

**MONTREAL PROTOCOL  
ON SUBSTANCES THAT DEplete  
THE OZONE LAYER**



**UNEP**

**April 1999 Report of the  
Technology and Economic Assessment Panel**



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**Technology and Economic Assessment Panel**

- Part I: The Quarantine and Pre-Shipment Exemption of Methyl Bromide**
- Part II: Essential Use Nominations for Parties Not Operating Under Article 5 for Controlled Substances for 1997 Through 2002**
- Part III: Exports of Controlled Substances in Annex A and Annex B to the Montreal Protocol from Non-Article 5 Parties to Meet the Basic Domestic Needs of Article 5 Parties**
- Part IV: Exemption for Laboratory and Analytical Uses**
- Part V: Control of New Substances with Ozone Depleting Potential**
- Part VI: Progress and Development in the Control of Substances**
- Part VII: Background Information for the TEAP and Contact Information for TEAP Members and TOCs**



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**APRIL 1999 REPORT OF THE**  
**TECHNOLOGY AND ECONOMIC**  
**ASSESSMENT PANEL**



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## Introduction

The Tenth Meeting of the Parties to the Montreal Protocol (Cairo, November 1998) took a number of decisions, which request actions by the UNEP Technology and Economic Assessment Panel (TEAP). Responses of the TEAP to several of the 1998 requests, as well as responses to requests made in earlier Meetings of the Parties, are presented in this April 1999 report. The response of the TEAP and its Replenishment Task Force to Decision X/13 on the Replenishment of the Multilateral Fund can be found in a separate report “Assessment of the Funding Requirement for the Replenishment of the Multilateral Fund for the Period 2000-2002”, which is also dated April 1999.

The April 1999 TEAP report provides the responses from TEAP on the following decisions:

*Decision X/11*     *“The Quarantine and Pre-shipment Exemption of Methyl Bromide”*

Part I addresses the issues mentioned in Decision X/11, Article 1, paragraphs (a) through (e).

*Decision VIII/9*     *“Essential Use nominations for Parties not operating under Article 5 for controlled substances for 1997 through 2002”*

In accordance with Decision VII/34(5) the essential use nominations are dealt with in Part II of this report. It is of a similar set-up as the Essential Use chapters in the April 1997 and April 1998 TEAP reports.

*Decision X/15*     *“Exports of Controlled Substances in Annex A and Annex B to the Montreal Protocol from non-Article 5 Parties to meet the basic domestic needs of Article 5 Parties”*

Part III addresses this decision by analysing production and consumption data and future trends for CFCs, halons, CTC and methyl chloroform.

*Decision X/19*     *“Exemption for Laboratory and Analytical Uses”*

This decision requests the TEAP to report annually on the development and availability of laboratory and analytical procedures that can be performed without using the controlled substances in Annexes A and B of the Protocol. Part IV of this report is the first response of TEAP to this decision.

*Decision IX/24 “Control of New Substances with Ozone Depletion Potential”*

In Decision VII/34 (c) the TEAP was requested to report on progress and developments in the control of substances each year. Decision IX/24 requests the TEAP to report to each ordinary Meeting of the Parties on any new substances with a certain Ozone Depletion Potential. A report of the Solvents Technical Options Committee on two new substances (CBM and n-PB) is given as part V of this report.

*Decision VII/34 “Progress and Development in the Control of Substances”*

In Decision VII/34 (c) the TEAP was requested to report on progress and developments in the control of substances each year. Progress reports of different TOCs (Aerosols, Halons and Methyl Bromide) can be found in Part VI of this report.

*Decision VII/34 “Background and Contact Information for TEAP Members and TOCs”*

TEAP reported on progress towards improved geographical balance and other structural adjustments in its March and June 1996, its 1997 and 1998 reports. Part VII of this 1999 report presents further information on the TEAP and its TOCs, including contact details of the TEAP members and membership lists of the different TOCs. It also gives background information of the TEAP members (Decision VII/34, paragraph (e)(iv)).

This report has also been transferred to the TEAP Internet Site (<http://www.teap.org>).



**UNEP**

**Technology and Economic Assessment Panel**

**Part I: The Quarantine and Pre-Shipment  
Exemption of Methyl Bromide**



# **1. Executive Summary**

## **1.1 Introduction**

The consumption of methyl bromide (MB) for quarantine and pre-shipment (QPS) by all Parties is an emissive use which is unregulated under the Montreal Protocol. For other ODS such as CFCs, there are some limited essential use exemptions agreed by the Parties but these apply only after phaseout. For MB, QPS consumption is currently exempt from all Protocol controls such as a freeze, reductions in consumption and phaseout. As there are no controls in place for QPS, Parties are not eligible for Multilateral Fund assistance for various types of projects to implement alternatives for QPS uses.

Decision X/11 taken at the Cairo Meeting of the Parties in November 1998 requested TEAP to provide a report on the QPS exemption, largely in response to concerns by the Parties that over 18% of the MB consumed was excluded from control and, moreover, this consumption appeared to be increasing. TEAP was requested by the Parties to specifically address the volumes and uses of MB for QPS; the existing and potential availability of alternative substances and technologies; the operation of the exemption; options for reducing the use of MB for QPS; and the scope and relevance of other definitions of QPS in other treaties and conventions, and their applicability to the Protocol definition and use of QPS.

In order to provide information to TEAP, the Methyl Bromide Technical Options Committee (MBTOC) met in San Francisco on 25-28 January 1999 to draft material addressing QPS topics requested by the Parties. Dr Bob Griffin, (Coordinator International Plant Protection Convention Secretariat, FAO, Rome) was invited and attended this meeting as a technical expert to address specific issues.

## **1.2 Options for the Parties to consider**

Options for the Parties to consider were outlined in the report following discussion on each topic. A list of these options was collated, and the implications of each option discussed in the Section 9 of this report. They are briefly summarised in this Section.

The Protocol definition of 'quarantine' is broader than the use of this term in other international conventions and treaties. However, this could be regarded by the Parties as appropriate as MB is currently being used for some pest control practices that involve human health. Human health aspects are not specifically considered in the definition of *plant* quarantine in other treaties and conventions.

The application of 'pre-shipment', as intended by the Parties, appears to be without a parallel in other treaties and conventions. One of the main uses of 'pre-shipment' is for treating cosmopolitan pests in durable commodities such as grain, and in treating empty vessels prior to loading. The Parties could consider inserting 'official' into the definition of 'pre-shipment' to ensure that MB is authorised appropriately by a government, and not commercial agents, which is in keeping with the intent previously ascribed to this definition by the Parties. In order to ensure efficient and clear implementation of the use of pre-shipment, insertion of the treatment period as '...within 14-days prior to export...' would ensure that a single treatment is applied, rather than multiple treatments applied during storage. In addition, 'stored product authority' could be added as in many cases pre-shipment treatments would be authorised by such authorities. If the Parties consider these suggestions useful, pre-shipment could be clarified as follows:

'Pre-shipment applications are those applied *within 14 days* prior to export to meet the *official* requirements of the importing country or existing *official* requirements of the exporting country. *Official* requirements are those which are performed by, or authorised by, a national plant, animal, environmental health or stored product authority.'

Parties may wish to note that additional information on QPS is desirable in the future and may wish to consider whether it is necessary to strengthen the requirement for reporting on QPS volumes and uses. MBTOC suggested that Parties might wish to consider making reporting on QPS volumes mandatory rather than voluntary.

In order to address the concern that Parties expressed about increasing amounts of MB being consumed for QPS, Parties could consider capping QPS MB consumption based on baseline consumption for an agreed number of years. This has been accepted by the European Union, for example, in a 'Common Position' on a new EC Regulation. The Parties could consider whether a similar measure could be appropriate under the Protocol.

While recovery-recycling of MB is feasible, it is currently expensive and therefore not widely applicable. The Parties could consider investment in such technology as an interim measure, but this would divert valuable funds away from projects that would result in non-MB alternatives and a more permanent solution. However, Parties could consider cost-effective, interim measures such as encouraging better *containment* of MB by ensuring fixed-wall facilities are as gas-tight as possible using testing procedures that are well documented. Parties could consider encouraging operators to reduce the volume of MB that is consumed in each fumigation cycle by developing treatments at elevated temperatures and/or for extended time periods, where

the commodity can tolerate such treatment and official importing country approval is forthcoming.

### 1.3 QPS Consumption

MBTOC sent a survey on QPS uses to 97 Parties, and received responses from 55 Parties (57% response rate). Some of the responses were incomplete. The respondents' QPS consumption in 1997 accounted for 5,828 tonnes of MB which was divided about equally between Article 5(1) and non-Article 5(1) Parties. Out of 55 countries responding, 9 (16%) reported more than 100 tonnes of MB consumed for QPS purposes, while 3 (5%) countries reported more than 500 tonnes consumed for QPS.

The poor response to the survey could have been due to the relatively short response time required from Parties, inconsistency in Party interpretation of 'quarantine' and 'pre-shipment', and lack of formal monitoring and reporting procedures by many Parties. These data were therefore insufficient to improve on previous estimates provided by TEAP (1995), and MBTOC (1998) that indicated QPS accounted for 12,900 - 15,000 tonnes or 18-22% of global consumption. Insufficient response by Parties to the survey made it impossible to confirm whether QPS consumption was increasing or decreasing. MBTOC will continue to collate information that arrives after this report is published with a view to presenting an update on QPS volumes in the future.

About half of the Parties used MB for pre-shipment purposes, mainly for treatment of logs, timber, wood products and packaging as a requirement of the importing country, while half reported no consumption for pre-shipment. Pre-shipment treatment of durable commodities was the most prevalent QPS use reported from the survey. Substantially more Parties consumed MB to meet the phytosanitary requirements of importing countries than the requirements of exporting countries.

Only 25% of the respondent Parties reported use of MB for perishable commodities, mainly for treatment of ornamental and propagative plant material to meet the requirements of importing countries. About 30% of the Parties reported use of MB for quarantine treatments of durable commodities. Products treated included grains, legumes, seeds, animal fodder, coffee, cocoa beans, dried fruit, nuts, dried herbs and medicinal plants, logs and timber.

#### 1.3.1 Operation of the QPS exemption

The process of collecting data for the QPS survey by MBTOC revealed that many Parties had not been monitoring QPS and therefore found it difficult to identify consumption volume and use. In addition, many Parties might have been interpreting the terms 'pre-shipment' and 'quarantine' inconsistently, and in some cases, incorrectly exempting use for contractual treatments.

Inconsistent interpretation and incorrect application of the exemption would create difficulties for data collection and reporting, and could result in multiple applications of a treatment whereas just one would satisfy the phytosanitary requirements.

Some Parties have implemented legislation and agreements to curb the use of MB consumed for QPS. Denmark has no exemption for QPS, instead relying on the use of alternatives to MB for QPS and the right of the Ministry of Environment and Energy to waive the ban in very exceptional cases. Recently, member states of the European Union agreed on a Common Position for a new EC Regulation on ozone depleting substances which would cap MB QPS consumption at an average of 1996-1998 consumption.

## **1.4 Alternatives to MB for quarantine and pre-shipment**

### **1.4.1 Definition of an alternative**

MBTOC (1998) defined 'alternatives' as those non-chemical or chemical treatments and/or procedures that are technically feasible for controlling pests, thus avoiding or replacing the use of MB. 'Existing alternatives' are those in present or past use in some regions. 'Potential alternatives' are those in the process of investigation or development.

### **1.4.2 Management of pest risk**

The majority of perishable and durable commodities in commercial trade are not exposed to pre-shipment or quarantine treatments. However, for some commodities, a treatment may be necessary to minimise the risk of pests becoming established in new regions. Once a pest is accidentally introduced, eradication is extremely difficult, costly and labour intensive. Quarantine pests detected in a country or region previously free of them can result in considerable cost caused by suspension of exports, eradication measures and implementation of a disinfection treatment if eradication is not achievable.

Most importing countries therefore inspect consignments and sample product for pests in order to minimise the risk of accidentally importing pests. If one or more pests of quarantine concern are detected, a treatment is undertaken or, if no treatment method is available for use, the consignment may be rejected, re-shipped to the country of origin or to some other destination, or destroyed.

Treatments with MB or alternatives aim to achieve a pest-free status for perishable and durable commodities by controlling pest infestation prior to shipment, during shipment or at point of receipt. Treatments may sometimes be required under exporting country legislation to meet domestic standards requiring lack of pest infestation at point of export. In the case of MB pre-shipment treatments, exemptions from Protocol controls only apply to those



countries whose domestic legislation was in effect at the time of the passing of Decision VI/11 for non-Article 5(1) Parties (7 October 1994) and at the time of the passing of Decision VII/5 (7 December 1995) for Article 5(1) Parties.

Mandatory treatments in the exporting country may be required if pests are difficult to detect, or if the pest is of extreme concern to the importing country. Such treatments aim to minimise pest risk through research that relies on extensive data collection and reporting aimed at achieving a level of phytosanitary security of Probit 9, equivalent to 99.9968% pest mortality. Probit 9 statistical analysis has been the accepted criterion for determining the success of a disinfestation treatment since it was first proposed in 1939. Acceptance of a new quarantine treatment by contracting Parties has traditionally taken from two to fifteen years because of extensive data collection, reporting requirements and bilateral negotiations to gain approval.

Acceptance criteria other than Probit 9 have been implemented by some Parties, some based on Guidelines recently developed by the IPPC that complement the principles of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the 'SPS Agreement'). These guidelines seek to harmonise quarantine policies between countries and it is clear that these principles will influence the development and use of alternative treatments in the future, principally by encouraging Parties to consider setting the level of security based on an appropriate level of protection that is proportional to the risk.

#### 1.4.3 Perishable commodities

Most treatments for perishable commodities are quarantine treatments. Perishable commodities include fresh fruit and vegetables, cut-flower exports, some fresh root crops and bulbs, propagation material and ornamental plants. In contrast, most treatments for durable commodities are pre-shipment treatments. Durable commodities are those with a low moisture content that, in the absence of pest attack, can be safely stored for long periods. They include foods such as grains, dried fruits and beverage crops; and non-foods such as wood products and tobacco.

MBTOC noted at least thirteen different categories of alternative treatments e.g. heat, cold, pre-shipment inspection, were officially approved by Regulatory Agencies in one or more countries for disinfestation of perishable commodities, but only for specific applications. For each category of alternative to MB, MBTOC identified country-specific, official approval for specific commodities, or approval of several commodities within a class (e.g. citrus): *heat* treatments for at least eleven commodities including citrus, mango, papaya, bell pepper, eggplant, pineapple, squash, tomato and zucchini; *chemical* treatments for citrus, vegetables, cut flowers and bulbs; *cold* treatments for apples, pears, citrus, grapes, kiwifruit, carambola and avocado;

*pest-free zones* for apples, berryfruit, some vegetables, cucurbits, avocado and papaya; the *systems approach* for citrus, apples and melons; and *irradiation* for papaya, litchi and carambola.

Many treatments are under development to control many different pests on a wide number of commodities. Commercialisation of any of these treatments as replacements for MB will depend on a number of factors that include: proven treatment efficacy; commodity tolerance; equipment design and commercial availability; cost competitiveness; regulatory approval; logistical capability; availability and agreement on the scientific research required for regulatory approval; and technology transfer.

MBTOC recorded more than 270 alternative treatments for perishable commodities approved by a Regulatory Agency, largely compiled from the United States Department of Agriculture - Animal and Plant Health Inspection Service Treatment Manual. However, despite approval actual use of these treatments is not well documented. Despite this number and range of quarantine treatments, only a small proportion of commodities in commercial trade are treated in the export country using these alternatives. Most countries will not accept an alternative for a specific commodity until the treatment efficacy is proven for each commodity-pest combination. Post-entry alternative treatments used by the importing country are particularly problematical because many alternatives have neither been approved for treating a specific product on arrival, nor would they be easy to implement. To solve this problem, a range of officially approved alternatives are urgently needed to cope with a large and highly varied volume of produce entering via multiple air and sea ports. Such treatments would need to be able to treat perishable commodities quickly in order to avoid congestion at busy ports and loss of products.

#### 1.4.4 Durable commodities and structures

There are some major quarantine issues in durables, the most recent example being disinfestation of wood packing material for control of the Asian longhorn beetle prior to export of manufactured goods from China to the USA, Canada and Australia. Because of the large volume of MB involved, consumption by China would result in a 25-35% increase in worldwide consumption of MB for QPS, until such time that an alternative treatment is implemented.

MBTOC recorded a wide variety of alternatives to MB for disinfestation of durable commodities and structures. The principal alternatives in use for durables are phosphine, heat, cold and contact pesticides; for wood products, they are sulphuryl fluoride, chemical wood preservatives and heat; for means of conveyances, they include sulphuryl fluoride and heat. The choice of appropriate alternatives is dependent on the commodity or conveyance to be

treated, the situation in which the treatment is required, the accepted level of risk, the speed of action required and the cost. Some alternatives (e.g. some fumigants, heat treatment) may be implemented as stand alone treatments to replace MB in certain situations. In general, however, the level of risk may be brought to an acceptable level by combining two or more alternatives. A treatment based on combinations of measures (commonly called a 'systems approach') may be optimal in many situations.

Phosphine is the only available in-kind alternative extensively used, principally for stored cereals and similar products. Insect populations are capable of developing resistance to phosphine relatively easily, therefore MBTOC considered it important to use correct exposure and application technology to avoid development of resistance and loss of this prevalent alternative. Other fumigants include ethyl formate, carbon bisulphide and ethylene oxide. Sulphuryl (sulfuryl) fluoride is mainly used for controlling wood-destroying pests in residences and other buildings.

Treatment with controlled atmospheres, based on carbon dioxide or nitrogen, offers an alternative to fumigation for insect pest control, but not fungal pests. They are unlikely to be used where fast turn-around is necessary, unless the technique is combined with such measures as high pressure or raised temperature. Other physical methods of insect control include mechanical measures, cold, heat and irradiation treatments. Cold treatments are now used as part of IPM systems for stored products and artifacts. Heating can also synergise the effects of other treatments, for example fumigants, controlled atmospheres and inert dusts.

Where registered for use, contact insecticides may provide persistent protection against reinfestation. In some situations, the use of dichlorvos offers a direct alternative to MB, for disinfestation of bulk grain during turning or loading at point of export. Contact insecticides are not normally registered for use on processed commodities or dried fruit, nuts and cocoa.

#### 1.4.5 QPS methyl bromide treatments without an alternative

For perishable commodities, MBTOC noted there were no approved alternatives for certain economically important exports: Apple, pear and stonefruit that are hosts to codling moth; for berryfruit; for grapes infested with, for example mites, exported to some countries; and a range of root crops exported by countries if soil was present or pests of concern were detected on arrival.

For durable commodities, non-MB alternatives were not available for disinfestation of military equipment contaminated with soil against soil pathogens; oak logs with oak wilt fungus; fresh chestnuts and walnuts for immediate sale; seed-borne nematodes from alfalfa and some other seeds for

planting; codling moth and a variety of other stored product pests contaminating products that were for 'immediate' sale; empty ships where other methods have failed; and organophosphate-resistant mites in traditional cheese stores.

## **1.5 QPS uses by Article 5(1) Parties**

Some Article 5(1) Parties that import and export large quantities of cereal commodities are heavily dependent on fumigation with MB to satisfy their own or other countries' quarantine regulations. Several Parties, for example, export large quantities of rice, almost all of which is fumigated with MB immediately prior to shipment over a 24-48 hour period. As the longer treatment period would require changes in the present storage and export system, phosphine was not regarded as an attractive alternative in this case. However, phosphine may be suitable for empty ships and barges prior to commodity loading, and where regulations will permit, for in-transit fumigation.

Members of MBTOC gave examples of commodities that required pre-shipment or quarantine treatments for import or export. These commodities included mainly durable ones such as wood packing materials, tobacco, dried fish maws, seeds, cotton, logs, straw materials, and grain.

## **1.6 Recovery, containment and recycling**

### **1.6.1 Recovery and recycling**

There has only been limited research into the development of recovery systems for MB from fumigation operations. Most of that research has been directed at recovery from fumigation chambers. Only a few special examples of recovery equipment are in current commercial use, but data on their performance and operating costs were not made available to MBTOC.

The industry has considered many of the technologies previously under development both expensive to install compared with the cost of the fumigation facility itself, and expensive to operate because of high running costs associated with energy requirements. Also, because of their technical complexity, many processes would require a higher level of operator technical competence than is normally found at fumigation facilities.

Unlike some other ozone depleting substances where the interim needs of Article 5(1) countries can be met in part by 'banks' of recycled material, it is unlikely that this method will be practical for MB. This is because some of the MB used in any application reacts and breaks down and because some of the

recovery and recycling technologies under development are only suitable for 'in-plant' recycling.

If recovery is to be recognised as an acceptable method of reducing MB emissions to the atmosphere, it would be necessary to set specifications on aspects of fumigation such as equipment efficiency and minimal levels of emission. It would also be necessary to develop simple, cost-effective recovery and recycling technology before any consideration of widespread implementation could be considered feasible.

#### 1.6.2 Containment

There are a number of practices that, while they should be recognised as interim measures, they might prove cost-effective in reducing both the amount of MB that is being used in each fumigation cycle and in reducing inadvertent leakage.

Operators could consider reducing the volume of MB that is consumed in each fumigation cycle by developing treatments at elevated temperatures and/or for extended time periods, where the commodity can tolerate such treatment and official importing country approval is forthcoming.

Parties could also consider encouraging better *containment* of MB by ensuring fixed-wall fumigation facilities are as gas-tight as possible, using testing procedures that are well documented.

### 1.7 QPS relationship to other conventions and treaties

Several other international agreements mention or cover terms relevant to the Protocol's definition of QPS.

#### 1.7.1 Technical Barriers to Trade Agreement

The World Trade Organisation (WTO) Technical Barriers to Trade Agreement aims to avoid unnecessary obstacles to trade associated with technical regulations and standards for industrial and agricultural products.

The TBT applies to measures which may be used to assure *quality*. Pre-shipment treatments would generally be considered to deal with 'quality' for WTO and IPPC purposes and they would regard pre-shipment as falling under the TBT Agreement.

#### 1.7.2 SPS Agreement

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) defines the basic rights and obligations of

Parties with regard to the use of measures applied to protect human, animal or plant life or health, including procedures to test, diagnose, isolate, control or eradicate diseases and pests. This Agreement encourages Parties to base their national SPS measures on relevant international standards, guidelines and recommendations. Risk assessment provides the basis for measures applied in the absence of international standards.

In assessing pest risks, WTO Members are required to take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of disease/pest free areas or areas of low pest prevalence; relevant ecological and environmental conditions; and quarantine or other treatment.

### 1.7.3 IPPC

The Secretariat of the International Plant Protection Convention (IPPC), in co-operation with regional organisations operating within the framework of the IPPC, is responsible for developing international standards, guidelines and recommendations for plant health. The IPPC is recognised by the SPS Agreement as the organisation under which international standards for phytosanitary measures are established. In practice, the IPPC focuses primarily on quarantine issues.

This international agreement is most relevant to quarantine treatments as defined by the Protocol as the IPPC promulgates guidelines for the implementation of measures for quarantine pests and regulated non-quarantine pests (see Glossary, Appendix 1). However, non-regulated pests do not fall within the scope of the application of phytosanitary measures under the IPPC as they are not classified as injurious to plant health. Non-regulated pests are often the target of pre-shipment MB treatments, as defined under the Protocol, as they are detrimental to the *quality* of the product in which they are found.

## 1.8 QPS Definitions

### 1.8.1 Quarantine

The Protocol defines ‘quarantine’ applications as follows:

*‘Quarantine applications’ with respect to methyl bromide, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases) or to ensure their official control, where:*

i) *Official control is that performed by, or authorised by, a national plant, animal or environmental protection or health authority;*

ii) *Quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.*

The Protocol definition of a quarantine pest was based on that from the 1994 FAO Glossary of Terms, with one change. The Glossary refers to pests of potential economic importance, whereas the Protocol excludes the term 'economic'. The definition agreed under the Protocol is deemed by the Parties to be *explicitly* broader than that of the IPPC as it encompasses not only the activities covered by IPPC (plant health) but also covers human and animal health and wider environmental considerations. The IPPC considers that environmental concerns related to plant health, while not specifically stated, are *implicit* in their definition.

The IPPC focuses on securing common and effective action to prevent the spread and introduction of damaging pests of plants and plant products. The Protocol has a broader definition as it also includes 'health authorities'. From a human health perspective, the jurisdiction of health authorities includes preventing the spread of disease from rodents which are found in ships, aircraft and other vehicles; and controlling particular micro-organisms such as bacteria or other disease-carrying organisms which are harmful or even fatal to humans and that may be prevalent in an imported food product.

The Protocol uses the term 'phytosanitary' to refer generally to 'officially-authorized pest control treatments applied to plants and plant products'. A recent revision of the IPPC resulted in expansion (from a 'quarantine' perspective) of the term 'phytosanitary' (previously just 'quarantine pests') to include 'regulated non-quarantine pests' which are associated with plants for planting (propagative material).

### 1.8.2 Pre-shipment

'Pre-shipment', as intended by the Parties, appears to have no parallel in other international treaties or conventions. Pre-shipment applications are:

*Those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country.*

IPPC adopted a definition which narrowed (from a pre-shipment perspective) 'phytosanitary measures' to those related to 'quarantine pests' and 'regulated non-quarantine pests which affect plants for planting'. This definition

specifically excluded non-quarantine, stored product pests from within the scope of 'phytosanitary measures' under the Convention. Such pests are often the target of pre-shipment MB treatments as defined under the Protocol as they are detrimental to the quality of the product in which they are found. 'Pre-shipment' therefore aims at using official authorised treatments to control 'quality' pests. Note that 'official' is not specifically part of the definition of 'pre-shipment'. TEAP (1998), however, provided interim explanatory notes to assist the Parties consider pre-shipment treatments as those '... 'phytosanitary or sanitary' officially authorised but non-quarantine treatments, fulfilling official requirements of the importing or exporting country at time of export...and not intended to cover informal or purely contractual or commercial arrangements not required under official regulations'. The Protocol's application of the term 'phytosanitary' to cover non-quarantine measures therefore differs from the new IPPC definition of this term.

Clarification of the Protocol usage of terms and the degree to which this is aligned with the IPPC and/or SPS will help regulatory and other border control agencies to better understand both agreements and facilitate a more consistent reporting under the Protocol. For effective implementation with Regulatory Agency staff undertaking 'border patrol' on import-export commodity inspection activities, it would be helpful to explain and provide guidance on deviations from the IPPC.



## 2. Introduction

### 2.1 Decision of Parties

The consumption of methyl bromide (MB) for quarantine and pre-shipment (QPS) by all Parties is an emissive use which is unregulated under Article 2H of the Montreal Protocol. For other ODS such as CFCs, there are some limited essential use exemptions agreed by the Parties which apply only after phaseout. For MB, QPS consumption is exempt from controls such as freeze, reduction in consumption and phaseout. Only emissions with controls agreed under the Protocol are eligible for Multilateral Funds. Such funding has been instrumental in the past for elimination of other ozone depleting substances (ODS) by financing projects on alternatives.

At the tenth Meeting of the Parties in Cairo 23-24 November 1998, the Parties noted that over 18% of MB consumption was estimated to have been excluded from control under the QPS exemption, and that this use was increasing in some regions according to official data, and furthermore, the operation of the exemption criteria might lead to unnecessary use of MB. Accordingly, the Parties requested TEAP address a number of issues relating to QPS. These are specified in Decision X/11:

1. *To request the Technology and Economic Assessment Panel, as part of its ongoing work:*
  - (a) *To assess the volumes and uses of methyl bromide under the quarantine and pre-shipment exemption, including the trend in use since the 1991 base year;*
  - (b) *To report on the existing and potential availability of alternative substances and technologies, identifying those applications where alternative treatments do not currently exist, and also on the availability and economic viability of recovery, containment and recycling technologies;*
  - (c) *To report on the operation of quarantine and pre-shipment exemptions as set out in decision VII/5, including the scope of the pre-shipment definition;*
  - (d) *To report on existing and potential options that individual Parties might consider to reduce the use and emissions of methyl bromide from its application under the quarantine and pre-shipment exemption and to elaborate further on their recommendations in previous reports, and taking into account the special circumstances of Parties operating under paragraph 1 of Article 5 of the Protocol;*

- (e) *To review and report on the amendment by the International Plant Protection Convention (IPPC) to its quarantine and non-quarantine pests definitions, and the FAO/IPPC structure relative to the use of pesticides for regulated non-quarantine pests, to help determine whether clarification of the definitions of quarantine and pre-shipment, taking into account these FAO/IPPC usages, would help encourage consistency in the quarantine and pre-shipment definitions;*
  - (f) *To submit its findings to the Open-ended Working Group of the Parties to the Montreal Protocol at its first meeting in 1999;*
2. *To request the Open-ended Working Group, in the light of the report of the Technology and Economic Assessment Panel, to make any appropriate recommendations for consideration by the Eleventh Meeting of the Parties;*
  3. *To request the Parties to submit to the Secretariat by 31 December 1999 a list of regulations that mandate the use of methyl bromide for quarantine and pre-shipment treatments;*
  4. *To remind the Parties of the need to report on the volumes of methyl bromide consumed under the quarantine and pre-shipment exemption as set out in decision IX/2*

The Methyl Bromide Technical Options Committee (MBTOC) was requested to submit a report to the TEAP addressing the issues raised in this Decision.

## **2.2 MBTOC Composition**

MBTOC was established by the Parties to the Montreal Protocol in 1992 to identify existing and potential alternatives to MB. This Committee addresses the technical feasibility of chemical and non-chemical alternatives for the current uses of MB, apart from its use as a chemical feedstock. MBTOC members have expertise in the uses of MB and its alternatives and come from 11 Article 5(1) and 12 non-Article 5(1) countries. There are 40 members of MBTOC comprising 13 (33%) from developing and 27 (67%) from developed countries.

MBTOC met in San Francisco on 25-28 January 1999 to draft the QPS report. Nine members of MBTOC elected not to attend the QPS meeting mainly because they considered the topic to be outside their area of expertise.

As most MBTOC members were not fully conversant with the role of the International Plant Protection Convention (IPPC), MBTOC invited Dr Robert Griffin (Coordinator IPPC Secretariat, FAO, Rome) to attend the MBTOC meeting. Dr Griffin attended as a Subsidiary Technical Body under terms of

reference of TEAP. Prior to his attendance, Dr Batchelor (Co-chair MBTOC) met with Dr Griffin in Rome to seek his guidance on IPPC definitions, how these related to key QPS issues raised in Decision X/11, and to define a range of topics that would need to be addressed by MBTOC members seeking to understand the relevance of IPPC to the Montreal Protocol.

### **2.3 Report content and issues to be addressed**

This report addresses Decision X/11 by discussing:

- QPS definitions and intent of the QPS Decision under the Montreal Protocol with other plant, animal, health and environmental regulations and treaties; and
- The consumption of MB for QPS activities;
- Alternatives to MB for QPS for both perishable and durable commodities;
- The prospects for recovery, containment and recycling of MB;
- Options that the Parties might wish to consider for making changes to the QPS exemption.



### 3. Montreal Protocol: Quarantine and pre-shipment

#### 3.1 Introduction

At the 1992 Meeting of the Parties in Copenhagen, Article 2H of the Protocol specifically excluded QPS when it stated, *inter alia*:

*'The calculated levels of consumption and production ...shall not include the amounts used by the Party for quarantine and pre-shipment applications'*

This was the first time that QPS was mentioned in the Protocol documentation. It is notable that in the report of this Meeting of the Parties there was no attempt to define 'quarantine' or 'pre-shipment' (UNEP/Ozl.Pro.4/15), but rather to defer this task to a later meeting.

Since that time, there have been a number of Decisions taken by the Parties to the Montreal Protocol related to this QPS exemption. These have mainly concerned definitions and clarification of definitions. TEAP and MBTOC have also examined QPS and reported on their interpretation of its scope and intent, assisted with clarification of the definitions, suggested methods for avoiding QPS altogether and provided examples of QPS.

#### 3.2 Decisions, definitions and comments on QPS

##### 3.2.1 Montreal Protocol Decisions Relevant to QPS

The main Decisions relating to QPS are Decision VI/11 in October 1994 which defined 'quarantine' and 'pre-shipment' for implementation by non-Article 5(1) Parties; and Decision VII/5 in December 1995 in which Article 5(1) Parties agreed to adopt the same definitions.

#### **The Sixth Meeting of the Parties 6–7 October 1994 decided in Dec. VI/11:**

1. *Recognizing the need for non-Article 5(1) Parties to have, before 1 January 1995, common definitions of 'quarantine' and 'pre-shipment' applications for methyl bromide, for purposes of implementing Article 2H of the Montreal Protocol, and that non-Article 5(1) Parties have agreed on the following:*

- (a) *Quarantine applications, with respect to methyl bromide, are applications to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control, where:*

- (i) *Official control is that performed by, or authorized by a national plant, animal or environmental protection, or health authority;*
  - (ii) *Quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled;*
- (b) *Pre-shipment applications are those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country;*
  - (c) *In applying these definitions, non-Article 5(1) countries are urged to refrain from use of methyl bromide and to use non-ozone-depleting technologies wherever possible. Where methyl bromide is used, Parties are urged to minimize emissions and use of methyl bromide through containment and recovery and recycling methodologies to the extent possible;*
2. *Acknowledging that Article 5(1) Parties have agreed to identify the following:*
- (a) *That definitions relating to pre-shipment applications affect Article 5(1) countries and that new non-tariff barriers to trade should be avoided;*
  - (b) *That the Article 5(1) countries still need to have more consultations and further approaches to the quarantine and pre-shipment application definitions related to methyl bromide;*
  - (c) *That the Food and Agriculture Organization of the United Nations should play a fundamental role in the establishment of common definitions concerning quarantine and pre-shipment applications related to methyl bromide use;*
  - (d) *That it is anticipated that the use of methyl bromide by Article 5(1) countries may increase in the forthcoming years;*
  - (e) *That adequate resources from the Multilateral Fund for the Implementation of the Montreal Protocol and other sources are needed to facilitate the transfer of non-ozone-depleting technologies for quarantine and pre-shipment applications related to methyl bromide to the Article 5(1) countries;*

3. *Further recognizing that containment, recovery and recycling methodologies relating to methyl bromide should be given a wider application among all Parties;*
4. *To request the Open-ended working group of the Parties at its eleventh and twelfth meetings*
  - (a) *To further study the most suitable definition for ‘quarantine’ and ‘pre-shipment’ applications relating to methyl bromide use, taking into consideration:*
    - (i) *The Methyl Bromide Technical Options Committee report;*
    - (ii) *The Methyl Bromide Scientific Assessment Report;*
    - (iii) *The FAO guidelines on Pests Risk Analysis; and*
    - (iv) *The development of lists of injurious pests;*
  - (b) *To consider jointly the definitions issues along with the methyl bromide issues contained in decision VI/13;*
  - (c) *To provide the necessary elements to be included for a decision of the Seventh Meeting of the Parties to the Montreal Protocol on all the above issues.*

***Decision VI/13: Assessment Panels***

*The Sixth Meeting of the Parties decided in Dec.VI/13 to request the Panels, as an inclusion in their ongoing work, to evaluate, without prejudice to Article 5 of the Montreal Protocol, the technical and economic feasibility, and the environmental, scientific, and economic implications for non-Article 5(1) countries, as well as Article 5(1) countries, bearing in mind Article 5(1), paragraph 1 bis, of the Copenhagen Amendment, of:*

- (b) *Alternatives to methyl bromide, in time for consideration by the Open-ended Working Group at its eleventh meeting;*

*In considering these matters, the Scientific Assessment Panel shall consider, if possible, atmospheric chlorine and bromine loadings and their impact on ozone depletion. The Technology and Economic Assessment Panel and Scientific Assessment Panel evaluations shall be solely for the purpose of discussions by the Parties and shall in no way be construed as recommendations for action.*

### 3.2.2 TEAP comments

The evolution of the intent and scope of QPS exemption has been commented on by TEAP from 1994 - 1998.

In response to Decision VI/11, TEAP (1994) put forward a draft definition of 'quarantine' and 'pre-shipment' prior to the adoption of a definition by the Parties the following year. For 'quarantine', it was considered important to restrict the definition to only include commodities and to specifically exclude buildings, transport vehicles and containers that may harbour quarantine pests, diseases or plants; to 'control' rather than 'eradicate' pests and disease; and to include quarantine treatments in intra-country trade that would occur between regions within the territory of the Party.

For 'pre-shipment', a narrow definition was proposed that restricted the treatment to a requirement of the importing or exporting government agency rather than at the request of commerce; that pre-shipment was not only for commodities but also for the buildings, transport vehicles and containers in which they are transported, and that these could be treated while empty; that non-quarantine pests could be targeted; and that a time limit for the treatment prior to shipment would be applied to promote single rather than multiple MB treatments.

TEAP noted that MBTOC did not achieve consensus on both draft definitions, and TEAP recommended to the Parties that the Essential Use process should be applied to each proposed exemption and considered on a case-by-case basis.

At the stage when the Parties were considering the scope and intent of QPS, TEAP (1995; P 67) made the Parties aware that QPS consumption in 1992 in Article 5(1) countries was 20% of their total consumption.

TEAP (1996) considered the possible terms of reference for Critical Uses of MB after phaseout, and assumed that QPS would remain separately exempt after phaseout. TEAP suggested changes to the Essential Use criteria to better accommodate the needs of MB users rather than constructing a separate category of 'Critical Use' to cater solely for MB.

TEAP (1997) suggested Parties consider some form of appropriately controlled incentive to encourage the use of emission reduction devices, especially as QPS consumption was now estimated to be more than 18% of global MB consumption and increasing. TEAP noted that virtually all perishable commodities, half of all durable commodities and some structural and transport use is carried out under the QPS exemption.



Decision VIII/16 requested TEAP provide further elaboration on possible definition and modalities for implementation of ‘critical agricultural use’ exemption in relation to non-QPS consumption of MB. This consumption may not be covered post-phaseout by the QPS exemption. TEAP (1997) considered that the options for an essential use exemption are fully workable and can be implemented at the time of the MB phaseout. For administrative efficiency and equity with other ODS uses, TEAP preferred that MB be accommodated within the existing Essential Use structure by making slight changes to the Essential Use criteria, as defined in the 1996 TEAP report. Parties could therefore consider eliminating the QPS exemption and rely solely on the Essential Use process including the provision of emergency use exemptions.

TEAP (1998) provided interim explanatory notes to the Protocol’s definitions of ‘quarantine’ and ‘pre-shipment’. For example, TEAP explained that:

- The Protocol had a narrower definition of ‘quarantine pest’ compared to the most recent IPPC-FAO definition which authorised treatments for ‘regulated pests’ which includes ‘quarantine’ and ‘non-quarantine pests that affect plants for planting’;
- Decision VII/5 could be interpreted to restrict quarantine treatments to those conducted or authorised by national, but not state authorities;
- ‘Pre-shipment’ treatments excluded those carried out under contractual or commercial arrangements;
- A pre-shipment application would be applied to export trade between countries and applied within a few days prior to export; and
- Suggested a list of examples of treatments considered ‘quarantine’ and ‘pre-shipment’ would clarify the scope and intention of QPS to Parties.

