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the Montreal Protocol on Substances that  
Deplete the Ozone Layer**  
Twenty-fifth meeting  
Montreal, 27–30 June 2005

## *Handbook on Essential Use Nominations*



*Handbook on  
Essential Use Nominations*

*Prepared by the  
Technology and Economic Assessment Panel*

2005

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## CHAPTER 1

### INTRODUCTION

#### 1.1 Genesis and Purpose of Handbook

The adjustments adopted at Copenhagen by the Fourth Meeting of the Parties to the Montreal Protocol mandated a phase out of production and consumption of CFCs, carbon tetrachloride, 1,1,1-trichloroethane and other fully halogenated controlled substances by 1 January 1996, while allowing Parties to authorise production for uses decided to be essential. Decision IV/25 of the Fourth Meeting set the criteria and the procedure for assessing an essential use nomination and requested each Party to nominate uses to the Secretariat, at least nine months prior to the Sixth Meeting of the Parties to the Protocol to be held in 1994. This decision also requested the Technical Options Committees to consider and make recommendations on the nominations.

Decision V/18 of the Parties to the Montreal Protocol calls upon the Technology and Economic Assessment Panel to

"assemble and distribute a handbook on essential use[s] nominations including copies of relevant decisions, nomination instructions, summaries of past recommendations, and copies of nominations to illustrate possible formats and levels of technical detail."

Decision XV/5 requests the Technology and Economic Assessment Panel to

"modify the Handbook on Essential Use Nominations to reflect the present decision."

The "Handbook on Essential Use Nominations" responds to these requests and is intended to assist the Parties in the preparation of essential use nominations. This handbook augments and updates the June 2001 Handbook.

#### 1.2 Content and Structure

The Handbook describes the nomination process for essential use exemptions as it has evolved through Articles of the Protocol and Decisions of the Parties; the procedures followed under the Protocol; and the experience of the Panel and its Technical Options Committees in managing the process to date. The Handbook contains three sections: review of the essential use process; instructions for the completion of essential use nominations; and appendices. The appendices contain provisions of the Montreal Protocol, decisions of the Parties to the Protocol and an essential use nomination form.

#### 1.3 Handbook Updates

The Panel may revise and update the Handbook as circumstances require. Please consult the Ozone Secretariat for updated handbooks to ensure use of the latest version.



## CHAPTER 2

### ESSENTIAL USE PROCESS

#### 2.1 Introduction

After production phase-out, Parties may nominate uses for an exemption. Parties have nominated essential halon uses for 1994 and 1995 (1 January 1994 phase-out) and CFCs, 1,1,1-trichloroethane and CTC exemptions for after their 1 January 1996 phase-out. Parties operating under Article 5(l) do not need to nominate for years prior to their production phase-outs (scheduled for 2010).

The phase-out of production does not control the use of substances manufactured prior to the phase-out (stockpiled or recycled). Therefore, Parties do not need to submit nominations to allow the continuing use of such substances. However, Parties are expected to deplete their stockpiles of substances manufactured prior to the phase-out before they submit nominations for essential uses.

Only Parties to the Protocol can submit nominations. Thus, companies and other organisations must first secure approval and endorsement of their national governments.

Parties may submit nominations for any future year and nominations may be for more than one year.

Nominations received by 31 January will be decided by the Parties at their annual meeting of that year. Nominations received after 31 January will be decided the next year. Parties allow the Secretariat, in consultation with the Technology and Economic Assessment Panel, to authorise, in an emergency situation, if possible by transfer of essential use exemptions, consumption of quantities not exceeding 20 tonnes of ODS for essential uses on application by a Party prior to the next scheduled Meeting of the Parties. The Secretariat will present this information to the next Meeting of the Parties for review and appropriate action by the Parties (see Decision VIII/10).

#### 2.2 Framework

The nomination and review process for essential use exemptions has evolved through Articles of the Protocol, Decisions of the Parties, and recommendations of the Technology and Economic Assessment Panel and its Technical Options Committees. The steps in this process are summarised below.

Article 2 of the Montreal Protocol mandates the phase-out of production and "consumption" of substances that deplete the ozone layer. "Consumption" is defined as production plus imports minus exports. Please note that the Parties are allowed to use stockpiled or recycled substances for as long as they are available after the production phase-out. Article 2 also authorises the Parties by decision to permit such production and "consumption" as may be necessary for those uses decided by the Parties to satisfy the essential use criteria.

Article 6 of the Montreal Protocol mandates the creation of expert panels to assist the Parties in assessing the control measures provided for in Article 2, including essential use exemptions. This provision led to the formation of the Technology and Economic Assessment Panel (TEAP) and its Technical Options Committees (TOCs).

The Technology and Economic Assessment Panel (TEAP) has six Technical Options Committees (Chemicals Technical Options Committee; Flexible and Rigid Foams Technical Options Committee; Halons Technical Options Committee; Medical Technical Options Committee; Methyl Bromide Technical Options Committee; and Refrigeration, Air Conditioning and Heat Pumps Technical Options Committee). TEAP membership also includes Senior Experts.

Excerpts from Articles 2 and 6 of the Montreal Protocol are attached as Appendix A.

At their fourth meeting, the Parties established by Decision IV/25 a procedure to review requests for exemptions from consumption/production phase-outs to meet the needs of essential uses of halons, CFCs, CTC, 1,1,1-trichloroethane and other fully halogenated substances. These exemptions are nominated for calendar years after scheduled production is phased out.

The substantive criteria for essential use exemptions are detailed in Decision IV/25 of the Parties. Paragraph I (a) of Decision IV/25 states that:

"Use of a controlled substance should qualify as essential only if:

- (i) it is necessary for health, safety or is 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."

Paragraph I (b) of Decision IV/25 states 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 minimise 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."

Decision IV/25 called on each Party to nominate uses to the Parties at least nine months prior to the Meeting of the Parties that is to decide on the exemption. Decision XII/2 (par. 2) supplements Decision IV/25 by stating:

"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(l) Party is not an essential use unless the product meets the criteria set out in paragraph I(a) of Decision IV/25."

Par. I of Decision XII/2 defines "chlorofluorocarbon metered-dose inhaler product" as a chlorofluorocarbon containing metered-dose inhaler of a particular brand name or company, active

ingredient(s) and strengths." Decision XII/2 also includes provisions to: (a) reduce the quantities of CFCs nominated for MDIs exported to Parties that have determined that CFC MDIs containing particular active ingredients or in particular therapeutic categories to be non essential; (b) encourage MDI companies to diligently seek approval of CFC free alternatives in their domestic and export markets; and (c) encourage Parties to develop and implement effective national transition strategies.

Decision XV/5 (par. 2) further supplements Decision IV/25 by stating:

"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."

The Plan of Action 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 paragraph 1 of 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."

Also, paragraph 3 of Decision XVI/12 calls on nominating Parties to take into consideration existing stocks of banked or recycled controlled substances, when preparing essential use nominations, with the objective of maintaining no more than one year's operational supply.

These and other Decisions specific to essential uses are attached as Appendix B.

## **2.3 Essentiality Criteria**

### **2.3.1 Decision IV/25**

Essential Use nominations are considered for exemptions on an annual basis. Exemptions granted for more than one year (if any) are subject to the review provisions described in paragraph 5 of Decision IV/25. Therefore, Parties that are given multiple year exemptions should update their nomination annually to facilitate that review.

Decision IV/25 also tasked the Technology and Economic Assessment Panel and its Committees with the review of nominations for essential use exemptions submitted by the Parties.

The TEAP and its TOCs develop recommendations on the nominations and submit their report through the Secretariat by 30 April of that year, which is at least three months prior to the Meeting of the Open Ended Working Group (OEWG). The OEWG may also choose to comment on the nominations and to recommend to the meeting of the Parties. The Parties take decisions at their annual meeting.

An essential use exemption is granted to the nominating Party for a specific quantity of a specified ODS for a specific time period. A Party granted an essential use exemption may produce or import the specified ODS. Any ODS production and "consumption" to meet the authorised essential uses must be identified in the annual data reporting to the Ozone Secretariat.

