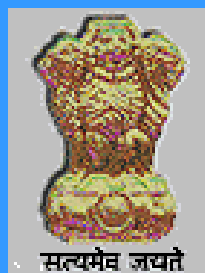




NATIONAL STRATEGY FOR TRANSITION TO NON-CFC MDIs AND PLAN FOR PHASE-OUT OF CFCs IN THE MANUFACTURE OF PHARMACEUTICAL MDIs IN INDIA



Ozone Cell
Government of India
Ministry of Environment and Forests



VIENNA CONVENTION AND MONTREAL PROTOCOL

- The Vienna Convention for the protection of the Ozone Layer was signed in **March 1985**.
- The Montreal Protocol on Substances that Deplete the Ozone Layer was signed on **16 September 1987**.



AMENDMENTS TO THE PROTOCOL

- London Amendment (1990)

Inclusion of additional controlled substances
(CFCs, Methyl Chloroform, CTC, etc)

Inclusion of HCFCs as transitional substances

Establishment of Financial Mechanism - Multilateral Fund

Ten year grace period for Article 5 parties.

- Copenhagen Amendment (1992)

Inclusion of HCFCs, HBFCs and Methyl Bromide as controlled substances.

- Montreal Amendment (1997)

Licensing system put in place

- Beijing Amendment (1999)

Bromo-chloromethane added as controlled substance for immediate phase-out. Production control of HCFCs



FINANCIAL SOURCES FOR IMPLEMENTATION OF THE PROTOCOL

- As per the London Amendment (1990), the Multilateral Fund (MLF) was set up and a financial mechanism was established to assist the Article 5 countries for phase-out of Ozone Depleting Substances (ODS).
- India has been receiving financial and technical assistance to phase out production and consumption of ODS since 1993.
- There is no budget allocation under planned scheme for implementation of the Montreal Protocol in India.
- MLF has no specific annual budget for any country.
- Projects are approved based on individual merit.



INDIA'S COMMITMENT TO THE MONTREAL PROTOCOL

- **19th June 1991** : India became a Party to the Vienna convention.
- **17th September 1992** : India became a Party to the Montreal Protocol.
- **3rd March 2003** : India ratified the London Amendment (1990), Copenhagen Amendment (1992), Montreal Amendment (1997) and Beijing Amendment (1999).
- **November 1993** : India's Country Program was prepared.
- **January 2006** : India's Country Program was updated.



INSTITUTIONAL FRAMEWORK IN INDIA

- **Ozone Cell** is established under the Ministry of Environment & Forests for undertaking activities relating to implementation of Vienna Convention and Montreal Protocol.
- **Empowered Steering Committee** (ESC) created in the MOEF with the approval of Cabinet is the apex body to take policy decisions with Secretary (E&F) as chairperson.
- **Two Standing Committees** set up to provide assistance on specific implementation issues to ESC are:-
 1. Technology and Finance Standing Committee.
 2. Standing Committee on Monitoring.



LIST OF ODS

As per Article 2 of the Montreal Protocol, the total number of controlled substances are 96.

The following 9 controlled substances are produced and consumed in India.

<u>Substances</u> <u>Consumption</u>	<u>Production</u>	
CFC-11	Yes	Yes
CFC-12	Yes	Yes
CFC-113	Yes	Yes
Halon-1211	No	Yes**
Halon-1301	No	Yes**
Methyl Chloroform	No	Yes
Carbontetrachloride	Yes	Yes
Methyl bromide	No	Yes*
HCFC-22	Yes	Yes

* Quarantine & Pre-shipment / ** Servicing of existing equipment.



PRODUCTION & CONSUMPTION CONTROL SCHEDULE AS PER MONTREAL PROTOCOL - ORIGINAL

ODS / Baseline (Prod. & Cons.)	2005	2007	2010	2015	2040
CFC–P(22588 MT) C(6681 MT)	50 %	85 %	100 %	NA	NA
Halon–P(95 MT) C(260 MT)	50 %	-	100 %	NA	NA
CTC–P(10507 MT) C(10459 MT)	85 %	-	100 %	NA	NA
MCF–P(Nil) C(1467 MT)	30 %	-	70 %	100 %	NA
MeBr–P(108 MT) C(-)*	20 %	-	-	100 %	NA
HCFCs**	-	-	-	-	100 %