### 3.2.3 Intent of QPS

At the time that Article 2H was documented in Copenhagen in 1992, the Parties understood that there were no alternatives to MB for a diverse range of treatments carried out with MB for QPS. The Parties recognised that although QPS consumption was about 10% of global MB consumption, this volume was nevertheless very significant in allowing inter- and intra-country trade in commodities treated with MB *in the absence of site-specific alternatives*. Unless site specific alternatives to MB were available for QPS that were tested and approved in both Article 5(1) and non-Article 5(1) countries, there was a strong likelihood of disruption to international trade if the exemption for QPS were not available. For some Article 5(1) and non-Article 5(1) that rely on export receipts for MB-treated commodities as a large proportion of their income, the exemption was considered very important as it specifically

avoided ‘...new non-tariff barriers to trade...’ (Decision VI/11) that could be introduced if such an exemption were not in place.

#### 3.2.4 Scope of QPS

There has been considerable discussion on the scope of the QPS exemption which is summarised here. For quarantine treatments, Parties decided to:

- Base the exemption on a narrow FAO 1994 definition of a quarantine pest, but to delete ‘economic’ from ‘...economic importance...’ in the definition as there were more than just ‘economic’ reasons when considering ‘importance’;
- Restrict the exemption under quarantine to treatments carried out by government plant, health, animal, or environmental authorities; and
- Include quarantine treatments for commodities moved interstate or region within the one territory.

Unlike ‘quarantine’, in 1994 there was neither a definition for ‘pre-shipment’ under the FAO or elsewhere. Currently, the concept of ‘pre-shipment’ remains peculiar to the Protocol. The Parties saw the need to introduce and define the term ‘pre-shipment’ to:

- Allow an exemption for MB applied prior to export for *non-quarantine* pests infesting commodities or associated structures and transport vehicles that stored or conveyed these commodities;
- Exempt treatments to those applied ‘directly preceding’ export, thus excluding multiple, routine, MB treatments from the exemption;
- Exclude treatments authorised by commercial or contractual purposes, and
- Require that the regulation specifying MB treatment must have been in place at the time of the Decision in order to avoid subsequent legislation that might allow exemptions to be generated without the consent of the Parties.

#### 3.2.5 MBTOC comments

MBTOC stated that QPS consumption accounted for about 22% of world-wide MB consumption (MBTOC 1998). Preliminary data from four countries indicated that MB used for QPS was increasing for both Article 5(1) and Non-Article 5(1) Parties.

MBTOC noted that there was potential for inconsistency in the interpretation of the terms 'quarantine' and 'pre-shipment'. For example, MB treatments of commodities that were required contractually, rather than officially, would not qualify as QPS but some Parties appeared to be including this use in their reported total of exempt MB consumption. This inconsistency would result in an understatement of a Party's calculated annual controlled consumption in a particular year.

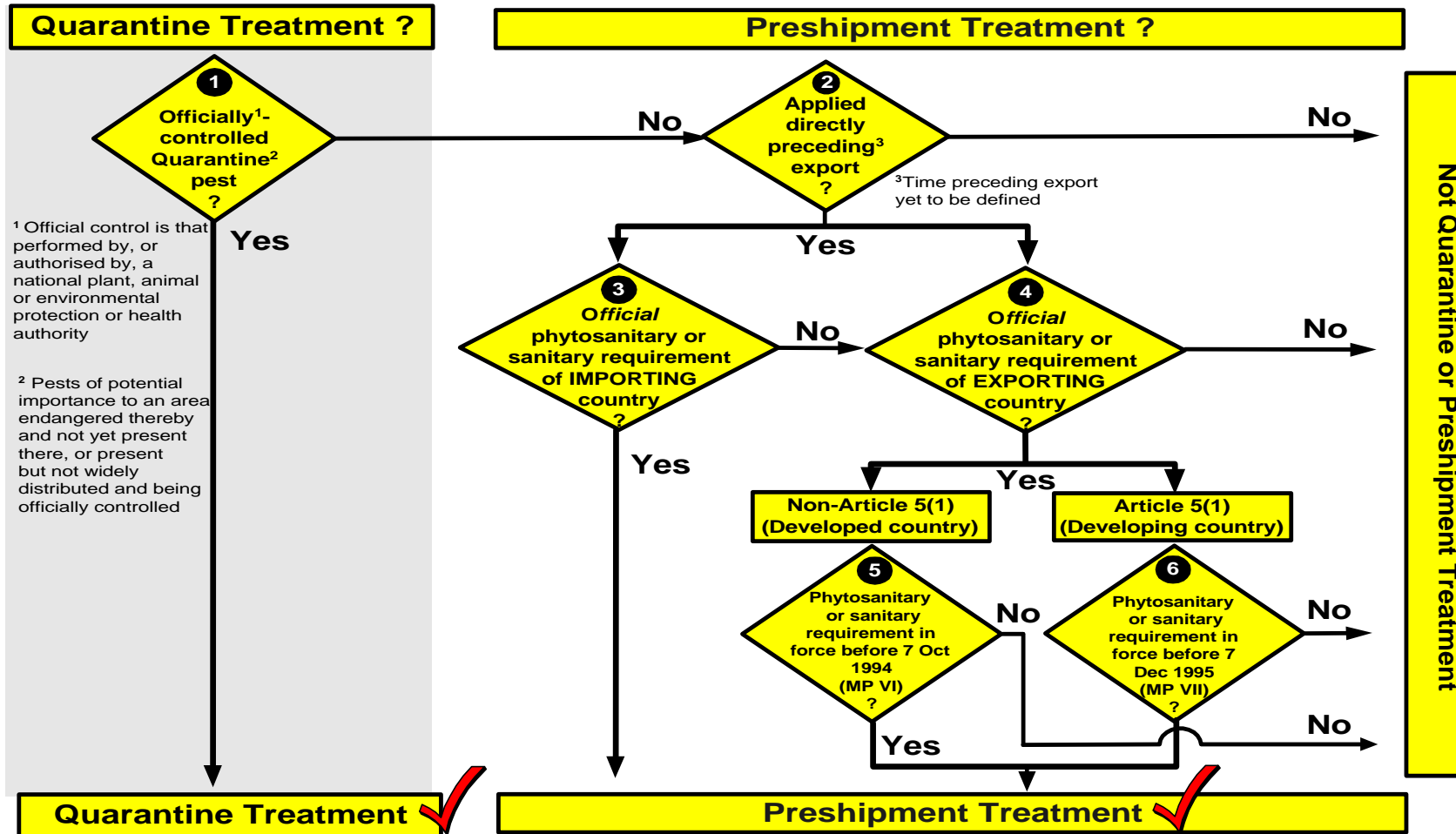
MBTOC commented that there might have been inconsistency in the interpretation of pre-shipment treatment defined as 'directly preceding...export'. The interpretation might result in multiple applications when a single application of MB just prior to shipment would fully satisfy the sanitary or phytosanitary requirements of the importing or exporting country. In order to be clear for practical implementation of this measure, MBTOC suggested that Parties might wish to define pre-shipment applications as those carried out within 14 days prior to shipment in addition to meeting the phytosanitary and sanitary requirements of the importing or exporting countries.

From current use world-wide, MBTOC (1998) provided examples of MB treatments MBTOC considered in compliance with the QPS definition and those which were not in compliance. MBTOC also designed a QPS Logic Diagram to assist in differentiating between QPS and non-QPS use (Figure 3.1). Should Parties wish to do so, the logic diagram could also be used to design forms at a national level to accurately monitor, record and quantify QPS consumption.

The official forms in which Parties report their annual consumption of ODS to the Ozone Secretariat includes a box for QPS production/imports/exports. While reporting MB QPS consumption is not mandatory, reporting is of assistance to the Parties as it provides a guide to global changes in MB consumption that can be attributed to QPS use and consequent atmospheric loading.

MBTOC considered that further data collection was required in order to assess the volume and uses of MB under QPS, the extent of the development of alternatives, the likely operation of exemptions in the future once MB is phased out and the regulations governing the use of QPS treatments.

**Figure 3.1:** QPS Logic Diagram to assist in deciding whether a treatment should be categorised as a ‘quarantine’ treatment, ‘pre-shipment’ treatment or neither.



### 3.3 Examples that May Assist in Categorising ‘Quarantine’ and ‘Pre-shipment’

This section provides examples of MB treatments considered by MBTOC to be Q, PS and non-QPS.

#### 3.3.1 Uses considered by MBTOC to be QPS

##### 3.3.1.1 *Official quarantine treatment in country of origin*

*A MB treatment required by officials in an importing country against a quarantine pest known to infest a particular commodity.*

- ◆ **Example:** Treatment of packed commodities subject to infestation such as rice, spices and expeller cake or materials packed in straw and wooden crates from a country known to have khapra beetle as an established pest.
- ◆ **Reasoning:** This is covered by the QPS exemption. It is a quarantine treatment because khapra beetle is an officially recognised quarantine pest in a number of countries. Typically MB is specified for its control.
- ◆ **Example:** MB treatment in the USA of oak logs to control oak wilt fungus. The logs are destined for Europe.
- ◆ **Reasoning:** This is covered by the QPS exemption because oak wilt fungus is a declared object of quarantine in the European Union.

##### 3.3.1.2 *Official quarantine treatment on arrival*

*Official treatment of imported consignment where a pest, declared as an object of quarantine, is detected.*

- ◆ **Example:** MB treatment of grapefruit from Florida found to be infested with Caribbean fruit fly on arrival in Japan.
- ◆ **Reasoning:** This is covered by the QPS exemption. It is a quarantine treatment because Caribbean fruit fly is not present in Japan and MB is specified as a control measure.

*Official treatment of a commodity transported within a country where there is potential for transfer of a quarantine pest into an area declared free of that pest, or when the pest is under official containment.*

- ◆ **Example:** MB treatment of rice shipped into Western Australia as a precaution against *Trogoderma variabile*, a pest established in the rice growing area of New South Wales, Australia.

- ◆ **Reasoning:** This is covered by the QPS exemption. It is a quarantine treatment because the pest is under official containment in Western Australia and is a declared object of State quarantine (although known to be present in a restricted area of Western Australia) and under official control.

### 3.3.1.3 *Eradication of a quarantine pest from an area*

MB may be required to control or possibly eradicate quarantine pests in limited and well-defined geographical areas. Pests may be recently established or under long term control.

*Treatment of an established quarantine pest with a view to its control and eventual eradication from a country.*

- ◆ **Example:** MB treatment of dry wood termites in houses and in other structures in Southern Queensland.
- ◆ **Reasoning:** This can be categorised under QPS as a quarantine treatment because dry wood termites are quarantine pests established in a few small regions of Australia and subject to official control. Treatment of quarantine pests established in a limited area is an example of a ‘post-entry’ quarantine treatment.

### 3.3.1.4 *Official pre-shipment treatment in country of origin in relation to exports*

*Treatment of a cargo prior to shipment to meet an importing country’s official phytosanitary requirements.*

- ◆ **Example:** MB treatment of wheat shipments destined for Kenya. The treatments against cosmopolitan grain pests are carried out in the seven day period prior to export.
- ◆ **Reasoning:** This is categorised under QPS as a pre-shipment application because treatment with MB is an official phytosanitary requirement of the Kenyan Government for wheat imported into Kenya. Although Kenyan authorities recognise phosphine as an alternative to MB for this application, the existence of an alternative does not invalidate the exemption.

*Treatment of a cargo preceding export to meet a country’s export regulatory requirements which were in force before 7 October 1994 (for non-Article 5(1) countries) or before 7 December 1995 (for Article 5(1) countries).*

- ◆ **Example:** MB fumigation of wheat at the point of export (seaboard terminal) within a few days prior to shipment from Australia to meet officially required ‘nil’ tolerance levels for insect infestation in export grain.

- ◆ **Reasoning:** This can be categorised under QPS as a pre-shipment treatment as it was applied at the time of export to meet the official requirements of the Grain, Plant and Plant Protection Orders under the Export Control Act (1982) which were in force at the time of Decision VII/5.

*Treatment of an empty ship prior to loading to meet exporting country's regulatory requirements.*

- ◆ **Example:** MB fumigation of empty ships' holds in ships due to load grain for export at a port in Canada, carried out under the direction of the inspection authorities, because cosmopolitan grain pests were intercepted on the ship.
- ◆ **Reasoning:** This would be categorised under QPS as a pre-shipment treatment as it was carried out in relation to exports to comply with the export requirements of the exporting country's legislation in force at the time of Decision VII/5.

*In-transit fumigation of freight containers loaded on a train and subsequently exported by ship.*

- ◆ **Example:** To meet official phytosanitary requirements, MB fumigation of milled rice in bags in freight containers at the rice mill some distance from a port. Subsequent transfer to port and export by ship within 14 days of treatment.
- ◆ **Reasoning:** This would be categorised under QPS as a pre-shipment treatment as it was carried out directly prior to export to meet official phytosanitary requirements.

### 3.3.1.5 *Treatment of land prior to export of crop*

*MB treatment of land prior to planting a crop destined for export.*

- ◆ **Example:** Fumigation of land prior to planting strawberry runners for export.
- ◆ **Reasoning:** This is covered by the QPS exemption as the treatment was for carried out for official phytosanitary reasons (pers. comm. Dr Frank Westerlund, MBTOC) against soil pathogens that could be carried by the exported strawberry runners.

Note: This was the only example identified by MBTOC for treatment of land, and is therefore a very unusual case. An example of QPS for export fruit, distinct from runner production, is discussed in 4.3.2.5.

3.3.2 Uses considered by MBTOC to not be QPS treatments

**3.3.2.1 *Exporter carries out MB treatment prior to export as a quality control measure***

*Treatment of a cargo at export against infestation of non-quarantine insects pests as a precaution against mandatory treatment if infestation is detected on import.*

- ◆ **Example:** MB fumigation of cut flowers destined for Japan at the point of export. No phytosanitary certificate is required by the importing country's quarantine authorities.
- ◆ **Reasoning:** This does not fall within the QPS exemption either as a quarantine or a pre-shipment treatment as the treatment was not specifically targeted against nominated quarantine pests, nor was it carried out as an officially required measure by either the importing or exporting country, despite being conducted at the point of export and shortly prior to shipment.

MB may be applied under direction of Japan's quarantine authorities if any live insects are intercepted on arrival. Fumigation carried out on detection of infestation at import similarly do not fall within the QPS exemption, as they are neither carried out against nominated quarantine pests nor conducted directly prior to export.

**3.3.2.2 *Importing contractor requests treatment prior to export as a quality control measure***

*Contractual requirement for MB fumigation of a commodity prior to export to meet the importer's quality specification.*

- ◆ **Example:** Importers of cassava chips from Thailand require MB treatment to manage infestation in the commodity for quality reasons and to avoid having to carry out disinfestation treatments on receipt.
- ◆ **Reasoning:** This is not covered under the QPS exemption as the MB treatment was not directed at a nominated quarantine pest and was not carried out under official direction or to meet an importing country's official phytosanitary requirements.

**3.3.2.3 *Contractor requests treatment as a quality control measure***

*MB treatment of a commodity in-store as a routine pest control measure against cosmopolitan pests weeks or months prior to transport.*



- ◆ **Example:** MB treatment of grain in long-term storage some distance away from an export terminal against cosmopolitan stored product pests. The grain is destined for local processing.
- ◆ **Reasoning:** This is not covered by the QPS exemption as the treatment was not directed against nominated quarantine pests and was not done immediately prior to export to meet official requirements.

#### 3.3.2.4 *Treatment of commodities by the importing country found to be infested on receipt*

*MB treatment of a commodity immediately after import when cosmopolitan or other non-quarantine pests are detected.*

- ◆ **Example:** Fumigation of containerised cocoa beans immediately after importation when found to be infested with cosmopolitan grain pests e.g. flour moths.
- ◆ **Reasoning:** This was not covered by the Q exemption as the treatment was not directed against declared objects of quarantine and the pests were already well-established in the importing country. It is not considered a PS treatment as MB is not an officially required treatment. There is no allowance in the definition of QPS for use of MB in the importing country as a result of inadequate pest control measures in the *exporting* country.

#### 3.3.2.5 *Treatment of land prior to export of crop*

*MB treatment of land prior to planting a crop destined for export.*

- ◆ **Example:** Fumigation of land prior to planting strawberries for fruit production for export.
- ◆ **Reasoning:** This is not covered by the QPS exemption as the treatment was not targeted at quarantine pests nor carried out directly prior to export for official phytosanitary reasons.

#### 3.3.3 Examples of pre-shipment treatments

Examples of pre-shipment treatment requirements are given below. These are general specifications for treatment of grain at export for import into the given countries (Pers. Comm., Australian Wheat Board, March 1998). In all cases they are official requirements of the importing country, not commercial or contractual obligations. It is noteworthy that most of these examples include phosphine treatment as an alternative, although at a longer exposure time than for MB.

<b>Chile</b>	All grain must be fumigated prior to export at 3 g m <sup>-3</sup> for 15 days with phosphine, or with MB at 35 g m <sup>-3</sup> for 24 hours.
<b>Colombia</b>	All grain must be fumigated prior to export at 1 g m <sup>-3</sup> for not less than 6 days with phosphine, or with MB at 24 g m <sup>-3</sup> for a period of 24 hours.
<b>Kenya</b>	All grain to be fumigated with MB at 32 g m <sup>-3</sup> for 24 hours, or MB at 20 gm <sup>-3</sup> for 48 hours, or phosphine at 2g t <sup>-1</sup> for minimum 120 hours.
<b>Mexico</b>	Grain must be fumigated with MB at 80 g m <sup>-3</sup> for 24 hours.
<b>Mozambique</b>	All grain to be fumigated with MB at 32 g m <sup>-3</sup> for 24 hours, or MB at 20 gm <sup>-3</sup> for 48 hours, or phosphine at 2g t <sup>-1</sup> for minimum 120 hours.
<b>Papua New Guinea</b>	All grain to be fumigated with MB at 42 g m <sup>-3</sup> for 12 hours at 21°C or above, or phosphine at 5 g m <sup>-3</sup> for 7 days at 25°C or above, or phosphine at 5 g m <sup>-3</sup> for 10 days at 15° to 25°C.
<b>Peru</b>	All grain must be fumigated with either phosphine or MB prior to shipment and details made available for inclusion on phytosanitary certificates.
<b>Zimbabwe</b>	Grain to be fumigated with MB at 32 g m <sup>-3</sup> for 24 hours, or MB at 20 g m <sup>-3</sup> for 48 hours, or phosphine at 2 g t <sup>-1</sup> for minimum 120 hours, or an equivalent <i>ct</i> -product.

## 4. QPS Consumption

### 4.1 Sources of data

The analysis of QPS consumption by non-Article 5(1) and Article 5(1) Parties was based on two main sources of data:

- A survey on QPS uses carried out by MBTOC in early 1999 in response to Decision X/11. Survey forms (Appendix A2) were sent to ozone officers or government representatives to the Montreal Protocol.
- Previous reports by MBTOC and TEAP.

MBTOC's QPS survey was sent to 96 Parties in December 1998. Table 4.1 shows that 55 (57%) Parties responded, and of these, 32 Parties provided sufficient data, while 23 provided incomplete data. The analysis in this section is based on the information received to date. MBTOC will continue to encourage countries to provide information on QPS so that an up-date can be provided to TEAP in the future.

*Table 4.1: Responses by Parties to MBTOC survey on QPS*

<b>Quality of response</b>	<b>Number of Parties responding</b>
Sufficient data	32
Incomplete data	23
<b>Sub-total</b>	<b>55</b>
No data	42
<b>Total</b>	<b>97</b>

#### 4.1.1 Limitations of the survey data

The data presented in the following Tables comprise a first attempt at quantifying MB use for quarantine and pre-shipment purposes in over 100 countries and are the best available to the date of this report. Although responses were received from 55 countries, responses were not received from 42 countries, including many of those who are considered to be important MB consumers. Additionally, many of the respondents only provided information for part of the survey.

MBTOC received several responses reporting the volume of MB used for QPS, but in most cases, the Party did not appear to know how this volume of MB was actually used. In fact, analysis of the survey data was difficult, and reliability is insufficient, given the lack of data. For example, only seven

Parties reported MB consumption for quarantine treatment of fruit; yet, fruit treatment by MB is considered to be much more common.

The quality of these data is influenced by several factors namely:

- The short time-span allowed for answering and the time of year when the survey forms were sent to the different countries. Information for consumption during the whole of 1998 was almost impossible to get in early January 1999;
- Problems arising from different interpretations and definitions of the terms ‘quarantine’ and ‘pre-shipment’. Many times the two appeared to be used interchangeably which added to confusion between these uses;
- Some Parties may have classified some QPS volumes as non-QPS, and visa-versa; and
- Given that Q and PS uses have been exempt for 4-5 years, many countries have not registered or kept track of actual quantities destined for these uses, focusing only on controlled uses.

## 4.2 Global trends

### 4.2.1 Review of available data on QPS volumes

The MBTOC 1998 Assessment estimated that QPS use accounted for about 15,000 tonnes in 1996. QPS was estimated to account for about 18% of MB consumption in 1992 (TEAP 1995), rising to an estimated 22% in 1996 (MBTOC 1998). It was not possible to provide more recent statistical information until further QPS responses are received to the MBTOC survey.

*Table 4.2: Estimates of volume of methyl bromide used for QPS*

Estimated methyl bromide volumes	1992	1996
	tonnes	tonnes
QPS consumed by Article 5(1) Parties	2,901 <sup>a</sup>	3,810
QPS consumed by non-Article 5(1) Parties	10,009	11,190
<b>Total QPS</b>	<b>12,911<sup>c</sup> (18%)</b>	<b>15,000<sup>c</sup> (22%)</b>
<b>Total MB</b>	<b>72,977<sup>b</sup></b>	<b>68,666<sup>b</sup></b>

(a) Based on estimate that Article 5(1) QPS volume was about 20% of total Article 5(1)(1) MB use

(b) Excluding feedstock – the 1996 figure may be slightly low due to under-reporting

(c) Estimate from MBTOC 1998 Assessment

#### 4.2.2 Regional analysis

The amount of MB used for QPS varied greatly from one country to the next. Survey respondents reported QPS volumes ranging from 0 to 2,030 tonnes per annum. Out of 55 countries responding, 9 (16%) reported consumption of more than 100 tonnes of MB for QPS purposes, while 3 (5%) countries reported consumption of more than 500 tonnes for QPS.

Nineteen (35%) countries reported zero QPS consumption. This included 11 Article 5(1) and 8 non-Article 5(1) Parties.

Based on the survey responses received to date, the QPS volume was 5,828 tonnes in 1997 for 55 countries (Table 4.3). Article 5(1) Parties consumed 2,801 tonnes (48%) of this, while non-Article 5(1) countries consumed 3,028 tonnes (52%). Note that data are not yet available for some Parties known to consume substantial QPS volumes.

**Table 4.3:** Number of countries reporting use of methyl bromide for QPS

Countries...	Article 5(1)	Non-Article 5(1)	Total
Using MB for QPS	22	15	37
Not using MB for QPS	11	7	18
<b>Total</b>	<b>33</b>	<b>22</b>	<b>55</b>

**Table 4.4:** Survey results for 55 countries showing reported QPS volumes by region in 1997

REGION	VOLUME OF METHYL BROMIDE (TONNES)			
	QPS	Non-QPS	Total	QPS %
Europe/CEIT	929.3	16,322.8	17,252.1	5.4%
Other Non-Article 5(1)	2,098.3	6,118.2	8,216.5	25.5%
<b>Sub-total for non-Article 5(1) regions</b>	<b>3,027.6</b>	<b>22,441.0</b>	<b>25,468.6</b>	<b>11.9%</b>
Latin America	1,383.4	2,963.2	4,361.3	31.7%
Africa	40.1	2,708.9	2,737.0	1.5%
Asia & Pacific	1,376.9	2,064.8	3,471.7	39.7%
CEIT	0.2	31.0	31.2	0.6%
<b>Sub-total for Article 5(1) regions</b>	<b>2,800.6</b>	<b>7,767.9</b>	<b>10,601.2</b>	<b>26.4%</b>
<b>Total for 55 countries</b>	<b>5,828.2</b>	<b>30,208.9</b>	<b>36,069.8</b>	<b>16.2%</b>

#### 4.2.3 Pre-shipment treatments for durable commodities

Twenty-one countries reported MB consumption for pre-shipment treatments for durable commodities, while 25 countries reported no use of MB for this purpose. Five countries reported MB consumption for all the major groups of durable commodities listed in Table 4.5.

MB was used for a variety of durable commodities. Table 4.5 indicates that the greatest number of countries reported use of MB for wood-related treatments, including logs, timber, wood products, craft products and packaging (probably cardboard and wooden pallets), as a requirement of the importing country. Table 4.5 indicates that substantially more countries reported consumption of MB to meet the requirements of importing countries than requirements of exporting countries.

*Table 4.5: Countries consuming MB for pre-shipment treatments for durable commodities.*

Durable commodities	Requirement of importing country		Requirement of exporting country	
	Parties using MB for this purpose	Parties not using MB	Parties using MB	Parties not using MB
Grains, legumes, seeds, fodder	11	26	4	34
Coffee, cocoa beans	10	26	4	33
Dried fruits, nuts	8	29	3	35
Dried herbs, spices, medicinal plants	8	27	2	35
Logs, timber	13	27	1	37
Wood products, etc	15	25	3	37
Packaging	13	25	1	37
Others	2	25	0	26
<b>Total</b>	<b>21</b>	<b>25</b>	<b>6</b>	<b>33</b>

Note: the numbers in the tables do not add up as some Parties applied QPS to more than one commodity

#### 4.2.4 Pre-shipment treatments for perishable commodities

Twelve countries reported MB consumption for quarantine treatments for perishable commodities, while 29 Parties did not report MB use for quarantine treatments. Three countries reported MB consumption for all the major groups of perishable commodities listed in Table 4.6, while the remainder used it for one or two groups.

Table 4.6 indicates that the greatest number of countries reported MB consumption for quarantine treatments on ornamentals, propagative materials

and fruit, as a requirement of the importing country. Table 4.6 shows that substantially more countries reported MB consumption for meeting the requirements of importing countries than the requirements of exporting countries.

**Table 4.6:** *MBTOC survey results of countries using MB for pre-shipment treatments for perishable commodities*

Perishable commodities	Requirement of importing country		Requirement of exporting country	
	Countries using MB	Countries not using MB	Countries using MB	Countries not using MB
Fresh fruit	7	34	1	38
Fresh vegetables	5	33	2	34
Ornamentals, propagative materials	9	29	2	35
Other	0	30	0	33
<b>Totals</b>	<b>12</b>	<b>29</b>	<b>3</b>	<b>33</b>

Note: the numbers in the tables do not add up as some Parties applied QPS to more than one commodity

#### 4.2.5 Quarantine treatments for durable commodities

Seventeen countries reported MB consumption for quarantine treatments for durable commodities, while 28 countries did not report use of MB for this purpose. Only three countries reported consumption of MB for all the groups of durable commodities listed in Table 4.7.

The survey did not specifically address fumigation of empty structures and transport. However, 3 countries mentioned that they use MB for fumigation of aircraft and shipholds.

Table 4.7 indicates that the greatest number of countries used MB as a quarantine treatment for the categories of logs/timber, wood products/furniture/craft products and grains/legumes.

**Table 4.7:** Countries consuming MB for quarantine treatments for durable commodities

<b>Durable commodities</b>	<b>Countries using MB for this purpose</b>	<b>Countries not using MB for this purpose</b>
Grains, legumes, seeds, fodder	10	28
Coffee, cocoa beans	8	29
Dried fruits, nuts	8	28
Dried herbs, spices, medicinal plants	8	28
Logs, timber	12	28
Wood products, furniture, crafts	11	30
Packaging	9	29
Others	1	28
<b>Total</b>	<b>17</b>	<b>28</b>

Note: the numbers in the tables do not add up as some Parties applied QPS to more than one commodity

#### 4.2.6 Quarantine treatments for perishable commodities

Twelve countries reported MB consumption for quarantine treatments for perishable commodities, while 27 countries did not report MB consumption for this purpose. Five countries reported MB consumption for all the categories of perishable commodities listed in Table 4.8.

Table 4.8 indicates that the greatest number of countries used MB as a quarantine treatment for fruit and ornamentals or propagative materials.

**Table 4.8:** Countries using MB for quarantine treatments for perishable commodities

<b>Perishable commodities</b>	<b>Countries using MB</b>	<b>Countries not using MB</b>
Fresh fruit	10	31
Fresh vegetables	7	30
Ornamentals, propagative materials	10	27
Other	0	28
<b>Totals</b>	<b>12</b>	<b>27</b>

Note: the numbers in the tables do not add up as some Parties applied QPS to more than one commodity

#### 4.2.7 Quarantine and pre-shipment treatments

Table 4.9 indicates that 24 (52%) of the countries providing information used MB for QPS treatments of durable commodities, while 16 (41%) of the countries reported MB used on perishable commodities.



Of the four major categories of applications reviewed in sections 4.2.3-4.2.6, it appeared that most countries used MB for pre-shipment treatments of durable commodities. In the majority of cases, MB was used to meet the requirements of importing countries.

**Table 4.9:** Summary of number of countries using MB for QPS applications – survey results to date

APPLICATION	----- NUMBER OF PARTIES -----			
	Durable commodities		Perishable commodities	
	Using MB	Not using MB	Using MB	Not using MB
Quarantine	17	28	12	27
Pre-shipment	21	25	13	28
Pre-shipment – requirement of importing country	21	25	12	29
Pre-shipment – requirement of exporting country	6	33	3	33
<b>Quarantine and pre-shipment</b>	<b>24</b>	<b>22</b>	<b>16</b>	<b>23</b>

Note: the numbers in the tables do not add up because some countries failed to report on certain topics.

### 4.3 Monitoring and reporting QPS consumption

#### 4.3.1 QPS reporting requirements

In responding to Decision X/11, MBTOC experienced difficulty in collecting data on QPS volumes and uses because:

- Under Decision IX/28 (6), Parties were encouraged but not required to report QPS volumes to the Ozone Secretariat;
- Many ozone offices (in both Article 5(1) and non-Article 5(1) Parties) have not been monitoring QPS as it was not mandatory and have therefore found it difficult to identify volumes and uses; and
- Some Parties have not ratified the Copenhagen amendment and are therefore not under any obligation to report consumption of MB.

Additional information on QPS is desirable, and MBTOC encourages all Parties to complete the QPS survey forms so that an update on QPS consumption may be provided to TEAP in the future. Parties may wish to consider whether it is necessary to strengthen the requirement for reporting on QPS volumes and uses. MBTOC suggests that Parties might wish to consider

1) Strengthening the voluntary commitment for reporting or 2) Making the commitment for reporting on QPS volumes and uses mandatory.

A draft reporting template has been added to the report (Appendix A3). When used in conjunction with the QPS Logic Diagram (see Section 3.2.5), the reporting format/template would be filled out by companies that use MB for QPS purposes. Parties may find that the format/template will help in identifying uses for which alternatives are available within their countries and those for which alternatives have yet to be developed. It may also help to assure Parties that exemptions are being appropriately applied in their domestic situation.

#### **4.4 Operation of QPS exemption**

MBTOC noted in the '1998 Assessment of Alternatives to Methyl Bromide' that there was inconsistency in the interpretation of the terms 'quarantine' and 'pre-shipment'. For example, treatment of commodities with MB required *contractually* rather than *officially* does not qualify as QPS but some Parties appear to be incorrectly exempting this use. This inconsistency would result in an understatement of an individual country's calculated annual non-QPS consumption in a particular year for developed countries, and could lead to additional efforts to meet agreed controls. Similarly, for Article 5(1) countries, this could result in a possible miscalculation of an individual country's base-line MB consumption, resulting in some countries having to make greater reductions than originally envisaged in order to meet the freeze in 2002 and the 20% reduction step in 2005.

Differences in interpretation could also create additional difficulties for data collection. For example, MBTOC noted that for at least one Party, treatments with MB carried out at the request of the importing country against a quarantine pest have been counted as pre-shipment instead of quarantine treatments.

MBTOC further noted that there may also be inconsistency in the interpretation of 'pre-shipment' treatment defined as "directly preceding...export". For example, the only exempted MB use for dried fruit stored for six months and fumigated 4-5 times to destroy pests would be the single MB fumigation that was required by official authorities and applied "...directly preceding...export". The Parties have yet to define this period which leaves open the possibility of multiple applications when a single application of MB just prior to shipment would fully satisfy the sanitary or phytosanitary requirements of the importing or exporting country.

A number of countries have regarded the QPS exemption to be a potential loophole and have taken measures under national legislation to either remove the exemption or to control the use of MB under the exemption. For example:

- Denmark in 1994 considered some alternatives to MB were available for QPS treatments, that more would be developed, and that if a critical treatment was not available, this could be considered for exemption by the Danish Environment and Energy Minister. Accordingly, Denmark phased out all QPS uses by 1998 ('Statutory Order from the Ministry of the Environment No 478 Of June 3 1994' prohibiting the use of certain ozone depleting substances). No exemptions have been granted since the complete phase out of MB on 1 January 1998.
- In February 1998, member states of the European Union agreed a Common Position on a new EC Regulation on ozone depleting substances that include:
  - ⇒ QPS: Capped at average of 1996-98 consumption;
  - ⇒ 2001: All uses except QPS, reduction of 60%;
  - ⇒ 2003: All uses except QPS, reduction of 75%;
  - ⇒ 2005: Phaseout non-QPS uses, with Montreal Protocol critical use exemption;
  - ⇒ 2006: Ban on sales and use of MB except for critical uses.



## **5. Alternatives to Methyl Bromide for Use in Quarantine and Pre-shipment**

### **5.1 Definition of an alternative**

MBTOC (1998) defined 'alternatives' as:

*Those non-chemical or chemical treatments and/or procedures that are technically feasible for controlling pests, thus avoiding or replacing the use of MB. 'Existing alternatives' are those in present or past use in some regions. 'Potential alternatives' are those in the process of investigation or development.*

MBTOC assumed that an alternative demonstrated in one region of the world would be applicable in another unless there were obvious constraints to the contrary e.g., a very different climate or pest complex. MBTOC is not required in its terms of reference to conduct economic studies on MB and alternatives. Additionally, while local registration, environmental and social impacts of an alternative were often discussed, these may be specific to the country or local region. Therefore, MBTOC did not consider it appropriate to omit alternatives on such grounds.

### **5.2 Managing pest risk**

For both perishable and durable commodities, quarantine treatments using MB or alternatives are crucial for minimising the risk of plant pests becoming established in new regions.

A pest or pathogen which establishes in a new habitat area may expand its distribution explosively, causing serious loss to agricultural and forestry production if the climatic and other environmental conditions are favourable for its reproduction and there are no natural enemies to suppress its population increase. Many pests can cover large distances by flying, or by being carried by wind or commerce. Today, many of the economically important species of pests are those that have been accidentally introduced through international trade of agricultural and other commodities.

Once a pest is introduced, eradication can be extremely difficult, costly and labour intensive. Quarantine pests detected in a country or region previously free of them can result in considerable cost caused by suspension of exports, eradication measures and implementation of a disinfestation treatment if eradication is not achievable.

Most importing countries therefore inspect consignments and sample product for pests in order to minimise the risk of accidentally importing pests. If one or

more pests of quarantine concern are detected, a treatment is undertaken or, if no treatment method is available for use, the consignment may be rejected, re-shipped to the country of origin or to some other destination, or destroyed. Treatments may also be required by Regulatory Authorities where there is an unacceptable risk that a consignment may contain a particular pest, although not detected by inspection.

Many countries have a list of pests that are considered serious quarantine pests. More recently, the importing country requests notification of pests associated with a commodity from the exporting country Regulatory Agency. If the importing country undertakes a pest risk assessment and categorises pests on the exporting country's list as regulated quarantine pests or regulated non-quarantine pests (see Glossary Appendix 1), some form of treatment may be required before the import ban will be lifted. In most cases, disinfestation treatments are required to achieve the highest level of security possible. In this respect, quarantine treatments differ from many pest control practices in the field in which the aim is to suppress pest populations below economic threshold levels.

### **5.3 Application of QPS treatments**

Treatments with MB or alternatives aim to achieve a pest-free status for perishable and durable commodities by controlling pest infestation prior to shipment, during shipment or at point of receipt. MB is sometimes specified for quarantine purposes for control of other organisms (e.g. ticks, snails) that may be incidental contaminants of durable foodstuffs or timber, but are known to not normally infest and damage the commodity.

Treatments may be required under exporting country legislation to meet domestic standards requiring lack of pest infestation at point of export. Where MB is used for pre-shipment, exemptions from control under the Protocol for this MB consumption only apply to those Parties whose domestic legislation requiring treatment was in effect at the time of the passing of Decision VI/11 for non-Article 5(1) Parties (7 October 1994) and at the time of the passing of Decision VII/5 (7 December 1995) for Article 5(1) Parties.

MB fumigation is by far the most predominant treatment to meet an importing country's phytosanitary requirements as it acts rapidly and it minimises delays in releasing the product to the market. It has the reputation for consistent effectiveness. MBTOC noted that MB was applied as a mandatory treatment for durable commodities a number of countries in several important situations. These MB applications were for disinfestation of bulk grain to meet phytosanitary requirements at the point of import or export; quarantine treatments against specific pests, particularly khapra beetle (*Trogoderma granarium*), the house longhorn beetle (*Hylotrupes bajulus*) and various

snails; and for disinfestation of dried vine fruit, some other dried fruit and nuts prior to export.

Treatment regimes for shipped product are often subject to stringent time constraints as both aircraft and ships can incur severe financial penalties or other consequences to operators if sailing or flight times are delayed. If the intercepted pest is non-injurious to plants, the shipment will be released from the inspection area. Mandatory treatments in the exporting country may be required if pests are difficult to detect, or if the pest is of extreme concern to the importing country.

#### **5.4 Comparison of QPS for perishable and durable commodities**

Perishable commodities include fresh fruit and vegetables, cut-flower exports, some fresh root crops and bulbs, and ornamental plants. In terms of 'QPS', the majority of treatments known to MBTOC for perishable commodities were categorised as 'Quarantine', with the possible exception of disinfestation of some fresh root crops and bulbs which may be categorised as 'Pre-shipment' treatments.

Durable commodities, on the other hand, are those with a low moisture content that, in the absence of pest attack, can be safely stored for long periods. They include foods such as grains, dried fruits and beverage crops; and non-foods such as wood products and tobacco. Wood products include artefacts and other items of historical significance; unsawn timber, timber products and bamboo ware; and packaging materials and other wooded items.

In contrast to perishable commodities, most treatments applied to durable commodities are pre-shipment as they typically aim to control pests that have cosmopolitan distributions that can increase in abundance in the commodity while in storage and during transportation.

Relatively few durable commodity treatments are applied to control quarantine pests. Treatments may be required by importing countries to ensure commodities are reasonably free of infestation and thus capable of being stored without immediate product loss and cross contamination of existing stock. However, such treatments do not fall within MBTOC's and TEAP's understanding of the scope of the QPS exemption as they are neither applied to control quarantine pests, nor are they applied at the point of export and immediately prior to shipment.

#### **5.5 Security of quarantine treatments**

Mandatory quarantine treatments in the exporting country may be required if pests are difficult to detect, or if the pest is of extreme concern to the importing country. Historically, acceptance of a new quarantine treatment by

contracting Parties has taken 2-15 years because of extensive data collection and reporting requirements. Such treatments aim for minimal risk of pest risk, achieved by research that relies on extensive data collection and reporting aimed at achieving a level of phytosanitary security of Probit 9, equivalent to 99.9968% pest mortality. Traditionally, this level of security may be achieved by a single well-conducted MB fumigation. Reports submitted to the overseas Regulatory Agency by governments (acting on behalf of researcher staff) can take many years to approve and are often the major reasons for the time taken to implement a new treatment.

