Montreal Protocol
On Substances that Deplete the Ozone Layer

Report of the
UNEP Technology and Economic Assessment Panel

May 2008
VOLUME 1

PROGRESS REPORT

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ACKNOWLEDGEMENT

The UNEP Technology and Economic Assessment Panel co-chairs and members wish to express thanks to all who contributed from governments, both Article 5 and non-Article 5, as well as to a large number of individuals involved in Protocol issues, without whose involvement the assessments and studies described in this progress report would not have been possible.

The opinions expressed are those of the Panel and its TOCs and do not necessarily reflect the reviews of any sponsoring or supporting organisation.

The TEAP thanks UNIDO in Vienna, Austria, for hosting the TEAP meeting, 21-25 April 2008, where this report was discussed, adopted and finalised for a last review by email circulation to all members.
Foreword

The May 2008 TEAP Report

The May 2008 TEAP Report consists of three volumes:

Volume 1: May 2008 TEAP Progress Report
Volume 2: May 2008 TEAP Replenishment Task Force Report
Volume 3: May 2008 TEAP CTC Emissions Report

Volume 1
Volume 1 contains the essential use report, progress reports, halon evaluations, the HCFC alternatives for high ambient temperature preliminary report, the MB CUN report, a consideration on the climate issue related to Decision XIX/6, TEAP organisation issues and TEAP member biographies (this report).

Volume 2

Volume 3
Volume 3 is the CTC Emissions Report by the TEAP CTC Task Force.

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1 Essential Uses

1.1 Executive Summary Essential Use Nominations for Metered Dose Inhalers

The following Table summarises the recommendations of the Technology and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC) on nominations for essential use production exemptions for chlorofluorocarbons (CFCs) for metered dose inhalers (MDIs).

<table>
<thead>
<tr>
<th></th>
<th>European Community</th>
<th>Russian Federation</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Unable to recommend exemption for CFCs for MDIs for 38 tonnes.</td>
<td>Recommend exemption for CFCs for MDIs for 248 tonnes (for single-moity salbutamol to be sold within the Russian Federation).</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td>Unable to recommend exemption for CFCs for MDIs for 182 tonnes.</td>
</tr>
</tbody>
</table>

European Community: MTOC does not consider that 65 per cent (about 25 tonnes) of the nominated quantities, designated for export to Article 5 Parties, meet the requirements of Decision IV/25(b)(ii) (regarding the availability of sufficient quantity of controlled substances from existing stocks) since MTOC believes that these nominated quantities could be supplied from the existing CFC stockpiles in the European Community (about 340 tonnes). If the European Community is unable to supply the amounts for CFC MDI manufacture for export to Article 5 Parties from existing stockpiles to meet manufacturing requirements for uses, which are demonstrated to be essential, in 2009 it could make a request to the Secretariat to authorise an emergency essential use in accordance with Decision VIII/9(10), which can provide up to 20 tonnes of ODS. The remaining 35 per cent (about 13 tonnes) requested is for combination MDI products to be used within the European Community. As previously stated, MTOC does not consider these combination CFC MDI products to be an essential use under Decision IV/25(a) when the individual components, or equivalents, are available as CFC-free alternatives.

Russian Federation: The Russian Federation states that 2009 will be the last year for which it will make an essential use nomination for CFCs for MDIs. Companies in the Russian Federation are in the process of developing new HFC MDIs containing salbutamol. However, the Russian Federation states that lack of financial resources and regulatory delays are impeding the large-scale conversion of their production facilities, which it anticipates should be completed in 2010. The Russian Federation also states “any financial assistance for MDI producers or technology transfer may provide some time-saving”. Therefore it is unclear whether the Russian Federation will require CFCs for MDI manufacture in 2010. MTOC recognises the immediate need of the nomination for 2009, and the quantity of CFC is justified based on consumption trends. Further clarification is needed on the final phase-out strategy for the Russian Federation, including stockpile management.

United States: MTOC does not consider that the United States’ nomination meets the requirements of Decision IV/25(b)(ii), regarding the availability of sufficient quantity of controlled substances from existing stocks. MTOC considers that the anticipated United States’ stockpile in 2010, estimated to be about 1,000 tonnes, should be adequate to supply CFC requirements, especially with the flexibility
afforded by the additional exempted quantity for 2009. MTOC does not consider that CFC MDIs for the drug moieties subject to the nomination are an essential use under Decision IV/25(a). According to the nomination, for the bronchodilators (pirbuterol and epinephrine CFC MDIs), there are four salbutamol HFC alternatives (MTOC considers salbutamol to be a suitable alternative bronchodilator in relation to this nomination). For the inhaled steroid triamcinolone CFC MDI, there are four suitable alternative moieties in a range of formulations (HFC MDIs and DPIs).

**General Comments:** MTOC notes that the timelines for drug development and approval in non-Article 5 Parties mean that any formulation that is going to be available by 2010 will already have to be a final commercial formulation, which has completed clinical studies and commenced regulatory assessment in 2008 (assuming regulatory approval takes a minimum of 12 months). Parties may wish to consider not allocating CFCs to companies without a final CFC-free formulation in regulatory assessment by the end of 2008.

For combination products for which the separate moieties are available as CFC-free alternatives, MTOC believes that these combination products continue to be used for patient convenience and commercial considerations. Patients will not come to any harm by using the drugs in separate CFC-free inhalers. The combination inhalers cannot therefore be considered to be essential under Decision IV/25. Parties may wish to consider a decision not to allocate CFCs for these combination products.

Parties have a range of suitable CFC-free alternatives for domestic use. For those Parties that continue to export CFC MDIs to Article 5 Parties, one option would be for Parties to consider regulations to restrict CFC MDI export and import (and encourage a transition to export/import of HFC MDIs or DPIs) to countries where these products are no longer needed. Parties may also wish to consider establishing a date by which exports and imports of all CFC MDIs cease.

MTOC believes that with the essential use exemption process for non-Article 5 Parties in its final phase and complete global transition a few years away, accurate and complete accounting frameworks of all CFC stockpiles, including pre-1996 stocks, should be provided by all Parties who hold them. Parties may wish to consider the advantages of requiring that plans for use or disposal of stockpiles be required with future accounting frameworks. Parties that have acquired CFCs under essential use exemptions are also reminded that accounting frameworks should continue to be submitted annually to account for destruction and depletion of stocks, including through transfers or use, even after nominations are no longer made and until no further stocks remain.

### 1.2 Essential Use Nominations for Metered Dose Inhalers

#### 1.2.1 Criteria for Review of Essential Use Nominations for MDIs

Decision IV/25 of the 4th Meeting and subsequent Decisions V/18, VII/28, VIII/9, VIII/10, XII/2, XIV/5, XV/5, XVI/12, and XVIII/16 have set the criteria and the process for the assessment of essential use nominations for MDIs for Parties not operating under paragraph 1 of Article 5 of the Protocol. Other essential use decisions relevant to these Parties are Decisions XIX/13, XVIII/7, and XVII/5.

#### 1.2.2 Review of Nominations

The review of essential use nominations by the MTOC was conducted as follows.

Three members of the MTOC independently reviewed each nomination, each preparing an assessment. The exception was for the assessment of the nomination from the Russian Federation this year, which was...
reviewed by the entire committee. Further information was requested where necessary. The MTOC considered the assessments, made recommendation decisions and prepared a consensus report at its meeting in Tokushima, Japan, 1-4 April 2008. Where appropriate, members declared a potential conflict of interest ahead of the discussion.

Nominations were assessed according to the guidelines for essential use contained within the Handbook on Essential Use Nominations (TEAP, 2005) and subsequent Decisions of the Parties.

Concurrent with the evaluation undertaken by the MTOC, copies of all nominations are provided to the Technology and Economic Assessment Panel (TEAP). The TEAP and its TOCs can consult with other individuals or organisations to assist in the review and to prepare TEAP recommendations for the Parties.

### 1.2.3 Summary of Parties’ Essential Use Nominations and Quantities for 2009 and 2010 (in tonnes)

<table>
<thead>
<tr>
<th></th>
<th>European Community</th>
<th>Russian Federation</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>38</td>
<td>248</td>
<td>-</td>
</tr>
<tr>
<td>2010</td>
<td>-</td>
<td>-</td>
<td>182</td>
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</table>

### 1.2.4 Observations

Three essential use nominations were received for consideration by the MTOC in 2008: the European Community for 2009, the Russian Federation for 2009, and the United States for 2010. The nomination from the Russian Federation was received on 27th March 2008, after the deadline of 31st January established by Parties. Supporting documentation, including the accounting framework, for the nomination from the United States was received on 2nd April 2008, after the deadline of 31st January established by Parties.

Decision VIII/10 (1) states “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”. The nominations for the European Community and the United States state that they have requested information on on-going research and development from individual companies, which remains confidential and is not provided for review by MTOC. While MTOC is confident that nominating Parties received information regarding research and development activity towards reformulation, MTOC is unsure that some companies can complete research and development before 2010.

MTOC notes that the timelines for drug development and approval in non-Article 5 Parties mean that any formulation that is going to be available by 2010 will already have to be a final commercial formulation, which has completed clinical studies and commenced regulatory assessment in 2008 (assuming regulatory approval takes a minimum of 12 months). This means that several of the drugs, which are included in CFC volumes requested in the current nominations, will not be commercially available in a CFC-free version within this timeline. Parties may wish to consider not allocating CFCs to companies without a final CFC-free formulation in regulatory assessment by the end of 2008.
Last year, the EC stated “Companies targeting the export of generic type of CFC MDI to developing countries tend not to pursue very active R&D activities to develop alternative products. This is a remaining issue to be dealt with consistently with the phase-out of CFC MDI in Article 5 Parties.” Parties have a range of suitable CFC-free alternatives for domestic use. For those Parties that continue to export CFC MDIs to Article 5 Parties, one option would be for Parties to consider regulations to restrict CFC MDI export and import (and encourage a transition to export/import of HFC MDIs or DPIs) to countries where these products are no longer needed. Parties may also wish to consider establishing a date by which exports and imports of all CFC MDIs cease.

In addition, in its 2008 submission to MTOC, the International Pharmaceutical Aerosol Consortium (IPAC) member companies have committed to “not seek new production of essential use CFCs after 2008 for use in MDIs intended for either Article 5 or non-Article 5 Parties, absent compelling evidence that existing stockpiles are unavailable – an exceptional and unlikely circumstance”. IPAC companies have also committed not to market CFC MDIs in markets in Article 5 Parties after 2009, except in very narrow circumstances. It is anticipated that CFCs for these MDIs would be sourced from existing stockpiles, rather than from new production. Rationalising small quantities of already-produced CFCs to meet patient needs in Article 5 (as well as non-Article 5) Parties, rather than simply destroying all remaining stockpiles, is a pragmatic approach.

For combination products for which the separate moieties are available as CFC-free alternatives, MTOC believes that these combination products continue to be used for patient convenience and commercial considerations. Patients will not come to any harm by using the drugs in separate CFC-free inhalers. The combination inhalers cannot therefore be considered to be essential under Decision IV/25. Parties may wish to consider a decision not to allocate CFCs for these combination products.

