MONTREAL PROTOCOL

ON SUBSTANCES THAT DEPLETE

THE OZONE LAYER

UNEP

REPORT OF THE
TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL

MAY 2014

VOLUME 2

ESSENTIAL USE NOMINATIONS REPORT

UNEP
MAY 2014 REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL

VOLUME 2
ESSENTIAL USE NOMINATIONS REPORT

Montreal Protocol
On Substances that Deplete the Ozone Layer

Report of the
UNEP Technology and Economic Assessment Panel

May 2014

VOLUME 2

ESSENTIAL USE NOMINATIONS REPORT

The text of this report is composed in Times New Roman.

Co-ordination:	**Technology and Economic Assessment Panel**
Composition of the report:	Lambert Kuijpers, Bella Maranion, Helen Tope
Layout and formatting:	Ozone Secretariat (UNEP) Lambert Kuijpers (UNEP TEAP)
Date:	May 2014

Under certain conditions, printed copies of this report are available from:

UNITED NATIONS ENVIRONMENT PROGRAMME
Ozone Secretariat, P.O. Box 30552, Nairobi, Kenya

This document is also available in portable document format from the UNEP Ozone Secretariat's website:

http://ozone.unep.org/new_site/en/assessment_panels_main.php

No copyright involved. This publication may be freely copied, abstracted and cited, with acknowledgement of the source of the material.

Disclaimer

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

UNEP, the TEAP Co-chairs and members, the Technical Options Committees Co-chairs and members, and the TEAP Task Forces Co-chairs and members, in furnishing or distributing this information, do not make any warranty or representation, either express or implied, with respect to the accuracy, completeness, or utility; nor do they assume any liability of any kind whatsoever resulting from the use or reliance upon any information, material, or procedure contained herein, including but not limited to any claims regarding health, safety, environmental effect or fate, efficacy, or performance, made by the source of information.

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

Acknowledgements

The Technology and Economic Assessment Panel, its Technical Options Committees and the Task Forces Co-chairs and members acknowledges with thanks the outstanding contributions from all of the individuals and organisations that provided support to Panel, Committees and Task Forces Co-chairs and members. The opinions expressed are those of the Panel, the Committees and Task Forces and do not necessarily reflect the reviews of any sponsoring or supporting organisation.

TEAP thanks the Multilateral Fund Secretariat for the Montreal Protocol, Montreal, Canada for hosting the TEAP meeting, 4-9 May 2014, where the elements for this report were first discussed and decisions were taken for a final review round, followed by the submission of the report.

Foreword

The May 2014 TEAP Report

The May 2014 TEAP Report consists of six volumes:

Volume 1: May 2014 TEAP Progress Report

Volume 2: May 2014 TEAP Essential Use Nominations Report

Volume 3: May 2014 TEAP Critical Use Nominations Report

Volume 4: TEAP Decision XXV/5 Task Force Report on information on alternatives to ODS

Volume 5: TEAP Decision XXV/6 Report on TOC appointment processes, future configurations and the streamlining of annual (progress) reports

Volume 6: TEAP Decision XXV/8 Task Force on the funding requirement for the 2015-2017 replenishment of the Multilateral Fund for the Implementation of the Montreal Protocol

- **Volume 1** contains the TOC progress reports, and a chapter "Other TEAP Matters", discussing the status of (re-) nominations and challenges to the participation of experts, as well as an annex with the list of TEAP and TOC members, status May 2014
- **Volume 2** contains the assessment of the 2014 essential use nominations by the CTOC and the MTOC
- **Volume 3** contains the assessment of the 2014 critical use nominations by the MBTOC
- **Volume 4** is the report of the TEAP Task Force responding to Decision XXV/5 on information on alternatives to ODS in the refrigeration and air conditioning, foams, medical uses, fire protection and solvent sectors
- **Volume 5** contains a description by the TEAP on the TOC appointment processes and their future configurations and the streamlining of the annual (progress) reports in response to Decision XXV/6
- **Volume 6** is the report of the TEAP Task Force responding to Decision XXV/8 on the funding requirement for the 2015-2017 replenishment of the Multilateral Fund for the Implementation of the Montreal Protocol.

This is Volume 2 on the assessment of Essential Use Nominations submitted in 2014.

The UNEP Technology and Economic Assessment Panel (TEAP):

Lambert Kuijpers, co-chair	NL	Jose Pons-Pons	VEN
Bella Maranion, co-chair	USA	Ian Porter	AUS
Marta Pizano, co-chair	COL	Miguel Quintero	COL
Paul Ashford	UK	Helen Tope	AUS
Mohamed Besri	MOR	Dan Verdonik	USA
David Catchpole	UK	Ashley Woodcock	UK
Marco Gonzalez	CR	Masaaki Yamabe	J
Sergey Kopylov	RF	Shiqiu Zhang	PRC
Kei-ichi Ohnishi	J	Jianjung Zhang	PRC
Roberto Peixoto	BRA		

UNEP
MAY 2014 REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL
VOLUME 2

ESSENTIAL USE NOMINATIONS

TABLE OF CONTENTS ..... **PAGE**

FOREWORD ..... **VI**

1 INTRODUCTION **1**

2 ESSENTIAL USE NOMINATIONS FOR CFC-113 IN AEROSPACE INDUSTRIES BY THE RUSSIAN FEDERATION **3**

2.1 EUN OF CFC-113 IN 2015 FOR AEROSPACE INDUSTRIES BY THE RUSSIAN FEDERATION 3
2.2 BACKGROUND OF THE NOMINATION 3
2.3 CTOC COMMENTS ON THE EUN FOR CFC-113 IN 2015 BY THE RUSSIAN FEDERATION 3
2.4 CONCLUSIONS 4

3 ESSENTIAL USE NOMINATION OF CTC LABORATORY AND ANALYTICAL USES ("TESTING OF OIL, GREASE AND TOTAL PETROLEUM HYDROCARBONS IN WATER") BY CHINA **5**

3.1 INTRODUCTION 5
3.2 EUN FOR CTC IN 2015-2016 BY CHINA 5
A. Steps to minimise use through standard revision *5*
B. Steps to minimise emissions *5*
3.3 CTOC COMMENTS ON EUN FOR CTC IN 2015-2016 BY CHINA 6
3.4 CONCLUSION 6

