

*Handbook on
Essential Use Nominations*

*Prepared by the
Technology and Economic Assessment Panel
(TEAP)*

2009

DISCLAIMER

The United Nations Environment Programme (UNEP), the Technology and Economic Assessment Panel co-chairs and members, the Technical Options Committee chairs and members and the companies and organisations that employ them do not endorse the performance, worker safety, or environmental acceptability of any of the technical options discussed. Every industrial operation requires consideration of worker safety and proper disposal of contaminants and waste products. Moreover, as work continues – including additional toxicity testing and evaluation – more information on health, environmental and safety effects of alternatives and replacements will become available for use in selecting among the options discussed in this document.

UNEP, the Technology and Economic Assessment Panel co chairs and members, and the Technical Options Committee chairs and members, in furnishing or distributing this information, do not make any warranty or representation, either express or implied, with respect to the accuracy, completeness, or utility; nor do they assume any liability of any kind whatsoever resulting from the use or reliance upon, any information, material, or procedure contained herein, including but not limited to any claims regarding health, safety, environmental effects of face, efficacy, or performance, made by the source of the information.

Mention of any company, association, or product in this document is for information purposes only and does not constitute a recommendation of any such company, association, or product, either express or implied, by UNEP, the Technology and Economic Assessment Panel co chairs or members, the Technical Options Committee chairs or members or the companies and organisations that employ them.

TABLE OF CONTENTS

HANDBOOK ON ESSENTIAL USE NOMINATIONS

DISCLAIMER AND ACKNOWLEDGEMENTSII

CHAPTERS

1 INTRODUCTION..... 1

1.1 GENESIS AND PURPOSE OF HANDBOOK..... 1

1.2 CONTENT AND STRUCTURE..... 1

1.3 HANDBOOK UPDATES 1

2 ESSENTIAL USE PROCESS 2

2.1 INTRODUCTION 2

2.2 FRAMEWORK 2

2.3 ESSENTIALITY CRITERIA 6

2.3.1 *Decision IV/25*..... 6

2.3.2 *Decision XII/2* 6

2.3.3 *Decision XV/5* 6

2.3.4 *Decision XVI/12* 7

2.3.5 *Decision XVIII/7*..... 7

2.3.6 *Decision XVIII/16*..... 8

2.3.7 *Decision XX/3* 8

2.4 STEPS LEADING TO AN ESSENTIAL USE EXEMPTION 8

2.5 INFORMATION REQUIREMENTS 9

2.6 TEAP/TOC REVIEW 12

3 INSTRUCTIONS 14

3.1 ESSENTIAL USE NOMINATION 14

3.2 SCHEDULE FOR SUBMISSIONS 15

APPENDIX A 16

EXCERPTS FROM PROTOCOL PROVISIONS 16

ARTICLE 2: CONTROL MEASURES 16

ARTICLE 6: ASSESSMENT AND REVIEW OF CONTROL MEASURES 17

APPENDIX B 18

DECISIONS OF THE PARTIES TO THE MONTREAL PROTOCOL 18

B.1 *Decision IV/25. Essential uses* 18

B.2 *Decision V/14. Essential uses of halons*..... 19

B.3 *Decision V/8. Timetable for the submission and consideration of essential use nominations*..... 19

B.4 *Decision VI/18. Essential use nominations for halons for 1995* 20

B.5 *Decision VI/9. Essential use nominations for controlled substances other than halons for 1996 and beyond* 20

B.6 *Decision VII/11. Laboratory and analytical uses*..... 20

B.7 *Decision IX/17. Essential-use exemption for laboratory and analytical uses of ozone-depleting substances*..... 21

B.8 *Decision X/19. Exemption for laboratory and analytical uses*..... 22

B.9	Decision XI/15. Global exemption for laboratory and analytical uses	22
B.10	Decision VII/28. Essential use nominations for controlled substances for 1996 and beyond.....	22
B.11	Decision VIII/9. Essential-use nominations for Parties not operating under Article 5 for controlled substances for 1997 through 2002.....	23
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.....	24
B.13	Decision VIII/11. Measures to facilitate a transition by a Party not operating under Article 5 from CFC-based MDIs.....	25
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.....	26
B.15	Decision IX/19. Metered-dose inhalers (MDIs)	27
B.16	Decision IX/20. Transfer of essential-use authorisations for CFCs for MDIs.....	28
B.17	Decision XII/2. Measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers	28
B.18	Decision XIV/5. Global database and assessment to determine appropriate measures to complete the transition from chlorofluorocarbon metered-dose inhalers.....	30
B.19	Decision XV/5. Promoting the closure of essential-use nominations for metered-dose inhalers.....	31
B.20	Decision XVI/12. Essential-use nominations for non-Article 5 Parties for controlled substances for 2005 and 2006.....	32
B.21	Decision XVII/5. Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2006 and 2007	32
B.22	Decision XVII/14: Difficulties faced by some Parties operating under paragraph 1 of Article 5 of the Montreal Protocol with respect to chlorofluorocarbons used in the manufacture of metered-dose inhalers.....	33
B.23	Decision XVIII/7. Essential-use exemptions for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2007 and 2008	33
B.24	Decision XVIII/16. Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons.....	34
B.25	Decision XIX/13. Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2008 and 2009	35
B.26	XX/2: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2009 and 2010	36
B.27	XX/3: Essential-use exemptions for Parties operating under paragraph 1 of Article 5.....	36
APPENDIX C.....		38
RECOMMENDED FORM FOR NOMINATION OF AN ESSENTIAL USE (OTHER THAN MDIs)		38
APPENDIX D.....		44
RECOMMENDED FORM FOR NOMINATION OF THE METERED-DOSE INHALER (MDI) AS AN ESSENTIAL USE.....		44
IV. REPORTING ACCOUNTING FRAMEWORK FOR ESSENTIAL USES OTHER THAN LABORATORY AND ANALYTICAL APPLICATIONS.....		53
APPENDIX E		54
ADDRESSES OF PROTOCOL SECRETARIAT AND TEAP MEMBERS		54
APPENDIX F		63
ACRONYMS		63

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."

Decision XX/3 requests the Technology and Economic Assessment Panel to

"reflect paragraphs 1– 3 above in a revised version of the handbook on essential-use nominations and to submit, for consideration by Parties, suggestions for any appropriate changes to the handbook and the timing to make such changes."

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 2005 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.

2 ESSENTIAL USE PROCESS

2.1 Introduction

After production phase-out, Parties may nominate uses for an exemption. Parties not operating under Article 5(1) 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(1) have nominated essential CFCs for after their 1 January 2010 phase-out.

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 pre-phase-out 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. 1 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.

Decision XX/3 (pars. 1-3) further supplements Decision IV/25 by stating:

"1. To make the following modifications to the decisions noted below:

(a) To remove reference to the term "not operating under Article 5" or, "for non-Article 5 Parties" from the following titles and provisions of the following past decisions of the Parties:

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

(b) To remove reference to the term "not operating under Article 5 of the Montreal Protocol" from the following titles and provisions of the following past decisions of the Parties:

- (i) Decision XVII/5, paragraph 2;
 - (ii) Decision XIX/13, paragraphs 2 and 3;
- (c) To remove and replace reference to the date “1996” with the term “phase-out” in the following provisions of past decisions of the Parties:

- (i) Decision XVII/5, paragraph 2;
- (ii) Decision XVIII/7, paragraph 2;
- (iii) Decision XIX/13, paragraph 2;

- (d) To add a new paragraph after paragraph 3 of decision XVII/5 to read as follows:

3 bis. With reference to paragraph 6 of decision XV/5, to request that Parties operating under paragraph 1 of Article 5 of the Montreal Protocol submit a date to the Ozone Secretariat prior to the Twenty-Second Meeting of the Parties, by which time a regulation or regulations to determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed;

- (e) To add a new paragraph after paragraph 5 of decision IX/19 to read as follows:

5 bis. To require Parties operating under paragraph 1 of Article 5 submitting essential-use nominations for chlorofluorocarbons for metered-dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease to present to the Ozone Secretariat an initial national or regional transition strategy by 31 January 2010 for circulation to all Parties. Where possible, Parties operating under paragraph 1 of Article 5 are encouraged to develop and submit to the Secretariat an initial transition strategy by 31 January 2009. In preparing a transition strategy, Parties operating under paragraph 1 of Article 5 should take into consideration the availability and price of treatments for asthma and chronic obstructive pulmonary disease in countries currently importing chlorofluorocarbon-containing metered-dose inhalers;

- (f) To add a new paragraph after paragraph 2 of decision XII/2 to read as follows:

2 bis. That any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2008, excluding any product in the process of registration and approved by 31 December 2009, for treatment of asthma and/or chronic obstructive pulmonary disease in a Party operating under paragraph 1 of Article 5, is not an essential use, unless the product meets the criteria set out in paragraph 1 (a) of decision IV/25;

- (g) To add a new paragraph after paragraph 4 of decision XV/5 to read as follows:

4 bis. That no quantity of chlorofluorocarbons for essential uses shall be authorized after the commencement of the Twenty-First Meeting of the Parties if the

nominating Party operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-ninth meeting of the Open-ended Working Group, a preliminary plan of action regarding the phase-out of the domestic use of chlorofluorocarbon-containing metered-dose inhalers where the sole active ingredient is salbutamol;"

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. For Parties not operating under paragraph 1 of Article 5, any such product approved by the appropriate health agency after 31 December 2000 will not be considered an essential use unless the product meets the criteria of Decision IV/25 paragraph 1 (a).