Baseline for CFC: 1995-97; Baseline for CTC: 1998-2000; Baseline for MeBr:1995-1998
 Baseline for Halon: 1995-97; ** Baseline to be determined and reported in 2013.
 Baseline of MCF: 1998-2000; *Baseline Cons. is 214 MT as Quarantine & Pre-shipment



PRODUCTION & CONSUMPTION CONTROL SCHEDULE AS PER MONTREAL PROTOCOL - REVISED

ODS / Baseline (Prod. & Cons.)	2005	2007	2008	2010	2015	2030
CFC-P(22588 MT) C(6681 MT)	50 %	85 %	100%	NA	NA	NA
Halon – P(95 MT) C(260 MT)	50 %	-	-	100 %	NA	NA
CTC-P(10507 MT) C(10459 MT)	85 %	-	-	100 %	NA	NA
MCF-P(Nil) C(1467 MT)	30 %	-	-	70 %	100 %	NA
MeBr-P(108 MT) C(-)	20 %	-	-	-	100 %	NA
HCFCs**	-	-	-	-	10%	100 %

** Baseline of HCFC : Production and Consumption average of 2009 and 2010



ODS USED IN SECTORS

	<u>Sector</u>	<u>ODS Used</u>	<u>Substitutes</u>
1.	Foam	CFC-11	HCFC-141b, Hydrocarbon, HFC-245fa
2.	RAC	CFC-11, CFC-12, HCFCs	HFC-134a,R-404A R- 410A R-407A,Hydrocarbon,
3.	Aerosol	CFC-11, CFC-12, HCFCs	Hydrocarbon Aerosol Propellants (HAPs)
4.	Solvent	CTC, Methyl Chloroform CFC-113	Trichloroethylene, Some patented chemicals etc.
5.	Fire Ext.	Halon-1211, Halon-1301, Halon-2402. HCFCs	ABC Powder, Water, CO2 , HFCs
6.	Q & P	Methyl Bromide	-



ACCELERATED PHASEOUT OF CFCs

The 19th Meeting of the Parties (MOP) held in Sept. 2007, in Montreal decided (Decision XIX/6) to advance the phase-out of production and consumption of HCFCs by 10 years for an early recovery of Ozone Layer



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

1. INTRODUCTION

- Funding for preparation of transitional strategy for MDIs in India was approved in the 41st Ex-Com meeting in December 2003.
- Funding for preparation of a proposal for addressing the phase-out of CFCs in the MDI sector in India was approved at the 52nd Ex-Com meeting in July 2007.
- UNDP was assigned the role as the lead implementing agency for the main proposal, UNEP as the cooperating agency for non-investment components and Italy as the bilateral cooperating agency.



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

2. BACKGROUND

- ❑ Asthma and COPD are considered significant health problems worldwide as well as in India.
- ❑ Use of MDIs has grown significantly in India in the past decade, due to better access to and better availability of drugs and devices.
- ❑ There are 5 MDI manufacturers in India. MDI production has increased from 29.3 million units (2003) to 55.5 million units (2007). About 56% of the MDIs manufactured in 2007, used CFCs as propellants. Remaining used HFA propellants.



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

2. BACKGROUND (Cont'd)

- In 2007, the total CFC consumption in manufacturing of MDIs in India was 608 tonnes.
- About 23 drugs and 42 formulations are manufactured in 7 facilities and 12 production lines. Most of these products are indigenously developed.
- In 2007, about 4.9% of the production (about 2.7 million units) of MDIs were exported to non-Article-5 countries.
- India has robust institutional and regulatory frameworks relating to both CFCs and MDIs.



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

2. BACKGROUND (Cont'd)

- It typically takes up to three years for formulation development, registration and approval, for a new product to be introduced in the market.
- The Drug Price Control Order regulates the market price of drugs, to ensure affordable access.
- Only two of the five manufacturers have developed HFA alternatives to CFC-based MDIs.
- Considering demand growth, constraints of time and resources, regulations and pricing, there will be a transitional period of about four years, during which CFCs will be needed, before complete conversion.



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

3. TRANSITION STRATEGY

Objectives

- To gradually reduce CFC consumption in MDIs and achieve their complete elimination by 2012
- To assimilate non-CFC technology into India.