### **2.3.2 Decision XII/2**

Decision XII/2 supplements Decision IV/25 with respect to the criteria that must be met for chlorofluorocarbon containing metered-dose inhalers. Any such product approved by the appropriate health agency after 31 December 2000 will be considered non-essential unless the product meets the criteria of Decision IV/25 paragraph I (a).

### **2.3.3 Decision XV/5**

Decision XV/5 further supplements Decisions IV/25 and XII/2 by asking that Parties "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."

Decision XV/5 (par. 3) directs the TEAP and Technical Options Committee to:

"make recommendations on nominations for essential-use exemptions for CFCs for metered-dose inhalers from Parties not operating under paragraph 1 of 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."

### **2.3.4 Decision XVI/12**

Decision XVI/12 specifies that a nominating Party may submit in its nomination data aggregated by region and product group for CFC-containing metered-dose inhalers intended for sale in Parties operating under paragraph 1 of Article 5 when more specific data are not available.

Decision XVI/12 also supplements the requirements for essential-use nominations by requesting that:

"Parties, when preparing essential use nominations for CFCs, should give due consideration to existing stocks, whether owned or agreed to be acquired from a metered-dose inhaler manufacturer, of banked or recycled controlled substances as described in paragraph 1(b) of Decision IV/25, with the objective of maintaining no more than one year's operational supply."

## 2.4 Steps Leading to an Essential Use Exemption

The essential use process consists of the following eight steps:

1. **Application:** An organisation in a non-Article 5(l) Party to the Protocol makes an application for an essential use exemption to the relevant authorities in its government. The government reviews the application and decides whether it should be nominated. Please note that it is not necessary for Parties operating under Article 5(l) to submit nominations for years prior to the date of their production or consumption phase-out.
2. **Nomination:** The Party submits its essential use nomination to the Montreal Protocol Ozone Secretariat by 31 January of the year of decision. The Party should name expert(s) in its country who are authorised to provide any clarifications sought on the nominations by the TEAP and its TOCs.
3. **Assignment:** The Ozone Secretariat forwards the nomination to the Technology and Economic Assessment Panel, which in turn assigns the nomination to the appropriate Technical Options Committee. In some circumstances, two or more Technical Options Committees may jointly consider the nomination.
4. **Review:** The Technical Options Committee reviews the nomination to determine if it meets the criteria for an essential use established by Decisions IV/25, XII/2, XV/5 and XVI/12 after obtaining clarifications, if any, from the expert(s) designated by the nominating Party. The Panel then reviews the report of the Technical Options Committee and either recommends the nomination to the Open Ended Working Group or reports that it is unable to recommend the nomination. The Panel Report to the Group is due by 30 April of the year of decision.
5. **Evaluation:** The Open Ended Working Group reviews the Panel Report and recommends a decision for consideration by the Parties.
6. **Decision:** The Meeting of the Parties decides whether to allow production for essential use in accordance with the Montreal Protocol and the Parties may attach conditions to their approval for the essential use.
7. **National Authorisation:** The Party in possession of an essential use exemption authorises the applicant to acquire the controlled substance according to the terms of the decision.
8. **Execution of Authorisation:** The applicant exercises its authorisation to use the controlled substance. Please note that the Protocol authorises but does not mandate production; each applicant must locate a willing supplier and negotiate supply.

## 2.5 Information Requirements

The following information is requested for each nomination (see nomination forms in Appendix C and, for MDIs only, Appendix D).

1. Provide a detailed description of the use that is the subject of the nomination. (Decision IV/25, pars. 2 and 3)
2. Provide details of the type, quantity and quality of the controlled substances that is requested to satisfy the use. (Decision IV/25, pars. 2 and 3)
3. Indicate the period of time and the annual quantities of the controlled substances that are requested. (Decision IV/25, pars. 2 and 3)
4. For CFC MDIs, specify the intended market(s) for sale or distribution for the use, the active ingredient(s) for the use in each market and the quantity of CFCs required for each active ingredient in each market. If necessary, provide the best estimate for quantities for intended markets, using available data from requesting companies. When more specific data are not available, data aggregated by region and product group may be submitted for CFC MDIs intended for sale in Parties operating under paragraph 1 of Article 5. (Decisions XV/5, par. 2 and XVI/12, par. 2)
5. For CFC MDIs, state whether each intended market for sale or distribution is subject to a transition strategy adopted and submitted to the Secretariat and posted by the Secretariat on its website pursuant to Decision XII/2 or Decision IX/19. (Decision XV/5, par. 3)
6. Explain why the nominated volumes and the intended use of these quantities are necessary for health and/or safety, or why it is critical for the functioning of society. (Decision IV/25, pars. 1(a)(i), 2 and 3)
7. Explain what other alternatives and substitutes have been employed to reduce the dependency on the controlled substance for this application. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d))
8. Explain what alternatives were investigated and why they were not considered adequate. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d))
9. For CFC MDIs, confirm that each company requesting essential use allocations has fully complied with Decision VIII/10.1 to respond to the request to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts. (Decision VIII/10, par. 1)
10. If the use is for a CFC MDI product approved after 31 December 2000 for the treatment of asthma and/or chronic obstructive pulmonary disease, provide documentation to demonstrate that this product is necessary for health or safety and that there are no technically and economically feasible alternatives available. (Decision XII/2, par. 2)
11. Describe the measures that are proposed to eliminate all unnecessary emissions. At a minimum, this explanation should include design considerations and maintenance

procedures. (Decision IV/25, pars. 1(b)(i), 2 and 3(b); Decision VI/9, par. 4; and Decision VIII/10, pars. 6 and 7)

12. Explain what efforts are being undertaken to employ other measures for this application in the future, including, in the case of MDIs, efforts to foster approval of alternatives in the domestic and export markets. (Decision IV/25, pars. 1(a)(ii), 3(d) and 4; Decision VIII/10, par. 1; Decision VIII/11; and Decision XII/2, par. 4)
13. Explain whether the nomination is being made because national or international regulations require use of the controlled substance to achieve compliance. Provide full documentation including the name, address, phone and fax number of the regulatory authority requiring use of the controlled substance and provide a full copy or summary of the regulation. Explain what efforts are being made to change such regulations or to achieve acceptance on the basis of alternative measures that would satisfy the intent of the requirement.
14. For CFC MDIs, confirm that the Secretariat's list of CFC MDI active ingredients and/or category of products determined to be non essential by a Party has been consulted and that none of the volumes requested shall be used for items posted on that list. (Decision XII/2, par. 3)
15. For CFC MDIs, beginning with the nomination following the submission of a national or regional MDI transition strategy to the Secretariat, briefly describe progress made on the transition to CFC-free alternatives under that strategy. (Decision IX/19, par. 5 and Decision XII/2, par. 5(c))
16. For CFC MDIs, describe progress made towards determining and submitting a specific date by which time the Party will cease making nominations for essential use exemptions for CFCs for metered-dose inhalers where the active ingredient(s) is not solely salbutamol and the metered-dose inhalers are expected to be sold or distributed on the market of any Party not operating under paragraph 1 of Article 5. (Decision XV/5, par. 6)
17. Describe the efforts that have been made to acquire stockpiled or recycled controlled substance for this application both domestically and internationally. Explain what efforts have been made to establish banks for the controlled substance. (Decision IV/25, par. 1(b)(ii))
18. For CFC MDIs, indicate the existing stock of pharmaceutical-grade CFCs (pre- and post-1996) held by the Party requesting an essential use exemption, describing the quantity (metric tonnes), the quality and the availability for the year prior to the nomination. Describe how this stockpile will be utilised in coming years. (Decision IV/25, par. 1(b)(ii) and Decision XVI/12, par. 3)
19. For CFC MDIs, confirm that the nominating Party has given due consideration to the following. That:

- (a) Each company's existing stock of pharmaceutical-grade CFCs (including CFCs the company possesses or has title to, pre- and post- 1996) aims not to exceed one year's operational supply (the amount used by the company to produce CFC MDIs in the preceding year);
- (b) The Party's aggregate stocks of pharmaceutical-grade CFCs (pre- and post-1996) aims not to exceed one year's operational supply for that Party;
- (c) The Party's nomination has been reduced, if necessary, with the objective of the Party's aggregate stocks of available pre- and post-1996 pharmaceutical-grade CFCs not exceeding one year's operational supply; and
- (d) All available pre-1996 stockpiles have been or will be depleted by companies before drawing on essential use quantities and thereby assure that pre-1996 stockpiles are taken into account in making essential use requests.

