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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fifty-fifth Meeting
Bangkok, 14-18 July 2008

PROJECT PROPOSALS: CHINA

This document consists of the comments and recommendations of the Fund Secretariat on the following project proposals:

Aerosol

Sector plan for phase-out of CFCs consumption in MDI sector	UNIDO

Fumigant

National phase-out of methyl bromide (phase II, third tranche)	Italy and UNIDO

Process agent

• Sector plan for phase-out of ODS process agent applications (phase II) and corresponding CTC production: 2008 annual programme	World Bank

Production

• Sector plan for phase-out of methyl bromide production: work programme covering 2008-2010 (phase II)	UNIDO

PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT
CHINA

PROJECT TITLE	BILATERAL/IMPLEMENTING AGENCY
Sector Plan for Phase-out of CFCs Consumption in MDI Sector	UNIDO

NATIONAL CO-ORDINATING AGENCY	Ministry of Environment Protection (MEP) State Food and Drug Administration (SFDA)

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2006AS OF OCTOBER 2007)

CFC	12,414.9		

B: COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES, 2006, AS OF OCTOBER 2007)

ODS	Aerosol	MDI			
CFC-11	98.9	46.0			
CFC-12	370.0	276.5			
CFC-114					
Total	468.9	322.5			

CFC consumption remaining eligible for funding (ODP tonnes)	423.2

CURRENT YEAR BUSINESS PLAN ALLOCATIONS	Funding US $	Phase-out ODP tonnes
	13,000,000	250

PROJECT TITLE:	
ODS use at enterprise (ODP tonnes):	340.5
ODS to be phased out (ODP tonnes):	322.5
ODS to be phased in (ODP tonnes):	n/a
Project duration (months):	40
Initial amount requested (US $):	18,850,502
Final project costs (US $):	
Incremental Capital Cost:	16,299,000
Contingency (10 %):	420,400
Incremental Operating Cost:	1,989,502
Total Project Cost:	
Local ownership (%):	100
Export component (%):	None
Requested grant (US $):	18,708,902
Cost-effectiveness (US $/kg):	58.01
Implementing agency support cost (US $):	1,403,168
Total cost of project to Multilateral Fund (US $):	20,112,070
Status of counterpart funding (Y/N):	Y
Project monitoring milestones included (Y/N):	Y

SECRETARIAT'S RECOMMENDATION	For individual consideration

PROJECT DESCRIPTION

1. On behalf of the Government of the People's Republic of China (China), UNIDO has submitted a sector plan to phase-out 322.5 ODP tonnes of CFCs used in the manufacture of metered dose inhalers (MDI Sector Plan) for consideration by the Executive Committee at its 55th Meeting. The total cost of the project, as submitted, is US $18,850,502 plus agency support costs of US $1,413,788 for UNIDO. Once this project is approved, there will be no more CFC consumption eligible for funding for China.

Background

2. At its 53rd Meeting, on behalf of the Government of China, UNIDO submitted a sector plan to phase-out 280.9 ODP tonnes of CFCs used in the manufacture of MDIs, at a total cost of US $22,316,189 plus agency support costs of US $1,673,714. An informal contact group was established by the Committee to discuss issues concerning the high costs of the MDI Sector Plan, the fact that several MDI plants had begun production as late as 2006, and the fact that the Government of China could still apply for critical-use exemptions in the future. Following deliberations, the Executive Committee deferred consideration of the project proposal until the 54th Meeting and requested the Government of China and UNIDO to take into consideration industrial rationalization and cost-effectiveness when resubmitting a revised project proposal **(**decision 53/23**).**

3. The MDI Sector Plan that has only been re-submitted to the 55th Meeting addressed the issues previously raised by the Executive Committee. Taking into consideration the complexity of the project proposal, and to facilitate its consideration by the Executive Committee, the Secretariat has prepared this document on the basis of that submitted to the 53rd Meeting (UNEP/OzL.Pro/ExCom/53/28). This document consists of the following sections:

(a) Project summary, providing a brief explanation of the activities undertaken by UNIDO in addressing the issues raised by the Committee at its 53rd Meeting (i.e., CFC consumption, production of DPIs, industrial rationalization, and capital and operating costs);

(b) Analysis of the MDI production facilities, taking into consideration the additional and/or revised information gathered by UNIDO (i.e., an updated version of paragraph 6 of the document ExCom/53/28);

(c) CFC requirement for MDI production post 2009;

(d) Selection of alternative technologies;

(e) Technical assistance activities;

(f) Capital and operating costs;

(g) Cost-effectiveness, and

(h) A proposal by the Secretariat.

Project summary

4. According to the MDI Sector Plan, there are 38 MDI manufacturing plants in China, with 104 production licenses. Sixteen manufacturing plants with 36 licenses have reported production in 2007[1] while 18 plants have not reported production for that year. The remaining five plants are owned by multinational corporations (one of which ceased production in 2005).

5. In the revised MDI Sector Plan, UNIDO has addressed the issues that were raised by the Executive Committee at its 53rd Meeting, as follows:

(a) CFC consumption: Based on the additional information gathered by UNIDO through site visits and a review of invoices and reports on production, sales and inventories, the level of CFC consumption used for the production of MDIs has increased from 280.9 ODP tonnes to 341.0 ODP tonnes, of which 322.5 ODP tonnes are eligible for funding;

(b) Dry powder inhalers (DPIs): The State Food and Drug Administration has considered the feasibility of starting production of DPIs at one or more of the MDI manufacturing plant and concluded that, at present, this option is not feasible for the following reasons: a new registration process has to be applied for DPIs; production of DPIs require new production lines that would need to be purchased and installed; dosing units would need to be imported, and installation of a plant to manufacture dosing units would require substantial resources and involves patent rights; the current price of the DPIs on the market in China is about five times more than MDIs; and a foreign company is establishing a DPI manufacturing facility in China to address the available niche market for DPIs (there seems to be no place on the market for another new DPI producer).

(c) Industrial rationalization: Taking into consideration that there are no legal instruments in China to enforce closure or consolidation of enterprises, industrial rationalization in the MDI sector is proposed through payment of incentives for 44 of the total 77 production licenses:

(i) For manufacturing plants without baseline-year production, US $20,000 will be paid per available license, as partial compensation for giving up their production license; and

(ii) For the plants with very low baseline-year production (less than 5 ODP tonnes of CFCs), US $20,000 will be paid per available license as partial compensation for registering or abandoning their production licenses, and an additional US $50,000 will be paid for either destruction of equipment and abandoning production or as a one time contribution to the capital and operating costs.

(iii) The Government of China and UNIDO are of the opinion that, using this approach, industrial rationalization will be achieved through market forces as some MDI manufacturing plants could face difficulties in the future to

[1] The 16 enterprises hold an additional 22 licenses without production.

raise funds for the conversion of their CFC-based production lines and would have to consider giving up as independent MDI manufacturers. Other plants could decide to pay the cost of the conversion of their production lines through other funding sources outside the Fund. This will lead to the production of MDIs in the country at a lower number of plants with larger capacity and with higher economic and technical viability. The proposed approach is also aimed at improving the cost-effectiveness of the sector plan in response to decision 53/23 of the Executive Committee.

(d) Capital and operating costs: The capital and operating costs of the MDI sector have been estimated as follows:

(i) Capital costs have been calculated according to the level of CFC consumption at the plant level: US $50,000 per production line for plants with an annual CFC consumption below 5 ODP tonnes (10 plants); US $200,000 for production lines with an annual CFC consumption between 5 and 50 ODP tonnes (2 plants); US$ 680,000 for production lines with an annual CFC consumption between 50 and 100 ODP tonnes (3 plants); and US $1,320,000 for one plant with an annual consumption above 100 ODP tonnes;

(ii) Costs for acquisition of patents will be paid partially, mainly to large manufacturing plants, while small plants would receive very limited or no compensation from the Fund;

(iii) Operating savings have been calculated over a one-year period.

6. After taking into account the above points, the total cost of the revised MDI Sector Plan is US $18,850,502, which is US $3,465,687 less than the total cost of the project submitted to the 53rd Meeting, as shown in Table 1 below:

Table 1. Summary of the total cost of the MDI Sector Plan for China

Cost item	**Total cost (US $)**		
	55th Meeting	**53rd Meeting**	**Difference**
Technical assistance	1,100,000	1,100,000	-
Patent cost	2,600,000	-	(2,600,000)
Dossier for licenses in production in 2007 (*)	6,435,000	7,020,000	585,000
Dossier for licenses not in production in 2007	880,000	3,485,000	2,605,000
Plant modifications of existing facilities	4,260,000	5,560,000	1,300,000
Production validation (per production line)	720,000	680,000	(40,000)
Training programme (per production line)	440,000	412,500	(27,500)
Operating cost	1,989,502	3,502,689	1,513,187
Contingency	426,000	556,000	130,000
Total	**18,850,502**	**22,316,189**	**3,465,687**

(*) Includes study of production process, study of quality, pharmacological study, toxicological study, special safety test and clinical test.

7. A copy of the MDI Sector Plan as submitted by UNIDO is attached to the present document.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

Analysis of the MDI production facilities

8. In reviewing the information presented in the MDI Sector Plan, the Secretariat noted as follows:

(a) CFC consumption for the production of MDIs increased from 152.1 ODP tonnes in 2004 to 340.5 ODP tonnes in 2007. Doctors are now using MDIs more frequently to treat patients with asthma and chronic obstructive pulmonary disease (COPD), instead of traditional treatments;

(b) Seven MDI manufacturing plants are also producing pharmaceutical aerosols in China.[2] Some of these plants have received funding for the conversion of pharmaceutical aerosol production lines to non-CFC propellant, for technical assistance, and for training programmes. These plants have different production lines and licenses for MDIs;

(c) Three transnational corporations[3] have been producing MDIs over the last three years, as shown in Table 2 below. No capital and operating costs are being requested for the conversion of these plants:

Table 2. Production of MDIs by multinational corporations

No.	Company name	Product	Active ingredient	CFC 2005 (kg)	CFC 2006 (kg)	CFC 2007 (kg)
1	AstraZeneca Pharmaceutical	B04	Budesonide	3,494.0	4,538.0	
1	AstraZeneca Pharmaceutical	B13	Terbutaline sulfate	7,460.0	8,665.0	
3	Beijing Shengdelaibao Pharmaceutical	B15	Salbutamol	745.9		730.0
3	Beijing Shengdelaibao Pharmaceutical	B01	Beclometasone dipropionate	180.3		
31	Weifang Zhongshi Pharmacy	B01	Beclometasone dipropionate	-	-	57.0
31	Weifang Zhongshi Pharmacy	B15	Salbutamol	1,350.0	900.0	597.0
31	Weifang Zhongshi Pharmacy	B16	Salbutamol (suspension)	-	-	70.7
Total				**13,230.2**	**14,103.0**	**1,454.7**

UNIDO indicated that the funding level requested for the above-mentioned plants had taken into consideration their low levels of production.

[2] The seven plants are: Beijing Haiderun Pharmaceutical (No. 2); Guangzhou Dongkang Pharmaceutical (No.8); Guiyang Dechangxiang Pharmaceutical (No. 9); Heilongjiang Tanglong Pharmaceutical (No. 16); Penglai Nuokang Pharmaceutical (No. 19); Shanghai Pharmaceutical Group (No. 28); and Wuxi Shanhe Group (No. 32).

[3] An additional multinational corporation, GlaxoSmithKlein, stopped producing CFC-based beclomethasone MDI from 2005.

(d) Three manufacturing plants started production of MDIs only in 2006 with a major reduction in production in 2007, as shown in Table 3 below:

Table 3. MDI manufacturing plants that started production only in 2006

No.	Company name	Product	Active ingredient	CFC2006 (kg)	CFC 2007 (kg)
2	Beijing Haiderun Pharmaceutical[4]	B15	Salbutamol	6,424.0	214.0
2	Beijing Haiderun Pharmaceutical	B22	Isoprenaline hydrochloride	2,915.0	-
2	Beijing Haiderun Pharmaceutical	B23	Iprartropium bromide	27.0	325.0
14	Henan Xinxin Pharmaceutical[5]	B11	Huashanshen	300.0	-
38	Jiangsu Tianji Pharmaceutical	B12	Ribavirin spray	4,202.0	-
Total				**13,868.0**	**539.0**

(e) In 5 manufacturing plants, several MDIs were produced for the first time in 2007, or restarted production in 2007 after several years without, as shown in Table 4 below. Some of the plants were already producing other MDIs in China:

Table 4. MDIs produced only in 2007 by established manufacturing plants

No.	Company name	Product	Active ingredient	CFC 2007 (kg)
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B14	Sodium cromoglicate	127.0
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B22	Isoprenaline hydrochloride	30.0
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B04	Budesonide	70.0
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.	B01	Beclometasone dipropionate	57.0
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.	B16	Salbutamol (suspension)	70.7
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B15	Salbutamol	3,200.0
35	Guandong Tongde Pharmaceutical Co., Ltd.	B15	Salbutamol	3,420.0
35	Guandong Tongde Pharmaceutical Co., Ltd.	B16	Salbutamol (suspension)	2,650.0
Total				**9,624.7**

UNIDO indicated that the funding level requested for the above-mentioned plants had taken into consideration their low levels of production.

(f) There are only 13 different active ingredients in MDIs that are currently produced in China, as shown in Table 5 below.[6] It should be noted that:

(i) The total production of MDIs with beclomethasone (B01), terbutaline sulphate (B13), sodium cromoglicate (B14), salbutamol - both in solution (B15) and suspension (B16), and isoprenaline (B22) represents more than 97 per cent of total production in 2007. These five active ingredients play a very important therapeutic role in the treatment of asthma and COPD;

[4] Due to environmental issues, in 1999 the plant was relocated to a new site; Trial production of CFC-MDIs started in the second half of 2005 with full production in 2006. CFCs consumption ranged between 3,567 kg and 4,459 kg between 1996 and 1998.

[5] The plant consumed 300 kg and 150 kg CFCs in 2001 and 2003 for the manufacturing of product B11.

[6] UNIDO indicated that 100,000 iprartropium MDIs (B23) were produced in 1997 with a total CFC consumption of 1,414 kg; huashanshen MDIs (B11) were produced in 2001 (32,000 MDIs) and 2003 (16,000 MDIs); the license for ketotifen fumarate MDI (B09) was approved in 1995, however there is no information on the production levels before 2004; salbutamol sulphate MDI (B25) is a newly approved application.

(ii) Total CFC consumption of seven different active ingredients in MDIs represents less than 3.0 per cent of total consumption (i.e., budesonide (B04), dimethicone (B05), ketotifun fumarate (B09), ribavirin (B12), salmeterol xinafoate (B17), iprartropium bromide (B23) and zhichuanling (B24)); and

(iii) MDIs containing ketotifen fumarate (B09), salmeterol xinafoate (B17) and iprartropium bromide (B23) commenced production only in 2006, with a total CFC consumption of 1,308.0 kg (this consumption increased to 1,606 kg in 2007).

Table 5. Active ingredients in MDIs currently manufactured in China

Product	Active ingredient	CFC consumption (kg)			% CFC*
		2005	2006	2007	
B17	Salmeterol xinafoate		10.0	10.0	0.00%
B05	Dimethicone	22.2	70.0	100.0	0.03%
B24	Zhichuanling	30.0	130.8	320.0	0.09%
B23	Iprartropium bromide	-	27.0	325.0	0.10%
B09	Ketotifun fumarate	-	1,271.0	1,271.0	0.37%
B12	Ribavirin	1,851.0	7,395.0	3,443.0	1.01%
B04	Budesonide	6,273.5	8,037.0	4,069.0	1.20%
B14	Sodium cromoglicate	6,902.0	7,541.5	13,591.0	3.99%
B13	Terbutaline sulfate	7,460.0	8,665.0	16,612.7	4.88%
B22	Isoprenaline hydrochloride	40,647.2	47,324.0	43,452.0	12.76%
B01	Beclometasone dipropionate	16,796.6	23,048.0	59,954.0	17.61%
B15	Salbutamol (solution)	69,905.3	91,650.0	85,378.0	25.07%
B16	Salbutamol (suspension)	93,793.1	85,396.2	111,968.7	32.88%
Total		**243,680.9**	**280,565.5**	**340,494.4**	**100.0%**

(*) Percentage of the total CFC consumption in 2007.

CFC requirements for MDI production post 2009

9. UNIDO has further discussed the issue of potential essential use exemptions for CFCs with the Government of China. When this issue was first raised by the Secretariat, UNIDO indicated that "the conversion of MDI production lines is planned to be partially completed by end of 2010 if the sector plan will be approved on 53rd ExCom. Due to the difficulties of conversion in this sector, some lines probably will not be possible to be converted by end of 2010. For the transitional period the stockpile which is currently being accumulated will be used. In order to protect the ozone layer, China is currently not planning to apply the essential use exemption". This situation has now changed. According to the revised MDI Sector Plan, CFC consumption will increase annually from 341 ODP tonnes in 2007 to a maximum level of 748.3 ODP tonnes in 2011 and then will decrease annually achieving the complete phase-out by 2014. The total cumulative CFC consumption between 2008 and 2014 amounts to 3,332.3 ODP tonnes. In explaining the reasons for the need for continued consumption up to 2014, UNIDO pointed to current patent situation and the reluctance of technology owners to provide technical assistance on affordable terms to China led the Government and UNIDO to believe that the phase-out schedule previously proposed was too ambitious and could not be implemented.

10. According to the CFC production closure agreement between the Government of China and the Executive Committee, a total of 1,100 ODP tonnes of CFCs could be produced in 2008 and 2009[7]. To address the remaining CFC requirements of 2,232.3 ODP tonnes, the Government is proposing an amendment to the current production agreement.

11. According to the MDI Sector Plan, CFC consumption will experience unconstrained growth between 2007 and 2011. Only in 2012 will project implementation result in a reduction of some 100 ODP tonnes from the previous year's consumption. However, considering that reformulation to HFA-134a propellant for MDIs with beclamethasone and salbutamol as active ingredients is well know, it could be expected that conversion of at least these two MDIs, representing more than 75 per cent of total CFC consumption in China, could have been done at an earlier stage, assuming that the project is approved at the 55th Meeting. If this is the case, the amount of CFCs that might be needed from 2010 could be substantially reduced. UNIDO responded by indicating that issues such as the limited availability of technology providers and the increasing demand for MDIs could reduce the pace of the implementation of the project. However, UNIDO is planning to start the conversion of MDIs with those active ingredients first, with a possible completion date of 2011. However, further reduction of the need for CFCs after 2010 phase-out cannot be proposed at this stage, although it will be pursued during the implementation process.

Selection of alternative technologies

12. According to the MDI Sector Plan, all CFC-MDIs could be converted to HFA propellant. In the proposal, it is reported that "many issues still have to be resolved for introduction of hydrofluoroalkane as propellants for MDIs". When this issue was first raised, UNIDO indicated that "the main issue is related to patent rights. As mentioned in the proposal, the patents valid in China cover almost all the MDIs using HFA as propellant. Other manufacturing plants have not yet finalized their studies of the technologies to be selected to replace CFCs". UNIDO stated that since the MDI Sector Plan was first submitted, MDI manufacturing plants in China have realized the urgency of phasing out their CFC consumption. Accordingly, most of the enterprises started research on the issues associated with the phase-out of CFCs in this sector.

Technical assistance activities

13. The Secretariat pointed out that although the cost for preparation of technical dossiers for licenses not in production has been reduced from US $85,000 (requested in the proposal submitted to the 53rd Meeting) to US $20,000, the total funding request for non-investment type activities, amounting to US $11.735 million, is very high. This amount consists of:

(a) US $7.315 million for the preparation of technical dossiers for registration of 80 products: 33 that were in production in 2007 (at US $195,000/product), and 44[8] that were not produced in 2007 (at US $20,000/product);

(b) US $1.1 million for technical assistance such as workshops, training programmes, public awareness, consultants, study tours, legislative support activities, auditing

[7] Under the agreement between the Government of China and the Executive Committee for the CFCs/CTC/halon accelerated phase-out plan, China could export 100 ODP tonnes of CFCs in 2008 and 50 ODP tonnes in 2009.
[8] Three of the 44 products will be abandoned in the near future.

CFC consumption for pharmaceutical aerosol manufacturers, development of a management information system and several other technical assistance activities;

(c) US $40,000 for each of the 18 production lines for validation of equipment, production process and other costs for a total of US $720,000; and

(d) US $2.6 million as a limited patent cost compensation. It is to be noted that this request was not included in the MDI Sector Plan submitted to the 53rd Meeting.

Capital and operating costs

14. The MDI Sector Plan project is proposing funding for the conversion of 16 manufacturing plants with current production of CFC-MDIs. A similar replacement production line has been proposed for all manufacturing plants irrespective of the baseline production equipment and installed capacity at each manufacturing plant. Except for the largest manufacturing plant (plant No. 21), the funding being proposed would result in a capacity increase from current capacity levels. Specifically,

(a) There are seven plants with an annual CFC consumption of 0.55 ODP tonnes (plants No. 2, 9, 11, 16, 22, 25 and 37) and three additional plants with a consumption below 4.2 ODP tonnes (plants No. 8, 24, 32). Each one of these plants would receive US $50,000;

(b) Two plants with annual CFC consumption between 6.1 and 9.8 ODP tonnes (plants No. 35 and 36) would receive US $200,000 each;

(c) Two plants with consumption between 21.7 and 26.1 ODP tonnes (plants 19 and 28) and one additional plant with a consumption of 73.3 ODP tonnes (plan No. 18), would receive US$ 680,000, each; and

(d) One plant with an annual CFC consumption of 175.2 ODP tonnes (plant No. 21), would receive US $1,320,000.

15. The Secretariat also indicated that although incremental operating costs have been reduced from US $3,502,689 (US $12.47/kg) to US $1,989,502 (US $7.08/kg), they are still much higher than operating costs for the MDI projects that have already been approved for Bangladesh (US $4.06/kg), Egypt (US $5.64), Iran (US $3.59/kg) and Mexico (US $2.70/kg).

16. UNIDO indicated that even the MDI manufacturing plants with very low production output in the baseline year have a relatively large installed capacity (i.e., 5 to 8 million cans/year), which has not been fully utilized due to market reasons. However, minimal funding is being requested for those plants, as an incentive to close production and destroy the equipment. In order to decrease the total funding level, the operating costs were reduced from US $3.5 million to less than US $2 million. The price of valves used in calculating the operating costs has been estimated assuming that the price could be reduced in the future when the valves are locally produced and the production volume reaches a reasonable level.

Cost-effectiveness

17. As in the previous submission of the MDI Sector Plan, the Secretariat undertook a more detailed review of the proposal. For this purpose, the Secretariat developed a table associating each unitary cost proposed in the Plan to each of the 16 manufacturing plants currently in operation. In this analysis, total requests for technical assistance (US $1,100,000) and for patents (US $2,600,000) were divided by the total amount of CFCs to be phased out and pro-rated among the 16 plants currently producing on the basis of their 2007 CFC consumption.

18. Based on this analysis, the Secretariat has the following additional observations:

(a) The overall cost-effectiveness (CE) of the project as submitted is US $58.46/kg, based on a CFC consumption of 322.475 ODP tonnes. The overall CE of the MDI Sector Plan is more than US $20.00/kg over the CE of already approved MDI projects for Bangladesh (US $38.08/kg); Iran (US $36.61/kg), Egypt (US $36.36/kg) and Mexico (US $37.75/kg);

(b) The Secretariat is aware that a CE threshold for projects in the MDI sub-sector has not been established by the Executive Committee. However, the Secretariat is correlating the calculated CE at the plant level with the potential sustainability of the manufacturing plants. On this basis, it is noted that:

(i) The most cost-effective enterprises are the two largest producer of MDIs in China (Plants No. 18 and 21), with a CE of US $32.93/kg and US $26.76/kg, respectively. The combined production of these two plants represents 74 per cent of the total MDIs produced in China and 77 per cent of total CFC consumption in the MDI sector in China;

(ii) Three manufacturing plants (plants No. 19, 28 and 35) have a CE value between US $67/kg and US $99/kg; six plants have a CE value between US $178/kg and US $788/kg (plants No. 2, 8, 11, 24, 32 and 36); three plants have a CE value between US $1,128/kg and US $1,619/kg (plants No. 9, 16 and 25); and two plants have a CE value between US $5,140/kg and US $5,145/kg (plants No. 22 and 37). Based on these values, the long term sustainability of these enterprises is in doubt;

(iii) US $880,000 associated with technical dossier for registration for MDI with a license but not producing in 2007 has not been distributed among the plants that are currently manufacturing MDIs in China.