The use of Probit 9 security is typically based on a policy directive rather than technical justification. Some scientists have suggested that Probit 9 mortality may not be necessary to achieve quarantine security as it may be too severe, impractical and unnecessary for commodities that are rarely or poorly infested (Landolt *et al.* 1984, Baker *et al.* 1990, Vail *et al.* 1993; Liquido *et al.* 1996). Many perishable commodities are adversely affected by MB dosage rates required to reach such mortality levels. In the US, USDA-APHIS requires Probit 9 treatments for fruit flies, with very few other treatments requiring Probit 9 as the basis for their approval. However, other countries such as Japan and Australia require Probit 9 security for a range of pests including fruit fly.

In order to avoid loss of exports or restriction on imports due to the unavailability of a commercial alternative to MB, treatment acceptance criteria other than Probit 9 for quarantine treatments should be developed and implemented as soon as possible. An alternative approach that has been proposed is to measure the risk as the probability of survival of one or more reproductive pest stages in a shipment. Harte *et al.* (1992) developed a probability model to quantify the quarantine risk from importing fruit fly hosts, based on pre-determined and known infestation levels in the host, lot size imported and the tolerance level permitted.

MBTOC noted that there is an inherent technical flaw with Probit 9 and any analysis based on mortality because it only indirectly accounts for survivors, which is the actual concern for quarantine security. Therefore, treatments based on mortality assume a worst case scenario and must aim for overkill to ensure that every possible application results in zero survivors though statistically variable in the level of confidence.

In 1995, the IPPC developed Guidelines called 'Principles of Plant Quarantine as related to International Trade' complementing the principles of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). These guidelines seek to harmonise quarantine policies between countries and it is clear that these principles will influence the development and use of alternative treatments in the future. For example, for regulated pests, the exporting country can request that the importing country define the pests of concern and level of security required. Under these guidelines, importing



countries are encouraged to consider basing the level of security based on an appropriate level of protection. Alternative treatments that are developed and implemented by integrating many technical, environmental and regulatory factors should be considered acceptable alternatives to a disinfestation treatment if demonstrated to achieve the appropriate level of protection (principle of equivalence). The alternative measures can therefore include pest mitigation activities such as pest control in the field, packing, distribution and inspection. These mitigation activities seek to minimise the incidence of pests in the commodity to meet the level of security required by the importing country.

The opportunity for researchers to identify alternative treatments to MB increases considerably when a single prescriptive requirement (such as fumigation with MB) can be replaced with a series of less stringent security events (e.g. field control, packing, inspection) that collectively meet the level of phytosanitary security required by the importing country.

Mamat and Husain (1994) have proposed a standard quarantine treatment protocol design to be considered by researchers when embarking on a treatment that will be evaluated by a regulatory agency. A useful summary of the regulatory factors affecting international trade has been provided by Ganapathi (1994) in which harmonisation of phytosanitary principles, plant quarantine procedures and pest risk assessment are discussed. Shannon (1994) also discusses the principles of international trade and outlines the system of pest risk analysis used by the United States Animal and Plant Health Inspection Service (US-APHIS). Most recently, the Japan Plant Quarantine Association has published the theory and practice of fumigation and thermal (heat treatments, cold treatments) disinfestation techniques, including procedures for undertaking and confirming treatments (Anon 1998).

The quarantine treatments available for perishable commodities are discussed in the next Section, whereas QPS treatments for durable commodities and structures are discussed in Section 5.9.

## **5.6 Quarantine treatments for perishable commodities**

The MBTOC 1998 Assessment estimated that 22% of MB global consumption was used for disinfestation of both perishable and durable commodities, with about 9% used for disinfestation of perishable commodities, mainly fruit, for quarantine purposes.

Although global consumption for quarantine treatments is relatively low in volume, this amount of MB is nevertheless very significant as, in the absence of alternatives officially approved for the commodity-pest combination, it allows import and export of high-value perishable commodities. One of the major uses of MB in this category is to disinfest consignments intercepted on arrival with pests deemed unacceptable to the importing country.

The MBTOC 1998 Assessment divided quarantine treatments into those that existed and are available in commercial practice ('Existing') and those that were under development ('Potential') for apples and pears, berryfruit, bulbs, citrus, cucurbits, cutflowers and ornamentals, grapes, root crops, stonefruit, subtropical fruit, tropical fruit and vegetables. A summary of that report is provided here with considerably more detail provided in the MBTOC 1998 Assessment.

## **5.7 Existing alternative treatments for perishable commodities**

There are at least thirteen different categories of alternative treatments e.g. heat, cold, pre-shipment inspection, that are approved by Regulatory Agencies in one or more countries for disinfestation of perishable commodities, but only for specific applications. MBTOC identified more than 270 cases where countries have approved a treatment that is an alternative to MB, largely compiled from the United States Department of Agriculture - Animal and Plant Health Inspection Service Treatment Manual (Table 5.1).

**Table 5.1:** *Examples of approved quarantine treatments for perishable commodities.*

<b>Procedure or treatment</b>	<b>Examples of approved quarantine applications</b>
Cold treatments	Many approved cases – see Table 5.2 for examples.
Heat treatments	Mangoes from Australia, Philippines, Taiwan and Thailand to Japan. Papaya from Hawaii to Japan. Tomato, bell pepper, zucchini, eggplant, squash, mango, pineapple, papaya and mountain papaya to USA. Orange, grapefruit, clementine, mango from Mexico to USA Mountain papaya from Chile to USA Citrus, papaya, lychee, from Hawaii to mainland USA. Papaya from Belize to USA. Mango from Taiwan to USA. Ear corn to USA Orchids, plants and cuttings to USA. Chrysanthemum cuttings to USA. Plant material unable to tolerate MB fumigation to USA. Banana roots for propagation to USA. Many bulbs and tubers to USA. Narcissus bulbs to Japan.
Certified pest-free zones or pest-free periods	Melons from a region of China and from the Netherlands to Japan. Squash, tomatoes, green pepper, eggplant from Tasmania (Australia) to Japan Cucurbits to Japan and USA. Nectarines from USA to New Zealand.
Systems Approach	Immature banana to Japan. Avocado. Citrus from Florida to Japan.
Pre-shipment inspection and certification	Certain cut flowers from Netherlands and Colombia to Japan. Apples from Chile and New Zealand to USA. Garlic from Italy and Spain to USA. Nectarines from New Zealand to Australia. Green vegetables to many countries.
Inspection on arrival	Small batches of seeds for propagation to USA.
Physical removal of pests.	Root crops are accepted by many countries if all soil removed. Hand removal of certain pests from cut flowers to USA. Propagative plant materials (unable to tolerate MB fumigation) to USA.
Controlled atmospheres	Apples from Canada to California.
Pesticides, fumigants and aerosols	Cut Flowers from New Zealand to Japan. Asparagus to Japan. Cut flowers from Thailand and Hawaii to Japan. Bulbs to Japan. Tomatoes from Australia to New Zealand. Propagative plant material to USA. Certain ornamental plants to USA.
Irradiation	Papaya, carambola, litchi, plums and garlic.
Combination treatments	Soapy water and wax coating for cherimoya and limes from Chile to USA. Warm soapy water + brushing for durian and other large fruit to USA. Vapour heat and cold treatment for litchi from China and Taiwan to Japan. Pressure water spray and insecticide for certain cut flowers to USA. Hand removal + pesticide for certain ornamental plants, Christmas trees and propagative plant materials to USA. Heat treatment + removal of pulp from seeds for propagation to USA.

Examples of the range of commodities treated by one alternative treatment such as ‘cold disinfestation’, and countries that accept the treatment, are provided in Table 5.2.

**Table 5.2:** *Examples of cold treatments approved as quarantine treatments by various countries and for a range of commodities.*

<b>Perishable commodity</b>	<b>Examples of cold treatments approved for quarantine</b>
Apple	<ul style="list-style-type: none"> <li>From Mexico, Chile, South Africa, Israel, Argentina, Brazil, Italy, France, Spain, Portugal, Jordan, Lebanon, Australia, Hungary, Uruguay, Ecuador, Guyana and Zimbabwe to USA</li> </ul>
Cherry	<ul style="list-style-type: none"> <li>From Mexico, Chile and Argentina to USA</li> </ul>
Grape	<ul style="list-style-type: none"> <li>From Chile to Japan.</li> <li>From South Africa, Brazil, Colombia, Dominican Republic, Ecuador, Peru, Uruguay, Venezuela and India to USA</li> </ul>
Citrus	<ul style="list-style-type: none"> <li>From Australia, Florida (USA), Israel, South Africa, Spain, Swaziland and Taiwan shipped to Japan</li> <li>From South Africa (Western Cape) and 23 countries to USA</li> </ul>
Orange	<ul style="list-style-type: none"> <li>From Israel, Mexico, Spain, Morocco, Costa Rica, Colombia, Bolivia, Honduras, El Salvador, Nicaragua, Panama, Guatemala, Venezuela, Guyana, Belize, Trinidad &amp; Tobago, Suriname, Bermuda, Italy, Greece, Turkey, Egypt, Algeria, Tunisia and Australia to USA</li> <li>Interstate USA</li> </ul>
Clementine	<ul style="list-style-type: none"> <li>From Israel, Spain, Morocco, Costa Rica, Colombia, Guatemala, Honduras, Ecuador, El Salvador, Nicaragua, Panama, Venezuela, Suriname, Trinidad &amp; Tobago, Algeria, Tunisia, Greece, Cyprus and Italy to USA</li> <li>Interstate USA</li> </ul>
Tangerine	<ul style="list-style-type: none"> <li>From Mexico, Australia and Belize to USA</li> <li>Interstate USA</li> </ul>
Grapefruit	<ul style="list-style-type: none"> <li>From Israel, Mexico, Costa Rica, Guatemala, Honduras, El Salvador, Nicaragua, Panama, Colombia, Bolivia, Venezuela, Italy, Spain, Tunisia, Australia, Suriname, Trinidad &amp; Tobago, Belize, Bermuda, Cyprus, Algeria and Morocco to USA</li> <li>Interstate USA</li> </ul>
Peach	<ul style="list-style-type: none"> <li>From Mexico, Israel, Morocco, South Africa, Tunisia, Zimbabwe, Uruguay and Argentina to USA</li> </ul>
Nectarine	<ul style="list-style-type: none"> <li>From Israel, Argentina, Uruguay, Zimbabwe and South Africa to USA</li> </ul>
Apricot	<ul style="list-style-type: none"> <li>From Mexico, Israel, Morocco, Zimbabwe, Haiti and Argentina to USA</li> </ul>
Plum	<ul style="list-style-type: none"> <li>From Mexico, Israel, Morocco, Colombia, Argentina, Uruguay, Guatemala, Algeria, Tunisia, Zimbabwe and South Africa to USA</li> </ul>
Plumcot	<ul style="list-style-type: none"> <li>From Chile to USA</li> </ul>
Kiwifruit	<ul style="list-style-type: none"> <li>From Chile to Japan</li> <li>From Chile, Italy, France, Greece, Zimbabwe and Australia to USA</li> </ul>
Pear	<ul style="list-style-type: none"> <li>From Israel, Chile, South Africa, Morocco, Italy, France, Spain, Portugal, Egypt, Tunisia, Algeria, Uruguay, Argentina, Zimbabwe and Australia to USA</li> </ul>
Persimmon	<ul style="list-style-type: none"> <li>From Israel, Italy and Jordan to USA</li> </ul>
Pomegranate	<ul style="list-style-type: none"> <li>From Israel, Colombia, Argentina, Haiti and Greece to USA</li> </ul>
Litchi	<ul style="list-style-type: none"> <li>From China, Israel and Taiwan to USA</li> </ul>
Loquat	<ul style="list-style-type: none"> <li>From Chile, Israel and Spain to USA</li> </ul>
Quince	<ul style="list-style-type: none"> <li>From Chile and Argentina to USA</li> </ul>
Carambola	<ul style="list-style-type: none"> <li>From Hawaii, Belize and Taiwan to USA</li> </ul>
Pummelo	<ul style="list-style-type: none"> <li>From Israel to USA</li> </ul>
Papaya	<ul style="list-style-type: none"> <li>From Chile to USA</li> </ul>
Ya pear	<ul style="list-style-type: none"> <li>From China to USA</li> </ul>

Ethrog	<ul style="list-style-type: none"> <li>From Israel, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Morocco, Spain, Italy, France, Greece, Portugal, Tunisia, Syria, Turkey, Albania, Algeria, Belize, Bosnia, Macedonia, Croatia, Libya, Corsica and Cyprus to USA</li> </ul>
Durian	<ul style="list-style-type: none"> <li>To USA</li> </ul>
Avocado (Sharwill)	<ul style="list-style-type: none"> <li>From Hawaii to mainland USA</li> </ul>

Despite this number and range of quarantine treatments, only a small proportion of commodities in commercial trade are treated in the exporting country using these alternatives. Most countries will not accept an alternative for a specific commodity until the treatment efficacy is proven for each commodity-pest combination. Post-entry alternative treatments used by the importing country are particularly problematical because many alternatives have neither been approved for treating a specific product on arrival, nor would they be easy to implement. To solve this problem, a range of officially approved alternatives are urgently needed to cope with a large and highly varied volume of produce entering via multiple air and sea ports. Such treatments would need to be able to treat perishable commodities quickly in order to avoid congestion at busy ports.

Alternatives to MB for perishable commodities can be based on: (1) pre-harvest practices and inspection procedures; (2) non-chemical treatments; and (3) chemical treatments.

Those based on pre-harvest practices include: a description of cultural techniques leading to pest reduction; agreement on pest-free zones; and inspection certification. In these cases, regulatory approval depends on a number of factors including: knowledge of the pest-host biology; evidence of commodity resistance to the pest; trapping and field treatment results; surveillance for pests and diseases; and careful documentation.

Non-chemical treatments kill pests by exposure to changes in temperature and/or atmospheric conditions, or high energy processes such as irradiation and microwaves, or physical removal using air or water jets. Often a combination of treatments is required to kill pests because they can be tolerant to treatments applied singularly. A greater understanding of the physiological changes occurring in both pests and commodities will be essential to expedite the development of disinfestation treatments based on these non-chemical alternatives.

Chemical fumigation treatments are feasible, but the number of chemicals is limited at present mainly because companies are reluctant to make submissions for registration, due to the high costs of demonstrating compliance with health and safety standards. However, for cut-flower exports without alternatives to MB, chemical dips can be a practical and efficacious method to control pests, particularly if occupational standards for their safe

use and disposal are implemented and the treatment is approved by the importing country.

For each category of alternative to MB, MBTOC noted country-specific official approval for specific commodities, commodity-pest combination or several commodities within a class (e.g. citrus): *heat* treatments for at least eleven commodities including citrus, mango, papaya, bell pepper, eggplant, pineapple, squash, tomato and zucchini; *chemical* treatments for citrus, vegetables, cut flowers and bulbs; *cold* treatments for apples, pears, citrus, grapes, kiwifruit, carambola and avocado; *pest-free zones* for apples, berryfruit, some vegetables, cucurbits, avocado and papaya; the *systems approach* for citrus, apples and melons; and *irradiation* for papaya, litchi and carambola.

## **5.8 Potential alternative treatments for perishable commodities**

The MBTOC 1998 Assessment identified where alternatives could be developed for a range of perishable commodities. Commercialisation of any of these treatments as replacements for MB will depend on a number of factors that include: proven treatment efficacy; commodity tolerance; equipment design and commercial availability; cost competitiveness; regulatory approval; logistical capability; availability and agreement on the scientific research required for regulatory approval; and technology transfer. Given all of these considerations, the time from conception to implementation of an alternative disinfestation treatment for perishable commodities has traditionally varied from 2 to 15 years. However, the process could be more rapid if countries were to give priority to approving alternatives.

In the future, if MB for quarantine treatments is not permitted and if no alternatives to MB are available to disinfest consignments intercepted with pests of quarantine concern, infested consignments may be prohibited, re-shipped or destroyed. In general, alternative 'on-arrival' quarantine treatments with full approval and speed of action have yet to be developed. Alternatively, import of consignments considered high risk for pest infestation may be prohibited until an alternative treatment has been implemented in the exporting country to reduce pest contamination to a level acceptable to the importing country.

## **5.9 QPS treatments for durable commodities and structures**

There are a large number and variety of alternatives to MB for disinfestation of durable commodities and structures. Some alternatives (e.g. some fumigants, heat treatment) can be implemented as stand alone treatments to replace MB in certain situations. In general, however, the level of pest risk may be brought to an acceptable level by combining two or more alternatives.

A treatment based on combinations of measures (commonly called a “systems approach”) may be mandatory in many situations. With careful management of storage facilities, control of pests is possible using a range of methods that results in grain at point of export not requiring a disinfestation treatment.

Most of the target pests of durables and structures that are treated with MB are insects and, to a lesser extent, mites. Fungi and nematodes are not typically target organisms, except with unsawn timber and seeds for planting, respectively.

The major uses of MB which MBTOC identified as quarantine applications for durables were treatment of:

- Export unprocessed logs infested with insects and/or fungi of quarantine concern;
- Packaging materials and dunnage infested by beetles and other quarantine pests of concern to the importing country; and
- A large variety of durable commodities (grains, processed meals and packaged materials) at risk of carrying *Trogodema granarium*.

The major uses of MB which MBTOC identified as pre-shipment applications for durables were treatment of:

- Grains or dried fruit at export under existing exporting country legislation or to meet the official requirements of importing countries;
- Empty ships prior to loading grain for export to meet existing exporting country legislation; and
- A variety of durable products to meet the official requirements of importing countries.

There are some applications of MB such as against the Khapra beetle (*T. granarium*) and various other wood-boring insects which are classified as quarantine by some countries but not others.

The principal alternatives in use for durable commodities are phosphine, heat, cold and contact pesticides; for wood products, they are sulphuryl fluoride, controlled atmospheres, chemical wood preservatives and heat; for means of conveyance, they include sulphuryl fluoride and heat. The choice of appropriate alternatives is dependent on the commodity or conveyance to be treated, the situation in which the treatment is required, the accepted level of pest risk, the speed of action required and the cost.

In many cases, an Integrated Pest Management (IPM) program combining several different measures can effectively replace a particular use of MB. Occasional full-site or curative treatments may be required to supplement IPM programs in the event of an unacceptable increase in a pest number. These may involve fumigation, possibly with MB, or other processes.

Phosphine is the only available in-kind alternative extensively used worldwide, principally for stored cereals and similar products. It has the potential to act as a direct substitute for MB in many situations, but can also act as a component of an IPM process to avoid MB use. Phosphine was approved by the European Plant Protection Organisation in 1994 as an alternative quarantine treatment to MB for disinfestation of cotton boll weevil (*Anthonomus grandis*) in bulk cotton. Its action against pests is much slower than MB, particularly at low temperatures. However, insect populations in grain and other commodities are capable of developing resistance to phosphine relatively easily. Therefore, it was considered important to use correct exposure and application technology to avoid development of resistance and thus loss of this useful alternative.

There are several other fumigants which may have limited potential as alternatives for MB (Table 5.3). Although hydrogen cyanide was once widely used for treatment of structures and durable commodities, its availability and limitations related to health and safety issues may prevent its immediate substitution for particular uses of MB. Hydrogen cyanide is an approved treatment in India for cotton infested with *A. grandis*. Ethyl formate, carbon bisulphide and ethylene oxide are useful in selected situations. Sulphuryl (sulfuryl) fluoride is mainly used for controlling wood-destroying pests in residences and other buildings as a direct, in-kind alternative to MB. It is also used for disinfestation of wood. However, its use is limited by a lack of registration in many countries.

**Table 5.3:** Examples of fumigants approved for quarantine treatments by USA authorities (USDA-APHIS) for durable commodities.

Treatment and commodities	Treatment information
Tobacco for export	96 hours phosphine
Cotton, cotton waste and cotton products in bulk, against boll weevil etc.	120 hours phosphine
Seeds of cotton, packaged or bulk	120 hours phosphine
Seeds & dried pods, okra, kenaf, etc.	120 hours phosphine
Bales of hay	72 hours phosphine
Wooden items with wood borers	72 hours phosphine
Non-plant articles infested with ticks	24 hours carboxide
Non-plant articles infested with ticks	24 hours sulphuryl fluoride
Wooden items with wood borers	24 hours sulphuryl fluoride
Wood products, containers with termites	24 hours sulphuryl fluoride



Treatment with controlled atmospheres, based on carbon dioxide or nitrogen, offers an alternative to fumigation for insect pest control, but not fungal pests. They are unlikely to be used where fast turn-around is necessary, unless the technique is combined with such measures as high pressure or raised temperature, but it can be applied in export situations with appropriate management.

Physical methods of insect control, including mechanical measures, cold, heat and irradiation treatments, offer further potential as non-chemical alternatives in individual circumstances. Cold treatments are now used as part of IPM systems for stored products and artifacts. Heat treatment technologies are now used and match the speed of treatment afforded by MB and other fast-acting fumigants. Heating can also synergise the effects of other treatments, for example fumigants, controlled atmospheres and inert dusts.

Where registered for use, contact insecticides may provide persistent protection against reinfestation. In some situations, the use of dichlorvos offers a direct alternative to MB, for disinfestation of bulk grain during turning or loading at point of export. Contact insecticides are not normally registered for use on processed commodities or dried fruit, nuts and cocoa.

Examples of alternatives available for disinfestation of durable commodities, structures and transport are listed in Table 5.4.

**Table 5.4:** *The main alternatives to methyl bromide available for disinfestation of durable commodities, structures and transport vehicles.*

<b>Alternative</b>	<b>Application</b>
CO <sub>2</sub> CO <sub>2</sub> (+ high pressure)	Containerised cargo in transit. Used for some exports from Australia. Dried fruit and beverage crops. High pressure reduces time to several hours. In limited use in Germany.
Cold	Disinfestation of artefacts and museum pieces. In widespread use.
Controlled atmospheres	Disinfestation of artefacts and museum pieces, and some export grain.
Debarking	Debarking logs in the exporting country to control bark beetles. Limited use at present.
Ethyl formate	Prepacked dried fruit. In use in Australia and South Africa
Heat	Controls the most important pest of bulk grain, khapra beetle <i>Trogoderma granarium</i> . Can be as fast acting as MB. As steam for fungal treatment of logs, may also be effective in killing insects, mites and snails. Increasingly use for disinfestation of mills and food processing premises. Kiln drying disinfests sawn timber.
Hydrogen cyanide	Once widely used in mills. Used against rodents in Singapore and France in ships and aircraft.
Insecticides	Dichlorvos as a bulk grain disinfestant applied several days prior to export. Subject to approval. Approved treatment in Japan for disinfestation of pests and fungi for logs restrained but floating in a harbour. Disinfestation of aircraft as aerosol and residual applications. Insecticides widely used, but often subject to approval. Pressure impregnation of insecticides approved by Australia for disinfestation of wooden pallets for control of <i>Sirex noctilio</i> and other wood pests. Combined with regulation and certification, control of seed-borne nematodes infesting rice, wheat, legumes and onions prior to import.
Integrated Pest Management	Diverse range of chemical and non-chemical control strategies that is becoming widespread for controlling pests in mills and commodities.
Irradiation	Not accepted as a quarantine treatment for durables. Some high dose levels for durable commodities can prevent germination and also make them unsuitable for processing.
Pest-resistant packaging	Common for many dried fruit, cereal and nuts
Phosphine	Bulk and bagged grain disinfestation in many countries. Where regulations permit, used for in-transit shipboard fumigation. Disinfestation of bark beetles, wood-wasps, longhorn beetles and platypodids in logs. Registered only in the USA. Approximate 72h treatment period restricts commercial acceptability. Bamboo treated in transit to avoid treatment on arrival in Japan. Rapidly lethal to rodents.
Rodenticides and traps	Disinfestation of structures and transport vehicles. Applicable where time is not a constraint.
Sulphuryl fluoride	Disinfestation of wood-destroying pests such as bark beetles, wood-wasps, longhorn beetles, powderpost beetles and dry wood termites in structures. Egg stages require high dosages for control. Not registered in many countries. Widely used in the USA. Where available, used for disinfestation of sea containers.
Water immersion	Disinfestation of logs over 30-day period. Needs expansive water area. Used in Japan in combination with insecticide for exposed log surfaces.

Specific examples of quarantine treatments for durable commodities that do not rely on MB are provided in Table 5.5.

**Table 5.5:** Examples of non-chemical treatments approved as quarantine treatments by USA authorities (USDA-APHIS) for durable commodities.

<b>Treatment and commodities</b>	<b>Temperature, duration</b>
<b><i>Heat treatments</i></b>	
Any durable commodity that can tolerate heat to control Khapra beetle	7 minutes at 150°F
Feeds & milled products for processing	7 minutes at 150°F
Bagasse/sugarcane	2 hours at 158°F
Bags for seeds	1 hour at 212°F
Lumber (3" thick) with wood borers	14 hours at 130°F or 7 hours at 140°F
Corn (maize) ears not for propagation	2 hours at 168°F
Rice straw novelties and articles	2 hours at 180°F
Niger seeds with soil or Khapra beetle	15 minutes at 212°F
<b><i>Steam treatments</i></b>	
Niger seeds with soil or Khapra beetle	15 minutes at 212°F
Seeds not for propagation	to 212°F
<b><i>Steam treatments with pressure</i></b>	
Rice straw and hulls, straw mats	30 minutes
Rice straw novelties	30 minutes
Novelties and articles from broomcorn	30 minutes
<b><i>Vacuum steam flow process</i></b>	
Leaf tobacco for export	15 minutes at 170°F
Blended strip tobacco for export	3 minutes at 160°F
<b><i>Hot water dips</i></b>	
Bulbs with <i>Ditylenchus</i> nematodes	2 hours at 75°F and 4 hours at 110°F
Lily bulbs with <i>Aphelenchoides</i> nematodes	102°F
Senecio with <i>Aphelenchoides</i> nematodes	1 hour at 110°F
Narcissus bulbs with bulb scale mite	1 hour at 110°F
Certain tubers with <i>Meloidogyne</i> spp.	30 minutes at 118°F
Horseradish root with golden nematode	30 minutes at 118°F
Banana roots	30 minutes at 110°F and 60 minutes at 120°F
Sugarcane	4 hours at 110°F
More than 17 other hot water treatment schedules	Various schedules
<b><i>Freeze treatments</i></b>	
Items with insects in soil	5 days at 0°F

Source: Compiled from US Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) 'Plant Protection and Quarantine Treatment Manual', revised edition, Hyattsville, 1993.

## 5.10 QPS methyl bromide treatments without an alternative

### 5.10.1 Perishable commodities

For perishable commodities, MBTOC noted there were currently no approved alternatives for certain economically important exports: Apple, pear and stonefruit that are hosts to codling moth; for many pests on berryfruit; for grapes infested with, for example mites, exported to some countries; and some root crops exported by countries if soil was present or pests of concern were

detected on arrival. For details, see MBTOC 1998 Assessment Report, page 226.

#### 5.10.2 Durable commodities

There are certain current QPS uses of MB for which MBTOC did not identify any existing alternatives. For durables, these were disinfestation of:

- Military equipment contaminated with soil against soil pathogens;
- Oak logs with oak wilt fungus;
- Fresh chestnuts and walnuts;
- Seed-borne nematodes from alfalfa and some other seeds for planting;
- Empty ships where other methods have failed; and
- Organophosphate-resistant mites in traditional cheese stores.

In the treatment of mills and food processing facilities where IPM systems have been applied inadequately and failed, it may be necessary to resort to occasional use of MB. Where hydrogen cyanide is not available as an alternative, for example, for disinfestation of aircraft, there are no proven alternatives to MB. The total of all of these QPS uses is unlikely to exceed 50 tonnes per annum worldwide.

### 5.11 QPS uses by Article 5(1) Parties

Responses to MBTOC's QPS survey indicated that, of the 33 Article 5(1) respondents, 15 reported they used MB for QPS, and 12 reported that they did not use MB for this purpose. Ten countries reported that they used MB for quarantine, and 11 reported that used it for pre-shipment. The quantity of MB for quarantine purposes in Article 5(1) countries is believed to be more significant than for pre-shipment purposes, but further responses to the survey are required in order to confirm this belief. Quarantine treatments are applied to both exported and imported commodities.

#### 5.11.1 Exported commodities

Some Article 5(1) Parties that import and export large quantities of cereal commodities are heavily dependent on fumigation with MB to satisfy their own or other countries' quarantine regulations. Article 5(1) MBTOC members noted that some treatments were not strictly QPS as they were being carried out in response to commercial purchase contracts that specified a treatment. Pre-shipment fumigation with MB is of major significance in certain countries that export large quantities of rice, almost all of which is fumigated with MB immediately prior to shipment. Treatments are completed in 24 - 48 hours. A change to another method of disinfestation such as phosphine would require a much longer treatment period and would require substantial changes to the

present storage and export system, particularly where fumigation has to be conducted at short notice. In-transit treatment with phosphine may be an alternative to MB at point of export, where regulations permit and suitable ships (well-sealed bulk carriers) are used in the trade.

Treatments allowing export include, for example:

- Wood packing material for control of the Asian longhorn beetle prior to export of manufactured goods from China to USA, Canada and Australia;
- Tobacco exported to Japan and Taiwan from Malawi, for control of cigarette beetle;
- Dried fish maws exported from Kenya, Uganda and Tanzania;
- Bixa seeds exported from Kenya;
- Grapes and other fruit exported from Chile to the USA;
- Citrus and vegetables exported from Argentina to Chile for control of Mediterranean fruit fly (*Ceratitis capitata*, *Anastrepha fretercullus*);
- Wood pallets exported from Argentina to Australia;
- Cotton exported from Argentina to Peru for control of Mexican boll weevil; and
- Logs exported from Malaysia to Australia and other countries.

#### 5.11.2 Imported commodities

MB fumigation is important in some countries as a quarantine treatment for disinfestation of imported commodities. On inspection at destination ports, durable commodities such as grains are often found to be infested on board ship. In some cases, this occurs because pre-shipment MB treatments were applied ineffectively. The plant protection authorities of many countries will not allow unloading to commence until the commodity has been disinfested, irrespective of whether or not the infestation is due to a quarantine pest. In order to avoid demurrage or other port charges it is necessary to fumigate the ship as quickly as possible and for this reason MB is almost always used.

Treatments include, for example:

- Straw used for packing melamine and marble;
- Cotton and used paper products imported into China;
- Grain imported into Kenya and the region (for refugees) for control of larger grain borer (*Prostephanus truncatus*);
- Ship holds in vessels from China for control of khapra beetle;
- Treatment of grain in transit within Eastern and Central Africa for the control of larger grain borer; and
- Growing substrates and logs imported by China.

Developing countries are particularly dependent upon the use of MB for quarantine treatments of seed lots because national authorities often permit imports only if fumigated in the country of origin or at ports of entry.

#### 5.11.3 Alternatives for Article 5(1) Parties

Phosphine may be suitable as an alternative to MB for treatment of empty ships and barges for rodent and insect control prior to loading commodity. Some developing countries currently use MB for this purpose. While phosphine is rapidly lethal to rodents, its slow action against insect pests and consequent demurrage costs may limit its usefulness. Where ships contain cargo and where regulations permit, in-transit fumigation with phosphine or modified atmosphere treatments may be feasible.

MBTOC noted that there are alternatives to MB for some QPS treatments available both in non-Article 5(1) and not Article 5(1) countries. Jamaica, Syria and Chile would benefit in particular by the transfer of this technology for quarantine treatment of perishable commodities.

#### 5.11.4 Options for the Parties to consider

In order to address QPS uses adequately in Article 5(1) countries, Parties could consider:

- Mandatory data reporting on MB consumption for QPS for all Parties that have ratified the Copenhagen Amendment, rather than voluntary reporting of QPS as at present;
- Assistance to Article 5(1) Parties for technology transfer on alternatives to QPS uses and on emission control (including recycling);
- Investment in recycling and recovery technology, recognising this as an interim solution to the final solution of MB alternatives; and
- Reviewing the necessity of MB treatments required by Article 5(1) Parties for products exported to non-Article 5(1) Parties.

## **6. Prospects for Recovery, Containment and Recycling**

### **6.1 Introduction**

This chapter describes the scope and options for reducing emissions of MB from QPS treatments. A fuller description and history of the technologies considered for recycling and recovery has been given in the two previous MBTOC reports (MBTOC 1994, 1998).

Emissions from fumigation operations occur through leakage and permeation during treatment (inadvertent emissions) and from venting at the end of a treatment (intentional emissions). For some commodities there can also be a significant retention of MB by the commodity or its packaging. Some of this MB reacts with other chemicals in the commodity and so is never emitted, but some will desorb slowly after the fumigation treatment, often for 1-2 days (or longer) depending on the temperature. None of the technologies described in this report is capable of recovering this desorbed MB. The quantity of MB emitted *during* a particular treatment can be minimised by better containment, but the quantity emitted from venting *after* treatment can only be addressed by use of recovery technology. Following recovery there are potential options of either direct reuse, recycling or destruction.

This chapter discusses opportunities for improved containment (section 6.2); options for MB recovery (section 5.3); and Article 5(1) Party considerations (Section 6.4).

### **6.2 Improved Containment and Management of Fumigation Operations**

In previous reports on reducing emissions from MB fumigation treatments, considerable emphasis was given to improved containment. A high degree of containment is a prerequisite for the efficient recovery of the used MB (as well as for effective fumigation).

Many fixed structure facilities used for fumigating perishables, particularly for quarantine, already have a high standard of gas-tightness leading to very low leakage rates (often less than 5% of applied dosage). However, the standard of gas-tightness of facilities or structures used for fumigating durable commodities is highly variable. While poor containment can lead to increased quantities of MB usage in order to ensure effective fumigation treatment, it should be noted that improved containment alone (ie without recovery) will not lead to reduced emissions. This is because the MB remaining after fumigation will escape during the venting phase.

Post-harvest disinfection of perishable commodities using MB is performed in fixed-wall structures such as fumigation chambers, or under gas-tight

taraulins. Improving the gas-tightness of fumigation facilities will prevent unwarranted leakage of MB into the atmosphere. Simple test criteria have been available to the industry for determining the gas-tightness of chambers (Bond 1984) and these are part of the mandatory fumigation requirements for export of many perishable commodities to Japan.

Controlled conditions allow manipulation of the key fumigation parameters: dosage, temperature and time. Greater control is potentially more achievable in an enclosed structure than in relatively uncontrolled field situations. The dosage can be reduced by either raising the temperature or increasing the time or both, providing the commodity is able to tolerate the conditions. Forced-air circulation could also allow reduction of the dosage as pests are exposed to the fumigant more frequently. MB could be conserved by developing high temperature schedules with or without extended fumigation duration, providing the marketability of the produce is acceptable. New fumigation schedules normally require official approval by the Regulatory Agency in the importing country.

Accurate measuring equipment to weigh MB will minimise excessive use of MB. This equipment could also be attached to equipment used for fumigation from small cylinders (e.g. 5 kg) which would avoid the use of small cans (about 1 kg).

The concentration and temperature (external to the commodity, and internal to the commodity) during fumigation treatments should be monitored, typically at three intervals during the first 15 minutes, and then at 30 minute intervals thereafter, to ensure the required Concentration-X-Time (CT-Product) is achieved.

To summarise options that Parties may wish to consider encouraging:

- The use of gastight fumigation enclosures;
- The development and adoption of raised temperature fumigation schedules where possible;
- The development and adoption of extended duration fumigation schedules where possible;
- Improved measurement of MB dose; and
- Better monitoring of MB concentrations during fumigation.



## 6.3 MB Recovery

Currently, most fumigation chambers or enclosures release MB into the atmosphere during venting at the end of the fumigation period. There are very few fumigation sites world-wide where any attempt is made to capture the used MB in order to reduce emissions. Where they do exist, the impetus has been to meet local clean air requirements and therefore retain operating permits. The 1998 MBTOC report provides details of the technologies that have been considered or developed in the past. The few technologies that are in regular use and those that are considered to have near potential are described below.

### 6.3.1 Existing technologies

Two large fumigation facilities in California, USA have installed equipment to recover MB. One site uses a system based on condensation followed by activated carbon adsorption to recover MB from cotton fumigation for reuse and has been in regular use since December 1993. At this particular site, fumigation is performed in chambers under vacuum and the potential discharge of MB occurs when the vacuum is released at the end of fumigation and after each of the subsequent air washes. The fumigation plant, with its condensation and activated carbon recovery system, is reported to meet the local air quality requirements. Access to the plant is restricted and no data have been supplied to determine either the level of recovery (emission reduction) or of recycling. It should be noted that very few fumigation chambers used for QPS are designed to operate at the vacuum levels used at this particular site.

A recovery plant was installed in late 1996 at another cotton fumigation site in California USA. It uses ozone to destroy the MB in the discharge and air washes from a vacuum chamber. Activated carbon is used to scrub any residual traces of MB from the discharge air stream. At the date of writing, results from two monitored trials indicated that more than 90% of MB used in each treatment was destroyed. The destruction plant is large and has a significant electrical power requirement for the ozone lamps and the blowers.

No data are available to determine the impact of the technologies on the cost of the fumigation operation, but it is understood that the capital cost of both recovery plants was in excess of US\$0.5 million. Furthermore, there were significant increases in operating costs due to the additional utilities required and the liquid nitrogen refrigerant.

### 6.3.2 Potential technologies

Zeolites are a special type of silica-containing material which have a porous structure that make them valuable as adsorbents and catalysts. A new

recycling process is under development and final pilot scale testing by a Canadian company which uses zeolites to recover available MB for subsequent reuse. It supersedes an earlier zeolite based process which was trialed unsuccessfully at the Port of San Diego, USA and in Santiago, Chile.

The new process has been altered and improved so that direct recycling is no longer necessary. Instead, the available MB is recovered from the zeolite bed, refined in an off-line step and is available as MB for another fumigation. This change significantly reduces the complexity of operation of the recovery plant because it is no longer necessary to have complex or expensive analytical equipment to measure MB concentrations, as there is no direct recovery and re-injection into the fumigation operation.

Indications from early tests of this equipment are that recoveries of at least 75% of the available MB are achievable (Willis pers. comm., 1998). An issue with this process is whether the recovered MB is sufficiently pure to be able to be reused as "pure MB" to comply with the specifications for established quarantine schedules. At the time of preparation of this report, data from the purity tests of the recovered MB were not available. This process has the potential to provide a means of reducing emissions from a range of fumigation operations, and in making MB available for uses such as soil treatment where purity is not a critical issue. No data are available on costs or regulatory issues.

Another process to control emissions has been developed by a US consortium which includes the USDA and the MB producing company Great Lakes Chemical Corporation. The process has been successfully tested on a prototype system using a slip stream from a fumigation system. The process is based on the well tested technology of using activated carbon to capture the MB. Instead of handling the captured MB directly at the fumigation site, the intention is that the activated carbon beds will be transported to Great Lakes Chemicals Corporations processing site in Arkansas where the MB will be stripped from the beds, converted to hydrobromic acid and reintroduced into their manufacturing process. It is understood that rather than having to purchase recovery systems, that MB users will be able to buy MB at a higher price that will include the cost of MB recovery, transport and disposal.

Preliminary data suggest that in excess of 95% of the MB in the vent stream can be removed, but that the cost of a complete MB supply and removal service would be about 7 times that of the current MB price (Leesch 1998). One of the critical features of this technique is environmental impact (truck fuel, energy use) of transporting equipment containing the activated carbon beds saturated with MB over some distance to the reprocessing plant. While it may be feasible to consider this in the continental USA and other areas where quarantine treatments are concentrated, it is unlikely to be cost effective in other parts of the world.