(Decision IV/25, par. 1(b)(ii) and Decision XVI/12, par. 3)

20. Briefly state any other barriers encountered in attempts to eliminate the use of the controlled substance for this application.

## 2.6 TEAP/TOC Review

**Please note:** TEAP and its TOCs may be unable to recommend essential use nominations that fail to comply with instructions from the Parties as explained in this Handbook. Review by the Technology and Economic Assessment Panel and its Technical Options Committee is conducted as follows:

To ensure full consideration, the Panel asks the Parties to fully address the requirements of Decisions IV/25, XII/2, XV/5 and XVI/12 by providing the information requested in this Handbook.

Members of the TOC evaluate each nomination and report their review to the TOC Chairs. The results of these reviews are discussed at full meetings of Committees and, in some cases, by select meetings of the Committees when not all members could attend. In some cases, members of the TOC travel to manufacturing sites to evaluate the nomination or schedule seminars and discussions with the applicants, or clarifications are sought from the nominating Party as necessary. The draft text is discussed in meetings and by phone and circulated by fax and mail for consideration by the full committee when they prepare a recommendation.

Concurrent with the evaluation being undertaken by the TOC, a copy of each nomination is made available to each member of the TEAP. Panel members sometimes consult with other appropriate individuals or organisations in order to assist in the evaluation and to prepare the Panel's recommendation to the Parties.

To date the Technology and Economic Assessment Panel has recommended that the Parties authorise production and consumption of controlled substances for a very limited number of uses:

1. Aerosol metered-dose inhalers (MDIs);
2. Specific cleaning, bonding and surface activation applications in rocket motor manufacturing for the Space Shuttle;
3. Global laboratory and analytical uses;
4. Fire fighting (Halon 2402) in the Russian Federation.

Among the uses the TEAP has not recommended to date are: servicing refrigeration equipment and certain medical aerosols not intended for oral inhalation for the treatment of asthma and chronic obstructive pulmonary disease.

Uses other than laboratory and analytical uses are subject to:

1. Annual review of the quantity of controlled substance authorised, and
2. Biennial (every two years) review of essentiality, including whether alternatives and substitutes have become technically and economically feasible.

The Parties have granted a "global exemption" for laboratory and analytical uses for 1996 and 1997 and then, later, until 31 December 2005 under certain conditions. On the basis of information reported by the TEAP, each year Parties decide on any uses of controlled substances, which are no longer eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply. The Parties decided at their 11<sup>th</sup> Meeting to eliminate from the year 2002: testing of oil, grease and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. Subject to future decisions of the Parties, further essential use nominations may be required for laboratory and analytical uses.

The 1994 Report of the Technology and Economic Assessment Panel contains a more thorough description of the essential use process. It is available upon request from the Ozone Secretariat.

The Reporting Accounting Framework for Essential Uses Other than Laboratory and Analytical Applications was requested by Decision VIII/9 of the Eighth Meeting of the Parties to the Montreal Protocol, San Jose, Costa Rica, November 1996. A format for reporting quantities and uses of ozone depleting substances produced and consumed for essential uses was approved at that Meeting (see Appendix D).

The Reporting Accounting Framework for Essential Uses Other than Laboratory and Analytical Applications should be duly completed by each of the Parties that have had essential use exemptions granted for previous years and submitted by 31 January of each year to the Ozone Secretariat (at the address given in Appendix E).



## CHAPTER 3

### INSTRUCTIONS

Nominations are expected to fully satisfy the criteria in Decision IV/25 paragraph 1, Decision XII/2 paragraph 2, Decision XV/5 paragraph 2, and Decision XVI/12 paragraph 3. All Parties are encouraged to exercise the utmost diligence in the assessment of essentiality and to provide detailed rationale for all nominations. Only nominations that provide complete information as requested by Parties and by TEAP can be reviewed. Nominations that identify a perceived essential use, but do not request a specific quantity of controlled substance for a specific consumption and/or production exemption are not evaluated by the Panel.

The submissions to the United Nations Environment Programme (UNEP) must be done by 31 January at the latest, for consideration by the Parties in that same year, i.e. submissions for 2007 must be received by 31 January 2006.

#### **3.1 Essential Use Nomination**

The form recommended for nominations, which addresses the information requirements set out in section 2.5, is attached as Appendix C. A customised form has been developed for MDIs as Appendix D. The general form is provided for all other nominations not previously reviewed and recommended. Information is required in the following areas:

- role of use in society;
- transition strategy and plan of action (for MDIs) if newly submitted or revised since any prior nomination;
- alternatives to use;
- steps to minimise use;
- steps to minimise emissions;
- recycling and stockpiling;
- quantity of controlled substances requested; and
- approval date and indications (for MDIs approved after 31 December 2000).

Answers to the questions posed in the nomination form should be brief but informative. In completing the nomination, Parties may refer to the prior nominations and reports of the Technology and Economic Assessment Panel and its relevant Technical Options Committee as appropriate.

### 3.2 Schedule for Submissions

The schedule for essential use submissions is as follows:

<b>September - October:</b> <sup>1</sup>	Applicant organisations prepare and submit essential use applications to national governments.
<b>November - December:</b> <sup>1</sup>	Governments review applications and prepare essential use nominations, following guidance contained in the "Handbook on Essential Use Nominations".
<b>January 31:</b> <sup>2</sup>	DEADLINE for essential use nominations to the Ozone Secretariat.
<b>April 30:</b> <sup>2</sup>	The TEAP and its TOCs develop recommendations and submit their report through the Secretariat.
<b>June / July:</b> <sup>2</sup>	The Open Ended Working Group (OEWG) to the Parties to the Protocol meets and recommends whether the nominations should be approved.
<b>September - November:</b>	Parties to the Protocol meet and decide whether to allow production for nominated uses and may specify conditions of the exemption.

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<sup>1</sup> These deadlines are set by national governments.

<sup>2</sup> These dates are deadlines established by the Parties.

## **APPENDIX A**

### **EXCERPTS FROM PROTOCOL PROVISIONS<sup>1</sup>**

#### **ARTICLE 2: CONTROL MEASURES**

##### **ARTICLE 2A: CFCs**

Each Party shall ensure that for the twelve month period commencing on 1 January 1996, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group I of Annex A does not exceed zero. Each party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero .... This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

##### **ARTICLE 2B: HALONS**

Each Party shall ensure that for the twelve month period commencing on 1 January 1994, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group 11 of Annex A does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero .... This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

##### **ARTICLE 2C: OTHER FULLY HALOGENATED CFCs**

Each Party shall ensure that for the twelve month period commencing on 1 January 1996, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group I of Annex B does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero .... This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

##### **ARTICLE 2D: CARBON TETRACHLORIDE**

Each Party shall ensure that for the twelve month period commencing on 1 January 1996, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group 11 of Annex B does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero. This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

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<sup>1</sup> For a consolidated description of Protocol provisions see "Handbook for the International Treaties for the Protection of the Ozone Layer", Fifth Edition, 2000, Ozone Secretariat; note that the Handbook does not reflect changes since December 1999.

#### **ARTICLE 2E: 1,1,1 - TRICHLOROETHANE (METHYL CHLOROFORM)**

Each Party shall ensure that for the twelve month period commencing on 1 January 1996, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group III of Annex B does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero. This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

#### **ARTICLE 2G: HYDROBROMOFLUOROCARBONS**

Each Party shall ensure that for the twelve month period commencing on 1 January 1996, and in each twelve month period thereafter, its calculated level of consumption of the controlled substances in Group 11 of Annex C does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero. This paragraph will apply save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.

