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**Twentieth Meeting of the Parties to the  
Montreal Protocol on Substances  
that Deplete the Ozone Layer**

Doha, 16–20 November 2008

Item 4 (c) (iii) of the provisional agenda\*

**Discussion of Montreal Protocol-related issues:  
issues related to essential uses:**

**Essential uses and campaign production of CFCs for metered-dose inhalers**

## **Review of essential-use decisions**

### **Introduction**

1. In its report to the Open-ended Working Group at its twenty-eighth meeting, the contact group on campaign production and essential uses noted that it had requested the Ozone Secretariat to review all relevant decisions on essential uses to extend their applicability to essential-use nominations submitted by Parties operating under paragraph 1 of Article 5.
2. In accordance with that request, the Secretariat has reviewed the title and operative paragraphs of all of the decisions of the Parties on essential uses in an effort to determine which paragraphs might need to be changed to indicate clearly that they are applicable to Parties operating under paragraph 1 of Article 5, together with Parties not so operating. In the course of that review, the Secretariat found that related decisions or provisions in decisions generally fell into one of three categories.
3. The first category is that of provisions originally drafted in a neutral manner so that they would apply to all Parties. As a consequence, many of the key provisions of the essential-use process already apply both to Parties operating under paragraph 1 of Article 5 and Parties not so operating. For example, decision VIII/9 refers to “Parties” and thereby makes timelines, reporting formats and an emergency exemption process applicable to all nominating Parties. In that specific case, and in many others, the Secretariat has only recommended a change to the title of the decision to make it clear that the decision applies to both categories of Parties.
4. The second category is that of language that specified that the provisions applied only to Parties not operating under paragraph 1 of Article 5. Provisions in this category would need to be changed to extend their applicability to Parties operating under paragraph 1 of Article 5. The Secretariat identified two main options to effect the required change. The first, which was not selected, was to extend the

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\* UNEP/OzL.Pro.20/1.

provisions' applicability by inserting the term "Parties operating under paragraph 1 of Article 5" in each such decision, to make it clear that the decisions applied to both categories of Parties. The second alternative, which was selected, was to change the language currently in those decisions, "Parties not operating under Article 5", to the more neutral term "Parties" already found in many of the generally applicable decisions. Making the change in this manner clearly indicates applicability to all Parties and also standardizes the language used across all decisions.

5. The Secretariat identified a third category of decisions: those which required submission of specific kinds of information from essential-use applicants by a specified historic date to enable their subsequent essential-use nominations to be considered, or which included a cut-off date for a determination of essentiality. For example, paragraph 4 of decision XV/5 states:

That no quantity of CFCs for essential uses shall be authorized after the commencement of the Seventeenth Meeting of the Parties if the nominating Party not operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-fifth meeting of the Open-ended Working Group, a plan of action regarding the phase-out of the domestic use of CFC-containing metered-dose inhalers where the sole active ingredient is salbutamol.

6. Given that the twenty-fifth meeting of the Open-ended Working Group has already taken place, the Secretariat is not certain whether the relevant mandate should be considered immediately applicable to nominators who are Parties operating under paragraph 1 of Article 5, or if the Parties would wish to consider allowing another date. Accordingly, in the context of the above decision, and others in this category, the Secretariat has noted that the Parties may wish to clarify whether the mandate is immediately applicable to nominations by Parties operating under paragraph 1 of Article 5. Furthermore, in the strike-and-insert versions of the related decisions that follow, provisions noted for specific consideration of the Parties are highlighted in bold and italic type.

## **A. Overview of the document**

7. The document that follows consists of two parts. The first comprises a table that lists by number and title every essential-use decision taken by the Parties, together with information on whether a change to the title or operative paragraphs of the decision is considered necessary, and, if not, why not. In this regard, the Secretariat did not review, and therefore did not recommend any changes to, any of the introductory paragraphs to the essential-use decisions (which are arguably not part of the actual decisions themselves), believing that they captured the intent of the Parties at the time and that changes to the title and operative paragraphs would be fully effective in extending the applicability of related decisions.