UNIDO indicated that those MDI manufacturing plants with very high C/E (absolute value) will be encouraged to close their MDI activities through the approach proposed in the MDI Sector Plan.

Proposal by the Secretariat

19. Based on the issues raised and observations made by the Secretariat in reviewing the MDI Sector Plan re-submitted by UNIDO, the request for funding of several project items where eligibility is in doubt, and on the basis of the experience that has been gained in the Multilateral Fund in the MDI sector, the Secretariat proposed to UNIDO the following alternative methodology for determining the incremental cost of the MDI Sector Plan for China. This methodology, which is consistent with the current policies and guidelines of the Multilateral Fund, could only be adopted if the relevant issues raised by the Secretariat were fully addressed.

Transition strategy

20. The MDI Sector Plan developed by the Government of China has identified several key elements that would allow for the transition from CFC to non-CFC alternatives in the MDI sector. These elements include the review and enforcement of policies and regulations governing the sector; consideration of the request for essential use exemptions beyond the 2010 phase-out date; policies related to CFC phase-out, the management of pharmaceutical grade CFC stocks if needed and the adaptation of the ODS licensing system to control CFC consumption in the MDI sector; further consideration of the development of a plan for the industrial rationalization; education campaigns for major stakeholders; and public awareness and information dissemination. Considering the number of manufacturing plants and the number of active ingredients in MDIs, the cost of the transition strategy would be US $300,000.

Product development

21. From the information included in the MDI Sector Plan and the limited information available in published literature on several of the active ingredients, it is not clear whether or not these ingredients are sold as pharmaceutical aerosols or MDIs in China. These active ingredients include ribavirin, dimethicone, ketotifen, isoprenaline, huashanshen and zhichuanling.

22. Of the 13 active ingredients in MDIs currently manufactured in China, four ingredients play a very important therapeutic role in the treatment of asthma and COPD. These ingredients are sodium cromoglicate, beclomethasone dipropionate, isoprenaline hydrochloride, and salbutamol in suspension and in solution. The total production of these MDIs represents more than 97 per cent of the total current CFC consumption in China (as shown in Table 5 above)

23. In order to determine the cost for the development of HFA MDIs, a total of US $2,400,000 is being proposed for sodium cromoglicate, beclomethasone dipropionate, isoprenaline hydrochloride (i.e., US $800,000 per active ingredient similarly to the levels approved for Egypt and Iran). An additional US $1,200,000 is being proposed for the development of salbutamol in both solution and suspension presentations. The terms of reference for the development of the HFA MDIs could be similar to those developed by UNIDO for the Egypt and Iran project proposals.

24. For addressing the remaining nine active ingredients (representing less than 3 per cent of the total CFC consumption for the production of MDIs), US $600,000 is being proposed as technical assistance calculated on the basis of the current CFC-12 price of US $3.43/kg and the current CFC consumption of 9,540 kg over a six-year period, when CFCs for MDI production will be completely phased out.

25. The total cost associated with the development of the HFA technology would be US $4,200,000.

Capital and operating costs

26. The Secretariat proposed the following level of funding for the conversion of 16 manufacturing plants with current production of CFC-MDIs:

(a) US $50,000 for each of the 12 production facilities with CFC consumption below 10 ODP tonnes. This cost is estimated on the basis of a new production line at about US $30,000 plus an additional US $20,000 for a small pressure tank required for the use of HFA propellant;

(b) US $400,000 for each of the three facilities with CFC consumption between 20 and 100 ODP tonnes. This cost is based on a recent quotation of a new complete production line that was included in the MDI project for Egypt;

(c) US $2,000,000 for the only plant with a CFC consumption of more than 100 ODP tonnes. This cost is based on costs of the production lines in the MDI projects for Egypt, Iran and Mexico;

(d) Therefore, the total capital cost associated with the conversion of eligible enterprises amounts to US $4,180,000 including a 10 per cent contingency.

27. The operating costs are calculated on the basis of a total CFC consumption of 322,475 kg and US $4.43/kg (representing the average value of operating costs approved for Bangladesh, Egypt and Iran). The resulting operating costs amount to US $1,430,000.

Project implementation and monitoring unit

28. In order to facilitate the transition from CFC to HFA propellant in the MDI sector in China, and taking into consideration the number of different active ingredients in MDIs produced by several plants geographically distributed throughout the country, the Secretariat proposed the establishment of a project implementation and monitoring unit at a total cost of US $2,380,000, that would be responsible for, among other things:

(a) Assisting in the preparation of 32 technical dossiers (at US $20,000 each) for the active ingredients currently being produced at the 16 manufacturing plants (the total cost for this activity is US $640,000);

(b) Validating the 16 manufacturing plants that are still producing (at US $30,000 per plant). The main activities include validation of workshops, of facility and equipment installation, of facility operation and performance, and products (the total cost for this activity is US $480,000);

(c) Training the relevant staff at the manufacturing plants. This training is in addition to the technical training that will be provided by the equipment supplier and included as part of the capital costs (the training cost is US $420,000 estimated at 10 per cent of the capital cost); and

(d) Monitoring, including the development of relevant management, monitoring and verification systems, as well as the management of stockpiles, if necessary. The cost of this activity is US $840,000 estimated at 20 per cent of the capital cost.

Funding summary

29. The total level of funding proposed for the complete phase-out of CFCs in the MDI sector in China is US $12,490,000 with the following distribution:

Transition strategy	US $300,000
Product development	US $4,200,000
Capital costs	US $4,180,000
Operating costs	US $1,430,000
Project implementation and monitoring unit	US $2,380,000

30. The Government of China will have flexibility in utilizing the funding available under the MDI Sector Plan for activities it deems adequate to achieve the complete phase-out of CFCs in the MDI sector and in accordance with relevant decisions and guidelines of the Multilateral Fund.

31. UNIDO responded to the above proposal that there are many manufacturing plants in China producing MDIs with several different active ingredients, while MDIs are manufactured in a very limited number of enterprises (one or two) in Article 5 countries with an approved phase-out project. For small and medium sized enterprises, each kind of product and license is a major asset of the enterprise. These issues and the specific situation of China have been taken into consideration in the preparation of the MDI Sector Plan. Therefore, assessing the project on its CE value would be misleading.

32. Furthermore, UNIDO indicated that the revised MDI Sector Plan has demonstrated the actual cost of the activities required to phase out CFC consumption in the MDI sector. These costs have been based on a correct calculation methodology. Taking into consideration the Secretariat's proposal, the capital costs associated with plants that are manufacturing both MDI and non-MDI pharmaceutical aerosols have been reduced. The revised project proposed by UNIDO is presented in Table 6 below:

Table 6. Total revised cost of the MDI Sector Plan proposed by UNIDO

Cost item	Total cost (US $)		
	55th ExCom	53rd ExCom	Difference
Technical assistance	1,100,000	1,100,000	-
Patent cost	2,600,000		(2,600,000)
Dossier for licenses in production in 2007	6,435,000	7,020,000	585,000
Dossier for licenses not in production in 2007	880,000	3,485,000	2,605,000
Plant modifications of existing facilities	4,204,000	5,560,000	1,356,000
Production validation (per production line)	640,000	680,000	40,000
Training programme (per production line)	440,000	412,500	(27,500)
Operating cost	1,989,502	3,502,689	1,513,187
Contingency	420,400	556,000	135,600
Total	**18,708,902**	**22,316,189**	**3,607,287**

33. The Secretariat notes that the revised project cost is US $3,607,287 less than as first submitted to the 53rd Meeting of the Executive Committee. The Secretariat further noted that, on the basis of decision 41/80, the MDI Sector Plan for China should not have been submitted for consideration by the Executive Committee since no agreement has been reached with UNIDO on the level of funding. However, being aware that this is the last CFC phase-out plan for China, the complexity of the proposal, its major implications for potential requests for essential uses post 2010, and the additional assistance required by the Government of China to reduce its CFC consumption in order to achieve the complete phase-out of CFCs by 1 January 2010, the Secretariat is submitting the project for consideration by the Executive Committee.

RECOMMENDATION

34. The Executive Committee may wish to consider the MDI Sector Plan in light of the above comments and observations.

PROJECT EVALUATION SHEET – MULTI-YEAR PROJECTS

China

(I) PROJECT TITLE	AGENCY
Methyl bromide	Italy, UNIDO

(II) LATEST ARTICLE 7 DATA (ODP Tonnes)			Year: 2006	
CFC: 12414.9	CTC: 774.4	Halons: 161	MB: 300.4	TCA: 279.9

(III) LATEST COUNTRY PROGRAMME SECTORAL DATA (ODP Tonnes)						Year: 2006							
Substances	Aerosol	Foam	Halon	Refrigeration		Solvent	Process Agent	MDI	Lab Use	Methyl Bromide		Tobacco fluffing	Total Sector Consumption
				Manufacturing	Servicing					QPS	Non QPS		
CFC	468.8	6,318.6		493.8	3,287.			280.9				21.3	10,870.4
CTC							356.5		534.6				891.1
Halons			795.										795.
Methyl Bromide										568.2	310.		878.2
TCA						279.9							279.9

(IV) PROJECT DATA			2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total
Montreal Protocol Consumption Limits		MB	1,102.1	1,102.1	1,102.1	881.7	881.7	881.7	881.7	881.7	881.7	881.7	881.7	881.7	881.7	0.	
Maximum Allowable Consumption (ODP Tonnes)		MBR	1,087.8	1,087.8	1,087.8	880.	723.8	570.6	390.	250.	209.	176.	150.	100.	50.	0.	
Project Costs (US$)	UNIDO	Project Costs		4,086,600.				1,200,000.	1,800,000.	1,300,000.	600,000.	500,000.	500,000.	500,000.	302,742.		10,789,342.
		Support Costs		306,495.				90,000.	135,000.	97,500.	45,000.	37,500.	37,500.	37,500.	22,706.		809,201.
	Italy	Project Costs				4,000,000.											4,000,000.
		Support Costs				470,000.											470,000.
Total Funds Approved in Principle (US$)		Project Costs		4,086,600.		4,000,000.		1,200,000.	1,800,000.	1,300,000.	600,000.	500,000.	500,000.	500,000.	302,742.		14,789,342.
		Support Costs		306,495.		470,000.		90,000.	135,000.	97,500.	45,000.	37,500.	37,500.	37,500.	22,706.		1,279,201.
Total Funds Released by the ExCom (US$)		Project Costs		4,086,600.		4,000,000.		1,200,000.	0.	0.	0.	0.	0.	0.	0.		9,286,600.
		Support Costs		306,495.		470,000.		90,000.	0.	0.	0.	0.	0.	0.	0.		866,495.
Total Funds Requested for Current Year (US$)		Project Costs							**1,800,000.**								0.
		Support Costs							**135,000.**								0.

(V) SECRETARIAT'S RECOMMENDATION:	Blanket approval

PROJECT DESCRIPTION

35. On behalf of the Government of China, UNIDO has submitted a progress report on the implementation of the second tranche of phase II of the national methyl bromide (MB) phase-out plan for China, and the request for funding of the third tranche of the project (2008 work programme) at a cost of US $1,800,000 plus agency support costs of US $135,000 for UNIDO. The project is being implemented with assistance from the Government of Italy.

Background

36. At its 44th Meeting, the Executive Committee approved in principle the national plan for the phase-out of MB in the consumption sector in China at a total funding level of US $14,789,342 (including the amount previously approved for UNIDO at the 41st Meeting to phase out 389 ODP tonnes of MB). It also approved an Agreement between the Government of China and the Executive Committee (decision 44/30). Since then, the Executive Committee has approved the first two tranches of the project at a total value of US $5,200,000 plus support costs of US $560,000 (US $470,000) for the Government of Italy and UNIDO (US $90,000).

Progress report

37. As agreed with the Government of China, the second phase of the project focused on the phase-out of MB used for soil fumigation in the tobacco and agricultural (i.e., tomato, cucumber and strawberry crops) sectors and in the fumigation of commodities. The alternative technologies selected were the floating tray system for the tobacco sector, biological control of soil-borne pests for the agricultural sector, and phosphine fumigation for the commodities sector.

38. The following activities have been implemented in the tobacco sector: technical assistance programmes have been conducted, training materials and protocols have been developed and distributed, an expert technical group has been established, training program have been created for trainers and farmers, and greenhouses have been set up, equipped and upgraded. To complement the funding being provided through the Fund, the State Tobacco Monopoly Administration has invested an additional US $55 million on greenhouses, polystyrene trays and other auxiliary equipment for tobacco seedling production using the floating tray system.

39. In regard to the use of MB for soil fumigation, several training programmes on use of equipment and MB alternatives have been implemented in Italy, Spain and Japan. The work plan was approved only in September 2007, therefore, implementation of MB phase-out activities started with the 2008 crop season. In the commodities sector, technical assistance programmes were implemented including the development of phosphine fumigation protocols, training of trainers and warehouse operators, equipment procurement and installation, and the establishment of a long-term technical assistance and monitoring system. The MB consumption in commodities was completely phased out by the end of 2006.

40. The import and export licensing system has been in effect since 1 January 2004. A regulation for banning the use of MB commodity applications was issued in September 2006 and enforced from 1 January 2007. On 21 May 2007, a notice on the implementation of MB production licensing and quota system was issued. MB import and export is monitored by the "ODS Import and Export Management Office". Two new harmonized system codes for MB have

been added, making it possible to unmistakably identify all MB uses in the customs statistics and management. For MB production, the regulation for MB sales that was put in place in January 2008 requires that each one of the three producers of MB obtain and keep records of production licenses, fumigation certificates issued for QPS uses, delivery orders, transportation orders and application type.

41. Of the total funding level so far approved for China (US $9,286,600), UNIDO (as the lead implementing agency) has disbursed US $7,731,598 (excluding agency support costs). US $1,555,002 will be disbursed by UNIDO once relevant progress reports are submitted by different authorities in the Government of China.

2008 work programme

42. Although the use of MB has been phased out in the commodity sector (2006) and will also be phased out in the tobacco sector in 2008, several activities are still under current implementation. In the commodity sector these activities include the continued operation of the technical assistance and monitoring system that was established in 2006 to control the effective and safe use of phosphine, provide up-to-date support to technical and managerial staff, and monitors treatment costs vis-à-vis various alternatives. In the tobacco sector, these activities include the completion of the installation of greenhouses (proposed by August 2008) and implementation of a long-term technical assistance and training programme to keep technical staff up to date, consolidate the alternative technology and sustain the phase-out of MB.

43. For MB used as a soil fumigant, equipment and farm materials will be provided to farmers to phase out its consumption in various regions and several crops, mainly in strawberry, cucumber, tomato and ginger crops. Training programmes that commenced in 2007 will continue to be conducted for farmers in the proper use of the alternative technologies.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

44. The 2007 MB consumption estimated by the Government of China of 389.5 ODP tonnes was already 492.1 ODP tonnes below the Protocol's maximum allowable level of consumption for that year of 881.6 ODP tonnes, and 181.1 ODP tonnes below that allowed under the agreement between the Government of China and the Executive Committee of 570.6 ODP tonnes.

45. Considering the major reductions in MB consumption achieved so far, the Secretariat sought additional information on measures and/or mechanisms established by the Government of China to avoid reverting back to the use of MB, and also to avoid using MB imported/produced for quarantine and pre-shipment applications (i.e., non-controlled uses) for soil and/or commodities fumigations. UNIDO indicated that long-term technical assistance and monitoring systems have been established in the commodity and tobacco seedlings sectors, where MB has been completely phased-out, to ensure the sustainability of the alternative technologies implemented. Both the State Grain Administration and the State Tobacco Monopoly Administration, which are well-established and important national institutions, are committed to the phase-out of MB in their respective sectors. They have their own structure, administration

and financial resources, and have consistently contributed to the phase-out of MB. In regards to the agriculture sector, where MB phase-out activities have only commenced, in addition to the provision of equipment and technical assistance, the phase-out programme foresees the implementation of a long-term technical assistance and monitoring system to ensure the long-term sustainability of the alternatives technologies.

46. Noting the very large number of trays needed to implement the floating tray system in the tobacco sector in China, the Secretariat asked UNIDO whether the Government has considered purchasing a few machines for manufacturing trays *in situ*. UNIDO indicated that the State Tobacco Monopoly strictly controls tobacco seedlings and their production, and releases the tobacco production quota for each area. The local tobacco companies use the production quotas to prepare the planting plan, with the calculation of seedlings and trays required. On this basis, the tobacco companies launch a national bid to purchase the required trays on the market. The machines for manufacturing trays are purchased by factories. The technology to produce trays is quite simple, the price is low and the life of a common tray is three years, therefore the increased demand for trays would not affect their production at the factories.

RECOMMENDATION

47. The Fund Secretariat recommends blanket approval of the third tranche of the national phase-out of methyl bromide project with associated support costs at the funding level shown in the table below.

	Project Title	Project Funding (US $)	Support Costs (US $)	Implementing Agency
(a)	National phase-out of methyl bromide (phase II, third tranche)	1,800,000	135,000	UNIDO

VERIFICATION OF THE CONSUMPTION OF CTC AS A PROCESS AGENT IN 2007 OF THE CTC SECTOR PLAN (PHASE II)

Introduction

48. The World Bank is submitting to the 55th Meeting, on behalf of the Government of China, the request for the release of the 2008 funding tranche of US $10 million and US $750,000 as support cost for the implementation of the 2008 work programme under Phase II of the China CTC sector plan. The Executive Committee approved the 2008 work programme at its 53rd Meeting but withheld the funds until the World Bank would submit the verification of the CTC consumption in 2007 for Phase II of the sector plan. A summary of the verification report is provided below and the report itself could be made available upon request.

Verification of CTC consumption under phase II of the CTC sector plan in 2007

49. The verification was carried out in April-May 2008 by the same consultant who had been contracted by the World Bank for the verification in previous years. The team visited 15 CTC-consuming enterprises, which are covered under Phase II of the sector plan.

50. The consultant followed the following methodology in conducting the verification:

(a) Briefing by the plant management on plant history, plant identification, and plant activities on the production of products using CTC as process agents and CTC consumption/purchase in 2007, and in the case of plant closures activities on shutting down the CTC-related production;

(b) Verified CTC purchases by reviewing the purchase orders and CTC daily movement records into the plant warehouse;

(c) Verified CTC opening and closing stocks by checking the inventory records, including the amount of CTC stored in the plant warehouse and what remained in the production system;

(d) Verified CTC consumption on the basis of CTC purchase + CTC opening stock – CTC closing stock;

(e) Verified production and sales by reviewing daily production logs, product packaging/transfer slips and daily movement records in and out of the product warehouse;

(f) Verified the opening and closing stocks of products by reviewing the product inventories;

(g) Verified the number of operating days by reviewing the daily plant production logbooks;

(h) Made a cross check of financial records by reviewing all VAT invoices related to the CTC purchased in 2007; and

(i) Inspected the production site, or the dismantled site in those cases of plant closures, and took photographs.

51. The report on each of the companies visited includes a description of the history, its main product lines, and the product line which is the focus of the verification. The results of the verification are presented by showing the opening stock, purchase, consumption, other uses and closing stock of CTC in the plant for 2007, including products. The verification covers the number of days that are dedicated to the products concerned and the ratio of CTC consumption per unit of product manufactured. It concludes by presenting the issues and problems that came out of the visit, and the actual CTC purchased by the plant in 2007 and the CTC quota received from SEPA.

52. The field visits by the consultant conclude that the 15 enterprises purchased a total of 3,066.25 ODP tonnes of CTC against a total quota of 3,474.6 ODP tonnes issued by SEPA. A summary of the results of the verification of the 15 enterprises, with data on the name of the enterprise, products that use CTC, production, CTC purchase, CTC consumed, opening CTC stock and closing stock, and status of production line (operating or closed), is contained in Annex II of this document.

53. The submission from the World Bank includes three annexes: Annex I contains the 2007 PA II verification records and closure activities; Annex II contains the photographs from verification visits; and Annex III presents documentation from plant closures.

Comments from the Secretariat

54. The methodology provided for in the Agreement of Phase II of the CTC sector plan for conducting the verification of the CTC consumption requires that “the Bank will verify consumption by companies and applications covered by the PA II Sector Plan. The annual verification should cover a random selection of at least 30 per cent of all enterprises representing at least 30 per cent of the PA II consumption”. The results of the verification are set out in paragraph 5. The sampling of the verification satisfies the requirement in the Agreement and could confirm the validity of the total consumption as reported by SEPA. The 5,175 ODP tonnes as reported by SEPA and verified by the consultant as the total CTC consumption under Phase II in 2007 is below the maximum allowable CTC consumption of 6,945 ODP tonnes as set in the Agreement for 2007.

RECOMMENDATIONS

55. The Secretariat recommends that the Executive Committee:

(a) Takes note of the verification of the CTC consumption of Phase II of the CTC sector plan in 2007;

(b) Approves the disbursement of US $10 million and US $750,000 as support costs for the implementation of the 2008 work programme of Phase II of the CTC sector plan.

SECTOR PLAN FOR THE PHASE-OUT OF METHYL BROMIDE PRODUCTION: WORK PROGRAMME FOR 2008-2010 (PHASE II)

Introduction

56. UNIDO has submitted to the 55th Meeting, on behalf of the Government of China, the work programme for Phase II of the sector plan for the phase-out of methyl bromide (MB) production covering the period of 2008-2010, and requested the release of US $3 million plus agency support cost of US $225,000 for its implementation. The submission includes a verification of the achievement of Phase I of the sector plan between 2005-2007, which is mandatory under the Agreement between the Government of China and the Executive Committee for releasing funding for Phase II of the sector plan. The verification report and the 2008-2010 work programme are not attached but could be made available upon request.

Background

57. At its 47th Meeting in 2005, the Executive Committee approved in principle a total of US $9.8 million to assist China in complying with the Montreal Protocol control schedule for the production of methyl bromide (MB) for controlled uses, and disbursed the first tranche of US $3 million for the implementation of Phase I of the sector plan for the period of 2005-2007. The following table, extracted from the Agreement covering the sector plan, sums up the annual MB production reduction targets and the schedule of funds to be released.

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total
Max. annual allowable production of methyl bromide for controlled uses (ODP tonnes)	621.0	600.0	570.6	390.0	250.0	209.0	176.0	150.0	100.0	50.0	0.0*	-
Project cost (US$ '000)	3,000	0	0	3,000	0	0	2,000	0	0	1,790	0	9,790
Agency fees (US$ '000)	225	0	0	225	0	0	150	0	0	134	0	734
TOTAL MLF Grant (US$ '000)	3,225	0	0	3,225	0	0	2,150	0	0	1,924	0	10,524

*save for QPS, feedstock and critical uses to be approved by Parties.

58. The Agreement stipulates that "The funds are to be approved at the second meeting in the years indicated above, upon the submission by UNIDO and the acceptance by the Executive Committee of the verification of the reduction targets in the preceding years specified."

Verification of MB production in 2005 through 2007

59. The verification was carried out by a team of two consultants from China in April 2008. One of the members has extensive experience in the chemical industry, although he does not have direct experience in the verification of methyl bromide production, while the other member is in finance accounting.

60. The objectives of the verification were to confirm that the MB production for controlled uses did not exceed the maximum allowable limits set in the Agreement, namely 621 ODP tonnes in 2005, 600 ODP tonnes in 2006, and 570.6 ODP tonnes in 2007.

61. There are three MB producing plants in China and an overview of these plants is provided below:

Company name	LianYunGang Dead Sea Bromide Co. Ltd	ChangYi City chemical plant	LinHai City Jian Xin Chemical Co.Ltd	**Total**
Address	Lianyungang Jiangsu	Changyi, Shandong	Linhai, Zhejiang	
Ownership	Joint venture 60% Israel / 40% Chinese	Private	Private	
History	The initial equipment was built in 1977. In 1995, 60 per cent of the capital came from an Israel company, and production capacity was increased to 4,000 mt/year	The initial equipment was installed in 1992, with a production capacity of 500 mt/year. The products are mainly used for agriculture and QPS.	Commissioned in 1989 methyl bromide production lines with a production capacity of 800 tones. In 1999, the production capacity has increased to 2,400 mt. Most products are used in QPS.	
Production capacity	4,000 mt/yr	1,500 mt/yr	2,400 mt/yr	7,900 mt/yr
2002-2004 production (mt)	2,582 2,023 1,920	149 176 241	828 794 308	

2002-2003 production data from Wakim's audit report. 2004 production data from SEPA/UNIDO investigation report.