#### **ARTICLE 6: ASSESSMENT AND REVIEW OF CONTROL MEASURES**

Beginning in 1990, and at least every four years thereafter, the Parties shall assess the control measures provided for in Article 2 and Articles 2A to 2E, and the situation regarding production, imports and exports of the transitional substances in Group I of Annex C (Articles 2A to 2H) on the basis of available scientific, environmental, technical and economic information. At least one year before each assessment, the Parties shall convene appropriate panels of experts qualified in the fields mentioned and determine the composition and terms of reference of any such panels. Within one year of being convened, the panels will report their conclusions, through the Secretariat, to the Parties.

## APPENDIX B

### DECISIONS OF THE PARTIES TO THE MONTREAL PROTOCOL<sup>1</sup>

#### *B.1 Decision IV/25. Essential uses*

1. To apply the following criteria and procedure in assessing an essential use for the purposes of control measures in Article 2 of the Protocol:
  - (a) that a use of a controlled substance should qualify as "essential" only if:
    - (i) it is necessary for the health, safety or is 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;
  - (b) 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 minimise 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;
  - (c) that production, if any, for essential use, will be in addition to production to supply the basic domestic needs of the Parties operating under paragraph I of Article 5 of the Protocol prior to the phase out of the controlled substances in those countries;
2. To request each of the Parties to nominate, in accordance with the criteria approved in paragraph I (a) of the present decision, any use it considers "essential", to the Secretariat at least six months for halons and nine months for other substances prior to each Meeting of the Parties that is to decide on this issue;
3. To request the Technology and Economic Assessment Panel and its Technical and Economic Options Committee to develop, in accordance with the criteria in paragraphs I (a) and 1 (b) of the present decision, recommendations on the nominations, after consultations with experts as necessary, regarding:
  - (a) the essential use (substance, quantity, quality, expected duration of essential use, duration of production or import necessary to meet such essential use);

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<sup>1</sup> For a consolidated description of Protocol provisions see "Handbook for the International Treaties for the Protection of the Ozone Layer", Sixth Edition (2003), Ozone Secretariat.

- (b) economically feasible use and emission controls for the proposed essential use;
  - (c) sources of already produced controlled substances for the proposed essential use (quantity, quality, timing); and
  - (d) steps necessary to ensure that alternatives and substitutes are available as soon as possible for the proposed essential use;
4. To request the Technology and Economic Assessment Panel, while making its recommendations to take into account the environmental acceptability, health effects, economic feasibility, availability, and regulatory status of alternatives and substitutes;
  5. To request the Technology and Economic Assessment Panel to submit its report, through the Secretariat, at least three months before the Meeting of the Parties in which a decision is to be taken. The subsequent reports will also consider which previously qualified essential uses should no longer qualify as essential;
  6. To request the Open ended Working Group of the Parties to consider the report of the Technology and Economic Assessment Panel and make its recommendations to the Fifth Meeting of the Parties for halons and at the Sixth Meeting for all other substances for which an essential use is proposed;
  7. That essential use controls will not be applicable to Parties operating under paragraph I of Article 5 of the Protocol until the phase out dates applicable to those Parties.

**B.2 *Decision V/14. Essential uses of halons***

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Halons Technical Options Committee pursuant to Decision IV/25 of the Fourth Meeting of the Parties;
2. That no level of production or consumption is necessary to satisfy essential uses of halon in Parties not operating under paragraph I of Article 5 of the Protocol, for the year 1994 since there are technically and economically feasible alternatives and substitutes for most applications, and since halon is available in sufficient quantity and quality from existing stocks of banked and recycled halon.

**B.3 *Decision V/8. Timetable for the submission and consideration of essential use nominations***

1. To request the Parties to submit their nominations for each production and consumption exemption for substances other than halon for 1996 in accordance with Decision IV/25, with the presumption that the Meeting of the Parties will be held on 1 September;
2. To modify the timetables in Decision IV/25 for nominations for halon production and consumption exemptions for 1995 and subsequent years, and for nominations for production and consumption exemptions for substances other than halon for 1997 and subsequent years

as follows: to set 1 January of each year as the last date for nominations for decisions taken in that year for any subsequent year;

3. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committees to develop recommendations on the nominations and submit their report through the Secretariat by 31 March of that year;
4. To request the Open ended Working Group of the Parties to consider the report of the Technology and Economic Assessment Panel and make its recommendations to the subsequent meeting of the Parties;
5. To request the Technology and Economic Assessment Panel to assemble and distribute a handbook on essential uses nominations including copies of relevant decisions, nomination instructions, summaries of past recommendations, and copies of nominations to illustrate possible formats and levels of technical detail.

#### **B.4 *Decision VI/18. Essential use nominations for halons for 1995***

The Sixth Meeting of the Parties decided in Decision VI/8 that, for the year 1995 no level of production or consumption is necessary to satisfy essential uses of halons in Parties not operating under paragraph 1 of Article 5 of the Protocol, since there are technically and economically feasible alternatives and substitutes for most applications, and since halons are available in sufficient quantity and quality from existing stocks of banked and recycled halons.

#### **B.5 *Decision VI/9. Essential use nominations for controlled substances other than halons for 1996 and beyond***

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties;
2. That, for 1996 and 1997 for Parties not operating under paragraph 1 of Article 5 of the Protocol, levels of production or consumption necessary to satisfy essential uses of chlorofluorocarbons and 1,1,1-trichloroethane for: (i) metered-dose inhalers (MDIs) for the treatment of asthma, chronic obstructive pulmonary disease (COPD), and for the delivery of leuprolide to the lungs and (ii) the Space Shuttle, are authorised as specified in Annex I to the report of the Sixth Meeting of the Parties, subject to annual review of quantities;
3. That for 1996 and 1997, for Parties not operating under paragraph I of Article 5 of the Protocol, production or consumption necessary to satisfy essential uses of ozone-depleting substances for laboratory and analytical uses are authorised as specified in Annex II to the report of the Sixth Meeting of the Parties;
4. That Parties shall endeavour to minimise use and emissions by all practical steps. In the case of metered dose inhalers, these steps include education of physicians and patients about other treatment options and good-faith efforts to eliminate or recapture emissions from filling and testing, consistent with national laws and regulations.

**B.6 *Decision VII/11. Laboratory and analytical uses***

1. To note with appreciation the work done by the Laboratory and Analytical Uses Working Group of the Technology and Economic Assessment Panel;
2. To urge Parties to organise National consultative Committees to review and identify alternatives to laboratory and analytical uses and to encourage the sharing of information concerning alternatives and their wider use;
3. To encourage national standards organisations to identify and review those standards which mandate the use of ozone-depleting substances in order to adopt where possible ODS-free solvents and technologies;
4. To urge Parties to develop an international labelling scheme and encourage its voluntary adoption to stimulate awareness of the issue;
5. To adopt an illustrative list of laboratory uses as specified in Annex IV of the report of the Seventh Meeting of the Parties to facilitate reporting as required by Decision VI/9 of the Sixth Meeting of the Parties;
6. To exclude the following uses from the global essential-use exemption, as they are not exclusive to laboratory and analytical uses and/or alternatives are available:
  - (a) Refrigeration and air-conditioning equipment used in laboratories, including refrigerated laboratory equipment such as ultra-centrifuges;
  - (b) Cleaning, reworking, repair, or rebuilding of electronic components or assemblies;
  - (c) Preservation of publications and archives; and
  - (d) Sterilisation of materials in a laboratory;
7. To request the Technology and Economic Assessment Panel to evaluate the current status of use of controlled substances and alternatives and report progress on the availability of alternatives to the Ninth Meeting of the Parties and later meetings;
8. To urge Parties operating under Article 2 to provide funding within their countries and on a bilateral basis for Parties operating under Article 5 to undertake research and development and activities aimed at ODS alternatives for laboratory and analytical uses;
9. To agree the controlled substances used for laboratory and analytical purposes shall meet the standards for purity as specified in Decision VI/9.

**B.7 *Decision IX/17. Essential-use exemption for laboratory and analytical uses of ozone-depleting substances***

1. That for 1999, for Parties not operating under paragraph 1 of Article 5 of the Protocol, production and consumption necessary to satisfy essential uses of controlled substances in

Annexes A and B of the Protocol only for laboratory and analytical uses, as listed in annex IV to the report of the Seventh Meeting of the Parties, are authorized, subject to the conditions applied to exemption for laboratory and analytical uses as contained in annex II to the report of the Sixth Meeting of the Parties;

2. That data for consumption and production should be reported annually under a global essential-use exemption framework to the Secretariat so that the success of reduction strategies may be monitored;
3. To clarify that essential-use exemptions for laboratory and analytical uses of controlled substances shall continue to exclude the production of products made with or containing such substances.