8. The second part consists of an annex containing strike-and-insert versions of the decisions that are believed to require changes to render them applicable to Parties operating under paragraph 1 of Article 5. The only exception is where only a change to the title is believed necessary to clarify the decision's applicability to all Parties; in those cases, a strike-and-insert version of the title is included, while the full text of the decision is not.

## **B. Summary**

9. In the second category of decisions mentioned in paragraph 4 above:

(a) The following titles or provisions of the past decisions of the Parties contain the term "not operating under Article 5" or "for non-Article 5 Parties" that may be considered for removal to make clear their applicability to all Parties:

- Title of decisions VIII/9, XI/14, XVII/5, VIII/10, VIII/11, XVIII/7, XIX/13
- Decision VIII/10, the first line of paragraphs 1-9
- Decision XV/5 paragraphs 2, 3, 5 (a) and 6
- Decision XVIII/7 paragraphs 2 and 3
- Decision XVIII/16, first line of paragraph 7

(b) The following titles or provisions contain the term “not operating under Article 5 of the Montreal Protocol”, which may be considered for removal to make clear their applicability to all Parties:

- Decision XVII/5 paragraph 2
- Decision XIX/13 paragraphs 2 and 3

10. In the third category of decision mentioned in paragraph 5 above, the following provisions include the date “1996” which may be replaced with the term “phase-out” to make clear their applicability after the relevant phase-out date:

- Decision XVIII/7, paragraph 2
- Decision XIX/13, paragraph 2
- Decision XVII/5, paragraph 2

11. The Secretariat suggests that the following provisions could benefit from a consideration of the “time” factor to make clear whether they should be immediately applicable to Parties operating under paragraph 1 of Article 5 or should be applicable after some specific duration:

- Decision XVII/5, paragraph 3
- Decision IX/19, paragraph 5
- Decision XII/2, paragraph 2
- Decision XV/5, paragraph 4

## Table of proposed actions on essential-use decisions to render them generally applicable to all Parties

<b>Decisions on essential uses or metered-dose inhalers or both</b>	
<b>Decision title</b>	<b>Comment</b>
Decision IV/25: Essential uses	No changes proposed – decision already makes clear in para. 7 that the exemption is applicable to Article 5 Parties following the applicable phase-out dates
Decision V/14: Essential uses of halons	No changes proposed – historic decision
Decision V/18: Timeline for the submission and consideration of essential-use nominations	No changes proposed – historic decision overtaken by later decisions
Decision VI/8: Essential-use nominations for halons for 1995	No changes proposed – historic decision
Decision VI/9: Essential-use nominations for controlled substances other than halons for 1996 and beyond	No changes proposed – historic decision overtaken by later decisions – general request to minimize emissions (in para. 4) is stated in language making it already applicable to all Parties
Decision VII/28: Essential-use nominations for controlled substances for 1996 and beyond	No changes proposed. General guidance in para. 3 is already in language making it applicable to all Parties
Decision VIII/9: Essential-use nominations for Parties not operating under Article 5 for controlled substances for 1997 through 2002	Proposed to change only the title of the decision to delete the words “not operating under Article 5” so that it is perfectly clear that paras. 8–10 of the decision are meant to apply to all Parties
Decision IX/18: Essential-use nominations for non-Article 5 Parties for controlled substances for 1998 and 1999	No changes proposed – historic decision
Decision X/6: Essential-use nominations for non-Article 5 Parties for controlled substances for 1999 and 2000	No changes proposed – historic decision
Decision XI/14: Essential-use nominations for non-Article 5 Parties for controlled substances for 2000 and 2001	Proposed to change only the title of the decision to delete the words “non-Article 5” so that it is perfectly clear that para. 3 of the decision is meant to apply to all Parties
Decision XII/9: Essential-use nominations for non-Article 5 Parties for controlled substances for 2001 and 2002	No changes proposed – historic decision
Decision XIII/8: Essential-use nominations for non-Article 5 Parties for controlled substances for the year 2002 and beyond	No changes proposed – historic decision
Decision XIV/4: Essential-use nominations for non-Article 5 Parties for controlled substances for 2003 and 2004	No changes proposed – historic decision
Decision XV/4: Essential-use nominations for non-Article 5 Parties for controlled substances for 2004 and 2005	No changes proposed – historic decision
Decision XVI/12: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol for controlled substances for 2005 and 2006	No changes proposed – historic decision – para. 2 on sales in Article 5 Parties is in language making it already applicable to all Parties
Decision XVII/5: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2006 and 2007	Proposed to change the title to delete the words “not operating under paragraph 1 of article 5”; in para. 2, delete the words “not operating under paragraph 1 of Article 5 of the Montreal Protocol”; and also in para. 2, change “1996” to “phase-out”. Parties may also wish to clarify if the mandate in para. 3 is immediately applicable as it relates to submission of a date by which a rule will be issued to make most CFC MDIs non-essential
Decision VIII/10: Actions by Parties not operating under Article 5 to promote industry’s participation on a smooth and efficient transition away from CFC-based MDIs	Proposed change to the title and the first line of paras 1–9 to delete the words “not operating under Article 5” so that it is perfectly clear that paras. 1–10 are meant to apply to all Parties