62. The verification team visited all three plants prior to which it collected data from the plants using a questionnaire designed for the exercise. The team reportedly took the following steps at each producing location and checked:

- The record list to verify the record keeping system;
- The plant conditions and apparent operational status;
- Daily production logs, raw materials record, feedstock consumption data of CH3OH and Br_2 and MB products;
- The annual products stock records to confirm the methyl bromide stocks correspond to annual productions and sales data;
- The raw materials stock record to calculate the cumulative inventory change of CH_3OH and Br_2 to confirm their consistency with MB production, both overall and per production cycle; and
- The production logs per hour, which include the in-plant flow rate data and changes of tank levels to verify the ratio of raw materials unit consumption. The ratio reportedly corresponds to the production levels although the ratio was found to be higher than the industry norm because of leakage, conditions of operation of the plants, and other factors.

63. The verification team analyzed, as a way of sampling, the data for four weeks during each production cycle. The data for raw material consumption and ODS production for the same week was also matched.

64. For the verification of production of MB for controlled use, QPS and feedstock, the team reported taking the following steps to check the sales records:

- For QPS: in China, only licensed fumigation companies can do QPS treatments. Furthermore, each QPS treatment has to be authorized by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). The verification team assessed the methyl bromide sales for QPS uses from the buyers' registration names and from the authorizations issued by AQSIQ.

- For controlled uses: only licensed buyers, such as agricultural goods dealers, farmers, grain depots and tobacco companies are authorized to buy methyl bromide. The team assessed the sales of controlled uses of methyl bromide from the buyers' names and from licenses obtained.

- For feedstock: only enterprises, such as drug manufactures, chemical manufactures and perfume manufactures are authorized to use methyl bromide as feedstock. The team assessed the sales of methyl bromide used as feedstock from the buyers' names and licenses obtained.

- For import and export: the team checked the bills of customs clearances, import and export contracts and invoices and then cross checked with import and export licenses issued by the ODS Import/Export Management Office to verify each methyl bromide import and export application.

65. The team then discussed the issues identified in the verification. For instance, the Lianyungang Dead Sea company packages the imported MB once it arrives, and then takes the stock inventory before the goods are transported. As a result, the loss in transport is not reflected and thus creates an imbalance between warehouse and workshop records. The other two plants that have a smaller operation do not have an up-to-standard record keeping system. One of the plants does not weigh its raw material and makes only an estimate. As a result the consumption of raw material to final production is inaccurate.

66. The team made a number of recommendations, among which was the need for the Government to formulate a programme for the further regulation of the production and sale of classified products, and to implement a specific management system for ODS. With respect to the plants, the team recommended that each sale must involve the signing of a sales contract, and those supplying methyl bromide for QPS use or for use as a raw material must provide sufficient fumigation treatment certification. There should be an improved production management system which would ensure that raw materials are weighed properly and that sales classification would be more accurate, and different contracts should be signed for different uses.

67. The team concluded that the three companies were not found to be exceeding production quotas of methyl bromide for use in controlled substances and the annual production of the total by the three plants for controlled use is as follows.

ODS (tonnes)	Maximum allowable production	Controlled quota	Actual production
2005	1035	1030	730.739
2006	1000	1000	985.085
2007	951	900	686.275

68. A breakdown of MB production by usage and the data reported to the Ozone Secretariat are shown as follows:

		2005	2006	2007
Verification data	Controlled use	730.739	985.085	686.275
	QPS	1,356.271	1,313.611	1,534.736
	Feedstock	1,098.364	992.955	1,461.426
	Total	**3,185.368**	**3,291.651**	**3,682.437**
Reported data	Controlled use	730.115	985.088	*
	QPS	1,357.753	1,313.615	*
	Feedstock	1,097.500	992.953	*
	Total	**3,185.368**	**3,291.656**	*****

Progress report on the implementation of the sector plan from 2005-2007

69. Progress is reported on compensation contracts being concluded with the three MB producers for the period 2005-2007 and the year of 2008. Subsequent contracts will be negotiated with the MB producers based on their performance and audit reports to be released on an annual base. Production quotas have been established by Ministry of Environment Protection (MEP), in consultation with MB producers, and in accordance with the Agreement between China and the Executive Committee. The quotas for the period 2005-2008 are shown in the table below.

Year	2005	2006	2007	2008*
Quota (ODS tonnes)	1,030	1,000	900	640
Annual production limit	1,035	1,000	951	650

70. The MEP works with the General Administration of Quality supervision, Inspection and Quarantine (AQSIQ) on all matters related to QPS uses of methyl bromide. The policy related to QPS uses of methyl bromide is under formulation, jointly by MEP and AQSIQ. AQSIQ is in charge of carrying out the capacity building programme, and is also in charge of data collection, monitoring, and releasing authorization and certifying QPS methyl bromide fumigations.

71. The "ODS Import and Export Management Office" of MEP, which is represented by MEP, the General Administration of Customs (GAC) and the Ministry of Commerce (MOC), is responsible for monitoring methyl bromide import and export, among all other ODS. All official data are certified and consolidated by this office. Following the survey results and

recommendations, MEP and GAC agreed to add two more HS codes for methyl bromide. As a result, methyl bromide will have three HS codes, respectively, for: (a) ODS, (b) QPS, and (c) feedstock. It will clearly identify exported methyl bromide uses in GAC statistics and management. According to the above change, MEP, GAC and the "ODS Import and Export Management Office" will conduct further training for custom officials and a survey in 2008.

72. With regard to the methyl bromide production sector MEP, jointly with the "ODS Import and Export Management Office", carried out the following activities:

No.	Programme	Status
1	Survey of methyl bromide import and export data with custom authorities	Completed on 16 November 2007
2	Revision of the Harmonized Code System according to the survey result.	Three HS codes agreed, respectively for: ODS, QPS and feedstock.
3	Survey and training to customs and methyl bromide import and export dealers for the administration and use of new HS codes.	On going, Completion expected in Sep. 2008.

73. The following policies have been issued for the management of methyl bromide production, consumption and trade in China:

(a) By a Circular from MEP, establishment, expansion or renovation of 1.1.1-tricholorethane and methyl bromide production equipment has been banned as of 1 July 2003:

(b) MB Production License and Quota Management System was introduced as of 21 May 2004;

(c) Licensing for import and export of methyl bromide (including QPS) has been effective since 1 January 2004. Methyl bromide export for controlled uses, excluding QPS, has been forbidden since 2004;

(d) A ban on sales and uses of methyl bromide in the grain fumigation sector was introduced by a circular from MEP issued on 26 September 2006; and

(e) A monitoring plan for MB production in China, which was firstly presented and discussed at the joint meeting between MEP, MoA, AQSIQ, Ministry of Public Security (MPS), State Forestry Administration (SFA), and State Administration of Work Safety (SAWS) has been implemented. It requires that producers have to obtain a signed declaration from buyers, which states for which application the methyl bromide has been purchased and, furthermore, only one true level of distribution is allowed.

74. The progress report presents the proposed work programme for phase II of the sector plan which contains 15 activities covering work to be carried by the various stakeholders for industry phase-out, government policy work, public awareness and technical assistance. The total budget is estimated at US $3 million.

Comments of the Secretariat

75. It is the first time that verification of the MB production has been carried out and it is acknowledged that UNIDO followed the guidelines of the Executive Committee, adopted in 2000, for verifying ODS production phase-out. It is also noted that the Government of China has been introducing policy measures to manage the complicated production of MB because of its dual uses, controlled use and QPS. Actually there are three uses in China, the third one being for feedstock use.

76. The issue that the Secretariat wishes to raise with respect to the verification carried out by UNIDO is whether the methodology applied to the verification of the production phase-out of ODS, without the complication of dual usage, is adequate for the verification of ODS with such complications as CTC and MB. Since the uses of these ODS cannot be identified by their physical appearance, the only way to ensure that the produced substance is sold for what it is intended is to verify it at the level of the end-users. This has been done by the World Bank in the verification of CTC production in India and China and two approaches have been adopted by the World Bank. In the case of the India CTC sector plan, the World Bank verified CTC consumption by feedstock users in addition to verifying CTC producers and volume of imports. After deducting the level of production for feedstock, the remaining CTC is for controlled use. In the case of China, the Bank verified the CTC producers and, on a sample basis, verified the end-users for controlled use. Actually the verification reports from both countries on CTC production and consumption are submitted to this meeting.

77. UNIDO argues that the MB production verification is different from the CTC verification in China and India because both the India and China CTC sector plans include CTC production and consumption, while the China MB sector plan is limited to MB production and does not cover consumption. While this is correct, it is also true that there is no requirement for MB consumption verification.

78. UNIDO considers that implementation of an end-user verification would be very expensive because there are 180 QPS applicants and 90 feedstock users of MB in China according to its data. While it is true, the precedents set by the World Bank for the verification of CTC however do not call for the verification of both uses. The Secretariat suggested that UNIDO could select a number of big MB feedstock users, which consume a relatively large share of the MB feedstock consumption, together with a number of small users and obtain a good feel for the total consumption picture in the country. In fact, MEP is already conducting a survey/audit of the MB feedstock users, which will be completed by year end and could serve as the first MB end-user verification.

79. With regard to the proposed phase II of the sector plan covering the period 2008-2010, the targets proposed for 2008 are consistent with those in the Agreement and presumably the targets for 2009-2010 will be formulated accordingly. The institutions that are involved in the implementation of the sector plan are strong and will be crucial to its successful implementation.

80. MEP has plans to continue tightening control for the production, import and export, sales and consumption of MB in China. The Secretariat is confident that MEP will consider the recommendations from the verification team and further strengthen the management of the MB production and sales at the three MB producing plants.

RECOMMENDATION

81. As a result of the precedents of the Multilateral Fund in verifying the production of ODS with dual uses, the Secretariat does not consider the verification of the MB production carried out by UNIDO as complete since it does not ascertain the levels of MB produced for feedstock and QPS uses. It is therefore not in a position to recommend the release of the next tranche of funding at this meeting. The Secretariat recommends that UNIDO supplements the existing verification by examining, on a sample basis, a reasonable number of either MB feedstock users or controlled users to confirm the MB production for the different uses, as described in the above paragraphs. UNIDO should re-submit the revised verification report to the 56th Meeting.

Annex I. Summary of analysis of the MDI manufacturing plants in China

No*	Company Name	Products (B)	CFC 2007	Can 2007	$License**	$Capital	$Prod Validation	$Training	$Operating	$Patent*	$Other TAS*	$Total	CE ($/kg)
22	Shandong Lino Kefeng pharmaceutical Co.	04, 22	540	48,306	390,000	55,000	40,000	27,500	4,367	4,354	1,842	523,063	968.63
37	Zigong Chenguang Pharmaceutical	5	1,780	141,360	390,000	55,000	40,000	27,500	13,127	14,352	6,072	546,050	306.77
9	Guiyang Dechangxiang Pharmaceutical	24	320	20,206	195,000	55,000	40,000	27,500	1,990	2,580	1,092	323,162	1,009.88
16	Heilongjiang Tianlong Pharmaceutical Co. Ltd	15	412	23034	390,000	55,000	40,000	27,500	2351	3,322	1,405	519,578	1,261.11
25	Pharmaceutical Factory of Shanxi Medical University	16	240	16,000	195,000	55,000	40,000	27,500	1553	1,935	819	321,807	1,340.86
11	Harbin Hengcang Pharmaceutical co.	14, 15	73,260	5,550,000	195,000	748,000	80,000	27,500	521,229	590,669	249,898	2,412,296	32.93
2	Beijing Haiderun Pharmaceutical	15, 23	26,100	2,216,150	585,000	748,000	80,000	27,500	202,656	210,435	89,030	1,942,621	74.43
8	Guangzhou Dongkang Pharmaceutical	15, 22	175,178	9,295,910	780,000	1,452,000	40,000	27,500	964,119	1,412,397	597,553	5,273,569	30.10
36	Chongqing Kerui Pharmaceutical	16	100	10,000	-	55,000	40,000	27,500	884	806	341	124,531	1,245.31
24	Shandong Lunan Beite Pharmaceutical	04, 17, 25	4,115	169,400	390,000	55,000	40,000	27,500	19,171	33,178	14,037	578,886	140.68
32	No.1 Pharmaceutical of Wuxi Shanhe Group	15	637	32,785	195,000	55,000	40,000	27,500	3,434	5,136	2,173	328,243	515.29
35	Guangdong Tongde Pharmaceutical Co. Ltd	15, 16	20,656	1,289,879	1,560,000	748,000	40,000	27,500	127,440	166,542	70,460	2,739,942	132.65
28	Shanghai Pharmaceutical (Group)	01, 04, 09, 12, 14, 15, 16, 22	3,200	195,560	390,000	55,000	40,000	27,500	19,440	25,800	10,916	568,656	177.71
19	Penglai Nuokang Pharmaceutical	15, 16, 22	6,070	550,000	390,000	220,000	40,000	27,500	49,588	48,940	20,705	796,734	131.26
18	Jinan Weiming Pharmaceutical	22	9,767	575,520	195,000	220,000	40,000	27,500	57,817	78,748	33,316	652,381	66.79
21	Jewim Pharmaceutical	01, 14, 15, 16	100	2,300	195,000	55,000	40,000	27,500	337	806	341	318,984	3,189.84
	Total production facilities		322,475	20,136,410	6,435,000	4,686,000	720,000	440,000	1,989,503	2,600,000	1,100,000	17,970,503	55.73
	MDIs not in production				880,000							880,000	
	Grand total		322,475	20,136,410	7,315,000	4,686,000	720,000	440,000	1,989,503	2,600,000	1,100,000	18,850,503	58.46

* The request of US $2.6 million for patents and US $1.1 million for technical assistance were prorated among eligible plants based on their 2007 CFC consumption

Annex II

CHINA PROCESS AGENT SECTOR PLAN

PHASE II

2007 CTC Consumption Verification Report

The World Bank

10 May 2008

CHINA PROCESS AGENT SECTOR PLAN

PHASE II

2007 CTC Consumption Verification Report

The World Bank

May 10, 2008

I SUMMARY

Under the Agreement on the CTC/PA Sector (Phase II), China is obligated to limit its CTC consumption to **6,945 ODP tonnes** in the verification year of 2007.

As guided by the Terms of Reference for April-May 2008 PA II Consumption Verification, the World Bank's mission conducted an independent verification on China CTC consumption and closure activities at each of the fifteen selected PA II enterprises that operated in 2007. The fifteen selected enterprises covered **37% of all enterprises** listed by the CTC/PA II Sector Plan.

Field visits of the verification mission started from April 7 to May 6, 2008 in Beijing. The Verification Team consisted of one technical expert from Canada, Mr. Zhiqun Zhang (Consultant of the World Bank), and accompanied by project officers[1] from SEPA.

In conclusion, the Verification Team confirmed that the CTC purchase and consumption of the fifteen selected enterprises in 2007 was **3,066.25 ODP tonnes (2,787.50 ODS tonnes)** and **2,646.50 ODP tonnes (2,409.51 ODS tonnes)** respectively, which shared **59.24% and 56.28%** of the total PA II purchase and consumption in 2007 as reported by SEPA at the national level[2].

Table 1 presented the verification schedule and operation status of the verified enterprises in 2007. Table 2 summarized the verified 2007 production and their CTC purchase, consumption and stockpiles for each of the fifteen visited enterprises. Individual plant verification reports are presented in following text of the summary report.

Detail information, verification data records and plant closure activities are included in Annex I of the summary report for each of the verified enterprise[3].

Digital photos taken from site inspection at each of the plant visits are included in Annex II[4].

Copy of the plant closure documents, dismantling photos and video CDs collected form each of the concerned enterprises are included in Annex III[5].

[1] Mr. Wang Linhong attended from April 8th to 20th, Mr. Li Yunpeng attended from April 21st to May 1st, and Mr. Feng Liulei attended from May 4th to 6th, 2008.
[2] Refers to Table 4 (a), CHINA: ODS IV PROJECT CTC/PA II Sector Annual Progress Reports for 2007 Annual Program, January 15, 2008.
[3] See a separate file attached to the verification report.
[4] To be submitted via separate e-mails on request due to the large volume of the digital photos.
[5] See a separate envelop submitted to Helen via WBOB courier service in May 2008, together with the verification report.

Table 1 Date of visit and verification status of the fifteen selected enterprises in 2007

Plant # in Sector Plan	Brief Name of Enterprise	Product that uses CTC PA	CTC use in 2003	Status in 2007	Date of visit
20	Guangzhou Jinzhujiang	CPP	430.91	Production	April 19, 2008
		CEVA	114.38	Production	
22	Jincheng Chemical	CPP	715.88	Production	April 17, 2008
		CEVA	114.38	Production	
38	Jingzhou Sanonda	MIC	42.25	Production	April 11, 2008
40	Hunan Gofar	MIC	88.21	Production	April 12-13, 2008
61	Jiangsu Anpon*	Buprofenzin	189.91	Production and Closure	April 21, 2008
63	Jiangsu Changlong**	MIC	175.27	Production	April 26-27, 2008
		Buprofenzin	126.96	Production	
		Imidacloprid	46.38	Converted 2004	
		Mefenacet	7.75	Converted 2006	
80	Jiangsu Yangnong Group	Imidacloprid	160.24	Production	April 24-25, 2008
84	Jiangyin Tongqi Tianlong	MPB	N/A	Plant closure	April 28, 2008
91	Liangyungang Yabang Jindun	Oxadiazon	57.00	Plant closure	April 20, 2008
126	Haili Guixi	MIC	202.60	Production	April 15, 2008
150	Xizhou Sihai	CPP	50.00	Plant closure	May 5, 2008
188	Zhejiang Hisun	Imidacloprid	23.25	Formulation only	April 9, 2008
207	Rudong Shidian	CPP	30.00	Production and Closure	April 23, 2008
N/A	Jiangsu Yixing Yonggu	CPP	N/A	Production	April 29-30, 2008
N/A	Xinzhou Local National (newly identified)	CPP	N/A	Plant closure	May 4, 2008

* The company had two buprofenzin production lines that use CTC as a process agent. Line #1 was stopped in March 2005 and dismantled in April 2007. Line #2 was in normal operation and converted to a non-ODS process in March 2007. The mission verified both line #1 closure and line #2 production activities in 2007.

** Historically, the company had four products that use CTC as a process agent, which are MIC, Buprofenzin, Imidacloprid and Mefenacet. However, the production of imidacloprid had been converted to a non-ODS process in 2004 and the use of CTC in mefenacet production was also phased out by end of 2006, therefore only two existing CTC-based products (MIC and buprofenzin) that received CTC quota and operated in 2007 were verified by the mission.

Table 2 Summary of 2007 verification result of the fifteen selected PA II enterprises

Plant #	Name of enterprise*	Product using CTC PA	Production (MT)	CTC opening stock (ODS tonne)	CTC purchase (ODS tonne)	CTC consumption (ODS tonne)	CTC closing stock (ODS tonne)
20	Guangzhou Jinzhujiang	CPP	1,333.09	359.99	349.88	383.12	326.75
		CEVA	564.40				
22	Jincheng Chemical	CPP	1,076.20	235.35	646.44	432.34	449.45
		CEVA	186.83				
38	Jingzhou Shanonda	MIC	577.00	6.75	80.00	73.75	13.00
40	Hunan Gofar	MIC	1,343.80	0.00	170.00	149.75	20.25
61	Jiangsu Anpon	Buprofenzin	1,169.57	66.97	0.00	Use: 38.57 Sale: 28.40	0.00
63	Jiangsu Changlong	MIC	1.535.20	0.00	660.30	216.05	151.97
		Buprofenzin	4,004.19			292.28	
80	Jiangsu Yangnong Group	Imidacloprid	602.00	19.89	198.20	192.42	25.65
84	Jiangyin Tongqi Tianlong	MPB*	0.00	0.00	0.00	0.00	0.00
91	Liangyungang Jindun	Oxadiazon*	0.00	0.75	0.00	0.00	0.75
126	Haili Guixi	MIC	721.39	16.00	155.74	Use: 148.75 Sale: 22.99	0.00
150	Shanxi Xizhou Sihai	CPP*	0.00	0.00	0.00	0.00	0.00
188	Zhejiang Hisun**	Imidacloprid	0.00	0.00	0.00	0.00	0.00
207	Rudong Shidian	CPP*	0.00	29.92	0.00	Sale: 29.51 Loss: 0.41	0.00
208	Yixing Yonggu	CPP	493.45	10.50	526.94	397.57	139.87
N/A	Xinzhou Local National	CPP*	0.00	0.00	0.00	0.00	0.00
Total verified CTC purchase, consumption and stocks in 2007			**(ODS tonnes)**	**746.12**	**2787.50**	**2405.91**	**1127.69**
			(ODP tonnes)	**820.73**	**3066.25**	**2646.50**	**1240.46**

* The CTC-based production line was shutdown and there was no CTC purchase and consumption in 2007.

** The company stopped the use of CTC in production of 2-chloro-5-chloromethyl-pyridine (CCP) at end of 2005 and turned to purchase CCP from outside for imidacloprid production. Further in 2007, the production of imidacloprid technical was also fully stopped and only kept the imidacloprid dispensing and formulation workshop in operation, with imidacloprid technicals purchased from outside. Therefore, in the verification year of 2007, there was neither imidacloprid technical production nor CTC purchase/consumption within plant.

PROJECT COVER SHEET – MULTI-YEAR PROJECTS

COUNTRY: China, People's Republic

PROJECT TITLE:	**IMPLEMENTING AGENCY:**
Sector Plan for Phase out of CFCs Consumption in China's MDI Sector	UNIDO

NATIONAL CO-ORDINATING AGENCY: Ministry of Environment Protection (MEP)
State Food and Drug Administration (SFDA)

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2006, AS OF MAY 2008)

Annex A, Group I	12,420.43	Annex B, Group II	890.93
Annex A, group II	795.01	Annex E, MeBr	

B: COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES, 2006, AS OF MAY 2008)

ODS	Foam	Refrigeration	Aerosol	MDI
CFC-11	6,318.55	405.8	98.87	40.9
CFC-12	0	3,264.34	370	236.7
CFC-114		27.69		3.3

CFC consumption remaining eligible for funding (ODP tonnes)	**423.2**

CURRENT YEAR BUSINESS PLAN: Total funding: **US$ 13,000,000** Total phase-out: **250 ODP tonnes**.

PROJECT DATA		**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
CFCs (ODP tonnes)	Montreal Protocol limits	8,672.8	8,672.8	8,672.8	0	0	0	0	0	n.a.
	Annual consumption limit	7,400	550	550	614.6	748.3	650.0	400.0	-	n.a.
	Annual phase-out newly addressed	0	0	0	0	0	98.3	250.0	400.0	748.3
Total ODS Consumption to Be Phased Out		0	0	0	0	0	98.3	250.0	400.0	748.3
Total ODS consumption to be phased-in (CFCs)		0	0	0	0	0	0	0	0	0
Project costs (US $):			18,850,502							18,850,502
Support costs (US $))			1,413,788							1,413,788
Total cost to Multilateral Fund (US $)			**20,264,289**							**20,264,289**
Project cost effectiveness (US $/kg):										**58,46**

FUNDING REQUEST: Approval of the MDI Sector CFCs Phase out Plan for China and its total project funding of **US$ 18,850,502** plus support cost of **US$1,413,788** as indicated above.

Prepared by: SFDA, MEP and UNIDO **Date: 15 May 2008**

EXECUTIVE SUMMARY

This sector plan will assist China to phase out all CFC consumption of MDI sector in China. This is the second submission of the Plan and it takes into consideration the request of the ExCom formulated in its Dec. 53/23.The funding request targets the eligible consumption of 322.5 ODP tonnes (276.5 tonnes of CFC-12, 46 tonnes of CFC-11). The sector plan will be implemented through a series of technical assistance, legislative and investment activities starting in 2008. The sector plan was prepared on the basis of a detailed analysis and on site surveys of Chinese owned MDI manufacturing enterprises in China, and covers all enterprises and production lines available in the sector. The sector plan proposes a mix of approaches for conversion to non-ODS substitute processes where economically feasible, and closure of production through market tools and incentives where other approaches are not feasible. The sector plan includes policy actions to ensure that the phase out proceeds on schedule, and that the ineligible enterprises, which are not financed under the project, will stop using ODSs as propellant or dispersant of MDI production. The sector plan also addresses transitional arrangements and policy issues related to production and consumption of CFCs for domestic MDI use in the post-compliance period of 2010-2014.