MTOC notes that both the European Community and the United States again report significant pre-1996 stockpiles. There are a number of issues related to the management of existing stockpiles (e.g. environmental, commercial, regulatory etc.) that are critical for Parties to resolve. MTOC believes that failure to address these issues could adversely affect final phase-out. MTOC emphasises that pre-1996 stocks should be used first; the management of stockpiles at this final stage of the phase-out will be extremely important to avoid unnecessary production of CFCs and the need for excessive destruction. Parties may wish to remind CFC MDI manufacturers that any CFCs approved under essential use exemptions must be used for this essential use (including through a transfer), transferred to an Article 5 Party for basic domestic needs, or destroyed. For essential use applications in 2010 and beyond, use of surplus CFCs for basic domestic needs is not allowable under the Protocol. Parties may also wish to review domestic laws to facilitate transfers of stockpiles between companies and/or countries.

MTOC believes that with the essential use exemption process for non-Article 5 Parties in its final phase and complete global transition a few years away, accurate and complete accounting frameworks of all CFC stockpiles, including pre-1996 stocks, should be provided by all Parties who hold them. Parties may wish to consider the advantages of requiring that plans for use or disposal of stockpiles be required with future accounting frameworks. Parties that have acquired CFCs under essential use exemptions are also reminded that accounting frameworks should continue to be submitted annually to account for destruction.

---

1 The International Pharmaceutical Aerosol Consortium is a group of companies (Abbott, AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Glaxosmithkline, Inyx, Inc. and Sepracor, Inc.) that manufacture medicines for the treatment of respiratory illnesses, such as asthma and COPD.
and depletion of stocks, including through transfers or use, even after nominations are no longer made and until no further stocks remain.

1.2.5 **Committee Evaluation and Recommendations**

Quantities are expressed in metric tonnes.

**European Community**

<table>
<thead>
<tr>
<th>Year</th>
<th>Quantity nominated</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>38 tonnes</td>
</tr>
</tbody>
</table>

*Specific Use:* MDIs for asthma and COPD

Active ingredients and intended markets for which the European Community nomination applies:

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Intended market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol</td>
<td>Chile</td>
</tr>
<tr>
<td>Beclomethasone</td>
<td>Colombia, Venezuela, Pakistan, Argentina, Mexico, Chile</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Colombia, Venezuela, Chile</td>
</tr>
<tr>
<td>Cromoglicic acid</td>
<td>European Community, Venezuela</td>
</tr>
<tr>
<td>Salbutamol+Ipratropium bromide (combination)</td>
<td>European Community</td>
</tr>
<tr>
<td>Salbutamol+Flunisolide (combination)</td>
<td>European Community</td>
</tr>
<tr>
<td>Salbutamol+Beclomethasone dipropionate (combination)</td>
<td>European Community, Chile</td>
</tr>
<tr>
<td>Isoproterenol HCl+Fenilefrina HCl (combination)</td>
<td>European Community</td>
</tr>
</tbody>
</table>

*Recommendation:* Unable to recommend.

*Comments*

MTOC notes that the transition within the European Community has continued to proceed well, with a significant reduction in the amount of CFCs nominated for 2009. MTOC also commends the European Community for making a commitment that there will be no nominations for 2010 and beyond.
However MTOC does not consider that 65 percent (about 25 tonnes) of the nominated quantities, designated for export to Article 5 Parties, meet the requirements of Decision IV/25(b)(ii) (regarding the availability of sufficient quantity of controlled substances from existing stocks) since MTOC believes that these nominated quantities could be supplied from the existing CFC stockpiles in the European Community (about 340 tonnes).

The remaining 35 percent (about 13 tonnes) requested is for combination MDI products to be used within the European Community. As previously stated, MTOC does not consider these combination CFC MDI products essential under Decision IV/25(a) when the individual components, or equivalents, are available as CFC-free alternatives.

MTOC notes with concern that the European Community continues to supply CFC-containing MDIs to some Article 5 Parties despite the availability of technically feasible alternatives in those countries. While supply to Article 5 Parties may be driven partly by economic, commercial and regulatory reasons, continuing supply may impede the speed of transition to CFC-free alternatives in Article 5 Parties. The European Community has not adequately demonstrated that continued supply of CFC MDIs to these export markets is essential.

The European Community also reported a total stockpile of about 340 tonnes (including pre-1996 stocks) at the end of 2007. This amount is higher than the total stockpile at the end of 2006 (333 tonnes, including pre-1996 stocks), contrary to expectations that Parties should be reducing their stockpiles as the final phase of the transition is entered. It appears likely that surplus CFCs will exist at the end of 2009. The European Community states that it is not known at this point to what extent the pre-1996 material (213 tonnes) will be destroyed or transferred. It also states that the assumption that the entire amount will be transferred would not be valid, as the stock of pre-1996 material contains CFC-11, -12, and -114 in quantities that may not meet the potential demand.

The European Community also states that some companies have indicated that they intend to destroy their stocks, while other companies may either transfer the rights to companies still holding a licensed quota or produce CFC MDIs for export to Article 5 Parties where the relevant CFCs “are deemed essential”. MTOC believes that best efforts should be made to facilitate the use of the stockpile for essential uses, and to avoid the production of new pharmaceutical-grade CFCs for the European Community and the need for destruction of usable CFCs.

Given the reasons outlined above, the MTOC is unable to recommend the quantity requested for CFC MDI manufacture for export to Article 5 Parties and is unable to recommend combination CFC MDIs as an essential use. However, if the European Community is unable to supply the amounts for CFC MDI manufacture for export to Article 5 Parties from existing stockpiles to meet manufacturing requirements for uses which are demonstrated to be essential, in 2009 it could make a request to the Secretariat to authorise an emergency essential use in accordance with Decision VIII/9(10), which can provide up to 20 tonnes of ODS.
**Russian Federation**

<table>
<thead>
<tr>
<th>Year</th>
<th>Quantity nominated</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>248 tonnes</td>
</tr>
</tbody>
</table>

*Specific Usage:* MDIs for asthma and COPD, for active ingredient salbutamol for use solely within the Russian Federation.

*Recommendation:* Exemption for CFCs for MDIs – 248 tonnes (for single-moiety salbutamol to be sold within the Russian Federation).

*Comments*

The MTOC reviewed a nomination for essential uses received from the Russian Federation on 27th March (after the 31st January deadline) for the production of CFCs for MDIs in the Russian Federation. The nomination is for 248 tonnes of CFCs to be used exclusively for the manufacture of salbutamol CFC MDIs for domestic use, by two local companies in 2009 (MTOC has been unable to confirm information from other sources suggesting that there could be some limited export to countries such as Mongolia).

The majority of salbutamol CFC MDIs used in the Russian Federation is locally made and substantially cheaper than imported MDIs (~ US$2 vs US$7). The remaining MDIs, which do not contain salbutamol, are largely imported.

In its nomination for 2008, the Russian Federation stated that it would not submit any further essential use nominations, and expected to have completed its CFC MDI transition by the end of 2008. However, it now states that 2009 will be the last year for which it will make an application for an essential use exemption for CFCs for MDIs. Companies in the Russian Federation are in the process of developing new HFC MDIs containing salbutamol. However, the Russian Federation states that lack of financial resources and regulatory delays are impeding the large-scale conversion of their production facilities, which it anticipates should be completed in 2010. The Russian Federation also states “any financial assistance for MDI producers or technology transfer may provide some time-saving”. Therefore it is unclear whether the Russian Federation will require CFCs for MDI manufacture in 2010.

MTOC recognises the immediate need of the nomination for 2009, and the quantity of CFC is justified based on consumption trends. Further clarification is needed on the final phase-out strategy for the Russian Federation, including stockpile management. MTOC notes that there were discrepancies in the stockpile accounting in the framework when compared with last year.

**United States**

<table>
<thead>
<tr>
<th>Year</th>
<th>Quantity nominated</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>182 tonnes</td>
</tr>
</tbody>
</table>

*Specific Use:* MDIs for asthma and COPD, for the following active ingredients for use solely within the United States: epinephrine, pirbuterol, triamcinolone.

*Recommendation:* Unable to recommend.
Comments

The nomination from the United States is for 182 tonnes CFCs for use in 2010, for the manufacture of epinephrine, pirbuterol, and triamcinolone CFC MDIs for domestic use only. This is a reduction of 35 percent on the exemption for 2009 (282 tonnes). Parts of the nomination were received on time, but the accounting framework and other supporting documentation were received during the MTOC meeting on 2nd April, after the 31st January deadline established by Parties.

MTOC does not consider that the nomination meets the requirements of Decision IV/25(b)(ii), regarding the availability of sufficient quantity of controlled substances from existing stocks. At the end of 2007, the United States’ stockpile was 1,489 tonnes of CFCs (including pre- and post-1996 stocks). In addition, the United States has an essential use exemption for 2009 of 282 tonnes. The Parties consider it reasonable to maintain a stock of one year’s operational supply (including Decisions XVI/12 and XVII/5). Taking these matters into account, MTOC considers that the anticipated United States’ stockpile in 2010 should be adequate to supply CFC requirements, especially with the flexibility afforded by the additional exempted quantity for 2009.

MTOC does not consider that CFC MDIs for these drug moieties are an essential use under Decision IV/25(a). According to the nomination, for the bronchodilators (pirbuterol and epinephrine CFC MDIs), there are four salbutamol HFC alternatives (MTOC considers salbutamol to be a suitable alternative bronchodilator in relation to this nomination). For the inhaled steroid triamcinolone, there are four suitable alternative moieties in a range of formulations (HFC MDIs and DPIs).

The US FDA is undertaking a further series of rule-making processes. Under these, the essential use designation under US law for salbutamol will be removed after 31st December 2008. Under two proposed rules to amend regulations, the essential use designation under US law of pirbuterol and triamcinolone CFC MDIs would be removed (and no longer for sale) after 31st December 2009, and epinephrine CFC MDI after 31st December 2010. The final rules are expected during 2008.

Salbutamol HFC MDI sales have increased steeply and by April 2008 it is estimated that they constitute 70 percent of total salbutamol inhaler sales. Consequently MTOC calculates that CFCs required for salbutamol MDI manufacture in 2008 could be reduced to about 150 tonnes in the United States. MTOC estimates that total CFC use for MDIs could be less than 500 tonnes in 2008, and less than 300 tonnes in 2009. With this declining consumption combined with a domestic allocation of 27 tonnes in 2008 (proposed by the United States) and an exemption of 282 tonnes in 2009, the stockpile may be about 1,000 tonnes in 2010.

One company (Armstrong) manufactures salbutamol CFC MDIs, and is also the only manufacturer of epinephrine CFC MDIs. Armstrong has indicated that a replacement epinephrine HFC MDI will not be available until 2011, raising the question of future essential use applications. MTOC believes that the company could instead consider using its existing CFC stock (originally designated for salbutamol) to produce epinephrine CFC MDIs in 2010.
2 Updated Response to Decision XVIII/16: Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons

2.1 Executive Summary

Progress has been made towards transition in the use of CFC metered dose inhalers (MDIs) in Article 5 Parties for certain key moieties, with a range of technically feasible alternatives available. However, for many Article 5 Parties, the conversion of locally owned CFC MDI manufacturing is only just commencing.