<b>Decisions on essential uses or metered-dose inhalers or both</b>	
<b>Decision title</b>	<b>Comment</b>
Decision VIII/11: Measures to facilitate a transition by a Party not operating under Article 5 from CFC-based MDIs	Proposal to delete “by a Party not operating under Article 5” from the title
Decision VIII/12: Information gathering on a transition to non-CFC treatments for asthma and chronic obstructive pulmonary disease for Parties not operating under Article 5	No changes proposed – historic decision; para. 3 request for Parties to submit transition strategies was extended to Article 5 Parties in subsequent decision; para. 5 directions to TEAP were given to enable it to prepare a study carried out 10 years ago
Decision IX/19: Metered-dose inhalers (MDIs)	The Parties may wish to clarify whether para. 5 requiring essential-use requestors to have submitted transition strategies by 1999 is immediately applicable to Article 5 nominators
Decision IX/20: Transfer of essential-use authorizations for CFCs for MDIs	No changes needed – already in language making it applicable to both Article 5 and non-Article 5 Parties
Decision XII/2: Measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers	The Parties may wish to clarify if para. 2 related to the essentiality of salbutamol approved after 2000 is immediately applicable to Article 5 nominators.
Decision XIII/9: Metered-dose inhaler (MDI) production	No changes proposed – decision already directed at Article 5 Parties
Decision XIII/10: Further study of campaign production of CFCs for metered-dose inhalers (MDIs)	No changes proposed – historic decision drafted in general language
Decision XIV/5: Global database and assessment to determine appropriate measures to complete the transition from chlorofluorocarbon metered-dose inhalers	No changes proposed – historic decision drafted in general language
Decision XV/5: Promoting the closure of essential-use nominations for metered-dose inhalers	Proposal to delete, in paras. 2, 3, 5a and 6, the words “not operating under paragraph 1 of Article 5”. The Parties may also wish to clarify if the time limit in para. 4 on consideration of salbutamol exemptions in the absence of phase-out plans is immediately applicable to Article 5 nominators.
Decision XVII/14: Difficulties faced by some Parties operating under paragraph I of Article 5 of the Montreal Protocol with respect to chlorofluorocarbons used in the manufacture of metered-dose inhalers	No changes proposed – historic decision directed at Article 5 Parties
Decision XVIII/7: Essential-use exemptions for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2007 and 2008	Proposal to delete the words “not operating under paragraph 1 of Article 5” in the title and in paras. 2 and 3 to make the decision mandates applicable to all Parties, and in para. 2 replace “1996” with “phase-out”
Decision XVIII/16: Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons	Proposal to delete the words “not operating under paragraph 1 of Article 5” from the first line in para. 7 to make it clear that export transition plans apply to all Parties exporting to Article 5 Parties
Decision XIX/13: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2008 and 2009	Proposal to delete from the title the words “not operating under paragraph 1 of Article 5”, to delete from paras. 2 and 3, the words “not operating under paragraph 1 of Article 5 of the Montreal Protocol” and to replace “1996” with “phase-out” in para. 2 to extend related essential-use requirements to all Parties
<b>Decisions on laboratory and analytical uses</b>	
<b>Decision title</b>	<b>Comment</b>
Decision VII/11: Laboratory and analytical uses	No changes proposed – historic decision with general applicability – no suggested change to para. 8 relative to bilateral support to Article 5 Parties