## 6.4 Article 5(1) Party Considerations

MB usage for QPS fumigation in Article 5(1) Parties is covered in Section 3.2.2.

The potential for benefit of improved containment and management of fumigation operations applies equally to Article 5(1) Parties as it does to non-Article 5(1) Parties, and could be achieved by expenditure on changed facilities and training on improved operating techniques.

Unlike some other ozone depleting substances where the interim needs of Article 5(1) Parties can be met in part by storage 'banks' of recycled material, it is unlikely that this method will be practical for MB. This is because some of the MB used in any application reacts and breaks down leaving a small proportion of contaminant in the MB, and because some of the recovery and recycling technologies under development are only suitable for 'in-plant' recycling.

Not all of the newer recovery and recycling technologies under development will be suitable for implementation by Article 5(1) Parties. The Great Lakes Chemical Corporation process relies on transporting the captured MB to a central reprocessing plant. It is unlikely that many Article 5(1) countries will be able to purchase MB on this expensive "sale and disposal" basis.



## **7. QPS relationship to other conventions and treaties**

Several other international conventions and treaties mention or define one or more of the terms used in the Protocol's definition of QPS, and these are discussed in this chapter.

### **7.1 WTO - Agreement on Technical Barriers to Trade**

The Agreement on Technical Barriers to Trade (the TBT Agreement), also known as the Standards Code of GATT (now WTO), has been in effect since 1980. The TBT aims to avoid unnecessary obstacles to trade associated with the application of technical measures. Technical regulations and standards for industrial and agricultural products, including packaging, labelling and marking, processing and production methods, as well as methods of testing and certification, fall within the ambit of the TBT. Under the Agreement, WTO Members agree to use relevant international standards where they exist, but the Agreement does not identify specific standard setting organisations as in the Sanitary and Phytosanitary (SPS) Agreement.

The TBT applies to measures which may be used to assure *quality*. Measures whose intent is the protection of plant, animal or human health or life fall under the SPS Agreement. Any QPS treatments whose objective is not to protect plant, animal, or human health or life fall under the TBT. This has particular significance for pre-shipment treatments that are not technically considered to be phytosanitary treatments under the IPPC or SPS. Although such treatments may be considered to be phytosanitary in a general sense, and may be described this way under the Protocol, these treatments would be considered by the IPPC to deal with quality for WTO and IPPC purposes, and therefore fall under the TBT Agreement.

### **7.2 WTO - Agreement on the Application of Sanitary and Phytosanitary Measures**

The World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) defines the basic rights and obligations of Parties with regard to the use of measures applied to protect human, animal or plant life or health, including procedures to test, diagnose, isolate, control or eradicate diseases and pests. The Agreement recognises the sovereign right of every government to apply measures to protect plant, animal and human health and life, but balances this with the obligation to ensure that such measures are based on scientific principles and evidence. SPS measures may directly or indirectly affect international trade and should not be used as a disguised restriction on trade.

The SPS Agreement encourages Parties to base their national SPS measures on relevant international standards, guidelines and recommendations. Governments may choose national measures that provide a higher level of protection than relevant international standards, subject to conformity with obligations relating to risk assessment. Risk assessment also provides the basis for measures applied in the absence of international standards.

In assessing risks, WTO Members are required to take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of disease/pest free areas or areas of low pest prevalence; relevant ecological and environmental conditions; and quarantine or other treatment.

The SPS identifies relevant international organisations responsible for promoting the use of harmonised sanitary and phytosanitary measures between Members on the basis of international standards, guidelines and recommendations as follows:

- (a) The Secretariat of the International Plant Protection Convention (IPPC), based at the FAO in Rome. In co-operation with regional organisations operating within the framework of the IPPC, it is responsible for developing international standards, guidelines and recommendations for plant health;
- (b) The Codex Alimentarius Commission, a joint FAO/WHO organisation, is responsible for food safety, the standards, guidelines and recommendations relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (c) The Office International des Epizooties (OIE) is responsible for developing guidelines standards and recommendations on animal health and zoonoses; and
- (d) Other relevant international organisations, identified by the Committee for Sanitary and Phytosanitary Measures, may be responsible for promulgating appropriate standards, guidelines and recommendations on matters not covered by the above organisations.

The IPPC is recognised by the SPS Agreement as the organisation under which international standards for phytosanitary measures are established. The IPPC is the international agreement that is most relevant to quarantine treatments as defined by the Montreal Protocol as the IPPC promulgates guidelines for the implementation of measures for quarantine pests and regulated non-quarantine pests (see Glossary, Appendix 1 for definitions).

However, non-regulated pests do not fall within the scope of the application of phytosanitary measures under the IPPC as they are not classified as injurious to plant health; nor are they under OIE as this organisation focuses largely on animal health. Non-regulated pests are often the target of pre-shipment MB treatments as defined under the Montreal Protocol as they are detrimental to the quality of the product in which they are found.

Under the SPS Agreement, a sanitary or phytosanitary measure is any measure that is applied:

1. To protect animal or plant life or health within the territory of the Party from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms (*IPPC and OIE responsibility*);
2. To protect human or animal life or health within the territory of the Party from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs (*Codex responsibility*);
3. To protect human life or health within the territory of the Party from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests (*OIE responsibility*);  
or
4. To prevent or limit other damage within the territory of the Party from the entry, establishment or spread of pests (*no specific responsibility*).

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

The intent of 1-3 above was to specifically *exclude* quality matters from consideration as Article 2 of the SPS Agreement states that: 'Members shall ensure that any sanitary or phytosanitary measure is applied only the extent necessary to protect human, animal or plant life or health'. One possible interpretation of 4) is that it might cover cosmopolitan pests that damage the quality of plant products, and logically be considered to cover pre-shipment requirements covered by the Protocol. This is not the case, however, as 4) was intended to cover damage from pests not included in 1-3 above, including for

example, protection from pests that block pipes, crack roads or damage electrical devices.

The Protocol definition of pre-shipment does not specify 'official' certification which could leave open the possibility of non-governmental certification including *commercial* certification to authenticate a pre-shipment treatment, and furthermore, to claim this consumption of MB exempt from control. The main text of the SPS agreement implies that SPS *measures* are regulations, procedures and activities that are the responsibility of governments, or tasks delegated by governments to private sector bodies to carry out accreditation on behalf of governments. However, Annex A of the definition of SPS measures does not specifically state that these measures are the activities of governments. It is therefore open to interpretation that SPS measures might include activities of governments and/or individual companies. This part of the SPS text has not been subject to dispute settlement and interpretation. On the other hand, the Protocol definition also includes '...requirements of the importing country...' and '...requirements of the exporting country...', indicating that this is government rather than commercial. Lastly, the Protocol mentions '...existing requirements...' which is meaningful to enforcement by government legislation rather than commercial contracts. Further information on the intent of pre-shipment was provided in Section 3.2.2.

In the light of this discussion, and in order to unambiguously convey the intent of 'pre-shipment' as originally drafted, Parties may wish to consider placing 'official' in the definition to minimise the occurrence of commercial certification in pre-shipment practices (see section 8.2.4 for further details).



## 8. QPS Comparison of Definitions

### 8.1 Quarantine

#### 8.1.1 Montreal Protocol definition

Decision VI/11 defined the term ‘quarantine’ which reads as follows:

(a) *‘Quarantine applications’ with respect to methyl bromide, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases) or to ensure their official control, where:*

- i) *Official control is that performed by, or authorised by, a national plant, animal or environmental protection or health authority;*
- ii) *Quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled;*

#### 8.1.2 Comparison with the International Plant Protection Convention Definition

MBTOC notes that although there are general similarities between the IPPC definition of quarantine and that adopted by the Parties to the Protocol, there are some significant differences that may affect implementation by some quarantine authorities.

The Protocol definition of a quarantine pest was based on the 1994 FAO Glossary of Terms with one change. The Glossary refers to pests of potential economic importance, whereas the Protocol excludes the term ‘*economic*’.

The definition agreed under the Protocol is deemed by the Parties to be *explicitly* broader than that of the IPPC as it encompasses not only the activities covered by IPPC (plant health) but also covers human and animal health and wider environmental considerations. Hence the word ‘*economic*’ was omitted from the Protocol definition, and the definition also included reference to authorities other than national plant health authorities. MBTOC noted that the IPPC considers that environmental concerns related to plant health, while not specifically stated, are *implicit* in the IPPC definition.

The Protocol uses the term ‘*phytosanitary*’ to refer generally to treatments applied to plants and plant products. The IPPC has previously limited the term in a technical sense to only quarantine pests. However, the recent revision of the IPPC resulted in minor expansion of the term to include also ‘*regulated non-quarantine pests*’ which are those pests (e.g., plant-feeding mites)

associated with plants for planting (propagative material). This was done to provide clarity to the legitimate application of phytosanitary measures (regulatory requirements) in the category of 'other injurious pests'. Pests that are neither 'quarantine' nor 'regulated non-quarantine' now fall outside the application of the term phytosanitary under the IPPC. The result is that the IPPC has moved somewhat closer to the Protocol usage of the term, but the Agreements continue to be inconsistent with respect to treatments for those pests that are not eligible for phytosanitary measures in a technical sense. Clarification of the Protocol usage of terms and the degree to which this is aligned with the IPPC and/or SPS will help regulatory and other agencies to better understand both agreements and facilitate a more consistent reporting under the Protocol.

The IPPC focuses on securing common and effective action to prevent the spread and introduction of damaging pests of plants and plant products. The Protocol definition is necessarily broader as it includes 'health authorities'. From a human health perspective, the jurisdiction of health authorities includes preventing the spread of disease from rodents which are found in ships, aircraft and other vehicles; and controlling particular micro-organisms such as bacteria or other disease-causing organisms which are harmful or even fatal to humans and that may be prevalent in an imported food product.

### 8.1.3 Implications of inconsistent interpretation

MBTOC noted that there is some inconsistency in the interpretation of the term 'quarantine' amongst Parties. This may lead to anomalies in reporting of consumption of MB under the quarantine part of the QPS exemption.

The term 'quarantine' may have different connotations to MB users and officials in some countries. For example, in some cases treatments regarded locally as quarantine are applied to kill non-quarantine pests, such as species of insects (eg. cosmopolitan grain pests) already present in the country. Detection by inspection authorities of pests or other living organisms in an incoming shipment may be sufficient to result in authorisation of a treatment regarded locally as 'quarantine'. This may be based on long established practice, though not consistent with the use and interpretation of current IPPC definitions. The definition adopted by the Protocol of 'quarantine' conforms to the international concept of plant quarantine agreed under the IPPC where the pest for which treatment is authorised must be a declared object of quarantine. MBTOC suggests that the Parties consider recommending adherence to the IPPC definition and not local definitions of quarantine.

In the latest IPPC language, 'quarantine' applications continue to be limited to 'regulated quarantine pests' and exclude applications for 'unregulated pests'. However, within the category of pests previously

known under the IPPC as other ‘injurious pests’ clarification has been provided to distinguish ‘regulated non-quarantine pests’ from other pests. This is significant in that the application of official phytosanitary measures under the IPPC is limited to regulated pests, i.e., ‘quarantine pests’ and ‘regulated non-quarantine pests’.

The definition in Decision VII/5 is silent on quarantine application in intra-country trade. However, at the time of drafting the definition of QPS, it was not intended to exclude official intra-country quarantine treatments from exemption, although the text of Decision VII/5 could be interpreted to restrict exempt quarantine treatments to those conducted or authorised by national, not state authorities.

MBTOC notes that inconsistency in the interpretation of the term ‘quarantine’ may lead to mis-classification of some officially required treatments which are not applied to quarantine pests and would be more appropriately categorised as pre-shipment treatments.

MBTOC notes that little has changed with respect to ‘quarantine’ between the IPPC and Protocol. However, further IPPC clarification of terms and their application through the establishment of standards and agreement on new terms or changes to existing terms can significantly affect harmonisation with the Protocol interpretation and application. For instance, IPPC definitions being developed for ‘official control, widespread and/or limited distribution’ will provide substantial additional clarity to the definition for quarantine pests, and by implication, could lead to changes in QPS.

#### 8.1.4 Options for the Parties to consider

There are two main mechanisms that may be considered in order to provide clarification to Parties for consistent interpretation of ‘quarantine’, and to harmonise with IPPC to the extent that is necessary and appropriate:

- a) Amend the Protocol definition of ‘quarantine’. The disadvantage of this approach is that further amendments may be required in the future to keep abreast of IPPC changes, and a definition is not likely to provide sufficient explanation for consistent application of ‘quarantine’ to the Parties.
- b) Provide an Explanatory Note (with legal support) and a mechanism for updating the Note by, for example a TEAP review, that harmonises the Protocol use of ‘quarantine’ with the relevant and appropriate changes as they arise in the IPPC definition; and Parties can be provided with guidance to enable consistent interpretation by all Parties.

Parties may therefore wish to consider these options:

- Exclude one or more of the different authorities which are referred to in the Protocol definition to narrow the scope of the exemption;
- Retain the current Protocol definition and thus the broad scope of the exemption;
- Insert the term ‘economic’ in the definition to harmonise the definition of quarantine pest with that of the IPPC;
- Full harmonisation with the IPPC terminology; and
- Request specific guidance on interpretation under the Protocol that differ from the IPPC (partial harmony in specified areas).

## **8.2 Pre-shipment**

### **8.2.1 Montreal Protocol Definition**

The Montreal Protocol defines pre-shipment applications as ‘...those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country.’

MBTOC is not aware of any other international definition of ‘pre-shipment’ with the same intent as that provided in the Protocol. There is, however, a WTO agreement on ‘pre-shipment inspection’ but this relates to specific activities on the ‘...quality, quantity, price...customs classification...’ of goods to be exported and not to the ‘pre-shipment’ treatment as described in the Protocol.

### **8.2.2 Chronology**

When MB was first added as a controlled substance under the Montreal Protocol in 1992, Parties allowed a blanket exemption for QPS use, although the terms were left undefined.

Subsequently, the Parties defined QPS and discussed the scope of the terms during their 6th meeting in 1994. As part of the discussion, Parties examined existing relevant international definitions and, given that there appeared to be definition for pre-shipment, the Parties looked to the FAO glossary and their own domestic procedures for guidance. The Food and Agricultural Organisation (FAO) glossary included a definition of ‘phytosanitary measures’ which was synonymous with ‘quarantine’, i.e. ‘Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests’. However, for many years, officials issued phytosanitary certificates which covered both quarantine and other injurious pests. At the time, other injurious pests were broadly interpreted to be those which affected quality pursuant to national regulations or standards.

In response to this practice, the decision of the Parties at the 6th meeting was to limit the definition of pre-shipment applications to treatments carried out immediately prior to export to meet phytosanitary requirements of importing countries or the existing phytosanitary requirements of exporting countries. Initially, these provisions related to non-Article 5(1) countries only. Between 1994 and 1995, at the request of the Meeting of the Parties, TEAP reviewed the definitions in line with current practices and guidelines. Based on TEAP's findings, the Parties decided at the 7th meeting not to alter the definition but rather to extend it to cover Article 5(1) Parties.

At about the same time in 1995, the SPS agreement came into force and the Parties to the IPPC began the process of revising its Convention to clarify the application of 'phytosanitary measures'. Members debated whether to include or exclude non-quarantine stored product pests from the scope of 'phytosanitary measures', where they involved injury to quality of products, not strictly to health of plants.

In 1997, the Parties to the IPPC adopted a definition which narrowed 'phytosanitary measures' to those related to 'quarantine pests' and 'regulated non-quarantine pests which affected plants for planting' (propagative material). This definition specifically excluded non-quarantine, stored product pests from within the scope of 'phytosanitary measures' under the Convention. Examples of cosmopolitan and thus, in most situations, non-quarantine stored product pests usually include Indian meal moth and *Sitophilus* grain weevils. These pests are damaging to stored grain, and yet under the IPPC narrow definition of phytosanitary measures, are specifically excluded. The Protocol, therefore, appears to have defined 'pre-shipment' as those treatments applied to control 'quality' pests. While the revised definition of 'phytosanitary measures' that was adopted by IPPC Members in 1997 has yet to be ratified, ratification is likely.

Also in 1997, TEAP suggested that one option for Parties might be the removal of the quarantine and pre-shipment exemptions. The Parties did not make a decision on this suggestion. In their 1998 report, TEAP recognised inconsistencies in the interpretation of the terms quarantine and pre-shipment by Parties and provided interim explanatory notes to assist the Parties:

- (3) "The definition of 'pre-shipment application' is restricted by the terms 'phytosanitary or sanitary' to officially authorised but non-quarantine treatments, fulfilling official requirements of the importing or exporting country at time of export. It was not intended to cover informal or purely contractual or commercial arrangements not required under official regulations."

and

- (5) ‘The intention of the definition of ‘pre-shipment applications’ was to limit exemptions to those treatments carried out at the time of export under official requirements, either of the importing country or regulations in force in exporting countries at the time of the Decision (December 1995). This excludes arrangements which are contractual only.’”

In recognition of the on-going inconsistencies in interpretation, and to assist the Parties in the correct interpretation of QPS, Section 3.3 of this report contains a QPS Logic Diagram and examples of QPS treatments.

### 8.2.3 Current Issues

As a result of inconsistent interpretation of the term ‘pre-shipment’, some Parties may be over or under estimating their controlled consumption of MB.

As a result of the divergence between the Protocol and IPPC interpretations of the term ‘phytosanitary’, the Protocol permits pre-shipment treatments for unregulated pests whereas under the IPPC definition, treatments should only be applied to regulated pests. Regulated pests are ‘quarantine pests’, and ‘non-quarantine pests that affect plants for planting’.

The primary issues are (1) whether the Parties to the Protocol wish to align QPS with the IPPC (or alternatively with the SPS) in the use of the term ‘phytosanitary’, and (2) whether the Parties wish to associate with IPPC Article VI (2) concerning the scope of the application of phytosanitary measures. In either case, deviations from the IPPC should have supporting rationale and will require explicit guidance to Parties if implementation by Regulatory Agency border control staff is to be effective.

### 8.2.4 Options on pre-shipment that Parties may wish to consider

There are several options which the Parties may wish to consider when reviewing the pre-shipment exemption. Regardless of which option is taken up, Parties may need to ensure that domestic regulatory agencies are able to interpret the protocol definitions consistently. The options are described briefly below:

#### **Option 1: Remove pre-shipment exemption before phase out**

This would mean that current pre-shipment uses would fall under the control schedule adopted by the Parties for all non-exempted MB uses. The use itself would continue until phase out.

## **Implications**

- 1.1 Current pre-shipment uses would no longer be exempt after the phaseout, except where they meet Critical Use Criteria. Consumption of MB for current pre-shipment uses such as disinfestation of grain, cocoa, dried fruit and nuts and treatment of empty shipholds would need to be allocated to current consumption volumes per country.
- 1.2 The incentive to develop and adopt alternatives for pre-shipment uses would increase.
- 1.3 Exemptions would not be allowed under the critical use and possibly the emergency use procedures until after phaseout.
- 1.4 The individual baseline volume for each Party might need to be increased to accommodate pre-shipment uses, if the Parties considered this necessary.
- 1.5 Pre-shipment treatments would need to compete with other controlled uses as the supply of MB diminishes as a result of interim reductions leading to phaseout.
- 1.6 Some national legislation or regulations requiring the use of MB ie., legislation which falls outside of ozone-depleting substances, would need to be amended.

### **Option 2: Remove pre-shipment exemption after phase out**

This would mean that current pre-shipment uses would remain in place until scheduled date for phaseout.

## **Implications**

As for 1.1, 1.2 and 1.5 above, but in addition:

- 2.1 Exemptions would be allowed under either critical use or emergency use after phaseout.

### **Option 3: Place a cap on pre-shipment consumption.**

- 3.1 The baseline would need to be agreed by the Parties.

Parties could consider capping QPS MB consumption based on baseline consumption for an agreed number of years. This has been agreed in a Common Position for a new EC Regulation by the European Union.

## Implications

Current pre-shipment consumption would continue at baseline level.

### **Option 4: Leave exemption in place, but interpret ‘phytosanitary’ following the IPPC definition that includes only those uses which apply to ‘regulated non-quarantine pests (that affecting plants for planting)’**

This would mean that the current definitions would remain, with the addition of the IPPC definition for ‘phytosanitary measures’.

## Implications

As for 1.2, 1.4, 1.5, 1.6 and 2.1 above, but in addition:

- 4.1 All other current pre-shipment uses to control pests that *do not* affect plants for planting would no longer be exempt. This would exclude almost all current exemptions, notably disinfestation of grain, cocoa, dried fruit and nuts and treatment of empty shipholds.

### **Option 5: Leave exemption in place with current definitions, but interpret ‘phytosanitary’ in the SPS definition to include all uses related to injurious pests.**

This would mean that the current definition would remain, with the addition of the SPS definition for ‘phytosanitary measures’.

## Implications

- 5.1 Would include all injurious pests that apply to plants, animals and human health.
- 5.2 May broaden the interpretation of the current definition to include all treatments applied directly preceding export, whether in response to official or contractual requirements alike, thereby increasing consumption under the exemption.

### **Option 6: Change existing definition or add an Explanatory Note**

One option would be to replace ‘phytosanitary and sanitary’ with the word ‘official’; and ‘within 14 days of export’ and add ‘stored product authority’. The definition would then read:

‘Pre-shipment applications are those applied *within 14 days* directly preceding and in relation to export to meet the *official* requirements of the importing country or existing *official* requirements of the exporting country. *Official*



requirements are those which are performed by, or authorised by, a national plant, animal, environmental, health or *stored product authority*.’

### **Implications**

- 6.1 No change to existing Protocol interpretation of pre-shipment, ie., it allows the 1994 interpretation to remain, consistent with 1998 TEAP explanatory notes 3 & 5 above.
- 6.2 Greater clarity for Parties.



## **9. Summary of options**

In addition to the options on ‘pre-shipment’ listed in Section 7.2.4, the Parties may wish to consider the following options that have been drawn together from various sections in this report including those related to QPS reporting, definitions, exemptions and recycling-recovery-containment.

### **9.1 QPS Reporting**

Parties might wish to consider:

- 9.1 Strengthening the voluntary commitment by the Parties for reporting QPS; or
- 9.2 Mandatory data reporting on QPS consumption in order to quantify QPS consumption more accurately in the future.

### **9.2 QPS Definitions**

#### **9.2.1 Quarantine**

The Protocol definition of ‘quarantine’ is broader than that used in other international conventions and treaties. However, a broader scope could be regarded by the Parties as appropriate since MB is currently being used for some pest control practices that involve human health. Human health aspects are not considered in the definition of quarantine in the IPPC.

There are two main mechanisms that may be considered in order to provide clarification to Parties for consistent interpretation of ‘quarantine’, and to harmonise with IPPC to the extent that is necessary and appropriate:

- a) Amend the Protocol definition of ‘quarantine’. The disadvantage of this approach is that further amendments may be required in the future to keep abreast of IPPC changes, and a definition is not likely to provide sufficient explanation for consistent application of ‘quarantine’ to the Parties.
- b) Provide an Explanatory Note (with legal support) and a mechanism for updating the Note by, for example a TEAP review, that harmonises the Protocol use of ‘quarantine’ with the relevant and appropriate changes as they arise in the IPPC definition; and Parties can be provided with guidance to enable consistent interpretation by all Parties.

**For ‘quarantine’, Parties might wish to consider:**

- 9.3 Full harmonisation with the IPPC terminology;

- 9.4 Partial harmonisation in specified areas, based on specific guidance provided on interpretation under the Protocol that differs from the IPPC;
- 9.5 Retaining the current Protocol definition and thus the broad scope of the exemption;
- 9.6 Inserting the term ‘economic’ in the definition to harmonise the definition of quarantine pest with this aspect of the IPPC;
- 9.7 Excluding one or more of the different authorities which are referred to in the Protocol definition to narrow the range of the exemption to specific areas of application;
- 9.8 Parties could consider capping quarantine MB consumption based on baseline consumption for an agreed number of years. This has been agreed in a Common Position for a new EC Regulation by the European Union. The baseline would need to be agreed by the Parties;
- 9.9 Parties could consider removing the blanket exemption for quarantine and instead rely on Critical Use for those treatments without an alternative to MB.

#### 9.2.2 Pre-shipment

‘Pre-shipment’, as intended under the Protocol, is without a parallel in other treaties and conventions. The Parties could regard the use of ‘pre-shipment’ as appropriate as it allows the treatment of grain, other durable commodities and empty vessels for cosmopolitan pests that affect the ‘quality’ of agricultural commodities. These pests would otherwise not be officially controlled under other phytosanitary agreements. However, the Parties could consider adding ‘official’ into the definition of ‘pre-shipment’ to ensure that MB is used appropriately by a government, and not commercial agents, and is in keeping with the intent originally ascribed to this definition by the Parties. In addition, in order to ensure efficient and clear implementation of the use of pre-shipment, defining the treatment period as ‘...within 14-days of export...’ would help conserve MB by ensuring that a single treatment rather than multiple treatments is applied to control pests.

Based on the options described in Section 8.2.4 and their implications, Parties might wish to consider:

- 9.10 Remove pre-shipment exemption before phase out
- 9.11 Remove pre-shipment exemption after phase out
- 9.12 Place a cap on pre-shipment consumption.

- 9.13 Leave exemption in place, but interpret ‘phytosanitary’ following the IPPC definition that includes only those uses which apply to ‘regulated non-quarantine pests (that affecting plants for planting)’
- 9.14 Leave exemption in place with current definitions, but interpret ‘phytosanitary’ in the SPS definition to include all uses related to injurious pests.
- 9.15 Change existing definition or add an Explanatory Note with legal force
- 9.16 Defining pre-shipment applications as those carried out within 14 days prior to shipment, in addition to meeting the phytosanitary and sanitary requirements of the importing or exporting countries. This time period would allow practical implementation of pre-shipment.
- 9.17 Review the disinfection requirements imposed on Article 5(1) Parties for products exported to non-Article 5(1) Parties.

### **9.3 Recovery, Containment and Recycling**

While recycling-recovery of MB is feasible, it is currently expensive and therefore not widely applicable. The Parties could regard investment in such technology as an interim measure as it diverts valuable funds away from projects that implement non-MB alternatives as a permanent solution.

However, Parties could consider other encouraging practices with a favourable cost-benefit such as better *containment* of MB by ensuring fixed-wall facilities are as gas-tight as possible using testing procedures that are well documented. In addition, Parties could encourage operators to reduce the volume of MB that is consumed in each fumigation cycle by developing treatments at elevated temperatures and/or for extended time periods, where the commodity can tolerate such treatment and official importing country approval is forthcoming.

#### **Parties may wish to consider encouraging:**

- 9.18 The use of gastight fumigation enclosures;
- 9.19 The development and adoption of raised temperature fumigation schedules where possible;
- 9.20 The development and adoption of longer than usual fumigation schedules where possible;
- 9.21 Improved measurement of MB dose; and
- 9.22 Better monitoring of MB concentrations during fumigation.

9.23 Assistance to Article 5(1) Parties for technology transfer on alternatives and emission control.

#### **9.4 Removing the blanket exemption for QPS**

Some alternatives are available for QPS and more can be developed. According, the Parties could consider:

9.24 Removing the QPS exemption. The Critical Use process could be used to address QPS treatments that remain without an alternative.

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## APPENDICES

### Appendix A1: Glossary Of Terms

Activated carbon	Carbon or charcoal derived from a variety of sources which has been treated so that it can absorb a large quantity of gas.
APHIS	Animal and Plant Health Inspection Service. US Regulatory Agency responsible for quarantine
Article 5(1)	A Party classified at a meeting of the parties as a developing country and whose annual per capita consumption of Annex A and Annex B substances are below the limits set in Article 5 of the Montreal Protocol.
CA(s)	Controlled atmosphere(s), typically low oxygen and high carbon dioxide atmospheres that are externally controlled. They are used for extending the life of fresh and durable commodities. Some CAs have pesticidal qualities.
Condensation	The cooling process which turns gases into liquids.
Containment (fumigation)	Securing the fumigation site so that inadvertent leakage from the treatment area does not occur during the actual fumigation treatment.
Containment	The application of phytosanitary measures in and around an infested area to prevent the spread of a pest
Control (of a pest)	Suppression, containment or eradication of a pest population
CT-product	The product of the fumigant <i>concentration</i> multiplied by the <i>time</i> it is applied for. This figure is often used as a guide to the severity or lightness of a fumigation treatment.

DE	Diatomaceous earth. Abrasive, fossilised remains of diatoms consisting mainly of silica with small amounts of other minerals that cause damage mainly to arthropod pests.
Destruction	The chemical or physical destruction of methyl bromide recovered from fumigation operations.
Durables	Commodities with a low moisture content that, in the absence of pest attack, can be safely stored for long periods.
Equivalence	The situation of phytosanitary measures which are not identical but have the same effect
Establishment	Perpetuation, for the foreseeable future, of a pest within an area after entry.
FAO	Food and Agriculture Organisation
Feedstock	Methyl bromide which is used as a raw material for manufacturing other chemicals.
Harmonisation	The establishment, recognition, and application by different countries of phytosanitary measures based on common standards
IMO	International Maritime Organisation
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations
Interception	The detection of a pest during inspection of an imported consignment
Introduction	Entry of a pest resulting in its establishment
IPM	Integrated Pest Management: Pest monitoring techniques, establishment of pest injury levels and a combination of strategies and tactics to prevent or manage pest problems in an environmentally sound and cost-effective manner.

IPPC	International Plant Protection Convention
Irradiation	In practice, the use of gamma energy, accelerated electrons or X-rays to penetrate the commodity to sterilise or kill pests.
MA(s)	Modified atmosphere(s).
MB	Methyl Bromide.
MBTOC	Methyl Bromide Technical Options Committee.
MF	Multilateral Fund.
NAPPO	North American Plant Protection Organisation.
National Plant Protection	Official service established by a government to discharge the Organisation functions specified by the IPPC
Non-Article 5(1)	A Party classified at a meeting of the parties as a developing country and whose annual per capita consumption of Annex A and Annex B substances are above the limits set in Article 5 of the Montreal Protocol.
Non-quarantine pest	Pest that is not a quarantine pest for an area
Non-regulated quarantine	A non-quarantine pest whose presence in plants for planting pest affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party
ODS	Ozone depleting substance.
Official control	That performed by, or authorised by, a national plant, animal or environmental protection or health authority (Montreal Protocol)
Official [control]	Established, authorised or performed by a National Plant Protection Organisation (IPPC definition)

PE Sheets	Plastic sheets or films made from polyethylene.
Perishables	Fresh fruit and vegetables, cut flowers, ornamental plants, fresh root crops and bulbs that generally have limited storage life.
Permeability	The degree to which MB can flow through a thin membrane or sheet.
Pest free area	An area in which a specific pest does not occur as demonstrated in scientific evidence and in which, where appropriate, this condition is being officially maintained
Pest risk assessment	Determination of whether a pest is a quarantine pest and evaluation of its introduction potential
Pest	Any species, strain, biotype of plant, animal or pathogenic agent injurious to plants or plant products
Pest-free zone	Establishment of a certified area where a regulated quarantine pest does not exist.
Pheromone	A chemical produced by one member of a species that are externally transmitted and influence the behaviour or physiology of another member of the same species.
Phytosanitary regulation	Official rule to prevent the introduction and or spread of quarantine pests, by regulating production, movement or existence of commodities or other articles, or the normal activity of persons, and by establishing schemes for phytosanitary certification
Phytosanitary	Pertaining to plant quarantine (IPPC)
Phytosanitary	Officially-authorized pest control treatment applied to plants and plant products (Montreal Protocol)

Phytosanitary	Treatments applied to regulated plant pests (i.e., quarantine pests and regulated non-quarantine pests) (recent expansion by IPPC to include more than just 'quarantine')
Phytotoxic	Toxic to plants.
Plants for planting	Plants intended to remain planted, to be planted or replanted
Pre-shipment	Those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country. (Montreal Protocol)
Quarantine pest	A pest of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. (IPPC definition is the same as Montreal Protocol)
QPS	Quarantine and pre-shipment.
Quarantine applications	Treatment to prevent the introduction, establishment and/or spread of quarantine pests (including diseases) or to ensure their official control (Montreal Protocol and IPPC)
Reclamation	The re-processing and upgrading of recovered methyl bromide by more complex physical or chemical treatments. Often this would involve storage for subsequent re-use, either on-site or at other sites.
Recovery	The collection and storage of methyl bromide from fumigation operations.
Recycling	The re-use of methyl bromide following a basic recovery and cleaning process. Normally this would only involve 'on-site' processing.
Regulated pest	A regulated pest or a regulated non-quarantine pest

Sanitation	Avoidance or elimination of pathogen inoculum or pest sources, such as infected plant residues, before planting.
SPS	Sanitary and Phytosanitary (Agreement, WTO)
Systems approach	Combines biological knowledge with scientifically-derived, quantifiable operational actions that together act as multiple safeguards in the country of export and result in a consignment meeting the requirements of the importing country.
TBT	Technical Barriers to Trade (Agreement, WTO)
TEAP	Technology and Economics Assessment Panel
UNEP	United Nations Environment Programme
USDA	United States Department of Agriculture
WHO	World Health Organisation
WTO	World Trade Organisation
Zeolite	Alumino-silicate minerals which, although they do occur naturally, can also be manufactured to have special pore sizes which allow them to be used to absorb large quantities of particular gases selectively.

#### Units Commonly Used In The QPS Report

<b>Unit</b>	<b>Meaning</b>
t	tonne, 1000 kg
g m <sup>-3</sup>	grams per cubic meter, or g/m <sup>3</sup>
kg	kilogram, 1000 grams
ml	millilitre, 1/1000 of a litre
g t <sup>-1</sup>	grams per tonne or g/t



**Appendix A2: MBTOC QPS Survey Form**

**United Nations Environment Programme  
- Methyl Bromide Technical Options Committee Survey**

**Quarantine And Pre-Shipment Uses Of Methyl Bromide**

Fax completed questionnaire by 20 January 1999 to:

Dr Tom Batchelor  
MBTOC meeting  
Clarion Hotel SF Airport  
San Francisco, USA  
FAX +1-650-692-4251

If you would prefer to have a copy of this form emailed to you, or if you require clarification on some aspect of the forms, please contact Dr Tom Batchelor by email on: [tombatchelor@compuserve.com](mailto:tombatchelor@compuserve.com)

Please read the attached logic chart (with “Yes” and “No” answers) which helps you determine whether uses of methyl bromide are quarantine or pre-shipment, as defined by the Parties to the Montreal Protocol. Use the definitions in the chart when answering the questions in this survey.

1. Does your country use methyl bromide for quarantine and/or pre-shipment?  
Yes – complete the rest of the survey.  
No – ignore questions 3-7 and fax only this page to +1-650-692-4251.
2. Contact details of person who completed this survey (required if you just completed question 1 or answered any other part of the survey):

Name: \_\_\_\_\_  
Position: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Email: \_\_\_\_\_

**THANK YOU FOR YOUR ASSISTANCE!**

3. For your country, please record the quantity of methyl bromide used in 1991, 1996, 1997, and 1998 for:
  - 1) Officially controlling quarantine pests;
  - 2) Meeting the official phytosanitary or sanitary requirements of the importing country; or
  - 3) Meeting the official phytosanitary or sanitary requirements of the exporting country.

**Table 1:** *Volumes of methyl bromide used in your country for quarantine and preshipment for 1991, 1996, 1997 and 1998. Please refer to the logic chart (with numbered diamond-shapes numbered ❶, ❷ and • ) attached. If you have no information, please write “no data”.*

Quantity (metric tonnes) of methyl bromide used for...	1 Jan to 31 Dec <b>1991</b>	1 Jan to 31 Dec <b>1996</b>	1 Jan to 31 Dec <b>1997</b>	1 Jan to 31 Dec <b>1998</b>
<b>1 Quarantine treatments</b> - Refer Diamond ❶ in logic chart				
<b>2 Pre-shipment treatments</b> Required by IMPORTING country - Refer Diamond ❷ in logic chart				
<b>3 Pre-shipment treatments:</b> Required by EXPORTING country - refer Diamond ❸ in logic chart				
<b>4 All other uses</b> of methyl bromide e.g. soil treatments etc				
<b>Total amount</b> of methyl bromide <b>1+2+3+4</b>				

4. Perishable commodities cannot normally be stored for long periods. Examples of perishable commodities are shown in Table 2 below.

Please identify the perishable commodities treated with methyl bromide in your country by completing the table as follows:

“Yes” = Treated with methyl bromide;  
 “No” = Not treated with methyl bromide;  
 “No info” = No information available.

You should give your answers under the following headings in the table:

- 1) fumigated with methyl bromide in storage (not QPS);
- 2) fumigated with methyl bromide to officially control quarantine pests;
- 3) fumigated with methyl bromide to meet the official phytosanitary or sanitary requirements of the importing country; or

- 4) fumigated with methyl bromide to meet the official phytosanitary or sanitary requirements of the exporting country.

Use the attached logic chart to help you with your answers.

**Table 2:** Pre-shipment treatment

<b>PERISHABLE commodities</b>	<b>(1) Storage treatments (not QPS)</b>	<b>(2) Quarantine treatments</b>	<b>(3) Official requirement of importing country<sup>1</sup></b>	<b>(4) Official requirement of exporting country<sup>2</sup></b>
<i>Example: Fresh Fruit</i>	<i>No info</i>	<i>Yes</i>	<i>Yes</i>	<i>No</i>
Fresh fruit				
Fresh vegetables				
Living plants, fresh ornamentals and cut flowers, propagation materials				
Other perishable commodities (please specify)				

<sup>1</sup> Refer Diamond ③ in the logic chart

<sup>2</sup> Refer Diamond ④ in the logic chart

5. Durable commodities have a long shelf-life and can be stored for relatively long periods. Examples of durable commodities are shown in Table 3.

Please identify the durable commodities treated with methyl bromide in your country by completing the table as follows:

- “Yes” = Treated with methyl bromide;  
 “No” = Not treated with methyl bromide;  
 “No info” = No information available.

You should give your answers under the following headings in the table:

- 1) fumigated with methyl bromide in storage (not QPS);
- 2) fumigated with methyl bromide to officially control quarantine pests;
- 3) fumigated with methyl bromide to meet the official phytosanitary or sanitary requirements of the importing country; or
- 4) fumigated with methyl bromide to meet the official phytosanitary or sanitary requirements of the exporting country.

Use the attached logic chart to help you with your answers.

**Table 3:** Pre-shipment treatment

Durable Commodities	(1) Storage treatments (not QPS)	(2) Quarantine treatments	(3) Official requirement of importing country <sup>1</sup>	(4) Official requirement of exporting country <sup>2</sup>
<i>Example: Grains, legumes, seeds, fodder</i>	<i>Yes</i>	<i>Yes</i>	<i>No</i>	<i>Yes</i>
Grains, legumes, seeds, fodder				
Coffee beans, cocoa beans				
Dried fruits, nuts				
Dried herbs, spices, medicinal plants				
Logs, timber				
Wood products, furniture, crafts				
Packaging				
Other durable commodities (please specify)				

<sup>1</sup> Refer Diamond ③ in the logic chart

<sup>2</sup> Refer Diamond ④ in the logic chart

6. Please list the main perishable and durable commodities that are treated with methyl bromide in your country, and identify the countries requiring treatments to:

- 1) Officially control quarantine pests;
- 2) Meet the official phytosanitary or sanitary requirements of the importing country; and/or
- 3) Meet the official phytosanitary or sanitary requirements of the exporting country.