Decision XX/3 supplements Decision XII/2 to add a new paragraph after paragraph 2 of that decision, which further supplements Decision IV/25 with respect to the criteria that must be met for chlorofluorocarbon containing metered-dose inhalers. For Parties operating under paragraph 1 of Article 5, any such product approved by the appropriate health agency after 31 December 2008, excluding any product in the process of registration and approved by 31 December 2009, will not be considered an essential use unless the product meets the criteria of Decision IV/25 paragraph 1 (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."

Decision XX/3 (par. 1) modifies Decision XV/5 (par.3) to remove reference to the term "not operating under Article 5".

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."

Decisions XVII/5, XVIII/7, XIX/13 and XX/2 further specify that Parties:

"when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer of metered-dose inhalers for asthma and chronic obstructive pulmonary diseases, shall take into account pre- and post-phase-out stocks of controlled substances as described in paragraph 1 (b) of decision IV/25, such that no more than a one-year operational supply is maintained by the manufacturer;"

2.3.5 Decision XVIII/7

Decisions XVIII/7 (and subsequent modifications made by Decision XX/3) supplements Decision VIII/10 and the requirements for Parties nominating essential-uses by specifying:

"That Parties will request companies applying for metered-dose inhaler essential use exemptions to demonstrate that they are making efforts, with all due diligence, on research and development with respect to chlorofluorocarbon-free alternatives to their products and are diligently seeking approval of their chlorofluorocarbon-free alternatives in their domestic and export markets aimed at transitioning those markets away from the chlorofluorocarbon products;"

Decision XIX/13 further supplements Decision XVIII/7 by specifying:

“That Parties will request each company, consistent with paragraph 1 of decision VIII/10, to notify the relevant authority, for each metered-dose inhaler product for which the production of CFCs is requested, of:

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

2.3.6 Decision XVIII/16

Decision XVIII/16 (and subsequent modifications made by Decision XX/3) supplements the requirements for essential-use nominations for Parties exporting to Parties operating under paragraph 1 of Article 5 by requesting that:

“each Party receiving essential-use exemptions for the production or import of chlorofluorocarbons to manufacture metered dose inhalers for export to Parties operating under paragraph 1 of Article 5 to submit to each importing Party a detailed export manufacturing transition plan for each manufacturer where the exports of an active ingredient to that Party exceed 10 metric tonnes, specifying the actions that each manufacturer is taking and will take to transition its exports to chlorofluorocarbon-free metered-dose inhalers as expeditiously as possible in a manner that does not put patients at risk;”

and,

“each Party referred to in paragraph 7 of the present decision, when deciding whether to nominate essential-use volumes for and/or grant essential-use licenses to a manufacturer, to take into account the manufacturer’s efforts to implement its export manufacturing transition plan and its contribution to transition towards chlorofluorocarbon-free metered-dose inhalers.”

2.3.7 Decision XX/3

Decision XX/3 specifies that the Parties submitting nominations for essential-use exemptions and the TEAP when reviewing nominations, shall consider the decisions amended and noted in Decision XX/3 when considering essential-use nominations in 2009 and beyond, subject to any further future decision of the Parties.

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 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.

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 determining 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, XVI/12, par. 2, and XX/3, par. 1(a)(iii)).

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. (Decisions XV/5, par. 3 and XX/3, par. 1(a)(iii)).
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 demonstrated ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborated with other companies in such efforts, has made a commitment to the reformulation of each CFC MDI product, has a timetable in which the formulation process for each CFC MDI product may be completed, and has provided evidence that it is diligently seeking approval of its chlorofluorocarbon-free alternatives in its domestic and export markets and transitioning those markets away from the chlorofluorocarbon products. (Decisions VIII/10, par. 1, XVIII/7, par. 3, XIX/13, par. 3 and XX/3, par. 1(a)(i) and (ii)).
10. If the use is for a CFC MDI product approved in non-Article 5 Parties after 31 December 2000, or approved in Article 5 Parties after 31 December 2008, excluding any product in Article 5 Parties that is in the process of registration and approved by 31 December 2009 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. (Decisions XII/2, par. 2 and XX/3, par. 1(f)).
11. Describe the measures that are proposed to eliminate all unnecessary emissions. At a minimum, this explanation should include design considerations and maintenance procedures. (Decisions IV/25, pars. 1(b)(i), 2 and 3(b); VI/9, par. 4; VIII/10, pars. 6 and 7; and XX/3, par. 1(a)(i) and (ii)).
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; Decision XII/2, par. 4; and Decision XX/3, par. 1(a)(i) and (ii)).

- 12.*bis* For CFC MDIs, for Parties exporting to Parties operating under paragraph 1 of Article 5 where the exports of an active ingredient to that Party exceed 10 metric tonnes, summarise the export manufacturing transition plans submitted to the importing Party pursuant to Decision XVIII/16, taking care to protect any confidential information. (Decisions XVIII/16, pars. 7, 8, 9 and 10, and XX/3, par. 1(a)(v)).
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, pars. 5 and 5 *bis*, Decision XII/2, par. 5(c), and Decision XX/3, par. 1(e)).
- 15.*bis* For CFC MDIs, briefly describe the Party's plan of action regarding the phase-out of the domestic use of CFC MDIs where the sole active ingredient is salbutamol, and describe progress towards implementing that plan. (Decision XV/5, pars. 4, 4 *bis* and 5, and Decision XX/3, par. 1(a)(iii) and (g)).
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. (Decision XV/5, par. 6, and Decision XX/3, par. 1(a)(iii)).
- 16.*bis* For CFC MDIs, describe progress made towards submitting a specific date by which time a regulation or regulations to determine the non-essentiality of the vast majority of CFCs for MDIs where the active ingredient is not solely salbutamol will have been proposed. (Decision XVII/5 pars. 3 and 3 *bis*, and Decision XX/3 par. 1(d)).
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-phase-out) 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), Decision XVI/12, par. 3, Decision XVII/5 par. 2, Decision XVIII/7 par. 2, Decision XIX/13 par. 2 and Decision XX/3 par. 1(c)).

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-phase-out) 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-phase-out) 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-phase-out pharmaceutical-grade CFCs not exceeding one year's operational supply; and
- (d) All available pre-phase-out stockpiles have been or will be depleted by companies before drawing on essential use quantities and thereby assure that pre-phase-out stockpiles are taken into account in making essential use requests.

(Decision IV/25, par. 1(b)(ii), Decision XVI/12, par. 3, Decision XVII/5 par. 2, Decision XVIII/7 par. 2, Decision XIX/13 par. 2 and Decision XX/3 par. 1(c)).

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, XVI/12, XVII/5, XVIII/7, XVIII/16, XIX/13 and XX/3 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 e-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 including:

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:

5. Annual review of the quantity of controlled substance authorised, and
6. 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 11th 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).

3 INSTRUCTIONS

Nominations are expected to fully satisfy the criteria in Decision IV/25, Decision XII/2, Decision XV/5, Decision XVI/12, Decision XVII/5, Decision XVIII/7, Decision XVIII/16, Decision XIX/13, and Decision XX/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 2011 must be received by 31 January 2010.

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 CFC 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:

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

¹ These deadlines are set by national governments.

² These dates are deadlines established by the Parties.

APPENDIX A

EXCERPTS FROM PROTOCOL PROVISIONS¹

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.

¹ 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 PROTOCOL¹

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);
 - (b) economically feasible use and emission controls for the proposed essential use;

¹ For a consolidated description of Protocol provisions see "Handbook for the International Treaties for the Protection of the Ozone Layer", Seventh Edition (2006), Ozone Secretariat.

- (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 authorized as specified in annex II to the report of the Eighth Meeting of the Parties, subject to the conditions established by the Seventh Meeting of the Parties in paragraph 2 of its decision VII/28;
- 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 Eighth 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 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;
- 5. To permit the transfer of essential-use authorizations 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 authorizations 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; however, for 1997 the report will be submitted by 1 April 1997;
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 of the Parties 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 authorize, 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 should present this information to the next Meeting of the Parties for review and appropriate action by the Parties.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

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

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

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

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

3. To request their national authorities to review the terms for public MDI procurement and reimbursement, so that purchasing policies do not discriminate against non-CFC alternatives.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

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;

5 bis. To require Parties operating under paragraph 1 of Article 5 submitting essential-use nominations for chlorofluorocarbons for metered-dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease to present to the Ozone Secretariat an initial national or regional transition strategy by 31 January 2010 for circulation to all Parties. Where possible, Parties operating under paragraph 1 of Article 5 are encouraged to develop and submit to the Secretariat an initial transition strategy by 31 January 2009. In preparing a transition strategy, Parties operating under paragraph 1 of Article 5 should take into consideration the availability and price of treatments for asthma and chronic obstructive pulmonary disease in countries currently importing chlorofluorocarbon-containing metered-dose inhalers

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

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(1) Party is not an essential use unless the product meets the criteria set out in paragraph 1(a) of decision IV/25;