Principles

- Prevent industrial dislocation/obsolescence, through technical and financial support to industry
- Ensure cost-effective and sustainable access to drugs
- Strengthen national stakeholder institutions
- Awareness in healthcare professionals and patients
- Formulate and implement appropriate policies/regulations



INDIA - MDI PROPOSAL

Key features, constraints and opportunities

3. TRANSITION STRATEGY (cont'd)

Components

- Technology conversions at five MDI manufacturers
- Technical assistance
- Policy and regulatory interventions
- Awareness, training and capacity building actions among wide range of national stakeholders
- Monitoring and management



KEY CHALLENGES IN PHASING-OUT OF HCFCs

- **Period for Change-Over is Short especially for first stage reduction targets**
- **Approximately 40% reduction of the base line consumption in few years (2013/2015)**
- **Technical Options are still emerging, Available options may not be the long term Solutions**
- **HFCs are the main options to HCFC for most of the applications in refrigeration and air-conditioning**
- **HFCs are the potent Green House Gases (GHG) and Emissions of these gases are controlled under Kyoto Protocol**



STRATEGY FOR MEETING CHALLENGES IN PHASING OUT HCFCs

- Roadmap has been developed with a long term vision, initiatives and action plan
- Policy instruments need to be aligned to meet the needs of accelerated phase-out schedule of HCFCs
- Strengthening of Institutional Set-up to cater the needs of HCFC phase-out
- UNDP as Lead Agency in Association with UNEP, UNIDO, World Bank Govt. Germany (bilateral agency) is responsible for preparation of HPMP
- Funding for preparation of HPMP is under consideration by the Ex-Com

The roadmap details are the part of agenda-Key feature are covered



BACKGROUND

- HCFCs are widely used chemicals. The applications include, Refrigeration & Air-conditioning, Foam blowing, Aerosols and Firefighting
- There are a number of chemicals which fall in this category like HCFC-22, HCFC-141b, HCFC-142b, HCFC-123, HCFC-225 and HCFC-124
- All these chemicals are the Ozone Depleting Substances (ODS) and are controlled by the Montreal Protocol in the schedule Annex C Group 1 Substances



OVERALL OBJECTIVES

- Phase out Production and Consumption of HCFCs in accordance with Montreal Protocol phase-out schedule without any commercial and financial dislocations in the country
 - Achieving compliance target set by the Montreal Protocol for stage-I
 - Establishment of base-line production and consumption sectors – an average of 2009 and 2010 for production and consumption respectively.
 - 2013 freeze
 - 10% reduction of baseline in 2015
 - Phase-out of production and consumption of HCFCs to achieve the Stage-II reduction targets: 2020, 2025 and total phase-out in 2030 with an allowance for servicing and annual average of 2.5% during the period 2030-2040.



INITIATIVES AND ACTIONS FOR MEETING THE STAGE-I PHASE-OUT TARGETS



POLICY SUPPORT INSTRUMENTS

ACTIONS:

- Review of existing national policy instruments including ODS (Regulation and Control) Rules, 2000 & its amendments and align them to the needs of HCFC phase-out.
- Strengthening of ESC and its Standing Committees to cater to the needs of HCFCs phase out regime
- Strengthening of institutional setup in the Ozone Cell – PMU and SPPU
- Review and strengthening of ODS control enforcement Measures and strengthening the Custom policies with regard to ODS to prevent illegal trade if any
- Review of existing fiscal incentives to promote non-ODS technologies for smooth transition from HCFCs to non-ODS technologies



AWARENESS AMONG STAKEHOLDERS

ACTIONS:

- Identification of Stakeholders
- Initiation of stakeholder interactions at the regional and national level
- Sensitization of Stake holders and users towards Environmental Concerns
- Ensuring participation of key stakeholders – Industry/ Industry Associations, NGOs, Research Institutions, Concerned Ministries/ Departments, Defense, Space Research, Shipping, Indian Railways etc.