**Table 4:** Pre-shipment treatment

Perishable And Durable Commodities	(1) Quarantine treatment (state which country the product is exported to)	(2) Official requirement of importing country <sup>1</sup> (name of country)	(3) Official requirement of exporting country <sup>2</sup> (name of country)
<i>E.g., Apples</i>	<i>Yes (Japan)</i>	<i>No</i>	<i>No</i>
<i>Grain [from Australia]</i>	<i>No</i>	<i>Yes (Kenya)</i>	<i>Yes (Australia)</i>

7. **Regulations** requiring use of methyl bromide for quarantine and pre-shipment.

For your country, please list any regulations requiring commodities to be fumigated with MB to:

- 1) Officially control quarantine pests;
- 2) Meet the official phytosanitary or sanitary requirements of the importing country; or
- 3) Meet the official phytosanitary or sanitary requirements of the exporting country.

**Table 5**

Name of official regulation or official policy requiring methyl bromide treatment	Which commodity or commodities are treated?	Date regulation first came into force

---

Thank you for completing this survey.  
 Please **fax this completed survey**  
**by 20 January 1999** to:

If **after 20 January**, please mail this  
 completed survey to:

Dr Tom Batchelor  
 MBTOC meeting  
 Clarion Hotel SF Airport  
 San Francisco, USA  
 FAX +1-650-692-4251

Dr Tom Batchelor  
 Co-Chair MBTOC  
 PO Box 308  
 Prospect, TAS 7250  
 AUSTRALIA

**NOTE: FIGURE 4.1 FROM THIS REPORT (QPS LOGIC DIAGRAM) WAS ALSO SENT TO PARTIES TO ASSIST WITH REPORTING 'QUARANTINE' AND 'PRE-SHIPMENT' DATA FOR THIS FORM**



## Appendix A3: Draft Methyl Bromide Record Sheets For Recording Quarantine And/Or Pre-Shipment Uses

This document is intended as an aid to Parties for gaining information about quarantine and pre-shipment (QPS) consumption of methyl bromide (MB) at a national level. Those involved in monitoring and reporting QPS should amend the requirements of this form to suit their needs. Parties wishing to make use of this or similar form would need to ensure that a system is in place for licensing companies and individuals carrying out MB fumigations.

Applications to be completed by licensed applicators of methyl bromide for quarantine and pre-shipment purposes. Please read instructions and definitions before completing the application form.

### ***Instructions***

You are required to provide information to the government of (specific name of country requesting information) if your company was involved with the use of methyl bromide for quarantine and pre-shipment applications. This form must be filled out on an annual basis and submitted by (specific day, month, year) for quarantine and pre-shipment uses (QPS) during the period of (day, month, year) to (day, month, year).

### ***Definitions***

**Quarantine applications** with respect to methyl bromide, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control.

**Official control** of a pest is that which is performed by, or authorised by, a national plant, animal or environmental protection or health authority.

**Quarantine pests** are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.

**Pre-shipment applications** are those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country.

- Please refer to the 'QPS Logic Diagram' (see Section 3.2.5, Figure 3.1 in the TEAP 1999 Report) for assistance in classifying methyl bromide uses as quarantine or pre-shipment.

Complete and return this form to:

Government Department: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_  
 Contact Person: \_\_\_\_\_  
 Telephone: \_\_\_\_\_  
 Fax: \_\_\_\_\_

**Section A**

*Information respecting your company's activities:*

1. Dates of reporting period: Start: \_\_\_\_\_ Finish: \_\_\_\_\_
2. Name of your company: \_\_\_\_\_
3. Address: \_\_\_\_\_  
 \_\_\_\_\_  
 Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_
4. Contact person: \_\_\_\_\_
5. Company's Activities:
  - (a) State the total quantity of methyl bromide applied or otherwise used by your company for quarantine and/or pre-shipment purposes during the reporting period: \_\_\_\_\_ kg
  - (b) Please complete Section B for quarantine treatments. Please complete Sections C & D for pre-shipment treatments.

**Section B**

Complete the following table for each use of methyl bromide for **quarantine** purposes **only**. Attach **official proof** of these quarantine treatments i.e., document from official authority which performed or authorised the treatment for each fumigation.

Date of fumigation (day/month/year)	Item(s) Treated with methyl bromide (includes products, packaging, transport vehicles)	Units Treated (# of boxes, containers e.g.)	Official Quarantine Pests Targeted	Country requiring MB fumigation	Amount of methyl bromide used*
e.g., 10-09-00	Apples	15,000 boxes	Codling moth	Japan	227 kg
					<b>Total Amount Used</b>



### Section C

**Pre-shipment treatments** required by official authorities in the **importing** country.

Complete the following table for each use of methyl bromide used for phytosanitary or sanitary purposes to meet the official requirements of countries importing the commodities or items.

Attach **official proof** that these methyl bromide fumigation(s) were required by official or national authorities in the importing country e.g. document from the national authority which performed or authorised the treatment for each fumigation.

<b>Date of application</b> (day, month, year)	<b>Date of Export</b> (day, month, year) (if known)	<b>Item(s) Treated with methyl bromide:</b> (includes products, packaging, transport vehicles)	<b>Units Treated</b> (# of boxes, containers, etc.)	<b>Official or national phytosanitary or sanitary requirement</b>	<b>Country requiring the pre-shipment fumigation</b>	<b>Amount of methyl bromide used*</b>
10-10-00	15-10-00	Wooden pallets	10 containers	[National] Grain Board	Kenya	27 kg
						<b>Total Amount Used</b>

### Section D

**Pre-shipment treatments** required by official authorities in the **exporting** country.

Complete the following table for each use of methyl bromide used for phytosanitary or sanitary purposes to meet the official requirements of countries exporting the commodities or items.

Attach **official proof** that these methyl bromide fumigation(s) were required by official authorities in the exporting country e.g. document from the national authority which performed or authorised the treatment for each fumigation.

<b>Date of application</b> (day, month, year)	<b>Date of Export</b> (day, month, year) (if known)	<b>Item(s) Treated with methyl bromide:</b> (includes products, packaging, transport vehicles)	<b>Units Treated</b> (# of boxes, containers, etc.)	<b>Official Phytosanitary or sanitary requirement</b>	<b>Amount of methyl bromide used*</b>
10-10-00	15-10-00	Ship	3 holds	Canadian Plant Protection Division #76-9	1 tonne
					<b>Total Amount Used</b>



UNEP

**Technology and Economic Assessment Panel**

**Part II: Essential Use Nominations for Parties  
Not Operating under Article 5 for  
Controlled Substances for  
1997 through 2002**



# 1. Essential Use Nominations

## 1.1 Review of essential use nominations for MDIs

Decision IV/25 of the Fourth Meeting and subsequent Decisions V/18, VII/28, VIII/9, VIII/10 set the criteria and the process for the assessment of essential use nominations for metered dose inhalers (MDIs)

### 1.1.1 Review of Nominations

The review by the Aerosols, Sterilants, Miscellaneous Uses and CTC Technical Options Committee (ATOC) was conducted as follows. Three members of the ATOC independently reviewed each nomination. Members prepared preliminary reports, which were forwarded to the Co-Chair. The full committee considered the results of these assessments and this drafted report. For nominations where some divergence of view was expressed, additional expertise was sought.

Concurrent with the evaluation being undertaken by the ATOC, copies of all nominations were provided to the Technology and Economic Assessment Panel (TEAP). The TEAP were able to consult with other appropriate individuals or organisations in order to assist in the review and to prepare the TEAP recommendations to the Parties.

### 1.1.2 Committee Evaluation and Recommendations

Nominations were assessed against the guidelines of the Essential Uses Handbook 1997 as developed by the TEAP. Further information was requested where nominations were found to be incomplete.

The ATOC reviewed all of the submitted nominations for a production exemption. Production in this context includes import of ozone depleting substances for the purposes of manufacture.

The following Parties nominated essential use production exemptions for MDIs (asthma and COPD).

Country	2000	2001
European Union	*	✓
Japan	✓	✓
Hungary	✓	✓
USA	*	✓

\*Approved in 1998

The ATOC notes that essential use nominations were not received from Canada (last approved year 1999), Switzerland (last approved year 1998), Israel (last approved year 1997) or the Russian Federation (last approved year 1998).

The ATOC notes that Australia and Poland have not yet nominated for 2001, but have approvals for essential use allowances for 2000.

### 1.1.3 Future Considerations

The essential use nominations and supplemental information received in 1999 enabled an adequate assessment of requested CFC use for MDI manufacture. In order to enable ATOC to better evaluate the appropriateness of future CFC requirements, Parties may wish to consider including in nominations an estimate of the overall proportion of CFC use for the manufacture of MDIs for:

1. domestic use
2. export to non-Article 5(1) Parties
3. export to Article 5(1) Parties.

### 1.1.4 Recommendations: Party Nominations (in metric tonnes)

#### European Union

ODS/Year	2001
CFC-11	1243
CFC-12	1813
CFC-113	7
CFC-114	207
<b>Total</b>	<b>3270</b>

**Specific Usage:** MDIs for asthma and COPD

**Recommendation:** Recommend Exemption

#### Comments:

The ATOC commends the EU on a complete and well-presented nomination, and notes the request shows a 13% decline from the request for the year 2000. The EU submitted a final transition strategy based on a category by category approach.

The EU nomination notes (i) the extensive community and professional educational campaign; (ii) decreasing strategic reserves, which reflect less

than one year CFC requirements and (iii) the voluntary commitment from major MDI manufacturers to destroy all strategic reserves when transition is complete.

### Hungary

<b>ODS/Year</b>	<b>2000</b>	<b>2001</b>
CFC-11	0.5	0.5
CFC-12	0.5	0.5
CFC-113	0.25	0.25
CFC-114	0.5	0.5
<b>Total</b>	<b>1.75</b>	<b>1.75</b>

**Specific Usage:** MDIs for asthma and COPD

**Recommendation:** Recommend exemption for 2000 and 2001

#### Comments:

It was noted that Hungary's use of CFCs had declined considerably as a result of a dramatic reduction in medical CFC uses other than MDIs. Two cromoglycate products for asthma and one bromhexine product for COPD are manufactured locally. This nomination represented the only application received from any country for CFC use to deliver bromhexine for inhalation. In future years further justification will be required as to why this method of administration should be regarded as essential (oral preparations are also available). It was noted that no new product registrations for CFC containing aerosols have been allowed since 1996. No specific information of educational activities to promote a move away from CFCs has been provided.

### Japan

<b>ODS/Year</b>	<b>2000</b>	<b>2001</b>
CFC-11	32	27
CFC-12	55	54
CFC-113	0.2	0.2
CFC-114	11	7
<b>Total</b>	<b>98.2</b>	<b>88.2</b>

**Specific Usage:** MDIs for asthma and COPD

**Recommendation:** Recommend Exemption

**Comments:**

This nomination is for the years 2000 and 2001. In comparison to previous years there is a welcome reduction in the volumes requested. The nomination is complete and well constructed. However it appears that the CFC stockpile has increased during 1998 by 45 tonnes (17%). The stockpile at the end of 1998 represents approximately 2.5 years of use for CFC MDI manufacture. ATOC recognises that there is a lengthy supply chain of bulk CFC required to support local manufacture of MDIs in Japan. Nevertheless the current stockpile is probably excessive and should be addressed in future nominations.

A transition strategy was received, which describes a process of brand by brand transition with a target for phaseout in 2005.

**USA**

<b>ODS/Year</b>	<b>2001</b>
CFC-11	918
CFC-12	1947
CFC-114	236
<b>Total</b>	<b>3101</b>

**Specific Usage:** MDIs for asthma and COPD

**Recommendation:** Recommend exemption

**Comments:**

The submission was well constructed and complete. The volume of the nomination for the year 2001 is comparable to the average annual actual use for 1996-1998.

The US nomination notes (i) recent introduction of one CFC-free MDI and three DPI formulations; (ii) the extensive community and professional educational campaign; (iii) decreasing strategic reserves, which reflect about one year CFC requirements and (iv) the voluntary commitment from major MDI manufacturers to destroy all strategic reserves when transition is complete.

1.1.5 Review of Previously Authorised Essential Uses (Decision VII/28 (2a))

Under Decision VII/28 (2a) and (2b), Parties decided that:



- “(a) *The Technology and Economic Assessment Panel will review, annually, the quantity of controlled substances authorised and submit a report to the Meeting of the Parties in that year;*
- (b) *The Technology and Economic Assessment Panel will review, biennially, whether the applications for which exemption was granted still meets the essential-use criteria and submit a report, through the Secretariat, to the Meeting of the Parties in the year in which the review is made;”*

The ATOC reviewed the essentiality of MDIs for asthma and COPD for 2000 and 2001, and concluded that they remain essential for patient health until an adequate range of technically and economically feasible alternatives are available.

New CFC-free product launches are likely to increase rapidly over the next two years. As most nominations are received 2 years in advance, Parties may wish to continue to monitor and manage their own CFC acquisition and usage under authorised essential use quantities, and adjust their nominated quantities annually on an “as needed” basis. The ATOC will continue to monitor the changing market situation.

The ATOC highlights the value of the accounting framework to its assessment of essential use exemption nominations. Three components of this framework warrant specific mention.

1. **Trends** – earlier nominations showed considerable discordance between actual use and volumes exempted for essential use. The accounting frameworks show increasingly realistic predictions of CFC requirements.
2. **Stockpile information** – information now available on Parties’ CFC stockpiles should allow optimal planning for future CFC management.
3. **Exports** – in order to monitor the export of CFC MDIs from one non-Article 5(1) Party to another, and to discourage export where transition to non-CFC products is progressing satisfactorily, Parties may wish to consider modifying the reporting accounting framework to include disclosure of the destination of the finished product ie. aggregated volumes intended for:
  - a) domestic consumption
  - b) export to Article 5(1) Parties, or
  - c) export to non-Article 5(1) Parties.



## **2. Nomination By Poland For Solvents Used In The Maintenance Of Oxygen Systems Of Torpedoes**

### **2.1 1999 Essential Use Exemption**

In 1999 Poland applied for use of 1700 kg of CFC-113 for the years 2000 up to 2003 for cleaning of torpedoes. The torpedo oxygen systems are overhauled in a workshop. After disassembly, individual parts are degreased and inspected and the necessary maintenance processing is performed for retaining the operational functionality of the components. The prime use of CFC-113 is for the elimination of oxygen compatible grease.

The STOCs assessment is as follows:

- the information provided so far is inadequate to support the essential use nomination,
- despite persistent efforts by the Polish Ministry of Environmental Protection, there has been a lack of concrete action in response to the suggestions made by TEAP, and
- therefore, the STOC is unable to recommend this nomination based on available information.

### **2.2 The TEAP Recommendation**

In December 1998, TEAP co-chairs asked the Head of the Ozone Protection Unit in Warsaw and the Head of the Polish Delegation, Ministry of Environmental Protection to organise a joint meeting with representatives of the Polish Navy, the manufacturers of the torpedoes and a team of STOC members. Kazakhstan was suggested as the venue. Subsequent direct communication between the Head of the Ozone Layer Protection Unit and a STOC co-chair agreed on scheduling the meeting in Kazakhstan during 3 – 5 May 1999. There have been problems in receiving a proper response from the manufacturer of the torpedoes.

TEAP therefore recommends that the nomination be forwarded to the 11<sup>th</sup> Meeting of the Parties to allow the opportunity to review supplemental information.

### **2.3 Background of Polish Nomination**

In 1997, Poland exercised its option under the Emergency Exemption (Decision VIII/9, paragraph 10). Import of 1,700 kilograms of CFC-113 for this use was authorised by the Secretariat after consultation with TEAP and its

STOC. At that time the Delegate of the Russian Federation (which was assumed to have manufactured the torpedoes) assured TEAP and the Polish Delegation that they would contact the torpedo manufacturer and schedule a technical meeting.

In 1998, Poland applied for 1700 kg of CFC-113 for use in 1999-2003. In February 1998, the STOC requested additional information such as: substrate alloys for components and assemblies, types of coatings applied, types of non-metallic components used and type of grease to be removed and its liquefying temperature and approximate thickness of grease layer. Details of the grease-removing process and working conditions such as ventilation were also requested. Information was requested regarding problems that might arise from the use of recycled CFC-113, which alternative processes or substances have been evaluated and technical reasons for their rejection, types of tests carried out and criteria used for qualification.

Late in 1998 The Russian Federation notified Poland that the torpedo manufacturer was not based in Russia but in Kazakhstan.

TEAP considered this nomination and in its report of April 1998 documented that STOC did not receive the information requested in February 1998 and, therefore, was unable to recommend this nomination for continued use.

According to information provided for substantiation of the nomination, the Polish Navy needs approval from the manufacturer for introducing any alternatives. Till now the manufacturer does not accept alternatives.

After additional consultations with the TEAP, the tenth meeting of the Parties approved the emergency authorisation by the Secretariat of 1'700 kg of CFC-113 for years 1997 and 1998 and approved the same quantity for the year 1999.

### **3. Review of an Essential Use Nomination Submitted by the Russian Federation**

An Essential Use request for 90 metric tonnes of halon 2402 for the year 2000 was received from the Russian Federation. The Halons Technical Options Committee reviewed the Essential Use nomination submitted by the Russian Federation in 1999. The substantiation that accompanied the nomination indicated that the amount requested would be used for the protection of nuclear power plants, for military installations, with most allocated to the halon bank.

The HTOC received extensive information from the Russian Federation in the form of a progress report and was able to assess progress made over the last years. In addition, the Russian Federation provided production, use, and stockpile data for 1996 through 1998, using the Reporting Framework as required by Parties. The actual production in 1998 (79.7 t) was lower than the amounts authorised by Parties (255 t). As explained in the progress report, this was due mainly to the development of programs to recycle halon 2402. The HTOC notes the comments provided by the HTOC member from the Russian Federation that the Russian Federation is planning to close all halon 2402 production facilities in the course of the year 2000. This has been confirmed by a letter from the Russian Government to the Co-Chairs of HTOC.

The TEAP and its HTOC recommend the Essential Use exemption by the Russian Federation for 90 metric tonnes of halon 2402 for the year 2000.





UNEP

**Technology and Economic Assessment Panel**

**Part III: Exports of Controlled Substances in  
Annex A and Annex B to the  
Montreal Protocol from  
Non-Article 5 Parties to Meet the  
Basic Domestic Needs of Article 5 Parties**





## **1. Introduction**

For exports of controlled substances in Annex A and B to the Montreal Protocol from non-Article 5(1) Parties to meet the basic domestic needs of Article 5(1) Parties, the Technology and Economic Assessment Panel was requested (Decision X/15):

- (a) To make an assessment of the quantities of controlled substances in Annex A and Annex B to the Protocol likely to be required and produced by Parties operating under Article 5 of the Protocol for the period 1999-2010;
- (b) To make an assessment of the quantities of controlled substances in Annex A and Annex B to the Protocol which need to be produced and exported by Parties not operating under Article 5 in order to meet the basic domestic needs of Parties operating under Article 5 during the period 1999-2010;
- (c) To present its report to the Open-Ended Working Group in time for the issue to be considered by the Eleventh Meeting of the Parties.



## **2. Balance between CFC Production and Consumption**

Maintaining an acceptable balance between production and consumption of CFCs for the Article 5(1) Parties during the phaseout process is a rising challenge for the Parties. So far the needs of the Article 5(1) Parties have been accommodated by production in both Article 5(1) and non-Article 5(1) Parties.

In Table 1 the production in Article 5(1) and non-Article 5(1) Parties is presented for the years 1995, 1996 and 1997 derived from the data that have been officially submitted to the UNEP Ozone Secretariat. Table 1 also presents the consumption data for all Article 5(1) Parties, with the exception of the consumption and production in the Republic of Korea. The produced amounts in the Republic of Korea are assumed to cover the domestic needs of the Republic of Korea only and they are therefore not considered in this table. Furthermore, the production in the Russian Federation has not been taken into account; small amounts may have been exported. Since production in the Russian Federation will be halted shortly, this aspect has not been taken into further account in this report.

Table 1 also presents the consumption estimates beyond 1997. These estimates are derived from calculations involving the implementation of projects under the Multilateral Fund as presented in the Report on the Replenishment of the Multilateral Fund 2000-2002.

In the years 1995 to 1997, annual production in the Article 5(1) Parties was about 100,000 ODP tonnes, of which approximately 75% was produced in Asia and 25% in Central and South America. In 1997, it was about 26,000 ODP tonnes less than the reported consumption. This residual amount is assumed to have been produced in the non-Article 5(1) Parties under the basic domestic needs clause of the Montreal Protocol.

Table 1 also presents the amounts expected to be produced until 2010 in the different Article 5(1) Parties. The production schedules have been taken from the relevant material in the report of the 27<sup>th</sup> Executive Committee Meeting for China, and from material agreed upon by India. In the case of production in South America, the production schedules have been determined from the baseline production determined as the average over the years 1995, 1996 and 1997. This determines the figures for the years 2000-2010 following the Montreal Protocol control schedules.

**Table 1:** ODS (CFC) production and consumption for all Article 5(1) Parties as reported to UNEP (ODP tonnes \* 1000) for the years 1995, 1996 and 1997. The Table also contains the results of calculations for the CFC consumption from the study on the replenishment of the Multilateral Fund during 2000-2002. The production levels given for the period 2000-2010 have been derived from material published for China and India (as agreed for China at the 27<sup>th</sup> ExCom Meeting) and from the 1995-97 base level.

Year	Article 5(1) CFC Consumption	Article 5(1) CFC Production	Difference (Production minus Consumption)	Non-Article 5(1) CFC Production
1994	163.83			
1995	159.25	99.76	-59.49	100.56
1996	128.54	92.02	-36.52	33.93
1997	126.27	100.64	-25.63	32.52
1998	111.71	102 (est)	-9.71	
1999	95.14	96 (est)	1.86	
2000	80.69	88.19	7.50	
2001	68.79	79.76	10.97	
2002	64.05	71.83	7.78	
2003	62.03	64.30	2.27	
2004	60.51	54.97	-5.54	
2005	58.59	43.79	-14.80	
2006	41.36	29.78	-11.58	
2007	20.57	17.11	-3.46	
2008	13.68	12.41	-1.27	
2009	6.84	5.71	-1.13	
2010	0	0	0	

If the Article 5(1) Parties maintain the anticipated production level for 1998, it is expected that Article 5(1) production will exceed consumption in 1999, which would imply that there would be no need for production from non-Article 5(1) Parties for “basic domestic needs” of the Article 5(1) Parties.

Anticipated production levels exceed calculated consumption levels only for a number of years, until probably 2004. If only Article 5(1) production would be possible, large shortages are predicted to occur particularly during 2004-2006 (2007). This shortage might possibly be avoided by increasing the production in the Article 5(1) countries by 10% of the base level for satisfying basic domestic needs. Production levels are also assumed to be somewhat too low to cover the needs during the period (2007) 2008-2009, however shortages may be covered from recycled material in this period. The above observations assume no extra production for “basic domestic needs” by the non-Article 5(1) Parties.

It should be mentioned that Article 5(1) Parties are allowed to produce a maximum extra amount of 10% of the base level for their “basic domestic needs”. This implies that an amount of 13,800 ODP tonnes (10% of the 1995-

1997 base level) could be produced for “basic domestic needs”. This would be sufficient to virtually cover the possible shortage during the period 2004-2006 and beyond. Therefore, in principle, no production from non-Article 5(1) Parties would be needed for “basic domestic needs”.

However, it may be that at short notice some production facilities in Article 5(1) Parties (owned by multinationals) will be closed which could lead to a shortage even already during the period 2000-2001. Production rationalisation is allowed for Article 5(1) Parties so that, in principle, the Article 5(1) consumption could be covered by production facilities in the Article 5(1) Parties provided that remaining production facilities can substantially increase their output under the rationalisation program.

On the other hand, it is also possible that production reduction may take place in Article 5(1) Parties more than mandated by the Montreal Protocol, or that the 10% additional production may not be produced because of agreements with the Multilateral Fund.

In summary, to date there has been surplus ODS manufacturing capacity and a surplus ODS production from both the non-Article 5(1) and the Article 5(1) country production facilities. This surplus has resulted in stockpiling, price discounts, and aggressive marketing, which has made phaseout difficult. Soon, however, more ODS production facilities will be closing and prices may then increase. Increased ODS prices would encourage investment in conversion and recycling in CEIT and Article 5(1) Parties.

Since a precise forecast is difficult at this stage, the producing Parties may consider reporting the closure plans of any of their CFC production facilities to the Ozone Secretariat whenever they have definite information. TEAP recommends that the reports be analysed and reported to the Parties annually.



### **3. Balance Between Halon Production and Consumption**

Table 2 shows the consumption and production levels for all Article 5(1) Parties with China being the main producer and consumer.

For the CIS countries, UNEP data show that production and consumption were more or less in balance during 1994 and 1995. The year 1996 shows a small production shortage which has not been taken into account in this study (note: the Republic of Korea has not been considered within this framework given that the 1993-1996 halon consumption reported to UNEP was offset by reported production).

Table 2 shows that the 1994 production was roughly 7,000 ODP tonnes lower than halon consumption for all Article 5(1) Parties together. Production in China was somewhat larger than consumption. 1994 Exports of roughly 7,000 ODP tonnes that were not consumed in the non-Article 5(1) Parties in 1993 (derived from UNEP reported data) would for the larger part have met a possible shortage on the Article 5(1) Parties' markets in 1994.

This situation changed drastically after 1994 when China substantially increased halon production. Excess production of about 2,300 ODP tonnes in 1996 increased to about 6,000 ODP tonnes in 1997. In the years 1996 and 1997, all Article 5(1) Parties, excluding China, consumed about 5,800 and 3,500 ODP tonnes, respectively. The 1995-1997 baseline for all Article 5(1) Parties, excluding China, is about 5,300 ODP tonnes.

At present China is the only halon producer. In Table 2 the data show China's halon production and consumption figures for the period 1998-2006, as a total for both halon-1211 and halon-1301. The Table also shows the consumption of other Article 5(1) Parties, as derived in the Replenishment of the Multilateral Fund study. Given the declining consumption by other Article 5(1) Parties, the availability of halons from China for export is expected to keep price levels low and will not stimulate the domestic policies of other Article 5(1) Parties during the coming years, particularly in relation to halon banking schemes.

The consumption by the Article 5(1) Parties except China, is calculated to be in the order of 1,600 ODP tonnes in 2005. However, this is dependent on the reduction schedules in the individual Article 5(1) Parties and it may well be lower.

**Table 2:** Halon production and consumption levels for all Article 5(1) Parties for the period 1994-1997 as reported to UNEP /UNE98a, UNE98b/ in ODP tonnes. Consumption and production levels for China are given as reported to UNEP for 1994-1997, and as prescribed for all years after 1997 in Decision 23/11 as taken in the 23rd Executive Committee meeting.

Year	Cons. all A 5(1) Parties	Cons. All A5 (1) without China	Cons. China	Production All A 5(1) Parties	Production China	Difference prod./ cons. in China
1994	29,148	8,998	20,150	21,946	(21,550)	(1,400)
1995	40,667	6,953	33,714	37,591	(37,350)	(8,700)
1996	38,972	5,857	33,115	40,574	(40,269)	(7,154)
1997	39,250	3,519	35,731	45,517	(45,196)	(9,465)
1998	27,100	2,620	24,480*	(30,060)*		(5,580)*
1999	21,700	2,590	19,110*	(24,090)*		(4,980)*
2000	16,200	2,460	13,740*	(18,120)*		(4,380)*
2001	14,800	2,450	12,351*	(16,131)*		(3,780)*
2002	11,800	2,330	9,462*	(13,962)*		(4,500)*
2003	9,200	2,030	7,170*	(11,970)*		(4,800)*
2004	9,100	1,930	7,170*	(11,970)*		(4,800)*
2005	8,800	1,630	7,170*	(11,970)*		(4,800)*
2006	2,200	1,200	1,000*	(3,000)**		(2,000)**

\* **Note:** These figures are given in the Executive Committee Decision on the Chinese halon sector phaseout strategy, and consist of both halon-1211 and halon-1301 data multiplied with the respective ODPs (3.0 and 10.0).

\*\***Note:** As of 2006, the production of halon-1211 in China will be halted, according to the strategy.

Taking the excess production of halons in China as given in Table 2 and comparing it to the consumption of all Article 5(1) Parties minus China, there is more than enough supply to cover all halon demand. Moreover, in many Article 5(1) Parties halon is available in non-critical uses which could be replaced by substitutes. Therefore there will be no need at all for production of halons in the non-Article 5(1) Parties for “basic domestic needs”.



#### **4. Balance Between CTC Production and Consumption**

CTC consumption will have to be reduced by 85% by the year 2005 under the control schedule of the Montreal Protocol. CTC is rather unique because its main use is as a feedstock for the manufacture of CFCs (95% of all CTC uses). As such, its production is not directly regulated by the Montreal Protocol, but follows that of its derivatives, CFC-11 and CFC-12.

CTC is currently manufactured in seven Article 5(1) Parties: Brazil, China, India, Korea, Mexico, Romania and South Africa. These Parties manufactured in 1996 a total of 90,491 ODP tonnes, according to UNEP figures. Despite this local manufacturing capacity, Article 5(1) Parties are net importers of CTC. The 1998 Aerosols Technical Options Committee (ATOC) report estimated that in 1996 Article 5(1) Parties needed some 152,600 ODP tonnes of CTC for CFC manufacture; the shortfall of more than 62,000 ODP tonnes would have been imported.

As Article 5(1) Parties reduce CFC production to meet the 50 % reduction scheduled for 2005, and the shortfall should disappear by 2002 according to the figures shown in Table 1, (ATOC estimated a consumption of 1.35 ODP tonnes of CTC to produce 1 ODP ton of CFC). It should also be pointed out that CTC emissions during the manufacture of CFCs are usually larger in facilities of Article 5(1) Parties than in facilities of non-Article 5(1) Parties. Therefore, from an environmental standpoint it would be better to keep in operation those facilities of non-Article 5(1) Parties with the best emission controls.

In conclusion, it appears that CTC production capacity in Article 5(1) Parties should be sufficient by the year 2002 to meet Article 5(1) Parties' production requirements. This implies that there may be no need for CTC production in non-Article 5(1) Parties for "basic domestic needs".

As it is difficult to accurately assess current trends in CTC production and consumption in most Article 5(1) Parties, TEAP recommends that CTC production and consumption reports be analysed and reported annually to the Parties.



## 5. **Balance Between Methyl Chloroform Production and Consumption**

Methyl chloroform needs to be reduced by 30% by the year 2005 and should be phased out by the year 2015.

When the UNEP 1997 reported data are studied, the following can be observed:

- production by China: 104 ODP tonnes
- production by all non-Article 5(1) countries: 883 ODP tonnes
- consumption by France: 223 ODP tonnes
- consumption by all Article 5(1) Parties: 1802 ODP tonnes

The total global production in 1997 has been much smaller than the total global consumption. With the relatively small production capacity in China, and the large consumption in Article 5(1) Parties, it must have been that consumption has been possible due to stockpiled supplies.

The production capacity available in the non-Article 5(1) countries for “basic domestic needs” seems to be smaller than consumption in Article 5(1) Parties. Since TEAP is unable to accurately assess the trends in methyl chloroform production and consumption. TEAP recommends that the development of methyl chloroform consumption patterns in Article 5(1) Parties be analysed on an annual basis and that Parties be informed of the observations.





**UNEP**

**Technology and Economic Assessment Panel**

**Part IV: Exemption for Laboratory and  
Analytical Uses**



## **1. Developments and Availability of Laboratory and Analytical Procedures without Using ODS**

Decision X/19 requested the Technology and Economic Assessment Panel to report annually on the development and availability of laboratory and analytical procedures that can be performed without using controlled substances in Annexes A and B of the Protocol.

In 1998 the TEAP received no new information on alternatives and substitutes to ozone-depleting substances. TEAP therefore reiterates the findings of the April 1998 TEAP Report:

The following three specific uses are identified with readily available cost-effective alternatives which have been implemented in many countries.

1. Testing of oil, grease, and total petroleum hydrocarbons in surface and saline waters and industrial and domestic aqueous wastes including the testing of water which is separated from oil and discharged from off-shore drilling and production platforms.
2. Testing of tar in road paving material by dissolving tar and separating it from aggregate.
3. Forensic fingerprinting.

The phaseout of ozone-depleting substances in this sector goes beyond the identification of suitable substitutes since it is necessary that adequate standards are approved by local quality control and regulatory bodies. Some countries may not have implemented new standards for the ODS free alternatives.

Parties may wish to consider eliminating the above three uses from the global exemption as there are readily available cost-effective alternatives. Any Parties unable to meet their statutory and quality control standards may need to consider applying for an essential use nomination if they cannot readily make these administrative changes.

TEAP requests all Parties to provide to the Ozone Secretariat any information on new developments in this area, as and when it becomes available. This information is necessary to allow the Parties to consider relevant Decisions to withdraw the global exemption for all of these uses.







UNEP

**Technology and Economic Assessment Panel**

**Part V: Control of New Substances with  
Ozone Depleting Potential**



## **1. N-Propyl Bromide**

### **1.1 Preface to the 1998 STOC Report on n-Propyl Bromide**

During the 17<sup>th</sup> OEWG meeting (July 98, Geneva) a Co-chair of the Science Assessment Panel (SAP) reported on the assessment of n-propyl bromide and mentioned that the ODP was 0.026 with a rider that the figure may not be valid because of the short lifetime (about 11 days).

The STOC received instructions in August 98 from TEAP that the ODP value for n-propyl bromide to be used for the purpose of this report was 0.026. On the basis of this information, a report was completed and forwarded to the TEAP Co-chairs with a request for further handling and distribution in time for the 18<sup>th</sup> OEWG meeting (November 1998, Cairo).

An administrative error prevented distribution to Parties of a STOC special report on n-propyl bromide in time for the 18<sup>th</sup> OEWG meeting and the 10<sup>th</sup> Meeting of the Parties. As a result, Parties took Decision X/8 in Cairo without consideration of the STOC report.

Although there is still an uncertainty on the ODP figure for n-propyl bromide, requiring further research work, the STOC continues to hold the position that without restraints there could be significant production and use of n-propyl bromide and this could be detrimental to the ozone layer. In the future the STOC will review this issue as new information becomes available.

### **1.2 Introduction**

By virtue of Decision IX/24 of the MP and the findings by the Scientific Assessment Panel reported to the OEWG in July 1998, the STOC offers a complement of information on brominated solvents to assist TEAP in reporting to the OEWG and the Parties. This information includes estimates of the potential use of brominated solvents over a five-year period, according to various scenarios, on the assumptions that

- there are no national or international restrictions imposed on the use of these solvents during this period, either for environmental or health and safety reasons;
- the potential industrial growth in Article 5(1) countries averages 10% per annum;
- there is no significant industrial growth in other countries; and
- all production quantities are used or otherwise emitted.

There are currently two substances falling into the class of ozone-depleting brominated solvents that are being manufactured in developed countries.

These are n-propyl bromide and chlorobromomethane. These substances are both blended with other solvents, stabilisers and inhibitors and are marketed under proprietary trade names and all these proprietary solvents have 80-95 percent of ozone-depleting brominated solvents in their composition.

### **1.3 Production of n-propyl bromide**

This substance is also known by its full name of *normal*-propyl bromide and its synonym of 1-bromopropane. It is often abbreviated to nPB. Its reported ODP is 0.026, similar to that of HCFC-225. There are currently at least six factories producing it or capable of producing it. Three of these are in the USA and one each in France, Israel and Japan. The French manufacturer does not produce a solvent blend because of health and safety concerns, but it is possible that independent blenders, of whom there are at least two, market the solvent. Two of the US manufacturers and the Israeli and the Japanese manufacturers have grouped into a consortium. Much of the data here is derived from consortium information.

### **1.4 Applications**

nPB has been commercially introduced as a substitute for ozone-depleting solvents (CFC-113, 1,1,1-trichloroethane, carbon tetrachloride and HCFCs) and non-ozone depleting chlorinated solvents (trichloroethylene, perchloroethylene and methylene chloride). Its solvency is similar to that of 1,1,1-trichloroethane. It is considered as a “drop-in” replacement for use in open-top vapour degreasers and for cold cleaning and precision cleaning. It may also be used for some electronics defluxing applications. Additional potential applications are to replace other solvents in aerosols, adhesives, coatings and inks, as well as a non-solvent fire-suppressant application.

There do not appear to be any applications where the unique properties of nPB preclude the use of any other cleaning solvents or methods. Notwithstanding, there may be applications where nPB may be an economically preferred option, although these would be rare.

### **1.5 Current consumption**

It is very difficult to estimate current production and consumption. Some available data is conflicting. The best available data is a current consumption of about 1,000 tonnes<sup>1</sup> per annum in Europe, supplied by an independent blender and the consortium members. There are about 600 tonnes per annum.

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<sup>1</sup> Please note that all quantities expressed in this report are in tonnes of the unblended products: to convert to ODP tonnes, multiply these figures by the ODP of the product concerned.

consumed in Japan, mainly from consortium sources. Precise figures of consumption in the USA are unknown but are estimated to be at least of the same order as Japan and Europe. It is believed that the consumption in Article 5(1) countries is relatively small but is nevertheless increasing quite rapidly. The total current consumption almost certainly lies within the broad range of 2,000 and 5,000 tonnes per annum, but is increasing. These figures relate to vapour phase cleaning alone. The cold cleaning market is currently small, but may increase.

## **1.6 Price**

The price for medium-to-large users is currently moderately high, in the range of US\$ 8 - 12/kg. This compares to typical prices of US\$ 1.00 - 1.20 for carbon tetrachloride, US\$ 1.25 - 1.50 for trichloroethylene and perchloroethylene, US\$ 1.50 - 1.75 for 1,1,1-trichloroethane and US\$ 5 - 8 for CFC-113 (these prices may vary considerably from market to market and the quantities involved). However, it is known that current manufacturing plants are not used to full capacity and the manufacturers state that the bulk price when the plants are used to economical capacities may drop to US\$ 1.50 - 2.00/kg in 1998 prices. The current price is a severe restriction to the market development but it is expected that the manufacturers will drop the prices considerably as an incentive as soon as it is known that there are no other impediments to full market development. The scenarios offered here are the most likely ones, based on the assumption of a price structure of about double that of trichloroethylene and perchloroethylene.

## **1.7 Targeted markets**

There is some confusion as to which markets will be targeted. The consortium members promote nPB used as a replacement for CFC-113, 1,1,1-trichloroethane, carbon tetrachloride and HCFC solvents, mainly for metal cleaning, under controlled conditions with limited emissions. This may be their main market target at this stage, but some of their sales literature also mentions replacing non-ozone-depleting solvents, such as trichloroethylene, perchloroethylene and methylene chloride. On the other hand, non-consortium members and blenders are actively promoting the sale of nPB for replacing non-ozone-depleting substances. The STOC is concerned that the substances could be offered, without conditions, to any enterprise for any use. Previous experience has shown that conditions of unrestricted solvent sales at relatively low prices leads to poorly managed use under highly emissive conditions.