**B.8 *Decision X/19. Exemption for laboratory and analytical uses***

1. To extend the global laboratory and analytical essential-use exemption until 31 December 2005 under the conditions set out in annex II of the report of the Sixth Meeting of the Parties;
2. To request the Technology and Economic Assessment Panel to report annually on the development and availability of laboratory and analytical procedures that can be performed without using the controlled substances in Annexes A and B of the Protocol;
3. That the Meeting of the Parties shall each year, on the basis of information reported by the Technology and Economic Assessment Panel in accordance with paragraph 2 above, decide on any uses of controlled substances which should no longer be eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply;
4. That the Secretariat should make available to the Parties each year a consolidated list of laboratory and analytical uses that the Parties have agreed should no longer be eligible for production and consumption of controlled ozone-depleting substances under the global exemption;
5. That any decision taken to remove the global exemption should not prevent a Party from nominating a specific use for an exemption under the essential uses procedure set out in decision IV/25.

**B.9 *Decision XI/15: Global exemption for laboratory and analytical uses***

To eliminate the following uses from the global exemption for laboratory and analytical uses for controlled substances, approved in decision X/19, from the year 2002:

- (a) Testing of oil, grease and total petroleum hydrocarbons in water;
- (b) Testing of tar in road-paving materials; and
- (c) Forensic finger-printing.

**B.10 *Decision VII/28. Essential use nominations for controlled substances for 1996 and beyond***

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties;
2. That, for 1996, 1997, 1998, 1999, 2000 and 2001 for Parties not operating under paragraph 1 of Article 5 of the Protocol, levels of production and consumption necessary to satisfy essential uses of CFC-11, CFC-12, CFC-113, CFC-114 and methyl chloroform are authorised as specified in Annex VI to the report of the Seventh Meeting of the Parties, for metered-dose inhalers (MDIs) for asthma and chronic obstructive pulmonary disease, nasal dexamethasone, and specific cleaning, bonding and surface activation applications in rocket motor manufacturing for the United States Space Shuttle and Titan, subject to the following conditions:
  - (a) The Technology and Economic Assessment Panel will review, annually, the quantity of controlled substances authorised and submit a report to the Meeting of the Parties in that year;
  - (b) The Technology and Economic Assessment Panel will review, biennially, whether the applications for which exemption was granted still meets the essential-use criteria and submit a report, through the Secretariat, to the Meeting of the Parties in the year in which the review is made;
  - (c) The Parties granted essential use exemptions will reallocate, as decided by the Parties, to other uses the exemptions granted or destroy any surplus ozone depleting substances authorised for essential use but subsequently rendered unnecessary a result of technical progress and market adjustments;
3. To urge the Parties to collate, co-ordinate and evaluate the individual company nominations for future years before submitting these nominations to the Secretariat.

**B.11 *Decision VIII/9. Essential use nominations for Parties not operating under Article 5 for controlled substances for 1997 through 2002***

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties and Decisions VII/28 and VII/34 of the Seventh Meeting of the Parties;
2. That the levels of production and consumption necessary to satisfy essential uses of CFC-11, CFC-12, CFC-113 and CFC-114, for metered-dose inhalers (MDIs) for asthma and chronic obstructive pulmonary diseases and nasal dexamethasone, and halon 2402 for fire protection are authorised as specified in annex II to this report, subject to the conditions established by the Seventh Meeting of the Parties in paragraph 2 of its Decision VII/23;
3. To correct the errors introduced by the reports of the Technology and Economic Assessment Panel and its Technical Options Committees in the United States MDI nomination of CFC-

12 and CFC-114 for the production year 1997 and its nomination of methyl chloroform for the production years 1996, 1997, 1998, 1999, 2000 and 2001 and to adjust the total amounts exempted to take into account the withdrawal of the New Zealand MDI nomination of CFC-11 and CFC-12 for production years 1996 and 1997, as specified in annex III to the report of the Seventh Meeting of the Parties.

4. That for 1998, for Parties not operating under Article 5 of the Protocol, production and consumption necessary to satisfy essential uses of controlled substances in Annexes a and B of the protocol only for laboratory and analytical uses, as listed in annex IV to the report of the Seventh Meeting of the Parties, are authorised and subject to the conditions applied to exemption for laboratory and analytical uses as contained in annex II to the report of the Sixth Meeting of the Parties;
5. To permit the transfer of essential use authorisations for MDIs for 1997 between New Zealand and Australia on a one-time basis only;
6. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to investigate the implications of allowing greater flexibility in the transfer of essential use authorisations between Parties;
7. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to review and report, by 30 April 1997, on the implications of allowing the production of CFCs for medical applications on a periodic "campaign basis" to satisfy estimated future needs, rather than producing small quantities in each year. Consideration should be given in particular to the economic implications of such an allowance;
8. To revise the timetables in Decision IV/25, as modified by Decision V/18, for nominations for production and consumption exemptions for 1998 and subsequent years, as follows: to set 31 January of each year as the last date for nominations for decisions to be taken in that year for production or consumption in any subsequent year; and to request the Technology and Economic Assessment Panel and its relevant Technical Options Committees to develop recommendations on the nominations and submit their report through the Secretariat by 30 April of that year;
9. To approve the format for reporting quantities and uses of ozone depleting substances produced and consumed for essential uses as set out in annex IV to the report of the Eighth Meeting and beginning in 1998 to request each of the Parties that have had essential use exemptions granted for previous years, to submit their report in the approved format by 31 January of each year;
10. To allow the Secretariat, in consultation with the Technology and Economic Assessment Panel, to authorise, in an emergency situation, if possible by transfer of essential use exemptions, consumption of quantities not exceeding 20 tonnes of ODS for essential uses on application by the Party prior to the next scheduled Meeting of the Parties. The Secretariat should present this information to the next Meeting of the Parties for review and appropriate action by the Parties.

**B.12 *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***

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 licence 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 minimise 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 minimises 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 of 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 I through 10 above in a revised version of the Handbook on Essential Use Nominations.

**B.13 *Decision VIII/11. Measures to facilitate a transition by a Party not operating under Article 5 from CFC-based MDIs***

The Parties note that a transition is occurring from the use of CFC-based MDIs to non-CFC treatments for asthma and chronic obstructive pulmonary disease. In order to ensure a smooth and efficient transition, and protect the health and safety of patients, Parties not operating under Article 5 are encouraged:

1. To promote co-ordination 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.

**B.14 *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***

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committee pursuant to Decision IV/25 of the Fourth Meeting of the Parties and Decision VII/28 of the Seventh Meeting of the Parties;
2. To note with appreciation that one new non-CFC-based MDI for one active ingredient has now entered the market in some countries, and that others are anticipated over the next one to three years. Other non-CFC treatments and devices already provide a suitable alternative for many patients in some Parties not operating under Article 5;
3. To request Parties not operating under Article 5 that have developed a national transition strategy to report to the panel and its relevant Technical Options Committee on the details of

that national transition strategy for non-CFC treatments of asthma and chronic obstructive pulmonary disease in time for meetings of the Technical Options Committee, beginning in 1997;

4. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to provide an interim report on progress in the development and implementation of national transition treatments of asthma and chronic obstructive pulmonary disease (COPD) and report to the Open-Ended Working Group in preparation for the Ninth Meeting of the Parties;
5. To request the Technology and Economic Assessment Panel to further examine and provide a progress report to the Ninth Meeting of the Parties and a final report to the Tenth Meeting of the Parties on issues surrounding a transition to non-CFC treatments of asthma and chronic obstructive pulmonary disease in Parties not operating under Article 5 that is fully protective of public health. In so doing, the Technology and Economic Assessment Panel should consult with international bodies, such as the World Health Organisation and other international bodies, and other institutions representing health-care professionals, patient-advocacy groups and private industry, and with national bodies and Governments. The Technology and Economic Assessment Panel should consider:
  - (a) In the context of a transition phase, how decisions taken within the Montreal Protocol framework and national strategies might complement each other;
  - (b) The impact on the right and ability of patients in Parties operating under Article 5, in countries with economies in transition, in Parties not operating under Article 5 with large disadvantaged communities and in importing countries to receive CFC-based MDIs where medically acceptable and affordable alternatives are not available due to reductions in essential-use exemptions in Parties not operating under Article 5 for CFC-based MDIs;
  - (c) The influence of potential transferable essential use exemptions as well as existing and potential trade restrictions by individual countries on a smooth transition and access to affordable treatment options;
  - (d) The international markets and fluidity of trade in CFC-based MDIs as well as alternative treatments for asthma and chronic obstructive pulmonary disease;
  - (e) The implications for patient subgroups which may have continuing compelling medical needs after a virtual phase-out;
  - (f) The range of regulatory and non-regulatory incentives for, and impediments to, research and development of alternative treatments for asthma and chronic obstructive pulmonary disease and market penetration of alternative treatments for asthma and chronic obstructive pulmonary disease;
  - (g) The degree to which dry powder inhalers (DPIs) and other treatments options may be considered medically acceptable and affordable alternatives for CFC-based MDIs

in consultation with the above bodies, as a result, the factors which may influence their ability to act as substitutes in different countries;

- (h) The relative implications for the phase-out of ozone-depleting substances of different policy options that facilitate the transition to non-CFC treatments;
- (i) Steps that could be taken to facilitate access to affordable non-CFC treatments.

**B.15 *Decision IX/19. Metered-dose inhalers (MDIs)***

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.

**B.16 *Decision IX/20. Transfer of essential-use authorisations for CFCs for MDIs***

1. That all transfers of essential-use authorizations for CFCs for MDIs be reviewed on a case-by-case basis at Meetings of the Parties for approval;
2. Notwithstanding paragraph 1 of the present decision, to allow the Secretariat, in consultation with the Technology and Economic Assessment Panel, to authorize a Party, in an emergency situation, to transfer some or all of its authorized levels of CFCs for essential uses in MDIs to another Party, provided that:

- (a) The transfer applies only up to the maximum level that has previously been authorized for the calendar year in which the next Meeting of the Parties is to be held;
- (b) Both Parties involved agree to the transfer;
- (c) The aggregate annual level of authorizations for all Parties for essential uses of MDIs does not increase as a result of the transfer;
- (d) The transfer or receipt is reported by each Party involved on the essential-use quantity-accounting format approved by the Eighth Meeting of the Parties by paragraph 9 of decision VIII/9.

**B.17 *Decision XII/2. Measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers***

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(l) 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(l) 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(l) 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(l) 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.

**B.17 Decision XIV/5. Global database and assessment to determine appropriate measures to complete the transition from chlorofluorocarbon metered-dose inhalers**

Noting that while the transition to chlorofluorocarbon-free (CFC-free) alternative treatments for asthma and chronic obstructive pulmonary disease (COPD) depends largely on non-Article 5(1) Parties adopting effective transition strategies and CFC metered-dose inhaler manufacturers diligently developing, seeking approval for, and launching CFC-free metered-dose inhalers and dry-powder inhalers;

Noting with concern the slow transition to CFC-free metered-dose inhalers in some Parties, and the need for affordable and available alternatives in Parties operating under Article 5(1);

Recognizing the desirability of a more transparent presentation of data to assist Parties in better understanding essential use CFC volumes and gauging progress on, and impediments to, the transition;

1. To request each Party or regional economic integration organization to submit available information to the Ozone Secretariat by 28 February 2003 and annual updates thereafter the following information concerning inhaler treatments for asthma and COPD that contain CFCs or that do not contain CFCs:
  - (a) CFC and non-CFC metered-dose inhalers and dry-powder inhalers: sold or distributed within the Party, by active ingredient, brand/manufacturer, and source (import or domestic production);
  - (b) CFC and non-CFC metered-dose inhalers and dry-powder inhalers: produced within the Party for export to other Parties, by active ingredient, brand/manufacturer, source and importing Party;
  - (c) Non-CFC metered-dose inhalers and dry-powder inhalers: date approved, authorized for marketing, and/or launched in the territory of the Party;
2. To request the Technology and Economic Assessment Panel to take into account information submitted pursuant to paragraph 1 and other available information in its annual assessment, and to request the Parties to pay due consideration to this information when reviewing their national transition strategies.

**B.18 Decision XV/5. Promoting the closure of essential-use nominations for metered-dose inhalers**

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 paragraph 1 of 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 paragraph 1 of 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 paragraph 1 of 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 paragraph 1 of 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 paragraph 1 of 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.

**B.19** *Decision XVI/12. Essential-use nominations for non-Article 5 Parties for controlled substances for 2005 and 2006*

1. To authorize the levels of production and consumption necessary to satisfy essential uses of CFCs for metered-dose inhalers for asthma and chronic obstructive pulmonary diseases as specified in the annex to this decision, subject to the conditions established by the Meeting of the Parties in paragraph 2 of its decision VII/28 and subject to a second review of the 2006 levels consistent with decision XV/5;
2. To urge the Technology and Economic Assessment Panel to specify in the Handbook on Essential Use Nominations that a nominating Party may submit in its nomination data aggregated by region and product group for CFC-containing metered-dose inhalers intended for sale in Parties operating under paragraph 1 of Article 5 when more specific data are not available;
3. That, in light of the fact that Aerosol Technical Options Committee's recommendations for future essential-use exemptions are based on past stock level information, Parties, when preparing essential use nominations for CFCs, should give due consideration to existing stocks, whether owned or agreed to be acquired from a metered-dose inhaler manufacturer, of banked or recycled controlled substances as described in paragraph 1(b) of decision IV/25, with the objective of maintaining no more than one year's operational supply.

## APPENDIX C

### NOMINATION FOR ESSENTIAL USE (OTHER THAN MDIs)

#### INSTRUCTIONS:

1. Please submit in English.
2. A separate nomination must be submitted for each proposed essential use.
3. Incorporate by reference, information from the prior nominations, as appropriate.
4. Where possible, electronic submission in addition to the paper copy is encouraged.

#### All nominations should be forwarded to:

The Secretariat for the Vienna Convention and the Montreal Protocol Ozone  
Secretariat  
United Nations Environment Programme (UNEP)  
P.O. Box 30552  
Nairobi  
Kenya

Telephone +254-2 62-1234 or 62-3850

Fax +254-2 62-3601 / 62-3913 / 62-3532

E-Mail [ozoneinfo@unep.org](mailto:ozoneinfo@unep.org)

**Please provide the following Nominating Party information:\***

Party/Country: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Title: \_\_\_\_\_

Address (include city/code numbers): \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-Mail: \_\_\_\_\_

Expert(s)\*\*

Organisation(s): \_\_\_\_\_

Contact Person(s): \_\_\_\_\_

Address(es): \_\_\_\_\_

Telephone(s): \_\_\_\_\_

Fax(es): \_\_\_\_\_

E-mail(s): \_\_\_\_\_

\* Article 5(l) Parties need not apply

\*\* Expert(s) in the country who can be contacted for clarification.

Nominations must be received no later than 31 January of the year prior to the first year for which an exemption is requested.

***PLEASE NOTE: TEAP and its TOO may be unable to recommend essential use nominations that fail to comply with instructions from Parties.***

**I. Summary of Nomination**

A. Please identify and describe in detail the proposed use.

B. Quantities of Controlled Substances Requested:

Please indicate below each substance required for the proposed use and the quantities requested of each substance in each year being nominated.

**Nominated Quantities (metric tonnes)**

<b>Ozone Depleting Substance*</b>	2006	2007
CFC-11		
CFC-12		
CFC-113		
CFC-114		
CFC-115		
1,1,1 -TCA		
CTC		
Halon 1211		
Halon 1301		
Halon 2402		
Other, specify		
<b>Total</b>		

**\*Complete this table only for nominated controlled substances.**

Please note that Parties have requested TEAP to review, biennially, whether the applications for which exemption was granted still meets the essential use criteria and submit a report, through the Secretariat, to the Meeting of the Parties in the year in which the review is made.

