

Decision XVI/___: Essential-use nominations for non-Article 5 Parties for controlled substances for 2005 and 2006

Noting the work done by the Technology and Economic Assessment Panel (TEAP) and its Aerosol Technical Options Committee (ATOC), in particular the Panel's recommendation for a further review of the 2006 essential-use nominations and for clarification of certain criteria to determine when CFCs are to be considered essential,

Mindful that although the Parties intended the essential-use process under Article 2A of the Protocol to be a temporary exemption, 2006 will be the eleventh year of essential-use authorizations under that exemption,

Recognizing, therefore, the need for stricter scrutiny of all essential-use nominations for years after 2005 in order to move toward closure of the essential-use exemption for Parties not operating under paragraph 1 of Article 5,

1. To authorise the levels of production and consumption specified in the annex to the present decision that are necessary to satisfy essential uses of CFCs for metered-dose inhalers (MDIs) for asthma and chronic obstructive pulmonary disease, provided that for 2006 no levels are authorised for MDIs in which the sole active ingredient is salbutamol unless the intended market of the MDI is an Article 5(1) Party;
2. To clarify that the plan of action referred to in paragraph 4 of decision XV/5 should be submitted to the Ozone Secretariat as soon as possible, but in any case no later than four weeks prior to the 2005 meeting of ATOC;
3. To request each nominating Party to submit to TEAP no later than four weeks prior to the 2005 meeting of ATOC the information specified in paragraph 6 of the present decision for its essential-use nomination for CFC-salbutamol for 2006 and any essential-use nomination for 2007, with the understanding that in accordance with decision XV/5 all essential-use nominations must show requested volumes for each active ingredient and each intended market;
4. To request TEAP to undertake an assessment in 2005 of any CFC essential-use nomination for CFC-salbutamol for 2006 and any essential-use nomination for 2007, focusing in particular on whether or not, under paragraph 1 of decision IV/25 and paragraph 3 of decision XV/5, specific uses remain essential for each active ingredient and each intended market due to the availability of CFC-free alternatives, and to submit its report to the Parties by 30 April 2005;
5. To clarify that the phrase "sufficient quantity" in paragraph 1(b)(ii) of decision IV/25 means that each MDI manufacturer owns, or has agreement to acquire from another company, no more than a one-year supply of CFCs;

6. To request each nominating Party to provide information, as part of its essential-use nomination, to demonstrate that each MDI manufacturer that has requested CFC volumes:
 - (a) Does not own, or has no agreement to acquire from another company, more than a one-year supply of CFCs;
 - (b) Following decision VIII/10, is conducting continuous research and development on alternatives to CFC MDIs with all due diligence and, where appropriate, in collaboration with other companies;

Provided that, if the submitting Party determines that any of the information is confidential, it may specify that such information be viewed only by the co-chairs of TEAP and ATOC;

7. To request TEAP to defer recommendation of any essential-use nomination, or part thereof, to the extent that any Party has not provided the information requested in paragraph 6 of the present decision;
8. To urge TEAP:
 - (a) To modify the Handbook on essential-use nominations to reflect the provisions of decision XV/5 and this decision, by no later than 1 February 2005;
 - (b) To specify in the Handbook that a nominating Party may submit in its nomination data aggregated by region or product groups for CFC MDIs intended for sale in the markets of Article 5(1) Parties, where more specific data are not available;
 - (c) To provide in its Progress Report to the Parties a clear description of the additional information required in cases where all or part of the volume of CFCs in a Party's nomination are not recommended.

Annex

Essential-Use Authorisations for CFC MDIs for Asthma and Chronic Obstructive Pulmonary Disease. CFC volumes approved for 2005 and 2006; and CFC volumes for re-assessment in 2006 (metric tonnes).

Party	2005		2006			
	Amount nominated	Amount approved	Amount nominated	Amount approved for MDIs where the sole active ingredient is not salbutamol	Amount approved for MDIs where the sole active ingredient is salbutamol but the intended market is an Article 5(1) Party	Amount for re-assessment in 2005 where the sole active ingredient is salbutamol and the intended market is a non-Article 5(1) Party
European Community	--	--	550	334 ^a	24 ^a	192 ^a
Poland	4.2	b	4.2	b	b	b
Russian Federation	--	--	286	c	c	c
Ukraine	53.1	53.1	--	--	--	--
United States of America	--	--	1,900 ^d	570	--	1,330
Total	57.3	53.1	2,830.2	904	24	1,522

- a. Supplementary information provided to TEAP by the European Community in July 2004;
- b. Data submitted in support of the nomination for 2005 and 2006 were incomplete and ATOC was unable to recommend the nomination. The nomination may be addressed within the essential use quota for the European Community of which Poland is a member;
- c. Technology and Economic Assessment Panel was unable to recommend and suggested a review of the nomination in 2005;
- d. Technology and Economic Assessment Panel noted that the US nomination stated that 70 percent of its nomination was for salbutamol and 30 percent for non-salbutamol active ingredients, and that the nominated quantities are almost exclusively for domestic use.