## **1.8 Manufacturing and consumption projections**

There are many possible scenarios of how an unhindered market will develop. The current manufacturing capacity of the consortium members has been

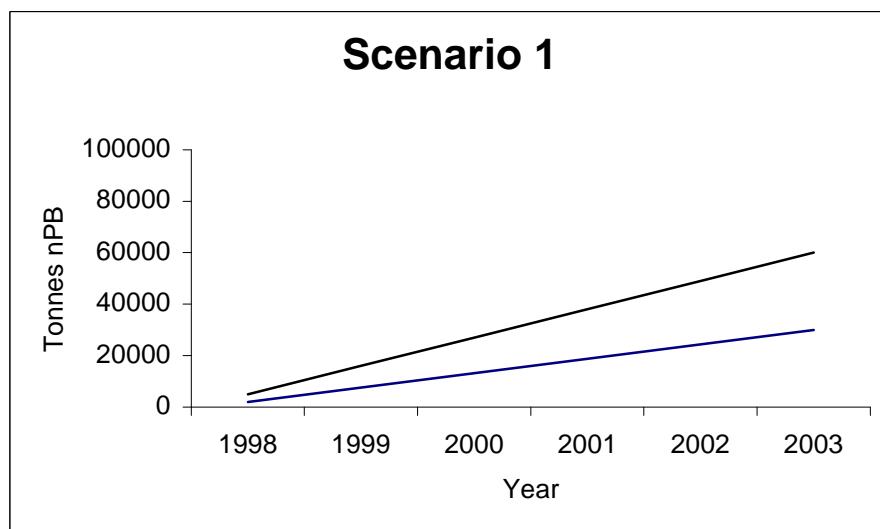
reported to the STOC by a representative at about 50,000 tonnes per annum. It is probable that non-consortium producers have a current capacity of 10,000 tonnes per annum. Increasing this capacity at current manufacturing sites may be difficult due to the limited quantities of easily and cheaply extracted bromine. Nevertheless, there are many other sites in the world where sizeable quantities of bromides can be found in reasonably concentrated form. This includes the waste stream from major desalination plants in the Red Sea and Gulf regions, where the natural sea bromide levels are higher than in the large oceans. There is little practical limit to the development of bromine extraction, but as the easily exploitable sources are used, so the cost of further extraction may rise. An arbitrary limit of 100,000 tonnes of low-cost nPB would therefore seem reasonable.

### 1.8.1 The linear scenario with no increase of production capacity

This scenario is the most conservative. Based on a steady, linear increase from current levels to the 2003 levels, it assumes that only the current production plants will be used for manufacture. This puts a ceiling of about 60,000 tonnes per annum. The linear hypothesis is based on the absence of a “snowball” effect whereby users state their satisfaction to other potential users and therefore increase the rate at which sales augment (see section 1.8.3). Consortium members forecast their sales at between about 25,000 and 50,000 tonnes. The area in Fig 1, between the maximum (upper) and minimum lines includes these forecasts plus expected production by existing non-consortium members. With this scenario, it is estimated that over 50% of the sales will be in developed countries.

**Figure 1.**

Five-year projection of expected nPB production assuming a linear increase and no new production plants, showing likely minimum and maximum

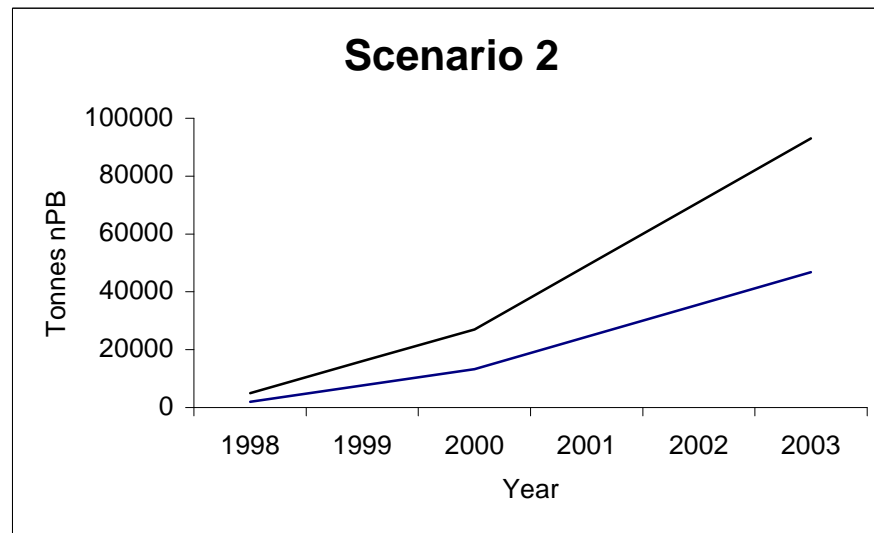


1.8.2 The linear scenario with new production capacity in Article 5(1) countries

At least one of the manufacturers and vendors have stated their intention to produce in 3 major Asian and one Latin American countries. If this takes place, production could begin as early as 2000 and, if the increase rates of these new plants were similar to that of existing ones, could almost double existing capacity by 2003. This would produce a drastic increase in use, especially in Article 5(1) countries, if the cost of local production was low, as would be expected. The lines in Fig 2 represent a probable minimum and maximum expected production, under these conditions. This scenario is quite probable as the STOC feels that nPB could be interesting to Article 5(1) nation users and it is known that some vendors are beginning to promote the product in some of these countries.

**Figure 2.**

Five-year projection of expected nPB production assuming a linear increase and new production plants in Article 5(1) countries coming on line from 2000, showing likely minimum and maximum.

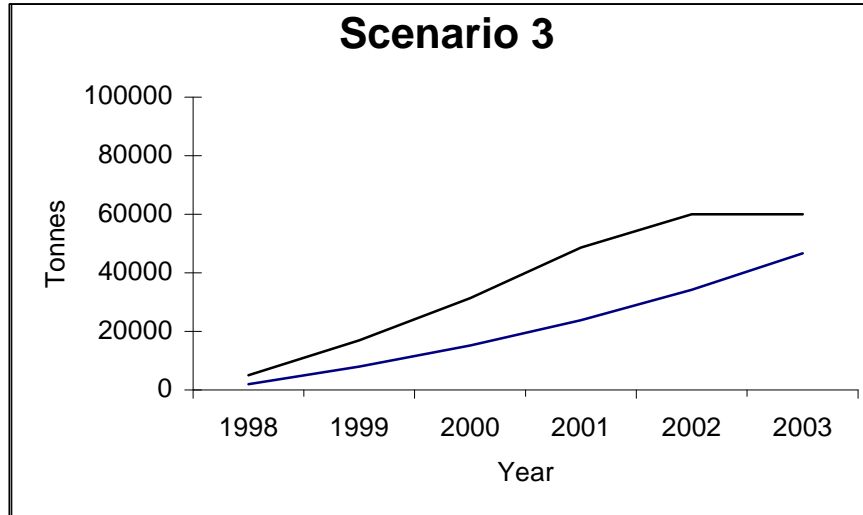


1.8.3 The exponential scenario with no increase of production

Scenarios 1 and 2 assume that the increase of production will follow a linear augmentation of demand. However, if the product is successful and is readily adaptable to users' operations, sales may increase exponentially. Figure 3 shows the effect this may have, assuming that the extra quantity produced would be 20 percent per annum more than would be expected under the linear scenario. Note that the maximum levels off to a ceiling value of 60,000 tonnes, this being the maximum aggregate capacity of existing consortium and non-consortium producers.

**Figure 3.**

Five-year projection of expected nPB production assuming an exponential increase and no new production, showing likely minimum and maximum.



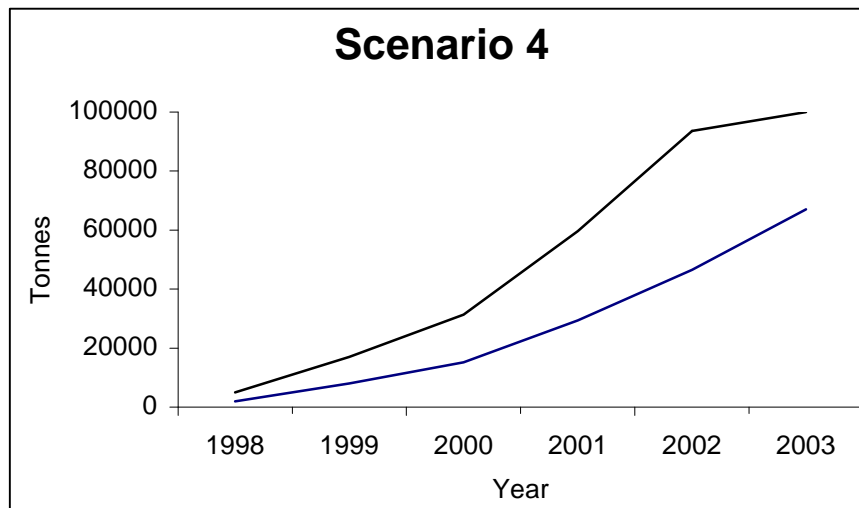
1.8.4 The exponential scenario with new production capacity in Article 5(1) countries

This combines the premises of scenarios 2 and 3. Of likely scenarios, this is the worst-case one. Figure 4 shows the probable maximum and minimum, but the maximum has been limited to an arbitrary maximum production capacity of 100,000 tonnes. This figure would seem to be a probable maximum of production capacity for plants already existing and likely to come on-line during the five-year period in question.



**Figure 4.**

Five-year projection of expected nPB production assuming an exponential increase and new production plants in Article 5(1) countries, showing likely minimum and maximum.



## 1.9 Alternatives to nPB

For low-cost vapour-phase cleaning, the obvious non-ozone-depleting options are trichloroethylene, methylene chloride and perchloroethylene, on both economical and environmental grounds. These three solvents are cheap and readily obtainable. On the other hand, they are moderately toxic and require special precautions (low-emission machines) to protect the operating personnel. The chronic toxicity of nPB has not been fully established but, from available information, it may be neurotoxic, genotoxic and cause problems to human fertility. Carcinogenicity has not been established because long-term tests have not yet been conducted. In any case, it seems advisable that, at least, similar precautions as are required for the chlorinated solvents should be installed, so that there is little difference required at our current state of knowledge. Similar remarks apply to cold cleaning.

Where the use of non-ozone-depleting chlorinated solvents is precluded, for any reason, other alternatives include aqueous, HCS and straight hydrocarbon (flammable) cleaning. These may be, in some circumstances, marginally more expensive. Other non-ozone-depleting halogenated solvents for vapour-phase cleaning include HFCs and HFEs but their cost price is much higher, requiring the use of more expensive zero-emission machinery for them to become competitively acceptable, especially in Article 5(1) countries, and to minimise the emission of strong “greenhouse gases”.

## **1.10 Conclusions (STOC)**

In view of the predicted quantities of nPB, if the market for this substance is developed unhindered and the ODP, which is within the same range as HCFCs regulated under the Montreal Protocol, the STOC recommends that the Parties consider appropriate action to prevent or limit further depletion of the ozone layer due to this substance.

## 2. Chlorobromomethane (CH<sub>2</sub>ClBr)

This substance is a very simple, low cost and easy-to-produce halocarbon. It is also known as bromochloromethane, or monochloromonobromomethane. It is also used as a fire extinguishant known as halon 1011. The usual abbreviation in the solvents sector is CBM. It has an ODP of about 0.12, similar to that of 1,1,1-trichloroethane and HCFC-141b. It would seem that there are probably two factories producing CBM in the USA and one in Europe. Historically, its sales as a solvent took off rapidly but were then set back by the introduction of nPB and data indicating that its ODP was higher than originally believed and that its toxicity gave cause for concern.

### 2.1 Applications

#### 2.1.1 Solvent applications

CBM can be used as a substitute for ozone-depleting solvents (CFC-113, 1,1,1-trichloroethane, carbon tetrachloride and HCFCs) and non-ozone depleting chlorinated solvents (trichloroethylene, perchloroethylene and methylene chloride). Its solvency is similar to that of 1,1,1-trichloroethane. It is considered as a “drop-in” replacement for use in open-top vapour degreasers and for cold cleaning and precision cleaning. It may also be used for some electronics defluxing applications. Other potential applications are to replace other solvents in aerosols, adhesives, coatings and inks.

As a solvent there are no known application where the unique properties of CBM precludes the use of any other cleaning solvents or methods. Notwithstanding, there may be applications where CBM may be an economically preferred solvent option, although these would be rare.

#### 2.1.2 Fire protection applications

Halon 1011, often referred to as “CB” or “BCM”, was used extensively in the past in wheeled units for military flight-line fire protection; however, it was replaced in the early 1970s with Halon 1211 in this application. Due to the relatively high toxicity of this material (8-hour mouse LC<sub>50</sub> = 15850 mg/m<sup>3</sup> (~0.3 vol%), it is used for fire and explosion protection only in normally unoccupied areas. Halon 1011 is used in some older model military cargo aircraft engine nacelles. These aircraft are relatively old and will be eventually phased out. There are no plans to use Halon 1011 in any other aircraft.

Halon 1011 has also been used in explosion suppression systems in industrial processes including; corn starch drying, coal processing, grain elevators, and fiberboard manufacturing. Halon 1011 is reported to be superior to halon 1301 for explosion suppression.

Halon 1011 has been considered for use as a replacement for other uses of ODS, including use as a replacement for halon 1301 and/or halon 1211, but is proposed unacceptable under the US SNAP program for use. Toxicity concerns make this substance unsuitable for widespread application as a fire extinguishant.

### 2.1.3 Other applications

It is estimated that approximately 80 percent of the chlorobromomethane produced were used in the past as feedstock for production of biocides, in particular, thiocyanomethylbenzothiosol (TCMBT). As feedstock, it is not subject to restrictions under the Montreal Protocol, assuming that it is completely consumed during the production of the biocide. The material is also used as a solvent/flotation agent to recover speciality metals such as beryllium.]

## 2.2 Current consumption

### 2.2.1 Solvent use

The current consumption is unknown, but it would seem unlikely that it would exceed 1,000 tonnes per year as a solvent. In a private communication (November 1996) from one manufacturer to a STOC member, a quantity of more than 23,000 tonnes per annum was evoked, but this would seem highly exaggerated. In any case, since that date, the production has certainly decreased.

### 2.2.2 Fire protection use

#### Fire Protection Use of Halon 1011

Installed base of halon 1011 contained in fire and explosion suppression systems	Annual use of halon 1011 for servicing and fire extinguishment
25,000 kg	<1,000 kg

## 2.3 Price

The price for CBM, if produced in large quantities, would be lower than for nPB but higher than the non-OD chlorinated solvents, probably in the range of US\$ 1.40-1.80 for medium-to-large users. The current market price is about US\$ 5 - 8/kg but this varies from country to country.

## **2.4 Targeted solvent markets**

The manufacturers of CBM are targeting all possible markets, including the replacement of non-OD chlorinated solvents. Marketing is aggressive. In view of the potential danger of this solvent, sales have drastically dropped in some developed countries but are still increasing in developing countries. If a manufacturing plant was established in a large developing nation, it may be expected that large quantities may be used for vapour phase and cold cleaning.

## **2.5 Manufacturing and consumption projections**

It is almost impossible to make reliable five-year projections for the manufacture of CBM. The best scenario is that the current production plants close down because the demand drops below the economically viable quantity. This could occur if sales were restricted to developed countries where there is more awareness of the potential dangers to health and safety and to the environment. However, it is known that sales are being increasingly targeted to developing countries. The worst scenario that could occur would be that production was transferred to one or more developing countries where the regulations involving such chemicals may be somewhat more lax. In such a case, each plant would have a range of viable capacity of between 1,000 and 10,000 or more tonnes per annum. It seems likely that total world-wide production in five years time would not exceed 25,000 tonnes per annum, under these circumstances. Probable forecasts would therefore be between 0 and 25,000 tonnes in 2003. In view of the high ODP, the latter figure would represent a significant threat to the ozone layer.

## **2.6 Alternatives to CBM use as a solvent**

For low-cost vapour-phase cleaning, the obvious non-ozone-depleting options are trichloroethylene, methylene chloride and perchloroethylene, on both economical and environmental grounds. These three solvents are cheap and readily obtainable. On the other hand, they are moderately toxic and require special precautions (low-emission machines) to protect the operating personnel. The chronic toxicity of CBM has not been fully established but, from available information, it would seem to be substantially more toxic than non-brominated solvents. In any case, it seems advisable that, at least, similar precautions as are required for the chlorinated solvents should be installed, so that there is little difference required at our current state of knowledge. Similar remarks apply to cold cleaning.

Where the use of non-ozone-depleting chlorinated solvents is precluded, other alternatives include aqueous, HCS and straight hydrocarbon (flammable) cleaning. These may be, in some circumstances, marginally more expensive. Other non-ozone-depleting halogenated solvents for vapour-phase cleaning

include HFCs and HFEs but their cost price is much higher, requiring the use of more expensive zero-emission machinery for them to become competitively acceptable, especially in Article 5(1) countries, and to minimise the emission of strong “greenhouse gases”.

## **2.7 CBM Conclusions**

### **2.7.1 Conclusions – CBM as a solvent (STOC)**

In view of the predicted quantities of CBM, if the market for this substance is developed unhindered and the ODP, which is within the same range as HCFCs regulated under the Montreal Protocol, the STOC recommends that the Parties consider appropriate action to prevent or limit further depletion of the ozone layer due to this substance.

### **2.7.2 Conclusions – CBM as a fire extinguishant (HTOC)**

Fire protection use of halon 1011 (CBM) appears to be insignificant.

### 3. Halon 1202

Halon 1202 is used in the aircraft engine nacelle fire protection system for three military aircraft types in fire protection systems for engine nacelles and auxiliary power units. The 1993 estimated amounts of halon 1202 in aircraft fire protection systems are shown in Table 2.

Halon 1202 also finds very limited use in an automotive wheel balancing apparatus. It is estimated that total use for the wheel balancing application is less than 3 tonnes.

Halon 1202 is also used as a feedstock for Halon 1211 production.

#### Halon 1202 in Aircraft Fire Protection Systems

Number of Aircraft	Total Installed Quantity of halon 1202	Annual Use of halon 1202 for servicing and use on fires
<1500	<110,000 kg	<2,000 kg

#### 3.1 Conclusions (HTOC)

Increases in atmospheric concentrations of halon 1202, recently reported in scientific journals, cannot be explained by use as a fire extinguishant. Parties may wish to examine the possibility that inadvertent production and release of halon 1202 during halon 1211 production in Article 5(1) countries is the source of these atmospheric concentrations.







**UNEP**

**Technology and Economic Assessment Panel**

**Part VI: Progress and Development in the Control of  
Substances**



## 1. Overview of the Sector Update - Aerosols, Etc.

### 1.1 Aerosol products (other than MDIs)

The ATOC estimates that 1998 CFC consumption in the aerosol sector was slightly over 10,000 tonnes in Article 5(1) Parties and some CEIT, excluding MDI use.

Lack of ready availability of good quality hydrocarbon aerosol propellants (HAPs) is the main factor impeding the elimination of CFCs in India and South East Asia Pacific (SEAP), and an important factor in the Russian Federation. The remaining use of CFCs in most countries – especially Latin America and SEAP – is concentrated in the industrial/technical aerosols (principally electronics contact cleaners) and/or in non-MDI pharmaceutical products. It is necessary to address the conversion requirements of these two sub-sectors to achieve total phaseout in aerosols.

CFC use in aerosols is declining, but the pace could be faster if the specific problems of (1) HAPs availability, (2) industrial/technical aerosols, and non-MDI pharmaceutical products, and (3) conversion of small and very small CFC users, were resolved.

### 1.2 Metered dose inhalers (MDIs)

#### *Essential use and accounting framework*

The ATOC reviewed the essentiality of MDIs for asthma and chronic obstructive pulmonary disease (COPD) for 2000 and 2001, and concluded that they remain essential for patient health until an adequate range of technically and economically feasible alternatives are available.

The following Parties nominated essential use production exemptions for MDIs (asthma and COPD). They were reviewed and recommended for exemption.

<b>Country</b>	<b>2000 (tonnes)</b>	<b>2001 (tonnes)</b>
European Union	*	3270
Japan	98.2	88.2
Hungary	1.75	1.75
USA	*	3101

\*Approved in 1998

From the reporting accounting frameworks submitted by Parties to date, it appears that a reduction in CFC usage in non-Article 5(1) Parties is occurring and that 1997 was the likely peak year for CFC consumption under the non-Article 5(1) Parties' essential use process.

### *Developments*

The prevalence of asthma and COPD continues to increase. There are at least 300 million people with asthma world-wide and there may be comparable numbers with COPD. Currently, approximately 400 million MDIs are used annually world-wide, using approximately 10,000 tonnes of CFC.

HFC MDIs have now been introduced into at least 39 countries. It is estimated that during 1998 approximately 25 million HFC MDIs were manufactured and supplied, primarily in Western Europe and the USA. This represents approximately 6% of global MDI use. Acceptance of the new inhalers appears to be excellent with few concerns being raised by patients. This issue will continue to be monitored as the use of these products becomes more widespread.

Dry powder inhalers (DPIs) continue to be introduced by a number of companies in many countries and provide a suitable alternative for many patients. In addition, the CFC phaseout process has partly been responsible for stimulating the development of a number of new technologies for aerosol delivery. The products include novel approaches to dry powder technology as well as new hand-held inhalers that utilise liquid formulations of drugs. These approaches do not utilise propellants.

### *Transition and phaseout issues*

Given the current rate of introduction of alternatives, it is likely that a wide range of reformulated products will be available in developed countries and transition will be making good progress by the year 2000. Minimal need for CFCs for MDIs is envisaged by the year 2005 in non-Article 5(1) Parties. Remaining technical, patent, safety and regulatory issues for some commonly used drugs still make it difficult to predict the schedule for full phaseout of CFC MDIs with precision.

The ATOC does not believe that a common rigid global strategy is appropriate. However the Parties could consider the benefits of a flexible "Global Transition Framework" which would underpin national strategies and ensure that they are complementary.

Under Decision IX/19, non-Article 5(1) Parties with essential use allowances were required to submit details of national transition strategies to the Ozone Secretariat by 31<sup>st</sup> January 1999: not all have done so. ATOC continues to encourage all Parties, including Article 5(1) Parties and CEIT, to develop their

own national and regional strategies and for this to contain specific advice to health professionals. In some countries new product launches of CFC-free MDIs have preceded the launch of a national transition strategy which, if present, might have triggered a reduction in requests for CFCs. Strategies received have described category by category approaches to phaseout, brand by brand combined with an overall target approach, overall targets and timetables, and other combinations of these.

For countries in which HFC MDIs have become available, these products are co-existing side-by-side with CFC MDIs for the same drug. It is evident that the mere availability of CFC-free alternatives may not be sufficient to trigger a material switch to these products. It is likely that the phaseout of CFC MDIs will not occur effectively until it is stimulated for example by regulatory intervention or through a decision by the manufacturing company to withdraw the corresponding CFC product. Parties may therefore wish to consider ways to facilitate the adoption of the CFC-free alternatives as part of their transition strategy.

The ATOC has previously suggested that further CFC MDI approvals could impede the phaseout program. Nonetheless, in 1998, CFC-based MDIs were still being introduced into the market in a number of countries. To facilitate the transition process, Parties could consider how to impede the continued introduction of CFC MDIs as part of their national transition strategy.

Strategic CFC stockpiles of reasonable size are prudent to safeguard public health needs. Maintenance of a strategic stockpile for a period of supply of about 12 months has been proposed as reasonable. Parties may wish to consider monitoring and adjusting stockpiles according to local circumstances.

The per capita use of MDIs is low in Article 5(1) Parties. An increasing prevalence of disease, an improved economic situation and enhanced professional awareness of the benefits of inhaled therapy is leading to an increased use of MDIs. In some countries this demand is met by a combination of local producers and products from international companies. Any shortfall in local production of MDIs may have a significant deleterious effect on public health in Article 5(1) Parties.

Most Article 5(1) Parties have developed Country Programs that delineated the country consumption of ODS and detailed plans for conversion to alternatives of industrial uses of these substances. The transition of CFC MDIs to alternatives was not considered during the preparation of these programs, which were carried out with funding from the Multilateral Fund (MLF). Parties may wish to consider assisting Article 5(1) Parties and CEIT in the development of their own transition strategies through the provision of funds from the Multilateral Fund (or the GEF, as appropriate).

There are only a limited number of locally owned companies in a few Article 5(1) Parties. These will most likely require assistance from the Multilateral Fund for the transfer of new technologies. There is little information available concerning conversion costs. This information would enable a special “cost effectiveness threshold” to be developed for the conversion of CFC MDI manufacture in Article 5(1) Parties to alternatives. The Executive Committee of the Multilateral Fund may wish to begin to consider investment project proposals in this area.

### **1.3 Sterilants**

By the beginning of 1997, CFC-12 use in non-Article 5(1) Parties for 12/88, a sterilant gas based on ethylene oxide (EO), had virtually disappeared, as final inventories were depleted. There remain no technical barriers to the phaseout of CFCs in sterilisation.

Global consumption of CFC-12 in this sector is very difficult to estimate since it is basically located in Article 5(1) Parties; it is estimated to be less than 1,500 tonnes. Estimated use of substitute HCFC replacement is thought to be less than 3,000 tonnes (some 90 ODP tonnes).

Although there are alternatives to 12/88, both in-kind and not-in-kind, HCFCs remain important as transitional products for sterilisation technology in some countries.

### **1.4 Laboratory and analytical uses**

An estimate for global use of controlled substances for laboratory and analytical uses is 1,500 metric tonnes in a wide range of small applications in many laboratories world-wide.

The identification of acceptable alternatives is complex. Questions of performance, cost, safety, availability and acceptability arise and require detailed discussion between stakeholders. The phaseout of ozone depleting substances goes beyond the identification of suitable substitutes since it is necessary that adequate standards are approved by local quality control and regulatory bodies. Furthermore the phaseout must be carefully planned to ensure that laboratories are not left without the necessary means to complete their work. This is especially critical where that work includes statutory analytical tests to protect human health.

The April 1998 Report of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee indicated that for the following applications of controlled substances, readily available and cost effective alternatives have been implemented by many countries:

- Testing of oil, grease and total petroleum hydrocarbons in surface and saline waters, and industrial, and domestic aqueous wastes, including the testing of water which is separated from oil and discharged from offshore drilling and production platforms
- Testing of tar in road paving materials by dissolving tar and separating it from aggregate
- Forensic fingerprinting.

Interaction with standards organisations has been occurring in the USA to limit current and future laboratory and analytical uses; actions to cease the use of controlled substances are progressing. The European Community is to hold a workshop covering all aspects of laboratory and analytical use during 1999. The ATOC will report the outcome of these developments, which may provide the subject of any additional advice to the Parties under Decision X/19.

## **1.5 Carbon tetrachloride**

World-wide production and emissions of CTC were reviewed in detail in the 1998 Report of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee.

The Parties at their 10<sup>th</sup> Meeting (Decision X/12) requested the Technology and Economic Assessment Panel to investigate further and report to the 12<sup>th</sup> Meeting:

- Emissions of CTC from its use as feedstock, including currently available and future possible options individual Parties may consider for the reduction of such emissions;
- Emissions of other ozone depleting substances arising from the use of controlled substances as feedstock;
- The impact of CFC production phaseout on the future use of CTC as feedstock and emissions from such use.

Furthermore, the Parties at their 10<sup>th</sup> Meeting adopted Decision X/14 on process agents which seeks to reduce emissions, primarily of CTC, to specified levels and mandates data collection on both emissions and containment technologies.

According to this Decision, the incremental costs of measures to reduce emissions of controlled substances from process agent uses in Article 5(1) Parties should be eligible for funding, in accordance with the rules and guidelines of the Executive Committee of the Multilateral Fund.





## 2. Sector update – Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride

### 2.1 Aerosol products (other than MDIs)

For aerosol products, other than metered dose inhalers (MDIs), there are no technical barriers to global transition to alternatives. The major issue remaining is the use of CFCs in Article 5(1) Parties and CEIT. Some significant reductions have been achieved in recent years, and further reductions can be expected in the near future. Conversions can be characterised as three types: (1) self-conversions, (2) conversions assisted by the Multilateral Fund (MLF) of the Montreal Protocol, and (3) conversions assisted by the Global Environment Facility (GEF). Self-conversions have occurred when good quality hydrocarbon propellant was available at reasonable cost. Where capital outlay is necessary assistance is generally required from the MLF or GEF. The former assists aerosol fillers in Article 5(1) Parties, while the latter may assist Parties that are not eligible for MLF financing.

The ATOC estimates that 1998 CFC consumption in the aerosol sector was slightly over 10,000 tonnes in Article 5(1) Parties and some CEIT, excluding MDI use. The ATOC estimate of regional break down of quantities for 1998 is as follows:

#### *1998 CFC Consumption in non-MDI Aerosols (metric tonnes)*

ASEAN countries (except Indonesia)	400
China	2,400
Indian Subcontinent Countries*	1,100
Indonesia	500
Latin America	500
Middle East, Africa	500
Russian Federation	3,800
Ukraine	700
Other CEIT and CIS**	100
Total	10,000

\* India, Pakistan, Sri Lanka, Bangladesh, Nepal and Bhutan

\*\* CIS: Successor States of the former Soviet Union

The use of CFCs in China has remained constant. Of the 2,400 tons, 2,000 tons represents non-MDI medical aerosols, and the remainder are industrial/technical aerosols.

A significant reduction in CFC use in aerosols in the Russian Federation was due to the conversion of one large manufacturer to hydrocarbon aerosol propellants (HAPs), funded by the GEF; and also to the actual depressed economy. CFC usage in Ukraine has also diminished, as export of CFC-based products is no longer allowed, and the economy is also depressed.

Economic conditions in South East Asia were responsible for a significant decrease in all aerosol production, including aerosols with CFCs. Additional reductions will occur upon completion of ongoing phaseout projects in several countries such as India, Indonesia, Malaysia, Thailand, and Vietnam.

The remaining use of CFCs in most countries – especially Latin America and South East Asia Pacific (SEAP) – is concentrated in the industrial/technical aerosols (principally electronics contact cleaners) and/or in non-MDI pharmaceutical products. It is necessary to address the conversion requirements of these two sub-sectors to achieve total phaseout in aerosols.

The specific problems of the industrial/technical aerosols and pharmaceutical products require technical assistance in reformulation, and often will result in more expensive products. Contact cleaners can be reformulated by using different new products such as HFC-43-10mee, volatile silicones or hydrofluoro-ethers. These chemicals are about four times more expensive than CFC 113.

In the case of pharmaceutical products, many topical sprays can use HAPs or dimethylether (DME), while HFC-134a is a more costly alternative.

Hydrocarbons are the preferred substitutes for CFCs used in aerosols. Where HAPs supplies were available at reasonable cost, transition out of CFCs has already taken place. Lack of ready availability of good quality hydrocarbon propellants is the main factor impeding the elimination of CFCs in India and SEAP, and an important factor in the Russian Federation.

A HAPs plant may be a simple facility that consists of storage tanks for crude and purified propane and butane and several towers with molecular sieves. Alternatively, it could also be a much more complicated facility that uses the petrochemical process of hydrogenation to saturate undesired olefin molecules. The type of process required depends entirely upon the quality of feedstock available. Transport and safety equipment is also needed.

Construction of suitable HAPs plants under the MLF is contingent on a corresponding volume reduction in CFC production. Unfortunately such a reduction cannot be guaranteed in most cases. Consequently although there are no technical barriers to transition, it is difficult to predict when total phaseout in the aerosol sector will occur.

The financial cost of retrofitting to handle flammable propellants is another factor constraining transition. This becomes especially important considering the proliferation of small and very small fillers that either continue to use CFCs, or that are using commercial LPG (fuel grade mixtures of butane and propane) in an unsafe manner. Haphazard conversions to hydrocarbons makes it obligatory for governments to develop suitable monitoring procedures to ensure safe practices including proper design, management and use of prescribed filling equipment, hydrocarbon storage and handling facilities. When considering the conversion of CFCs to hydrocarbons, the problems facing small aerosol fillers operating in congested areas in Article 5(1) Parties need to be resolved.

A test project is underway in India to evaluate hand-powered production filling equipment. Should this test prove positive, it will facilitate the conversion of very small aerosol industries, by providing an inexpensive and safe alternative that uses HAPs. Final results of this test are expected in late 1999.

Other propellants such as DME, HFC 134a and HFC 152a, and compressed gases are also used in aerosol products. DME and HFC 152a consumption has increased in the USA because of usage to meet volatile organic compounds (VOC) limitations. HFC 134a is the main non-flammable propellant and has found use in industrial products.

CFC use in aerosols is declining, but the pace could be faster if the specific problems of (1) HAPs availability, (2) industrial/technical aerosols, and non-MDI pharmaceutical products, and (3) conversion of small and very small CFC users, were resolved.

## **2.2 Metered dose inhalers**

### **2.2.1 CFC-containing metered dose inhalers**

CFC-containing metered dose inhalers (MDIs) are reliable and effective therapy for respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). MDIs generally use CFC-12 as a propellant and most use CFC-11 and CFC-114 either alone or in a mixture to suspend or dissolve medication. HFC-134a and HFC-227ea have been approved as propellants in MDIs.

The prevalence of asthma and COPD continues to increase. There are at least 300 million people with asthma world-wide and there may be comparable numbers with COPD. Evidence now confirms that asthma prevalence is increasing as urbanisation of developing countries continues. Currently, approximately 400 million MDIs are used annually world-wide, using approximately 10,000 tonnes of CFC.

There is international consensus that primary treatment of these diseases should be by the inhaled route. This permits treatment to be delivered quickly and efficiently to the airways, with minimal risk of adverse reactions. Therapy necessitates regular treatment, often with more than one drug. MDIs remain the dominant inhaled delivery system in most countries and for all categories of drugs.

Overall use of inhaled medication is increasing because of increased disease prevalence. World Health Organisation/US National Heart, Lung and Blood Institute (WHO/NHLBI-GINA) Guidelines in asthma management also encourage the inhaled route as the preferred method of administering medicine. The mainstay of therapy for asthma/COPD is likely to remain therapy administered by the inhaled route.

## 2.2.2 Status of introduction of alternatives

Given the current rate of introduction of alternatives, it is likely that a wide range of reformulated products will be available in many developed countries and transition will be making good progress by the year 2000. Minimal need for CFCs for MDIs is envisaged by the year 2005 in non-Article 5(1) Parties. Remaining technical, patent, safety and regulatory issues for some commonly used drugs still make it difficult to predict the schedule for full phaseout with precision.

### 2.2.2.1 *Availability of HFC MDIs*

As of March 1999, a number of pharmaceutical companies have introduced or plan to introduce HFC MDI products.

The International Pharmaceutical Aerosol Consortium (an association of manufacturers with members from Astra, Boehringer Ingelheim, Chiesi Farmaceutici, Glaxo Wellcome, Medeva Americas, Norton Healthcare, Rhône Poulenc Rorer, and 3M Pharmaceuticals) provided a listing of HFC products currently available among its member companies, for some countries and for some drug substances as of 1 March 1999. The following listing combines IPAC information with some information available to ATOC members. It is indicative only of the number of products available and is not intended to be fully comprehensive.

Country	Salbutamol	Active Ingredient	
		Inhaled	Corticosteroids
		Beclomethasone Dipropionate	Fluticasone Propionate
Argentina	Airomir (3M)		
Australia	Airomir (3M) Ventolin (GW) Asmol (Alpha Pharm)		
Austria	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Barbados	Airomir (3M)		
Belgium	Airomir (3M)		
Canada	Airomir (3M)		
Chile	Airomir (3M)		
Costa Rica	Airomir (3M)		
Denmark	Airomir (3M) Ventolin (GW)	Qvar (3M)	Flixotide (GW)
El Salvador	Airomir (3M)		
Finland	Airomir (3M) Ventolin (GW)		Flixotide (GW)
France	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Germany	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Greece	Airomir (3M) Ventolin (GW)		
Guatemala	Airomir (3M)		
Honduras	Airomir (3M)		
Iceland	Ventolin (GW)		
Ireland	Airomir (3M)	Beclazone (Norton)	
Italy	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Japan	Airomir (3M) Ventolin (GW)		
Luxembourg	Airomir (3M)		
Malaysia	Airomir (3M)		
Malta	Airomir (3M)		
Netherlands	Airomir (3M) Ventolin (GW)		Flixotide (GW)
New Zealand	Airomir (3M)		Flixotide (GW)
Norway	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Panama	Airomir (3M)		
Philippines	Airomir (3M)		
Portugal			Flixotide (GW)
Singapore	Airomir (3M)		
South Africa	Airomir (3M)		
Spain	Ventolin (GW)		Flixotide (GW)
Sweden	Airomir (3M) Ventolin (GW)		
Switzerland	Airomir (3M) Ventolin (GW)		Flixotide (GW)
Thailand	Airomir (3M)		
Turkey	Airomir (3M) Ventolin (GW)		Flixotide (GW)
United Kingdom	Airomir (3M) Ventolin (GW)	Qvar (3M)	
United States	Proventil HFA (3M/Schering)		
Uruguay	Airomir (3M)		

#### **2.2.2.2 Further developments – HFC MDIs**

Boehringer Ingelheim has submitted for marketing authorisation for Berotec (fenoterol) non-CFC MDI in the European Union in late 1998. Registration applications for other products will follow during 1999.

Rhône Poulenc Rorer expects to have received approvals for five different reformulated respiratory products (some of which may be approved in multiple dosage forms). Applications for HFC MDIs have been submitted to 35 countries, with approvals for two products already received in 8 countries and 5 countries respectively.

Several other companies are developing HFC MDI alternatives but the timetable for availability has not been stated.

#### **2.2.2.3 Patient acceptance**

It is estimated that during 1998 approximately 25 million HFC MDIs were manufactured and supplied, primarily in Western Europe and the USA. This represents approximately 6% of global MDI use. To date a number of patient acceptability studies have been carried out with favourable results with few concerns being raised by patients. This issue will continue to be monitored as the use of these products becomes more widespread.

#### **2.2.2.4 Availability of dry powder inhalers**

Dry powder inhalers (DPIs) continue to be introduced by a number of companies in many countries. The overall trend is that the usage of all inhaled therapy is increasing. There is good evidence that the increased rate of DPI usage continues and the increase in use of CFC and HFC MDIs continues at a steady rate. Although DPIs are now available for a number of molecules, in some countries, including a recent introduction in Japan, they are not universally available. The penetration of DPIs into markets will depend on health professional and patient acceptance and cost, which may be decreasing. Several new DPI technologies are under development.

#### **2.2.2.5 Novel aerosol technologies**

The CFC phaseout process has partly been responsible for stimulating the development of a number of new technologies for aerosol delivery in addition to the traditional MDI and DPI inhalers. These products, which are being developed both for asthma and COPD, may serve as alternatives to CFC MDIs. The products include novel approaches to dry powder technology as well as new hand-held inhalers that utilise liquid formulations of drugs. These approaches do not utilise propellants. Many of these products however are still

early in development and may not be available as viable alternatives for CFC MDIs until well into the new millennium.

Several examples of technologies under active development which utilise liquid formulation are as follows:

- A drug solution when forced through a nozzle with two small channels results in two streams of liquid, which generate the aerosol by impaction. For example, one of these delivery systems is a multi-dose inhaler, which releases a soft mist aerosol of medication. Promising results for this type of inhaler have been reported for beta agonists, anti-cholinergics, inhaled corticosteroids and combination bronchodilators.
- “Piezoelectric” materials change their shape in response to an applied electric current. The movement of the piezoelectric material when transmitted to a liquid causes droplets to be thrown off the surface of the liquid. Piezoelectric devices are now used in nebulisers to generate a fine droplet mix by means of a rapidly vibrating crystal.
- Another technology forces liquid through a break-up plate, mesh cap, or open-cell foam, resulting in droplets slightly larger than the size of the holes.
- An ultrasonic horn can be used to generate an aerosol cloud by capillary wave action.