The mandated phase-out date under the Montreal Protocol for the global production of CFCs is only a little more than one year away. The Montreal Protocol’s Decision IV/25 allows for the production of CFCs for essential uses, if approved by Parties, after the mandated phase-out date. The pace of implementation of projects to convert CFC MDI manufacturing in Article 5 Parties will largely determine the quantities of CFCs that will be required for CFC MDI manufacturing after 2009. However, the economics of CFC production will make impractical the continued production of small amounts of pharmaceutical-grade CFCs after 2009.

Given the uncertainties and risks associated with the long-term supply after 2009 of suitable quality CFCs, the Medical Technical Options Committee (MTOC) emphasises that the highest priority for continued supply of inhalers is to complete transition as quickly as possible and ensure the expeditious introduction of CFC-free alternatives.

As an update to its response to Decision XVIII/16 in the April 2007 Progress Report of the Technology and Economic Assessment Panel, the MTOC considered a number of options for the production of pharmaceutical-grade CFCs after 2009 and recommends a preferred option that can best facilitate the final phase-out of CFCs MDIs in countries that are still manufacturing CFC MDIs.

Open-ended annual CFC production after 2009 (under annual essential use exemptions) is not recommended. It does not provide a clear target or timetable for ending CFC production, predictability for CFC producers, or incentive for those companies currently manufacturing CFC MDIs to switch to CFC-free alternatives. At a certain point, the economics of CFC production would not be favourable, and would make impractical and too uncertain the continued production of relatively small amounts of pharmaceutical-grade CFCs. At this point, continuity of affordable healthcare would be jeopardised. Overall destruction costs for out-of-specification CFCs would be relatively high with this option.

In its 2007 report, MTOC proposed a final campaign in 2009, which is no longer recommended for 2009 for two reasons. In 2007 Parties did not adopt a decision on a final campaign, deferring consideration until a later date. To manage a final campaign in 2009, it will be necessary to make several decisions, for which lead times are needed. Also, the large-scale conversion of local CFC MDI manufacturing in Article 5 Parties is slower than anticipated, and so the quantity for a final campaign in 2009 is now larger, estimated be about 5,000 tonnes. The logistics of organising such a large production campaign no later than 2009, the short timeframe for the associated essential use nomination and approval process, and the large costs of inventory and storage make this option impractical.
MTOC believes that with appropriate planning and co-ordination a final campaign production of pharmaceutical-grade CFCs could be feasible in 2011, providing for CFC MDI manufacturing countries that do not have domestic CFC production. This option assumes that project implementation is not delayed further, and presumes that China maintains domestic production of pharmaceutical-grade CFCs and continues annual CFC production, if approved by Parties under the essential use process, until it completes its national CFC MDI phase-out. Anticipating a final campaign production at an agreed date provides a clear target for ending CFC production, predictability for CFC producers, and incentive for those companies currently manufacturing CFC MDIs to switch to CFC-free alternatives.

It will be necessary to wait at least another year to assess the progress of phase-out projects and their impact on future requirements of CFCs before confirming the date of a final campaign production. Based on estimated CFC requirements, the economics of CFC production should be favourable, firstly in 2010 to allow annual production (of between 1,200-1,700 tonnes) in that year under an essential use, and then in 2011 for a final campaign production for multiple years. The quantity of the final campaign production, for all countries excluding China, would be between 1,000-2,000 tonnes (depending on whether India ceases CFC production and import for MDI production at the end of 2009 or not). Costs would be relatively lower than for open-ended annual CFC production (for destruction of out-of-specification CFCs) and the costs and logistics of organising a more modest campaign make a final campaign in 2011 more practical than in 2009 or 2010.

Article 5 Parties’ essential use nominations will need to be submitted by 31st January 2009 for Parties to consider essential use exemptions for CFC production in 2010. In order to anticipate a final campaign production, accurate forward projections will be needed of annual quantities of each CFC required for MDI manufacture for 2010 and for each year thereafter until each Party’s agreed phase-out date. These projections should accompany and justify each year’s nomination for 2010 and onwards, starting with the nominations submitted in 2009. This would allow an accurate global picture to be developed from 2009, and a recommendation by TEAP on the preferred date for a final campaign to be made. It is anticipated that in 2009, Parties would consider Decisions to approve the CFC volumes intended for manufacture in 2010 only. In the next year (2010), the remaining volumes to complete phase-out in each Party would be considered and, if appropriate, approved to allow a final campaign production to occur in 2011.

A final campaign production risks exaggerated and non-essential use of CFCs produced for multiple years. Therefore a multi-year essential use production exemption to allow a final campaign production will need to work in parallel with an annual exemption process to approve annual quantities to be used from the stockpile produced under a final campaign, and to signal the need for destruction of any surplus CFCs.

MTOC believes that a co-ordinated approach to the final phase of the CFC MDI transition is needed to overcome some of the technical challenges. The current pace of CFC MDI manufacturing phase-out in Article 5 Parties is slow because access to suitable CFC-free technology is difficult. The implementing agencies are being asked to undertake very challenging projects with very short timelines, and delays will inevitably occur – this is the nature of “new product development”.
A co-ordinated approach could:

- Maximise the chances of successful product development;
- Allow equipment manufacturers transparent understanding of the timing of future equipment needs for HFC MDI production lines; and
- Better estimate the need for final campaign production of pharmaceutical-grade CFCs, and facilitate stockpile storage and destruction.

Parties may wish to consider the appointment of a single entity to co-ordinate these urgent and complex issues and activities, while also recognising the need to continue to address country specific requirements and country/company-specific project implementation.

Pharmaceutical-grade CFCs to supply CFC requirements for MDI production after 2009 could also be sourced from remaining surplus CFC stockpiles in non-Article 5 Parties. Sourcing CFCs from existing stockpile of pharmaceutical-grade CFCs in preference to new CFC production is a requirement of Decision IV/25(1)(b). A co-ordinated approach to identifying, locating and transferring surplus stockpiles would be an advantage for Article 5 Parties, and would avoid destruction of CFCs that could otherwise be diverted to an essential use. Parties may also wish to review domestic laws to facilitate transfers of stockpiles between companies and/or countries.

MTOC has reviewed the Protocol’s current essential use decisions and supporting guidance in the *Handbook on Essential Use Nominations* (TEAP, 2005), to conclude whether the essential use process can accommodate the situation of Article 5 Parties, the last stages of global transition and final campaign production. As a result, MTOC has suggested options to refine and modify the essential use framework. Parties may wish to consider these options in making a set of new Decisions that build on the previous essential use Decisions and associated guidance on information requirements in the Handbook. Parties may wish to consider a suite of new Decisions because some of the existing Decisions are currently not applicable to Article 5 Parties but their intended effects are still relevant; other Decisions may need strengthening; and new Decisions may be needed to take account of issues not currently included.

### 2.2 Background

At their 17th Meeting, the Parties to the Montreal Protocol discussed the difficulties faced by some Article 5 Parties with respect to the phase-out of chlorofluorocarbons (CFCs) used in the manufacture of MDIs. In Decision XVII/14 the Parties expressed their concern that Article 5 Parties that manufacture CFC MDIs might find it difficult to phase out these substances without incurring economic losses to their countries. There was the further risk that, for some Article 5 Parties, consumption levels in 2007 of CFCs for MDIs might exceed the amounts allowed for all CFC uses under the Protocol.
The Parties considered the issue again at their 18th Meeting and took Decision XVIII/16. Paragraph 12 of this Decision requested:

“TEAP to assess and report on progress at the 27OEWG and to report to the MOP19 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.”

The TEAP and its MTOC included its response to Decision XVIII/16 in the April 2007 Progress Report of the Technology and Economic Assessment Panel to the 27th Open-ended Working Group Meeting. The Open-ended Working Group discussed the possibility of maintaining the current system of “just-in-time production”. However, the Working Group did not achieve consensus, and accordingly agreed that interested Parties would consult informally on the text of a draft decision on the matter for consideration by the 19th Meeting of the Parties. In the ensuing discussion, one representative stated that her Government was currently engaged in consultations with pharmaceutical companies that manufactured CFCs for metered-dose inhalers and was not yet in a position to make a decision on the item. The Meeting of the Parties agreed to defer further consideration of the matter until a later meeting.

In this updated response to Decision XVIII/16, MTOC has reviewed new information available from the Multilateral Fund Secretariat, implementing agencies, countries, and industry sources. This report considers not only those Parties manufacturing CFC MDIs but also issues surrounding CFC MDI transition in importing Article 5 Parties.

MTOC also drew on the resources, information, and outcomes of the recent South Asia and Southeast Asia & Pacific Regional Thematic Workshop on Phasing-out CFC Metered Dose Inhaler (MDI) in Langkawi, Malaysia, during 13-15 March 2008, which was attended by 23 countries and 6 industries in the region producing MDIs, and also a number of MTOC members. Some of the key outcomes were the Langkawi Declaration on Public-Private Partnership on Phasing Out CFC Metered Dose Inhalers and the conclusions and recommendations, which are referred to further in this report. The UNEP DTIE OzoneAction Programme wrote to TEAP on 27th March 2008 conveying some of the important findings of the workshop and requesting TEAP to consider some aspects in its report, including:

1. “Options for storage and handling of stockpile pharmaceutical-grade CFCs and their surrounding issues;

2. Logistics and transfer to destruction facilities of “Out of Specification” CFCs;

3. Safe specifications for pharmaceutical-grade CFCs and appropriate testing method to ensure that specifications are met;

4. Procedures for a Multi-year Essential Use Nomination.”

These and other issues are addressed below.
2.3 Progress and challenges in CFC MDI manufacturing transition in Article 5 Parties

Most Article 5 Parties have their inhalers provided by importation. As elaborated in section 2.3, progress has been made towards transition in the use of CFC MDIs in Article 5 Parties for certain key moieties, with a range of technically feasible alternatives available. However, for many Article 5 Parties the conversion of locally owned CFC MDI manufacturing is only just commencing.

MDIs may be manufactured in at least 20 Article 5 Parties (Algeria, Argentina, Bangladesh, Brazil, China, Colombia, Croatia, Cuba, Egypt, India, Indonesia, Iran, Jordan, Mexico, Pakistan, South Africa, Syria, Tunisia, Uruguay, Venezuela), with an estimated consumption of about 2,100 tonnes in 2007. Many have locally owned MDI manufacturing companies that are not affiliated with multi-national pharmaceutical companies.

Some countries (e.g. Croatia and Tunisia) have successfully completed their manufacturing transition to CFC-free inhalers. A number of countries (e.g. Cuba, Uruguay, Egypt, and Iran) have requested financial assistance in recent years from the Multilateral Fund (MLF) to achieve the conversion of their industry to produce CFC-free alternatives, and a number are in the process of seeking assistance from the MLF (e.g. China and India). A number of countries (e.g. Algeria, Brazil, Jordan, Syria) are not eligible for funding by the MLF under the decisions of the Executive Committee. At its 54th Meeting, the Executive Committee of the MLF decided (Decision 54/35) that all requests for MDI investment projects be submitted for Executive Committee consideration no later than the 56th Meeting at the end of 2008, and that requests would not be considered eligible for funding after that meeting.