4 ESSENTIAL USE NOMINATIONS AND REPORTING ACCOUNTING FRAMEWORKS FOR CFCS FOR METERED DOSE INHALERS **7**

4.1 EXECUTIVE SUMMARY OF ESSENTIAL USE NOMINATIONS FOR METERED DOSE INHALERS 7
4.2 ESSENTIAL USE NOMINATIONS FOR METERED DOSE INHALERS 7
4.2.1 Criteria for Review of Essential Use Nominations for MDIs *7*
4.2.2 Review of Nominations *7*
4.2.3 Observations *8*
4.2.4 Stockpiles *8*
4.2.5 China *9*
4.3 REPORTING ACCOUNTING FRAMEWORKS FOR ESSENTIAL USE EXEMPTIONS 14
4.3.1 Argentina *14*
4.3.2 Egypt *15*
4.3.3 European Union *15*
4.3.4 India *15*
4.3.5 Mexico *15*
4.3.6 Pakistan *16*
4.3.7 Russian Federation *16*
4.3.8 Syria *17*
4.3.9 United States *17*

1 Introduction

This is volume 2 of 6 of the May 2014 TEAP Report and contains:

- Essental Use nomination by the Russian Federation for CFC-113 evaluated by the CTOC;
- Essential Use nomination by China for CTC evaluated by the CTOC; and
- Essental Use nominations for CFCs in MDIs evaluated by the MTOC.

2 Essential Use Nominations for CFC-113 in Aerospace Industries by the Russian Federation

2.1 EUN of CFC-113 in 2015 for Aerospace Industries by the Russian Federation

On 14 January 2014, the Russian Federation submitted to the Ozone Secretariat a new request for an Essential Use Exemption for 75 metric tonnes of CFC-113 in 2015 for use in the manufacture of missiles and space equipment. The application was submitted by the Ministry of Natural Resources and Ecology of the Russian Federation.

The CTOC has reviewed this nomination and recommends an EUE for 75 metric tonnes of CFC-113 in 2015 for the Russian Federation.

2.2 Background of the nomination

Decision XXV/3 in MOP-25 approved an essential use exemption of 85 metric tonnes of CFC-113 in 2014 for applications in the missile and aerospace industries in the Russian Federation, taking into consideration the evaluation and recommendation of the CTOC on the essential-use nomination for CFC-113 for aerospace applications. CTOC notes that the Russian Federation continues to explore the possibility of importing CFC-113 for its aerospace industry needs from available global stocks and that the Russian Federation has been successful in reducing use and emissions in line with the technical adaptation timetable developed in collaboration with the CTOC.

2.3 CTOC comments on the EUN for CFC-113 in 2015 by the Russian Federation

The Russian Federation has been successful in reducing the annual consumption of CFC-113 in the missile and space industry from 241 metric tonnes in 2001 to 85 metric tonnes in 2014. However, no solvent is currently available that is similar to CFC-113 in terms of cleaning efficiency, versatility and compatibility with structural materials. Consequently, CFC-113 phaseout in this application is directly related to technical modernization and new equipment installation.

The new request by the Russian Federation for an Essential Use Exemption for 75 metric tonnes of CFC-113 in the year 2015 describes and explains in detail why this application is urgent for health and safety or vital for the society, what efforts are made to investigate currently available alternatives and why these are insufficient for immediate complete phaseout, and also efforts for minimizing emission of CFC-113.

Unique physicochemical and operational characteristics of CFC-113 grant the required cleanliness levels of parts and assembly units, high tightness levels of the missile and space equipment. Faultless and reliable operation in those applications, and consequently, the life and health of spacecraft crews, personnel and communities in the launching area depend on proper selection of the cleaning solvent for those parts and equipment. In particular failures of gyro instruments of the launch vehicle or space vehicle control system can lead to fatal situations and. insufficient liquid-propellant rocket systems, which use liquid oxygen as an oxidizer, can result in explosions during launching

The tested CFC-113 alternatives are discussed as well as many other non-ozone-depleting solvents produced by Du Pont (Vertel XF, Vertel MCA), 3M (Novec HFE-7100, HFE-71DE, HFE-72DE), Asahi Glass (Asahiklin AK-225, AK-225 FPL, AE-3000), Honeywell (Solstice 1233zd), etc. But none of those candidates meets all requirements for the replacement of CFC-113.

The interested industrial enterprises have already tested and implemented where possible the procedures for cleaning, degreasing and washing of parts and assembly units of missile and space equipment with alternative organic, chlorocarbon, hydrochlorofluorocarbon (HCFC-141b, etc.) solvents and aqueous detergents. This allowed considerable decrease in CFC-113 use. However, the CFC-113 phaseout is to be finished when all CFC-113 dependent equipment is replaced. According to the earlier submitted time-schedule (see Russian EUN for 2013) the use of CFC-113 by the Russian missile and space industry is to be completely terminated starting from 2016.

In order to minimise emissions of CFC-113, recirculation and stock accumulation have been attempted, but recycled and accumulated stock of CFC-113 is not available in sufficient quality for the expected application.

In addition, the enterprises developed and implemented closed-type sealed equipment with solvent vapor phase recuperation units, and developed and implemented new production technologies that minimize loss of volatile solvents in the manufacture of parts and assemblies for missile and space equipment.

The EUN submitted by Russia satisfies, in principle, the following criteria to qualify as "Essential" under Decision IV/25:

1. It is necessary for the health, safety or critical for the functioning of the society.
2. There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.
3. All actions have been attempted to minimize CFC-113 emissions.

2.4 Conclusions

The CTOC recommends the Essential Use Exemption for 75 metric tonnes of CFC-113 in 2015 for the Russian Federation.

Taking into account the achievements so far and timely realization of the industrial program on conversion of the missile and space industry to technologies that avoid or restrict application of CFC-113, the Russian Federation has provided the future reduction plan as follows: 75 metric tonnes in 2015, and 0 metric tonnes in 2016.

The CTOC acknowledges the achievement of the projected reduction, and recommends continued efforts for the introduction of appropriate alternatives, development of materials compatible with alternatives and adoption of newly designed equipment to complete phase-out of CFC-113 in 2016.

The CTOC understands also that some of CFC-113 alternatives currently adopted by the Russian Federation in the manufacture of missile and space equipment (HCFCs) are transitional ODS substances with very small but non-zero ODP values, and they are regulated by the Montreal Protocol. HCFCs are scheduled to be phased out in the near future, and CTOC strongly recommends that efforts continue to plan for the upcoming transition.