Contents

Chapter I Introduction

1) **Montreal Protocol and achievement of CFCs phase out in China**. In September 1989, China joined the worldwide effort to protect the ozone layer by ratifying the Vienna Convention on the Protection of Ozone Layer. China deepened its commitments by signing the Montreal Protocol and its London Amendment in June 1991 and ratifying its Copenhagen Amendment in April 2003. To implement the phase out of Ozone Depleting Substances (ODS), China has been meeting its obligations to these international agreements by implementing the Country Program for Phase out of Ozone Depleting Substances (CP), which the government approved in January 1993 and updated in November 1999. By 1 July 2007, China successfully completed the Accelerated Phase-out Plan for CFC and Halon Production and Consumption in China, i.e. two and a half years earlier than the requirements of the Montreal Protocol. Excluding CFCs used in MDI sector, all CFCs consumption has been phased out, thus the phase out of CFCs in the MDI sector represents the main challenge for China to complete the total phase out of CFCs production and consumption.
2) **Institutional arrangements for management of ODS phase out.** To monitor and manage the CP implementation, China established a National Leading Group (NLG) for Ozone Layer protection. The NLG provides strategic guidance and inter-sectoral coordination for ODS phase-out. The State Environmental Protection Administration (MEP) leads the NLG, which includes the Ministry of Foreign Affairs, Ministry of Finance, Ministry of Science and Technology, National Development and Reform Commission, Ministry of Public Security, Ministry of Information Industry, State Food and Drug Administration (SFDA) and selected government departments responsible for the industrial sector. For the day-to-day management, China has established an Implementation Office for Compliance with the Montreal Protocol (IOC for MP, the former Project Management Office) hosted by MEP. There are nine special working groups in the IOC, which consist of staff from MEP and other ministries, commissions and sector industrial associations.
3) **Policy and Regulation**. China issued and implemented a number of national and sectoral policies for ODS phase out during the past 15 years. The key policies include: (1) Air Pollution Prevention and Control Act, which is the basis for the ODS regulatory system in China; (2) Circular on the ban of establishment of new production facilities producing or consuming ODS, (ODS production control); (3) Management Measures on the Import and Export of ODS. (4) The Guiding Catalogue of Industrial Structure Regulation (2005) (issued by the National Development and Reform Commission at the end of 2005), which classifies over 1,000 industries into the categories of encouragement, restriction and elimination. The ODS industries were classified into the latter two categories (i.e. restriction and elimination).
4) **Efforts made for phase-out of CFCs in the MDI sector.** The Chinese Government and the stakeholders of the country's MDI sector have attached great importance to the CFCs phase-out tasks, which are to be undertaken with active yet careful attitude in the MDI manufacturing sector. They carried out preparations for alternative technology identification, exchange of information with experts from home and abroad, and conducted two rounds of preliminary surveys. In March 1995 and

December 1998, entrusted by MEP, the Aerosol Newsletter (a professional magazine of China's aerosol sector), organised two International MDI Technology Workshops in Beijing. Experts from international companies and Chinese MDI enterprises, research institutes and government agencies participated in these workshops. In 1997, MEP established the MDI Sector Technical Team for CFCs Phase-out, which was composed by experts from research institutes, national testing centres and MDI producers. In December 2003 and during the preparation of this proposed sector plan, MEP and SFDA established a special technical expert team, which is composed of the Chinese Academia: Chinese Academy of Engineering, Chinese Academy of Medical Sciences, MDI aerosol researchers from universities and research institutes, experts from factories, etc. Since then, the technical expert team carried out a comprehensive study of alternatives as well as other options to phase-out CFCs in MDI sector.

5) **Development of the MDI CFC Phase-out Sector Plan (MDISP)**. Funding of US$ 90,000 was approved at the 43rd ExCom meeting in July 2004 to prepare the Sector Plan for Phase-out of CFCs Consumption in China's MDI Sector. As the leading agency for the implementation of Montreal Protocol, MEP in cooperation with SFDA selected National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) to prepare this sector plan. The development of MDISP started in early 2005 under the auspices of MEP and SFDA. The first draft of MDISP was completed in April 2007 and was endorsed at a national workshop in August 2007.
6) The project document developed on the basis of the MDISP was submitted to the 53rd ExCom for its consideration. The Secretariat and the ExCom raised several questions, part of them was answered, however some issues e.g. the cost-effectiveness, the actual consumption data, industrial consolidation etc., required additional work as stipulated in Decision 53/23 of the ExCom. This work was carried out by MEP, SFDA and UNIDO through resurvey of enterprises and further dialogues with the stakeholders. The new data collected and the agreements reached with the beneficiaries are reflected in this document.
7) **Main contents of the sector plan and the impact of the project on the country's Montreal protocol obligations.** This sector plan address the MDI sector in terms of:
   a) Data survey and analysis,
   b) Current regulations and policies governing the sector,
   c) Technical options, selection of most appropriate alternatives and technologies,
   d) Strategy of phase out and policy framework, transitional arrangements in the compliance period,
   e) Incremental costs analysis,
   f) Operating mechanism, and
   g) Action plan.
8) Upon approval of this Sector Plan with the requested funding of US$ 18,850,502 (without agency support cost) the Chinese Government will ensure the phase out of all the remaining eligible unfunded CFC consumption in the MDI sector amounting to 322.5 ODP tonnes /year, including the phase out of all CFC consumption at 38 enterprises, producing 25 types of MDIs (104 product licenses).

Chapter II Sector Baseline

A Development of MDI in China

9) The first pharmaceutical aerosols made of sulfamido compound aerosols were developed in 1942, while the first metered dose inhaler (MDIs) aerosol was born in Riker Laboratories and came to the market in 1956. The medical aerosol industry in China started fairly late. In 1964, an anti-asthmatic aerosol, the first Chinese medicinal aerosol product, had been developed and produced jointly by Shanghai Institute of Pharmaceutical Industry, Shanghai Sine Pharmaceutical Factory, Wuxi First Pharmaceutical Factory and Chongqing Seventh Pharmaceutical Factory. However, during the first 20 years after the initiatial stage of the production, i.e. until the 1980s, the development of medicinal aerosols in China was comparatively slow due to the scarcity of cans, valves and satisfactory metering devices. Great progress was made along with the solution of all these technical problems after 1980s. Up to 2007, 104 MDI production licences were approved in China. These are applied by 38 producers manufacturing 25 types of CFC MDIs, based on 22 active chemical ingredients and 3 MDIs based on Chinese traditional medicines.

Table 1. Basic information on production licences and producers

	Product licenses	Types of products	Producers	Remarks
All registration licences issued for CFC-based MDI products	104	25	38	Including those holding registration licences but currently not producing
Currently produced CFC-based MDI products	36	13	16	

10) MDI has irreplaceable advantages in curing asthma and COPD: easy to carry, low dose, fast relieve and control of symptoms like dyspnoea of the patients.

B Asthma and COPD in China

11) According to the Global Initiative for Asthma (GINA) asthma is a chronic inflammatory disorder of the airways. Chronically inflamed airways are hyperresponsive; they become obstructed and airflow is limited (by bronchoconstriction, mucus plugs, and increased inflammation) when airways are exposed to various risk factors.
12) The common risk factors for asthma symptoms include exposure to allergens (such as those from house dust, mites, animals with fur, cockroaches and pollens.), occupational irritants, tobacco smoke,

respiratory (viral) infections, exercise, strong emotional expressions, chemical irritants, and drugs (such as aspirin and beta blockers).

13) A stepwise approach to pharmacologic treatment to achieve and maintain control of asthma should take into account the safety of treatment, potential for adverse effects, and the cost of treatment required to achieve control.

14) Asthma causes recurring episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning. Unfortunately asthma is one of the most common chronic diseases worldwide. The prevalence of asthma symptoms in children varies from 1 to more than 30 percent in different populations and is increasing in most countries, especially among young children. Fortunately asthma can be effectively treated and most patients can achieve good control of their disease through treatment and medication.

15) Development of anti-asthma drugs is targeting the inflammatory factors as leukotriene, the platelet-activating factor - thromboxane A2, cytokines, phospholipase A2-inhibitor, and tachykinin, in view of the complicated mechanism of the occurrence. Anti-inflammation has become the front line treatment, mainly including carbohydrate corticosteroid and antagonists against inflammatory mediators. Although the side effects of inhaled treatment are dramatically decreased compared with the systematic treatment with carbohydrate corticosteroid, the safety of the long term treatment is still widely disputed; especially when it has been found that the incidence and mortality still can not be lowered by long term treatment of inhaled carbohydrate corticosteroid. Thus the research about antagonists against inflammatory mediators is more and more becoming the hotspot of asthma treatment.

16) The incidence of asthma in China is rising during the past few years: in 2000 the number of annual incidence of asthma among the Chinese residents amounted to 15.6 million, or 1.2%, which shows an increase of 75% (with a rate of 4% per year), compared with the data in 1980. The incidence of asthma is highest in the population of children under 14 years of age, based on a medical report, the incidence is ranging between 0.5 and 3.6%. The second highest incidence is 2.6% among people more than 60 years old. The incidence is higher in the regions of coastal and southern China, with a highest 3.03% in Fujian province and 2.53% in Guangzhou. In the northern and inland region of China it is lower, with 0.5% in Shandong province and 0.11% in the Tibet autonomous region.

C Treatment of Asthma and COPD in China

17) Based on old habits of treatment, some doctors and patients still many times choose less effective oral medicines or injections instead of MDI to relieve or cure asthma. Some patients also take Chinese traditional medicines. Based on an incomplete investigation, only about 10% of the patients are using MDI, but the numbers are growing fast along with the rapid development of the country.

18) The types of asthma treatment were classified by the Coordination Group of Asthma Treatment under the Chinese Medical Association on Respiratory Diseases and the classification was published in "*The Directory of prevention and control of Bronchial Asthma*". Seven kinds of treatment were recommended in the directory, which could be classified into 3 kinds of drug delivery manners: inhalation, oral and intravenous.

Table 2. The Recommended Treatment Methods for Preventing and Control of Bronchial Asthma

Drug type	Drug Delivery	Drug Name	Remarks
Glucocorticoids	Inhalation	BeclometasoneDipropionate	
		Budesonide	
		FluticasonePropionate	
	Oral	Prednisone	
		Prednisolone	
		Methyl Prednisone	
	Intravenous injection	Succinic Hydrocortisone	
		Methyl Prednisolone	
		Dexamethasone	
β-adrenergic receptor agonists (not suitable for severe cases)	Inhalation	Ssalbutamol	
		Terbutalin	
		Fenoterol	
		Formoterol	Long-acting
		Salmeterol	Long-acting
	Oral	Salbutamol	
		Terbutalin	
		Procaterol	
		Bambuterol	
	Injection		High incidence of systematic adverse reactions
Theophyllines	Oral	Aminophylline	
		Controlled (Sustained)Released Theophylline	
	Intravenous	Aminophylline	
		Doxofylline	
		Bis 2-Hydroxylpropylene Theophylline	
Anticholinergic drugs	Inhalation	Ipratropium Bromide	
		Atropine oxybromide	
		Tiotropium bromide	
	Oral	Zafirlukast	

Drug type	Drug Delivery	Drug Name	Remarks
Leukotriene regulators	Oral	Zafirlukast	
		Montelukast	
		Ibudilast	
Noncortical hormone (slight asthma)	Inhalation	Sodium Cromoglycate	
		Nedocromil sodium	
Antihistamine	Oral	Ketotifen fumarate	
		Loratadine	
		Astemizole	
		Azelastine	
Antiallergic drugs	Oral	Tranilast	
		Repirinast	
Chinese traditional medicine	Oral Inhalation	Guilong Kechuanming Aerosol,, Hajie Dingchuan Aerosol, Huashanshen Aerosol, Zhichuanling Aerosol	

19) China Asthma Alliance (CAA) was set up in June 2005. It is led by the Coordination Group of Asthma Treatment under Chinese Medical Association on Respiratory Diseases. CAA aims to disseminate the standard treatments of asthma, and improve the control and research level of asthma in China, by ways of strengthening the cooperation with other asthma control organizations throughout the country.
20) For the time being, 26 provinces (including municipalities directly under the central government) have their own asthma alliances. The activities to propagate standard treatments and to develop doctor training programmes with the help of asthma control organizations follow the directives of GINA and "The Directory of Prevention and Control of Bronchial Asthma in China". Accordingly, MDI should be recommended by the doctors as the first choice to treat asthma.
21) Based on the statistics derived from the report of "Market investigation of anti-asthma drugs", published recently by the South China Institute of Medical Economic Research, which is an affiliated organization of SFDA, more than 70% of asthma drugs was sold in hospitals. The market has been increasing steadily from 2004 to 2006.
22) It is expected that in China MDI will be used more and more to treat the asthma.

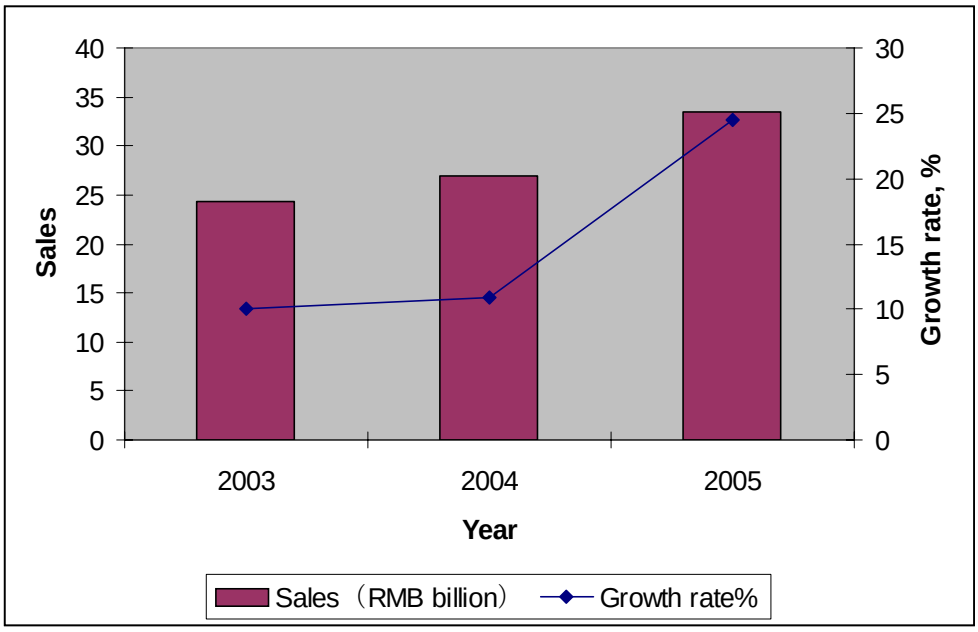

Fig. 1: The Sales of MDI Products in China

D Production process of MDIs

23) As other medicines, MDIs should be registered at SFDA prior to the start of their production. The detailed registration process is described in Section A, chapter III.

24) The MDI production process is simply described on the following figure.

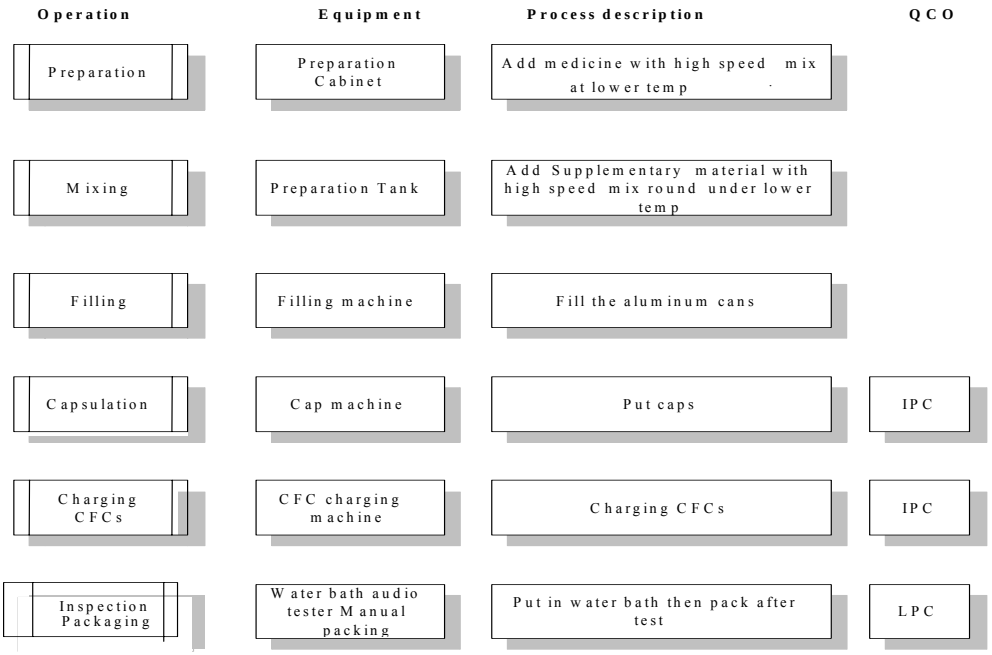

Fig. 2: The production process for Salbutamol Aerosol (suspension)

E Data Survey

25) NICPBP was entrusted by SFDA, MEP and UNIDO to carry out an investigation of the MDI sector and prepare the sector plan to phase out CFCs in the MDI sector of China.
26) The date survey process is shown in following figure 3.
27) The data survey was planned to be conducted by the following ways:
    a) Identify all the MDIs manufacturers in the drug registration system;
    b) Send a comprehensive questionnaire to related enterprises for completion;
    c) Visit enterprises to verify the CFC consumption;
    d) Verify all data again during consultation on the draft sector plan.

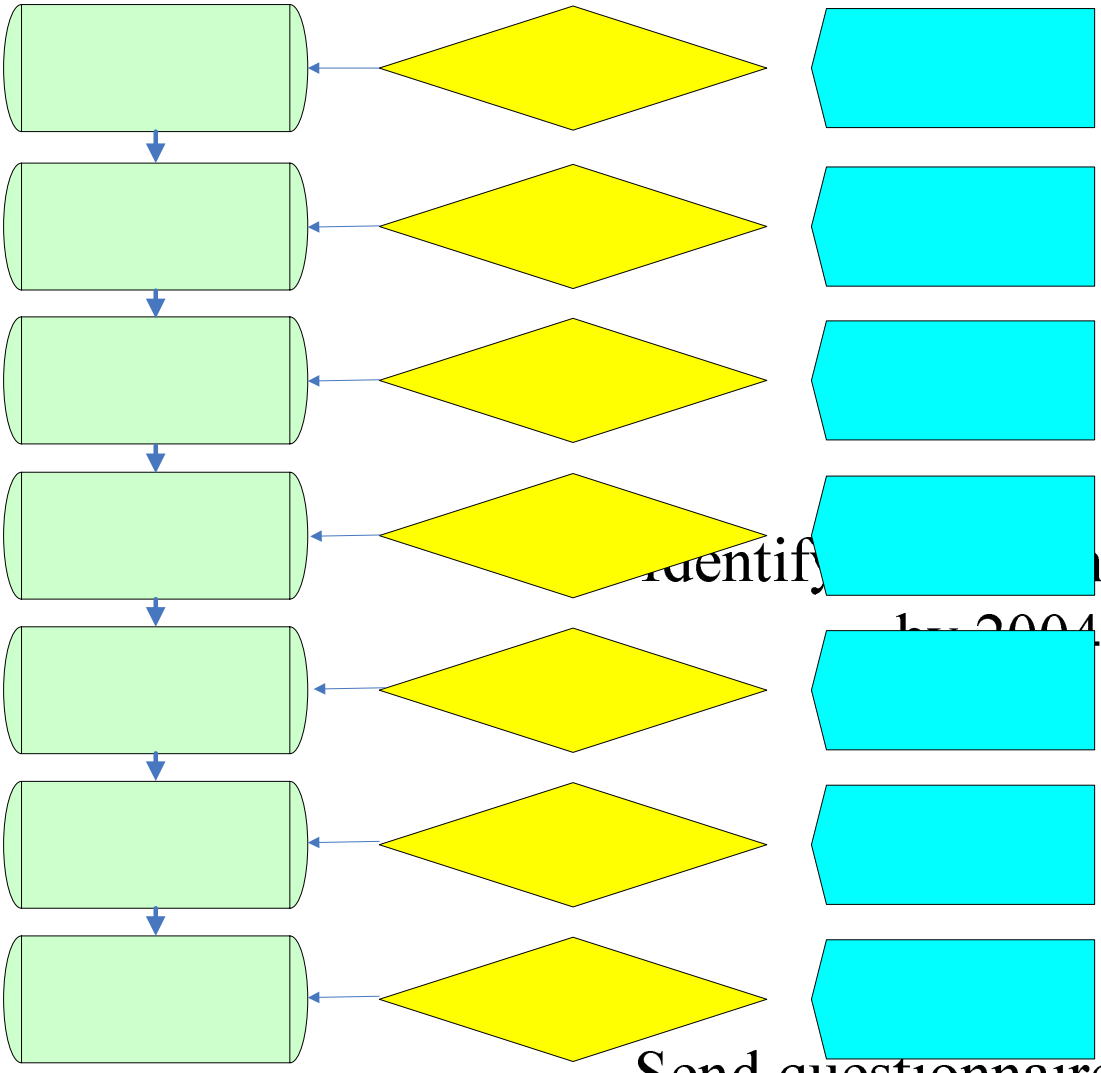

Fig. 3: Data survey process

28) The actual chronology of events was as follows:

a) SFDA and NICPBP identified all MDI producers;

b) SFDA, MEP and NICPBP prepared a questionnaire to collect the consumption, production and technical data under support of UNIDO;

c) The questionnaire was distributed to all the MDI producers in China;

d) Up to the November 2004, SFDA received feedback from all companies;

e) In August 2004, MEP, NICPBP and SFDA carried out field investigations at three pharmaceutical aerosol producers, namely: S&P Pharmaceutical Co. Ltd., Xinjiang Biochemistry Pharmaceutical Co., Ltd., and Xinjiang Pharmaceutical Factory.

f) In September 2005, SFDA and NICPBP visited 38 producers to collect and verify the required information.

g) In March 2006, SFDA requested local Food and Drug Bureaus through-out the country to confirm the status of MDI enterprises and their products.

Workshop for initially survey in 2004 and 2006

h) In April 2006, SFDA organized a meeting to initially discuss the plan of CFCs phase-out; this was attended by all MDIs enterprises. During the meeting, all the enterprises confirmed their data once again.

i) In May-June 2006 UNIDO reviewed the outcomes of the first surveys and plan with MEP, SFDA and NICPBP in Beijing and visited several major producers in Hangzhou, Shanghai and Wuxi to verify the data.

j) In May 2007, MEP, NICPBP re-visited three enterprises which showed the biggest consumptions of CFCs in the years 2003 to 2005.

k) In June 2007, MEP, NICPBP, and SFDA re-visited all the above mentioned 21 enterprises to collect MDI production and CFCs consumption data for the year 2006 and verify the data of previous years.

l) UNIDO has organized several meeting through the recent years to harmonise the data collection exercise, discuss the status of the preparation of the Sector Plan and advise on various issues of concern.

29) The 53rd ExCom reviewed the project document and decided to postpone the consideration of the approval of the project to a future meeting. Since there were some differences between the previously reported CFC consumption data and the ones reflected in the document presented to the 53rd ExCom, it was agreed that prior to the resubmission of the project UNIDO in close cooperation with SFDA and MEP/FECO will revisit the data in the framework of a new survey of the enterprises to reflect the latest verified data in this revised document.