<b>Decisions on essential uses or metered-dose inhalers or both</b>	
<b>Decision title</b>	<b>Comment</b>
Decision IX/17: Essential-use exemption for laboratory and analytical uses of ozone-depleting substances	No changes proposed – historic decision extended by future decisions
Decision X/19: Exemption for laboratory and analytical uses	No changes proposed – historic generally applicable decision
Decision XI/15: Global exemption for laboratory and analytical uses	No changes proposed – historic generally applicable decision to exclude certain uses from the exemption
Decision XV/8: Laboratory and analytical uses	No changes proposed – historic extension of the exemption
Decision XVI/16: Laboratory and analytical uses	No changes proposed – historic decision
Decisions XVII/13 and XIX/17: Use of carbon tetrachloride for laboratory and analytical uses in Parties operating under paragraph 1 of Article 5 of the Montreal Protocol	No changes proposed – decisions already directed to Article 5 Parties
Decision XIX/18: Laboratory and analytical-use exemption	Decision already applicable to all Parties after the relevant phase-out dates

## Annex

### Strike-and-insert versions of decisions with suggested revisions or requests for clarification

#### **Decision VIII/9: Essential-use nominations for ~~Parties not operating under Article 5~~ for controlled substances for 1997–2002**

#### **Decision XI/14: Essential-use nominations for ~~non-Article 5 Parties~~ for controlled substances for 2000 and 2001**

#### **Decision XVII/5: Essential-use nominations for ~~Parties not operating under paragraph 1 of Article 5~~ for controlled substances for 2006 and 2007**

The Eighth, Ninth and Seventeenth Meetings of the Parties decided:

1. To authorize the levels of production and consumption for 2006 and 2007 necessary to satisfy essential uses of chlorofluorocarbons for metered-dose inhalers for asthma and chronic obstructive pulmonary disease as specified in the annex to the present decision;
2. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~, when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer, shall take into account pre- and post-1996 *phase-out* stocks of controlled substances as described in paragraph 1 (b) of decision IV/25, such that no more than a one-year operational supply is maintained by that manufacturer;
3. *With reference to paragraph 6 of decision XV/5, to request that Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol submit a date to the Ozone Secretariat prior to the Eighteenth Meeting of the Parties by which time a regulation or regulations to determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed.*

#### **Decision VIII/10: Actions by Parties ~~not operating under Article 5~~ to promote industry's participation on a smooth and efficient transition away from CFC-based MDIs**

The Eighth Meeting of the Parties also decided:

1. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts and, with each future request, to report in confidence to the nominating Party whether and to what extent resources are deployed to this end and progress is being made on such research and development, and what license applications if any have been submitted to health authorities for non-CFC alternatives;
2. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to demonstrate that they are undertaking individual or collaborative industry efforts, in consultation with the medical community, to educate health-care professionals and patients about other treatment options and the transition to non-CFC alternatives;
3. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to demonstrate that they, or companies distributing or selling their product, are differentiating the packaging of the company's non-CFC MDIs from its CFC MDIs and are applying other appropriate marketing strategies, in consultation with the medical community, to encourage doctor and patient acceptance of the company's non-CFC alternatives subject to health and product-safety considerations;