3 Essential Use Nomination of CTC laboratory and analytical uses ("testing of oil, grease and total petroleum hydrocarbons in water") by China

3.1 Introduction

In China, as in every other country in the world, it is a fundamental necessity to be able to test the presence of oil in water to monitor water quality. Most countries have their own national standard for this type of analysis. China's national standard *HJ 637-2012 Water quality - Determination of petroleum oil, animal and vegetable oils- Infrared photometric method* is in use since 2012. The scope of water quality monitoring includes headwaters, lake waters, river waters, surface waters, groundwater, seawater, drinking water, domestic sewage, and industrial effluents. Carbon tetrachloride (CTC) is specified by the *HJ 637-2012* standard as the agent to extract oily substances, which are then analysed with the infrared photometric method.

Decision XXIII/6 specifies that after 31 December 2014, the use of CTC for the testing of oil, grease and total petroleum hydrocarbons in water would only be allowed under an Essential-Use Exemption. In accordance with this Decision, on 30 January 2014, China's Ministry of Environmental Protection (MEP) submitted an Essential Use Nomination (EUN) for 90 metric tonnes of CTC in 2015 and 90 metric tonnes of CTC in 2016 for "testing of oil, grease and total petroleum hydrocarbons in water".

3.2 EUN for CTC in 2015-2016 by China

In its EUN, China reports that it has successfully reduced the annual consumption of CTC for "testing of oil, grease and total petroleum hydrocarbons in water" from 90 metric tonnes to 70 metric tonnes during 2010 to 2012. However, during this period, China has significantly increased its focus on environmental protection measures and, as a consequence, has required more water quality testing. These tests are required to follow the *HJ 637-2012* standard and, as a result, the demand for CTC is increasing.

China recognizes that non-ODS substances, such as cyclohexane and tetrachloroethylene, could be used in the test as a replacement for CTC. China indicates that the MEP has initiated revision of the national standard *HJ 637-2012* that will specify the use of non-ODS substitutes to replace CTC for future testing, however, issuing the revised standard will take some time.

A. Steps to minimise use through standard revision

The proposed revisions to the standard *HJ 637-2012* will be submitted for review by 31 December 2014. Two related draft standards on monitoring methods - *Water quality- Determination of volatile petroleum hydrocarbon- Purge and Trap/Gas chromatography (C6-C9)* and *Water quality- Determination of extractive petroleum hydrocarbon- liquid-liquid extraction/Gas chromatography (C10-C40)"* - are planned to be launched by the MEP in April 2014. The submission date of these two drafts is 31 December 2015.

The revised national standard and the two monitoring methods mentioned above are expected to be completed and put into effect in 2016.

B. Steps to minimise emissions

Approximately 20% of the total CTC use in this application is consumed by the environmental monitoring departments, which recycle the CTC reagent. A further 50% of the

total CTC use is consumed by many other testing and analysis organizations and university laboratories, where the used CTC reagent will be collected and destroyed.

3.3 CTOC Comments on EUN for CTC in 2015-2016 by China

The CTOC acknowledges the effort made by China in its endeavour to reduce the use of CTC for this application. The CTOC also acknowledges that determination of oil in water is essential to monitor water quality, which is needed for health, safety and for the functioning of society.

One consideration for CTOC was justification for the 90 MT of CTC to conduct the water analysis. When asked by the CTOC, China submitted additional information on the amount of CTC used per sector; for instance, MEP monitors water in 113 major cities and 340 prefecture-level cities, for a total of roughly 500 sites. For each site, tests are conducted at least once a month by five sections. Multiplying 500 sites by 5 sections by 12 months gives a total of approximately 30,000 tests per year, each using 300 ml CTC, for an estimated total use of 10 tonnes of CTC per year (CTC has a density of 1.59). Other users include oil and petrochemical companies like Sinopec and public testing organizations.

In the past, a General Essential Use Exemption was granted to Laboratory and Analytical Uses because it was difficult to identify and quantify the requirements of many small users. Some of these, such as quality control in private companies or analyses in universities, might be unlikely to meet the specific essential use criteria established under Decision IV/25, where the use must be essential for the health, safety and for the functioning of society. An assessment of China's Essential Use Nomination for laboratory and analytical uses requires justification of the continued use of ODS in this application in its range of uses. Therefore, the CTOC would need additional information to see whether the request of 90 MT of CTC can indeed be considered essential.

Although China requests an essential use exemption, no newly produced carbon tetrachloride will be needed, since it would come from CTC byproduct in the chloromethane production, which is normally used as feedstock in other processes, converted into non-ODS substances or disposed by the producers. It is likely that the CTC byproduct needs further purification to be usable as a reagent. The nomination does not discuss the possibility to use stockpiled material while the new standards are put in place. Considering the large number of laboratories where the analyses are conducted and the high degree of fragmentation, CTOC would need to better understand the situation with regard to the availability of stockpiled laboratory-grade CTC.

CTOC also considered the significant delays in drafting, submitting and implementing the revised standards, as described in the nomination, even though ODS-free alternative methods have been available for 15 years. CTOC is aware that China signed a CTC Phase-Out Plan with the Multilateral Fund of the Montreal Protocol and requests additional clarification of how this nomination relates to that plan.

3.4 Conclusion

After careful review and detailed discussion, and for the reasons outlined above, the CTOC is unable to recommend the Essential Use Nomination of 90 MT CTC in 2015 for "testing of oil, grease and total petroleum hydrocarbons in water" for China as presented. In addition, the CTOC is not recommending the nomination for 2016 given that it is unable to recommend the amount requested for 2015 without additional information, which may affect future nominations. At this advanced stage of CTC phase-out, replacement technologies are well known and the only issues remaining are the implementation of these technologies and the management of stockpiles. Under these circumstances, CTOC believes any essential use nomination should be presented one year in advance and for one year only.

4 Essential Use Nominations and Reporting Accounting Frameworks for CFCs for Metered Dose Inhalers

4.1 Executive Summary of Essential Use Nominations for Metered Dose Inhalers

MTOC received an essential use nomination from China requesting a total of 217.34 tonnes of CFCs for the manufacture of metered dose inhalers (MDIs) for 2015.