Table 2-1 summarises MTOC’s current understanding of transition status for most Article 5 Parties with CFC MDI manufacturing. Detailed country information is also available from Executive Committee documents, such as ExCom/51/391.

The implementing agencies of the MLF (UNDP and UNIDO) are responsible for implementing MLF-funded MDI investment projects and work with the companies and the respective governments to achieve the agreed timelines. This has proven to be a challenging task, and it appears likely that production of CFCs will be needed to supply MDI manufacture after 31 December 2009 in a number of countries where manufacturing conversion will not have been completed.

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Table 2-1  Status of transition in Article 5 Parties with CFC MDI manufacturing

| Status of transition in Article 5 Parties with CFC MDI manufacturing | Algeria | Argentina | Bangladesh | Brazil | China | Colombia | Cuba | Egypt | India | Indonesia | Iran | Jordan | Mexico | Pakistan | South Africa | Syria | Uruguay | Venezuela |
| Approved investment projects with MLF funding |  ✔ 1 |  ✔ 2 |  ✔ 3 |  ✔ 4 |  ✔ 5 |  ✔ 6 |  |  |  |  |  |  |  |  |  |  |  |  |
| Requesting MLF funding for MDI investment project or for project preparation of an MDI investment project |  ✔ 7 |  ✔ 8 |  ✔ 9 |  ✔ 10 |  ✔ 11 |  |  |  |  |  |  |  |  |  |  |  |  |  |

1. MDI investment project approved (ExCom decision 52/32). Expected completion date 48 months after commencement (UNEP/OzL.Pro/ExCom 52/26).
2. MDI investment project approved. Expected completion date was March 2008 (UNEP/OzL.Pro/ExCom/51/39), but is now October 2008.
3. MDI investment project approved. Expected completion date December 2009 (UNEP/OzL.Pro/ExCom/51/39), but is now about 2010.
4. MDI investment project approved. Expected completion date is 28 to 30 months after the national transition strategy and the MDI phase-out investment project have been approved by ExCom (UNEP/OzL.Pro/ExCom 52/36), which is now about 2010-2011.
5. MDI investment project approved (ExCom/53/67). Expected completion date February 2011 (UNEP/OzL.Pro/ExCom/53/44).
6. MDI investment project approved. Expected completion date was July 2007 (ExCom/51/39), but is now at least the 2nd quarter of 2008.
8. Project proposal expected to be submitted for ExCom consideration during 2008.
10. Project preparation proposal approved under ExCom decision 52/25. MDI investment project proposal expected to be submitted for ExCom consideration at its 55th Meeting in July 2008.
11. MTOC understands that there may be CFC consumption for medical aerosols in Indonesia, but not for MDIs.
12. Project preparation proposal expected to be submitted by UNDP for ExCom consideration during its 55th Meeting (UNEP/OzL.Pro/ExCom/54/19).
13. Not eligible for funding under ExCom decision 35/57. Project proposal expected to be submitted for ExCom consideration at its 56th Meeting, November 2008.
Table 2-1: Status of transition in Article 5 Parties with CFC MDI manufacturing (cont.)

| Status of transition in Article 5 Parties with CFC MDI manufacturing | Algeria | Argentina | Bangladesh | Brazil | China | Colombia | Cuba | Egypt | India | Indonesia | Iran | Jordan | Mexico | Pakistan | South Africa | Syria | Uruguay | Venezuela |
| Not eligible for funding by the MLF | ✓ | 14 | | ✓ | 15 | | | | | | | | | | | | | | | |

14 Not eligible for funding (ExCom decision 35/57). Project proposal expected to be submitted for ExCom consideration at its 56th Meeting, November 2008.
15 Not eligible for funding by the MLF. There are two producers in Brazil for which shareholder composition is fully from non-Article 5 Parties, and which are working without assistance from the Multilateral Fund on the conversion of their CFC MDIs to alternatives.
16 Not eligible for funding (ExCom decision 35/57). Project proposal expected to be submitted for ExCom consideration at its 56th Meeting, November 2008. MTOC understands that there may be CFC consumption for medical aerosols in Jordan, but not for MDIs.
17 Not eligible for funding by the MLF. CFC consumption for MDIs is estimated to be about 71 tonnes, and there are 18 locally owned MDI manufacturers.
18 Not eligible for funding (ExCom decision 35/57). Project proposal expected to be submitted for ExCom consideration at its 56th Meeting, November 2008.
2.4 Elements needed for successful transition in Article 5 Parties

Elements needed for successful transition in Article 5 Parties include:

- National CFC MDI transition strategies: to facilitate the transition through national networks working towards shared goals, with a focus on patient health;
- Global partnerships and co-operation: to share information, facilitate decision-making and global consistency, and respond quickly to resolve any potential barriers; and
- Adequate funding, capacity building and support through the institutions of the Montreal Protocol: to facilitate timely CFC MDI manufacturing transition, and to ensure a framework suited to the circumstances of Article 5 Parties and the final stages of phase-out.

Some of these elements are elaborated below.

2.4.1 National CFC MDI transition strategies

National transition strategies to non-CFC-MDI alternatives need to be developed on a country-by-country basis with the participation of major stakeholders, such as the relevant environment, health and trade authorities, physician and patient groups, pharmaceutical companies, and CFC/HFC importers (where there is local MDI manufacture). All stakeholders must be involved, and the formation of private/public partnerships is essential. Transition strategies must have a clear, final date by which time the country expects no longer to need CFC MDIs. The details of a strategy vary according to the circumstances of the country, its health system and whether it imports or locally manufactures CFC MDIs. Transition strategies need to ensure adequate supplies of inhaled therapy throughout the transition period. Protection of patient health should be the key guiding principle in transition strategies.

In preparing their national transition strategies, Parties may wish to consider successful strategies adopted by Article 5 and non-Article 5 Parties. Several Article 5 Parties, including Fiji, Malaysia, Thailand and the Philippines, have already successfully implemented their national transition strategies, and are on track to complete transition by 2010. The regional workshops currently being conducted (such as the Langkawi workshop for the South Asia and South East Asia Pacific region) will greatly assist Parties in the development and implementation of national strategies.

The slow progress of some countries to develop national transition strategies is of concern. It is important that Article 5 Parties develop their own national transition strategy and provide them to the Secretariat, to be posted on its website, and then to report each year on progress in transition, both in accordance with Decision XII/2. Parties may also wish to consider making a national transition strategy a requirement for Article 5 Parties nominating for an essential use exemption to produce CFCs for MDIs, as has been the case for Parties not operating under Article 5.

Issues and actions to be addressed in national transition strategies are:

- Determination of a final phase-out date for CFC MDIs, setting a target and timetable;
- Availability and affordability of CFC-free alternatives, through an investigation of CFC and CFC-free alternatives on the national market;
- Fast-track approval for CFC-free alternatives, and assuring seamless availability of inhaled therapy;
- Serious consideration by relevant authorities of pricing policies favourable to CFC-free alternatives and removal of any associated tariffs and import taxes;
- Timely withdrawal of CFC MDIs following a reasonable post-marketing period for CFC-free inhalers (absent compelling circumstances, MTOC recommends 12 months), and consideration of establishment of policies and regulations to ban parallel marketing and imports of CFC MDIs after a certain date;
- Educational activities for patients, doctors and other healthcare providers on the reasons for phase-out, supported by pharmaceutical companies and health authorities;
- CFC-free MDIs to be clearly labelled as such on the packaging, with consideration given to the development and promotion of an agreed CFC-free logo to be displayed on CFC-free MDIs; and
- The anticipated timelines of any MDI investment projects funded by the MLF to assist technology transfer.

Some Parties may also wish to consider application to the Asthma Drug Facility (ADF) of the International Union Against Tuberculosis and Lung Disease for the supply of low cost CFC-free MDIs (www.GlobalADF.org). The ADF provides access to affordable good quality essential asthma drugs, promotes the use of CFC-free inhalers and the monitoring of asthma management for quality care. Some countries have indicated that the necessary commitment to data collection could be challenging for them. The conclusions of the Langkawi Workshop suggested that Sri Lanka applies to the ADF as a pilot program.

### 2.4.2 Global partnerships

Partnerships between government, industry, and non-government organisations can facilitate successful transition in Article 5 Parties.

Regional alliances of Article 5 Parties may facilitate transition through common strategies. The Langkawi MDI Workshop for the Asia-Pacific region held in March 2008, as well as other workshops scheduled later in the year for other regions, is a prime example of how such collaborative efforts can be of value in advancing common goals in this regard. Future MLF-funded regional meetings that are planned for other regions, include Africa, Eastern Europe and Central Asia, and Latin America.

The Langkawi Workshop developed a Langkawi declaration as a public-private partnership between government and industry. This partnership model could be propagated to resolve common challenges facing Article 5 Parties that require a concerted effort by governments and industry.

Some of the factors that may impact CFC phase-out in the Article 5 Parties that could be addressed through a partnership approach, include:

- Timely withdrawal of CFC MDIs as alternatives become available. This can be addressed through co-operation between government and industry (and included in a national transition strategy), including through import bans;
• Prompt government regulatory actions to approve CFC-free alternatives, through a commitment by governments to industry to facilitate regulatory approvals;
• Pricing policies favourable to CFC-free alternatives, through a commitment by governments to review and remove tariffs and import taxes.

2.4.3 Adequate funding and capacity building

Capacity building through transfer of technology or expertise in accordance with Article 10A (of the Protocol) is necessary to help countries in which companies are still trying to develop CFC-free MDI formulations.

Timely and effective management of projects by the implementing agencies (UNIDO and UNDP) will be critical to successful transition. At the present time there is no successfully completed project, and most approved projects are behind schedule. Projects need to be initiated and completed within realistic timelines that take account of the experience gained so far.

Current approved projects are often for new product development by locally owned companies in Article 5 Parties. Projects may take in excess of five years to complete due to the requirement for new manufacturing processes, clinical testing, regulatory approval and commercialisation. Delay in project implementation will further prolong CFC MDI phase-out. In-licensing of established products may be faster than new product development, and should be considered as an option.

Dry powder inhalers (DPI) are less commonly used in Article 5 Parties, because the more recently introduced DPI devices are technically sophisticated and more expensive than MDIs. However, single dose DPIs using simple devices (eg. Rotahaler®) are widely used in India and elsewhere. The technology required to manufacture such devices and units may be easier to transfer and the cost of setting up a manufacturing facility should also be less.

The principal supplier of manufacturing lines for HFC MDIs (Pamasol Willi Mäder AG, Switzerland) currently has a lead-time of 6-12 months to supply new plant. This means that planned scheduling of orders for new lines is essential, and needs a co-ordinated approach by the implementing agencies to minimise delays.

MTOC believes that a co-ordinated approach to the final phase of the CFC MDI transition is needed to overcome some of the technical challenges. Regional level workshop(s) facilitated by the implementing agencies can assist transition efforts and this process is now underway. However, the current pace of CFC MDI manufacturing phase-out in Article 5 Parties is slow because access to suitable CFC-free technology is difficult. The implementing agencies are being asked to undertake very challenging projects with very short timelines, and delays will inevitably occur – this is the nature of “new product development”.