4. That Parties ~~not operating under Article 5~~ will request companies manufacturing, distributing or selling CFC MDIs and non-CFC alternatives not to engage in false or misleading advertising targeted at non-CFC alternatives or CFC MDIs;
5. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to ensure that participation in regulatory proceedings is conducted with a view toward legitimate environmental, health and safety concerns;
6. That Parties ~~not operating under Article 5~~ will request companies manufacturing CFC MDIs to take all economically feasible steps to minimize CFC emissions during the manufacture of MDIs;
7. That Parties ~~not operating under Article 5~~ will request companies manufacturing, distributing or selling CFC MDIs to dispose of expired, defective, and returned MDIs containing CFCs in a manner that minimizes CFC emissions;
8. That Parties ~~not operating under Article 5~~ will request companies manufacturing CFC MDIs to review annually CFC requirements and current MDI market forecasts, and notify national regulatory authorities if such forecasts will result in surplus CFCs obtained under essential-use exemptions;
9. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to provide information on the steps that are being taken to provide a continuity of supply of asthma and chronic obstructive pulmonary disease (COPD) treatments (including CFC MDIs) to importing countries;
10. That Parties ~~not operating under Article 5~~ will request companies applying for MDI essential-use exemptions to provide information that demonstrates the steps being taken to assist the company's MDI manufacturing facilities in Parties operating under Article 5 and countries with economies in transition in upgrading the technology and capital equipment needed for manufacturing non-CFC asthma and chronic obstructive pulmonary disease (COPD) treatments;
11. To request the Technology and Economic Assessment Panel to reflect paragraphs 1 through 10 above in a revised version of the Handbook on Essential-Use Nominations.

### **Decision VIII/11: Measures to facilitate a transition ~~by a Party not operating under Article 5~~ from CFC-based MDIs**

The Eighth Meeting of the Parties also decided:

1. To promote coordination between national environmental and health authorities on the environmental, health and safety implications of any proposed decisions on essential-use nominations and MDI transition policies;
2. To request their national authorities to expedite review of marketing/licensing/pricing applications of non-CFC treatments of asthma and chronic obstructive pulmonary disease, provided that such expedited review does not compromise patient health and safety
3. To request their national authorities to review the terms for public MDI procurement and reimbursement, so that purchasing policies do not discriminate against non-CFC alternatives.

### **Decision IX/19: Metered-dose inhalers (MDIs)**

The Ninth Meeting of the Parties also decided:

1. To note with appreciation the interim report of the Technology and Economic Assessment Panel (TEAP) pursuant to decision VIII/12;
2. To request the Technology and Economic Assessment Panel to continue its work and submit the final report to the Tenth Meeting of the Parties, through the Open-ended Working Group, taking into account the approach indicated in paragraph 5 of decision VIII/12 and the comments made during the fifteenth and sixteenth meetings of the Open-ended Working Group and the Ninth Meeting of the Parties;

3. To note the expectation of TEAP and its relevant Technical Options Committee that it remains possible that the major part of the MDI transition may occur in non-Article 5 countries by the year 2000 and there will be minimal need for CFCs for metered-dose inhalers by 2005, however, at this point in time there are still many variables and an exact time-scale is not possible to predict with certainty;

4. To note the concerns of some non-Article 5 Parties that they may not be able to convert as soon as they would like unless their independent MDI manufacturers are able to license non-CFC technologies;

**5. *To require non-Article 5 Parties submitting essential-use nominations for CFCs for MDIs for the treatment of asthma and chronic obstructive pulmonary disease (COPD) to present to the Ozone Secretariat an initial national or regional transition strategy by 31 January 1999 for circulation to all Parties. Where possible, non-Article 5 Parties are encouraged to develop and submit to the Secretariat an initial transition strategy by 31 January 1998. In preparing a transition strategy, non-Article 5 Parties should take into consideration the availability and price of treatments for asthma and COPD in countries currently importing CFC MDIs.***

