

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 existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances."

B. Under What Authority Does EPA Allocate Essential Use Allowances?

Title VI of the Act implements the Protocol for the United States.³ Section 604(d) of the Act authorizes EPA to allow the production of limited quantities of class I ODSs after the phaseout date for the following essential uses:

(1) Methyl Chloroform, "solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane parts susceptible to metal fatigue) for which no safe and effective substitute is available." EPA issues methyl chloroform allowances to the U.S. Space Shuttle and Titan Rocket programs.

(2) Medical Devices (as defined in section 601(8) of the Act), "if such authorization is determined by the Commissioner [of the Food and Drug Administration], in consultation with the Administrator [of EPA] to be necessary for use in medical devices." EPA issues allowances to manufacturers of metered-dose inhalers, which use CFCs as propellant for the treatment of asthma and chronic obstructive pulmonary diseases.

(3) Aviation Safety, for which limited quantities of halon-1211, halon-1301, and halon 2402 may be produced "if the Administrator of the Federal Aviation Administration, in consultation with the Administrator [of EPA] determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes." Neither EPA nor the Parties have ever granted a request for essential

use allowances for halon, because alternatives are available or because existing quantities of this substance are large enough to provide for any needs for which alternatives have not yet been developed.

The Protocol, under Decision X/19, additionally allows a general exemption for laboratory and analytical uses through December 31, 2005. This exemption is reflected in EPA's regulations at 40 CFR part 82, subpart A. While the Act does not specifically provide for this exemption, EPA has determined that an allowance for essential laboratory and analytical uses is allowable under the Act as a *de minimis* exemption. The *de minimis* exemption is addressed in EPA's final rule of March 13, 2001 (66 FR 14760-14770). The Parties to the Protocol subsequently agreed (Decision XI/15) that the general exemption does not apply to the following uses: testing of oil and grease, and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exclusion at Appendix G to Subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

C. What Is the Process for Allocating Essential Use Allowances?

Before EPA may allocate essential use allowances, the Parties to the Protocol must first approve the United States' request to produce or import essential class I ODSs. The procedure set out by Decision IV/25 calls for individual Parties to nominate essential uses and the total amount of ODSs needed for those essential uses on an annual basis. The Protocol's Technology and Economic Assessment Panel evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on whether to approve a Party's essential use nomination at their annual meeting. This nomination cycle occurs approximately two years before the year in which the allowances would be in effect. The allowances allocated through today's action were first nominated by the United States in January 2001.

Once the U.S. nomination is approved by the Parties, EPA allocates essential use exemptions to specific entities through notice-and-comment rulemaking in a manner consistent with the Act. For medical devices, EPA requests information from manufacturers about the number and type of devices they plan to produce, as well as the amount of CFCs necessary for production. EPA then forwards the information to the Food and Drug

Administration (FDA), which determines the amount of CFCs necessary for metered-dose inhalers in the coming calendar year. Based on FDA's assessment, EPA proposes allocations to each eligible entity. Under the Act and the Protocol, EPA may allocate essential use allowances in quantities that together are below or equal to the total amount approved by the Parties. EPA may not allocate essential use allowances in amounts higher than the total approved by the Parties. For 2004, the Parties authorized the United States to allocate up to 2,975 metric tons of CFCs for essential uses.

For methyl chloroform, Decision X/6 by the Parties to the Protocol established that " * * * the remaining quantity of methyl chloroform authorized for the United States at previous meetings of the Parties [will] be made available for use in manufacturing solid rocket motors until such time as the 1999-2001 quantity of 176.4 tons (17.6 ODP-weighted tons) allowance is depleted, or until such time as safe alternatives are implemented for remaining essential uses." Section 604(d)(1) of the Act terminates the exemption period for methyl chloroform on January 1, 2005. Therefore, between 1999 and 2004 EPA may allow production or import up to a total of 176.4 metric tonnes of methyl chloroform for authorized essential uses.

III. Essential Use Allowances for Medical Devices

The following is a step-by-step list of actions EPA and FDA have taken thus far to implement the exemption for medical devices found at section 604(d)(2) of the Act for the 2004 control period.

1. On March 10, 2003, EPA sent letters to MDI manufacturers requesting the following information under section 114 of the Act ("114 letters"):

- a. The MDI product where CFCs will be used.
- b. The number of units of each MDI product produced from 1/1/02 to 12/31/02.
- c. The number of units anticipated to be produced in 2003.
- d. The gross target fill weight per unit (grams).
- e. Total amount of CFCs to be contained in the MDI product for 2004.
- f. The additional amount of CFCs necessary for production.
- g. The total CFC request per MDI product for 2004. The 114 letters are available for review in the Air Docket ID No. OAR-2003-0202. The companies requested that their responses be treated as confidential business information; for

³ According to Section 614(b) of the Act, Title VI "shall be construed, interpreted, and applied as a supplement to the terms and conditions of the Montreal Protocol * * * and shall not be construed, interpreted, or applied to abrogate the responsibilities or obligations of the United States to implement fully the provisions of the Montreal Protocol. In the case of conflict between any provision of this title and any provision of the Montreal Protocol, the more stringent provision shall govern." EPA's regulations implementing the essential use provisions of the Act and the Protocol are located in 40 CFR part 82.