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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fifty-third Meeting
Montreal, 26-30 November 2007

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 China's MDI Sector — UNIDO

Foam
- Plan for CFC-11 phase-out in the polyurethane (PU) foam sector in the China (2007 and 2008 tranches) — World Bank

Halon
- Sector plan for halon phase-out: 2008 annual programme — World Bank

Process agent
- Phase-out the production and consumption of CTC for process agent and other non-identified uses (phase I): 2008 annual programme — World Bank
- Phase-out the production and consumption of CTC for process agent and other non-identified uses (phase II): 2008 annual programme — World Bank

Production
- Sector plan for CFC production phase-out: 2008 annual programme — World Bank

Refrigeration
- Refrigeration servicing sector CFC phase-out plan (fourth tranche) — UNEP, UNIDO and Japan

Solvent
- ODS phase-out in China solvent sector: 2008 annual programme — UNDP

PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT
CHINA

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

NATIONAL CO-ORDINATING AGENCY	State Environmental Protection Administration (SEPA) State Food and Drug Administration (SFDA)

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2005, AS OF OCTOBER 2005)

CFC	13,123.8		

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

ODS	Aerosol	MDI			
CFC-11	98.9	40.9			
CFC-12	370.0	236.7			
CFC-114		3.3			
Total	468.9	280.9			

CFC consumption remaining eligible for funding (ODP tonnes)	423.2

CURRENT YEAR BUSINESS PLAN ALLOCATIONS	Funding US $	Phase-out ODP tonnes
	3,225,000	100.6

PROJECT TITLE:	
ODS use at enterprise (ODP tonnes):	280.9
ODS to be phased out (ODP tonnes):	280.9
ODS to be phased in (ODP tonnes):	n/a
Project duration (months):	40
Initial amount requested (US $):	22,316,189
Final project costs (US $):	
Incremental Capital Cost:	16,717,500
Contingency (10 %):	556,000
Incremental Operating Cost:	3,502,689
Total Project Cost:	20,776,189
Local ownership (%):	100
Export component (%):	None
Requested grant (US $):	20,776,189
Cost-effectiveness (US $/kg):	79.45
Implementing agency support cost (US $):	1,558,214
Total cost of project to Multilateral Fund (US $):	22,334,403
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 280.9 ODP tonnes of CFCs used in the manufacture of metered dose inhalers (MDI Sector Plan) for consideration by the Executive Committee at its 53rd Meeting. The total cost of the project, as submitted, is US $22,316,189 plus agency support costs of US $1,673,714 for UNIDO. Once this project is approved, there will be no more CFC consumption eligible for funding for China.

Background

2. At its 51st Meeting, the Executive Committee approved a project for the phase-out of 485.1 ODP tonnes of CFCs used in the pharmaceutical aerosol sector in China. The project was approved on the understanding that no more funding would be approved for new sector plans for the phase-out of CFC consumption in China, excluding the MDI sub-sector (decision 51/27).

Project summary

3. According to the MDI Sector Plan, there are 38 MDI manufacturing plants in China, with 27 production lines producing MDIs with 25 different active ingredients, including three Chinese traditional medicines. Of all the manufacturing plants, 32 plants with 22 production lines and 77 production licenses are eligible to receive assistance from the Multilateral Fund.

4. The total cost of the MDI Sector Plan is based on the costs shown in Table 1 below:

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

Cost item	Unitary cost (US $)	Units	Total cost (US $)
Technical assistance	1,100,000	1	1,100,000
Technical dossier for licenses in production in 2006 (*)	195,000	36	7,020,000
Technical dossier for licenses not in production in 2006	85,000	41	3,485,000
Plant modifications of existing facilities(**)	5,560,000	1	5,560,000
Production validation (per production line)	40,000	17	680,000
Training programme (per production line)	27,500	15	412,500
Operating cost	3,502,689	1	3,502,689
Contingency	556,000	1	556,000
Total			**22,316,189**

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

(**) Calculated as follows: US $1,320,000 for lines with CFC consumption over 100 ODP tonnes; US $680,000 for production lines with CFC consumption between 10 and 100 ODP tonnes; and US $200,000 for production lines with CFC consumption below 10 ODP tonnes.