30) The resurvey was carried out in the first quarter of 2008 by the following methodology:

a) Early 2008, SFDA sent to the local food and drug bureaus an official document requesting all local FDAs to conduct a survey on production of MDI producers within their area of authority and report the survey results to NICPBP.

b) According to the feedback from local FDA, an on-site survey of all MDI producers with CFC consumption in 2007 was carried out by NICPBP as a lead agency jointly with MEP and SFDA. The verification of the affected 13 MDI producers was conducted by 4 groups.

c) The following official documents and data were reviewed and crosschecked:

i) Subsidiary ledger of the use of raw materials for 2007 (by types and amounts): quantity of CFCs procured, consumption of CFCs, opening and closing stockpiles, and origin of raw material;

ii) Subsidiary ledger on sales for 2007 (by product and amount): unit price and quantity of products, sales and destination;

iii) Subsidiary ledger on products 2007: warehouse-entry amount, warehouse-out amount and opening and closing inventory of products;

iv) Collecting copies of invoices, on procurement of CFCs and product sales.

v) Collecting and reviewing the questionnaires on ODS consumption 2007 completed by the MDI producers.

d) The flow chart of verification is shown below:

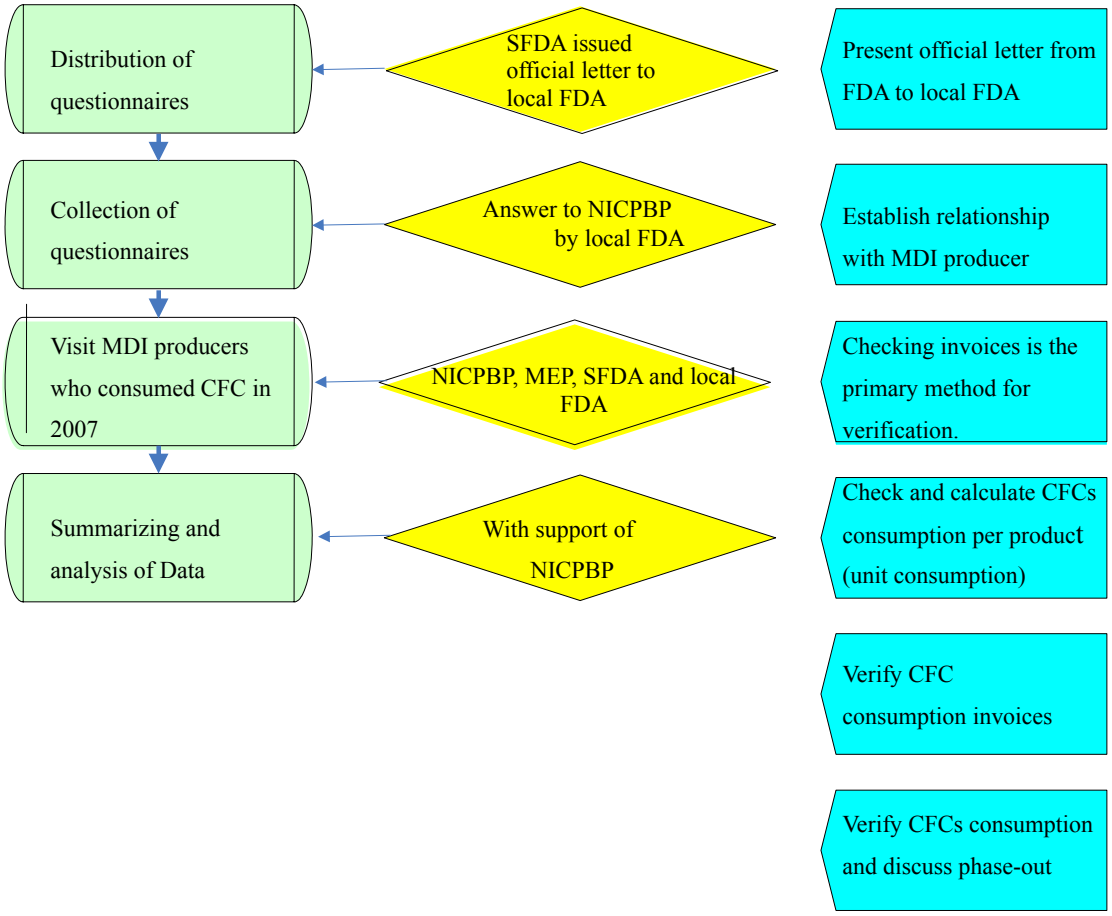

Fig. 4: Flow Chart of Verification

31) The new survey shows that the total CFCs consumption in 2007 amounted to 340.5 tonnes. In which, the 322.5 tonnes is accounted for Chinese-owned enterprise.
32) There are 16 enterprises who consumed CFCs in 2007, holding 60 licenses, of which, 36 have been in production and 24 without production.
33) The Chinese owned enterprises do not export MDI to non-A5 countries. They were all established before the cut-off date proposed, thus, in 2007 the eligible for funding CFC consumption in the MDI sector of China amounted to **322.5 ODP tonnes**.
34) The data deriving from the new enterprise level survey are reflected in the following Table 3 through Table 7.

F Enterprise information, CFC Consumption in the MDI Sector

35) Until today, there have been totally 25 types of MDIs (including three Chinese traditional medicine) produced in China by 38 companies (including 5 with foreign ownership).

36) In the period 2004-2007 25 companies produced 17 types of MDIs using CFCs. Due to market reasons eight types of MDIs were not produced during 2004-2007. The companies and their CFC consumptions are listed in Table 3:

Table 3. Products and CFC Consumption by enterprises

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
01	AstraZeneca Pharmaceutical Co., Ltd.	B13	Terbutaline Sulfate Aerosol	17.5	4,240.0	4,559.0	5,536.0	0
01	AstraZeneca Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	9.9	3,262.0	3,494.0	4,538.0	0
01	AstraZeneca Pharmaceutical Co., Ltd.	B13	Terbutaline Sulfate Aerosol	9.9	4,010.0	2,901.0	3,129.0	16,612.70
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	11.0	0.0	0.0	6,424.0	214
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	11.0	0.0	0.0	2,915.0	0
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B23	Iprartropium Bromide Aerosol	11.3	0.0	0.0	27.0	325
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	21.9	504.6	745.9		730
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B01	Beclometasone Dipropionate Aerosol	22.0	270.5	180.3		0
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclometasone Dipropionate Aerosol	27.3	12,203.1	0.0		0
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclometasone Dipropionate Aerosol	20.4	2,733.6	0.0		0
06	GlaxoSmithKline (Chongqing) Co., Ltd. *	B15	Salbutamol Aerosol	25.5				0

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
06	GlaxoSmithKline (Chongqing) Co., Ltd.*	B01	Beclometasone Dipropionate Aerosol	27.3				0
06	GlaxoSmithKline (Chongqing) Co., Ltd.*	B26	Beclomethasone Dipropionate Aerosol	13.1				0
06	GlaxoSmithKline (Chongqing) Co., Ltd.*	B01	Beclometasone Dipropionate Aerosol	19.8				0
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	12.5	2,370.0	2,010.0	1,341.0	1,660
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	12.5	250.0	400.0	219.0	120
09	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	B24	Zhichuanling Aerosol	12.0	393.6	30.0	130.8	320
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B14	Sodium Cyomoblicate Aerosol	17.89	0	0	0	127
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	22.5	172.1	179.5	0.0	286
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	B11	Huashanshen Aerosol	9.8	0.0	0.0	300.0	0
15	Henan Zhongfu Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	14.7	670.3	1,380.3	2,205.0	0
16	Heilongjiang Tanglong Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	13.9	27.8	0.0		240
18	Jinan Weimin Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	13.2	22,560.1	29,676.2	33,652.0	39,600

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
18	Jinan Weimin Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol	13.2	24,492.6	26,574.2	30,134.0	33,660
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol (solution)	11.3	12,219.0	12,395.0	16,025.0	18,098
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol	11.3	12,028.0	10,618.0	12,769.0	7,912
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	20.9	7.5	7.4	41.7	90
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B14	Sodium Cyomoglicate Aerosol	25.3	0.0	0.0	50.5	0
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	20.9	0.0	0.0	41.7	0
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B16	Salbutamol Aerosol (suspension)	17.2	37,405.7	79,163.9	70,000.0	90,507
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	23.2	7,288.5	16,526.3	22,950.0	59,807
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B15	Salbutamol Aerosol (solution)	16.2	2,947.4	9,801.2	20,250.0	11,479
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B14	Sodium Cyomoglicate Aerosol	16.9	2,109.9	6,902.0	7,378.0	13,386
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	10.2	0	0	0	30

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	9.8	0	0	0	70
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	49.4	3,459.0	2,344.5	3,210.0	3,551
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B25	Salbutamol Aerosol Compound Salbutamol Sulfate Aerosol	22.4			100.0	544
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	3.3			10.0	10
25	Pharmaceutical Factory of Shanxi Medical University	B16	Salbutamol Aerosol (suspension)	19.5	1,003.0	858.0	689.0	637
25	Pharmaceutical Factory of Shanxi Medical University	B01	Beclomethasone Dipropionate Aerosol (suspension)	19.5	62.0	90.0	19.0	0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B15	Salbutamol Aerosol (solution)	15.6	2,617.1	7,222.2	7,035.0	6,890
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B16	Compound Salbutamol Aerosol (suspension)	19.5	4,767.8	6,233.8	7,289.0	8,247
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B12	Ribavirin Aerosol	15.0	0.0	1,851.0	3,193.0	3,443
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B09	Ketotifun Fumarate Aerosol	20.1	0.0	0.0	1,271.0	1,271

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B04	Budesonide Aerosol	20.9	198.0	435.0	289.0	448
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B22	Isoprenaline Hydrochloride	15.6	165.0	200.0	165.0	190
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B01	Beclometasone Dipropionate Aerosol	23.3	0.0	0.0	79.0	90
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B14	Sodium Cyomoglicate Aerosol	21.9	0.0	0.0	113.0	78
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B17	Salmeterol Xinafoate Aerosol	15.0	33.6	0.0	0.0	0
29	Tianjin Century Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol	0	0.0	0.0	0.0	0
29	Tianjin Century Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	9.8	0.0	0.0	0.0	0
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.	B01	Beclometasone Dipropionate Aerosol	20	0	0	0	57
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol (solution)	11.6	3,150.0	1,350.0	900.0	557
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	15.0	0.0	0.0	0.0	70.7

Company Code	Company Name	Product Code	Product Name (active ingredient)	Consumption of CFC (g/can)	Annual CFC Consumption (kg),			
					2004	2005	2006	2007
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B15	Salbutamol Aerosol	11.5	7,570.0	6,755.0	4,840.0	3,200
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B22	Isoprenaline Hydrochloride Aerosol	11.5	1,470.0	1,245.0	0.0	0
35	Guandong Tongde Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	11.41	0	0	0	3,420
35	Guandong Tongde Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	10.6	0	0	0	2,650
36	Chongqing Kerui Pharmaceutical Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	16.8	5,550.0	7,530.0	7,376.5	9,767
37	Zigong Chengguang Pharmaceutical Co.,Ltd.	B05	Dimethicone Aerosol	25.2	307.1	22.2	70.0	100
38	Jiangsu Tianji Pharmaceutical Co.,Ltd.	B12	Ribavirin Spray	9.0	0	0	4,202.0	0.00

Table 4. CFC Consumption of MDI Sector in China 2004 - 2007 (unit: tons ODP)

Year	**2004**	**2005**	**2006**	**2007**
CFC-11	27.1	40.1	40.9	46
CFC-12	152.6	200.9	236.7	294.5
CFC-114	2.9	2.7	3.3	0
CFCs	182.5	243.7	280.9	340.5
Of which consuming by 5 foreign companies	30.4	13.2	14.1	18
Of which consumption by 18 domestic companies*	**152.1**	**230.5**	**266.8**	**322.5**

* There are 15 domestic companies, which have registered MDI products but have had no production during 2004-2007.

** The ODP tonnes of CFC-11, CFC-12 and CFC-114 are same as the metric tonnes.

Table 5. Production of CFCs MDI in China 2004 - 2007

Year	**2004**	**2005**	**2006**	**2007**
Output (Cans)	12,027,255	15,871,614	18,857,763	21,589,832

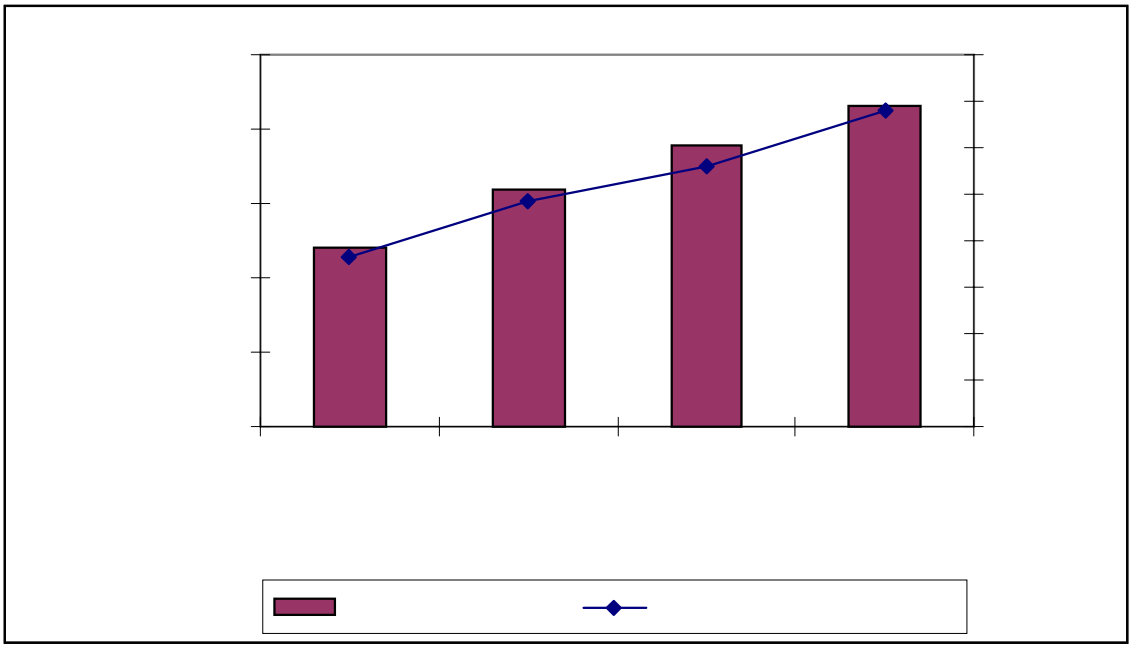

Fig. 5: CFC Consumption and MDI production during 2004 - 2007

Table 6. General Information of the MDI Manufacturing Enterprises

Company Code	Company Name	Year of Establishment	Chinese share of ownership	Number of line	Number of Licences	Type	CFC Consumption in 2007, (kg)	Output in 2007, (cans)
1	AstraZeneca Pharmaceutical Co., Ltd.	1992	0%	1	1	B13	16,613	1,364,859
2	Beijing Haiderun Pharmaceutical Co., Ltd.	1978	100%	1	2	B15, B23	540	48,306
3	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	1991	0%	1	1	B15	730	33,333
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1988	100%	1	2	B15, B22	1,780	141,360
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	1979	100%	1	1	B24	320	20,206
11	Harbin Hengcang Pharmaceutical Co., Ltd.	1993	100%	1	2	B14, B15	412	23,034
16	Heilongjiang Tanglong Pharmaceutical Co.,Ltd.	1997	100%	1	1	B15	240	16,000
18	Jinan Weimin Pharmaceutical Co.,Ltd.	1979	100%	2	2	B15, B22	73,260	5,550,000
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	1993	100%	2	3	B15, B22 B16	26,100	2,216,150
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	1993	100%	1	4	B15, B14 B16, B01	175,178	9,295,910

22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	1991	100%	1	2	B15, B22	100	10,000
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	2001	100%	1	3	B17, B25, B04	4,115	169,400
25	Pharmaceutical Factory of Shanxi Medical University	1994	100%	1	1	B16	637	32,785
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	1982	100%	1	8	B12, B15, B22 B16 B09 B04 B14 B01	20,656	1,289,879
31	Weifang Zhongshi Pharmaceutical Co.,Ltd.		0%	1	3	B15 B16 B01	685	55,230
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	1965	100%	1	1	B15	3,200	195,560
35	Guangdong Tongde Pharmaceutical Co.,Ltd.	1993	100%	1	2	B15 B16	6,070	550,000
36	Chongqing Kerui Pharmaceutical Co.,Ltd.	1975	100%	1	1	B16	9,767	575,520
37	Zigong Chenguang Pharmaceutical Co.,Ltd.	1981	100%	1	1	B05	100	2,300
38	Jiangsu Tianji Pharmaceutical Co.,Ltd.			18	36		340,503	21,589,832

Note:

1. Companies marked with * don't produce anymore.
2. Companies with no MDI lines are using contract fillers to fill their products.

37) The summary of information on enterprises for the year 2007 is as follows:

Table 7. Summary of information of enterprises for 2007

	Number of producers	Number of Licences	Number of Licences in production
Number of MDI producers	38	104	40
Domestic ownership in production	16	51	36
Domestic ownership with idling capacities	18	36	0
Foreign ownership in production	4	17	4
Foreign ownership, closed*	1	*	*
Consumption (tons):			
CFC-11	46		
CFC-12	294.5		
CFC-114	0		
Total CFC consumption (MT)	340.5		
Consumption of 5 foreign companies (MT)	18		
Consumption of 15 domestic companies (MT)	322.5		

* One of foreign companies stopped producing in Chongqing and shifted its registered products to its sister company in Tianjin.

38) The CFC consumption data survey did not show the expected rapid growth of CFC based MDI production and CFC consumption. The reason is that from late 1990's, MEP began to conduct public awareness raising activities on CFCs phase out in this sector. Currently, a large amount of imported DPI and CFC-free MDIs are on the Chinese market.

39) According to the discussion with enterprises during the site visits, MDI manufacturing enterprises in China face many problems and difficulties in the process of CFCs replacement. Up to now, only one product from one enterprise got approval from SFDA for clinical tests. The preparation of the National MDI Strategy and the project document raised awareness among the enterprises and they are seriously studying and developing their strategies to phase out CFCs in their companies.

Chapter III Regulation and Policy for the MDI Sector and CFC Phase out

A Regulatory framework for Drug, especially for MDI

40) CFCs are used as an inactive carrier substance (excipient) in the production of MDI. According to the laws, regulations and policies concerning drug management in China, strict procedures must be followed when formulation of a drug including the excipient is changed. The main laws, regulations and policies governing the drug management are as follows:

Drug Administration Law of the People's Republic of China (took effect on 1 December 2001)

41) This law is a national law to be observed strictly by all pharmaceutical products related production enterprises and institutions. The stipulations of the Drug Administration Law of PRC are used as the guiding principle in this Sector Plan of CFCs Phase out in the MDI Sector. This law aims to strengthen drug administration, guarantee drug quality, safeguard the safety of use of drugs in human body, safeguard human health, and protect legal rights to use the drug. As specified in its Clause 2, this law must be observed strictly by any unit or individual functioning in R&D, production, operation, use, and supervisory administration of drugs within Chinese territory. The MDI aerosol is one kind of drugs, and thus its supervisory administration (including the substitution of excipient/propellant and the modification of the form of drug) shall comply with various regulations of *Drug Administration Law of PRC*. Some clauses related to the MDI sector plan include, but not limited to:

a) Control over Manufacturers. Article 9 states that "drug manufacturers shall conduct production according to the Good Manufacturing Practices for Pharmaceutical Products (GMP) formulated by the Drug Administration Department under the State Council on the basis of this Law. The drug regulatory department shall inspect drug manufacturers on their compliance with the GMP requirements and issue a certificate to the manufacturers passing the inspection. The specific measures and schedule for implementing the GMP shall be formulated by the Drug Administration Department under the State Council."

b) Control over Drugs. Article 29 states that the dossier on a new drug research and development, including the manufacturing process, quality specifications, results of pharmacological and toxicological study, and the related data and the samples shall, in accordance with the regulations of the Drug Administration Department under the State Council, be truthfully submitted to the said department for approval, before clinical trial is conducted. Measures for verifying the qualifications of clinical study institutions for drugs shall be formulated jointly by the drug regulatory department and the administration department for health under the State Council. When a new drug has gone through clinical trials and passed the evaluation, a New Drug Certificate shall be issued upon approval by the Drug Administration Department under the State Council.

c) Control over Production. Article 31 states that "A drug manufacturer may produce the drug only after an approval number (production license) is granted to it."

Regulation on Drug Registration revised recently by SFDA (No. 28, effective as of 1 October 2007)

a) Article 12 states that "a new drug application means a registration application for a drug that has not been marketed in China. A drug that has been marketed in China, for which an application is made for a change in dosage form, or route of administration of medicaments, addition of new indication shall be treated as a new drug application." ….. "Supplementary application means an application for the change, addition, or cancellation of any item or content in the existing registration approval of a new drug, or of a drug already with national standards (approved for another company), or import drug."
b) Article 18 stipulates, that regarding a drug or its formulation, manufacturing process and indication etc. the applicant shall submit documents to explain the patent status and ownership rights in China. If patent(s) related to the above is valid in China the applicant shall submit a letter of guarantee to declare that the drug will not infringe the patent rights of others and that the applicant assumes liability for any possible infringement. If any disputes on patent occur in the process of registration, the related parties shall try to resolve the matter according to relevant laws, regulations.
c) Article 113 requires that if there is a change a.) in drug registration standards, b.) excipient, or c.) the production process, which may affect product quality a supplementary application should be processed. The application should be submitted to the FDA of the Province, Autonomous Region or Municipality under the Central Government, who shall review the application and submit recommendations to SFDA for approval. Then applicant will be notified subsequently.
d) Article 150 authorises SFDA to administer the technical review during the drug registration process in accordance with the following requirement:
    i) Complete approval procedure in 90 days for a drug to apply new clinical study, complete approval procedure in 80 days if a drug meets the requirements under Article 48 of this Regulation;
    ii) Complete approval procedure in 150 days for production of new drug, complete approval procedure in 120 days if a drug meets the requirements under Article 48 of this Regulation;
    iii) Complete approval procedure in 160 days for an imitated drug already with national standards, or a change in dosage form.
    iv) Complete approval procedure in 40 days for supplemental application if a technical review is needed.

