, that product must also meet the criteria of Decision XII/2. The user should then send a completed application in order to notify EPA of the candidate use and provide information for U.S. government agencies and the Protocol Parties to evaluate that use according to the criteria under the Protocol.

Upon receipt of the essential use exemption application, EPA reviews the information provided and works with other interested Federal agencies to determine whether it meets the essential use criteria and warrants being nominated 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 of requests for CFCs for MDIs is to determine 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 from the United Nations Ozone Secretariat to the Montreal Protocol's Technical and Economic Assessment Panel (TEAP) and its Technical Options

Committees (TOCs), which review the submissions and make recommendations to the Protocol 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 issue the necessary exemption from the 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 (CAA or Act). Applicants should be aware that essential use exemptions granted to the United States under the Protocol in recent years have been limited to chlorofluorocarbons (CFCs) for metered dose inhalers (MDIs) to treat asthma and chronic obstructive pulmonary disease, and methyl chloroform for use in manufacturing solid rocket motors.

The timing of this process is such that in any given year the Parties review nominations for essential use exemptions from the production and consumption phaseout intended for the following year and subsequent years. This means that, if nominated, applications submitted in response to today's notice for an exemption in 2005 and 2006 will be considered by the Parties in 2004 for final action.

The quantities of controlled ODSs that are requested in response to this notice, if approved by the Parties to the Montreal Protocol in 2004, will then be allocated as essential use allowances (EUAs) to the specific U.S. companies through notice and comment rulemaking. EUAs for the year 2005 will be allocated to U.S. companies at the end of 2004, and EUAs for the year 2006 will be made at the end of 2005.

II. Information Required for Essential Use Applications for Production or Importation of Class I Substances in 2005 and 2006

Through this action, EPA requests applications for essential use exemptions for all class I substances, except methyl bromide, for calendar years 2005 and 2006. This notice is the last opportunity to submit new or revised applications for 2005. This notice is also the first opportunity to submit requests for 2006. Companies will have an opportunity to submit new, supplemental, or amended applications for 2006 next year. All requests for exemptions submitted to EPA must present information as prescribed in the current version of the TEAP "Handbook on Essential Use Nominations" (or "handbook"), which was published in June 2001. The handbook is available

electronically on the Web at <http://www.teap.org>, or at <http://www.epa.gov/ozone>.

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

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

First, in order to obtain complete information from essential use applicants for CFC MDIs, EPA requires that parties (such as the International Pharmaceutical Aerosol Consortium) who request CFCs for multiple pharmaceutical companies make clear the amount of CFCs requested for each member company. Second, all essential use applications for CFCs must provide a breakdown of the quantity of CFCs necessary for each MDI product to be produced. This detailed breakdown of EUAs will allow EPA and the Food and Drug Administration to make informed decisions on the amount of CFC to be nominated by the U.S. Government for the years 2005 and 2006. Third, all new drug application (NDA) holders for CFC MDI products produced in the United States must 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 must determine the total amount of CFCs necessary to produce the NDA holder's entire product line of CFC MDIs. The NDA holder must 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 EUAs. Since the U.S. Government cannot forward incomplete or inadequate nominations to the Ozone Secretariat, it is important for applicants to provide all information requested in the Handbook, including the information specified in the supplemental research and development form (page 45).

The accounting framework matrix in the handbook entitled "Table IV: Reporting Accounting Framework for Essential Uses Other Than Laboratory and Analytical" requests data for the year 2003 on the amount of ODS exempted for an essential use, the amount acquired by production, the