Table 4-1 summarises the recommendations of the Technology and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC) on the nomination for essential use production exemptions for chlorofluorocarbons (CFCs) for MDIs. Recommendation is made in accordance with Decision XV/5(3), which requests TEAP and its MTOC to make recommendations on nominations for essential use exemptions for CFCs for MDIs with reference to the active ingredient of the metered-dose inhalers in which the CFCs will be used and the intended market for sale or distribution. The recommendation is for a total of 182.61[1] tonnes of CFCs for the manufacture of MDIs in 2015.

Table 4-1 Recommendations for essential use nominations

Party	2015	Active Ingredients	Intended Markets
China	182.61	Beclomethasone, budesonide, dimethicone, ipratropium/salbutamol, salbutamol, datura metel extract/clenbuterol	China

MTOC thanks the Ozone Secretariat for providing meeting venue sponsorship for the MTOC meeting held in Manchester, United Kingdom, 2-4 April 2014. MTOC co-chair, Professor Ashley Woodcock, and the University of Manchester, provided a range of organisational assistance and personal hospitality, for which MTOC is sincerely thankful.

4.2 Essential Use Nominations for Metered Dose Inhalers

4.2.1 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, XVIII/16, XX/3, XXI/4, XXII/4, XXIII/2, XXIV/3 and XXV/2 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 and Parties operating under paragraph 1 of Article 5 of the Protocol. Other relevant essential use decisions are Decisions XVII/5, XVIII/7 and XIX/13.

4.2.2 Review of Nominations

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

Four members of MTOC independently reviewed the nomination from China, preparing an initial assessment. Further information was requested of China during March. MTOC

[1] 182.6055 tonnes exactly, according to the nominated quantities.

considered the assessment and additional information received, made recommendations and prepared this consensus report at its meeting in Manchester, United Kingdom 2-4 April 2014.

Members disclosed any potential conflicts of interest ahead of the discussion. Where necessary, members are recused from the decision-making process of the nomination relevant to any potential conflict of interest.

The nomination was assessed according to the guidelines for essential use contained within the *Handbook on Essential Use Nominations* (TEAP, 2009) and subsequent Decisions of the Parties. Recommendations are made in accordance with Decision XV/5(3), which requests TEAP and its TOC to make recommendations on nominations for essential use exemptions for CFCs for MDIs with reference to the active ingredient of the metered-dose inhalers in which the CFCs will be used and the intended market for sale or distribution.

Concurrent with the evaluation undertaken by the MTOC, the nomination was also provided to the co-chairs of 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.

4.2.3 Observations

MTOC received one essential use nomination from China requesting a total of 217.34 tonnes of CFCs for the manufacture of metered dose inhalers (MDIs) in 2015. MTOC recommendations are for a total of 182.61 tonnes of CFCs for the manufacture of MDIs.

In 2009, the first year of the essential use process for Article 5 Parties, MTOC reviewed nominations from eight Article 5 Parties. It is very encouraging to note that, four years on, only one Article 5 Party is nominating CFCs for MDIs for 2015. There have been significant reductions from about 2,400 tonnes of authorised essential use CFCs for Article 5 Parties in 2010 to about 220 tonnes of CFCs nominated by China for 2015, which is stated to be its last nomination. Also, no nomination was received from Russia, meaning that no non-Article 5 Party nominated CFCs for MDI manufacture. Both of these developments signal the imminent global phase-out of CFC MDIs. Parties are to be commended for their efforts to phase-out CFCs from the manufacture of MDIs, which in the last two decades has consumed almost 70,000 tonnes of CFCs under essential use exemptions.

It is possible that China may be able to manage its phase-out from CFC stockpiles, although this is not yet clear. Despite reported stockpiles, MTOC is recommending an essential use exemption for CFC production and consumption for 2015 in the expectation that China would supply its requirements from accumulated stockpile, with new CFCs produced only if absolutely necessary.

Some Parties are still reporting that CFC MDIs are being imported into and are available in their markets. Removal of import licences for CFC MDIs would resolve this issue.

4.2.4 Stockpiles

Stockpiles of pharmaceutical-grade CFCs exist around the world. It is difficult to quantify stockpiles accurately in the absence of accounting frameworks being provided and other information on stockpiles from some Parties. Some CFCs are surplus and may need to be destroyed. Judicious management of these stockpiles may avoid the need for new CFC manufacture. However, in practice, it has proved difficult to transfer stockpiles of CFCs between Parties or even companies due to complex commercial, technical, regulatory and logistical reasons. Stockpiles might also still be used to manufacture CFC MDIs in countries that are no longer nominating for essential use CFCs. Some countries advise that CFC MDIs

continue to be imported despite a range of alternatives already existing. Trade in obsolete CFC MDIs is likely to continue until CFC stockpiles to manufacture MDIs are depleted or destroyed.

4.2.5 China

Year	Quantity nominated
2015	217.3355 tonnes

Specific Use: MDIs for asthma and COPD

Active ingredients and intended markets for which the nomination applies:

Active Ingredient	Intended market	2015 Quantity (Tonnes)
Beclomethasone	China	9.473
Budesonide	China	11.8875
Datura metel extract/clenbuterol	China	2.0
Dimethicone	China	0.2
Ipratropium/Salbutamol	China	0.745
Isoprenaline	China	28.0
Salbutamol	China	160.46
Sodium cromoglycate	China	4.57
Total		**217.3355**

Recommendation:

Recommend 182.61[2] metric tonnes of CFCs for the manufacture of MDIs for the active ingredients beclomethasone, budesonide, datura metel extract/clenbuterol, dimethicone, ipratropium/salbutamol, and salbutamol for 2015.

Unable to recommend 34.73 tonnes CFCs for the manufacture of MDIs for the active ingredients beclomethasone, isoprenaline, salbutamol, and sodium cromoglycate for 2015.

Comments:

China is commended for the detailed analysis undertaken in its essential use nomination for 2015 and in its clarity and responsiveness to additional questions from MTOC. The Chinese nomination for 2015 is for a total of 217.34 tonnes. This is marginally less (4.2 tonnes) than the nomination received for the year 2015 in 2013 and an 8% decrease on the exempted quantity for 2014 (235.05 tonnes). Furthermore, the reported usage of CFCs for MDI production in 2013 was 165.16 tonnes, a significant reduction from the 353 tonnes used in 2012, and a smaller quantity than those nominated for subsequent years. In response to questions regarding past, current and future requirements, China explained that the main reasons for the decrease of CFC consumption in 2013 were successful transition to HFC

[2] 182.6055 tonnes exactly, according to the nominated quantities.