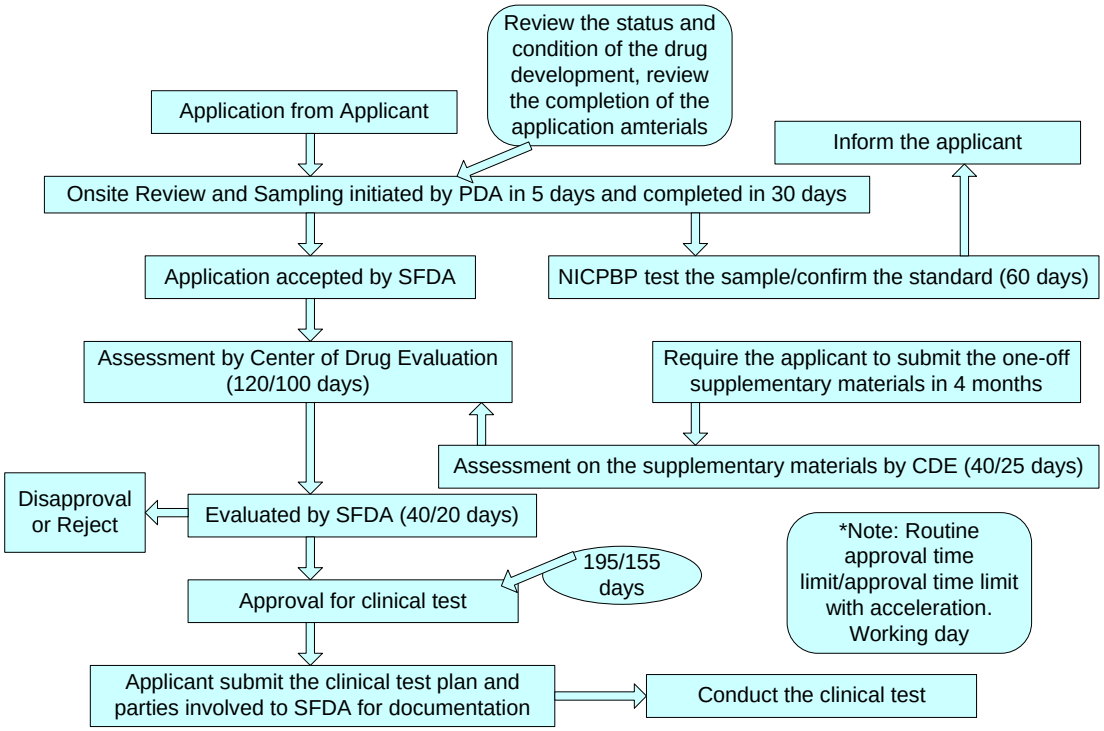

Fig. 6: Approval Procedure for Clinical Test of the New Drug

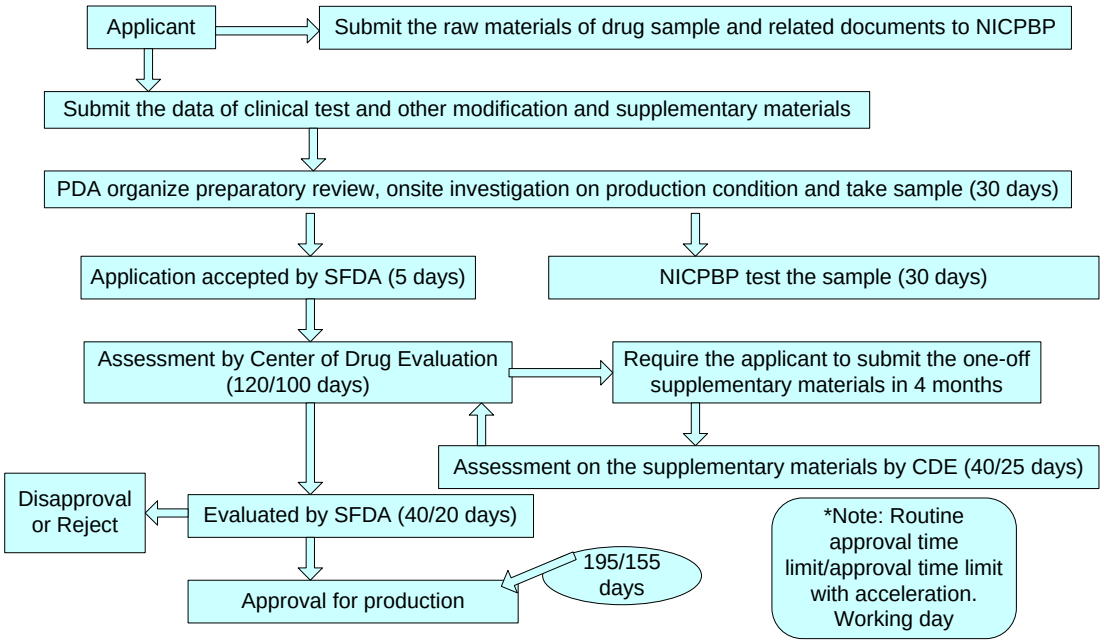

Fig. 7: Approval Procedure for the Production of New Drug

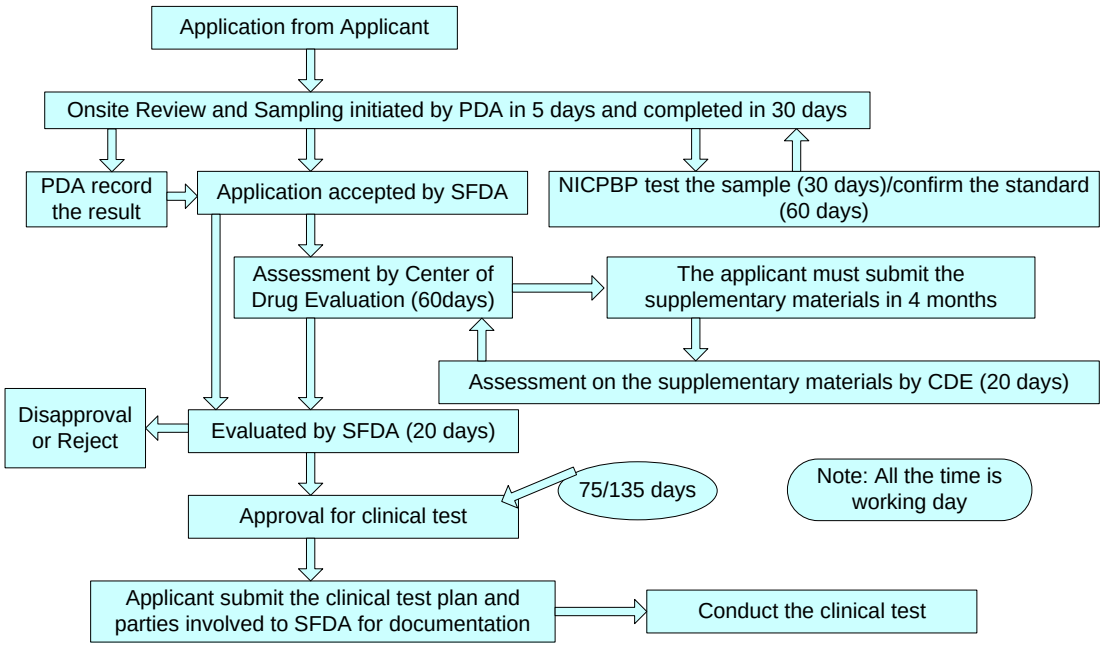

Fig. 8: Approval Procedure for Clinical Test for Change to Existing Drug

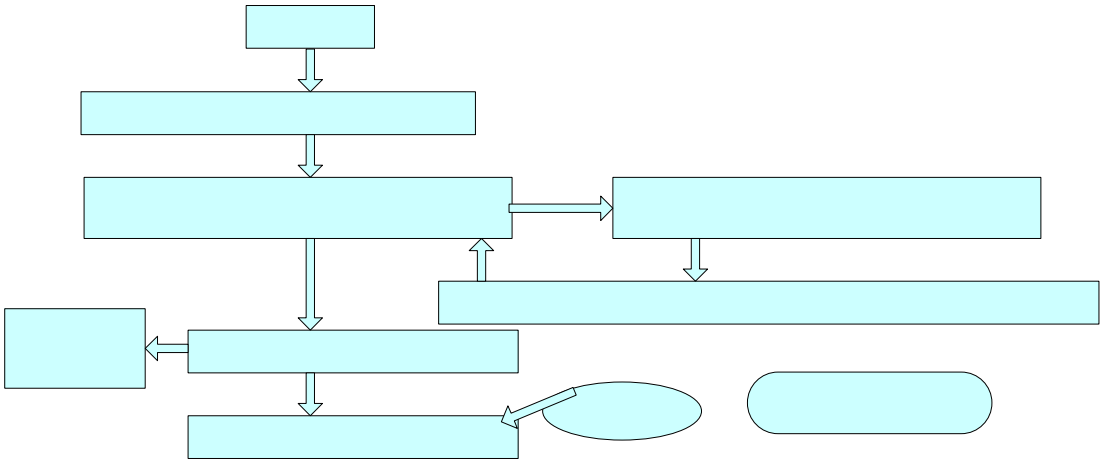

Fig. 9: Approval Procedure for Production for Change to Existing Drug

B Policies Related to CFC Phase out

Notice on Terminating the Use of Chlorofluorocarbons (CFCs) as Excipient for Medical Aerosols (Guo Si Yao Jian Zhu No. [2006] 279):

42) This notice issued by SFDA on 22 June 2006, specifies the following relevant matters in order to accomplish the commitment of the Chinese Government and guarantee the smooth phase out of CFCs in line with accelerated CFC Phase-out Plan of China:

a) China stopped using CFCs as pharmaceutical excipient in the production of external-use aerosol from 1 July 2007. The external-use aerosols produced with CFC based excipient before this date can be circulated and used until the expiration of their validity date.
b) China stopped importing the CFC based external-use aerosol from 1 July 2007, and the external aerosols imported before this date can be circulated and used until the expiration of their validity date. China will stop importing the CFC based metered inhalant aerosol from 1 January 2010, and the inhalant aerosol imported before this date can be circulated and used until the expiration of their validity date.
c) China stopped examining and approving registration applications for CFC based external-use aerosols (including that for imported ones) from 1 July 2007 and that of CFC based metered inhalant aerosol (including that of imported ones) from 1 January 2010.
d) To eliminate CFCs in line with the Sectoral Phase out Plan, drug producers shall, according to the relevant requirements of the Regulations on Drug Registration, apply for modification of the pharmaceutical excipient or drug form of pharmaceutical aerosols.

Chapter IV Technical Options

A Potential Ways to Phase out CFCs in the MDI Sector

43) There are two major issues to be considered when converting CFCs based MDIs to non-ODS alternatives:

a) In-kind: find the substitute excipient to replace CFCs,

b) Non in-kind: adopt other drug delivery system: e.g. compressed air atomizer, ultrasonic atomizer, two-phase system, self-pressurising system or dry powder inhalation.

Table 8. Comparison of Different Types of Asthma Treatment Drugs

Type of inhaler	Advantages	Disadvantages
Metered dose inhalers (MDI)	1. Simple actuation system 2. Reliable accurate dose regardless of the patient's breathing capacity 3. Compact and portable 4. Easy to use 5. Economical 6. Good resistance to moisture	1. Mostly use CFCs as propellants 2. The method of pressing and breathing requires coordination between actuation and breathing (breath-actuated systems do not have this drawback). 3. Dosage accuracy may be dependant on the formulation. 4. Complex manufacturing process.
Dry Power Inhalers (DPI)	1. No propellant used	1. Drug release depends on the patients breathing capacity. 2. The inhaled fraction is reduced if the patient breath is directed into the system. 3. Relatively expensive. 4. Costly conversion and patent rights
Nebulisers	1. No special breathing coordination required. 2. Works with patients using mechanical breathing. 3. Useful to administer new or less used drugs.	1. Not portable. 2. Depends on an electric supply. 3. Expensive. 4. Operation takes a long time. 5. Requires the use of preservatives to reduce risk of bacteria contamination.

44) For the time being, the potential substitutes of CFCs used for MDI are HFA 134a and HFA 227.

B DPI Production

45) SFDA together with the industry and representatives of the academia reviewed the possibility to introduce DPI at one or more of the MDI producers. The findings of their investigations can be summarised as follows:

a) As a new kind of product a whole cycle registration process has to be applied. It is an even more expensive and time consuming procedure that the one to be applied for change of propellant.
b) There is a need for purchase and installation of a totally different plant, including some special and very costly machinery for the production of very fine and homogenous powder.
c) The dosing units are not available in China. Their import would be expensive and installation of a plant to manufacture the dosing units would require substantial resources and involves patent right issues.
d) The current market price of the DPIs in China is about five times higher than the same of MDIs. This is a serious market obstacle in view of the weak purchasing power of many Chinese asthma patients.
e) A Japanese company is establishing a DPI factory in China to address the available niche market for DPIs. Currently, there seems to be no place on the market for another new (Chinese) producer.
f) In view of the above, the consideration of introducing DPI manufacturing in the present conversion process had to be dropped.

C Alternative excipient - Hydrofluoroalkanes (HFA)

46) HFA have similar properties as CFCs, however their chemical stability and polarity are slightly lower than that of CFCs. Table 9 below shows the comparison between HFA and CFCs in terms of the physical and chemical characteristics and their environmental properties.

Table 9. Comparison of Properties between Fluoroalkanes and CFCs

Property	**CFC-11**	**CFC-12**	**CFC-114**	**HFA-134a**	**HFA-227**
Chemical formula	$CFCl_3$	CF_2Cl_2	CF_2ClCF_2Cl	CF_3CFH_2	F_3CHFCF_3
Vapour pressure (kPa,21.1 ^{0}C)	92.4	484	88.9	569 (20 ^{0}C)	3.99
Boiling point (^{0}C)	24	-30	4	-26.5	-17.3
Density (g/ml)	1.49	1.33	1.47	1.22	1.41
ODP	1	1	1	0	0
GWP	4,000	8,500	9,300	1,300	2,900
Life time in the atmosphere (year)	75	111	7200	15	33

Table 10. Advantages and Disadvantages of using HFA for MDIs

	Advantages	**Disadvantages**	**Comments**
HFA	1. Low inhalation toxicity 2. Higher chemical stability 3. High purity 4. No harm to ozone layer	1. Bad solvent, low polarity 2. High GWP - greenhouse effect 3. Higher cost	1. HFA may be used by the MDI aerosol producers in China as a potential substitute to CFCs

D Alternative Technologies

47) In recent years, international MDI producers did intensive research on the technology of substitution of CFCs and change of drug formulation. The substitute propellants currently used in the world are mainly HFA-134a and HFA-227a. Except for terbutaline, the CFCs used with all the other active ingredients could be replaced by HFA. The leading companies in the world such as Boehringer, Fisons, 3M, Glaxo and Riker have obtained relevant formulation patents, which cover the propellant system including components, co-solvent, hydrocarbon surfactant and fluoro-surfactant.

48) In contrast with the above, the results of our sector investigation show that Chinese MDI manufacturing enterprises are now preparing themselves for the process of CFCs replacement. It is reported that many issues still have to be resolved for introduction of Hydrofluoroalkane as propellants for MDIs:

a) **Co-solvent with Low Boiling Point.** Both tetrafluoroethane (HFA-134a) and heptafluoropropane (HFA-227a) have higher vapour pressure and are in gaseous state under normal atmospheric temperature. No Hydrofluoroalkane is available, which has the same high boiling point as CFC-11 does. Therefore, it brings challenges to design the formulation and production process. One of the solutions is to seek for proper solvents without toxicity or irritation but with certain volatility and good compatibility with Hydrofluoroalkane. Today, the commonly used co-solvents

include low-molecular-weight alkane (e.g. propane and butane) and low-molecular-weight alcohols (e.g. ethanol and isopropanol).

b) **Surfactant Selection.** Surfactant is used to disperse medicament particles and lubricate the valve. As Hydrofluoroalkane has lower polarity than CFCs, it can not dissolve majority of surfactants. One solution is to identify surfactants with good solubility and compatibility with medicaments. Another solution is to add a co-solvent which can dissolve the surfactant.

c) **Drug Characteristics.** Some medicaments easily form solvates in the new propellant system, thus increasing the tendency of crystal growth. Some poly-crystalline drugs (such as steroid hormone) are easier to undergo crystalline transformation and promote crystal growth. Thus, drug characteristics should be taken into account in formulation design, particularly in the design for suspended aerosols.

d) **Valve Selection.** As Hydrofluoroalkane is chemically less stable than CFCs, valve components (e.g. airproof rubber and its additive) should be compatible with the new propellant. Similarly, valve components should not cause HFA to decompose. At present, several major valve companies such as Bespak, 3M and Valois conduct research on the valve system for Hydrofluoroalkane.

e) **Alternative Actuator.** In case a medicament can not be formulated into suspended aerosol, it is generally made into solution aerosol. In general, solution aerosol has poorer atomisation effect. Decreasing vapour pressure of the canister results in bigger atomized particle size. Though increasing the pressure can reduce the particle size, it also causes majority of particulate medicaments to be accumulated at throat due to the bumping of particles arising from the increased initial speed. Thus, it is needed to design new actuators, which can both crash the particles and reduce the initial speed.

E Policy and Patent Issues

49) Phase out of CFC is the commitment made by the government of China. The obstacles include lengthy and costly drug registration, lack of funds and technologies.

a) Based on “The Drug Administration Law of the People's Republic of China”, change of excipient leads to the re-registration of the drug. Preparation of the technical dossier is required for the re-registration, for which lengthy and voluminous pharmaceutical and pharmacodynamic studies must be done.

b) Modification of production and market promotion of new drugs cost large amounts of money. It’s a heavy burden for most of the MDI enterprises.

c) In addition, the patent issue is a major obstacle to conduct CFC phase out in MDI sector.

50) There are two major HFA MDI related patents in China. They cover the

a. formulation, which use HFA134a, HFA227 and their mixture as propellant for all the applications currently produced in China, and

b. co-solvent and surfactant as well.

51) The cost for the patent transfer is extremely high. It seems, however even more difficult and costly to develop new technologies. The detailed content of the patents are listed in the Table 11 below:

Table 11. MDI related patents in China

Patent Name	CFC-free aerosol to cure the diseases in the respiratory system	**Patent Number**	00133271.6
Publication Number	CN1296814	**Date published**	2001.05.30
Applicants	China Pharmaceutical University		
Inventor	Junshou Zhang, Li Ding, Yizhong You	**International Application**	

Patent Name	New aerosol reagent containing polarized fluoride molecules	**Patent Number**	**01815467.0**
Publication Number	CN1455663	**Date published**	2003.11.12
Applicants	AstraZeneca Co. Ltd.		
Inventor	P. Rogda	**International Application**	PCT/SE01/01606 2001.7.10

Chapter V Phase-out Strategy and Policy Framework

A Objectives

52) The main objectives of this plan are:
   a) To ensure sustained phase out of CFC consumption in China's MDI sector and the related CFC production of the Country;
   b) To maintain the phase-out momentum and to avoid risk in compliance with the Montreal Protocol for phase out of CFCs;
   c) To encourage new alternatives in China's MDI sector; introduce ozone friendly technologies and to maintain MDI production at the level to meet the clinical demands.

B CFC Consumption Phase-out Schedule

53) Earlier China planned to meet the phase out schedule of CFCs for protection of the Ozone layer and compliance with Montreal Protocol as indicated in Table 12.

Table 12. Current phase out control targets for CFC consumption in MDI sector (tons ODP)

Maximum Allowable CFCs consumption	**2006**	**2007**	**2008**	**2009**	**2010**
National level	13,500	7,400	550	550	0**
MDI sector	280.9		550	550	0
Max allowable CFCs production *	13,500	7,400	550	550	0

* Appendix 2-A. The targets, and funding, AGREEMENT BETWEEN CHINA AND THE EXECUTIVE COMMITTEE FOR THE CFCS/CTC/HALON ACCELERATED PHASE-OUT PLAN, ANNEX XII.39 Policies, procedures, guidelines, criteria.

** Except the essential use agreed by the parties.

54) The most important prerequisites of the phase out of CFCs in the MDI sector in China is that it should not impose any negative impact on the clinical demand and supply situation for MDI products, i.e. it should enable China to maintain its MDI production at a level to meet the clinical demand by quality and quantity and at acceptable prices.
55) In China, the average growth rate of CFC containing MDI production over the past four years amounted to 22%/year; the CFC consumption grew at a similar rate. This trend will continue in the coming years unless it is curbed by conversion of MDI producers to new technologies replacing CFCs in the production of MDIs to other alternatives.

56) Due to the limited time before 1 January 2010, when according to the original CFC phase-out schedule the use of virgin CFCs should be stopped in all sectors, it will be not possible for the MDI producers to complete the drug re-registration process. Thus, CFC will have to be used in 2010 and onwards.
57) In case the project is approved by the 55th ExCom, the majority of the enterprises will be in a position to complete the phase out of CFC by end 2013.
58) Some specialty products (Chinese medicines) do not have known alternative technologies. While the companies will continue the research and development work in this field, it might happen that small quantities (below 10 tonnes annually) of CFC would be required for some period of time. The Government and the enterprises will make efforts to satisfy these needs from stockpiled CFCs.

C Transitional Arrangement and Need for Essential Use Exemption

59) China is committed to phase out CFCs as soon as practically feasible taking into consideration the above situation and a reasonable project implementation time schedule.
60) Based on the current survey, the consumption for the whole MDI sector will be steadily growing.
61) Table 13 shows the strategy foreseen at the current stage for the phase out process and the likely essential use exemption requirement of the Government of China.
62) The unconstrained growth and phase out schedule proposed in this plan are contained in Table 13.

Table 13. Unconstrained growth and phase-out plan of CFC consumption in China's MDI sector

Year	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Output, (Million cans)	12.03	15.87	18.86	21.59	26.29	32.01	38.97	47.45	57.77	70.34	85.64
Unconstrained CFC consumption, MT	182.5	243.7	280.9	341	414.6	504.8	614.6	748.3	911.1	1,109.3	1,350.6
CFC Consumption if project is approved at 55th ExCom	182.5	243.7	280.9	341	414.6	504.8	614.6	748.3	650.0	400.0	0

63) The impact of the project is well illustrated on Fig.10, which compares the unconstrained growth scenario with the proposed phase out schedule.

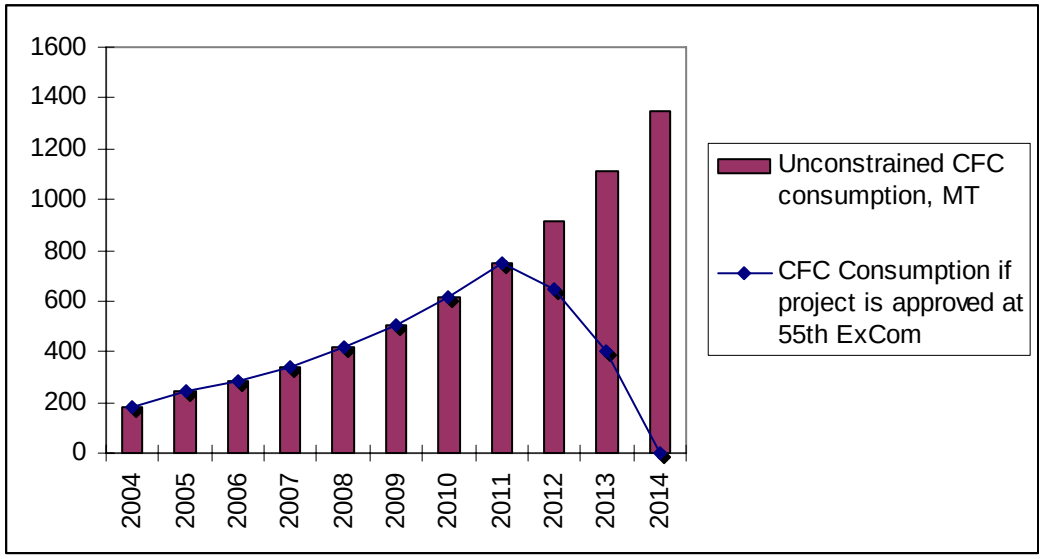

Fig. 10: Unconstrained growth and proposed CFC phase out schedule in China's MDI sector

D CFC production during 2008-2013

64) It is crucial to cover the domestic demand of the MDI sector after 2008 with freshly produced CFCs. Since this MDI sector plan is the last CFC phase out plan in China, during the period 2008-2013, the CFCs production for domestic sales will be limited for MDI sector and possible essential uses only.

65) Taking into consideration that China has the capacity to cover this demand, the Government proposes to integrate the necessary requirements in the Agreement between China and the Executive Committee for the CFCs/CTC/Halon Accelerated Phase-Out Plan (ANNEX XII.39 Policies, Procedures, Guidelines and Criteria) and set up a new CFC production plan for the duration of the implementation of this project.

66) If, the project is approved by the 55th ExCom the conversion process will show its first results in 2012 through completing some phase out project(s) by end 2011. In 2012 and 2013 further reductions in CFC consumption will occur and upon completion of the project in 20013, the complete phase-out of the use of freshly produced CFCs will be achieved. Thus, considering the implementation schedule of this sector plan as well as the current consumption and the export demand, the maximum production quota to be issued will be 550 tonnes/year in 2008 and 2009 respectively. Currently, if no other decisions will be taken by the Parties in the future, it is planned to cease export as of end 2009 and based on future approval of the Meeting of the Parties the production is planned to be maintained in the period 2010-2013 as indicated in Table 14.

Table 14. Planned CFC demand and related production in China

	2008	2009	2010	2011	2012	2013	2014
Production approved	550	550	0	0	0	0	0
Consumption of the MDI sector*	415	505	615	748	650.0	400.0	0**
Exports planned	135	45	0	0	0	0	0
Additional production required*	0	0	615	748	650.0	400.0	0*

*Essential use exemption for 2010-2013 to be requested from the Parties

**The possible essential use exemption for this and following years will be considered based on the progress of the project

E Policies and Measures

67) ***Adaptation of ODS licensing system to control CFCs consumption in the MDI sector***. To propose, based on current ODS licensing system, a monitoring and evaluation plan for CFCs consumption control in the MDI sector, including review of enterprise information, issuance of CFCs licenses and quotas for consumption, as well as regular site supervision. The key points of the licensing system include (1) no trade in CFCs is allowed between the licensed enterprises and the non-licensed ones; (2) no change of licenses from one type of CFC to another one is allowed between the enterprises holding licenses for different ODS substances; (3) no purchase of CFCs from other licensed enterprises is allowed exceeding the issued quota; (4) all transactions and trade must be approved by MEP, and (5) all transaction and trade process must be entered into the information management system.

68) ***Issue CFCs consumption ban for MDI sector***. The National Leading Group of Ozone Layer Protection under the State Council will issue a ban on CFCs consumption to ensure that all CFC producers and consumers are informed and prepared. The date of issuance of the CFC ban for the MDI sector will follow the date of approval by the ExCom of the MDI sector plan.

69) ***Strengthen supervision and capacity of sector plan implementation***. A monitoring system will be developed for the implementation of the MDI sector plan. It will track the implementation of the sector plan by (1) review of CFCs consumption data and information reported by the enterprises, (2) review of transactions and trade processes of CFCs, and (3) timely adjustment of CFCs quotas and its license holders. A supervisory and monitoring team will be established.

70) ***Strengthen formulation of technical standards for the CFCs alternatives.*** China will revise the relevant technical standards and codes of CFCs alternatives based on its production and alternative technology development and the progress of CFC phase out in MDI sector.