- 2 bis. That any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2008, excluding any product in the process of registration and approved by 31 December 2009, for treatment of asthma and/or chronic obstructive pulmonary disease in a Party operating under paragraph 1 of Article 5, is not an essential use, unless the product meets the criteria set out in paragraph 1 (a) of decision IV/25;
3. With respect to any chlorofluorocarbon metered-dose inhaler active ingredient or category of products that a Party has determined to be non-essential and thereby not authorized for domestic use, to request:
 - (a) The Party that has made the determination to notify the Secretariat;
 - (b) The Secretariat to maintain such a list on its Web site;
 - (c) Each nominating Party to reduce accordingly the volume of chlorofluorocarbons it requests and licenses;
 4. To encourage each Party to urge each metered-dose inhaler company within its territory to diligently seek approval for the company's chlorofluorocarbon-free alternatives in its domestic and export markets, and to require each Party to provide a general report on such efforts to the Secretariat by 31 January 2002 and each year thereafter;
 5. To agree that each non-Article 5 Party should, if it has not already done so:
 - (a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) is/are no longer essential;
 - (b) Submit the text of any such strategy to the Secretariat by 31 January 2002;
 - (c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;
 6. To encourage each Article 5(1) Party to:
 - (a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) can be replaced with chlorofluorocarbon-free alternatives;
 - (b) Submit the text of any such a strategy to the Secretariat by 31 January 2005;
 - (c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;
 7. To request the Executive Committee of the Multilateral Fund to consider providing technical, financial and other assistance to Article 5(1) Parties to facilitate the development of metered-dose inhaler transition strategies and the implementation of approved activities contained therein, and to invite the Global Environment Facility to consider providing the same assistance to those eligible countries with economies in transition;

8. To decide that, as a means of avoiding unnecessary production of new chlorofluorocarbons, and provided that the conditions set out in paragraphs (a) - (d) of decision IX/20 are met, a Party may allow a metered-dose inhaler company to transfer:
 - (a) All or part of its essential use authorization to another existing metered-dose inhaler company; or
 - (b) Chlorofluorocarbons to another metered-dose inhaler company provided that the transfer complies with national/regional licence or other authorization requirements;
9. To request the Technology and Economic Assessment Panel to summarize and review by 15 May each year the information submitted to the Secretariat;
10. To modify as necessary the Handbook for Essential Use Nominations to take account of the requirements contained in this decision as they pertain to non-Article 5(1) Parties;
11. To request the Technology and Economic Assessment Panel to consider and report to the next Meeting of the Parties on issues related to the campaign production of chlorofluorocarbons for chlorofluorocarbon metered-dose inhalers.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.18 *Decision XIV/5. Global database and assessment to determine appropriate measures to complete the transition from chlorofluorocarbon metered-dose inhalers*

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.19 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;
- 4 bis. That no quantity of chlorofluorocarbons for essential uses shall be authorized after the commencement of the Twenty-First Meeting of the Parties if the nominating Party operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-ninth meeting of the Open-ended Working Group, a preliminary plan of action regarding the phase-out of the domestic use of chlorofluorocarbon-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.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.20 *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.

B.21 *Decision XVII/5. Essential-use nominations for Parties ~~not operating under paragraph 1 of Article 5~~ for controlled substances for 2006 and 2007*

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

determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed;

3 bis With reference to paragraph 6 of decision XV/5, to request that Parties operating under paragraph 1 of Article 5 of the Montreal Protocol submit a date to the Ozone Secretariat prior to the Twenty-Second Meeting of the Parties, by which time a regulation or regulations to determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.22 *Decision XVII/14: Difficulties faced by some Parties operating under paragraph 1 of Article 5 of the Montreal Protocol with respect to chlorofluorocarbons used in the manufacture of metered-dose inhalers*

1. To consider at the Eighteenth Meeting of the Parties a possible decision which would address the difficulties that some Parties operating under paragraph 1 of Article 5 may face in relation to metered-dose inhalers;
2. To request the Executive Committee of the Multilateral Fund to examine situations such as these and consider options that might assist this potential situation of non-compliance;
3. To request the Executive Committee to consider appropriate regional workshops to create awareness and educate stakeholders, including doctors and patients, on alternative metered-dose inhalers and on the elimination of chlorofluorocarbons in metered-dose inhaler uses and technical assistance to Article 5 Parties to phase out this use;
4. To request the Open-ended Working Group at its twenty-sixth meeting to consider the issue;

B.23 *Decision XVIII/7. Essential-use exemptions for Parties ~~not operating under paragraph 1 of Article 5 for controlled substances for 2007 and 2008~~*

1. To authorize the levels of production and consumption for 2007 and 2008 necessary to satisfy essential uses of chlorofluorocarbons for the production of metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in annex III to the present report;
2. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~, when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer of metered-dose inhalers for asthma and chronic obstructive pulmonary diseases, shall take into account pre-and post-1996 phase-out stocks of controlled substances as described in paragraph 1 (b) of decision IV/25, such that no more than a one-year operational supply is maintained by the manufacturer;
3. That Parties ~~not operating under Article 5~~ will request companies applying for metered-dose inhaler essential use exemptions to demonstrate that they are making efforts, with all due diligence, on research and development with respect to chlorofluorocarbon-free alternatives to their products and are diligently seeking approval of their chlorofluorocarbon-free alternatives in their domestic and export markets aimed at transitioning those markets away from the chlorofluorocarbon products.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.24 *Decision XVIII/16. Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons*

1. To request the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol to consider as a matter of urgency the funding of projects in relation to those Parties operating under paragraph 1 of Article 5 that experience difficulties due to high consumption of chlorofluorocarbons for manufacturing metered-dose inhalers, in order to facilitate the transition from chlorofluorocarbon-based metered-dose inhalers;
2. To request the Executive Committee to consider within the context of the existing Multilateral Fund guidelines to review its decision 17/7 with regard to the existing cut-off date for consideration of metered-dose inhaler conversion projects consistent with the reality of the pace of technological advances in the metered-dose inhaler sector;
3. To request the Implementation Committee under the Non-compliance Procedure of the Montreal Protocol to consider all possible options on how to address the potential non-compliance difficulties of some Parties operating under paragraph 1 of Article 5 resulting from their high proportion of chlorofluorocarbon consumption in the metered-dose inhaler sector;
4. To further request the Implementation Committee to give special consideration to the situation of such Parties, particularly in the context of paragraph 4 of the non-compliance procedure of the Protocol, in the light of information received from the Parties concerned and having due regard to health considerations;
5. To consider again the matter referred to in paragraphs 3 and 4 at the twentieth Meeting of the Parties in 2008;
6. To request the Executive Committee to consider including on the agenda of the United Nations Environment Programme thematic regional workshops, information to clarify the steps required to advance the transition from chlorofluorocarbon metered-dose inhalers;
7. To request each Party ~~not operating under paragraph 1 of Article 5~~ receiving essential-use exemptions for the production or import of chlorofluorocarbons to manufacture metered-dose inhalers for export to Parties operating under paragraph 1 of Article 5 to submit to each importing Party a detailed export manufacturing transition plan for each manufacturer where the exports of an active ingredient to that Party exceed 10 metric tonnes, specifying the actions that each manufacturer is taking and will take to transition its exports to chlorofluorocarbon-free metered-dose inhalers as expeditiously as possible in a manner that does not put patients at risk;
8. That each manufacturer's export manufacturing transition plans should include specific details for each of the manufacturer's export markets and for each metered-dose inhaler by active ingredient concerning:
 - (a) Timing of submission to the health authority of marketing applications for chlorofluorocarbon-free alternatives, expected approval and launch of such alternatives and withdrawal of associated chlorofluorocarbon product or products;
 - (b) Indicative information on facilitative pricing, licensing and/or technology transfer arrangements under consideration;

- (c) Contribution to, and participation in, programmes for educating health care professionals, government health authorities and patients about the transition to chlorofluorocarbon-free treatments for asthma and chronic obstructive pulmonary disease;
9. Consistent with decision IV/25 and paragraph 4 of decision XII/2, to request each Party referred to in paragraph 7 of the present decision, when deciding whether to nominate essential-use volumes for and/or grant essential-use licenses to a manufacturer, to take into account the manufacturer's efforts to implement its export manufacturing transition plan and its contribution to transition towards chlorofluorocarbon-free metered-dose inhalers;
 10. To request each Party referred to in paragraph 7 to submit each year to the Technology and Economic Assessment Panel, as part of the Party's essential-use nomination, a report summarizing the export manufacturing transition plans submitted, taking care to protect any confidential information;
 11. To request the Technology and Economic Assessment Panel to consider such reports in its assessment of each Party's essential-use nominations;
 12. To request the Technology and Economic Assessment Panel to assess and report on progress at the twenty-seventh meeting Open-ended Working Group and to report to the Nineteenth Meeting of the Parties on the need for, feasibility of, optimal timing of, and recommended quantities for a limited campaign production of chlorofluorocarbons exclusively for metered-dose inhalers in both Parties operating under paragraph 1 of Article 5 and Parties not operating under paragraph 1 of Article 5.