## **II. Substantiation of Nomination**

### **A. Role in Society**

1. Why is this use necessary for the health and/or safety or critical for the functioning of society?

### **B. Alternatives/Substitutes**

1. Explain what substitutes and alternatives to the proposed use are currently available.
2. Explain what steps are being taken to implement these substitutes and alternatives.
3. Explain why alternatives and substitutes are not sufficient or appropriate to eliminate the proposed use.

### **C. Steps to Minimise Use**

1. Describe all steps that are being taken, including the development of ODS free replacement products, to minimise the proposed uses.
2. Describe all steps that are being taken, including the development of ODS free replacement products, to minimise the proposed uses.
3. Describe factors that affect the timetable for the introduction of alternatives and substitutes (including regulatory requirements).

### **D. Steps to Minimise Emissions**

1. What steps are being taken to minimise the emissions associated with the proposed uses?
2. Please estimate the ultimate portion of each nominated Ozone Depleting Substance emitted in manufacture or use, or destroyed or recycled.

### Breakdown

Ozone Depleting Substance	% Contained in Product	% Released in Manufacture or Use	% Destroyed or Recycled	Total
CFC-11				100%
CFC-12				100%
CFC-I 13				100%
CFC-114				100%
CFC-115				100%
1,1,1 -TCA				100%
CTC				100%
Halon 1211				100%
Halon 1301				100%
Halon 2402				100%
Other, specify				100%

#### E. Recycling and Stockpiling

1. Explain why recycled and stockpiled substances are not available in adequate quantity for the proposed uses. Give a detailed technical and chemical explanation including descriptions of the appropriate standards of purity for such use.

### III. Substantiation of Volumes

1. Please indicate below the actual or estimated quantities of controlled substances used in years prior to the first year for which an exemption is requested.

**Year Prior to Nomination (metric tonnes)**

<b>Ozone Depleting Substance</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
CFC-11										
CFC-12										
CFC-113										
CFC-114										
CFC-115										
1, 1, 1 -TCA										
CTC										
Halon 1211										
Halon 1301										
Halon 2402										
Other, specify										
Total										

Explain the trends in quantities used in years prior to the nominated year(s).

## APPENDIX D

### NOMINATION OF THE AEROSOL METERED-DOSE INHALER (MDI) AS AN ESSENTIAL USE

#### INSTRUCTIONS:

1. Please submit in English.
2. A separate nomination must be submitted for each proposed essential use.
3. Incorporate by reference, information from the prior nominations, as appropriate.
4. Where possible, electronic submission in addition to the paper copy is encouraged.

The term "metered-dose inhaler" refers to orally inhaled aerosol products for the delivery of medicines directly to the lungs using a propellant. Nominations for any other medical aerosol (e.g., nasal inhalers) should be submitted separately.

#### All nominations should be forwarded to:

The Secretariat for the Vienna Convention and the Montreal Protocol  
Ozone Secretariat  
United Nations Environment Programme (UNEP)  
P.O. Box 30552  
Nairobi  
Kenya

Telephone +254-2 62-1234 or 62-3850

Fax +254-2 62-3601 / 62-3913 / 62-3532

E-Mail [ozoneinfo@unep.org](mailto:ozoneinfo@unep.org)

**Please provide the following Nominating Party information:\***

Party/Country: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Title: \_\_\_\_\_

Address (include city/code numbers): \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-Mail: \_\_\_\_\_

Expert(s)\*\*

Organisation(s): \_\_\_\_\_

Contact Person(s): \_\_\_\_\_

Address(es): \_\_\_\_\_

Telephone(s): \_\_\_\_\_

Fax(es): \_\_\_\_\_

E-mail(s): \_\_\_\_\_

\* Article 5(l) Parties need not apply

\*\* Expert(s) in the country who can be contacted for clarification.

Nominations must be received no later than 31 January of the year prior to the first year for which an exemption is requested.

***PLEASE NOTE: TEAP and its TOC may be unable to recommend essential use nominations that fail to comply with instructions from Parties.***

**I. Summary of Nomination**

- A. Please identify and describe in detail the proposed uses. Please indicate for what disease or treatment the proposed use is intended. (Decision IV/25, pars. 2 and 3)
- B. Please specify the active ingredient(s) used. (Decision IV/25, pars. 2 and 3)
- C. Please identify the intended market(s) for sale or distribution for each active ingredient. (Decision XV/5, par. 2)
- D. Please indicate below the quantity of CFCs<sup>1</sup> requested for the proposed use in each year being nominated for each active ingredient and for each intended market for sale or distribution; if necessary, the quantities for intended markets may be best estimates from requesting companies. If more specific data are not available, data aggregated by region and product group may be submitted for Article 5(1) intended markets for sale or distribution. (Decision IV/25, pars. 2 and 3 and Decision XV/5, par. 2)

**Nominated quantities of CFCs (metric tonnes) for essential uses by active ingredient and intended market for sale or distribution**

	<b>2007</b>
Active Ingredient or Product Group 1	
Country/Region	
Country/Region	
Active Ingredient or Product Group 2	
Country/Region	
Country/Region	
Active Ingredient or Product Group 3	
Country/Region	
Country/Region	

(Specify name of active ingredient and country or region – if region, specify names of countries included. Add additional rows as needed).

---

<sup>1</sup> The Parties decided in Decision X/6 to approve CFCs in the aggregate rather than by individual compound. Therefore, Parties need only provide the total requested quantity of CFC-11, CFC-12, CFC-113, and/or CFC-114 in the aggregate.

Please note that Decision VII/28 requests TEAP to review, annually, the quantity of controlled substances authorised and submit a report and to review, biennially, whether the applications for which exemption was granted still meets the essential use criteria and submit a report, through the Secretariat, to the Meeting of the Parties in the year in which the review is made.

## **II. Substantiation of Nomination**

### **A. Role in Society**

1. State whether the nomination is for the treatment of asthma and/or chronic obstructive pulmonary disease. If not, explain why this use is necessary for health and/or safety or critical for the functioning of society? (Decision IV/25, pars. 2 and 3)
  - *Describe the nature of the disease(s) that the proposed use is intended to treat, e.g., the nature and prevalence of the disease and the role of MDIs (versus other forms of therapy) in treating the disease(s).*
2. Does this use include any MDI product approved after 31 December 2000 for the treatment of asthma and/or chronic obstructive pulmonary disease? (Decision XII/2, par. 2)
  - *If so, provide documentation to demonstrate that this product is necessary for health or safety and that there are no technically and economically feasible alternatives available.*

### **B. Description of Transition Status**

The following elements should be addressed or updated in each year's nomination:

1. Has a transition strategy applicable to the intended market(s) for sale or distribution and a plan of action been submitted to the UNEP Ozone Secretariat under Decision XII/2, or IX/19, and XV/5? (Decisions IX/19, par. 5, XII/2, par. 5(c)), and XV/5, par. 4.
2. Explain, if known, how any such transition strategy applies to the active ingredient(s) for each intended market for sale or distribution as set forth above. (Decision XV/5, par. 3)
3. Describe progress in the transition to alternatives pursuant to the national or regional transition strategy submitted to the Secretariat in the domestic market. (Decision XII/2, par. 5(c))
4. Briefly describe the action plan adopted by the Party pursuant to paragraphs 4 and 5 of decision XV/5 (providing for plans of action including a specific phase-out date for salbutamol CFC MDIs sold or

distributed in non-Article 5 Parties, specific measures and actions sufficient to deliver the phase-out; and actions and measures needed to ensure continuing access to or supply of CFC-containing MDIs by Article 5 Parties, where appropriate). (Decision XV/5, pars. 4 and 5)