71) ***Policies Ranging over the Transition Period (after 2012)***. China will stop using CFCs as excipients for MDI as of end 2012. That means that there will be no virgin CFCs produced for the MDI sector. After this date, MDI manufacturers can (in case of necessity) use only stockpiled CFCs. However, using of stockpiled CFCs would be under stringent supervision of the government. SFDA will make

the necessary transitional arrangements. When receiving the application from the manufacturers for using stockpiled CFCs during the transition period, SFDA and MEP will review and approve the applications.

72) ***Public awareness and education***. China will continue to strengthen the education and training programme for enterprises, public, and those who are responsible for implementation of ODS policies, especially stakeholders in the MDI sector.

73) ***Supervision after 2012***. After 2012, SFDA and MEP will monitor non-CFCs aerosol products so as to guarantee its safety and efficacy of clinical application.

Chapter VI Incremental Cost Calculation

74) The incremental costs for the MDI sector have been calculated taking into consideration:
   a) MLF guidelines,
   b) Activities identified for conversion of CFCs based technologies to no-CFC based ones;
   c) Remaining eligible consumption of CFCs in the sector;
   d) Enterprise level incremental conversion costs for all the identified eligible enterprises, according to their activities;
   e) Identified Technical Assistance activities;
   f) Possible industrial rationalization for enterprises without CFC-MDI production or very low production in baseline year.

A Incremental Costs Identified

Incremental Cost at Enterprise Level

75) The conversion activities at enterprise level include seven items:
   a) Research & Development of non-CFC MDIs (including technology screening and formulation development);
   b) Adaptation of new alternatives and technologies including procurement of rights to use the related patents;
   c) Registration of the new products;
   d) Modification of existing facilities;
   e) Training to meet the new production requirements;
   f) Validation of new production process ;
   g) Incremental operating cost of materials and utilities for production;
   h) Promotion of new products on the market.
76) In order to reduce the cost of the project to the Multilateral Fund two kinds of costs of the conversion process, were excluded from the IC requested from MLF and will be paid by the beneficiaries as their counterpart contribution, namely:
   a) Cost for Research & Development of non-CFC MDIs (including technology screening and formulation development), and
   b) Cost for marketing and promotion of new products.
77) The relationship between conversion activities at enterprise level and the IC requested from MLF are shown as follows:

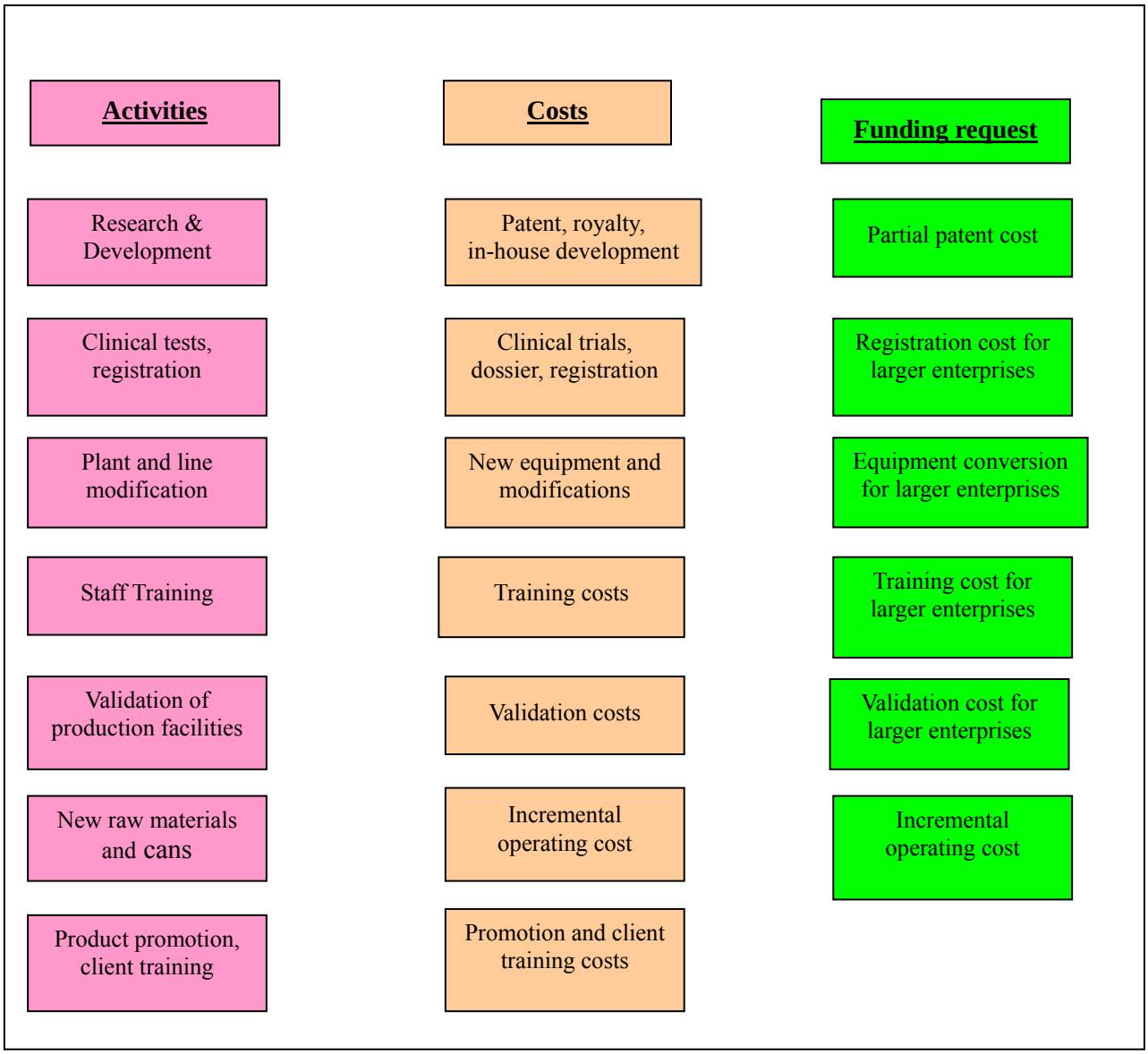

Fig. 11: The relationship between conversion activities at enterprise level to the incremental cost items requested from MLF

78) ***Cost for research & development of new formulation.*** Since research and development of the new formulations of MDI would be done by the MDI producers themselves, or would be bought from the patentees, the cost for the new formulation could be very different. If the MDI producers buy the technologies from the patentees, royalty fee will be required based on their annual production. These costs, according to the information received, are very high and will substantially increase the cost of Research & Development of the new formulation of MD Is. For this reason at least partial compensation is sought for the purchase of unavoidable patents valid in China.

79) ***Cost for marketing and promotion of new products.*** CFC-MDIs are familiar to the patients and have been widely used in China. The non-CFC MDIs have some different properties, thus in addition to the normal advertisement and sales promotion extra efforts are needed from the MDI producers to

promote their non-CFC-MDI products on the market. This campaign has to address both the doctors and the patients. However, these kinds of costs are difficult to be estimated at enterprise level.

Incremental Cost for Technical Assistance

80) Beside the enterprise level costs, as described in Section 4.3, there are a series of activities of technical assistance nature, like: capacity building, training, data collection, public awareness, development and implementation of policies, progress monitoring, performance verification, and supervision.

B Industrial Rationalization and Cost Effectiveness – Implementation of ExCom Decision 53/23

81) In its decision 53/23(b) the ExCom decided to:

"To request the Government of China and UNIDO to take into consideration industrial rationalization and cost-effectiveness when resubmitting a revised project proposal."

82) The decision of f the ExCom was implemented as follows:

a) During the site visits and data survey carried out early 2008, SFDA and MEP discussed with related stakeholders of mainly smaller and less viable enterprises to seriously consider their participation in an industrial rationalization process. It was found that no enterprise is willing to abandon their MDI production lines and production licenses on a voluntary basis.

b) As a next step, the possibility of forced rationalization was investigated. It was found that the within the current legal framework of China there is no legal tool to enforce closure or consolidation of enterprises or some of their production lines with the aim of industrial rationalization in the MDI sector.

c) Thus, the only viable option to curb the production of small MDI producers through consolidation is to use market forces in the form of incentives and disincentives. In order to achieve this aim the following measures are proposed in this sector plan:

   i) <u>For enterprises without production in baseline year</u>, no ICC, IOC, cost for validation, training is being requested and will be paid, except for only 20,000 US$/licence, which equals to a partial cost compensation of giving up their production license;

   ii) <u>For the enterprises with very low production in baseline year</u> representing max. 5 tonnes annual CFC consumption, very much reduced ICC and IOC along with only US$ 20,000/licence is being requested and will be paid as partial compensation for registration or abandoning their production licenses;

   <u>The above two measures will be applied for 44 of the total 77 production licences.</u>

   iii) The ICC was calculated in several categories. Thus, enterprises with an annual CFC consumption:

(1) Below 5 tonnes, i.e. those, which demonstrated quite low production in baseline year, will receive only limited ICC amounting to US$ 50,000/line equal to partial compensation of the cost of destruction of the CFC based MDI manufacturing equipment and abandoning CFC based MDI production. There will be 10 enterprises in this category (63% of the total);

(2) Between 5-50 tonnes/year the ICC compensation will be reduced to US$ 200,000. This will affect two enterprises.

(3) The remaining four enterprises will receive a compensation of US$ 680,000 (3 companies with CFC consumption between 50 tonnes and 100 tonnes) and US$ 1,320,000 (one company with consumption above 100 tonnes) for the conversion of their existing facilities.

iv) The cost of acquisition of patents will be compensated partially and mainly to the large enterprises only. Small enterprises would hardly benefit from MLF compensation requested for acquisition of patents.

d) It is strongly believed that if the sector plan is implemented in this manner, some enterprises could face difficulties in the future to raise funds for the implementation of conversion process and would have to consider giving up as an independent MDI producer. Others could decide to involve non-MLF financial resources to cover the total cost of conversion. This will lead to concentration of MDI production in China at a lower number of enterprises with larger capacity and higher economic and technical viability.

e) The said approach, if approved by the ExCom, will substantially improve the cost-effectiveness of the sector plan in addition to the sectoral level techno-economic benefits, which are expected to be achieved through eventual rationalization and consolidation. Thus, the decision 53/23 of the ExCom will be fulfilled.

C Basic Assumptions for the Incremental Cost Calculation

Eligibility Criteria for Incremental Cost Calculation

83) There are three factors impacting eligibility: (1) the installation date of the production facility; (2) ownership of the company and (3) export ratio of MDI production..

a) **The installation date of the production facility**. The cut-off date of 25 July 1995 normally applied for other CFC consuming sectors should not be applied to the MDI sector, because:

i) in 1995 no alternative technology was available;

ii) as in many other countries, even until 2006 it was not yet clear for SFDA if CFC consumption in MDI production could be phased out in China at all.

Therefore, it is suggested to apply as cut-off date 30 November 2004, when the preparatory assistance project for the MDI sector plan was approved.

b) **Ownership of the company.** There were four enterprises with foreign ownership in 2007, which were not considered in the calculation of the incremental costs. The baseline consumption (2007) of these enterprises with foreign ownership is 18 ODP tonnes ODP.

c) **Export ratio of MDI production.** As mentioned in Section F, Chapter II, China imports and exports MDI products. The export ratio is high at the four foreign ownership enterprises, due to their partnership arrangements. However, others, especially the 100% domestic ownership enterprises, export very small amounts of MDIs (well below 10%) due to the limitations of registrations of their medical products in foreign countries. They carry out no export to non A5 countries. Therefore, no deduction of export ratio of MDI production is considered.

Key Assumptions for Incremental Operating Cost Calculation

84) There are several factors, which have bearing on the incremental cost, e.g. (1) the alternative technology selected and (2) the period for calculation of incremental operating cost.

85) **Alternative technology**. According to the survey, the majority of Chinese MDI manufacturers may use HFAs (e.g. HFC-134a, HFC-227) as CFCs alternatives after screening a variety of technologies. As discussed in Chapter IV, based on the recent sector investigation and the literature review of international experience, HFA-134a will be the first choice for most MDI producers. Besides, conversion to HFA is financially more feasible in China than the DPI route, because, as described in Chapter IV B, paragraph 45.

86) **Period for calculation of incremental operating cost**. In the approved MLF projects different periods are used for the calculation of incremental operating costs. In order to reduce the total cost of the project only 1 year was used in the calculation of the request for incremental operating cost compensation.

D Incremental Investment Cost for Conversion of MDI manufacturers

Preparation of Technical Dossier Required for non-CFC MDI Registration

87) On the basis of preliminary screening tests, the MDI producer shall determine the substitution route according to the specific conditions (such as the properties and cost of alternative product), and apply for approval of modification of the medical excipient according to the Law of Drug Administration of PRC, the *Regulations on Drug Registration*, and the application requirement of the substitute. According to the *Regulations on Drug Registration*, different sets of technical documents shall be submitted corresponding to the following two cases of modification of medicinal adjuvant:
   a) the excipient was already approved in China for medical applications;
   b) new medicinal excipient to be used first time in China (to register as new medicinal adjuvant, and determine the application type according to the actual conditions of the aerosol producers).

88) Table 15 lists the content of the dossier for application for change of excipient to a new one, already within the National Standards.

Table 15. Technical Documents on Registration Application for Changing the Adjuvant of Medical Aerosol to a new one, already within the National Standard

Modification Item	Document Required
Excipient of medical requirement approved for other products	1. Copy of drug approval certification documents and their appendix
	2. Certification documents
	3. Sample of revised *Package Insert* enclosed with detailed revision illustrations
	4. Sample of revised package/ label enclosed with detailed revision illustrations
	5. Documents of pharmacological research
	6. Real sample of drug
	23.Research documents & literature of genital toxicity research
	24.Research documents & literature of carcinogenesis research
	25.Domestic and relevant foreign overview of clinical trial documents
	26.Plan & scheme of clinical trial
	27.Clinical researcher manual
	28. Sample of Informed Consent, and approval document of Ethics Committee.
	29.Clinical Trial Report

89) Table 16 lists the content of dossier for Drug Registration Application for the Use of New Excipients.

Table 16. Technical Documents required for Registration Application for Modifying the Adjuvant of Medical Aerosol

Modification Item	Document Required
New medicinal adjuvant	1. Name & naming basis of medicinal adjuvant
	2. Certification documents
	3. Objective & basis of topic establishment
	4. Summary & assessment of main research results
	5. Sample of *Package Insert*, drafting illustrations, and latest reference
	6. Design sample of package & label
	7. Overview of pharmacological research documents
	8. Research documents & literature of production process
	9. Research documents & literature verifying chemical structure or compositions
	10. Research documents & literature of quality research work
	11. Research documents & literature of drug-related compatibility
	12. Standard draft and drafting illustrations, with standard product or control product
	13. Inspection Report on 3 continuous batches of samples
	14. Research documents & literature of stability research

	15. Selection basis & quality standard of packing materials and containers in direct contact with medicinal adjuvant
	16. Overview of pharmacological & toxicological research documents
	17. Research documents & literature of pharmaco-dynamics influence on to-be-applied drug
	18. Research documents & literature of general pharmacological research
	19. Research documents & literature of acute toxicological research
	20. Research documents & literature of long-term toxicological research
	21. Research documents & literature of main local/systemic administration -related special safety test, such as allergy (local, systemic, and light), hemolysis, and local irritability (blood vessel, mucosa, muscle)
	22. Research documents & literature of mutagenesis research
	23. Research documents & literature of genital toxicity research
	24. Research documents & literature of carcinogenesis research
	25. Domestic and foreign relevant overview of clinical trial documents
	26. Plan & scheme of clinical trial
	27. Clinical researcher manual
	28. Sample of Informed Consent, and approval document of Ethics Committee.
	29. Clinical Trial Report

90) Table 17 lists the dossier for Drug Registration Application for Change in Dosage Form.

Table 17. Technical Documents for Registration Application for Modifying the Drug Dosage Form of Medical Aerosol

Modification Item	**Document Required**
Modification of dosage form of drugs already sold on the Chinese market, not modifying their administration route	1. Drug name
	2. Certification documents
	3. Objective & basis of topic establishment
	4. Summary & assessment of main research results
	5. *Package Insert*, drafting illustrations, and relevant reference
	6. Design sample of package & label
	7. Overview of pharmacological research documents
	8. Research documents & literature of production process for raw drugs, and research documents & literature of prescription and process for preparation
	9. Research documents & literature verifying chemical structure or compositions
	10. Research documents & literature of quality research work
	11. Drug standard and drafting illustrations, with standard product or control product
	12. Inspection Report on samples

	13. Origin, quality standard, and Inspection report of raw drugs and adjuvant
	14. Research documents & literature of drug stability research
	15. Selection basis & quality standard of packing materials and containers in direct contact with drug
	16. Overview of pharmacological & toxicological research documents
	17. Research documents & literature of special safety test, such as allergy (local, systemic, and light), hemolysis, and local irritability (blood vessel, mucosa, muscle)
	18. Research document & literature other than clinical pharmacokinetics research
	19. Domestic and foreign relevant overview of clinical trial documents
	20. Plan & scheme of clinical trial
	21. Clinical researcher manual
	22. Sample of Informed Consent, and approval document of Ethics Committee.
	23. Clinical Trial Report

91) The cost of preparation of the technical dossier will depend on the application of the selected propellant and the production process. It can not be accurately calculated at the current stage. Therefore, Table 18 is the best estimate based on past experience. Six key items are included for the estimation, though there are some other items as well, which were not included.

92) In accordance with the relevant regulations, each manufacturer has to make registration and get its license for their new MDI aerosol product based on its formulation and production process, though some products may also be produced by multiple manufacturers. Therefore, if all enterprises would wish to convert their MDIs they would have to make re-registration applications for new licenses for a total of 77 MDIs (excluding 17 application in foreign enterprises and 10 applications in domestic enterprises, which confirmed that they do not to produce MDIs any longer). Referring to Table 7, Section F in Chapter II for the 33 licenses in production in 2007 the US$ 195,000 will be requested from MLF, as detailed in Table 18. For licenses not in production in 2007 companies will only be compensated at the level of US$ 20,000 to give up their licence rights.

Table 18. Cost of Preparation of Technical Dossier for Registration

No	Application Materials	For Licences in Production in 2007 (US$ $)	For Licences Not in Production in 2007 (US$ $)
1	Study of Production Process	12,500	0
2	Study of Quality	7,500	0
3	Pharmacological Study	20,000	0
4	Toxicological Study	20,000	0
5	Special safety Test	15,000	0
6	Clinical Test	120,000	0
7	Compensation to abandon the licence		20,000
	Subtotal	*195,000*	*20,000*
	Number of License with Production in 2007	33	44
	Sub – Total	6,435,000	880,000
Grand Total			**7,315,000**

Patent Cost

93) The investigation of the patent issues shows that the patent cost for the transfer and/or application of HFA based MDI technology is extremely high. There are at least two relevant patents valid in China. To reduce the total budget for this project, it is proposed that the enterprises will be responsible to develop the technology and acquire the required patent rights. However, at least a limited patent cost compensation at the level of 2.6 million US$ is requested for all the eligible MDI producers in total..

Cost of Modification of Existing Production Facilities

94) The requested incremental cost for modification of existing facilities shown in Table 19 is based on the assumption that these manufacturers will convert to HFA-134a excipient. As HFA-134a is not compatible with the hermetic seals and materials and some components of the existing facilities, it is necessary to modify or replace the existing pumps, pipes, hermetic pipe fittings, valves as well as the filling & charging equipment and associated instruments.

95) Based on information in Table 7, Section F in Chapter II, currently, 19 enterprises produced CFC based MDIs in baseline year 2007, among which only 16 enterprises with production lines are of 100% Chinese ownership. The cost of conversion of these 18 production lines in the 16 Chinese enterprises will be requested from the MLF.

96) The cost for converting/replacing of the drug mixing tank, piping, valves, sealings, labour etc. for the enterprise with annual CFC consumption of
   a) More than 100 tonnes, will be calculated at USD 800,000/line.
   b) Less than 100 tonnes and more than 10 tonnes, cost for the modification of the same items will be compensated at the level of as USD 420,000/line.
   c) Less than 10 tonnes, the compensation for these changes are calculated at USD 100,000/line.

d) Less than 5 tonnes, a compensation of US$ 25,000 will be paid for destruction of the equipment and abandoning CFC based MDI production.

97) The cost of conversion/replacement of filling/crimping line equipment is also classified into three categories:

a) USD 520,000 for those with more than 100 tonnes of annual CFC consumption;
b) USD 260,000 for those with more than 50 tonnes of annual CFC consumption;
c) USD 100,000 for those with more than 5 tonnes of annual CFC consumption.
d) Less than 5 tonnes, a compensation of US$ 25,000 will be paid for destruction of the equipment and abandoning CFC based MDI production.

Table 19. Cost of Modification of Existing Facilities

Company Code	Company Name	CFC Consumption (kg)	Output (can)	Cost for Mixing Tank and Related (US$)	Cost for Filling/ Crimping Line (US$)	Total (US$)
2	Beijing Haiderun Pharmaceutical Co., Ltd.	540	48,306	25,000	25,000	50,000
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1,780	141,360	25,000	25,000	50,000
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	320	20206	25,000	25,000	50,000
11	Harbin Hengcang Pharmaceutical co.	412	23034	25,000	25,000	50,000
16	Heilongjiang Tianlong Pharmaceutical Co. Ltd	240	16,000	25,000	25,000	50,000
18	Jinan Weiming Pharmaceutical Co., Ltd.	73,260	5,550,000	420,000	260,000	680,000
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	26,100	2,216,150	420,000	260,000	680,000
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	175,178	9,295,910	800,000	520,000	1,320,000
22	Shandong Lino Kefeng pharmaceutical Co.	100	10,000	25,000	25,000	50,000
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	4,115	169,400	25,000	25,000	50,000
25	Pharmaceutical Factory of Shanxi Medical University	637	32,785	25,000	25,000	50,000
28	Shanghai Pharmaceutical Co., Ltd Sine Pharma Laboratory	20,656	1,289,879	420,000	260,000	680,000
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	3,200	195,560	25,000	25,000	50,000
35	Guangdong Tongde Pharmaceutical Co. Ltd	6,070	550,000	100,000	100,000	200,000
36	Chongqing Kerui Pharmaceutical Co., Ltd.	9,767	575,520	100,000	100,000	200,000
37	Zigong Chenguang Pharmaceutical Co., Ltd.	100	2,300	25,000	25,000	50,000
Grand Total						**4,260,000**

Validation Process

98) *Provisions on Quality Management for Pharmaceutical Production* (SFDA #9,) was issued by SFDA in 1998 and is effective as of 1 August 1998. Article 57 stipulates that validation of pharmaceutical production shall consist of
   a) Validation of the workshop,
   b) Validation of installation of facilities and equipment,
   c) Validation of facility operation and performance, and
   d) Validation for products.

99) Article 58 states that re-validation shall be carried out in case of a change of main quality related factors such as production process, quality control method, main excipients and production facility.

100) In accordance with *Guidance of Validation of Pharmaceutical Production* (2004), Drug production validation includes prospective validation, concurrent validation, retrospective validation and revalidation. Due to the replacement of propellant or change of dosage form, new production equipment, production technology and product application will be introduced.

101) Therefore, it is necessary to carry out prospective validation before commercial production could start. The purpose of prospective validation is to evaluate and confirm the reproducibility and reliability of production process.

102) Concurrent validation has to be conducted after the start of commercial production in order to obtain data from the actual process operation, so as to prove that it fulfils the expected requirements.

103) After normal production for a certain period of time of normal commercial production retrospective validation is to take place to collect statistical data and make trend analysis, thus discovering the worst conditions for the process operation and indicating the risk of potential malfunctions.

104) Revalidation includes compulsive validation, alternate validation and regular validation

(1) Validation for Changing Excipient (Alternative Propellant)

105) Changing of excipient requires prospective validation, concurrent validation, retrospective validation and revalidation. The validation includes:
   a) Validation of workshop;
   b) Validation of public utilities;
   c) Validation of computer system;
   d) Validation of production equipment;
   e) Validation of production process;
   f) Validation of personnel;
   g) Validation of other relevant items.

(2) Validation of Workshop, Public Utility System and Computer System

106) Validation of workshop is needed to confirm that 1) the reconstructed workshops is in compliance with design standards; 2) the flow of people and materials is proper; 3) workshop cleanliness is up to the level of 300,000 grade.