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.25 *Decision XIX/13. Essential-use nominations for Parties ~~not operating under paragraph 1 of Article 5~~ for controlled substances for 2008 and 2009*

1. To authorize the levels of production and consumption for 2008 and 2009 necessary to satisfy essential uses of CFCs for metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in the annexes to the present decision;
2. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~, when licensing, authorizing or allocating essential-use exemptions for a manufacturer of metered-dose inhalers, shall ensure, in accordance with paragraph 1 (b) of decision IV/25, that pre- and post-~~1996~~phase-out stocks of controlled substances are taken into account such that no more than a one-year operational supply is maintained by the manufacturer;
3. That Parties ~~not operating under paragraph 1 of Article 5 of the Montreal Protocol~~ will request each company, consistent with paragraph 1 of decision VIII/10, to notify the relevant authority, for each metered-dose inhaler product for which the production of CFCs is requested, of:
 - (a) The company's commitment to the reformulation of the concerned products;
 - (b) The timetable in which each reformulation process may be completed;
 - (c) Evidence that the company is diligently seeking approval of any chlorofluorocarbon-free alternative(s) in its domestic and export markets and transitioning those markets away from its chlorofluorocarbon products;

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

Note: text indicated in ~~strike through~~ and underline has been deleted or added in accordance with the provisions of Decision XX/3.

B.26 ~~XX/2: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2009 and 2010~~

1. To authorize the levels of production and consumption for 2009 and 2010 necessary to satisfy essential uses of chlorofluorocarbons for metered-dose inhalers for asthma and chronic obstructive pulmonary disease as specified in the annex to the present decision;
2. That Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol, when licensing, authorizing or allocating essential-use exemptions for a manufacturer of metered dose inhalers, shall ensure, in accordance with paragraph 1 (b) of decision IV/25, that pre-1996 and post-1996 stocks of controlled substances are taken into account such that no more than a one-year operational supply is maintained by the manufacturer;

B.27 ~~XX/3: Essential-use exemptions for Parties operating under paragraph 1 of Article 5~~

1. To make the following modifications to the decisions noted below:
 - (a) To remove reference to the term “not operating under Article 5” or, “for non-Article 5 Parties” from the following titles and provisions of the following past decisions of the Parties:
 - (i) Title of decisions VIII/9, VIII/10, VIII/11, XI/14, XVII/5, XVIII/7, XIX/13;
 - (ii) Decision VIII/10, first line of paragraphs 1–9;
 - (iii) Decision XV/5, paragraphs 2, 3, 5(a) and 6;
 - (iv) Decision XVIII/7, paragraphs 2 and 3;
 - (v) Decision XVIII/16, first line of paragraph 7;
 - (b) To remove reference to the term “not operating under Article 5 of the Montreal Protocol” from the following titles and provisions of the following past decisions of the Parties:
 - (i) Decision XVII/5, paragraph 2;
 - (ii) Decision XIX/13, paragraphs 2 and 3;
 - (c) To remove and replace reference to the date “1996” with the term “phase-out” in the following provisions of past decisions of the Parties:
 - (i) Decision XVII/5, paragraph 2;
 - (ii) Decision XVIII/7, paragraph 2;
 - (iii) Decision XIX/13, paragraph 2;
 - (d) To add a new paragraph after paragraph 3 of decision XVII/5 to read as follows:

3 *bis* With reference to paragraph 6 of decision XV/5, to request that Parties operating under paragraph 1 of Article 5 of the Montreal Protocol submit a date to the Ozone

Secretariat prior to the Twenty-Second Meeting of the Parties, by which time a regulation or regulations to determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed;

- (e) To add a new paragraph after paragraph 5 of decision IX/19 to read as follows:

5 bis. To require Parties operating under paragraph 1 of Article 5 submitting essential-use nominations for chlorofluorocarbons for metered-dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease to present to the Ozone Secretariat an initial national or regional transition strategy by 31 January 2010 for circulation to all Parties. Where possible, Parties operating under paragraph 1 of Article 5 are encouraged to develop and submit to the Secretariat an initial transition strategy by 31 January 2009. In preparing a transition strategy, Parties operating under paragraph 1 of Article 5 should take into consideration the availability and price of treatments for asthma and chronic obstructive pulmonary disease in countries currently importing chlorofluorocarbon-containing metered-dose inhalers;
 - (f) To add a new paragraph after paragraph 2 of decision XII/2 to read as follows:

2 bis. That any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2008, excluding any product in the process of registration and approved by 31 December 2009, for treatment of asthma and/or chronic obstructive pulmonary disease in a Party operating under paragraph 1 of Article 5, is not an essential use, unless the product meets the criteria set out in paragraph 1 (a) of decision IV/25;
 - (g) To add a new paragraph after paragraph 4 of decision XV/5 to read as follows:

4 bis. That no quantity of chlorofluorocarbons for essential uses shall be authorized after the commencement of the Twenty-First Meeting of the Parties if the nominating Party operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-ninth meeting of the Open-ended Working Group, a preliminary plan of action regarding the phase-out of the domestic use of chlorofluorocarbon-containing metered-dose inhalers where the sole active ingredient is salbutamol;
2. That both the Parties submitting nominations for essential-use exemptions and the Technology and Economic Assessment Panel reviewing nominations for essential-use exemptions shall consider the decisions noted above in their amended form when considering essential-use nominations in 2009 and beyond, subject to any further future decisions of the Parties;
 3. To request the Secretariat to include the changes above in the relevant decisions of the Parties contained in the Montreal Protocol handbook at the time of its next revision, and to note in that handbook that the related decisions include the modifications adopted by the present decision;
 4. To request the Technology and Economic Assessment Panel to reflect paragraphs 1–3 above in a revised version of the handbook on essential-use nominations and to submit, for consideration by Parties, suggestions for any appropriate changes to the handbook and the timing to make such changes;

APPENDIX C

RECOMMENDED FORM FOR NOMINATION OF AN 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:

Executive Secretary

Ozone Secretariat
United Nations Environment Programme
United Nations Avenue, Gigiri
P.O. Box 30552
Nairobi 00100
Kenya
Telephone:(254 20) 762 3851/3611
Facsimile: (254-20) 762 46 91/92/93
E-mail: 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): _____

* 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 decisions of 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)

Ozone Depleting Substance*	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		
Total		

***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)

Ozone Depleting Substance	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
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

RECOMMENDED FORM FOR NOMINATION OF THE 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:

Executive Secretary

Ozone Secretariat
United Nations Environment Programme
United Nations Avenue, Gigiri
P.O. Box 30552
Nairobi 00100
Kenya
Telephone:(254 20) 762 3851/3611
Facsimile: (254-20) 762 46 91/92/93
E-mail: 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): _____

* 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 CFCs¹ 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, Decision XV/5, par. 2, Decision XVI/12, par. 2, and Decision XX/3, par. 1(a)(iii))

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

	2011
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).

¹ 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.

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. For non-Article 5 Parties, 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).

For Article 5 Parties, does this use include any MDI product approved after 31 December 2008, excluding any product in the process of registration and approved by 31 December 2009 for the treatment of asthma and/or chronic obstructive pulmonary disease?

- *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 regarding the phase-out of the domestic use of CFC MDIs where the sole active ingredient is salbutamol been submitted to the UNEP Ozone Secretariat? (Decisions IX/19, par. 5, XII/2, par. 5(c), XV/5, par. 4, 4 *bis* and 5, and XX/3, par. 1).
2. Explain, if known, for each intended market for sale or distribution as set forth above how any national transition strategy covering that intended market applies to the active ingredient(s) . (Decision XV/5, par. 3 and Decision XX/3, par. 1)

3. Describe progress in the transition to CFC-free alternatives pursuant to the national or regional transition strategy submitted to the Secretariat in the domestic market. (Decision IX/19, pars. 5 and 5 *bis*, Decision XII/2, par. 5(c), and Decision XX/3, par. 1(e))
4. Briefly describe the plan of action adopted by the Party pursuant to paragraphs 4, 4 *bis* and 5 of Decision XV/5, which provides for a plan of action including a specific phase-out date for salbutamol CFC MDIs sold or distributed in non-Article 5 Parties (for non-Article 5 Parties) or for domestic use (for Article 5 Parties), specific measures and actions sufficient to deliver the phase-out (for non-Article 5 Parties); and actions and measures needed to ensure continuing access to or supply of CFC-containing MDIs by Article 5 Parties, where appropriate (for non-Article 5 Parties). (Decision XV/5, pars. 4, 4 *bis*, and 5, and Decision XX/3, par.1(a)(iii) and (g))
5.
 - (a) 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. (Decision XV/5, par. 6, and Decision XX/3, par. 1(a)(iii))
 - (b) Describe progress made towards submitting a specific date by which time a regulation or regulations to determine the non-essentiality of the vast majority of CFCs for MDIs where the active ingredient is not solely salbutamol will have been proposed. (Decision XVII/5 pars. 3 and 3 *bis*, and Decision XX/3 par. 1(d))
6. For Parties exporting to Parties operating under paragraph 1 of Article 5 where the exports of an active ingredient to that Party exceed 10 metric tonnes, summarise the export manufacturing transition plans submitted to the importing Party pursuant to Decision XVIII/16, taking care to protect any confidential information. (Decisions XVIII/16, pars. 7, 8, 9 and 10, and XX/3, par. 1(a)(v)).
7. Explain what substitutes and alternatives to the proposed use are currently available and efforts being undertaken to employ alternatives in the future. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2, 3(d) and 4; Decision VIII/10, par. 1; Decision VIII/11; Decision XII/2, par. 4; and Decision XX/3, par. 1(a)(i) and (ii))

- *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 on the need for CFCs for MDIs in the year for which nomination is made.*
 - *Describe efforts to employ alternatives to this application in the future, including efforts to foster approval of alternatives in the domestic and export markets.*
8. Explain steps being taken to implement these substitutes and alternatives. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d))
- *Describe 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.*
 - *State any other barriers encountered in eliminating the use of the controlled substance for this application.*