A co-ordinated approach could:

• Maximise the chances of successful product development;
• Allow equipment manufacturers transparent understanding of the timing of future equipment needs for HFC MDI production lines; and
• Better estimate the need for final campaign production of pharmaceutical-grade CFCs, and facilitate their storage and destruction.
Parties may wish to consider the appointment of a single entity to co-ordinate these urgent and complex issues and activities, while also recognising the need to continue to address country specific requirements and country/company-specific project implementation.

2.5 Estimated CFC requirements to supply MDIs in 2010 and beyond

Table 2-2 summarises MTOC’s analysis of CFC consumption for MDI manufacture in those Article 5 Parties with local production of CFC MDIs. This analysis estimates future requirements of CFCs up to the year 2013 and updates the data presented in the April 2007 Progress Report of the Technology and Economic Assessment Panel.

MTOC’s updated analysis includes data provided by industry and government representatives at the Langkawi South Asia and SEAP Regional Workshop on Phasing-out CFC based Metered Dose Inhalers. New information regarding the situation of approved CFC MDI phase-out projects was available from a range of sources including the MLFS, the implementing agencies and MTOC members. Information available from the April 2008 54th Executive Committee Meeting was also taken into account. In particular, Decision 54/35 establishes a CFC production phase-out agreement for India by 1 August 2008, including limits on CFC production and consumption for MDIs for 2008 and 2009, and with no allowance for CFC imports after 2009. However, it is not clear whether this agreement will mean that India does not seek essential use consumption (production and import) of CFCs for MDIs after 2009. Table 3-2 includes previously unreported production in Venezuela. No data were available for Algeria, Jordan, or South Africa, where CFC MDI manufacture may also be occurring.

The main constraint in the implementation of MDI investment projects has been access to suitable CFC-free inhaler technology. The implementing agencies are facing major challenges in securing technical assistance for what have become individual “new product development” projects for CFC-free alternatives. It now appears that the time required for new product development and the time to have a formulation available on the market were underestimated at the time of project preparation. In a few cases the projects have faced delays in the delivery of the MDI manufacturing equipment. The equipment for the manufacture of HFC MDIs is highly specialised and the principal supplier has a significant backlog of orders.

Given the delays in the preparation, approval and implementation of projects, MTOC has made assumptions about the annual consumption data for a number of countries, combined with information provided by technical experts and from the Langkawi meeting. The table shows consumption up to and including 2013, although it is too early to know whether this would actually be the final year of CFC MDI production need or not. A few countries (including China and India) in Langkawi indicated that they might continue production of CFC MDIs up to 2014-2015.

The assumption that some Parties would still need CFCs in 2013 was used to estimate a global requirement for future production of CFC MDIs in Article 5 Parties. These estimates were then used to evaluate preferred strategic options for the final phase-out of CFC MDI production. Any CFC consumption after 2013 is difficult to estimate; if any, it is likely to be relatively small and unlikely to be a significant proportion of the overall projected quantity, but that would still need to be phased out.
### 2.6 Pharmaceutical-grade CFC supply during transition

Pharmaceutical-grade CFCs for MDIs are manufactured in a few locations globally: USA (Honeywell); Spain (Arkema); India (Navine and possibly others); and China (Juzhou). The plants in India and China are currently scheduled to cease production in August 2008 and in 2009, respectively, based on agreements with the Multilateral Fund.

China stopped production of CFCs in 2007 with the exception of one plant with capacity to produce 550 tonnes of CFCs to cover its pharmaceutical-grade CFC requirements. The phase-out project for CFC MDIs in China has been under discussion during the last year and will be resubmitted at the 55th Executive Committee meeting. This project will cover a number of MDI products including those that deliver traditional Chinese medicine. It is unlikely that reductions...
in CFC consumption for MDIs due to the implementation of this project would be noticeable before 2013. China has the production capacity to supply its own pharmaceutical-grade CFC requirements.

India has local production of pharmaceutical-grade CFCs for the manufacture of MDIs, and also currently imports some of its CFC requirements. Under Decision 54/35 of the 54th Executive Committee, India has agreed to cease CFC production in August 2008, and is allowed to sell up to 825 tonnes (690 tonnes to be produced before August 2008, and 135 tonnes from existing stockpile) of pharmaceutical-grade CFCs into MDI production in 2008 and 2009. The agreement also states, “India will not import any more CFCs of any kind”. However, it is not clear whether this agreement will mean that India does not seek essential use consumption (production and import) of CFCs for MDIs after 2009.

There are several MDI producers in India, including at least one multinational, that intend to close CFC MDI production in 2009. Several of the local producers have also already developed alternative HFC-based products and DPIs. Despite this, it is not yet clear whether MDI manufacturers will seek essential use exemptions for 2010 onwards to import pharmaceutical-grade CFCs. MTOC has assumed consumption of CFCs for MDIs according to the data received from Indian representatives of government and industry during the Langkawi workshop. However, it should also be noted that, in the case of India, there are widespread alternatives to CFC MDIs already available.

All other Article 5 Parties with CFC MDI manufacture rely on imported CFCs for MDI production.

2.6.1 Final campaign production considerations

Some Article 5 Parties have approved projects for the phase-out of their CFC MDI manufacturing, some of which may not be completed by the end of 2009. Under Decision 54/35, the Executive Committee agreed that Parties with requests for funding investment projects for CFC MDI manufacture must come forward for consideration by the Executive Committee by the 56th Meeting, November 2008 “to provide ample time for project initiation before the 2010 phase-out and to avoid, to the extent possible, the need for essential-use exemption requests”.

After 2009, Article 5 Parties may be in potential non-compliance unless CFC production for MDIs is under an essential use exemption.

There is no co-ordinated manufacture of pharmaceutical-grade CFCs and competition/anti-trust legislation would forbid such an arrangement. There are no dedicated pharmaceutical-grade CFC plants left, except for one in China, and there are only a few multi-product plants that can make pharmaceutical-grade CFCs.

Depending upon operational parameters, a bulk CFC production facility will produce a certain percentage of CFCs that do not meet the pharmaceutical-grade specifications required by MDI manufacturers. Although the expectations for purity may vary between Article 5 Parties, the percentage of production not fit for pharmaceutical use is projected to be no lower than 25 per cent and may be as high as 50 per cent of CFC production. Currently, CFCs that do not meet pharmaceutical specifications can be used for basic domestic consumption. This will not be possible after 2009 when these non-pharmaceutical-grade CFCs would need to be destroyed.

Further, the larger the quantity of a single campaign production of CFCs, the lower the proportion of low quality, out-of-specification, CFCs will be produced. Conversely, the smaller the quantity
is, the higher the proportion of low quality CFCs produced. For a single plant, a quantity of about 200 tonnes may be the limit below which CFC production becomes impractical, both for the efficiency and cost of CFC production.

These factors mean that the economics of CFC production will make impractical the continued production of small amounts of pharmaceutical-grade CFCs after 2009. These are important factors that need to be kept in mind when considering options for CFC production after 2009 and for final campaign production needs and timing.

Given the uncertainties and risks associated with the long-term supply of suitable quality CFCs after 2009, MTOC emphasises that the best option for continued supply of inhalers is to complete transition as quickly as possible and ensure the expeditious introduction of CFC-free alternatives. This can be achieved in many countries by establishing a clear end date for ceasing the manufacture and/or import of CFC MDIs and planning phase-out activities with this deadline in mind. Parties are encouraged to consider policies and regulations that establish phase-out dates for the manufacture and/or import of CFC MDIs. For countries that manufacture CFC MDIs, much is dependent on the successful, timely completion of conversion projects.

The MTOC considered three options for the production of CFCs to supply requirements for MDI manufacture after 2009. MTOC considered issues such as security of CFC supply, predicted volume requirements, relative costs for production, storage and destruction, and recommends a preferred option that can best facilitate the final phase-out of CFCs MDIs in countries that still currently manufacture CFC MDIs. These options are outlined below.

1. **Open-ended annual CFC production after 2009**

   Open-ended annual CFC production after 2009 (under annual essential use exemptions) does not provide a clear target or timetable for ending CFC production, predictability for CFC producers, or incentive for those companies currently manufacturing CFC MDIs to switch to CFC-free alternatives. At a certain point, the economics of CFC production will not be favourable, and will make impractical and too uncertain the continued production of relatively small amounts of pharmaceutical-grade CFCs. At this point, continuity of affordable healthcare would be jeopardised. Overall destruction costs for out-of-specification CFCs will be relatively high with this option. This option is not recommended.

2. **An Extensive Final Campaign Production in late 2009**

   Although this option looks attractive from an environmental perspective and is consistent with the Protocol phase-out date, the logistics of organising such a large production campaign no later than 2009, in terms of the total multi-year quantity (estimated to be up to about 5,000 tonnes) and the associated essential use nomination and approval process, make this option impractical.

   The costs of inventory and storage would also be large. Historically in the earlier years of the essential use process, non-Article 5 Parties made over-projections of CFC requirements because of uncertainty in the ‘ground-up’ development of alternatives at that time. For this option, a premature final campaign would almost certainly again lead to over-production. This would result in costly destruction of surplus CFC volumes or unnecessarily prolonged CFC MDI production.

   In its 2007 report, MTOC proposed a final campaign in 2009. This option is no longer recommended for 2009. There are two reasons that now make it necessary to postpone the date for a final campaign.
- Procedural: In 2007 Parties did not adopt a decision on this subject, deferring consideration until a later date. To manage a final campaign and to produce CFCs after 2009 it will be necessary to make several decisions, for which lead times are needed. Parties may wish to consider the proposals made in section 3.8 concerning adjustments to the essential use process that takes into account the special circumstances of Article 5 Parties and final transition.

- Technical: The large-scale conversion of local CFC MDI manufacturing in Article 5 Parties is slower than anticipated. It will be necessary to wait at least another year to assess the progress of phase-out projects and their impact on future requirements of CFCs.

3. Final Campaign Production in 2011

MTOC believes that with appropriate planning and co-ordination a final campaign production of pharmaceutical-grade CFCs, for CFC MDI manufacturing countries that do not have domestic CFC production, could be feasible in 2011. This option assumes that project implementation is not delayed further.

This option also presumes that China maintains domestic production of CFCs and continues annual CFC production, if approved by Parties under the essential use process, until it completes its national CFC MDI phase-out. China has consumption and CFC production capacity at a scale that enables self-sufficiency.

Anticipating a final campaign production at an agreed date provides a clear target for ending CFC production, predictability for CFC producers, and incentive for those companies currently manufacturing CFC MDIs to switch to CFC-free alternatives.

Based on estimated CFC requirements, the economics of CFC production should still be favourable, firstly in 2010 to allow annual production (of less than 1,700 tonnes) in that year under an essential use, and then in 2011 for a final campaign production. The quantity of the final campaign production, for all countries excluding China, depends on whether India ceases CFC MDI production at the end of 2009 (as implied by Executive Committee Decision 54/35) or not. If India continues CFC MDI production after 2009, then the quantity of a final campaign would be about 2,000 tonnes, for all countries excluding China. If India ceases CFC MDI manufacture at the end of 2009, then the quantity of a final campaign would be about 1,000 tonnes, for all countries excluding China. With either of these outcomes with this option, overall destruction costs for out-of-specification CFCs would be relatively lower than for open-ended annual CFC production.