MDIs by two of its largest manufacturers and production problems with some CFC MDI manufacturers. The nomination is only for CFC MDIs for domestic use. The Chinese nomination clearly states that CFCs will not be used to manufacture MDIs for export in 2015.

Demand is expected to grow for CFC MDIs in 2014 and 2015 due to an increased emphasis on inhaled therapy. Some doctors and patients in China still choose less effective oral medicines or injections instead of MDIs as well as traditional medicines to relieve or cure asthma. According to a 2012 investigation carried out as part of an awareness campaign, only about 10 per cent of the patients were using MDIs, but these numbers are growing in line with the rapid development of the country.

Furthermore, China has stated that 2015 will be the last year to manufacture salbutamol CFC MDIs, thereby providing sufficient product to allow salbutamol HFC and CFC MDIs to co-exist over a subsequent transition period of one year. Thus, this will be the last year of nomination by China for salbutamol, with a complete phase-out of salbutamol CFC MDIs by December 31, 2016. For beclomethasone, China has stated that 2016 will be the last year to manufacture CFC MDIs, with complete phase-out by December 31, 2017. The nominated quantity of CFCs for beclomethasone and budesonide is less than 22 tonnes for 2015; future requirements for beclomethasone and budesonide could be met from stockpiles.

According to the Accounting Framework and the nomination, China's total stock of CFCs at the end of 2013 was 476.6 tonnes, including 132.6 tonnes held by China MDI manufacturers with the balance of 344 tonnes held by China's CFC manufacturer. This took into account the sale and export of 212 tonnes of CFCs to Russia in 2013. MTOC notes that this supply was achieved from stocks of existing bulk CFC, with no new manufacture required. Combining the exemption for 2014 (235 tonnes) with the MTOC recommendation of 182.61 tonnes for 2015, there may be sufficient stockpiles to permit a successful transition without the need for further manufacture of bulk CFCs. This assumes that the stocks of bulk CFC contain the requisite amounts of CFCs 11 and 12. Also, it does not take into account quantities that might be supplied by China to the Russian Federation to meet its authorised essential use CFC quantity for 2014 (up to 212 tonnes). MTOC has previously recommended that prudent strategic reserves (stockpiles) should be limited to no more than 12 months of use, and less as phase-out nears completion. Cautious management of CFC stockpile in the final stages of CFC MDI manufacturing phase-out will be required to avoid the manufacture of new CFCs unnecessarily on the one hand and the costly destruction of surplus on the other.

MTOC notes that the conversion projects supported by UNIDO remain on track for a projected completion of December 2015 (revised from the original date of December 2013). In China, the lack of capital in small companies and high price of patent rights and royalties has been an impediment factor in technology transfer. This caused delays in starting early production of CFC-free MDIs. MTOC has observed that some countries had significant surplus CFCs remaining at the end of phase-out of CFC MDIs, which can result in destruction costs to industry or unnecessary use of CFCs to manufacture MDIs that are no longer essential to patients. Uniquely, China is both the last manufacturer of CFCs and consumer of CFC MDIs. Therefore it will need to ensure stockpiles are effectively managed to avoid surplus at the end of transition, including the evaluation of MDI manufacturers' stockpiles as part of the allocation of CFC quotas.

CFCs for the manufacture of salbutamol MDIs account for about 74 per cent of the nominated quantities for 2015 (160.46 tonnes). The CFC quantities nominated for 2015 for the manufacture of salbutamol MDIs are a 10 per cent reduction of those nominated for 2014 (177.52 tonnes). This is against a background of two salbutamol CFC-free MDIs now sold by domestic manufacturers (Shandong Jewim Pharmaceutical Co., Ltd. and Yanghzou Sanyao Pharmaceutical Co., Ltd.) and one approved imported salbutamol HFC MDI, marketed at the same price as the local products. There are a further 6 companies that should be in position within the next 12 months to submit applications to manufacture salbutamol HFC MDI

products. The production of CFC-free MDIs in China is expected to reach 20 million cans in 2015. In the next few years, companies will adjust the production to meet the needs of the patients according to the clinical demand. So it appears that China is well on track to meet its proposed salbutamol CFC MDI manufacturing phase-out date by the end of 2015.

Final phase-out

The China transition strategy states that the manufacturing phase-out date for salbutamol CFC MDIs will be the end of 2015, and for other CFC MDIs the end of 2016. Decision IV/25 implies that when a Party applies for an essential use exemption, it qualifies only for the amount that cannot be supplied from available stockpiles. It is possible that China has stockpile available to supply its CFC requirements in 2015. Despite reported stockpiles, MTOC is recommending an essential use exemption for CFC production and consumption for 2015 in the expectation that China would supply its requirements from accumulated stockpile, with new CFCs produced only if absolutely necessary. A similar approach was applied to nominations from the United States and the European Union when it was unclear to MTOC to what extent stockpiles might have been available to meet future requirements.

Companies undertaking active research and development

In 2008, the 56th ExCom meeting approved a project for China for the phase-out of 323 ODP tonnes (for a baseline in 2007) for MDI conversion. At the time, the project was established to phase out ODS consumption in 38 enterprises, including licence cancellations, for conversion of a total of 25 MDI product types. The Ministry of Environmental Protection and the China Food and Drug Administration (CFDA), in conjunction with the China Center of Pharmaceutical International Exchange, have been working in cooperation with UNIDO to implement the project. The project has seen some rationalisation of the number of enterprises manufacturing MDIs, with fewer than the original 38 enterprises entering contracts. This is reflected in the decreasing number of enterprises requesting CFCs under China's essential use nominations each year.

In 2014, 13 companies have stated they are undertaking research to re-formulate at least one of the entities they are already marketing. One company, Shanxi Medical University, is only just beginning to research reformulation of salbutamol CFC MDIs and has not yet begun research to reformulate beclomethasone CFC MDIs.

Some progress has been made, with a number of companies applying for licences to manufacture and market HFC MDIs. However, for isoprenaline, 5 companies have either not begun formulation or given up. One company (Jinan Weimin) is only at the stage of formulation screening.