9. Assure that each company requesting essential use allocations has demonstrated ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborated with other companies in such efforts, has made a commitment to the reformulation of each CFC MDI product, has a timetable in which the formulation process for each CFC MDI product may be completed, and has provided evidence that it is diligently seeking approval of its chlorofluorocarbon-free alternatives in its domestic and export markets and transitioning those markets away from the chlorofluorocarbon products. (Decisions VIII/10, par. 1, XVIII/7, par. 3, XIX/13, par. 3 and XX/3, par. 1(a)(i) and (ii))

10. Describe the steps being taken by companies to provide a continuity of supply of asthma and chronic obstructive pulmonary disease treatments to importing countries. For non-Article 5 Parties, also describe the steps being taken by companies to assist their MDI manufacturing facilities in Parties operating under Article 5(1) and countries with economies in transition 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, and Decision XX/3, par. 1(a))

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	2006	2007	2008	2009	2010	2011	2012	2013
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. (Decision XII/2, par. 3)
3. Describe measures to minimise emissions of CFCs during the manufacture of the essential use products, including design considerations and maintenance procedures. (Decision IV/25, pars. 1(b)(i), 2 and 3(b); Decision VI/9, par. 4; Decision VIII/10, pars. 6 and 7; and Decision XX/3, par. 1(a)(i) and (ii))
4. Describe efforts that have been made to acquire stockpiled or recycled controlled substance for this application both domestically and internationally. (Decision IV/25, par. 1(b)(ii))
5. Provide details of the management of the stockpile and any surplus. (Decision IV/25, par. 1(b)(ii))
6. Provide details of the existing stock of pharmaceutical-grade CFCs (pre- and post-phase-out) 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, Decision XVII/5 par. 2, Decision XVIII/7 par. 2, Decision XIX/13 par. 2 and Decision XX/3 par. 1(c))

7. 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- phase-out) 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-phase-out) 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-phase-out pharmaceutical-grade CFCs not exceeding one year's operational supply; and
 - d. All available pre-phase-out stockpiles have been, or will be, depleted by companies before drawing on essential use quantities and thereby assure that pre-phase-out stockpiles are taken into account in making essential use requests.

(Decision IV/25, par. 1(b)(ii) and Decision XVI/12, par. 3, Decision XVII/5 par. 2, Decision XVIII/7 par. 2, Decision XIX/13 par. 2 and Decision XX/3 par. 1(c))

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 ^{1,2}	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 ³	H (G+E) Available for Use in Current Year	I Used for Essential Use	J Quantity Contained in Products Exported	K Destroyed	L ² (H-I-K) On Hand End of Year ⁴
			Amount I	Country(s)								

- 1 Note that an 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 for non-Article 5 Parties or as of 1 January 2010 for Article 5 Parties. National governments not able to estimate quantities on hand as of 1 January 1996 or 1 January 2010 respectively 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.

APPENDIX E

ADDRESSES OF PROTOCOL SECRETARIAT AND TEAP MEMBERS

Ozone Secretariat

Executive Secretary

Ozone Secretariat
United Nations Environment Programme
United Nations Avenue, Gigiri
P.O. Box 30552
Nairobi 00100, Kenya
Telephone: (254 20) 762 3851/3611
Facsimile: (254-20) 762 46 91/92/93
E-mail: ozoneinfo@unep.org

Technology and Economic Assessment Panel Members

The following contains the background information for all TEAP members as at April 2009.

Dr. Stephen O. Andersen

(Panel Co-chair)
P.O. Box 257
2317 North Road
Barnard, Vermont USA
Telephone: 1-802-234-5251

Stephen O. Andersen, Co-chair of the Technology and Economic Assessment Panel since 1989, is Director of Strategic Climate Projects in the Climate Protection Partnerships Division of the U.S. Environmental Protection Agency and previously Deputy Director of the Stratospheric Protection Division. He created EPA's first voluntary partnerships including accelerated phase-out agreements in food packaging foam, mobile AC, and solvents and he helped organise the Halon Alternatives Research Corporation and the Industry Cooperative for Ozone Layer Protection. Prior to joining EPA he was a university professor, a consultant, and an employee of environmental, law, and energy NGOs. With K Madhava Sarma he is author of "Protecting the Ozone Layer: The United Nations History," (Earthscan 2002); with Durwood Zaelke he is author of "Industry Genius: Inventions and People Protecting the Climate and Fragile Ozone Layer," (Greenleaf 2003); with K. Madhava Sarma and Kristen N. Taddonio he is author of "Technology Transfer for the Ozone Layer: Lessons for Climate Change," (Earthscan 2007); and with Guus J.M. Velders, John S. Daniel, David W. Fahey, and Mack McFarland he is author of "The Importance of the Montreal Protocol in Protecting Climate," Proceedings of the National Academy of Sciences, 20 March 2007. He earned his M.S. and Ph.D. from the University of California Berkeley. He chaired and co-chaired the Solvents TOC from 1989 to 1995, chaired the 1999 HFC and PFC Task Force, and co-chaired several Task Forces. He served on the Steering Committee to the "IPCC/TEAP Special Report Safeguarding the Ozone Layer and the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons" and he participated in the Science Assessment Panel in 2006. Dr. Andersen's spouse works for the U.S. EPA Office of Pesticide Programs and Toxic Substances in a division that registers bio-pesticides, including potential substitutes for methyl bromide. The U.S. EPA makes in-kind contributions of wages, travel, communication, and other expenses and some travel is sponsored by the U.S. DoD. With approval of its government ethics officer, EPA allows expenses to be paid by other governments and organisations such as the United Nations Environment Programme (UNEP).

Mr. Paul Ashford

(Foams TOC Co-chair)
Principal Consultant
Caleb Management Services
The Old Dairy, Woodend Farm Cromhall,
Wotton-under-Edge
Gloucestershire, GL12 8AA, United Kingdom
Telephone: 44 1454 269330
Fax: 44 1454 269197
Mobile: 44 7774 110 814

Paul Ashford, Co-chair of the Rigid and Flexible Foams Technical Options Committee since 1998, is the owner and managing director of Caleb Management Services Ltd., a consulting company working in the chemical regulatory and sustainability arenas. He co-chaired the TEAP Task Force on the Supplement Report to the "IPCC/TEAP Special Report: Safeguarding the ozone layer and the global climate system: issues related to hydrofluorocarbons and perfluorocarbons" (2005) and the Task Force on Emissions Discrepancies in 2006. Paul Ashford has been involved in the work for the Task Force for Decision XX/8 and co-ordinated the Interim Report of the Task Force for Decision XX/7. Until 1994, he worked for BP Chemicals in the division that developed licensed foam technology using ODS and was responsible for the adoption of alternatives. He has over 25 years direct experience of foam related technical issues and has conducted numerous studies to characterise the foam sector and inform future policy development. His funding for TEAP activities, which includes some sponsorship of time, is provided jointly under contract by the Department of Business, Enterprise and Regulatory Reform (BERR) and the Department of Environment, Food and Rural Affairs (DEFRA) in the UK. Much of his earlier work on banks, emissions and foam end-of-life management, performed to inform both IPCC and TEAP processes was supported by the US EPA. There is increasing overlap with IPCC and UNFCCC climate objectives in support of greenhouse gas emissions reporting and reduction by Governments, including the assessment financial mechanisms to support this process. This and other related non-TEAP work is covered under separate contracts from relevant commissioning organisations including international agencies (e.g. UNMFS, UNDP and UNEP DTIE), governments, industry associations and corporate clients. A considerable portion of the work with private clients relates to the lifecycle assessment of products based on ODS alternatives and advice on carbon management strategies.

Dr. Jonathan Banks

(QPS Taskforce Co-chair)

Grainsmith Pty Ltd

10 Beltana Rd

Pialligo ACT 2609

Australia

Telephone: 61 2 6248 9228

Fax: 61 2 6248 9228

Dr. Jonathan Banks, Cochair of TEAP's QPS Task Force, is a private consultant. He was a member of the 1992 Methyl Bromide Assessment and from 1993 to 1998 and 2001 to 2005 co-chaired the Methyl Bromide TOC. He worked as a Research Scientist with the Australian Commonwealth Scientific and Industrial Research Organization (CSIRO) from 1972 to 1999 on grain storage technologies, including use of improved use of fumigants. He is co-inventor of carbonyl sulfide, an alternative fumigant to methyl bromide in some applications. Patent rights have been assigned to his employer, CSIRO. Dr Banks has no proprietary interest in alternatives or substitutes to ODSs, does not own stock in companies producing ODS or alternatives or substitutes to ODSs. He has stock in Brambles Ltd, a company that inter alia leases wooden pallets for freight. The pallets may or may not be treated with methyl bromide or alternatives. His spouse is co-owner of their commercial organic apple orchard. She has no financial interests relating to ozone-depleting substances. He has served on some national committees concerned with ODS and their control; within the last 4 years he has received contracts from UNEP, other institutions and public companies related to methyl bromide alternatives and grain storage technology--including training in fumigation (methyl bromide and alternatives), fumigation technology and recapture systems for methyl bromide. In 2005, 2006 and 2009 he received some support from UNEP for TEAP activities. Other funding for his current activities has been from personal contributions.