5. Describe progress made towards determining and submitting a specific date by which time the Party will cease making nominations for essential use exemptions for CFCs for metered-dose inhalers where the active ingredient(s) is not solely salbutamol and the metered-dose inhalers are expected to be sold or distributed on the market of any Party not operating under paragraph 1 of Article 5. (Decision XV/5, par. 6)
6. Explain what substitutes and alternatives to the proposed use are currently available in the domestic market and, to the extent known, in each intended market for sale or distribution. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d))
  - *Describe any new or existing forms of treatment available if not previously described in a prior essential use nomination.*
  - *List the substitutes and alternatives to the proposed use that are currently licensed and describe availability, including trends in the availability and usage of alternative inhalation devices and the likely impact of these trends on the need for CFCs for MDIs in the year for which nomination is made.*
7. Explain steps being taken to implement these substitutes and alternatives in the domestic market. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d))
  - *List and describe in detail the education efforts being undertaken to accomplish the transition.*
  - *Describe how MDI manufacturers or distributors differentiate the packaging of non-CFC MDIs from CFC-driven MDIs and describe what marketing strategies are being taken to assure that their non-CFC MDIs are used, and describe the steps that companies applying for essential use exemptions have taken to obtain approval for CFC-free alternatives in their domestic and export markets.*
  - *Describe what steps have been taken to ensure that companies manufacturing, distributing, or selling CFC MDIs and non- CFC*

*alternatives do not engage in false and misleading advertising targeted at non-CFC alternatives or CFC MDIs.*

- *Describe what steps have been taken to ensure that companies applying for MDI essential use exemptions participate in regulatory proceedings with a view toward legitimate environmental, health and safety concerns.*
- *Explain why alternatives and substitutes are not sufficient or appropriate to eliminate the proposed use.*

8. Assure that each company requesting essential use allocations has fully complied with Decision VIII/10.1 to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts. (Decision VIII/10, par. 1)

*NOTE: As a basis for responding to this element, each Party should request that companies applying for MDI essential use exemptions report in detail to that Party how and to what extent resources are deployed and the progress being made on research and development, as well as what license applications, if any, have been submitted to health authorities in the company's domestic and export markets for non-CFC alternatives. A model format for this report is attached to this nomination application form.*

9. Describe the steps to minimise emissions of CFCs during the manufacture of the essential use products. (Decision IV/25, pars. 1(b)(i), 2 and 3(b); Decision VI/9, par. 4; and Decision VIII/10, pars. 6 and 7)
10. Describe the steps being taken to provide a continuity of supply of asthma and chronic obstructive pulmonary disease treatments to importing non-Article 5(l) countries, Article 5(l) countries and CEIT. Also describe the steps being taken by companies to assist their MDI manufacturing facilities in Parties operating under Article 5(l) and CEIT in upgrading the technology and capital equipment needed for manufacturing non-CFC asthma and chronic obstructive pulmonary disease treatments. (Decision VIII/10, pars. 9 and 10)

### III Substantiation of Volumes

1. Please indicate below the actual or estimated quantities of CFCs used in years prior to the first year for which an exemption is requested.

#### Year Prior to Nomination (metric tonnes)

Ozone Depleting Substance	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
CFC-11, 12, 113, 114 (aggregate)											

2. For the nominated quantities intended for use in MDIs for export, assure that the Secretariat's list of CFC MDI active ingredients and/or category of products determined to be non-essential by an importing Party has been consulted, and that none of the volumes requested shall be used for items posted on that list.
3. Provide details of the management of the stockpile and any surplus. (Decision IV/25, par. 1(b)(ii))
4. Provide details of the existing stock of pharmaceutical-grade CFCs (pre- and post-1996) held by the Party requesting an essential use exemption, describing the quantity (metric tonnes), the quality and the availability for the year prior to the nomination. Describe how this stockpile will be utilised in coming years. (Decision IV/25, par. 1(b)(ii) and Decision XVI/12, par. 3)
5. Confirm that the nominating Party has given due consideration to the following. That:
  - a. Each company's existing stock of pharmaceutical-grade CFCs (including CFCs the company possesses or has title to, pre- and post- 1996) aims not to exceed one year's operational supply (the amount used by the company to produce CFC MDIs in the preceding year);
  - b. The Party's aggregate stocks of pharmaceutical-grade CFCs (pre- and post-1996) aim not to exceed one year's operational supply for that Party;

- c. The Party's nomination has been reduced, if necessary, with the objective of the Party's aggregate stocks of available pre- and post-1996 pharmaceutical-grade CFCs not exceeding one year's operational supply; and
- d. All available pre-1996 stockpiles have been, or will be, depleted by companies before drawing on essential use quantities and thereby assure that pre-1996 stockpiles are taken into account in making essential use requests.

(Decision IV/25, par. 1(b)(ii) and Decision XVI/12, par. 3)

#### IV. Reporting Accounting Framework for Essential Uses Other than Laboratory and Analytical Applications

Please complete this Reporting Accounting Framework. All quantities should be in metric tonnes.

A Year of Essential Use	B Amount Exempted for year of Essential Use <sup>1,2</sup>	C Amount Acquired by Production	D Amount Acquired for Essential Uses by Import and Country(s) of Manufacture		E (C+D) Total Acquired for Essential Use	F (B-E) Authorised but not Acquired	G On Hand Start of Year <sup>3</sup>	H (G+E) Available for Use in Current Year	I Used for Essential Use	J Quantity Contained in Products Exported	K Destroyed	L <sup>2</sup> (H-I-K) On Hand End of Year <sup>4</sup>
			Amount I	Country(s)								

- 1 Note that essential use for particular year may be the sum of quantities authorised by decision in more than one year.
- 2 If a transfer between Parties of an essential use has been made for the year, then the Parties should report the quantity transferred to or from another Party and identify the other Party involved in the transfer.
- 3 Where possible, national governments should include quantities on hand as of 1 January 1996. National governments not able to estimate quantities on hand as of 1 January 1996 can track the subsequent inventory of ODS produced for essential uses (Column L).
- 4 Carried forward as "On Hand at Start of Year" for next year.

**CONFIDENTIAL BUSINESS INFORMATION  
TO BE REVIEWED BY NATIONAL AUTHORITIES ONLY**

**DO NOT FORWARD TO OZONE SECRETARIAT**

**RESEARCH AND DEVELOPMENT  
SUPPLEMENT TO NOMINATION REQUEST  
(Decision VIII/10, par. 1)**

1. List the CFC MDI products (by drug and dosage) for the treatment of asthma and chronic obstructive pulmonary disease currently manufactured and/or marketed by your company.
- 2.(a) Identify those drugs (and doses) listed in question #1 which your company by itself or in collaboration with others plans to replace with non-CFC alternatives.
- 2.(b) For those products not being reformulated, identify projected availability of CFC-free alternatives in the same therapeutic class and projected withdrawal date of the CFC product.
3. For each of the products identified in question 2(a), project your timetable for the submission of license applications with national authorities in your domestic and export markets.
4. Describe the resources that your company has committed to the research effort to develop alternatives to your CFC MDI products for each of your markets worldwide.

*What is the approximate total cost (absolute and as a percentage of annual revenue) of your company's research effort to develop alternatives to CFC MDIs to date?*

*How many (e.g., 1 of 2) of your company's laboratories are involved in the research effort to develop alternatives to CFC MDIs (including contract labs)?*

*Please list the countries where these laboratories are located.*

*Approximately how many laboratory scientists are or have been involved in your company's total research effort to develop alternatives to CFC MDIs (including CROs and direct contract labs, but not external physicians)?*

*Describe any other investments made by your company to reduce continued reliance on CFCs for the products listed in question #1.*

5. Describe the nature and extent of your company's collaboration with other companies in conducting research and development on alternatives to your CFC MDI products for each of your markets worldwide.

## APPENDIX E

### ADDRESSES OF PROTOCOL SECRETARIAT AND TEAP MEMBERS

#### Ozone Secretariat

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The Secretariat for the Vienna Convention and the Montreal Protocol  
P.O. Box 30552, Nairobi, Kenya  
Telephone +254-2 62-1234 or 62-3850  
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## **APPENDIX F**

### **ACRONYMS**

CFC	-	Chlorofluorocarbon
CTC	-	Carbon Tetrachloride
EEAP	-	Environmental Effects Assessment Panel
MDI	-	Metered-Dose Inhaler
ODS	-	Ozone-Depleting Substance
OEWG	-	Open Ended Working Group
SAP	-	Scientific Assessment Panel
TCA	-	1,1,1-Trichloroethane
TEAP	-	Technology and Economic Assessment Panel
TOC	-	Technical Options Committee