Salbutamol

The nominated CFC quantities, to manufacture salbutamol MDIs for 2015, account for about 74 per cent of the total requested. China's salbutamol phase-out plan is predicated on the marketing of four locally produced salbutamol HFC MDIs in order for CFCs to be considered non-essential for salbutamol MDIs. The plan also states that salbutamol CFC MDI manufacturing should conclude by the end of 2015.

There are currently two salbutamol HFC MDIs on the market. A third salbutamol HFC MDI is the subject of a production registration application made in March 2014. One further locally produced salbutamol HFC MDI is needed to meet the criteria for phase-out. China is likely to succeed in phasing out salbutamol CFC MDIs within its transition strategy's target date of end 2015.

However, as stated above, one company, Shanxi Medical University, is only just beginning research to reformulate salbutamol CFC MDIs. MTOC is unable to recommend the nominated CFC quantity for this company for salbutamol due to the low likelihood of timely reformulation.

MTOC recommends 159.19 tonnes for the manufacture of salbutamol CFC MDIs for 2015 (160.46 tonnes less 1.27 tonnes).

Isoprenaline

The nomination includes 28 tonnes of CFCs for MDIs containing the non-selective[3] beta-agonist isoprenaline for 2015 from one company (Jinan Weimin). In the 2013 report, MTOC indicated that it would be unlikely to recommend CFCs for the manufacture of isoprenaline MDIs unless replacement isoprenaline HFC MDIs were in clinical trials. However, Jinan Weimin reports slow progress in reformulation and also increased its CFC stockpile by 50 per cent during 2013. Isoprenaline HFC MDIs are still undergoing stability testing and are not in clinical trials.

In 2013, MTOC stated that due to the low likelihood of timely reformulation and the emerging availability of suitable salbutamol CFC-free alternatives, MTOC would be unlikely to recommend CFCs for isoprenaline MDIs in any future nomination. Since reformulation of isoprenaline is not making significant progress, MTOC believes that reformulation and marketing in an HFC MDI is unlikely to be completed before the end of 2015. This means that China's phase-out plan is likely to proceed with salbutamol as the only alternative in the beta-agonist category, as elsewhere in the world.

MTOC is unable to recommend 28 tonnes of CFCs for the manufacture of isoprenaline MDIs due to the low likelihood of timely reformulation.

Inhaled corticosteroids

For the inhaled corticosteroid category, one company has received manufacturing approval for beclomethasone HFC MDIs, with production licence granted in September 2012 and the product coming into the market in 2013. Another company is planning to submit an application to CFDA for a beclomethasone HFC MDI in the first quarter of 2014. In addition, licence applications were made for two ciclesonide HFC MDIs, with production licences granted in December 2012. Progress is also being made with budesonide. One company has completed clinical trials for budesonide inhalant suspension, for which it has applied for manufacturing licence. The same company has also completed clinical trials for a budesonide powder inhaler. Once these CFC-free products have reached the market, of which at least two are beclomethasone, according to China's transition strategy, CFC MDIs will then become non-essential for this category.

One company, Shanxi Medical University, has not yet begun research to reformulate beclomethasone CFC MDIs. MTOC is unable to recommend the nominated CFC quantity (0.89 tonnes) for this company for beclomethasone CFC MDIs due to the low likelihood of timely reformulation.

For 2015, MTOC recommends 8.583 tonnes of CFCs to manufacture beclomethasone MDIs (9.473 tonnes less 0.89 tonnes) and 11.8875 tonnes of CFCs to manufacture budesonide MDIs.

Sodium cromoglycate

The nomination includes 4.57 tonnes of CFCs to manufacture sodium cromoglycate MDIs for 2015, to be used by one company. This company has made a registration application for sodium cromoglycate HFC MDI and has received the acceptance form. Another company has developed a DPI formulation (replacing its CFC MDI), which is expected to be submitted for regulatory approval in the first quarter of 2014. Another company has been marketing a DPI formulation for several years. Under China's transition strategy, CFCs become non-essential

[3] Non-selective refers to beta-agonists that affect the lungs and heart. Selective beta-agonists have much fewer, if any, cardiac effects.

for this category when there is one CFC-free product available. Last year MTOC indicated that it would recommend the nominated quantities for one last year to facilitate transition to CFC-free products during 2014. MTOC is unable to recommend the requested CFCs (4.57 tonnes) to manufacture sodium cromoglycate MDIs in 2015 because alternatives are or will be available.

Combination products

The nomination requests a total of 2.745 tonnes of CFCs to manufacture two combination inhaler products, namely, ipratropium with salbutamol sulphate (0.745 tonnes) and datura metel extract with clenbutarol (2 tonnes), the latter which is discussed under traditional Chinese medicines.

The quantity of CFCs requested for ipratropium and salbutamol combination product (0.745 tonnes) for 2015 is the same requested for 2014, and is maintained at the same level based on the prediction that clinical demand of inhaled drugs is not decreasing.

MTOC restates its position from last year that, at this stage of the phase-out, a combination product is not essential when the separate drugs are available in CFC-free formulations. Ipratropium is already non-essential under China's transition strategy, and the shift to salbutamol HFC MDIs is underway. However, to ease market transition, MTOC recommends 0.745 tonnes of CFCs to manufacture ipratropium and salbutamol combination product for 2015 as the final year.

Dimethicone for pulmonary oedema

Dimethicone in CFC MDIs is used only in China to treat acute toxic pulmonary oedema. This use is supported by anecdotal rather than scientific evidence in the nomination. The nomination requests 0.2 tonnes of CFCs for 2015, as in previous years. An alternative propellant is being investigated but reformulation has been difficult. In its 2013 report, MTOC recommended 0.2 tonnes of CFCs for dimethicone MDIs for 2014 due to the progress in reformulation reported at that time. In this current 2014 nomination, China has reported that the testing of the new formulations has not yet moved into clinic trials, however there seems to be a commitment to reformulation with the company planning to submit registration application in 2015. MTOC has some concerns that reformulation might take longer than expected. However, due to the lack of alternative emergency treatment for acute toxic pulmonary oedema in remote areas of China, and the expectation of registration application submission in 2015, MTOC recommends 0.2 tonnes of CFCs to manufacture dimethicone MDIs for 2015. MTOC anticipates that this is likely to be the last nomination from China for CFCs used for dimethicone MDIs. MTOC may be unable to recommend any future requested CFC quantities for this use without significant progress in reformulation.