Prof. Mohamed Besri

(MBTOC Co-chair)

Department of Plant Pathology

Institut Agronomique et Vétérinaire Hassan II

BP 6202-Instituts

Rabat, Morocco

Telephone: 212 37 778 364 (office);

212 37 710 148 (home)

Fax: 212 37 778 364

Prof. Mohamed Besri, is a full time Professor of Plant Pathology, ecology of soil borne pathogens, and Integrated Pest Management at the Hassan II Institute of Agronomy and Veterinary Medicine, Rabat, Morocco (HII IAVM). The HII IAVM has an interest in the topics of the Montreal Protocol because it houses specialists in Soil-borne Plant Pathogens and MLF projects (strawberries, bananas, cut flowers, vegetables). It advises the Ministry of Agriculture on all aspects of alternatives to Methyl Bromide. Dr Besri, his spouse, his business partner and dependant children have no proprietary interest in alternatives or substitutes to ODSs, nor do any of them own stock in companies producing ODS or alternatives or substitutes to ODSs. Dr Besri works occasionally as a consultant to UNEP, UNIDO and other international organisations on matters related to the Montreal Protocol. Costs associated to travel, communication, and others related to participation in the TEAP, MBTOC, and relevant Montreal Protocol meetings, are paid by UNEP's Ozone Secretariat.

Mr. David Catchpole
(Halons TOC Co-chair)
Technical Consultant
Petrotechnical Resources Alaska
Anchorage
Alaska, U.S.A.
Telephone
And fax: 1 907 868 3911

Mr. David V. Catchpole, Co-Chair of the Halons Technical Options Committee and Member of the Technology and Economics Assessment Panel since 2005, works part time for Petrotechnical Resources Alaska (PRA), an Anchorage, Alaska based company that provides consulting services to oil companies in Alaska. From 1991 to 2004 he was a member of the HTOC. From 1970 until 1999, he was an employee of the BP group of companies, most recently BP Exploration Alaska, where he worked for nine years in the environmental department on alternatives to halon and on halon banking. Mr. Catchpole advises BP Exploration Alaska on fire protection and halon issues as his main activity for PRA. BP Exploration Alaska has an interest in the topics of the Montreal Protocol because it uses halon 1301 for explosion prevention and fire suppression in its enclosed oil and gas processing modules on the North Slope of Alaska. Mr. Catchpole has no proprietary interest in alternatives or substitutes to ODSs, does not own stock in companies producing ODS or alternatives or substitutes to ODSs, however his retirement portfolio contains stock in BP plc. Mr. Catchpole's spouse does not work for or consult for any organisation that has an interest in the topics of the Montreal Protocol. His spouse has no proprietary interest in alternatives or substitutes to ODSs, does not own stock in companies producing ODS or alternatives or substitutes to ODSs and does not consult for organisations seeking to phase-out ODSs. Mr. Catchpole typically receives funding to support salary and travel to TEAP/TOC meetings from the United States Environmental Protection Agency and the United States Department of Defense; and the Halon Recycling Corporation and the Halon Alternatives Research Corporation, which are not-for-profit industry coalitions that in turn receive contributions for this funding from members. Contributors are: BP Exploration Alaska, ConocoPhillips Alaska, DuPont, Chemtura, American Pacific, Firetrace, Halon Banking Systems, Westco and Remtec.

Prof. Dr. Biao Jiang
(Chemicals TOC Co-chair)
Shanghai Institute of Organic Chemistry
(SIOC), Chinese Academy of Sciences (CAS)
354 Fenglin Road
Shanghai 200032
The People's Republic of China
Telephone: 86 21 54925201
Fax: 81 21 64166128

Dr Biao Jiang, Co-chair of the Chemicals Technical Options Committee and TEAP member since 2005, is Professor of Chemistry of Shanghai Institute of Organic Chemistry, Chinese Academy Of Sciences and a member of editorial advisory board of Chemical Communication, Royal Society of Chemistry, United Kingdom. He received his Ph. D. in 1988 from Lanzhou University. After two years as postdoctoral research in the organometallic chemistry at Shanghai institute of organic chemistry, he spent three years as a visiting scientist working on the medicinal chemistry in Dupont-Merck Pharmaceutical Co. at the Dupont experimental station, Delaware, USA. In 1995, he returned to SIOC, where he is currently professor of Chemistry and Director. The research projects of Professor Jiang's group involve the development new methodology of asymmetric synthesis, total synthesis of marine natural alkaloids and steroids, fluorine-containing bioactive molecular, as well as organic process research and development of green chemistry. Professor Jiang has no proprietary interest in alternatives or substitutes to ODSs, nor does he own stock in companies producing ODS or alternatives or substitutes to ODSs. Costs of travel, communication, and other expenses related to participation in the TEAP, its Chemicals TOC, and relevant Montreal Protocol meetings, are paid by UNEP's Ozone Secretariat.

Dr. Sergey Kopylov
(Halons TOC Co-chair)
Head of Research Centre
All Russian Research Institute for Fire Protection
VNIPO
12, Balashikha
Moscow Region
Telephone: 7 495 5219747
Fax: 7 495 5214394

Dr. Sergey Kopylov, Halons Technical Options Committee (HTOC) Consulting Expert, is the Head of the Scientific Centre of the All-Russian Scientific Research Institute for Fire Protection (VNIPO). VNIPO has an interest in the topics of the Montreal Protocol as a body responsible for technical control of Montreal Protocol related issues in Russia. VNIPO has no

proprietary interest in alternatives or substitutes to ODSs, does not own or own stock in companies producing ODSs or alternatives or substitutes to ODSs. Dr. Kopylov works as a technical expert to the Russian government on matters related to the implementation of the Montreal Protocol. Dr. Kopylov's spouse does not work for or consult for any organisation or company. Dr. Kopylov's spouse and children have no proprietary interest in alternatives or substitutes to ODSs, do not own or own stock in companies producing ODSs or alternatives or substitutes to ODSs and do not consult for organisations seeking to phase-out ODSs. Dr. Kopylov's travel to HTOC meetings is paid for by UNEP's Ozone Secretariat.

Dr. Lambert Kuijpers

(Panel Co-chair, Refrigeration TOC Co-chair)

Technical University, Connector 1.15b

P.O. Box 513

NL - 5600 MB Eindhoven

The Netherlands

Telephone: 31 49 247 6371 / 31 40 247 4463

Home: 31 77 354 6742

Fax: 31 40 246 6627

Lambert Kuijpers, Co-chair of the Technology and Economic Assessment Panel since 1992 and Co-chair of the Refrigeration, Air-conditioning and Heat Pumps Technical Options Committee since 1989, works on a part-time basis for the Department "Technology for Sustainable Development" at the Technical University Eindhoven, The Netherlands. He co-chaired the TEAP Replenishment Task Forces since 1996 (the last one being the 2008 TEAP Replenishment Task Force). He served on the Steering Committee to the "IPCC/TEAP Special Report "Safeguarding the ozone layer and the global climate system: issues related to Hydrofluorocarbons and Perfluorocarbons". Dr. Kuijpers co-chaired the 2005 Task Force for the TEAP Supplementary Report to the IPCC/TEAP Special Report, the 2006 Task Force on Emissions Discrepancies and the 2007 Task Force on the Response to Decision XVIII/12. He co-ordinated the activities for the Task Force on Decision XX/8 and was involved in the work of the Task Force for Decision XX/7. He was a Lead Author for both the Third and the Fourth IPCC Assessment Report. He also was a member of the Ozone Science Assessment Panel in 2005-2006. Until 1993, he worked for Philips Eindhoven (NL) in the development of refrigeration, air conditioning, and heat pump systems to use alternatives to ozone-depleting substances. He is financially supported (through the UNEP Ozone Secretariat) by the European Commission (and in certain years by some EU member state governments) for his activities related to the TEAP and the Refrigeration TOC. Dr. Kuijpers has no proprietary interest in alternatives or substitutes to ODS and does not own stock in companies producing ODS or alternatives or substitutes to ODS. He occasionally is a consultant to governmental and non-governmental organisations, such as the World Bank, UNIDO, UNEP DTIE and the Multilateral Fund. Dr. Kuijpers is also an advisor to the Re/genT Company, Netherlands, which he co-founded in 1993 and where he still has a minority interest (this company is involved in the R&D of components and equipment for refrigeration, air-conditioning and heating).

Ms. Michelle Marcotte

Marcotte Consulting Inc.