Other possible future initiatives include use of microelectronics in breath-actuated devices to improve dosing accuracy and allow compliance monitoring.

### 2.2.3 CFC consumption and essential use nominations

Essential use nominations for 2000 and 2001 were submitted by several non-Article 5(1) Parties.

From reporting accounting frameworks submitted by Parties to date, the volumes of CFCs nominated and the reported volumes of CFCs used for the period 1996-1998 are shown below. It appears from this data that a reduction in CFC usage in non-Article 5(1) Parties is occurring and that 1997 was the likely peak year for CFC consumption under the non-Article 5(1) Parties' essential use process.

*Table of CFC Usage in Nominating Parties*

Year	1996		1997		1998	
	Exempted	Used	Exempted	Used	Exempted	Used
Australia	259.5	244.9	195	291.1	140	140**
Canada	599	126	648	132.3	513	11
Czech Republic	68.5	41.8	--	--	--	--
European Union	7452	4822	6636	5592	5610	5322
Hungary	10	11.6	10	4.9	10.2	3.2
Israel	7.3	7	--	--	--	--
Japan	240	142.1	240	133.6	181.5	122.4
Poland	700	526.6	380	314.2	380	230**
Russian Federation	--	--**	532	181.92	--	--**
Switzerland	24	0.75	8	0.75	--	--
USA	4235.7	2368	4656	2255	4363	2425.5
<b>Total</b>	<b>13686</b>	<b>8290.7</b>	<b>13305</b>	<b>8905.82</b>	<b>11197.7</b>	<b>8254.1</b>

\*\* Data was either not submitted or estimates were made from information available to the ATOC.

The use of CFCs by Parties that requested essential use nominations for MDIs is in line with a global use estimate of 10,000 tonnes.

#### 2.2.4 Transition issues

A Final Report on Transition Issues is presented in response to Decision VIII/12 and IX/19 of the Parties later in this Sector Update report. The comments below relate to some specific issues associated with transition.

##### ***2.2.4.1 National transition strategies have not been developed by all Parties***

In the 1998 report to the Parties ATOC recommended that TEAP might wish to recommend that non-Article 5(1) Parties be encouraged to produce transition strategies by February 1999. Seven Parties have reported to ATOC that they have national transition strategies and these are reproduced on the TEAP web site at <http://www.teap.org/>.

Under Decision IX/19, non-Article 5(1) Parties with essential use allowances were required to submit details of national transition strategies to the Ozone Secretariat by 31<sup>st</sup> January 1999: not all have done so.

ATOC continues to encourage all Parties, including Article 5(1) Parties and CEIT, to develop their own national and regional strategies and for this to contain specific advice to health professionals.



In some countries new product launches of CFC free MDIs have preceded the launch of a national transition strategy which, if present, might have triggered a reduction in requests for CFCs.

Strategies received have described category by category approaches to phaseout, brand by brand combined with an overall target approach, overall targets and timetables and other combinations of these.

#### **2.2.4.2 *Continued CFC product approvals***

In countries in which HFC MDIs have become available, these products are coexisting side-by-side with CFC MDIs for the same drug. The uptake of CFC-free inhalers has been slow in many countries. It is evident that the mere availability of CFC-free alternatives may not be sufficient to trigger a material switch to these products. It is likely that the phaseout of CFC MDIs will not occur effectively until it is stimulated for example by regulatory intervention or through a decision by the manufacturing company to withdraw the corresponding CFC product. Parties may therefore wish to consider ways to facilitate the adoption of the CFC-free alternatives as part of their transition strategy.

The ATOC has previously suggested that further CFC MDI approvals could impede the phaseout program. Nonetheless, in 1998, CFC-based MDIs were still being introduced into the market in a number of countries. These introductions include markets where HFC MDIs are already available. To facilitate the transition process, some Parties have already begun to adopt one of the following options as part of a national strategy to impede the continued introduction of CFC MDIs:

- disallow further regulatory approval of CFC MDIs where the law permits (e.g. Hungary)
- withdraw health service reimbursement for CFC MDIs where suitable HFC alternatives exist (e.g. Australia)
- actively discourage manufacturers from submitting essential-use applications for CFC quotas for use in new products or for products for which non-CFC alternatives are already available (e.g. European Union)

Other Parties may wish to consider adopting one of these options.

#### **2.2.4.3 *Stockpiles***

Strategic CFC stockpiles of reasonable size are prudent to safeguard public health needs. Stockpile size will vary according to country and company specific situations. However, excessive stockpiles could be utilised to prolong

CFC MDI manufacture against the spirit of the Montreal Protocol, and act as an impediment to the transition to CFC-free alternatives.

Strategic CFC stockpiles can safeguard manufacturing supplies against unforeseen production contingencies and other uncertainties. Pharmaceutical manufacturers advocate the maintenance of reserves of CFCs to protect against supply disruptions. Maintenance of a strategic stockpile for a period of supply of about 12 months has been proposed as reasonable. Parties may wish to consider monitoring and adjusting stockpiles according to local circumstances.

#### **2.2.4.4 *Article 5(1) Parties considerations***

The per capita use of MDIs is low in Article 5(1) Parties. In many this reflects availability, cost, and health professional practice rather than a reduced need. Recent international studies (Worldwide Variations in the Prevalence of Asthma Symptoms: the International Study of Asthma and Allergies in Childhood [ISAAC]; Eur Respir J 1998; 12:315-335) have suggested that asthma is a very significant health problem in many of the large population countries such as India and Pakistan, with slightly lower rates in China. In all of these countries the rapidly increasing burden of smoking due to heavy promotion of tobacco products has also led to an increasing prevalence of suffering due to COPD.

An increasing prevalence of disease, an improved economic situation and enhanced professional awareness of the benefits of inhaled therapy is leading to an increased use of MDIs. In some countries this demand is met by a combination of local producers and products from international companies. Any shortfall in local production of MDIs may have a significant deleterious effect on public health in Article 5(1) Parties.

#### **2.2.4.5 *MDI transition strategies for Article 5(1) Parties***

Most Article 5(1) Parties have developed Country Programs that delineated the country consumption of ODS and detailed plans for conversion to alternatives of industrial uses of these substances. The transition of CFC MDIs to alternatives was not considered during the preparation of these programs, which were carried out with funding from the Multilateral Fund (MLF).

To assure supply of MDI medication, Parties may wish to consider assisting Article 5(1) Parties and CEIT in the development of their own transition strategies through the provision of funds from the Multilateral Fund (or the GEF, as appropriate). Such transition strategies would help to understand patient needs in these countries, and to accelerate the introduction of CFC free inhalers. They should include educational programs for health care

professionals, gradual substitution of available MDI medication, and awareness that such transition could increase health care costs.

The cost implications to individual patients of the transition in any one Party will be dependent upon the proportion of their previous use comprised of locally produced branded and generic MDIs compared with branded products (either domestic or imported). Transition strategies for Article 5(1) Parties could lead to an assessment of the funding requirements for the Multilateral Fund to facilitate the transition.

#### **2.2.4.6 *Technology transfer***

The Parties to the Montreal Protocol recognise the importance of technology transfer as a means to facilitate the phaseout of CFCs in Article 5(1) Parties and have established the Multilateral Fund to assist the conversion to alternatives.

The broad issues of technology co-operation for pharmaceutical products are currently under review by the World Trade Organisation (WTO), the World Intellectual Property Organisation (WIPO), the World Health Organisation (WHO), the International Federation of Pharmaceutical Manufacturers Associations (IFPM), and other expert bodies.

Technology transfer is a complex issue. To ensure continued availability of MDIs after CFC phaseout will involve consideration of the following possibilities:

- Licensing arrangements to permit local manufacturers to acquire the technological expertise to set up or adapt production facilities to produce HFC inhalers
- The availability of finance for the licensing arrangement
- The availability of finance for the new manufacturing facilities
- The likelihood of a need for rationalisation of the number of manufacturing facilities available
- The possibility of joint manufacturing facilities between local and multinational companies.

MDIs are manufactured by a number of companies based in different Article 5(1) Parties. These are either multinational companies that have affiliates or independent locally owned companies. There are only a limited number of locally owned companies in a few Article 5(1) Parties, e.g. Argentina, India,

China and Turkey. These will most likely require assistance from the Multilateral Fund for the transfer of new technologies.

There is little information available concerning conversion costs. This information would enable a special “cost effectiveness threshold” to be developed for the conversion of CFC MDI manufacture in Article 5(1) Parties to alternatives. The Executive Committee of the Multilateral Fund may wish to begin to consider investment project proposals in this area.

#### **2.2.4.7 *Co-ordination with International Bodies***

In 1998, the World Health Organisation and the International Federation of Pharmaceutical Manufacturers Associations agreed:

“...flexibility is required on technology transfer since it offers opportunities; but it is complex, needing to be separated from public health goals, and is broader than just the transfer of manufacturing; a good domestic environment (e.g. Intellectual Property Rights, reduced regulatory red-tape), commitment and grassroots efforts are required for success.”

There are several factors that are unique to the MDI transition that may require special attention:

- the fact that the use of CFC MDIs has global environmental and human health impacts
- the complication that HFCs currently necessary to replace CFCs in MDIs are included in the basket of greenhouse gases to be controlled under the Kyoto Protocol
- the availability of MLF financing of the incremental costs of eliminating CFCs
- decisions may need to be taken under the Montreal Protocol before technology co-operation is resolved for pharmaceutical products in general.

Therefore, Parties may wish to consider the advantage of instructing the Ozone Secretariat to inform relevant international bodies such as the World Trade Organisation (WTO), the World Intellectual Property Organisation (WIPO), the World Health Organisation (WHO), the International Federation of Pharmaceutical Manufacturers Associations (IFPM), about MDI transition under the Montreal Protocol and to seek early action to facilitate technology co-operation, if needed.

#### **2.2.4.8 *The need for specific advice for health professionals to be contained in strategies***

Appropriately, in many countries the national transition strategy has been environmentally led. The TOC suggests that Parties may wish to additionally consider developing health transition guidance that spells out specific practical advice for physicians and other health care workers.

The advantages of following a co-ordinated approach are:

- to avoid confusion
- permit use of the media to prepare patients for transition
- to permit development of materials containing the key messages about transition
- to prevent patients alternating between new and old products
- to avoid interface problems between primary and secondary care
- to allow adjustment of budgets to accommodate any increased costs in a planned manner, and
- to reduce the period of time over which community pharmacists have to hold dual stocks.

The development of such specific health transition advice should be undertaken at a national, district or institutional level and can clearly only be undertaken when adequate alternatives are available. Advice needs to be drawn up by a multi-disciplinary team of doctors, nurses, pharmacists, health providers, and professional and patient support organisations.

Once such a strategy is available active dissemination of its contents amongst health professionals is necessary. Experience in many countries suggests that educational activities regarding Montreal Protocol issues have been poorly attended and it is possible that this reflects activities having been undertaken before specific prescribing information could be offered. Once new products have been launched it is likely that educational activities will be perceived as being more relevant and necessary.

#### **2.2.4.9 *Worldwide perspective***

In March 1999, members of the ATOC carried out a survey of inhaler availability and prices within their own countries and regions. Results are presented below. All prices are given in US\$. These prices do not necessarily compare identical doses and pack sizes, and are not definitive.

### *Australia and New Zealand*

Australian and New Zealand health systems, independently, provide universal health cover and reimbursement of approved pharmaceuticals. A variety of DPIs containing beta-agonists and inhaled corticosteroids have been available under each countries' health scheme, for some years.

Salbutamol HFC MDIs are now marketed in both countries and HFC corticosteroids in New Zealand.

In New Zealand, government reimbursement is for the least expensive product in a therapeutic group. Salbutamol CFC MDIs are reimbursed by the health care scheme. One HFC product (Airomir, 3M) is partly reimbursed and requires a patient co-payment. At present, there is little economic incentive for the phaseout of CFC products.

In Australia, phaseout of CFC salbutamol is proceeding satisfactorily as a result of internal company decisions to cease production of CFC product and government agreement to reimburse the higher cost salbutamol HFC MDI. From May 1999, salbutamol CFC MDIs will no longer be reimbursed under the health scheme; only salbutamol HFC MDIs will be reimbursed. Prescriptions for salbutamol MDI will be routinely dispensed as HFC MDIs (unless the patient wishes to pay privately for a non-reimbursed CFC product). It is expected that this will reduce CFCs used in the bronchodilator segment of the market by some 60%.

### *Brazil*

It is estimated that 10% of the population (approximately 16 million people) suffers from asthma. The sales of asthma medications have nearly doubled for the period of 1994 to 1997.

Five million inhalers are sold in Brazil annually and CFC MDIs represent 98% of inhaler sales. Currently there are no HFC MDIs available in Brazil and less than 1% of products are DPIs.

Physicians are not addressing CFC phaseout, and there are no initiatives for discussing transition strategies. The retail price of inhalers varies widely as follows: salbutamol CFC MDI US\$9-30, DPI e.g. turbohaler US\$25; inhaled steroids CFC MDI US\$14-42, DPI e.g. turbohaler US\$25.

### *Canada*

In Canada, only one HFC MDI for salbutamol is available, together with a range of DPIs. For salbutamol the HFC MDI is less expensive than some CFC MDIs. In response to the evolving transition, Canada (mainly an MDI

importing country) has developed a transition strategy based on a target for CFC phaseout.

### *China*

There is currently a small use of CFC MDIs for asthma and COPD in China. Only a small proportion of patients with asthma and COPD in China are currently treated with CFC MDI; this could increase enormously. The market structure in China is different from elsewhere in the world. MDIs are manufactured as solution aerosols and suspension MDIs in over 60 individual hospital and small manufacturing plants. Some medical aerosol manufacturers have obsolete production facilities and high consumption of CFCs, but are locally owned providing affordable products and valuable employment.

Over 60 different CFC medical aerosol products are available, some of which are used for asthma and COPD, but also for topical applications and for Chinese traditional medicines. The multinationals also produce suspension MDIs in China for asthma and COPD (e.g. Chongqing Glaxo Wellcome, Astra, Baker-Norton). The locally produced solution inhalers are considerably cheaper, approximately US\$0.63 versus e.g. Ventolin Glaxo Wellcome US\$4.25. Locally made single-dose DPI formulations of cromoglycate, salbutamol and beclomethasone are available but not widely accepted.

No HFC MDIs for asthma and COPD are available in China as yet. Two technology workshops with over 100 attendees have been held. These workshops highlighted affordability and technology transfer as major impediments to CFC MDI substitution, and requested support in the promotion of a transition to CFC-free technology. A particular area of concern is with popular aerosolised Chinese traditional medicines, for which there will be no experience of CFC substitution outside China.

### *Europe*

The European Union has published its transition strategy, with a category-by-category and drug-by-drug based approach.

In many European countries, three or more HFC MDIs are now available in addition to a wide range of DPIs. In particular, two salbutamol HFC MDIs are already available in many countries. Providing post marketing surveillance is satisfactory, under the EU strategy bulk CFC for the manufacture of salbutamol CFC MDIs will be withdrawn in the near future.

The UK has developed a national strategy operating within the EU framework. With the imminent withdrawal of CFC for salbutamol MDIs, local health authorities are planning a co-ordinated transition for this drug in many areas.

For salbutamol in the UK, approximate recommended prices are (British National Formulary): Ventolin CFC (GlaxoWellcome) US\$3.70; Generic CFC Salbutamol US\$2.86; Airomir CFC-free \$3.10; Ventolin CFC-free US\$3.70. Prices vary according to negotiation with Health Authorities.

### ***India***

HFC MDIs are not available at present, nor any indications of likely price.

For salbutamol there are three brands available in India, manufactured by CIPLA (a large Indian pharmaceutical company), Glaxo Wellcome and NATCO PHARMA (an Indian pharmaceutical company based in Hyderabad). The retail selling price of the inhalers are all comparable at around US\$1.65.

For inhaled steroids, CIPLA market an inhaler containing both salbutamol and beclomethasone dipropionate at US\$2.83. CIPLA also market inhalers containing beclomethasone with dosages of 50mg, 100mg and 200mg at US\$3.46, US\$4.33 and US\$5.29 respectively. Astra market their CFC inhaler (Pulmicort) at US\$3.59.

It is likely that Indian manufacturers will require technological support and financial assistance for transition.

### ***Indonesia***

HFC MDIs are not available. The cost of salbutamol CFC MDIs is approximately US\$5. Prices in local currency have doubled in the last year due to currency fluctuations.

### ***Japan***

Two HFC MDIs for salbutamol are available. Japan has developed a transition strategy based on a brand by brand approach combined with a target date for complete transition of 2005.

In Japan, the prices of salbutamol HFC MDIs are about US\$10, which are the same as CFC MDIs.

### ***Kenya***

One brand of HFC MDIs for salbutamol is available and widely accepted by both health professionals and patients. The cost of HFC MDIs is approximately US\$5.30.



### *Pakistan*

HFC MDIs are not available in Pakistan as yet. Approximately 1.7 million inhalers are used annually, salbutamol CFC MDIs cost approx. US\$1.50.

### *Poland*

6.4 million inhalers were sold in Poland in 1998, as follows: MDIs – 95%; DPIs – 5%. At least 10 different DPIs are available, but no HFC MDIs are available as yet. Approximately 70% of inhaled drugs are bronchodilators and 30% are anti-inflammatory.

DPIs are generally more expensive. Retail prices vary in the following range:

Beta-2 agonists: MDIs US\$1.60-36.00; DPIs US\$18-32

Inhaled steroids: MDIs US\$1.60-54.00; DPIs US\$9-51

### *Russia*

HFC MDIs are not available in Russia as yet. Salbutamol CFC MDIs are produced locally and imported. The cost is US\$1.70 - US\$ 3.00 per unit.

### *USA*

The United States is still relatively early in its transition process, with only one HFC salbutamol MDI on the market. This now accounts for approximately 8% of salbutamol use in the USA. Various DPI products have become recently available, but represent a relatively minor part of the asthma therapy market so far. The pace of filings for registration and the pace of introduction of HFC MDIs and other alternatives to CFC inhalers is expected to increase over the next year or two.

The US transition strategy continues to be developed. In the initial draft, drug-by-drug, category-by-category, and hybrid approaches were proposed for determinations of non-essentiality. As more HFC MDIs come to the market in the coming years, the need for continued, effective education for the public, patients and practitioners, will increase in importance.

A comparison is made between pricing information for salbutamol MDIs in the USA. Salbutamol CFC (generic) average approx. US\$20; Ventolin CFC (GlaxoWellcome) approx. US\$30; Proventil CFC (Schering Plough) US\$32; Proventil HFA (HFC MDI from Schering Plough) US\$33.

2.2.5 Response to Decisions VIII/12 and IX/19: Final report on issues surrounding a transition to non-CFC containing treatments for asthma and COPD and national transition strategies

**2.2.5.1 *ATOC consultation process***

The ATOC is continuing to consult widely with representatives of the asthma/COPD community and has contact with the following organisations:

- Global Initiative on Asthma (NHLBI/WHO Initiative)
- American Thoracic Society/American Lung Association
- European Respiratory Society
- American Academy of Allergy, Asthma and Immunology
- National Asthma Education and Prevention Programme (USA)
- National Asthma Campaign (UK)
- National Asthma Campaign (Australia)
- Many health and environment regulatory authorities and patient support groups
- IPAC, MDI manufacturers and bulk CFC manufacturers

**2.2.5.2 *How a global framework and national strategies might be complementary***

The ATOC was asked to consider, “in the context of a transition phase, how decisions taken within the Montreal Protocol framework and national strategies might complement each other” (Decision VIII/12(5)(a)).

The ATOC recognises that no single strategy will be applicable to all countries. There are pronounced differences among the Parties in national health care practices, regulatory requirements and reimbursement policies. The process of transition to non-CFC alternatives is complex involving the need for dialogue between health authorities, environmental agencies and other interested groups. To address these concerns, the ATOC believes that all Parties should develop their own national transition strategies to facilitate smooth transition, *irrespective of status or whether they import or export CFC MDIs*.

For the reasons outlined above, the ATOC does not believe that a rigid global strategy is appropriate. However the Parties could consider the benefits of a “Global Transition Framework” which would underpin national strategies and

ensure that they are complementary. The Essential Use Process under the Montreal Protocol provides the opportunity for the review of progress and seeks to balance the twin aims of rapid CFC phaseout at the same time as protecting patients.

### 2.2.5.3 *Global transition framework*

A global transition framework would ensure coherence and support discrete national transition strategies. Any global framework should contain certain principles, but also sufficient flexibility for each Party to develop a national transition strategy that protects patient needs while conforming to that Party's unique legal and regulatory system. These principles include:

- specifying a target date for completing the transition. There must be sufficient time and resources available for education of health professionals and patients. Having a Protocol goal of an ongoing transition which will be completed by 2005 in non-Article 5(1) Parties will help in this regard by giving physicians and other health professionals a sense of the overall timing in which the transition should be completed. In the interim, Parties may wish to consider reducing the need for CFCs for MDIs as rapidly as is reasonably possible.
- addressing transition issues that transcend national boundaries, such as the flow of CFC MDIs from exporting countries to importing countries. Importing countries need to be assured of access to CFC MDIs and CFC-free products as the transition progresses. All countries should consider implementing measures to stop the inward flow of CFC MDIs once transition has been completed in that country.
- approval of new CFC MDIs is continuing to occur and will discourage some manufacturer's reformulation efforts. In keeping with the 1997 and 1998 recommendations, Parties may like to discourage approvals of new CFC-containing products in non-Article 5(1) Parties now, and to consider setting a time scale for the same objective in Article 5(1) Parties.
- clarifying what constitutes a reasonable strategic CFC reserve. Good manufacturing practice requires maintaining such reserves to guard against the risk of supply disruption. However, care must be taken to ensure that such reserves do not undermine the progress of the transition. Parties could consider limiting strategic reserves (stockpiles). The TEAP and its ATOC have suggested that 12 months of current use might constitute a reasonable strategic reserve. Some Parties have indicated that strategic reserves may need to vary according to local circumstances.
- making continued availability of essential use allowances conditional on satisfactory progress in transition. In particular, in accordance with

Decision VIII/10, the Parties should verify whether a manufacturer is actively pursuing research and development efforts on non-CFC alternatives or actively entering into licensing agreements.

- supporting a rapid introduction of CFC-free inhalers and technologies into Article 5(1) Parties and CEIT.

#### **2.2.5.4 *The development of a national strategy***

A number of factors need to be evaluated in detail and individual Parties may wish to consider the following issues and principles when developing national strategies for CFC phaseout:

- Phasing out CFCs as rapidly as possible while maintaining patient safety.
- Availability of sufficient technically and economically feasible alternatives to assure an uninterrupted supply of medications in that country.
- One or more separate formulations of each therapeutic substance may need to be available.
- Sufficient post marketing assessment of the reformulated products.
- Sufficient choice to assure that patient sub groups, especially children, are served by alternatives (i.e., full range of doses).
- Adequate availability of supply of alternative non-CFC products.
- Stopping approvals of new CFC MDIs.
- Availability of sufficient time and resources for health professional and patient education.
- The regulatory framework for drug approval.
- The legal and economic framework in that country.
- The level of company commitment regarding reformulation efforts (consistent with Decision VIII/10). Company statements should be verified by Parties.
- How national strategies may impact on the transition occurring in other Parties.
- How to control imports of CFC MDIs once transition has occurred.

The ATOC notes that the Australia, Canada, EU, Hungary, Japan, New Zealand and the USA have submitted draft or final transition strategies. In line with Decision IX/19, non-Article 5(1) Parties with essential use allowances are required to submit details of national transition strategies to the Ozone Secretariat by 31st January 1999. Other non-Article 5(1) and Article 5(1) Parties are encouraged to develop and submit national transition strategies.

Parties might additionally consider developing health transition guidance that spells out specific practical advice for physicians and other health care workers.

The advantages of following a co-ordinated approach are:

- to avoid confusion,
- permit use of the media to prepare patients for transition,
- to permit development of materials containing the key messages about transition
- to prevent patients alternating between new and old products,
- to avoid interface problems between primary and secondary care
- to allow adjustment of budgets to accommodate any increased costs in a planned manner, and
- to reduce the period of time over which community pharmacists have to hold dual stocks.

The development of such specific health transition advice should be undertaken at a national, district or institutional level and can clearly only be undertaken when adequate alternatives are available. Advice needs to be drawn up by a multi-disciplinary team of doctors, nurses, pharmacists, health providers, and professional and patient support organisations.

Once such a strategy is available active dissemination of its contents amongst health professionals is necessary. Experience in many countries suggests that educational activities regarding Montreal Protocol issues have been poorly attended and it is possible that this reflects activities having been undertaken before specific prescribing information could be offered. Once new products have been launched it is likely that educational activities will be perceived as being more relevant and necessary.

#### **2.2.5.5 *Implications of different policy options for the transition***

The ATOC has considered a variety of approaches that an individual Party might take to facilitate the transition from CFC MDIs. The ATOC has tried to reflect some of the considerations that individual Parties might make in developing its own transition strategy in the light of its own circumstances.

It is difficult to defend a strategy under which CFCs are to remain available until every single CFC product has been individually reformulated. This would risk prolonging the phaseout indefinitely, as certain products currently using CFCs may never be reformulated and others may take many years before successful reformulations are launched. This would not be compatible with obligations under the Montreal Protocol. Under the Protocol, essential uses allowances for CFCs will stop once there is available a technically and economically feasible alternative which is acceptable from the standpoint of environment and health. This does not imply that the alternative must be identical either in brand or drug to the CFC product it replaces. For example, some patients currently using one brand of beta-agonist might find they could easily switch to an alternative manufactured by another company. Others for example, currently using an inhaled steroid might find they could change to another drug with similar properties whether or not manufactured by the same company. Many patients currently using a CFC MDI might be able to change to a dry powder inhaler.

Some products may not be reformulated for economic reasons and others may ultimately prove impossible to reformulate for technical reasons. Where possible, physicians and patients will have to switch to an alternative treatment within a reasonable timeframe.

There are substantial differences in the regulatory and pricing approval process for reformulated products in different countries. Some countries regulations allow approval of new products as variations on existing licences, whilst other countries require new product applications. This together with other considerations means that approvals in some countries may be 1-2 years behind others.

#### ***Options for national transition strategies***

The four approaches listed below are not mutually exclusive and it should be stressed that transition is likely to involve a combination of approaches.

Brand by brand substitution may occur to a variable degree according to individual company decisions, but may not by itself lead to phaseout of CFC MDIs, for example those produced by a company that has no plans for reformulation.

Transition will therefore be driven by balancing the twin aims of a rapid reduction in CFC use versus full protection of patient safety (by assuring an uninterrupted supply of needed inhaled medications). One approach to this would be by a combination of a drug by drug and a category by category approach.

In addition, the mechanism by which CFC products that are deemed no longer essential are phased out will likely differ among Parties. For instance, in the US draft transition policy, once a product is determined to be no longer essential (due to the availability of acceptable alternatives), further sales of that product will not be allowed. This approach of restricting sale of non-essential products allows for precise control (including control of imports). However it could result in residual stockpiles of CFCs if manufacturers do not plan properly.

In contrast, the proposed control over products which are no longer essential in the EU is via the withdrawal of licensing for bulk CFC production for use in that product. Considering CFC stockpiles and product on the shelf, the phaseout of CFC MDIs might therefore take up to 2 years after the licence has been withdrawn. This approach is less precise in its control, but allows for use of any stockpiled CFCs during the phaseout.

***By individual product brand (brand by brand)***

When a company produces a new reformulated product which replaces its existing product, it would be required to introduce the new product and phase out the old over a time scale consistent with production process, distribution and a reasonable post marketing surveillance period if necessary.

The advantages of this approach might include:

- maintenance of physician/patient choice through brand continuity
- minimal market disruption.

The disadvantages of this approach might include:

- does not address the issue of products which are not reformulated
- does not consider non-MDIs as alternatives
- no incentive for changeover unless linked with some form of volume reduction
- takes no account of new CFC-free brands.

The ATOC does not generally commend this approach *by itself* for a national strategy since it does not encourage complete phaseout of CFC MDIs. Some Parties are considering a brand by brand approach in combination with a target date for complete phaseout.

### ***By Individual Drug (Drug by Drug)***

Under a drug by drug approach, after a CFC-free MDI containing a given drug is launched, and a period of post-marketing surveillance undertaken, then a mechanism is triggered to phase out all CFC MDIs containing that drug within a specified period.

The advantages of this approach might include:

- maintenance of physician/patient choice through drug continuity
- provides fast removal of CFC MDIs provided the withdrawal period is reasonably short
- rewards the innovating company.

The disadvantages of this approach might include:

- the patient population may be better served by waiting until at least two CFC-free MDIs are available to cover the unlikely event of product failure
- physicians and patients have potentially no choice of brands and major brand switching will be necessary with consequent market disruption and the potential creation of monopolies.

The ATOC believes that this approach could provide the cornerstone of a transition policy with three important provisos:

- Some large volume drug substances (e.g. salbutamol) may require more than one replacement product for transition to occur safely.
- This approach needs to be combined with volume reduction and category by category approach (see below) to ensure effective completion of phaseout.
- Attention needs to be paid to product characteristics so that all patient needs are satisfied e.g. an adequate range of doses and devices.

### ***Category by Category Transition***

There are several types of drugs used in the treatment of asthma and COPD. These types of drugs can be grouped into categories as shown below. The



number of drugs in each category will vary from country to country depending on domestic availability of products. Drug categories are as follows:

- A. Short acting beta agonist bronchodilators  
e.g. salbutamol (albuterol in USA) terbutaline, fenoterol
- B. Inhaled Steroids  
e.g. beclomethasone, budesonide, flunisolide, fluticasone, triamcinolone
- C. Non-steroidal anti-inflammatories  
e.g. cromoglycate, nedocromil
- D. Anticholinergic bronchodilators  
e.g. ipratropium bromide
- E. Long acting beta agonists bronchodilators  
e.g. salmeterol, formoterol
- F. Combinations

It is important to realise that, on a global basis, categories A and B combined account for approximately 75% of CFC MDIs.

For each of the above categories A-F, when “sufficient” CFC alternatives become available in that drug category, the remaining CFC-containing products in that category can be phased out within a specified time (“sufficient” to be defined and determined by each Party).

The advantages and disadvantages of this approach will depend on the numbers of alternatives determined for safe transition for that category in each country.

The advantages of this approach might include:

- tailoring the policy to individual national needs
- with limited alternatives in a category, fast transition is possible
- with many alternatives in a category patient safety would be maintained.

The disadvantages might include:

- CFC-free alternatives may not be available for all drugs in a category before they are phased out
- with limited alternatives in a category patient safety might be compromised

- with too many alternatives in a category transition would be slow.

Drugs of the same category can have different therapeutic indications, adverse effects and drug-drug interactions. The ATOC recognises the safety of ensuring an adequate range of treatments with this approach, provided an adequate range of reformulated drugs is available in each category. This approach enables management and completion of phaseout and some Parties are implementing this approach.

### ***Volume reduction***

Another strategy might involve setting targets for CFC reduction to zero over a fixed time. If patients are to continue to have access to appropriate medicine they require, including where necessary a choice of suitable therapies, it will be important to ensure that CFCs are not withdrawn prematurely before adequate alternatives are available. A simple volume reduction approach will not meet these criteria. A general cut in CFCs, for example 50% in 2000, would be arbitrary, and could not necessarily protect the patients using CFC products for which no alternative had yet been developed. It may be difficult for Parties adopting this approach to predict when alternatives might be launched. Greater safe guards for health and safety are provided if the phaseout of CFCs is triggered by the de facto availability of acceptable alternatives (i.e. category or drug based transition strategy), rather than based on a future prediction of when these alternatives might be launched.

The ATOC believes that a strategy based on volume reduction *alone* is unacceptable, but it could work in conjunction with a brand by brand, drug by drug or a category by category approach. A volume reduction goal for full phaseout of CFC manufacture for use in MDIs in non-Article 5(1) Parties by 2005 remains desirable.

#### ***2.2.5.6 Implications of transferable essential use exemptions and trade restrictions on the transition and access to treatment options***

The ATOC acknowledges that transfer of essential use exemptions between Parties in line with Decision IX/20 will facilitate the CFC transition and patient access to treatment options. As transition proceeds MDI manufacturers may choose to rationalise production for economic, technical and logistical reasons. Flexibility in the transfer of rights between Parties will facilitate the transition with no net environmental impact.

#### ***2.2.5.7 International markets and fluidity of trade in CFC MDIs and their alternatives***

In February 1998, the International Pharmaceutical Aerosol Consortium (IPAC) conducted a confidential survey of its member companies on the

manufacture and export of CFC MDIs in 1997. The results of this were presented in the April 1998 TEAP Report.

Once transition has taken place in a Party, there is potential for imports of CFC-containing products from another Party. Under the Montreal Protocol, there is no restriction on movement of finished goods, i.e. manufactured MDIs. Any import ban to control imports of CFC MDIs to a Party once a transition is completed would need to comply with international treaties on trade. To do so it would need to be non-discriminatory and compatible with domestic policy. In a number of countries this could be controlled through existing regulations on the import of therapeutic goods and product licence approvals but in other countries there is no precedent for the withdrawal of drugs on any grounds other than safety.

In the absence of trade controls, it is probable that continued importation of CFC MDIs could prevent complete phaseout in a country nearing completion of their own transition process. This aspect should be considered in national transition strategies.

In 1998 the ATOC requested that the TEAP clarify the application of Decision IV/25, i.e. can Parties which have completed domestic transition continue to export to Parties which have not. In 1998, the TEAP responded as follows. The Essential Use Process allocated ODS production or import for uses satisfying the terms of Decision IV/25. CFC MDIs are manufactured in only a few countries but are marketed and used worldwide. Therefore, Parties could qualify for essential use allocations for export to other Parties still dependent on CFC MDIs for their health requirements where the importing Party has not completed its transition. However, if importing countries have completed their transition, the exporting Party could not qualify for essential use allocations to serve that market.

#### **2.2.5.8 *Incentives and impediments to research and development and market penetration of alternatives***

##### ***Research and development***

The world market for inhaled products is several billion US dollars and is continuing to grow. This provides a clear incentive to develop replacements. The reformulation of CFC MDIs to replace the propellants began in 1988 and has proved to be much more technically difficult than was originally envisaged. Over 90 laboratories in at least 10 countries are involved in reformulation efforts with a total estimated cost to date of over US \$1 billion.

There are differences between the CFC and HFC MDIs which have resulted in the need for extensive clinical investigations and revision of long-standing manufacturing methods. This has necessitated significant capital investment in

new manufacturing facilities. In addition the regulatory requirements for approval of HFC products in some countries are significantly greater than for the approval of CFC MDIs.

There are currently in excess of 100 patents or patent applications in the area of CFC-free MDI technologies. However, new technology is being made available for licensing to other companies.

### ***Market penetration***

Multinational companies have developed CFC-free alternatives (including HFC MDIs and DPIs) which they are marketing themselves or by licensing agreements to exploit their commercial advantage. Now that adequate experience is being gained many large volume branded products are changing over as manufacturing capacity increases in a “brand by brand” transition.

Factors slowing uptake of HFC product include lack of national strategies to encourage smooth transition, lack of incremental benefit to patients, apathy of physicians to environmental benefits, and higher cost than generic products. It is important to note that the lack of motivation to physician prescribing and economic considerations makes it unlikely that marketing and education programs alone will produce a significant switch away from CFC products in the absence of clearly defined and implemented national transition policies; containing specific prescribing advice to health professionals.

Several years after the introduction of the first salbutamol HFC MDI by 3M, this product has only reached a relatively low market share in Europe. Early experience in Europe with Glaxo Wellcome’s HFC salbutamol product has demonstrated that a substantial market share can be maintained through a company-driven brand by brand switch to HFC MDIs. Glaxo Wellcome’s global policy has been to undertake this approach.

In a few countries, there are now several HFC MDIs available. Awareness of the CFC transition issue may be high (e.g. in a survey conducted in the UK during 1997 by the National Asthma Campaign, 92% of primary care physicians were aware that CFCs were likely to be removed from MDIs by the year 2000) but initial uptake of the HFC MDI products was low. Awareness alone, without an adequate range of products and without locally derived health professional guidance, will not achieve successful phaseout.

### ***Potential impediments***

There are several potential impediments to the rapid transition to HFC MDIs. These include:

- lack of national transition strategies;

- continued regulatory approval of CFC MDIs;
- the lack of timely regulatory review of HFC MDIs;
- slow acceptance by local drug formularies;
- no perceived therapeutic advantage to patients;
- excessive CFC stockpiles resulting in continued manufacture of CFC MDIs;
- lack of specific health professional guidance;
- continued CFC MDI imports once alternatives are available.

These factors all need to be addressed in the development of national transition approaches.

### *The role of education in transition*

There should be co-operation between the professionals involved on a local or regional basis to discuss how the transition is to be implemented. Contacts with patient representatives should be established at an early stage to ensure that patients receive adequate information, both verbally and in writing. This is essential to build the confidence of patients in the new products. Further, the changeover of patients in one area should be done at roughly the same time to reduce the problems of primary and secondary care and the difficulties which would arise from a long period during which both the old and the new products would be available.

Choice of medication is invariably made by the physician and not by the patient. Patients consider this within the competence of the physician and a reason for consultation. However, the patient does expect an explanation for the choice of a specific medicine, especially where a change from a familiar product is involved. Surveys have shown that when the change is recommended by the physician and adequate information is given, most patients are happy to change to the new devices and do so successfully.

Education is a continuous process, a partnership between professionals and patients involving an exchange of information and adequate opportunity for patients to express their fears and concerns. Although physicians are the patients' first source of information on medication, they do consult other professionals in asthma treatment as well as patient associations when they have questions about the treatment of their disease. It is therefore of the utmost importance that all these groups have the same information and give consistent advice to the patients. With adequate preparation and reinforcement

of the key messages, most patients are expected to undergo an easy transfer from their existing CFC inhalers to CFC-free devices.

To raise awareness, the following approaches could be considered:

(i) at government level:

National Governments may consider developing a strategy for the transition and health regulatory agencies may wish to consider providing circulars for health professionals, as well as unbiased information leaflets for patients. Appropriate sources of finance should be identified to support the awareness raising campaign. National health systems and/or health insurance schemes may consider preparing a plan to manage the period during which new products are becoming available while cheaper CFC products remain on the market.

(ii) at professional and patient association level:

Doctors, nurses and pharmacists need to be aware that the transition is not optional, and that, over the next few years, all patients currently using CFC products will have to change to non-CFC devices. They should be prepared to help patients understand the reasons for the change and assist them during transition. Patients will require reassurance that:

- the new treatment is as safe and as effective as the previous CFC products;
- the new inhaler devices operate in very similar ways to the CFC inhalers;
- CFCs are damaging to the environment but not damaging to the individual using the inhalers.

Although they will experience differences in appearance, dosage, taste and sensation when using the new products, these differences do not imply any reduction in effectiveness of the medicines.

Educational activities for patients and health professionals might involve:

- *Professional associations* – through medical journals, medical symposia, reports and newsletters. The ATOC welcomes national initiatives such as the professional/pharmaceutical collaboration embodied in the National Asthma Education and Prevention Program in the USA, symposia and newsletters arranged by the British Thoracic Society, workshops arranged by the European Respiratory Society, the American Thoracic Society, the American Academy of Asthma Allergy

and Immunology and other initiatives in France, Australia and Brazil amongst many others.