Traditional Chinese Medicines

The nomination includes 2 tonnes of CFCs used to manufacture combination MDIs containing clenbuterol, a short-acting beta-agonist, and "datura metel extract", a herbal form of an anticholinergic medicine (like ipratropium). China has stated that this CFC MDI is supplied to remote areas of south-west China where other inhaler products are less freely available.

No evidence has been presented to differentiate the effectiveness of the different ingredients, or to suggest that the inhaled herbal component is of any additional value over and above the known bronchodilator, clenbuterol. Moreover, no evidence has been presented that shows the combination product to be superior or even equivalent to more common asthma treatments, such as the bronchodilator salbutamol.

Nevertheless, the manufacturer is converting its manufacture to HFC MDIs and since 2013 has finished formulation, process and quality research of CFC-free MDIs, and has gained CFDA supplementary registration approval. Since there has been reformulation progress, and due to the current lack of alternatives in the remote region where the product is used, MTOC

recommends 2 tonnes of CFCs to manufacture MDIs containing clenbuterol/datura metel extract for 2015. MTOC anticipates that this will be the last nomination from China for this product.

Recommended quantities in accordance with Decision XV/5(3):

Active Ingredient	**Intended market**	**2015 Quantity (Tonnes)**
Beclomethasone	China	8.583
Budesonide	China	11.8875
Datura metel extract/clenbuterol	China	2.0
Dimethicone	China	0.2
Ipratropium/Salbutamol	China	0.745
Isoprenaline	China	0.0
Salbutamol	China	159.19
Sodium cromoglycate	China	0.0
Total		**182.6055**

4.3 Reporting Accounting Frameworks for Essential Use Exemptions

Regarding reporting accounting frameworks for essential use exemptions, Decision VIII/9(9) states, "*...to request each of the Parties that have had essential-use exemptions granted for previous years, to submit their report in the approved format by 31 January of each year*".

Having information on stockpiles, accumulated under CFC essential use exemptions granted by Parties for previous years, allows Parties to track management and deployment of stockpile until depleted. Information on stockpiles is particularly important in the last stages of global CFC MDI phase-out and valuable in avoiding new production.

The following section describes information provided in reporting accounting frameworks by Parties with authorised essential use exemptions for 2013 that are not nominating essential uses for 2015. It also provides updates on Parties with authorised essential use exemptions in previous years that have not reported accounting frameworks. A summary regarding the reporting accounting framework for China is included in the preceding section.

4.3.1 Argentina

Argentina originally expected to nominate essential CFC uses until 2014. However, the transition proceeded faster than expected, with the result that Parties last authorised an essential use exemption in 2011; Argentina has not made any essential use nominations since then. Argentina's accounting framework for 2012 showed that it used about 15 tonnes from CFC stockpiles to manufacture MDIs. CFC stocks on hand at the end of 2012 decreased to about 5 tonnes. Argentina has not submitted a subsequent accounting framework.

All the companies except one in Argentina opted for technologies using HFC-134a as the excipient. Laboratorio Pablo Cassará initially converted their salbutamol MDI production to HFCs, but is now implementing its MLF project to ultimately use isobutane as the propellant. MTOC understands that Laboratorio Pablo Cassará plans to launch a salbutamol isobutane

MDI in 2016. Manufacturers in Argentina advised there have been no reported adverse reactions to the replacement HFC MDIs (although no statistical data were provided) except for some complaints about a change in taste.

4.3.2 Egypt

Parties authorised an essential use exemption of 227.4 tonnes of CFCs for the manufacture of MDIs in Egypt for 2010. However, no accounting framework has been reported for authorised essential uses in 2010. Egypt has not made any essential use nomination since 2010. MTOC understands that Egypt had been manufacturing CFC MDIs until third quarter 2011 using the existing CFC stockpile and that the CFC MDI manufacturing conversion to CFC-free alternatives had been completed by the end of 2011. MTOC has not received any information concerning any residual CFC stockpiles or inventories of CFC MDIs, including any programs to destroy them.

4.3.3 European Union

The European Union has not had any authorised essential use exemptions since 2009. An accounting framework for 2013 was received from the European Union. For 2013, the European Union destroyed 0.3 tonnes of CFCs and used 2.8 tonnes CFCs for MDI and MDI valve manufacture in Italy. At the end of 2013, the European Union had completely depleted its CFC stockpile. During 2013, Italy ceased using CFCs to manufacture a combination inhaler containing salbutamol sulphate and ipratropium bromide sold into that market. CFCs used by an Italian company in the manufacturing process for valves supplied to CFC MDI manufacturers also ceased during 2013. This indicates that those countries historically receiving valves from the Italian manufacturer (Egypt, Pakistan, Russian Federation and Syria) will no longer be supplied with those valves. The entire stocks of CFCs in the European Union have now been consumed or destroyed.

4.3.4 India

Accounting frameworks on available stockpiles have not been received from India since 2011. In 2011, India reported CFC stocks of 226.295 tonnes, including 24.402 tonnes of non-pharmaceutical grade CFCs manufactured during start-up of CFC manufacturing. It is understood that India has converted its MDI manufacturing to be CFC-free. There is no information available on remaining CFC stockpiles in India.

India has a wide range of CFC-free inhalers, including dry powder in a variety of devices. Single-dose DPIs have been found to be cheap, effective and easy to use as well as being environmentally friendly. These may prove to be a useful alternative to MDIs for most patients with asthma and COPD in the long term.

4.3.5 Mexico

Parties authorised an emergency essential use of 6 tonnes CFCs for the manufacture of MDIs in Mexico in 2011 under an arrangement where Mexico agreed to destroy an equivalent ODP weighted amount of ODS. Mexico originally planned to destroy CFC-11 to compensate the emergency essential use acquired by import. MTOC has been informed that Mexico has completed conversion of CFC MDI manufacturing to CFC-free MDIs. A large part of the CFCs that remained in Mexico were used by Boehringer Ingelheim to manufacture a CFC MDI product. This product has since been discontinued, and 18 tonnes of remaining stocks of mixed CFC-11, -12, and -114 will be destroyed or deployed for essential use. A local producer, Laboratorios Salus, has about 15 tonnes of out of specification CFC stockpile remaining, which is intended for destruction, and a small additional amount that may be

suitable for MDI production but will be destroyed if necessary. Mexico reported that CFC MDIs are still entering the country, mostly from India. Mexico is trying to remove the registrations for these products.