The logistics of organising a more modest final production campaign in 2011 (in terms of a total multi-year quantity of about 1,000-2,000 tonnes and the associated timelines for essential use nomination and approval no later than 2010) make a final campaign in 2011 more practical than in 2009. The costs of inventory and storage would also be relatively lower than for a final campaign in 2009 or 2010.

Suggested adjustments to the essential use process to accommodate this option are outlined in section 2.8.

2.6.2 Production and stockpiling considerations for final campaign production

Production of pharmaceutical-grade CFCs beyond 2009 will require firm contractual commitments (quantity, cost, timing) from MDI manufacturers to CFC manufacturers for producing, storing and distributing pharmaceutical-grade CFCs. Contractual arrangements
should aim to avoid opportunistic pricing that takes advantage of the limited supply situation. CFC producers require that payment for any CFC production will be made upfront, with sufficient notice to run plants for pharmaceutical CFC production. Such payment will include costs for the destruction of off-specification material. Without the certainty of guaranteed orders, production plants may either take the commercial decision to shut down or dedicate production to other fluorocarbons. The liability for destruction of unused surplus CFCs will reside with the owner of the material.

Pharmaceutical-grade CFCs to supply CFC requirements for MDI production after 2009 could also be sourced from remaining surplus CFC stockpiles in non-Article 5 Parties. Sourcing CFCs from existing stockpile of pharmaceutical-grade CFCs in preference to new CFC production is a requirement of Decision IV/25(1)(b). A co-ordinated approach to identifying, locating and transferring surplus stockpiles would be an advantage for Article 5 Parties, and would avoid destruction of CFCs that could otherwise be diverted to an essential use.

Stockpiling of pharmaceutical-grade CFCs will be an important element of the efficient management of the pharmaceutical-grade CFC supply as part of a final campaign production. The critical steps to manage stockpiles include the following:

1. Agree on the quantity and quality of pharmaceutical-grade CFCs to be stored;
2. Identify and source ISO tanks/cylinders/drums for storage and distribution;
3. Identify general storage location;
4. Agree all key quality protocols (specifications, testing, traceability);
5. Resolve any repacking issues (CFC-11);
6. Identify an entity to manage stockpile procurement, dispatch, maintenance, and destruction of final surplus.

Storage and handling of stockpiled pharmaceutical-grade CFCs is considered further in section 2.7.

MDI manufacturing companies in CFC MDI producing countries must begin to engage in discussions with pharmaceutical CFC producers to ensure the appropriate cost, appropriate quantity and quality issues are agreed upon prior to any final production being commenced.

2.6.3 Volume justification and timing

For 2010 onwards, production of CFCs can only occur under an essential use exemption for Parties including Article 5 Parties. As concluded earlier, final campaign production is less advisable for 2010 but an essential use exemption will still be needed for that year for CFC production for MDIs. Article 5 Parties’ essential use nominations will need to be submitted by 31st January 2009 for Parties to consider essential use exemptions for CFC production in 2010.

In order to anticipate a final campaign production, accurate forward projections will be needed of annual quantities of each CFC required for MDI manufacture for 2010 and for each year thereafter until each Party’s agreed phase-out date. These projections should accompany and justify each year’s nomination for 2010 and onwards, starting with the nominations submitted in 2009. This would allow an accurate global picture to be developed from 2009, and a recommendation by TEAP on the preferred date for a final campaign to be made.
A final campaign production risks exaggerated and non-essential use of CFCs produced for multiple years. Therefore a multi-year essential use production exemption to cover a final campaign production will need to work in parallel with an annual exemption process to approve annual quantities to be used from the stockpile, and to signal the need for destruction of any surplus CFCs.

National transition strategies will also be needed to justify the volume and timing of a final campaign production, along with a complete justification (for both domestic and export use) to demonstrate the use to be essential.

Article 5 Parties will need to work closely with implementing agencies, industry, and other stakeholders to prepare essential use nominations for 2010, with all necessary multi-year data, by 31st January 2009.

It is anticipated that in 2009, Parties would consider Decisions to approve the CFC volumes intended for manufacture in 2010 only. In the next year (2010), the remaining volumes to complete phase-out in each Party would be considered and, if appropriate, approved to allow a final campaign production to occur in 2011.

2.6.4 CFC Specification

Specifications are agreed on a "case-by-case" basis between CFC suppliers and MDI manufacturers as part of the normal commercial negotiations. One important element of a final campaign would be an agreement on a suitable specification against which the CFC manufacturer would supply pharmaceutical-grade material. Parties may wish to highlight the need for national health authorities to work with CFC suppliers and MDI manufacturers to ensure that acceptable specification are in place. Independent actions could lead to a multiplicity of different specifications, which would complicate a final campaign, however, given the few CFC production facilities remaining, this situation is unlikely.

Of the existing specifications, the British Pharmacopoeia (1988) has already been withdrawn and there is a possibility that the USP (1998) specification may follow.

2.7 Storage and handling of stockpiled pharmaceutical-grade CFCs

2.7.1 Physical-chemical properties and storage

Three different CFCs are used in the manufacture of MDIs and their storage requirements change according to their pressures. CFC-12 accounts for roughly 60 per cent of total consumption for MDIs and at room temperature is a gas with a pressure of several atmospheres, which requires the use of expensive storage tanks. The value of a 30 tonne CFC 12 pressure tank is in the order of US$100,000. CFC-11 accounts for approximately 30 per cent of total consumption for MDIs and can be stored as a bulk liquid or in disposable drums. In the latter case the storage temperature should not raise above 30°C. CFC-114 is not used in all CFC MDIs and accounts roughly for the remaining 10 per cent of global consumption for MDIs; it has a much lower pressure than CFC-12, but still needs to be stored in a pressurised tank.

When an MDI manufacturer used a fixed ratio of different CFCs in its products, it was common practice that the CFC supplier shipped the pre-mixed blend to the MDI producer. If the CFCs were stockpiled as a pre-mixed blend, their use by another MDI manufacturer would require
some adjustment of the composition unless both used the same CFC ratio in their formulations. However, it is not believed that the use of mixtures is common practice at present because CFC-11 is generally used as solvent for suspending the active ingredient.

CFC-12 and CFC-114 are very stable compounds that will not undergo chemical transformations, therefore they can be stored safely provided contamination is prevented and they are stored under proper conditions. However, CFC-11 can decompose in the presence of water, and it is therefore important that drums are stored in a warehouse that prevents their exposure to rain. Large temperature fluctuations should also be avoided as the drums are not designed to withstand the resultant pressure changes, and will deform and may eventually leak.

### 2.7.2 Size of Storage

Bulk pressurised tanks usually have a capacity of 20-100 tonnes; those in the upper size range are usually used at the CFC manufacturer site, while a 20 tonne tank will hold sufficient CFC to produce approximately 1,000,000 MDIs.

ISO tanks are another bulk storage option that are built to fit a 20’ shipping container and can be easily transported. CFC manufacturers usually use ISO tanks to export CFCs, but because their availability is limited CFC manufacturers normally expect that their contents will be emptied at the MDI facility and the ISO tank returned promptly. ISO tanks can also be rented, but this is expensive at around US$40 per day. If several ISO tanks were used to store CFCs, a suitable area for proper storage would be needed.

Small MDI manufacturers usually purchase their CFCs in one-tonne cylinders. These will provide sufficient CFC-12 propellant to produce close to 50,000 MDIs. Usually the smaller the container used to store the CFC, the larger the losses proportionately. Handling of these cylinders is costly and time-consuming; CFC manufacturers or suppliers usually demand that they are returned empty after a reasonable amount of time.

Apart from large storage facilities at CFC manufacturing plants, there are some storage complexes that have been used by pharmaceutical companies in the European Community and the United States to hold their stocks during the phase-out of CFC MDIs. It is unlikely that similar storage complexes exist in Article 5 Parties. Use of this type of facilities will be needed when a campaign for the final production of CFCs is defined.

### 2.7.3 Quality control and risks associated with storage

Pharmaceutical regulations demand that stockpiled material is re-circulated and tested periodically. Usually sampling is conducted every six months. Discharging of material stored in a large vessel into a smaller container requires specialised equipment and personnel. Assurance that containers are clean and free of contaminants is crucial, particularly to avoid contamination of the material stored in the larger vessel.

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1. Taken from a presentation given by Dr Tim Noakes at the South Asia and Southeast Asia and Pacific Regional Thematic Workshop on Phasing-out CFC Metered Dose Inhaler (MDI) in Langkawi, Malaysia, during 13-15 March 2008.
The risks of catastrophic failure and venting also have to be considered. Tanks must be located in a secure area where only authorised personnel can enter. Tanks must also be in a site where there are no risks of fires that could cause undesired high temperatures and eventual rupture of a safety valve.

2.7.4 Transfer of existing stockpiles of pharmaceutical-grade CFCs

Transfer of existing stockpiles would be logistically possible through the use of dedicated ISO tanks, provided adequate planning could be established. Timing and costs would be dependent upon the distance of the transfer as well as testing requirements. Costs would also be determined by the need for storage of the "transferred" product. Should it be necessary to keep the product on-site in ISO tanks then, as described earlier, extra charges would apply. Quality would need to be ensured through testing procedures.

Sourcing CFCs from existing stockpile of pharmaceutical-grade CFCs in preference to new CFC production is a requirement of Decision IV/25(1)(b), but not one that has been strictly adhered to by non-Article 5 Parties. In the final stages of transition, Parties should be encouraged to facilitate the identification and transfer of suitable stocks. Parties should be encouraged to facilitate intra-company, international CFC transfers. Nominating Parties must confirm that nominated quantities cannot be sourced from existing global stockpile to meet the requirements of Decision IV/25(1)(b). Decisions VII/28(2)(c), IX/20 and XII/2(8) address the means and conditions for the transfer of essential use exemptions and authorisations by Parties. Parties may wish to clarify that with these Decisions, Parties can transfer CFCs already produced under an essential use exemption and ensure that the Decisions provide the flexibility and accountability needed to allow the transfer of stockpile. In addition, it is not clear whether a stockpile produced before the phase-out date (that is, not produced under an essential use exemption) can be transferred. Parties may wish to consider authorising through a Decision the transfer of any stockpile under the conditions of IX/20.

The import/export of CFCs is subject to strict licensing requirements between Parties. These would have to be dealt with on a "case-by-case" basis with the assistance of national authorities. Parties may also wish to review domestic laws to facilitate transfers of stockpiles between companies and/or countries.

2.7.5 Logistics

The costs associated with stockpiling are substantial. The cost of the stock itself is of the order of $7/kg or $14,000,000 for a 2,000 tonne stockpile. Apart from the financial cost of carrying the inventory, storage costs per year could be in the order of $100/tonne\(^2\). CFC producers and the operator of the storage facility will probably prefer to deal with a single entity that would assume ownership or stewardship of the stock and its costs.

Parties may wish to consider establishing a single entity, such as an implementing agency, to be responsible for the stockpile and its costs.