(Marcotte Consulting is a Canadian corporation)

home address:

10104 East Franklin Ave

Glenn Dale, Maryland 20769

USA

Telephone: 1-301-262-9866

www.marcotteconsulting.com

Ms Michelle Marcotte was a member of the 1992 Methyl Bromide Assessment and subsequently a member of the Methyl Bromide Technical Options Committee between 1992 and 2005; she was confirmed as Co-Chair in 2005. Until 1993 she worked for MDS Nordion, a supplier of radiation processing equipment which is an alternative to the use of methyl bromide in some commodity and quarantine situations. Since then, Ms Marcotte, through Marcotte Consulting, has provided consulting services to governments and agri-food companies in eight countries on agri-environmental issues, food technology, regulatory affairs and radiation processing. Marcotte Consulting has an interest in the topics of the Montreal Protocol because of its long time market development work in food irradiation, an alternative to some methyl bromide uses, and because of its interest in food processing, food safety and trade. In the field of methyl bromide alternatives, Ms Marcotte has published case studies in pest control in food processing, in stored commodities, in alternatives for quarantine and in greenhouse use. She is a member of the Canada Industry-Government Methyl Bromide Working Group and the Canada-US Methyl Bromide Working Group; both organisations work to achieve the phase-out of methyl bromide in the agri-food sector. Marcotte has consulted to companies, industry associations, the International Atomic Energy Agency and US AID on irradiation as a methyl bromide alternative in food processing, quarantine and trade. She has also prepared consulting reports summarising research in methyl bromide alternatives and case studies on food processing for the U.S. Environmental Protection Agency. Ms Marcotte has no proprietary interest in alternatives or substitutes to ODSs, does not own stock in companies producing ODS or alternatives or substitutes to ODSs. Ms Marcotte's spouse works for United States Department of Agriculture managing research in methyl bromide alternatives and is a member of MBTOC. He does not have proprietary interest in alternatives or substitutes to ODS and does not own stock in companies producing ODS or alternatives or substitutes to ODSs. Ms Marcotte receives a consulting contract from the Government of Canada, Environment Canada. The

funds for Ms Marcotte for travel to TEAP, MBTOC and Montreal Protocol meetings and to support her work on the MBTOC are provided by the the Government of Canada, Environment Canada.

Mr. E. Thomas Morehouse Jr.

(Senior Expert Member)
Institute for Defense Analyses
4850, Mark Center Drive
Alexandria, VA 22311
U.S.A.
Telephone: 1 703 750 6840
Fax: 1 703 750 6835

Thomas Morehouse, Senior Expert Member for Military Issues since 1997, is a Research Adjunct at the Institute for Defense Analyses (IDA), Washington D.C., USA. From 1989 until 1996 he co-chaired the Halons TOC. From 1986 to 1989 he was an officer in the United States Air Force responsible for developing alternatives to halon. From 1989 until 1994 his responsibilities as an Air Force officer included broader environmental and energy policy issues for the U.S. Department of Defense. IDA makes in-kind contributions of communications and miscellaneous expenses. IDA is a not-for-profit Federally Funded Research Center (FFRDC) that undertakes work exclusively for the US Department of Defense. Funding for wages and travel is provided by grants from the Department of Defense. He also occasionally consults independently to corporate clients, national laboratories and other government agencies on environmental and energy related issues. Mr. Morehouse's spouse consults occasionally for the U.S. National Oceanographic and Atmospheric Administration (NOAA) on management issues. NOAA conducts research on stratospheric ozone and climate. Mr Morehouse –and his spouse- have no proprietary interest in alternatives or substitutes to ODSs, nor do they own stock in companies producing ODS or alternatives or substitutes to ODSs.

Ms. Marta Pizano

(MBTOC Co-chair and QPSTF Co-chair)
Consultant
Calle 85 No. 20 – 25 Of 202B
Bogotá, Colombia
Telephone: 57 1 6348020 or 5302036
Fax: 57 1 2362554

Ms Marta Pizano is a consultant on methyl bromide alternatives, particularly for cut flower production, and has actively promoted methyl bromide alternatives among growers in many countries. She is a regular consultant for the Montreal Protocol Multilateral Fund (MLF) and its implementing agencies. In this capacity, she has contributed to the methyl bromide phase-out programs in nearly twenty Article 5 Parties around the world, assisting growers with the adoption of sustainable alternatives and the implementation of IPM programs. She is a frequent speaker at national and international methyl bromide conferences and has authored numerous articles and publications on alternatives to this fumigant. She has been a member of MBTOC since 1998 and a co-chair since 2005. She became co-chair of the revitalised QPS Task Force in 2008. Neither Ms Pizano nor her husband or their children own stock or have proprietary interest in companies producing ODS or their alternatives or substitutes. Costs associated with travel, communication, and others related to participation in the TEAP, MBTOC, and relevant Montreal Protocol meetings, are paid by UNEP's Ozone Secretariat.

Mr. Jose Pons Pons

(Panel Co-chair, Medical TOC Co-chair)
Spray Química
Urb.Ind.Soco, Calle Sur #14
La Victoria 2121, Edo Aragua
Venezuela
Telephone: 58 244 3223297 or 3214079 or 3223891
Fax: 58 244 3220192

Jose Pons, Co-chair of the Technology and Economic Assessment Panel since 2004 and of the Medical Technical Options Committee since 1991, is President of Spray Química C.A. . Spray Química had an interest in the topics of the Montreal Protocol because it used ODS in some of its aerosol products for industrial maintenance. Mr. Pons is president of the Venezuelan Chamber of Aerosols, CAVEA and has worked in ozone layer protection since 1989. He has participated in several TEAP Task Forces and on the Steering Committee to the "IPCC/TEAP Special Report Safeguarding the Ozone Layer and the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons". Mr Pons has no proprietary interest in alternatives or substitutes to ODS, does not own stock in companies producing ODS or alternatives or substitutes to ODS, does not have an interest in the outcome of essential use nominations, and does not consult for organisations seeking to phase out ODS. Mr Pons's spouse has no interest in matters before the Protocol; she is also a manager/engineer at Spray Química. Mr Pons has worked occasionally as a project reviewer for the MLF and implementing agencies on matters related to the Montreal Protocol. Travel related to participation in the TEAP and MTOC, and relevant Protocol meetings, are paid by

UNEP's Ozone Secretariat. Spray Química makes in-kind contributions of wage, and miscellaneous and communication expenses.

Dr. Ian J. Porter

(MBTOC Co-chair)
Consultant and Principal Research Scientist
Primary Industries Research Victoria
Department of Primary Industries
Private Bag 15, Ferntree Gully Delivery Centre 3156,
Victoria, Australia.
Telephone: 61 3 9210 9222
Fax: 61 3 9800 3521
Mobile: 61(0) 417 544 080

Dr Ian Porter is an Associate Professor with LaTrobe University and Principal Research Scientist with the Victorian Department of Primary Industries (DPI), but takes leave from his organisation to conduct Montreal Protocol duties. DPI has an interest in developing sustainable alternatives to methyl bromide and integrated pest management strategies for control of plant pathogens and pests, and issues related to biosecurity. He has been a member of a number of National Committees regulating ODS, has led the Australian research program on methyl bromide alternatives for soils since 1992 and has 28 years experience in researching sustainable methods for soil disinfection of plant pathogens with over 250 research publications. He has been a member of MBTOC since 1997, chair of the Soils sub committee from 2001 to 2005 and MBTOC Co-chair since 2005. Neither Ian, his wife or children have any proprietary interest in alternatives or substitutes to ODSs, nor own stock in companies producing ODS or alternatives or substitutes to ODSs. Dr Porter is presently leading national programs on integrated pest management and soil health in the Australian horticultural industries. He has acted as a key consultant for UNEP and UNIDO in developing programmes to assist China, Mexico and CEIT countries to replace methyl bromide. He regularly participates in workshops to assist countries with alternatives to methyl bromide and gives keynote addresses to international conferences on alternatives to methyl bromide in horticultural industries. He is presently funded by the European Commission through the Ozone Secretariat to support and attend MBTOC and TEAP meetings. In kind contributions from the Victorian Department of Primary Industries and Australian Federal Government Research Funds have provided past support.

Prof. Miguel W. Quintero

(Foams TOC Co-chair)
Consultant
Avenida Carrera 1 # 78-10, IV-601
Bogotá, Colombia
Telephone: +57 1 3492325
Mobile: +57 314 263 7857

Prof. Miguel W. Quintero, Co-chair of the Foams Technical Options Committee since 2002, is a consultant in the area of polyurethane technology. He has been a professor at the Chemical Engineering Department at Universidad de los Andes in Bogota, Colombia, in the areas of polymer processing and transport phenomena during 2000- 2006. Prof. Quintero worked during 21 years (until 2000) for Dow Chemical at the Research & Development and Technical Service & Development Departments in the area of rigid polyurethane foam. In the period January 2007- October 2008, he returned to Dow Europe as Development Leader for Polyurethane Product Research, located in Freienbach, Switzerland. He owns stock in companies that now or previously manufactured ozone-depleting substances and products made with or containing ozone depleting substances and their substitutes and alternatives. He is a regular consultant for the Montreal Protocol's implementing agencies. Costs associated to travel, communication, and others related to participation in the TEAP, FTOC and relevant Montreal Protocol meetings are paid by UNEP's Ozone Secretariat.

Dr. Ian D. Rae

(Chemicals TOC Co-Chair)
16 Bates Drive
Williamstown, Vic 3016
Australia
Telephone: 61 3 9397 3794
Fax: 61 3 9397 3794

Dr. Rae, Co-chair of the Chemicals Technical Options Committee since 2005, is a Honorary Professorial Fellow at the University of Melbourne, Australia, and a member of advisory bodies for several Australian government agencies dealing with chemical issues and in particular the Stockholm Convention. He co-chaired the 2001 and 2004 Process Agent Task Forces. He is a member of the POPs Review Committee for the Stockholm Convention. On occasions, he acts as consultant to government agencies and to universities and companies and he has been an expert witness in a case involving alleged patent infringement involving HFC- 134a and its lubricants. Neither he nor his wife owns stock in any company dealing with

ozone depleting substances or their alternatives. He contributes the time for his own participation in TEAP activities. The Australian Government Department of the Environment, Water, Heritage and the Arts finances the cost of travel and accommodation for Dr. Rae's attendance at meetings of the CTOC, TEAP, OEWG and MOP.

