

**Open-ended Working Group of the Parties to
the Montreal Protocol on Substances that
Deplete the Ozone Layer
Thirty-second meeting
Bangkok, 23–27 July 2012
Agenda item 4 (a)**

**Issues related to exemptions from Article 2 of the Montreal Protocol:
Nominations for essential-use exemptions for 2013 and 2014**

Draft decision on essential-use nominations for controlled substances for 2013

Submission by China and the Russian Federation

The Twenty-Fourth Meeting of the Parties decides:

Noting with appreciation the work done by the Technology and Economic Assessment Panel and its Medical Technical Options Committee,

Mindful that, according to decision IV/25, the use of chlorofluorocarbons for metered-dose inhalers does not qualify as an essential use if technically and economically feasible alternatives or substitutes are available that are acceptable from the standpoint of environment and health,

Noting the Panel's conclusion that technically satisfactory alternatives to chlorofluorocarbon-based metered-dose inhalers are available for some therapeutic formulations for treating asthma and chronic obstructive pulmonary disease,

Taking into account the Panel's analysis and recommendations for essential-use exemptions for controlled substances for the manufacture of metered-dose inhalers used for asthma and chronic obstructive pulmonary disease,

Welcoming the continued progress in several parties operating under paragraph 1 of Article 5 in reducing their reliance on chlorofluorocarbon-based metered-dose inhalers as alternatives are developed, receive regulatory approval and are marketed for sale,

1. To authorize the levels of production and consumption for 2013 necessary to satisfy essential uses of chlorofluorocarbons for metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in the annex to the present decision;
2. To request nominating parties to supply to the Medical Technical Options Committee information to enable assessment of essential-use nominations in accordance with the criteria set out in decision IV/25 and subsequent relevant decisions as set out in the handbook on essential-use nominations;
3. To encourage parties with essential-use exemptions in 2013 to consider sourcing required pharmaceutical-grade chlorofluorocarbons initially from stockpiles where they are available and accessible, provided that such stockpiles are used subject to the conditions established by the Meeting of the Parties in paragraph 2 of its decision VII/28;

4. To encourage parties with stockpiles of pharmaceutical-grade chlorofluorocarbons potentially available for export to parties with essential-use exemptions in 2013 to notify the Ozone Secretariat of such quantities and of a contact point by 31 December 2012;

5. To request the Secretariat to post on its website details of the potentially available stocks referred to in the paragraph 4 of the present decision;

6. That the parties listed in the annex to the present decision shall have full flexibility in sourcing the quantity of pharmaceutical-grade chlorofluorocarbons to the extent required for manufacturing metered-dose inhalers, as authorized in paragraph 1 of the present decision, from imports, from domestic producers or from existing stockpiles;

7. To request parties to consider domestic regulations to ban the launch or sale of new chlorofluorocarbon-based metered-dose inhalers products, even if such products have been approved;

8. To encourage parties to fast-track their administration processes for the registration of metered-dose inhaler products in order to speed up the transition to chlorofluorocarbon-free alternatives.

Annex

Essential-use authorizations for 2013 of chlorofluorocarbons for metered-dose inhalers

(Metric tonnes)

<i>Parties</i>	<i>2013</i>
China	[395.82] [386.82]
Russian Federation	[212]