\(^2\) Taken from a presentation given by Dr Tim Noakes at the South Asia and Southeast Asia and Pacific Regional Thematic Workshop on Phasing-out CFC Metered Dose Inhaler (MDI) in Langkawi, Malaysia, during 13-15 March 2008.
2.7.6 Destruction of surplus or out-of-specification CFCs

Destruction of out-of-specification CFCs can take place at any CFC manufacturing facility with destruction technology approved by Parties (Decision XV/9), such as high-temperature incineration, and with the ability to handle fluorinated chemicals. Virtually all CFC production facilities have such incinerators or access to them, and there are many more commercial operators.

Parties are reminded that surplus CFCs, acquired under an essential use exemption, have to be used in another essential use or destroyed according to means approved by the Montreal Protocol (Decision XV/9). Destruction technologies for ozone-depleting substances have been discussed previously in the 2002 Report of the TEAP Task Force on Destruction Technologies.

Destruction of surplus CFCs will require consideration of the logistics of collection, handling, and transport to a facility with approved destruction technology. It will be important to use tracking and reporting systems, such as through the accounting frameworks for essential uses, to avoid unauthorised venting. The requirements of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal will also need to be considered. Liaison with government officers responsible for Basel Convention requirements for a Party will need to be consulted.

The costs of destruction are extremely difficult to estimate accurately since they are regionally driven and dependent on the distance and means for transporting waste CFCs to destruction facilities, and the destruction facility used. Nonetheless, TEAP has reported previously in its 2005 Supplement to the IPCC/TEAP Report Special Report “Safeguarding the Ozone Layer and the Global Climate System: Issues related to Hydrofluorocarbons and Perfluorocarbons” that average destruction costs (destruction only, excluding collection and transport) are US$2,500-4,500 per tonne (up to US$5/kg in 2005). Consolidation of national stocks for destruction, and a co-ordinated collection and transport system, could reduce the total costs of destruction through economies of scale. Liability for destruction, including associated costs, would reside with the MDI manufacturer that had been allocated the CFCs under an essential use exemption.

2.8 Recommended modifications to the essential use process to accommodate Article 5 Parties and final campaign production

MTOC has reviewed the Protocol’s current essential use decisions and supporting guidance in the Handbook on Essential Use Nominations (TEAP, 2005), to conclude whether the essential use process can accommodate the situation of Article 5 Parties, the last stages of global transition and final campaign production.

While Decision IV/25 and subsequent related essential use decisions provide a good starting point for an essential use process for 2010 and beyond, much has changed since 1992 when the framework was established. The final stages of global transition after 2009 will be characterised by circumstances that make desirable refinement of and modifications to the essential use framework and guidance on information requirements in the Handbook.

Parties may wish to consider the following suggested options in making a set of new Decisions that build on the previous essential use Decisions and associated guidance on information requirements in the Handbook. Parties may wish to consider a suite of new Decisions because:
some of the existing Decisions are currently not applicable to Article 5 Parties but their intended effects are still relevant; other Decisions may need strengthening; and new decisions may be needed to take account of issues not currently included.

These circumstances and suggested options include the following.

- While Decision IV/25 is applicable to Article 5 Parties after the 2009 phase-out, many of the subsequent Decisions related to essential use nomination requirements and procedures have language that make them specifically applicable only to Parties not operating under Article 5. All of the Decisions on MDIs and essential uses have been reviewed with a view to suggesting options for consideration by Parties on a new set of Decisions that provide for an essential use process after 2009 that includes Article 5 Parties.

- Under Decision IX/19(5) and other Decisions (including Decision XII/2), Parties not operating under Article 5 have been required to develop and implement national transition strategies and report on progress each year, and included as a requirement in making essential use nominations. To date, Article 5 Parties have been encouraged but not required to develop national transition strategies (under Decision XII/2(6)). Parties may wish to consider making a national transition strategy a requirement for Article 5 Parties nominating for an essential use exemption to produce CFCs for MDIs, as has been the case for Parties not operating under Article 5. Prompt financing for development of these national transition strategies, as encouraged in Decision 54/35 of the Executive Committee, will assist these efforts.

- Global manufacturing transition is well progressed except in some Article 5 Parties manufacturing CFC MDIs. There are many technically feasible alternatives to CFC MDIs for a range of active ingredients available in Article 5 Party markets. However price may be one issue affecting the uptake of alternatives in some countries (where government or commercial pricing policies do not favour the alternatives), and the rate of regulatory approval may be another issue. These factors make technical feasibility of the alternatives no longer as relevant as economic feasibility when considering the essential nature of CFC MDIs, and more information is needed about the circumstances in consuming countries, including the availability and affordability of CFC-free alternatives in the intended markets. Adjustments to the Handbook can provide additional guidance to nominating Parties. Parties may also wish to consider strengthening Decision VIII/11 to include Article 5 Parties and to request, rather than encourage, the promotion of co-ordination between government authorities to facilitate the transition and the expeditious review of regulatory approvals and launch of CFC-free alternatives.

- The cost to manufacture CFC and HFC MDIs is now generally comparable, and arguments to justify essentiality will be difficult to sustain where intentional or inadvertent pricing policies are unfavourable to CFC-free alternatives. Parties may wish to consider strengthening Decision VIII/11 to include Article 5 Parties, and to request, rather than encourage, Parties to set pricing policies that do not discriminate against CFC-free alternatives.

- With the implementation of projects in Article 5 Parties it should be possible for manufacturing countries to establish phase-out policies and deadlines for stopping the manufacture of CFC MDIs. Essential use nominations will need to justify the volume and timing of a final campaign production in accordance with national transition strategies, project timelines, the status of CFC free alternative development and approval,
and the anticipated timing of introductions. Article 5 Parties will need to work closely with implementing agencies, industry, and other stakeholders to prepare essential use nominations. The Executive Committee of the MLF may wish to consider the advantages of assisting the Article 5 Parties with MDI manufacturing to establish phase-out policies and deadlines under regulations in this regard.

- Reformulation/development and registration of inhalers is a complex undertaking. Criteria will need to be considered to properly elaborate the status of research and development by companies in Parties nominating essential uses, as well as limits on a reasonable period for the reformulation/development and registration of products where there is limited opportunity of alternatives becoming available. Parties may wish to consider strengthening and expanding the existing Decisions around research and development (Decisions XIX/13(3), XVIII/7(3), and VIII/10(1)) to include Article 5 Parties and also to establish clear criteria for reasonable levels of active research and development (removing ambiguity around what constitutes ‘active’), and an end-point or trigger point for the conclusion of reformulation/development efforts that may ultimately prove unsuccessful.

- Despite the fact that the date of CFC production phase-out for Article 5 Parties has been known for many years, some MDI manufacturers in Article 5 Parties are even recently registering and marketing new CFC MDIs in markets in Article 5 Parties. Parties may wish to consider that a CFC MDI approved in an Article 5 Party after 31st December 2007 should not be considered an essential use, similar to the requirement for non-Article 5 Parties under Decision XII/2(2). Parties may also wish to require nominating Parties to specify the date that CFC MDI production commenced for each active ingredient subject to a nomination.

- Some MDI manufacturing companies are practising dual marketing of CFC MDIs and their CFC-free alternatives for the same active ingredient. After an adequate post-marketing period for the CFC-free alternative of not more than 12 months, absent compelling circumstances, the company’s corresponding CFC MDI product cannot be considered essential. Parties may wish to consider clarifying this in a Decision, that is, absent compelling circumstances, CFCs should not be requested in an essential use nomination or allocated to a company for a product where the company has launched the corresponding CFC-free alternative, after an adequate parallel marketing period of not more than 12 months. The Governments of such Parties may wish to consider the advantages of establishing policies and regulations to ban such dual marketing.

- Parties may wish to consider the advantages of encouraging Parties not manufacturing CFC MDIs to establish bans on the import of CFC MDIs at a certain date, when adequate alternatives to CFC MDIs will be available. MTOC will consider information in essential use nominations next year, and can suggest options for a possible date to ban the import of CFC MDIs in Article 5 Parties.

- Due to the uncertainty surrounding the security of future supply of pharmaceutical-grade CFCs, there will be a point in the next few years when annual just-in-time CFC production will no longer be economically feasible and a final campaign production will be needed. From 2010 onwards, production of CFCs can only occur under an essential use exemption. As concluded earlier, final campaign production is less advisable for 2010 but an essential use exemption will still be needed for that year for CFC production for MDIs. In order to anticipate a final campaign production, accurate forward
projections will be needed of annual quantities of CFCs required for MDI manufacture for 2010 and for each year thereafter until each Party’s agreed phase-out date in national transition strategies. This should accompany and justify each year’s nomination for 2010 and onwards, starting with the nominations submitted in 2009. This would allow an accurate global picture to be developed from 2009, and a recommendation by TEAP on the necessary date for a final campaign to be made. Parties may wish to consider a Decision to clarify information for a final production campaign in each year’s essential use nomination. Information needs for a final campaign are elaborated below.

- Final campaign production for CFC MDI manufacturing countries that do not have domestic CFC production could be feasible in 2011. This assumes that project implementation is not delayed any further, and that China maintains domestic production of CFCs beyond 2011 to complete its national phase-out. Lead times need to be considered for a Decision on the quantity for a final campaign production, to ensure nominations for multiple years are made in time to allow a decision in the year prior to the production campaign. For example, multi-year essential use nominations for a final campaign in 2011 would be required by 31st January 2010 at the latest.

- A final campaign production risks exaggerated, non-essential use of CFCs produced for multiple years. Therefore a multi-year essential use exemption to allow a final campaign production will need to work in parallel with an exemption process to approve annual quantities to be used from the stockpile produced under a final campaign, and to signal the need for destruction of any surplus CFCs. Decision IV/25 and subsequent Decisions imply review provisions for previously qualified essential uses, but do not clearly articulate yearly processes such as might be needed. Parties may wish to consider a Decision to clarify an essential use nomination process that would allow approval by Parties of future annual use of the stockpile produced in a final campaign previously approved by Parties.

- Exporting countries nominating for essential uses need to demonstrate that importing countries deem the nominated products to be essential. Decision XII/2(3) requests Parties, including Article 5 Parties, to notify the Ozone Secretariat of any MDI products determined to be non-essential, which is then posted on the website of the Ozone Secretariat, and for Parties to take this information into consideration when nominating for essential uses. However only one Party’s information is listed on the Ozone Secretariat’s website. Given the complexity and fluidity of export markets, Parties may wish to consider strengthening this decision, with a request for all Parties, including those operating under Article 5, to make annual declarations of any MDI products determined to be non-essential within their own country, and that these declarations accompany essential use nominations from Parties manufacturing and exporting CFC MDIs to these countries, in order to justify an essential use under Decision IV/25. Decision XIV/5 also requests each Party to supply annual data on CFC MDIs and their CFC-free alternatives to the Ozone Secretariat. Twenty-two Article 5 Parties have submitted data pursuant to Decision XIV/5 since its inception, but in many cases the data have not been updated annually. Parties may wish to consider a decision emphasising the importance of providing such data as part of the final stages of transition.