## **Decision XII/2: Measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers**

The Twelfth Meeting of the Parties decided:

1. For the purposes of this decision, "chlorofluorocarbon metered-dose inhaler product" means a chlorofluorocarbon-containing metered-dose inhaler of a particular brand name or company, active ingredient(s) and strength;

**2. *That any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2000 for treatment of asthma and/or chronic obstructive pulmonary disease in a non-Article 5(1) Party is not an essential use unless the product meets the criteria set out in paragraph 1(a) of decision IV/25;***

3. With respect to any chlorofluorocarbon metered-dose inhaler active ingredient or category of products that a Party has determined to be non-essential and thereby not authorized for domestic use, to request:

- (a) The Party that has made the determination to notify the Secretariat;
- (b) The Secretariat to maintain such a list on its Web site;
- (c) Each nominating Party to reduce accordingly the volume of chlorofluorocarbons it requests and licenses;

4. To encourage each Party to urge each metered-dose inhaler company within its territory to diligently seek approval for the company's chlorofluorocarbon-free alternatives in its domestic and export markets, and to require each Party to provide a general report on such efforts to the Secretariat by 31 January 2002 and each year thereafter;

5. To agree that each non-Article 5 Party should, if it has not already done so:

- (a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) is/are no longer essential;
- (b) Submit the text of any such strategy to the Secretariat by 31 January 2002;
- (c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;

6. To encourage each Article 5(1) Party to:

- (a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) can be replaced with chlorofluorocarbon-free alternatives;

- (b) Submit the text of any such a strategy to the Secretariat by 31 January 2005;
  - (c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;
7. To request the Executive Committee of the Multilateral Fund to consider providing technical, financial and other assistance to Article 5(1) Parties to facilitate the development of metered-dose inhaler transition strategies and the implementation of approved activities contained therein, and to invite the Global Environment Facility to consider providing the same assistance to those eligible countries with economies in transition;
8. To decide that, as a means of avoiding unnecessary production of new chlorofluorocarbons, and provided that the conditions set out in paragraphs (a) - (d) of decision IX/20 are met, a Party may allow a metered-dose inhaler company to transfer:
- (a) All or part of its essential use authorization to another existing metered-dose inhaler company; or
  - (b) Chlorofluorocarbons to another metered-dose inhaler company provided that the transfer complies with national/regional licence or other authorization requirements;
9. To request the Technology and Economic Assessment Panel to summarize and review by 15 May each year the information submitted to the Secretariat;
10. To modify as necessary the Handbook for Essential Use Nominations to take account of the requirements contained in this decision as they pertain to non-Article 5(1) Parties;
11. To request the Technology and Economic Assessment Panel to consider and report to the next Meeting of the Parties on issues related to the campaign production of chlorofluorocarbons for chlorofluorocarbon metered-dose inhalers.

#### **Decision XV/5: Promoting the closure of essential-use nominations for metered-dose inhalers**

The Fifteenth Meeting of the Parties decided:

1. That the present decision shall not affect the operation of paragraph 10 of decision VIII/9 relating to the authorization of a quantity of CFCs in an emergency situation;
2. To request that Parties ~~not operating under Article 5~~, when submitting their nominations for essential-use exemptions for CFCs for metered-dose inhalers, specify, for each nominated use, the active ingredients, the intended market for sale or distribution and the quantity of CFCs required;
3. To request the Technology and Economic Assessment Panel and its Technical Options Committee to make recommendations on nominations for essential-use exemptions for CFCs for metered-dose inhalers from ~~Parties not operating under Article 5~~ with reference to the active ingredient of the metered-dose inhalers in which the CFCs will be used and the intended market for sale or distribution and any national transition strategy covering that intended market which has been submitted according to decision XII/2 or decision IX/19;
4. ***That no quantity of CFCs for essential uses shall be authorized after the commencement of the Seventeenth Meeting of the Parties if the nominating Party not operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-fifth meeting of the Open-ended Working Group, a plan of action regarding the phase-out of the domestic use of CFC-containing metered-dose inhalers where the sole active ingredient is salbutamol;***
5. That the plans of action referred to in paragraph 4 above must include:
  - (a) A specific date by which time the Party will cease making nominations for essential-use exemptions for CFCs for metered-dose inhalers where the sole active ingredient is salbutamol and where the metered-dose inhalers are expected to be sold or distributed on the market of any Party ~~not operating under Article 5~~;
  - (b) The specific measures and actions sufficient to deliver the phase-out;