- *Treatment guidelines* issued by the country's medical authority which document the advantages and drawbacks of different forms of therapy and recommend specific forms of care for specific patient groups. All countries with guidelines continually review and revise their nations guidelines and many now include reference to the CFC/MDI issue. During 1995 the US National Heart Lung and Blood Institute (NHLBI) and WHO introduced a Global Initiative on Asthma (GINA). GINA symposia have been held in many Article 5(1) and non-Article 5(1) Parties and GINA guidelines translated into over 25 languages. The latest draft revision (1998) includes a section on CFC transition.
- *Promotional material and media coverage* – Advertising and promotional material placed in medical journals and circulated to physicians by pharmaceutical companies. Also articles in popular media promote awareness in the public of new products.
- *Pharmaceutical industry* – Education of the medical profession, support of medical symposia, reprint of pertinent articles and reports and information sheets to patients are strategies to help to inform both professionals and the public of developments and alternatives. The International Pharmaceutical Aerosol Consortium (IPAC) developed a brochure for health professionals entitled “Moving Towards CFC-free Metered Dose Inhalers” and a patient brochure entitled “Your Metered-Dose Inhaler Will Be Changing...Here Are The Facts”. IPAC has also established a site on the World Wide Web - <http://www.ipacmdi.com>
- *Medical literature* – Articles appearing in the medical journals inform professionals of developments, and several have been published since 1994, many written by members of the ATOC, with further major editorials due to be published in 1998.
- *Support groups* that provide information, seminars and programs aimed at both the general community and through schools, sporting groups etc., e.g. National Asthma Campaign (Australia), Asthma Society of Canada. The United Kingdom National Asthma Campaign has produced a fact sheet to help prepare patients for changeover of their inhalers and is extending telephone helpline (with the support of IPAC and the UK Department of Health) to handle concerns regarding CFC transition. To prepare patients for the change to alternatives, various methods are needed. Spoken advice, together with written and audio-visual reinforcement is likely to be necessary, and the UK Royal College of Nursing has produced a video on the subject.

The amount of educational activity being undertaken varies from country to country and should involve increasing awareness of DPIs as well as the reformulated MDI products. As more alternatives become available it is essential that a more active patient strategy is developed. This will involve concerted effort by the industry, and by health professional associations and national health authorities working together with patient support associations (e.g. National Asthma Campaigns and Asthma Foundations). For countries without patient support associations it is possible that the NHLBI/WHO Global Initiative (GINA) may be able to have available suitable literature for copying in the same way as they do with their current patient booklet, or add transition information to the GINA page on the Internet (<http://www.ginasthma.com>).

Professional bodies and patient associations are most likely to address this issue if governments take a lead in highlighting the importance of the subject. These educational activities are likely to cost money and responsibility and adequate funding need to be identified if a successful transition is to occur. Increasing numbers of medical symposia have taken place and are scheduled. The World Asthma Meeting in December 1998 was supported by the major world respiratory organisations (European Respiratory Society, European Society for Asthma, Allergy and Immunology, American Thoracic Society, Asia-Pacific Society of Respiriology, American Academy for Asthma, Allergy and Immunology, International Union Against Tuberculosis and Infectious Disease and GINA), and highlighted issues surrounding the safe transition to non-CFC treatments. UNEP is a co-sponsor of the World Asthma Meeting. Major meetings in Brazil, Argentina, Pakistan, UK and USA amongst others will include specific CFC Transition Symposia in 1999/2000.

#### **2.2.5.9 *The degree to which DPIs and other alternatives may be considered medically acceptable and affordable alternatives***

Dry powder inhalers (DPIs) are now available for most inhaled drugs in many countries and the introduction of new DPIs is foreseen in the future. The introduction of new multi-dose DPIs to markets such as the USA and Japan may have significant impact on CFC requirements in future years. There is good evidence that the previously noted trend of increased DPI usage will accelerate, although the rate of increase in use and penetration differs from country to country.

Main factors that influence the use of DPIs as alternatives to MDIs include:

- the range of DPIs products available in a country;
- the relative cost of DPIs compared to MDIs in some countries (although new cheaper DPIs are becoming available);



- DPIs not being suitable or effective for all age and patient groups, e.g. young children, the elderly and COPD patients, due to dependence on inspiratory flow rate;
- lack of awareness by physicians and patients of potential benefits of DPIs.

Except for DPIs, no other currently available inhalation systems are considered practical alternatives to MDIs. However, the ATOC notes with interest that a number of portable, hand-held nebulisers, and similar systems are under development. These may be potential future alternatives to MDIs and DPIs.

Novel oral compounds (leukotriene modifiers) for the treatment of asthma have been introduced in some countries. These may be of value to a certain number of those with asthma, but it is unlikely that these will be a full substitute for current effective inhaled preventive therapy. Thus, the mainstay of therapy for asthma and COPD is likely to remain therapy administered by the inhaled route.

#### **2.2.5.10 *Implications for importing countries of the transition and reductions in essential use CFC production***

In 1998 the ATOC requested that the TEAP clarify the application of Decision IV/25, i.e. can Parties which have completed domestic transition continue to export to Parties which have not. In 1998, the TEAP responded as follows. The Essential Use Process allocated ODS production or import for uses satisfying the terms of Decision IV/25. CFC MDIs are manufactured in only a few countries but are marketed and used worldwide. Therefore, Parties could qualify for essential use allocations for export to other Parties still dependent on CFC MDIs for their health requirements where the importing Party has not completed its transition. However, if importing countries have completed their transition, the exporting Party could not qualify for essential use allocations to serve that market.

Supply will need to be continued until importing countries have completed transition to non-CFC alternatives, or until alternative sources of supply can be secured. It is particularly important that CFC allowances be available for manufacture of CFC MDIs for export to Article 5(1) Parties, for CEIT and non-Article 5(1) Parties until economically feasible non-CFC MDI alternatives become available. Otherwise the supply of MDIs will be interrupted, posing risks for patient care.

#### **2.2.5.11 *Steps to facilitate access to affordable non-CFC treatment options and technology***

As previously noted in this report, the ATOC recognises that the transition to non-CFC treatment options may carry a financial burden for some countries and health authorities. Non-CFC MDIs are likely to be introduced at a price similar to existing CFC branded products, but this may be higher than available CFC generics and locally branded CFC products, thus carefully planned national transitions are needed.

It is desirable that new HFC propellants are utilised in MDI manufacture in developing countries in parallel with their introduction in developed countries. One company is committing resources to install manufacturing capacity in Latin America (Brazil) and Eastern Europe (Poland) to manufacture HFC MDIs. These plants should be operational during 1999 and will serve local and regional market needs.

The local production of CFC MDIs is likely to continue for some time after cessation of their use in non-Article 5(1) Parties and will overlap with the importation of CFC-free alternatives. Local production of CFC-free alternatives by a local producer, a multi-national company, or by a local producer in collaboration with a multinational company will require the transfer of new technologies and may require new licensing arrangements and transfer of intellectual property. The cost of such local production of CFC-free alternatives will involve capital costs and either multiple year or one-off licensing arrangements. Multinational companies operating in Article 5(1) Parties should be encouraged to make the technology transfer as soon as possible.

However, the issues associated with CFC transition should be differentiated from the ongoing need to provide affordable inhaled therapy for Article 5(1) Parties; this is a huge health care issue irrespective of CFC transition.

#### **2.2.5.12 *Implications for patient sub-groups with compelling medical needs***

The ATOC has considered the implications of the transition for patient subgroups which may have compelling medical needs. There are a number of considerations, some major and some minor:

##### ***Demographic considerations***

Due to the wide variety of products and formulations already introduced and anticipated, there do not appear to be readily identifiable, discrete demographic subgroups which cannot be served by CFC-free products. However, although multi-dose DPIs may be considered as alternatives for the purposes of the transition, they may not be suitable for very young children or

some elderly or severely impaired patients (due to inadequate inspiratory flow rates). These patient subgroups should have available to them a wide variety of HFC MDIs (which for children and others may be administered through holding chambers/spacers) and these should adequately meet their needs. However the specific effects and benefits of holding chambers/spacers when used for delivery of HFC MDIs may differ from that of CFC MDIs and will require further study and experience.

### ***Those experiencing worsening symptoms with alternative products***

The efficacy of current alternative products and devices is generally comparable to CFC MDIs. However, some patients may have a personal preference for CFC MDIs. This matter is likely to be overcome by educational endeavours and should not be the basis for an essential use nomination. Whilst problems with reformulated HFC MDIs are not anticipated, asthma is a condition which varies in severity with time and those with COPD often suffer exacerbations. It is likely that some patients' condition will coincidentally worsen after changing to a new inhaler, and some may die as a result of their disease. Post-marketing should help detect any true but unexpected problems with tolerability resulting from varied excipients or other aspects of reformulation. Due to spontaneous disease variability, any perceived worsening experienced after a patient is switched to a new non-CFC product will require empathic handling and extra educational efforts by care givers. For patients who do not feel that they can continue with the new product, alternate CFC-free inhalers (including DPIs) will be available for most drug categories.

### ***Allergic reactions***

Concerns have been expressed regarding the non-reformulation of adrenaline (epinephrine) MDIs for the treatment of allergic reactions. This has occurred for commercial and technical reasons and not as a result of the Protocol. However, most experts believe that the alternative of injectable adrenaline is the preferred route.

### ***Economically disadvantaged***

A final subgroup which may have a compelling need for CFC products well into the phaseout is the low income patient (whether in Article 5(1) or non-Article 5(1) Parties) who rely on less expensive generic or locally branded products for control of their diseases. As stated elsewhere in this report, this issue has less to do with HFC MDIs versus CFC MDIs than it does with branded versus locally manufactured product price differentials since it does not appear that HFC MDIs will be more expensive to the patient than their branded CFC counterparts. The Parties may wish to consider the impact of restricted access to generic or locally branded products which may occur as a

result of the transition. Such considerations may need to be included in the formulation of a Party's national transition strategy.

In consultation with Parties, the ATOC will monitor the continuing medical needs of particular patient subgroups.

Details of individual national strategies are available on the TEAP website at <http://www.teap.org/>. Some local and regional strategies from the United Kingdom are also available on the TEAP website; these contain some of the information that may be needed at the local level for successful and safe transition.

### **2.3 Sterilants**

By the beginning of 1997, CFC-12 use in non-Article 5(1) Parties for 12/88, a sterilant gas based on ethylene oxide (EO), had virtually disappeared, as final inventories were depleted. There remain no technical barriers to the phaseout of CFCs in sterilisation, but in some Article 5(1) Parties there are indications of increased use of CFC-12 as a sterilant gas diluent.

In non-Article 5(1) Parties, low temperature medical device sterilisation is being met by HCFC-diluent replacement sterilant gas and 8.5/91.5 EO/CO<sub>2</sub>, both of which are non-flammable. Pure EO can also be used, but since it is a flammable/explosive gas precautionary measures are necessary to use it safely. In some European countries formaldehyde is also used. There are a variety of not-in-kind substitutes, but some of these substitutes may either have materials compatibility problems or may be less robust processes with serious quality implications. Not-in-kind substitutes include radiation (gamma and electron beam), plasma systems, and liquid chemical systems. In other instances medical devices compatible with the steam process have been developed.

Global consumption of CFC-12 in this sector is very difficult to estimate since it is basically located in Article 5(1) Parties; it is estimated to be less than 1,500 tonnes. Estimated use of substitute HCFC replacement is thought to be less than 3,000 tonnes (some 90 ODP tonnes). CEIT and Article 5(1) Parties could convert to EO/HCFC-124 sterilant gas rapidly with reasonable cost and minimal changes in operating procedures.

HCFCs remain important as transitional products for sterilisation technology. Quality health care is dependent upon sterility assurance of medical devices. An HFC/EO sterilant blend has been developed and is being used in Hungary. A new HFC/EO sterilant blend has also been tried in the USA, but has not proven to be successful due to low sterilisation efficacy, high pressure limitations, and high cost. This alternative was developed in reaction to the EU ban on HCFC emissive uses in new equipment.

## 2.4 Laboratory and analytical uses

Typical laboratory and analytical uses include: equipment calibration; extraction solvents, diluents, or carriers for specific chemical analyses; inducing chemical-specific health effects for biochemical research; as a carrier for laboratory chemicals; and for other critical purposes in research and development where substitutes are not readily available or where standards set by national and international agencies require specific use of the controlled substances.

The Parties to the Montreal Protocol granted at their 10<sup>th</sup> Meeting (Decision X/19):

*“To extend the global laboratory and analytical essential use exemption until 31 December 2005 under the conditions set out in the Annex II of the report of the Sixth Meeting of the Parties”*; and that;

*“The Meeting of the Parties shall each year, on the basis of information reported by the Technology and Economic Assessment Panel, decide on any uses of controlled substances which should no longer be eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply.”*

The April 1998 Report of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee noted that a number of Parties had reported on the use of controlled substances for analytical and laboratory uses and the licensing systems that they had adopted to manage supplies into these applications. These systems license supplies to the distributors of controlled substances into the laboratory and analytical sector.

### 2.4.1 Estimation of global use of controlled substances for laboratory and analytical uses

It can be estimated that the total global use of controlled substances for these applications in non-Article 5(1) Parties will not exceed a maximum of 500 metric tonnes. Use in CEITs is unlikely to be more than a few hundred metric tonnes. An estimate of Indian use of CTC of 150 metric tonnes as a laboratory reagent would indicate that up to 500 metric tonnes could be used for analytical and laboratory uses in Article 5(1) Parties. An estimate for global use of controlled substances for laboratory and analytical uses is 1,500 metric tonnes.

### 2.4.2 Currently available alternatives

The identification of acceptable alternatives is not an easy matter. Questions of performance, cost, safety, availability and acceptability arise and require

detailed discussion between stakeholders. The phaseout of ozone depleting substances must be carefully planned to ensure that laboratories are not left without the necessary means to complete their work. This is especially critical where that work includes statutory analytical tests to protect human health.

The April 1998 Report of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee indicated that for the following applications of controlled substances, readily available and cost effective alternatives have been implemented by many countries:

- Testing of oil, grease and total petroleum hydrocarbons in surface and saline waters, and industrial, and domestic aqueous wastes, including the testing of water which is separated from oil and discharged from offshore drilling and production platforms
- Testing of tar in road paving materials by dissolving tar and separating it from aggregate
- Forensic fingerprinting.

In the USA, a number of organisations have taken actions to cease the use of controlled substances. The American Society for Testing and Materials (ASTM) does not recommend methods that use ozone-depleting substances and provides substitutes or correlations. The Association of Official Analytical Chemists International (AOAC) brings to attention methods using ODS at the proposal stage or encourages the downscaling of volumes. The American National Standards Institute (ANSI) does not develop standards but facilitates development by establishing consensus among qualified groups. ANSI established a data network at web site (<http://www.nssn.org/>) to provide information on standards. ASTM and AOAC contribute to this data network. The US EPA will publish a new method using n-hexane to determine oil and grease, and petroleum hydrocarbons in wastewater discharges. This method will replace two methods that use CFC-113.

The European Commission is planning to organise a seminar to explore the availability of alternatives to ozone depleting substances in laboratory and analytical uses in 1999. This will include a review of both current uses of ozone depleting substances and the regulations and standards that require their use.

The ATOC will report the outcome of these developments, which may provide the subject of any additional advice to the Parties under Decision X/19.

## 2.5 Carbon tetrachloride

Carbon tetrachloride (CTC) is a heavy, colourless liquid at normal temperature and pressure (boiling point 77 C). It is non-flammable, miscible with organic liquids and is a powerful solvent. CTC is the most toxic of the chloromethanes (10 ppm by volume in air, threshold limit as a maximum safe concentration for daily 8 hour exposure). It is harmful if swallowed, inhaled or absorbed through the skin and its vapour decomposes on contact with flame or very hot surfaces to give off phosgene and other toxic products. CTC vapour or mist is irritating to the skin, eyes, mucous membranes and upper respiratory tract. Exposure can cause stomach pains, vomiting, diarrhoea, nausea, dizziness and headaches, and damage to the eyes, liver and kidneys.

CTC is an easily manufactured chemical that is widely available. Because of its relevance to ozone depletion, CTC has been extensively reviewed in the 1994 and 1998 Reports of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee. Specific applications of CTC have been investigated in the 1995 Reports of the Process Agents Working Group and were further elaborated by the Process Agent Task Force (PATF) in 1997; review can also be found in the 1995 Report of the Laboratory and Analytical Uses Working Group. Inadvertent Emissions and Process Losses were discussed in the 1994 Report of the Technology and Economic Assessment Panel (TEAP).

Worldwide production and emissions of CTC were reviewed in detail in the 1998 Report of the Aerosols, Sterilants, Miscellaneous Uses and Carbon Tetrachloride Technical Options Committee.

This report concluded that while CTC atmospheric levels have reduced as a result of the phaseout of CFC consumption in the majority of non-Article 5(1) Parties, they will only fall significantly in the near future if the use of CFCs and CTC in Article 5(1) Parties is phased out at a faster pace than required by the Montreal Protocol. Otherwise use of CTC might remain frozen until 1 January 2005 and CTC emissions could remain unchanged until that time.

A number of measures were identified that could lead to reductions in CTC emissions to the environment:

- Closure of CFC manufacturing facilities in Article 5(1) Parties and CEIT with accelerated introduction of alternatives.
- Conversion of facilities using CTC as process agents in Article 5(1) Parties to alternatives.
- Use of improved emission control technology in CTC and CFC manufacturing facilities in all countries.

- Use of improved emission control technology in manufacturing facilities using CTC as process agents.

Due to the complexity of the industries using CTC, the TOC recommended that these options be considered on a case by case basis taking into account technical, economic and environmental considerations.

The Parties at their 10th Meeting (Decision X/12) requested the Technology and Economic Assessment Panel to investigate further and report to the 12th Meeting:

- Emissions of CTC from its use as feedstock, including currently available and future possible options individual Parties may consider for the reduction of such emissions;
- Emissions of other ozone depleting substances arising from the use of controlled substances as feedstock;
- The impact of CFC production phaseout on the future use of CTC as feedstock and emissions from such use.

Furthermore, the Parties at their 10th Meeting adopted Decision X/14 on process agents, which seeks to reduce emissions, primarily of CTC, to specified levels and mandates data collection.

According to this Decision, process agents will be treated in a manner similar to feedstock from 1998 until 31 December 2001 for non-Article 5(1) Parties. In the case of Article 5(1) Parties, the emissions of controlled substances from process-agent use will have to be reduced to levels agreed by the Executive Committee before 1 January 2002, in order to have a similar treatment. This provision applies only for plants and installations in operation before 1 January 1999.

Furthermore, data should be reported to the Secretariat by 30 September 2000, and each year thereafter; and should include use of controlled substances as process agents, levels of emissions, and descriptions of containment technologies.

The incremental costs of measures to reduce emissions of controlled substances from process-agent uses in Article 5(1) Parties should be eligible for funding, in accordance with the rules and guidelines of the Executive Committee of the Multilateral Fund.

The TEAP is requested, in this Decision, to report to the Meeting of the parties in 2001 on the progress made in reducing emissions from process agent uses, on implementation of emission-reduction techniques and on alternative ODS free processes.



### **3. Sector Update - Clarification Regarding Applicability of Halocarbon Replacements for Halon 1301 in Fixed Systems**

#### **3.1 Introduction**

The phaseout of halon production has had a dramatic impact on the fire and explosion protection industry. Halons were clean, non-conductive, safe for people, and highly effective. Replacing them in their many applications continues to present challenges for fire protection professionals.

Halocarbon alternatives have been introduced at a rapid pace. The purpose of this explanation is to provide a brief review of the types of alternatives that are available, including information on physical and chemical characteristics, fire protection capabilities, toxicity, and key environmental parameters.

#### **3.2 Alternatives for Fixed Systems**

##### **3.2.1 Halocarbon Agents**

These agents share several common characteristics, with the details varying between chemicals. These common characteristics include the following:

6. All are electrically non-conductive;
7. All are clean agents; they vaporise readily and leave no residue;
8. All are liquefied gases or display analogous behaviour (e.g., compressible liquid);
9. All can be stored and discharged from fire protection system hardware that is similar to that used for halon 1301;
10. All (except HFC-23) use nitrogen superpressurisation for discharge purposes;
11. All (except CF<sub>3</sub>I) are less efficient fire extinguishants than halon 1301 in terms of storage volume and agent weight. The use of most of these agents requires increased storage capacity;
12. All are either permanent gases after discharge or are liquefied compressed gases which vaporise upon discharge (except HCFC Blend A which consists of 3.75% of a non-volatile liquid). Many require additional care relative to nozzle design and mixing.

13. All (except CF<sub>3</sub>I) produce more decomposition products (primarily HF) than halon 1301 given similar fire type, fire size, and discharge time; and
14. All are more expensive at present than halon 1301 on a weight (mass) basis.
15. For all practical purposes none of these agents can be used as a direct (drop-in) replacement for halon 1301 in existing systems.

These agents differ widely in the areas of toxicity, environmental impact, storage weight and volume requirements, cost, and availability of approved system hardware. Each of these categories will be discussed for each agent in the following sections.

### **3.2.1.1 Toxicity**

Table 1 summarises the toxicity information available for each chemical. The NOAEL is the No Observed Adverse Effect Level. This is the concentration at which no adverse effect was observed in the test specimen. The LOAEL is the Lowest Observed Adverse Effect Level. This is the lowest concentration at which an adverse effect was observed. For halocarbon agents, these levels are usually driven by the cardiotoxicity level of the agent. Several compounds including HFC-23 and FC-3-1-10 have little or no cardiotoxicity. Historically, it has been recommended that halon replacement agents should not normally be used at concentrations above the NOAEL in occupied areas. Use of agents up to the LOAEL has been permitted in occupied areas if adequate time delays and pre-discharge alarms were provided and time required for escape was short. New recommendations have been proposed that would allow use at or above the LOAEL based on the use of a physiologically-based pharmacokinetic (PB-PK) model.

It should be carefully noted that where the NOAEL value (%) is lower than the Design Concentration (%) the agent is not suitable for use in occupied areas. The term "Occupied Area" means both an area that is normally occupied by people or an area where people could be present during discharge of the fire protection system. The vast majority of fire protection applications are categorised as "Occupied Areas".

### **3.2.1.2 Environmental Factors**

The primary environmental factors to be considered for these agents are ozone-depletion potential (ODP), global-warming potential (GWP), and atmospheric lifetime, and these are summarised in Table 1. It is important to select the fire protection choice with the lowest environmental impact that will adequately provide the necessary fire protection performance for the specific application. The use of any synthetic compound that accumulates in the

atmosphere carries some potential risk with regard to atmospheric equilibrium changes. PFCs, in particular, represent an unusually severe potential environmental impact due to the combination of extremely long atmospheric lifetime and high GWP.

International agreements and individual actions by national governments may affect future availability of these compounds and subsequent support for installed fire protection systems that utilise them. Some examples are presented below:

- HCFCs are scheduled for a production and consumption phaseout under the Montreal Protocol in 2020-2030 in developed countries and 2040 in developing countries.
- The European Union restricts HCFCs use for fire protection.
- HFCs and PFCs are included in the basket of six gases (SF<sub>6</sub>, carbon dioxide, methane, nitrous oxide) for which flexible and binding emission reduction targets were agreed as part of the Kyoto Protocol to the United Nations Framework Convention on Climate Change (UNFCCC). The Kyoto Protocol requires developed countries to reduce their aggregate emissions of the six gases by an average of 5% below 1990 levels. HFCs and PFCs represent less than 2% of current greenhouse gas emissions on a carbon-equivalency basis.
- The United States allows use of PFCs only when no other agent or engineering approach will meet the fire protection needs.

**Table 1: Halocarbon Agents for fixed systems**

Generic Name	Halon 1301	HCFC Blend A	HCFC-124	HFC-23	HFC-125	HFC-227ea	HFC-236fa	FC-2-1-8	FC-3-1-10	FIC-131I
Trade Name	BTM	NAF S-III	FE-24	FE-13	FE-25	FM-200	FE-36	CEA-308	CEA-410	Triodide
Heptane Extinguishing Concentration	3.2	9.9	6.7	12.5	8.1	6.6	6.1	7.3	5.9	3
Minimum Class B Fire Design Concentration	5	12	8	18	9.7	7.9	7.3	8.8	7.1	3.6
NOAEL (vol%)	5	10	1	50	7.5	9	10	30	40	0.2
LOAEL vol %	7.5	>10	2.5	<50	10	10.5	15	>30	>40	0.4
Suitable for Use in Occupied Areas	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No
Mass Required Relative to Halon 1301	1	1.6	1.5	2.0	1.6	1.9	1.6	2.3	2.3	0.9
Cylinder Storage Volume Relative to Halon 1301	1	1.9	1.5	2.5	2.2	1.8	1.4	2.2	1.9	0.6
Ozone Depletion Potential	10	HCFC-22 = 0.05 HCFC-124 = 0.02 HCFC-123 = 0.02	0.02	0	0	0	0	0	0	0.0001
Global Warming Potential 100 yr*	6'900	HCFC-22 = 1,900 HCFC-124 = 620 HCFC-123 = 120	620	14'800	3'800	3'800	9'400	8'600	8'600	<1
Global Warming Potential 500 yr*	2'700	HCFC-22 = 590 HCFC-124 = 190 HCFC-123 = 36	190	11'900	1'200	1'300	7'300	12'400	12'400	<<1
Atmospheric Lifetime (years)*	65	HCFC-22 = 11.8 HCFC-124 = 6.1 HCFC-123 = 1.4	6.1	243	32.6	36.5	226	2'600	2'600	0.005

Limited use due to unsuitability for use in occupied areas or environmental concerns

\* Source of GWP and ALT values "Scientific Assessment of Ozone Depletion: 1998." World Meteorological Organization, Global Ozone Research and Monitoring Project - Report No. 44

### **3.3 Discussion**

From the table it can be seen that the only viable halocarbon alternatives for widespread application are HFC-227ea, HFC-236fa and HFC-23. The other halocarbon agents are unsuitable for widespread application due to toxicity concerns or regulatory restrictions by environmental agencies. In all cases the halocarbon agents are less effective on a weight/volume basis than halon 1301. As a result all require more storage cylinders than a halon system for protection of a similarly sized hazard. In addition, as more extinguishing agent is required, the piping system and discharge nozzles will differ significantly than that normally used to discharge halon 1301.

Fire protection systems are stringently tested by certifying agencies. Recognition of success in meeting these stringent test requirements results in a listing or certification by these agencies. A change of extinguishing agent requires re-test of the equipment with the alternative agent. This usually means that the original equipment manufacturer must accept the change in responsibility for the performance of the system with the alternative agent. In general, to meet national fire protection regulations, all fire protection systems must be listed or certified by a testing body recognised by the national fire regulations. This requirement adds to the impracticality of replacing an existing halon 1301 system by simply replacing the halon with an alternative halocarbon.

### **3.4 Conclusions**

The Halons Technical Options Committee advises Parties that for all practical purposes there are no alternative extinguishing agents that can be used as a direct (drop-in) replacement for halon 1301 in existing systems.





**UNEP**

**Technology and Economic Assessment Panel**

**Part VII: Background Information for the TEAP and  
Contact Information for TEAP Members  
and TOCs**





## 1. Progress on TEAP Operation

In 1998-99 the Scientific, Environmental Effects, and Technology and Economics Assessments Panels undertook an integrated full assessment for the Montreal Protocol. The TEAP assessment included separate full reports for each sector by its Technical Options Committees (TOCs). In preparation for this assessment TEAP restructured its membership in accordance with the Terms of Reference approved by Parties in 1996

The principal TEAP goals of restructuring under the TOR are to increase Article 5(1) and CEIT participation and to improve its expertise balance so that it can provide a full inventory of alternatives and substitutes including descriptions of environmental acceptability, technical performance and economic feasibility. The TEAP will complete the implementation of the TOR approved by the Eighth Meeting by limiting the size of the TOCs to 20-35 experts avoiding duplication of expertise and retiring members who are not actively participating. All TOCs are making continuous efforts to meet these goals.

Table 1 and 2 present an overview of the composition of TEAP and its TOCs. It can be seen that greater geographical balance has been achieved.

*Table 1: Country representation in TEAP as of March 1999*

Body	Total Membership	Article 5(1)/CEIT	Non-Article 5(1)	% Article-5(1)/CEIT
TEAP	23	10	13	45

\* TEAP includes 17 TOC-Co-Chairs

*Table 2: Country representation in TOCs as of March 1999*

Body	Total Membership	Article 5(1)/CEIT	Non Article 5(1)	% Article 5(1)/CEIT
ATOC	33	10	23	30
EOC	14	6	8	43
FTOC	20	6	14	30
HTOC	20	7	13	35
MBTOC	39	13	26	33
RTOC	45	11	34	24
STOC	31	11	20	35
<b>Total</b>	<b>202*</b>	<b>64</b>	<b>138</b>	<b>32</b>

\* Includes Co-Chairs who serve as TEAP members

The Methyl Bromide TOC (MBTOC) has reduced its membership of experts from Non-Article 5(1) countries, increased the proportion of members from Article 5(1) countries, and simultaneously strengthened its expertise on alternatives and substitutes. The number of members in MBTOC now is consistent with the Parties directive in 1997 to limit the size of TOCs to 20-35 members. It is important for MBTOC to retain this critical mass when moving into a period when expertise is needed to both document alternatives and to respond to questions raised by the Parties.

The Foams TOC (FTOC) was composed of 21 members in 1998 out of which six are from Article 5(1) countries. There are likely to be changes in the membership but efforts are made to retain at least the present level of representation of Article 5(1)- countries. There may be few additions from non-Article 5(1) countries keeping "in view" the interface of the Montreal Protocol with the Framework Convention on Climate Change to broaden the choice of solutions.

The Halons TOC (HTOC) presently has 20 members from 14 countries including 7 members from Article 5(1) and CEITs. 11 consulting experts support the committee. The membership is based on expertise and reflects geographical balance. In future the HTOC plans to undertake as much work as possible by correspondence. In the future the HTOC will meet only to prepare work specially requested by the Parties.

The Refrigeration, Heat Pumps, and Air Conditioning TOC (RTOC) presently has 45 members including 11 members from CEIT and Article 5(1) countries. The RTOC membership is being adjusted to increase participation of CEIT and Article 5(1) countries. Several members from non-Article 5(1) countries have retired. RTOC has maintained members with specialisation for all sub-sectors.

The Solvents, Coatings, and Adhesives TOC (STOC) has 31 members including 11 members from CEIT and Article 5(1) countries. STOC membership has changed considerably over the last two years. Three members from non-Article 5(1) countries were replaced with new members having special background and knowledge and to improve the balance of membership. A total of 5 new members were added from CEIT and Article 5(1) countries.

The Aerosol Products, Sterilants, Miscellaneous, and Carbon Tetrachloride TOC (ATOC) has 33 members with 10 members from CEIT and Article 5(1) countries. The ATOC will continue to increase membership of MDI experts, particularly from CEIT and Article 5(1) countries.

The Economic Options Committee (EOC) has 14 members with 6 from Article 5(1) countries and 8 from non-Article 5(1) countries. Consideration is being given to equalise representation by reducing the non-Article 5(1) membership by one and increasing the CEIT or Article 5(1) membership by one.

TEAP recommends that it be allowed to simplify its annual reports to present only new information and responses to requests from Parties. This will allow Technical Options Committees to meet only "as needed," typically one time or less per year. Full TEAP and TOC Assessment Reports would be made at the same time as Science and Environmental Effects Assessment Reports.

## 2. **Technology and Economic Assessment Panel Co-Chairs, Senior Expert Members and Members' background information**

TEAP has interpreted the Terms-of-Reference (TOR) regarding Code-of-Conduct to require disclosure statements by TEAP members. These are presented in full in annual TEAP Reports. Disclosure for members of TOC and others subsidiary bodies and compliance with the Code-of-Conduct are reviewed each year by TEAP and reported to Parties. The TOC Co-Chairs are currently requesting disclosure statements for 1998-99.

Since 1988 many Parties have made substantial in-kind and financial contributions to the operation of TEAP and its TOCs, Working Groups and Task Forces. The principal financial contributors include Australia, Canada, Germany, Japan, Netherlands, Norway, Sweden, Switzerland, United Kingdom, and the United States. In a typical year TEAP requires US\$100,000-150,000 in administrative and management wages, communication, word processing, printing, and mailing costs. TOCs typically spend US\$35,000-100,000 depending on whether the time of chairs is an in-kind contribution or a sponsored contribution.

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Jorge Corona	CANACINTRA (National Chamber of Industry)	Mexico
Barbara Kucnerowicz-Polak	State Fire Service	Poland
Mohinder Malik	Lufthansa German Airlines	Germany
David Okioga	Ministry of Environmental Conservation	Kenya
Jose Pons Pons	Spray Quimica	Venezuela
Rodrigo Rodriguez-Kabana	Auburn University	USA
Lalitha Singh	Independent Expert	India
Gary Taylor	Taylor/Wagner	Canada
Helen Tope	Environment Protection Authority, Victoria	Australia
Robert van Slooten	Consultant	UK
Ashley Woodcock	University Hospital of South Manchester	UK
Shiqiu Zhang	Peking University	China
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Jacek Rozmiarek	Polfa Poznan	Poland
Abe Rubinfeld	Royal Melbourne Hospital	Australia
Daisaku Sato	Ministry of Health and Welfare	Japan
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Greg Simpson	CSIRO, Molecular Science	Australia
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Ian Tansey	3M Health Care	UK
David Townley	Boehringer Ingelheim International	Germany
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You Yizhong	Journal of Aerosol Communication	China

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<b>Co-Chairs</b>	<b>Affiliation</b>	<b>Country</b>
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Lalitha Singh	Consultant	India

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Kee-Bong Lee	LG Electronics	Korea
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Dave Williams	Allied Signal	USA

### TEAP Halons Technical Options Committee

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Barbara Kucnerowicz-Polak	State Fire Service Headquarters	Poland
Gary Taylor	Taylor/Wagner	Canada

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Nicolai P. Kopylov	All-Russian Research Institute for Fire Protection.	Russia
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Arthur Lim	ABL Lim (FPC)	Singapore
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John J. O'Sullivan	British Airways	UK
Erik Pedersen	World Bank	Denmark
Reva Rubenstein	US Environmental Protection Agency	USA
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Robert L. Darwin	Naval Sea Systems Command	USA
Steve McCormick	US Army SARD-ZCS-E	USA
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Ronald Sheinson	Navy Research Laboratory	USA
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Malcolm Stamp	Great Lakes Chemical (Europe) Limited	UK
Daniel Verdonik	Hughes Associates	USA
Brian Ward	Kidde Fire Protection	UK

Robert T. Wickham	Wickham Associates	USA
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### TEAP Methyl Bromide Technical Options Committee

<b>Co-Chairs</b>	<b>Affiliation</b>	<b>Country</b>
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Rod Rodríguez-Kábana	Auburn University	USA
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Mohamed Besri	Institut Agronomique et Vétérinaire Hassan II	Morocco
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Chettanachitara		
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Don Smith	Industrial Research	New Zealand
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Bob Taylor	Natural Resources Institute	UK
Bill Thomas	Environmental Protection Agency	USA
Ken Vick	Department of Agriculture	USA
Chris Watson	Igrox	UK
Jim Wells	Jellinek Schwartz & Connolly	USA
Frank Westerlund	California Strawberry Commission	USA
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Jose Driessen	Embraco	Brazil
Hans Haukas	Consultant	Norway
Robert Heap	Cambridge Refrigeration Technology	UK
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Ftouh Kallel	Batam	Tunisia
Michael Kauffeld	DTI Aarhus	Denmark
Fred Keller	Carrier Corporation	USA
Holger König	Solvay Chemie	Germany
Horst Kruse	FKW Hannover	Germany
Anders Lindborg	Ammonia Partnership	Sweden
Michael Löhle	Behr GmbH & Co	Germany
Louis Lucas	International Institute of Refrigeration	France
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Mark Menzer	Air Conditioning and Refrigeration Institute	USA
Haruo Ohnishi	Daikin Industries	Japan
Hezekiah B. Okeyo	Ministry of Commerce and Industry	Kenya
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Frederique Sauer	Dehon Service	France
Erik Schau	Unitor Ships Service	Norway
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Stephan Sicars	Sitec Consultancy	Germany
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Ganesan Sundaresan	Copeland Corporation	USA
Pham Van Tho	Ministry of Fisheries	Vietnam
Trude Tokle	SINTEF Energy	Norway
Vassily Tselikov	ICP "Ozone"	Russia
Paulo Vodianitskaia	Multibras	Brazil
Lau Vors	L&E Teknik og Management	Denmark
Kiyoshige Yokoi	Matsushita Refrigeration.	Japan

## TEAP Solvents, Coatings and Adhesives Technical Options Committee

<b>Co-Chairs</b>	<b>Affiliation</b>	<b>Country</b>
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Mohinder Malik	Lufthansa German Airlines	Germany
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Brian Ellis	Protonique	Switzerland
Joe Felty	Raytheon TI Systems	USA
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William Kenyon	Global Centre for Process Change	USA
A.A. Khan	Indian Institute of Chemical Technology	India
V. N. Kudryavtsev	Mendeleyev University of Chemical Technology	Russia
Stephen Lai	Singapore Inst. of Standards and Industrial Research	Singapore
Colin Lea	National Physical Laboratory	UK
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James Mertens	Dow Chemical	USA
Fritz Powolny	Pfizer	Brazil
Patrice Rollet	Promosol	France
Hussein Shafa'amri	Ministry of Planning	Jordan
John Shirtz	Coastal Safety & Health Services	USA
Darrel Staley	Boeing Defense and Space Group	USA
John Stemniski	Consultant	USA
Katsuyuki Takei	Japan Association for Hygiene of Chlorinated Solvents	Japan
John Wilkinson	Vulcan Materials	USA
Masaaki Yamabe	Asahi Glass	Japan
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## HFC/PFC Task Force

<b>Chair</b>	<b>Affiliation</b>	<b>Country</b>
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Paul Ashford	Caleb Management Services	UK
Paul Atkins	Glaxo Wellcome	UK
James A. Baker	Delphi Harrison	USA

Walter Brunner	envico	Switzerland
Nick Campbell	ICI Klea	UK
Suely Carvalho	Montreal Protocol Unit - UNDP-NY	Brazil
Denis Clodic	Ecole des Mines	France
Jorge Corona	CANACINTRA (National Chamber of Industry)	Mexico
Yuichi Fujimoto	Japan Industrial Conference for Ozone Layer Protection	Japan
Mike Jeffs	ICI Polyurethanes	Belgium
Michael Kauffeld	DTI Aarhus	Denmark
Barbara Kucnerowicz-Polak	State Fire Service	Poland
Lambert Kuijpers	Technical University Eindhoven	Netherlands
Mohinder Malik	Lufthansa German Airlines	Germany
Mack McFarland	DuPont Fluoroproducts	USA
Abid Merchant	DuPont Fluoroproducts Fluorochemicals Laboratory	USA
Thomas Morehouse	Institute for Defense Analyses	USA
Haruo Ohnishi	Daikin	Japan
Roberto de A. Peixoto	Maua Institute of Technology	Brazil
Wiraphon Rajanuraks	Department of Industrial Works	Thailand
Sally Rand	Environmental Protection Agency	USA
Robert Russell	Dow Plastics	USA
Lee Kheng Seng	Department of Environment	Singapore
Rajendra Shende	United Nations Environment Programme TIE	India
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#### **Replenishment Task Force**

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Jose Pons Pons	Spray Quimica	Venezuela
Sateev Seebaluck	Ministry of Environment, Human Resource Development and Employment	Mauritius
Robert van Slooten	Consultant	UK
Shiqiu Zhang	Peking University	China