ESTABLISHING SUPPLY AND DEMAND SCENARIOS

ACTIONS:

- Carrying out Surveys and Reach-out Workshops at National and Regional levels
- Collection of data on HCFC production and consumption for the strategy year
- Establishing the overall growth rates of HCFCs consumption commensurate with National GDP and Economic growth
- Estimation of unconstrained HCFC consumptions demand in the country ascertaining that all the applications are on board
- Developing Demand and Supply Scenarios



SECTOR SPECIFIC STRATEGY

ACTIONS:


- Formation of Sector Specific Strategy Groups : Industry Association (s), User Organizations, Research Institutions and other stakeholders
- Identification of Applications Addressing the Sector & Sub-Sectors
- Establishment of sector-wise/ and/or sub-sector-wise growth rates
- Estimation of sector-specific consumption for the freeze year
- Assessment of application specific, energy efficient economically viable alternative technologies
- Assessment of technology transfer through MLF
- Information dissemination on alternative technologies through Sector Specific national/regional level workshops/conferences



INDIVIDUAL INDUSTRY SPECIFIC PROJECTS PREPERATION

ACTIONS:

- Prioritization of the sub-sectors for Stage-I Phase-out targets
- Identification of eligible enterprises for MLF Assistance in various sub-sectors
- Creation interest among the industry partners through awareness to convert their manufacturing facilities to non-ODS at an early stage
- Technical assistance for project preparation through International/National experts
- Review and endorsement by MoEF, Govt. of India
- Monitoring of implementation of enterprise level projects to achieve the desired ODS reduction impacts
- Review of the strategy at regular intervals



SECTOR PHASE-OUT PLAN FOR SMALL AND MEDIUM ENTERPRISES

ACTIONS:

- Strategy for Reach-out to the Small/Medium Sector
- Identification of clusters of enterprises and assessment of their needs related to phase-out of HCFCs
- Demonstration of proven and adaptable Application Specific Alternative non-ODS technologies
- Development of Application Specific Group Projects with the help of International/National Experts
- Technical and Financial Assistance through MLF funding mechanism for Conversion of manufacturing facilities and Operational Costs
- Implementation and Monitoring of Time-bound Conversion Projects



REFRIGERATION AND FOAM MANUFACTURING PHASE-OUT OF PLAN

ACTIONS:

- Identification of small/tiny Informal Sector enterprises engaged in Refrigeration and foaming manufacturing operations
- Assessment of equipment and technical assistance needs to convert their operations from HCFCs to non-ODS technologies
- Project preparation in association with enterprises
- Implementation and monitoring



SERVICING SECTOR PHASE-OUT PLAN

ACTIONS:

- National survey for identification of refrigeration and air-conditioning servicing enterprises and technicians employed
- Assessment of training and equipment needs of refrigeration servicing enterprises
- Up-gradation of existing training network set-up under National CFC Phase-out Plan (NCCoPP) to cater to the needs of HCFC phase-out
- Developing strategy for providing training to minimize the use of HCFCs and adoption of alternative technologies
- Implementation and monitoring of servicing sector plan



PRODUCTION SECTOR PHASE-OUT PLAN

ACTIONS:

- Estimation of Base Line and Freeze Year HCFC-22 production
- Amendment of ODS regulations to align to the needs of Phase-out schedule as mentioned under “ National policy instruments”
- Establish link between Production and Consumption Sector Phase-out schedules
- Seeking MLF funding for HCFC swing production plants Closure
- Implementation and monitoring of production phase-out sector plan



INITIATIVES AND ACTIONS FOR MEETING THE STAGE-II PHASE-OUT TARGETS



UPDATING HCFC PHASE-OUT STRATEGY

ACTION :

- Review of Initiatives and Actions on based Lessons learned and modify/adjust them to cater needs of Stage-II phase-out targets:2020,2025 and complete phase-out in 2030 in consultation with Stake-holders.



OZONE DEPLETING SUBSTANCES (Regulation and Control) Rules 2000

- Production and consumption control
- Ban on trade with non-Parties
- Trade of ODS is regulated
- Ban on creation of new capacity/ expansion of ODS based industry
- Mandatory registration for production, sale and use of ODS
- Mandatory registration of manufacturer, importer and exporter of Compressors
- Registration for recycling, recovery and destruction of ODS Authorities and procedures for registration are defined.



IMPORTANT PROVISIONS

- Use of CFCs in manufacturing various products beyond 1.1.2003 is prohibited except in Metered Dose Inhaler (MDI) and for other medical purposes.
- Use of halons is prohibited after 1.1.2001 except for servicing and essential use.
- Import and Export of ODS are subject to License issued by the Directorate General of Foreign Trade (DGFT) with consent from MOEF.
- Registration of enterprises using ODS has been extended upto 31.12.2009.
- Import of CFCs are banned from 18.09.2007.



THANK YOU