(c) Where appropriate, the actions or measures needed to ensure continuing access to or supply of CFC-containing metered-dose inhalers by Parties operating under paragraph 1 of Article 5;

6. To request each Party ~~not operating under Article 5~~ to submit to the Ozone Secretariat as soon as practicable for that Party specific dates by which time it will cease making nominations for essential-use exemptions for CFCs for metered-dose inhalers where the active ingredient is not solely salbutamol and where the metered-dose inhalers are expected to be sold or distributed on the market of any Party ~~not operating under Article 5~~;

7. To request the Technology and Economic Assessment Panel to report, in time for the twenty-fourth meeting of the Open-ended Working Group, on the potential impacts of the phase-out of CFCs in Parties not operating under paragraph 1 of Article 5 on the availability of affordable inhaled therapy in Parties operating under paragraph 1 of Article 5;

8. To request the Ozone Secretariat to post on its web site all data submitted pursuant to decision XIV/5 that are designated non-confidential by the submitting Party;

9. To request the Technology and Economic Assessment Panel to modify the Handbook on Essential Use Nominations to reflect the present decision.

### **Decision XVIII/7: Essential-use exemptions for Parties ~~not operating under paragraph 1 of Article 5~~ for controlled substances for 2007 and 2008**

The Eighteenth Meeting of the Parties decided:

1. To authorize the levels of production and consumption for 2007 and 2008 necessary to satisfy essential uses of chlorofluorocarbons for the production of metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in annex III to the present report;

2. That Parties ~~not operating under Article 5~~, when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer of metered-dose inhalers for asthma and chronic obstructive pulmonary diseases, shall take into account pre- and post-~~1996~~**phase-out** stocks of controlled substances as described in paragraph 1 (b) of decision IV/25, such that no more than a one-year operational supply is maintained by the manufacturer;

3. That Parties ~~not operating under Article 5~~ will request companies applying for metered-dose inhaler essential use exemptions to demonstrate that they are making efforts, with all due diligence, on research and development with respect to chlorofluorocarbon-free alternatives to their products and are diligently seeking approval of their chlorofluorocarbon-free alternatives in their domestic and export markets aimed at transitioning those markets away from the chlorofluorocarbon products;

### **Decision XVIII/16: Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons**

The Eighteenth Meeting of the Parties also decided:

1. To request the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol to consider as a matter of urgency the funding of projects in relation to those Parties operating under paragraph 1 of Article 5 that experience difficulties due to high consumption of chlorofluorocarbons for manufacturing metered-dose inhalers, in order to facilitate the transition from chlorofluorocarbon-based metered-dose inhalers;

2. To request the Executive Committee to consider within the context of the existing Multilateral Fund guidelines to review its decision 17/7 with regard to the existing cut-off date for consideration of metered-dose inhaler conversion projects consistent with the reality of the pace of technological advances in the metered-dose inhaler sector;

3. To request the Implementation Committee under the Non-compliance Procedure of the Montreal Protocol to consider all possible options on how to address the potential non-compliance difficulties of some Parties operating under paragraph 1 of Article 5 resulting from their high proportion of chlorofluorocarbon consumption in the metered-dose inhaler sector;