- One-year operational supply has been an important mechanism to control over-production and hoarding of CFCs produced annually for essential uses. However in the final stages of transition and after a final campaign production, a one-year operational supply may not be as desirable as part of an essential use process. Prior to a final
campaign, flexibility in stockpiling may be desirable for Article 5 Parties wishing to build a stockpile prior to a final campaign, and thereby reduce the final campaign production quantity. After a final campaign production, one-year operational supply is not relevant to a multi-year stockpile. Decisions XIX/13(2), XVIII/7(2), XVII/5(2), regarding one-year’s operational supply, do not include Article 5 Parties. Decision XVI/12(3) asks Parties, in general, nominating for essential uses to give due consideration to existing stocks with the objective of maintaining no more than one year’s operational supply. Parties may wish to consider more flexibility in stockpiling for the final stages of transition than is available through the current Decisions.

- Sourcing CFCs from existing stockpiles of pharmaceutical-grade CFCs in preference to new CFC production is a requirement of Decision IV/25(1)(b), but not one that has been strictly adhered to by non-Article 5 Parties. In the final stages of transition, Parties should be encouraged to facilitate the identification and transfer of suitable stocks. Parties should be encouraged to facilitate intra-company, international CFC transfers. Nominating Parties must confirm that nominated quantities cannot be sourced from existing global stockpile to meet the requirements of Decision IV/25(1)(b). Decisions VII/28(2)(c), IX/20 and XII/2(8) address the means and conditions for the transfer of essential use exemptions and authorisations by Parties, although in the case of Decision VII/28(2)(c) for non-Article 5 Parties only. Parties may wish to clarify that with these Decisions, Parties can transfer CFCs already produced under an essential use exemption and ensure that the Decisions provide the flexibility and accountability needed to allow the transfer of stockpile. Parties may also wish to review domestic laws to facilitate transfers of stockpiles between companies and/or countries. In addition, it is not clear whether a stockpile produced before the phase-out date (that is, not produced under an essential use exemption) can be transferred. Parties may wish to consider authorising through a Decision the transfer of any stockpile under the conditions of IX/20. Parties may wish to strengthen Decision VII/28(2)(c) to include Article 5 Parties. Parties may also wish to consider minor modifications to the accounting framework under Decision VIII/9 to allow reporting of stockpile transfers.

- Well-monitored and accounted stockpile management and destruction of out-of-specification or surplus CFCs becomes even more critical after 2009. Any out-of-specification CFCs produced after 2009 and any pharmaceutical-grade CFC remaining at the conclusion of MDI transition must be destroyed by approved technologies. Parties may wish to strengthen Decision VII/28(2) to include Article 5 Parties regarding the requirement to destroy any surplus essential use CFCs. In relation to a nomination for a final campaign production, Parties may wish to consider requiring nominating Parties to describe storage capacity, facilities and maintenance arrangements, access to approved destruction technologies and contingency plans for destruction of surplus stocks, including consideration of Basel Convention requirements. Parties may also wish to consider strengthening the accounting framework under Decision VIII/9 to require Parties to report the destruction via approved technologies of out-of-specification CFCs or surplus essential use pharmaceutical-grade CFCs.

MTOC lists below the Decisions that might be considered relevant in making modifications to the essential use process to provide coverage for Article 5 Parties and final campaign production:
Decision IV/25; Decision V/18 par. 5; VI/9 par. 4; VII/34 par. 5(b); VII/28 par. 2; VIII/9 pars. 8, 9 and 10; VIII/10; VIII/11; VIII/12 par. 3; IX/19 par. 5; IX/20; X/6 par. 5; XII/2 pars. 2, 3, 4, 5, 6 and 8; XIV/5; XV/5; XVI/12 pars. 2 and 3; XVII/5 par. 2; XVIII/7 pars. 2 and 3; XVIII/16 pars. 7 and 8; and XIX/13 pars. 2 and 3.

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This list may not be complete but represents the most relevant Decisions, in MTOC’s view, that might need modification and incorporation into a new set of Decisions.

TEAP and its MTOC remain ready to assist Parties in these refinements and modifications (and with subsequent accompanying changes to the Handbook) for which Decisions by Parties will be needed this year (to allow essential use nominations to be considered in 2009 for any CFC production in 2010).

2.8.1 Information needed to define quantities for a final campaign production of pharmaceutical-grade CFCs

In 2007 MTOC reported information needs for a final campaign. These information requirements have been updated since last year and are elaborated below. All of the information requirements can be accommodated under the existing Decisions and with the suggested modifications to the essential use Decisions and associated changes to the Handbook recommended in this report.

In order to calculate the quantities to be produced in a final campaign, the following information will be needed on a country-by-country basis:

- Country transition strategy for CFC MDIs, including a phase-out date for CFC MDI production;
- Quantity required for each year (2010 and beyond), and historical three-year consumption data;
- Within the Party, a summary of conversion projects for CFC MDI manufacturing plants, including: timelines; availability of manufacturing equipment, delivery and commissioning dates;
- Availability of CFC-free alternatives from local manufacture and from import, status of CFC-free alternative development and approval, anticipated timing of introduction, relative pricing of imports compared with locally manufactured products and whether this presents a barrier to transition;
- The destination, quantity and essentiality of CFC MDIs intended for export;
- Information on storage capacity, facilities and maintenance arrangements, access to approved destruction technologies and contingency plans for destruction of surplus stocks, including consideration of Basel Convention requirements;
- The date CFC MDI production commenced; and
- Existing stockpile size, CFC type, availability and quality, and demonstrated efforts to acquire CFCs through the transfer of stockpile from within and outside of the Party.

The annual accounting process will need to continue to track the quantities of CFCs: produced for MDI manufacture; transferred for MDI manufacture; used in MDI manufacture; within exported finished product and to what destinations; stockpiled; and destroyed.
2.8.2  **Suggested changes to Section 2.5 of the Handbook on information requirements**

MTOC has some initial suggestions for changes to Section 2.5 of the Handbook, relating to information requirements for essential use nominations. These suggestions are based on the current Section 2.5, taking into account the recommendations above for changes to the essential use process and the Handbook, and are presented for the purposes of illustration. A final set of changes to the Handbook can be recommended following Decisions by Parties about the form of any new essential use process to include Article 5 Parties and final campaign production.

Due to the timelines for adoption of any Decisions by Parties at the 20th MOP and subsequent related changes to and publication of an updated Handbook, Parties may wish to consider provisional approval of the suggested changes below to Section 2.5 of the Handbook to assist Parties planning to submit essential use nominations in early 2009.

The following information is requested for each essential use nomination.

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. Specify whether the quantity is requested for production or for use from existing stockpile. (Decision IV/25, pars. 2 and 3).

3. Indicate the period of time and the annual quantities of the controlled substances that are requested. For CFC MDIs, indicate the expected annual future requirements until CFC MDI transition is completed and historic 3-year consumption data to satisfy the use. (Decision IV/25, pars. 2 and 3) [This Decision is flexible and allows for multi-year essential use nominations, as would be required for a final campaign production, and also allows for Parties to provide data for all future years until anticipated phase-out].

5. 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 export markets. (Currently covered by Decisions XV/5, par. 2 and XVI/12, par. 2). Specify the date that CFC MDI production commenced for each active ingredient subject to the nomination.

6. 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 current Decision XII/2 or Decision IX/19). (Currently covered by Decision XV/5, par. 3) Summarise the nominating Parties national transition strategy, including national phase-out dates and CFC MDI manufacturing plant conversion timelines (including new manufacturing equipment delivery and commissioning dates).

7. For CFC MDIs, briefly describe progress made on the transition to CFC-free alternatives under a national or regional MDI transition strategy. (Currently covered by Decision IX/19, par. 5 and Decision XII/2, par. 5(c) for non-Article 5 Parties only. Decision XII/2(6) encourages, rather than requires, Article 5 Parties to develop strategies and annually report on progress, and there is no equivalent requirement for Article 5 Parties submitting essential use nominations to present national transition strategies as for non-Article 5 Parties in Decision IX/19, par.5).
8. 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).

9. 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). Attach annual declarations by Parties, for each of the intended markets subject to the nomination, of active ingredients and/or CFC MDI products determined to be non-essential by the Party.

10. Explain what other alternatives and substitutes have been employed to reduce the dependency on the controlled substance for this application in the intended markets subject to the nomination. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d)).

11. Explain what alternatives were investigated or are available in the intended markets and why they were not considered adequate. Describe information on the availability and affordability of alternatives in the intended markets subject to the nomination. Explain whether any barriers, such as the pace of regulatory approvals or unfavourable pricing policies, are slowing the uptake of alternatives. (Decision IV/25, pars. 1(a)(ii), 1(b)(i), 2 and 3(d)). For CFC MDIs, confirm that the global database of CFC MDIs and their alternatives has been consulted and taken into account in the nomination (Decision XIV/5). For the intended markets for sale or distribution, confirm that each company, requesting essential use allocations, does not have a CFC-free alternative marketed for more than 12 months for each active ingredient for which a CFC MDI is also being marketed that is subject to the nomination. Confirm that CFCs are not requested for and will not be allocated to a company, absent compelling circumstances, for a product where the company has launched the corresponding CFC-free alternative (for any of the intended markets for sale or distribution), after an adequate parallel marketing period of not more than 12 months.

12. For CFC MDIs, confirm that each company requesting essential use allocations has demonstrated ongoing active research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts. (Currently covered by Decision VIII/10, par. 1 for non-Article 5 Parties only) Describe the status of the development of alternatives to CFC MDIs, plans for their approval and expected launch dates.

13. 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 XII/2, par. 4; and current Decisions VIII/10, par. 1 and VIII/11 for non-Article 5 Parties only).

14. If the use is for a CFC MDI product approved after 31 December 2000 for non-Article 5 Parties (currently covered by Decision XII/2, par. 2 for non-Article 5 Parties only) or after 31 December 2007 for Article 5 Parties 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.

15. Describe the measures that are proposed to eliminate all unnecessary emissions. At a minimum, this explanation should include design considerations and maintenance procedures. (Decision IV/25, pars. 1(b)(i), 2 and 3(b); Decision VI/9, par. 4; and current Decision VIII/10, pars. 6 and 7 for non-Article 5 Parties only)
16. 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. [MTOC queries the need for this requirement for MDIs.]

17. For CFC MDIs, describe progress made towards determining and submitting a specific date by which time the Party, for those not operating under paragraph 1 of Article 5, will cease making nominations for essential use exemptions for CFCs for metered-dose inhalers where the active ingredient(s) is not solely salbutamol and the metered-dose inhalers are expected to be sold or distributed on the market of any Party not operating under paragraph 1 of Article 5. (Decision XV/5, par. 6) [MTOC queries whether this is relevant to Article 5 Parties where salbutamol will likely be reformulated in parallel with other active ingredients.]

18. 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)). For CFC MDIs, in relation to a nomination for a final campaign production or for the use of a final campaign stockpile, describe storage capacity, facilities and maintenance arrangements, access to approved destruction technologies and contingency plans for destruction of surplus stocks, including consideration of Basel Convention requirements.

19. For CFC MDIs, indicate the existing stock of pharmaceutical-grade CFCs (pre- and post-1996 for non-Article 5 Parties, and pre- and post-2010 for Article 5 Parties) 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. Confirm that existing stockpiles have been taken into account in making essential use requests. Describe how this stockpile will be utilised in coming years. (Decision IV/25, par. 1(b)(ii), current Decision XVI/12, par. 3, and current Decisions XVII/5 par. 2 and XIX/13 par. 2 for non-Article 5 Parties only)

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