Mr. K. Madhava Sarma

(Senior Expert Member)

AB50, Anna Nagar,

Chennai 600 040

India

Telephone: 91 44 2626 8924

Fax: 91 44 4217 0932

K. Madhava Sarma, Senior Expert Member since 2001, and member of the Task Force on the TEAP Legacy, retired in 2000, after nine years as Executive Secretary, Ozone Secretariat, UNEP. Earlier, he was a senior official in the Ministry of Environment and Forests (MOEF), Government of India and held various senior positions in a state government in India. He works occasionally as a consultant to UNEP and is an unpaid member of the Technical and Finance Committee of the Ozone Cell, MOEF, Government of India. He has worked as consultant for two chemical companies to work out the likely amendments needed to the Montreal Protocol if HFCs were made controlled substances under the Protocol. He is working as consultant to the UNFCCC Secretariat to assist its Expert Group on Technology Transfer to prepare a Strategy for scaling up Technology Development, Deployment and Diffusion. Neither he or his spouse own stock in any company connected to ODS or alternatives or substitutes. Costs of travel, communication, and other expenses related to participation in the TEAP and relevant Montreal Protocol meetings, are paid by UNEP's Ozone Secretariat.

Dr. Helen Tope

(Medical TOC Co-chair)

Principal Consultant

Energy International Australia

Director, Planet Futures

Unit 2, 9 Osborne Street

Williamstown, Victoria 3016

Australia

Telephone: 61 414 563 474

Fax: 61 3 9397 0341

Helen Tope, Co-chair Medical Technical Options Committee since 1995, is Principal Consultant of Energy International Australia and also Director of Planet Futures with whom she is an independent consultant providing strategic, policy and technical advice and facilitation services to government, industry and other non-governmental organisations on climate change, ozone-depleting substances, and other environmental issues. Dr Tope's business has an interest in the topics of the Montreal Protocol because her potential clients are also interested in these topics. Dr Tope has no proprietary interest in alternatives or substitutes to ODS, does not own stock in companies producing ODS or alternatives or substitutes to ODS, does not have an interest in the outcome of essential use nominations, and does not currently consult for organisations seeking to phase out ODS. Dr Tope's spouse has no interest in matters before the Protocol. At the invitation of UNEP ROAP, Dr Tope participated as MTOC co-chair in the 2008 Langkawi regional workshop on MDIs. UNEP ROAP has contracted the National Asthma Council Australia to produce a package of resources on awareness raising on the transition to CFC-free MDIs to assist countries preparing for CFC MDI phase-out. At the invitation of the National Asthma Council Australia, Dr Tope is a member of the Advisory Panel for this project. In 2009 Dr Tope's funding for travel to MTOC, TEAP and Montreal Protocol meetings are provided from two sources. The Ozone Secretariat provides a grant for Dr Tope's travel to the MTOC and TEAP meetings from funds granted to the Secretariat unconditionally by the International Pharmaceutical Aerosol Consortium (IPAC), which is a non-profit corporation. The Australian Government Department of the Environment, Water, Heritage and the Arts provides funding for the cost of travel and accommodation for Dr Tope's attendance of the OEWG-29 and MOP-21.

Dr. Daniel P. Verdonik

(Halons TOC Co-chair)
Hughes Associates
3610 Commerce Drive, STE 817
Baltimore, MD 21227-1652
U. S. A.
Telephone: 1 443 253 7587
Fax: 1 410 737 8688

Dr. Daniel P. Verdonik, Co-Chair, Halons Technical Options Committee and Member, Technology and Economic Assessment Panel, is the Director, Environmental Programs, Hughes Associates, Inc. Dr. Verdonik is a full time, salaried employee at Hughes Associates, Inc., in Baltimore, MD and Arlington, VA providing consulting services in fire protection and environmental management. Hughes Associates, Inc. has an interest in the topics of the Montreal Protocol because it provides a wide range of fire protection research, design and consulting services to government and corporate clients, including work related to halons and halon alternatives. Dr. Verdonik has no proprietary interest in alternatives or substitutes to ODSs, does not own stock in companies producing ODSs or alternatives or substitutes to ODSs and through Hughes Associates, Inc. provides consulting services for organisations seeking to phase-out ODSs. Dr. Verdonik is a share holder in Hughes Associates, Inc., which does not own stock in companies producing ODSs, or alternatives or substitutes to ODSs. Dr. Verdonik currently provides consulting services through Hughes Associates, Inc. for the U.S. Army and U.S. Navy on matters related to the Montreal Protocol and has previously provided services through Hughes Associates Inc. for Implementing Agencies, U.S. EPA, U.S. Air Force and Chemtura (now DuPont). Dr. Verdonik's spouse works for the USEPA, which has an interest in the topics of the Montreal Protocol because the Agency is responsible for implementing national regulations and policies to meet the US commitments under the Protocol. Dr. Verdonik's spouse and dependent child have no proprietary interest in alternatives or substitutes to ODSs, do not own stock in companies producing ODSs or alternatives or substitutes to ODSs, and do not consult for organisations seeking to phase-out ODSs. Hughes Associates, Inc. typically receives funding to support Dr. Verdonik's salary and travel to TEAP/HTOC/TSB meetings from MLF, UNEP, the U.S. Department of Defense, the U.S. EPA, the U.S. National Aeronautics and Space Administration, the Halon Recycling Corporation, and the Halon Alternatives Research Corporation, who in-turn currently receives funding to support these efforts from the following sponsors: BP Exploration, Alaska; ConocoPhillips, Alaska; DuPont; American Pacific; Firetrace; Halon Banking Systems; Wescor; Remtec. From time-to-time, Hughes Associates, Inc may also provide support for labour and travel.

Prof. Ashley Woodcock

(Medical TOC Co-chair)
North West Lung Centre
South Manchester University Hospital Trust
Manchester M23 9LT
United Kingdom
Telephone: 44 161 291 2398
Fax: 44 161 291 5020

Prof. Ashley Woodcock, Co-chair of the Medical Technical Options Committee and Member of the Technology and Economic Assessment Panel, is a Respiratory physician at the University Hospital of South Manchester, and Head of the School of Translational Medicine for the University of Manchester. The Hospital and University have no direct interest in the topics of the Montreal Protocol. Prof. Woodcock has no proprietary interest in alternatives or substitutes to ODS, does not own stock in companies producing ODS or alternatives or substitutes to ODS, does not have an interest in the outcome of essential use nominations. Prof. Woodcock carries out unrelated consulting, research and educational lectures for pharmaceutical companies, all of which are near completion of phase out of CFC MDIs. He advises companies on study design for new drugs, some of which have been ODS replacements. Prof. Woodcock's spouse has no interest in matters before the Protocol. Prof. Woodcock does not work as a consultant to the UN, UNEP, MLF or Implementing Agencies. In the past, he has responded to requests for technical information on CFC MDI phase-out from the European Community and the United Kingdom Government. Travel and subsistence for meetings of TEAP, MTOC, OEWG, MOP meetings is paid from Hospital and University funds, and Prof. Woodcock's employers allow leave of absence.

Dr. Masaaki Yamabe

(Chemicals TOC Co-chair)
National Institute of Advanced Industrial
Science and Technology (AIST)
Onogawa 16-1 AIST West, Tsukuba
Ibaraki 305-8569, Japan
Telephone: 81 29 861 2926
Fax: 81 29 861 8195

Dr. Masaaki Yamabe, Co-Chair of the Chemicals Technical Options Committee since 2005, is a research advisor of the Research Institute of Science for Safety and Sustainability at the AIST. He was a member of the Task Force on the TEAP Legacy and he co-chaired the 2004 Process Agent Task Force. He was a member of the Solvents TOC during 1990-1996. Until 1999, Mr. Yamabe was Director of Central Research for Asahi Glass Company, which previously produced CFCs, methyl chloroform, and carbon tetrachloride, and currently produces and distributes HCFC, carbon tetrachloride, and HFCs. He is the co-inventor of HCFC-225, which is controlled under the Montreal Protocol as a transitional substance in the phase-out of ozone-depleting substances and is a substitute for CFC-113 in solvent and process agent applications. He owns stocks in Asahi Glass Company that produces ozone-depleting substances and their substitutes. He also works for the Japan Industrial Conference for Ozone Layer and Climate Protection (JICOP) as a senior advisor. AIST, JICOP and the Ministry of Economy, Trade and Industry (METI) share the financing involved in the travel and accommodation for Mr. Yamabe's attendance at the meetings of the CTOC, TEAP, OEWG and MOP.

Prof. Shiqiu Zhang

(Senior Expert Member)
College for Environmental Sciences
Peking University
Beijing 100871
The People's Republic of China
Telephone: 86 10-627-64974
Fax: 86 10-627-60755

Dr. Shiqiu Zhang, Senior Expert Member for economic issues of the TEAP since 1997, is a Professor on Environmental Economics and Policy at the College for Environmental Sciences and Engineering of Peking University. She co-chaired the 2002, 2005 and 2008 Replenishment Task Forces. Dr. Zhang has no proprietary interest in alternatives or substitutes to ODSs, nor does she own stock in companies producing ODS or alternatives or substitutes to ODSs. Costs of travel, communication, and other expenses related to participation in the TEAP and relevant Montreal Protocol meetings, are paid by UNEP's Ozone Secretariat.

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