4. To further request the Implementation Committee to give special consideration to the situation of such Parties, particularly in the context of paragraph 4 of the non-compliance procedure of the Protocol, in the light of information received from the Parties concerned and having due regard to health considerations;
5. To consider again the matter referred to in paragraphs 3 and 4 at the twentieth Meeting of the Parties in 2008;
6. To request the Executive Committee to consider including on the agenda of the United Nations Environment Programme thematic regional workshops, information to clarify the steps required to advance the transition from chlorofluorocarbon metered-dose inhalers;
7. To request each Party not operating under paragraph 1 of Article 5 receiving essential-use exemptions for the production or import of chlorofluorocarbons to manufacture metered dose inhalers for export to Parties not operating under paragraph 1 of Article 5 to submit to each importing Party a detailed export manufacturing transition plan for each manufacturer where the exports of an active ingredient to that Party exceed 10 metric tonnes, specifying the actions that each manufacturer is taking and will take to transition its exports to chlorofluorocarbon-free metered-dose inhalers as expeditiously as possible in a manner that does not put patients at risk;
8. That each manufacturer's export manufacturing transition plans should include specific details for each of the manufacturer's export markets and for each metered-dose inhaler by active ingredient concerning:
- (a) Timing of submission to the health authority of marketing applications for chlorofluorocarbon-free alternatives, expected approval and launch of such alternatives and withdrawal of associated chlorofluorocarbon product or products;
  - (b) Indicative information on facilitative pricing, licensing and/or technology transfer arrangements under consideration;
  - (c) Contribution to, and participation in, programmes for educating health care professionals, government health authorities and patients about the transition to chlorofluorocarbon-free treatments for asthma and chronic obstructive pulmonary disease;
9. Consistent with decision IV/25 and paragraph 4 of decision XII/2, to request each Party referred to in paragraph 7 of the present decision, when deciding whether to nominate essential-use volumes for and/or grant essential-use licenses to a manufacturer, to take into account the manufacturer's efforts to implement its export manufacturing transition plan and its contribution to transition towards chlorofluorocarbon-free metered-dose inhalers;
10. To request each Party referred to in paragraph 7 to submit each year to the Technology and Economic Assessment Panel, as part of the Party's essential-use nomination, a report summarizing the export manufacturing transition plans submitted, taking care to protect any confidential information;
11. To request the Technology and Economic Assessment Panel to consider such reports in its assessment of each Party's essential-use nominations;
12. To request the Technology and Economic Assessment Panel to assess and report on progress at the twenty-seventh meeting Open-ended Working Group and to report to the Nineteenth Meeting of the Parties on the need for, feasibility of, optimal timing of, and recommended quantities for a limited campaign production of chlorofluorocarbons exclusively for metered-dose inhalers in both Parties operating under paragraph 1 of Article 5 and Parties not operating under paragraph 1 of Article 5.

**Decision XIX/13: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2008 and 2009**

The Nineteenth Meeting of the Parties decided:

1. To authorize the levels of production and consumption for 2008 and 2009 necessary to satisfy essential uses of CFCs for metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in the annexes to the present decision;

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2. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~, when licensing, authorizing or allocating essential-use exemptions for a manufacturer of metered-dose inhalers, shall ensure, in accordance with paragraph 1 (b) of decision IV/25, that pre- and post-1996 stocks of controlled substances are taken into account such that no more than a one-year operational supply is maintained by the manufacturer;

3. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~ will request each company, consistent with paragraph 1 of decision VIII/10, to notify the relevant authority, for each metered-dose inhaler product for which the production of CFCs is requested, of:

- (a) The company's commitment to the reformulation of the concerned products;
- (b) The timetable in which each reformulation process may be completed;
- (c) Evidence that the company is diligently seeking approval of any chlorofluorocarbon-free alternative(s) in its domestic and export markets and transitioning those markets away from its chlorofluorocarbon products;

4. The Parties listed in Annex A to the present decision shall not nominate for the production of essential use volumes of CFCs for the manufacture of metered-dose inhalers in 2010 or any year thereafter.

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