107) Validation of public utilities consists of six items, namely, heating, ventilation, air conditioning, discharging system, cooling system and propellant supply system.

108) Validation of computer system consist of four items, namely, batch record/SOP management system, material management system, lab system and the management system for production/engineering spare parts.

(3) Validation of Production Equipment

109) Validation of production equipment comprises six items, namely, weighing scales, containers, valve cleansing equipment, and compound vessel system, filling equipment, weight inspection system and spray inspection system.

(4) Validation of Production Process

110) Validation items for dispensing preparation includes: temperature of liquid product in compound vessels, particle sizes and homogenization of the drug liquid.

111) Validation of cleaning effect of containers: various impurities placed into the container should be totally removed by cleaning.

112) Validation items for filling process include appearance, filling weight and leakage. At least three batches shall be inspected. Samples shall be taken from different places to check the appearance, filling weight, active ingredient and leakage.

113) Validation items for weighing equipment include weighing accuracy and elimination of under-weighed and over-weighed samples.

114) Validation items for timing of product inspection include leakage and shot weight per actuation. Different inspection times shall be selected to test the leakage and the shot per actuation so as to find out the best inspection time.

115) Validation item for spray inspection include the performance of spray and elimination of samples that don't spray or don't spray continously.

116) Validation of metered aerosols is done based on the product quality standards. The items include validation of appearance, active ingredient per actuation, quantity of actuation per canister, shot weight per actuation, spray distribution, microbes, etc. At least three batches of samples shall be inspected with validated sampling and analysis methods to ensure that finished products are produced steadily in compliance with product delivery standards.

117) Validation items for cleanliness include the cleanliness of compound vessels and filling lines. There shall be no cross-contamination between different batches. After cleaning of the filler, the contents of raw medicinal material, water and solvent shall be measured, to make sure that no active medicinal material or solvent remained.

(5) Validation for Personnel and Other Relevant Items

118) Validation for personnel consists of establishment of filing system for each person engaged in aerosol production, including records for training, health, safety and personnel performance, etc.

119) Validation for other relevant items includes document recording, instrument calibration, preventative maintenance, production areas and area for changing clothes as well as waste cleansing and sterilization.

(6) Validation for Change in Dosage Form

120) For change in dosage form, it is required to conduct prospective validation, concurrent validation, retrospective validation and revalidation. The validations are basically the same as those for Part A, except that there are some differences in validation items for finished product. Validation for metered aerosol includes appearance, total times of actuation per canister, shot weight per actuation, active ingredient per actuation, spray distribution, variation of filling amount (filling amount) and microbes, etc. At least three batches of samples shall be inspected with validated sampling and analysis methods to ensure that finished products are produced steadily in compliance with product delivery standards.

121) There are 18 eligible production lines in 16 eligible enterprises, which had MDI production in 2007. Cost for production validation is detailed in Table 20.

Table 20. Cost of Production Validation

No.	Item	Content	Expenses (US$)
1	Equipment	Scales, Containers, Valve Cleansing Equipment; Compound Vessel System; Filling &Charging Equipment; Weight Checking System; Spray Checking System	12,500
2	Production process	Liquid Drug Processing, Cleaning effectiveness for Containers; Filling Process; Weight Checking System; Product Checking Time; Spray Checking; Finished Products; Cleaning Effectiveness.	20,500
3	Others	Workshop; Public Utilities; Computer System; Others	7,000
	Subtotal for one production line		*40,000*
	Number of production lines at 16 enterprises with production in 2007		18
	Grand Total, Validation		**720,000**

(7) Staff Training

122) Due to the introduction of new substitutes, it is necessary to provide training for the staff of the manufacturers. Those people who should receive training include quality control technicians, operators, recorders, engineers, management staff and those working for procurement, transportation

and maintenance. It is estimated that each manufacturer has 20 for production and 40 for the other areas.

Table 21. Cost for Staff Training

	Production Staff	**Other Staff**	**Public Training**
Number of Trainees	20	40	10,000
Unit cost (US$/person)	125	375	
Subtotal (US$)	2,500	15,000	
Subtotal of one production line (US$)			*27,500*
Number of eligible enterprises with production in 2007			16
Grand Total, Training (US$)			**440,000**

E Incremental Operating Cost

123) The calculation is based on the consumption, production and cost data collected from manufacturers during the survey undertaken by NICPBP, SFDA, MEP and UNIDO. On the recommendation of the Secretariat the calculation IOC was revisited. As indicated in Paragraph 87, in the calculation of IOC one year was selected for the period of compensation. IOC is calculated based on the CFC consumption and production output of the year preceding the submission of the document, i.e. in 2007. The price differences for HFA MDIs and CFC MDIs are shown in Table 22.

Table 22. Price difference for HFA products and CFC products

	Original Product		Product after Conversion	
Item	(CFC as propellant)		(HFA-134a as propellant)	
	US$/kg	Unit Cost (US$/can)	US$/kg	Unit Cost (US$/can)
1. propellant	**3.43**		**7.38**	
2. Packaging				
Canister		0.169		0.175
Valve		0.048		0.113
Subtotal for packaging		**0.217**		**0.288**

124) In the process of IOC calculation foreign ownership enterprises were excluded.

125) Literature reviews indicate that on average, HFA MDI uses 30% less propellant than a CFC MDI.

126) The calculation for each enterprises based on the above parameters is shown below in Table 23. The total IOC request is US$1,989,502.

Table 23. Enterprise level IOC Calculation

Company Code	Company Name	Year of Establ.	CFC Consumption (kg)	IOC, Propellant,	Output (can)	IOC, Can, US$	Total IOC
2	Beijing Haiderun Pharmaceutical Co., Ltd.	1978	540	937	48,306	3,430	4,367
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1988	1,780	3,090	141,360	10,037	13,127
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	1979	320	556	20206	1,435	1,990
11	Harbin hengcang Pharmaceutical co.		412	715	23034	1,635	2,351
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	1982	0	0	0	0	0
15	Henan Zhongfu Pharmaceutical Co., Ltd.	1992	0	0	0	0	0
16	Heilongjiang Tianlong Pharmaceutical Co. Ltd		240	417	16,000	1,136	1,553
18	Jinan Weiming Pharmaceutical Co., Ltd.	1979	73,260	127,179	5,550,000	394,050	521,229
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	1993	26,100	45,310	2,216,150	157,347	202,656
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	1993	175,178	304,109	9,295,910	660,010	964,119
22	Shandong Lino Kefeng pharmaceutical Co.		100	174	10,000	710	884

24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	2001	4,115	7,144	169,400	12,027	19,171
25	Pharmaceutical Factory of Shanxi Medical University	1994	637	1,106	32,785	2,328	3,434
28	Shanghai Pharmaceutical (Group) Co., Ltd Sine Pharma Laboratory	1982	20,656	35,859	1,289,879	91,581	127,440
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	1965	3,200	5,555	195,560	13,885	19,440
35	Guangdong Tongde Pharmaceutical Co. Ltd		6,070	10,538	550,000	39,050	49,588
36	Chongqing Kerui Pharmaceutical Co., Ltd.	1975	9,767	16,956	575,520	40,862	57,817
37	Zigong Chenguang Pharmaceutical Co., Ltd.	1981	100	174	2,300	163	337
38	Jiangsu Tianji Pharmaceutical Co., Ltd.		0	0	0	0	0
Grand Total, IOC			**322,475**	**559,817**	**20,136,410**	**1,429,685**	**1,989,502**

F Contingency of incremental capital cost

127) Contingency is calculated as 10% of the cost of modification of the production facilities.

G Technical Assistance (TA)

128) In order to implement the sector plan smoothly, it is necessary to undertake TA activities. The total fund requested for Technical Assistance is 1.1 million US dollars covering the following activities:

a) Workshops for equipment manufacturers and technical experts during the implementation of the sector plan;
b) Training of responsible staff of government agencies such as local Food and Drug Administration Bureaus and Environmental Protection Bureaus on the implementation of the phase out policies in the MDI sector;
c) Legislative support activities;
d) Preparation and appraisal of feasibility study reports to decide on the group of eligible enterprises and the funding needs;
e) Technical support and harmonisation of product and process conversion activities;
f) Development of a MIS system, monitoring and management of the Sector Plan, verification of performance indicators;
g) Auditing of CFCs consumption annually for pharmaceutical aerosol manufacturers;
h) Study tours;
i) Public awareness promotion activities;
j) General training of doctors, patients and pharmacists, environmental and health officials, the medical community, clinics, pharmaceutical companies and non-governmental organizations
k) Other TAs as necessary.

H Summary

129) The total costs requested from the MLF, includes the one time investment cost and the one year operating cost for the eligible producers as well as the cost of technical assistance activities required for the implementation of this sector plan. The incremental cost will be used to phase out of 322.5 ODP tonnes/year CFCs in the MDI sector of China.

Table 24. Summary of incremental costs

Item	Incremental Cost (US$)
Development of conversion technologies, registration of products	7,315,000
Patent Cost	2,600,000
Modification of Existing Production Facilities	4,260,000
Production Validation	720,000
Staff Training	440,000
Incremental Operating Cost	1,989,502
Technical Assistance and transition strategy	1,100,000
Contingency*	426,000
Total	**18,850,502**
Implementing Agency Support Cost	1,413,788
Total Funding Requested	**20,264,289**
Cost Effectiveness, US$/kg	**58.46**

* The contingency is calculated as 10% of Cost of Modification of Existing Production Facilities.

Chapter VII Operating Mechanism

A Agreement between MEP and UNIDO

130) Following approval of the Sector Plan by the ExCom, MEP and UNIDO will sign an agreement, which will indicate that UNIDO entrusts MEP to implement the Sector Plan under UNIDO's supervision. According to the Agreement, UNIDO will disburse grants to MEP based upon (a) submission of a detailed Work Plan on the implementation for the Sector Plan, hereafter referred to as the Work Plan and (b) satisfactory performance of implementation and (c) meeting the agreed performance indicators.

131) The Work Plan will include the key activities and schedule for conversion of enterprises, the amount of CFC elimination, conditions and amount of fund disbursement, the necessary technical assistance activities and their schedules.

132) After signing the Agreement with UNIDO, MEP and SFDA will jointly establish a special working group (SWG). SWG will organize, manage and monitor the implementation of the sector plan in close cooperation with the recipient companies.

133) Based on the satisfactory progress report of MEP and verified achievement of the phase-out target. UNIDO will disburse funds to a special account; ODS Special Account set up in MEP after receiving MEP's funding request.

B Roles and Responsibilities

134) The MDI Sector Plan will be executed by MEP, acting on behalf of Chinese Government. The daily work will be done by FECO, one affiliated institution of MEP. MEP and SFDA will jointly set up the SWG, whose office will be located in FECO. SWG will be responsible for preparing the Work Plan. MEP and SFDA will jointly select through a bidding process a domestic implementing agency (DIA) for the management of daily works during the implementation of the Sector Plan.

135) Roles and Responsibilities of each institution involved are described as follows.

I. UNIDO

136) Will be responsible for overall implementation of the Sector Plan and accomplishment of its objectives as approved by the ExCom. UNIDO will:

a) Establish working and reporting arrangement with MEP and SFDA;
b) Supervise MEP, SFDA and the recipient companies to complete this Sector Plan;
c) Provide necessary technological and managerial support to MEP and SFDA for the implementation of this Sector Plan;
d) Pay the fund of the Sector Plan to MEP based on the agreed conditions;

e) Monitor the implementation of the Work Plan, conduct necessary audit and inspection, review bidding processes of selecting the DIA, eligible enterprises and the institutions undertaking the technical assistance projects; and
f) Report to the ExCom. on the implementation status of the Sector Plan.

II. MEP

137) Will be through PMO, be responsible for overall project management and coordination for the implementation of the Sector Plan. MEP will:

a) Set up a SWG consisting of staff from PMO and SFDA, and selected technical experts from the industry jointly with SFDA;
b) Set up an ODS Special Account;
c) Select a DIA jointly with SFDA, supervise the work of DIA;
d) Review the funding request submitted by the Working Group and DIA, and approve the disbursement;
e) Review the CFC consumption quota submitted by the work group and issue the quota to the enterprises;
f) Submit progress report to UNDIO semi-annually;
g) Verify and ensure the realization of CFC phase out target of the Sector Plan, and the destruction of CFC equipment in enterprises involved; and
h) Prepare and issue the related regulations jointly with SFDA.

II. SFDA

138) Will cooperate with MEP to implement this Sector Plan. SFDA will:

a) Help PMO to set up the SWG and select qualified technical experts for SWG;
b) Set up SWG office and facilitate its operation;
c) Select a DIA jointly with MEP;
d) Coordinate the relationships among MEP, SWG, DIA and counterpart enterprises;
e) Help MEP to realize the CFC phase out target indicated in the Sector Plan,
f) Monitor the destruction of CFC equipment at the recipient enterprises according to MLF rules;
g) Provide support on sector policy and technology, lead MDI manufacturing enterprises to eliminate CFC consumption and prepare relevant regulations jointly with MEP so that they can be issued and enter into force subsequently；
h) Design CFCs phase-out policies in MDI sector, in cooperation with MEP;
i) Organize local FDAs to implement phase-out policies and undertake irregular spot check to the MDI manufacturers;
j) Supervise CFCs consumption of MDI aerosol manufacturers;

k) Ensure adequate clinical supply of MDI products.

IV. SWG

139) Will, with the backstopping of MEP and SFDA, be responsible for implementing the Work Plan and undertake the following activities:

a) Manage daily works of implementing the Sector Plan, coordinate the activities among all relevant parties;
b) Establish an implementing and monitoring mechanism as well as a computerized database in English, which should include the status of the implementation of the Sector Plan for all eligible and non-eligible CFC-based MDI manufacturers, so that SWG, MEP/PMO, SFDA and UNIDO can easily learn each project's situation.
c) Select most cost-effective contractors to execute the conversion project;
d) Through bidding, select contractors of the technical assistance projects, and manage their implementation;
e) Review DIA's payment requests and submit them to PMO for disbursement;
f) Monitor DIA's work, submit progress report to PMO quarterly, timely report to PMO on technical, managerial, or implementation problems, which might arise;
g) Visit beneficiaries, inspect project implementation, take part in the destruction of their CFC equipment;
h) With the help of DIA, organize official project commissioning;
i) Help MEP/PMO prepare quarterly and annual reports on the status of ODS Special Account, including budget revisions requested from PMO and UNIDO. With PMO's entrustment, prepare requests for replenishment of funds and submit it to UNIDO; and
j) Provide assistance to verification audits as may be required by the Government, UNIDO and the ExCom.

V. DIA

140) With the backstopping of PMO, SFDA and SWG, DIA will be responsible for the project activities at enterprise level as follows:

a) Provide necessary managerial and technological assistance to SWG;
b) Conduct equipment and service procurement for beneficiary enterprises, help the enterprises in converting their production lines;
c) Prepare payment requests for beneficiaries, or review beneficiaries payment request before submitting it to PMO;
d) Submit regular report on project implementation to SWG, help SWG prepare progress reports on project implementation;
e) Verify and inform SWG and PMO on problems that might arise at enterprises; and
f) Organize official project commissioning.

C Auditing and Reporting

141) SWG will execute the Work Plan; submit progress reports to PMO four times a year. PMO will submit semi-annual and annual reports to UNIDO. The reports will be prepared in a format agreed by MEP, SFDA and UNIDO. UNIDO will report to ExCom on the progress of implementation and financial status of the project.

142) UNIDO will audit each year's project implementation.

143) UNIDO will supervise the implementation of the Work Plan, including spot check of project records and periodic check on enterprises. MEP will be responsible for conducting local annual audits according to regulations set for the ODS Special Account.

D Destruction of CFC Equipment and Certification

144) Confirmation of the destruction of CFC equipment and its certification should be obtained from an authorized organization in a form as specified in the ODS Phase out Contracts between MEP and enterprises. MEP will be responsible for preparing a completion report for each enterprise confirming that all terms and conditions of the ODS Phase out contract, including the destruction of equipment, have been fulfilled. UNIDO will retain the right to carry out factory inspections.

Chapter VIII Action Plan

145) This Chapter presents the schedule of implementation of CFC Phase-out Plan for China's MDI Sector. The proposed Action Plan is summarized in Table 25.

Table 25. Phase-out Targets, Funding Request Activities and Indicators from 2008 to 2014

	2007 (Baseline)	2008 (Estimate)	2009	2010	2011	2012	2013	2014
CFC Consumption Targets								
Maximum Allowable CFC Consumption/Production under the Accelerated CFC Phase out Plan (except for essential use consumption)		550	550	0	0	0	0	0
CFCs Consumption (newly produced CFCs)	340.5	414.6	504.8	614.6	748.3	650.0	400.0	0
Funding Request (USD)								
Enterprise-Level Activities	n.a.	17,750,502						
Technical Assistance Activities	n.a.	1,100,000						
Support Cost (7.5%)	n.a.	1,413,788						
Total MLF Cost	n.a.	20,264,289						
Actions								
Enterprise-level Activities	n.a.	Sign CFC phase out contract with SFDA/MEP		Modification of Existing Facilities				
		Identification of alternatives			Validation and New Production			
			Registration of Applications.					
			Workshops, Trainings					

<table>
<tr><th></th><th>2007 (Baseline)</th><th>2008 (Estimate)</th><th>2009</th><th>2010</th><th>2011</th><th>2012</th><th>2013</th><th>2014</th></tr>
<tr><td rowspan="4">Technical Assistance Activities</td><td rowspan="4"></td><td></td><td colspan="3">Workshops on alternatives, new processes, technical requirements, consumption quota, contract issues etc.</td><td></td><td></td></tr>
<tr><td></td><td></td><td colspan="3">Workshops on new products and technical standards.</td><td></td><td></td></tr>
<tr><td colspan="2">Study of standards and other technicalissues.</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Study of conversion techniques</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="4">Policies and legislative measures</td><td rowspan="4"></td><td></td><td colspan="6">Issue and enforce consumption quota licenses to MDI producers</td></tr>
<tr><td></td><td></td><td colspan="5">Verification audit of CFCs consumptions</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">Prepare and issue ban on use of CFCs for MDI production.</td><td></td></tr>
<tr><td></td><td colspan="6">Preparation of Progress Reports covering all sector plan activities.</td></tr>
<tr><td colspan="2">Indicators</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td></td><td>Eligible MDI producers using at least 65% of CFC signed phase out contract</td><td>All eligible MDI producers signed contract for CFC phase out.</td><td></td><td></td><td></td><td rowspan="2">CFC production and consumption of fresh CFC for MDI are 0 ODP tonnes.</td></tr>
<tr><td></td><td>Consumption quota system is established.</td><td>CFC production and CFC consumption quota are equal or below the agreed target.</td><td>CFC production and CFC consumption quota are equal or below the agreed target.</td><td>CFC production and CFC consumption quota are equal or below the agreed target.</td><td>CFC production and CFC consumption quota are equal or below the agreed target.</td></tr>
</table>

	2007 (Baseline)	2008 (Estimate)	2009	2010	2011	2012	2013	2014
			Annual TA activity contracts are signed.	Annual TA activity contracts are signed.	Annual TA activity contracts are signed.	Annual TA activity contracts are signed.		
					At least 3 producers completed conversion.		All producers completed conversion.	
							Ban on use of CFCs for MDI production is issued.	

Appendix 1

Chinese Producers and Varieties of MDI Products

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
01	AstraZeneca Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol (100d)	H20030410	
01	AstraZeneca Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	H20030411	
01	AstraZeneca Pharmaceutical Co., Ltd.	B13	Terbutalin Sulfate Aerosol (400 sprays)	H10930058	
01	AstraZeneca Pharmaceutical Co., Ltd.	B13	Terbutalin Sulfate Aerosol (200 sprays)	H10930059	
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H11021384	
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H11021180	
02	Beijing Haiderun Pharmaceutical Co., Ltd.	B23	Ipratropium Aerosol	H11022421	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (50μg)	H11020191	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (100μg)	H11020192	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (200μg)	H11020193	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250μg)	H11020194	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B12	Ribavirin Spray	H11020195	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H11020196	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H11020197	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B19	Isopropyl Scopolamine Bromide Aerosol	H11022168	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B23	Ipratropium Aerosol	H11021801	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B23	Ipratropium Aerosol	H11021802	
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250ug/200 sprays)	H20056231	
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (50ug/200 sprays)	H20056259	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H44023113	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H44023121	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B20	Clenbuterol Hydrochloride Aerosol	H44025373	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H44023123	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H44024063	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H44020217	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H44020226	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
09	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	B24	Zhichuanling Aerosol	Z52020225	yes
10	Harbin Guangji Pharmaceutical Factory	B15	Salbutamol Aerosol (liquid)	H23020561	
10	Harbin Guangji Pharmaceutical Factory	B16	Salbutamol Aerosol (suspension)	H23020684	
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H23023413	
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020333	
12	Harbin Huili Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	H19980105	
13	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H33021444	
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	B11	Physochlaina infundibulris Kuang Aerosol	z41022146	yes
15	Henan Zhongfu Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H41021424	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H23020369	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020370	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020371	
17	Jilin Xiuzheng Pharmaceutical (Group) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H22023411	
18	Jinan Weiming Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H37020653	
18	Jinan Weiming Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (28mg,0.2%(g/g)	H37020653	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
18	Jinan Weiming Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37020655	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	H37023690	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H20003867	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37020545	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37020544	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37020549	
20	Qiqihar Pharmaceutical Factory	B15	Salbutamol Aerosol	H23022108	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250μg/100 sprays)	H20059866	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250μg/200 sprays)	H20059867	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37022928	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H37022929	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H19983227	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37022817	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37022314	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B18	Isosorbide Dinitrate Aerosol	H37022845	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37023560	
23	Shandong Lukang Cisen Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37021846	
23	Shandong Lukang Cisen Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37022070	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	H20030987	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	H20052614	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B25	Salbutamol Sulfate Aerosol	H20060409	
25	Pharmaceutical Factory Shanxi Medical University	B01	Beclomethasone Dipropionate Aerosol	H14020317	
25	Pharmaceutical Factory Shanxi Medical University	B16	Salbutamol Aerosol (suspension)	H14020757	
25	Pharmaceutical Factory Shanxi Medical University	B18	Isosorbide Dinitrate Aerosol	H14023848	
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B08	Compound Ipratropium Aerosol (5ml)	H20046117	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B08	Compound Ipratropium Aerosol (10ml)	H20046118	
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B23	Ipratropium Aerosol (Atrovent Aerosol, 10ml)	H20033863	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B02	Beclomethasone Dipropionate Aerosol (suspension)	H31021090	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H31021094	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H31020802	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B01	Beclomethasone Dipropionate Aerosol	H31020770	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B04	Budesonide Aerosol	H20010552	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	H31022807	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B09	Ketotifun Fumarate Aerosol	H31022604	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B10	Carbochromen Aerosol	H31022283	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B12	Ribavirin Aerosol	H10970349	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B14	Sodium Cromoglicate Aerosol	H31020681	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B15	Salbutamol Aerosol (liquid)	H31020606	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B16	Salbutamol Aerosol (suspension)	H31020560	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B17	Salmeterol Xinafoate Aerosol	H20010548	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B20	Clenbuterol Hydrochloride Aerosol	H31022809	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B21	Bromhexine Hydrochloride Aerosol	H31022607	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B22	Isoprenaline Hydrochloride Aerosol	H31021141	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B22	Isoprenaline Hydrochloride Aerosol	H31022858	
29	Tianjin Century Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H12020083	
29	Tianjin Century Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H12020084	
30	Tonghua Baishan Pharmaceutical Co., Ltd.	B06	Compound Danshen Aerosol	Z10950049	yes
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37022152	
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37023628	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37022160	
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37022161	
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B15	Salbutamol Aerosol	H32021545	
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B22	IsoprenalineHydrochlorideAerosol	H32022731	
33	Xian Lisheng Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H61020946	
34	Xinjiang Pharmaceutical Factory	B15	Salbutamol Aerosol	H65020321	
35	Zhanjiang New Ton Tex Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H44023669	
35	Zhanjiang New Ton Tex Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H44023668	
36	Chongqing Kerui Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H50020452	
36	Chongqing Kerui Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H50020453	
36	Chongqing Kerui Pharmaceutical Co., Ltd.	B20	Clenbuterol Hydrochloride Aerosol	H50021660	
36	Chongqing Kerui Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H50020323	
37	Zigong Chenguang Pharmaceutical Co., Ltd.	B05	Dimethicone Aerosol	H51021906	
38	Jiangsu Tianji Pharmaceutical Co., Ltd.	B12	Ribavirin Spray	H20059502	