4.3.6 Pakistan

Parties authorised an essential use exemption of 24.1 tonnes of CFCs for the manufacture of MDIs in Pakistan for 2012. In its accounting framework for 2012, Pakistan reported 12 tonnes of CFCs in stockpile at the end of the year. An accounting framework for Pakistan for 2013 has not been received in 2014.

One company, Macter, had a small stockpile of CFCs purchased from Honeywell. This company stopped manufacturing CFC MDIs in December 2012, and so, would likely need to dispose of any remaining stockpile. Zafa, despite having successfully applied to receive funding for plant conversion, is not proceeding with this process. GSK Pakistan currently imports salbutamol HFC MDIs but has installed a new plant to manufacture salbutamol HFC MDIs locally, which is likely to start production later in 2014 and replace the more expensive imported products. Chiesi imports HFC MDIs from Europe, which are priced higher than locally manufactured or Chinese imported HFC MDI brands.

The regulatory authorities banned the import of CFC MDIs, as of December 2012. Despite this, 70 per cent of unit sales in 2013, as in 2012, were CFC MDIs, mainly imported by Getz Pharma from Jewim Pharmaceuticals in China. From January 2014, Getz Pharma stopped the sale of CFC MDIs, instead importing HFC MDIs from Jewim Pharmaceuticals. Macter also manufactured CFC MDIs before the end of 2012, which were sold in 2013 and will continue to be sold in 2014. The imported Chinese MDIs are popular, as are Macter's, because of their affordability. Macter is now converting its manufacturing lines to HFC MDIs, anticipating production will commence in 2015.

Imported DPIs are currently used by about 20 per cent of asthma and COPD patients, having been only 9 per cent one year previously. Single-dose DPIs imported by Highnoon Laboratories from Cipla India are more immediately affordable for patients because they contain fewer doses than pressurised MDIs. Macter has also launched a new DPI for tiotropium.

MTOC notes that Pakistan is making some progress in transition to HFC MDIs but it does not yet have one locally produced HFC MDI on the market. To date, salbutamol HFC MDIs imported from Australia by GSK cost US$2.00, and the Getz Pharma salbutamol HFC MDI imported from China costs US$1.75. In comparison, the locally produced Macter salbutamol CFC MDI costs US$1.25.

4.3.7 Russian Federation

The Russian Federation did not submit a nomination this year for 2015, in line with its announcement in 2013, that its nomination for 2014 would be its last. The Russian Federation provided an accounting framework for 2013 that reflects imports of CFCs from China to produce CFC MDIs. The amount imported was 212 tonnes, which equals the value of the nominated amount for that year.

According to the accounting framework, there was no stockpile of CFCs in the Russian Federation at the start of 2013. Russia acquired the entire amount of 212 tonnes under an essential use exemption authorised by Parties but there was a decrease in the use of CFCs for the production of MDIs in 2013 when only 142.80 tonnes were used. This is a reduction of almost one third in the level of consumption in recent years that had previously remained constant at around 210 tonnes (2010-2012). The reason behind the reduced consumption of

CFCs in 2013 was late delivery of imported CFCs, which arrived in the second half of 2013. As a result of this, the inventory at the end of the year 2013 was 69.20 tonnes.

The Russian Federation was authorised an essential use exemption of 212 tonnes CFCs to produce MDIs in 2014. Therefore the two MDI manufacturers of the Russian Federation will have up to 281.2 tonnes at hand for the production of CFC MDIs in 2014 if the entire 212 tonnes were acquired.

MTOC understands that the filling equipment to produce HFC MDIs under the project sponsored by GEF and carried by UNIDO is planned for delivery in November 2014. MTOC has not been able to learn whether regulatory approval of Moschimpharmpreparaty's salbutamol HFC MDIs, which was expected in the second half of 2013, has yet been granted.

The Russian Federation has stated[4] that it intends to source its pharmaceutical grade CFCs from China. MTOC has learned that one of the two CFC MDI producers is importing its CFCs directly from China, whereas the other producer uses the services of the intermediary importing Russian company. MTOC understands that this importing company has had some management problems, but MTOC has also been informed that, in principle, this should not affect its operations. MTOC does not know whether this will impact the pace of transition or the availability of sufficient MDIs for patients.

4.3.8 Syria

Parties authorised an essential use exemption of 44.68 tonnes of CFCs for the manufacture of MDIs in Syria for 2010. However, no accounting framework was reported for authorised essential uses in 2010 or subsequently. Syria has not made any essential use nomination since 2010. MTOC understands that Syria had been importing valves to manufacture CFC MDIs, indicating that CFC MDI manufacture would have been continued in this country until 2012. MTOC was aware that local manufacturers planned to invest on HFC MDI manufacturing facilities since 2011. The political situation of the country has not permitted to get further information about CFC stockpiles, CFC MDI production and phase-out.

4.3.9 United States

The United States has now phased out CFC MDIs, and has a wide range of CFC-free alternatives on the market. Under a US FDA rulemaking, the last CFC MDIs became non-essential on December 31, 2013. Primatene Mist, an over-the-counter CFC MDI for epinephrine, was withdrawn from sale in August 2013. On safety grounds, an epinephrine HFC MDI was not recommended for over-the-counter marketing by an advisory committee of the US FDA in February 2014.

Accounting frameworks and information on stockpiles have not been reported by the United States in 2014. There have been two separate CFC stockpiles in the US, one held by the MDI manufacturers, and one by the CFC manufacturer Honeywell on behalf of Boehringer Ingelheim. Some of the surplus reported was manufactured pre-1996. For the MDI manufacturers, the US previously reported a stockpile of 169 tonnes at the end of 2010, which has been running down in order to manufacture CFC MDIs. In 2013, the United States

[4] Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, Report of the Sub-Group on the Production Sector, UNEP/OzL.Pro/ExCom/71/63, 71st Meeting, Montreal, 2-6 December 2013.

reported a stockpile of 280 tonnes of pharmaceutical-grade CFCs (owned by Boehringer Ingelheim and Honeywell), which potentially were available for export to Parties with approved essential-use exemptions. MTOC understands that export had not occurred as of March 2014. The Russian Federation has stated that it intends to source its pharmaceutical grade CFCs from China. Unless circumstances change, it appears that remaining US stocks of CFCs will require destruction.