5. 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

6. 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 266.8 ODP tonnes in 2006. Doctors are now more frequently using MDIs 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.[1] These plants have received funding for the conversion of their production lines to non-CFC propellant, for technical assistance and for training programmes. These enterprises have different production lines and licenses for MDIs;

(c) Four transnational corporations 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 2004 (kg)	CFC 2005 (kg)	CFC 2006 (kg)
1	AstraZeneca Pharmaceutical	B04	Budesonide	3,262.0	3,494.0	4,538.0
1	AstraZeneca Pharmaceutical	B13	Terbutaline sulfate	8,250.0	7,460.0	8,665.0
3	Beijing Shengdelaibao Pharmaceutical	B15	Salbutamol	504.6	745.9	
3	Beijing Shengdelaibao Pharmaceutical	B01	Beclometasone dipropionate	270.5	180.3	
5	GlaxoSmithKline (Tianjin)	B01	Beclometasone dipropionate	14,936.7	-	-
31	Weifang Zhongshi Pharmacy	B15	Salbutamol	3,150.0	1,350.0	900.0
Total				**30,373.8**	**13,230.2**	**14,103.0**

(d) There has been no production of MDIs in two manufacturing plants over the last three years (i.e., Plant No. 16, Heilongjiang Tanglong Pharmaceutical[2] and Plant No.29, Tianjin Century Pharmaceutical);

(e) Three manufacturing plants started production of MDIs only in 2006, as shown in Table 3 below:

[1] 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).

[2] Only 27.8 kg of CFCs were used by company No. 16 for the production of MDIs in 2004.

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

No.	Company name	Product	Active ingredient	CFC2006 (kg)	Cans 2006
2	Beijing Haiderun Pharmaceutical	B15	Salbutamol	6,424.0	584,000
2	Beijing Haiderun Pharmaceutical	B22	Isoprenaline hydrochloride	2,915.0	265,000
2	Beijing Haiderun Pharmaceutical	B23	Iprartropium bromide	27.0	2,389
14	Henan Xinxin Pharmaceutical	B11	Huashanshen	300.0	30,612
38	Jiangsu Tianji Pharmaceutical	B12	Ribavirin spray	4,202.0	466,889
Total				**13,868.0**	**1,348,890**

UNIDO indicated, however, that these three enterprises were established between 1978 and 1992. One enterprise was relocated in 2003 and restarted production again at the end of 2005. The other two enterprises had reported production prior to 2004;

(f) Several MDIs were produced for the first time in 2006 by manufacturing plants that were already producing other MDIs as shown in Table 4 below:

Table 4. MDIs produced only in 2006 by established manufacturing plants

No.	Company name	Product	Active ingredient	CFC 2006 (kg)	Cans 2006
19	Penglai Nuokang Pharmaceutical	B14	Sodium cromoglicate	50.5	1,996
19	Penglai Nuokang Pharmaceutical	B07	Isoprenaline hydrochloride	41.7	1,995
24	Shandong Lunan Beite Pharmaceutical	B25	Salbutamol sulfate	100.0	4,464
24	Shandong Lunan Beite Pharmaceutical	B17	Salmeterol xinafoate	10.0	3,030
28	Shanghai Pharmaceutical (Group)	B09	Ketotifen fumarate	1,271.0	63,234
28	Shanghai Pharmaceutical (Group)	B01	Beclomethasone dipropionate	79.0	3,391
28	Shanghai Pharmaceutical (Group)	B14	Sodium cromoglicate	113.0	5,160
Total				**1,665.2**	**83,270**

UNIDO indicated that except for products B17 and B25, relevant licenses for the other active ingredients had been issued prior to 2000;

(g) There are only 15 different active ingredients in MDIs that are currently produced in China, as shown in Table 5 below[3]. It should be noted that:

(i) The total production of MDIs with beclomethasone (B01), sodium cromoglicate (B14), salbutamol - both in solution (B15) and suspension (B16), and isoprenaline (B22) represents more than 95 per cent of the total production in 2006. These four active ingredients have a very important therapeutic role in the treatment of asthma and COPD;

(ii) MDIs containing isoprenaline hydrochloride (B07), ketotifen fumarate (B09), huashanshen (B11), iprartropium bromide (B23) and salbutamol sulphate (B25), commenced production only in 2006. Total production amounted to 102,695 MDIs with a total CFC consumption of 1,739.7 kg.

[3] 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.

US $975,000 is being requested for technical dossiers for registration of these MDIs; and

(iii) Very small quantities of MDIs with salmeterol xinafoate (B17) as the active ingredient were produced in 2004 (2,240 MDIs with a total CFC consumption of 33.6 kg) and in 2006 (3,030 MDIs with a total CFC consumption of 10.0 kg).

Table 5. Active ingredients in MDIs currently manufactured in China

Active ingredient	CFC 2006 (kg)	Cans 2006	%age CFC
Salmeterol xinafoate (B17)	10.0	3,030	0.004%
Iprartropium bromide (B23)	27.0	2,389	0.010%
Isoprenaline hydrochloride (B07)	41.7	1,995	0.016%
Dimethicone (B05)	70.0	2,778	0.026%
Salbutamol sulfate (B25)	100.0	4,464	0.037%
Zhichuanling (B24)	130.8	10,900	0.049%
Huashanshen (B11)	300.0	30,612	0.112%
Ketotifen fumarate (B09)	1,271.0	63,234	0.476%
Budesonide (B04)	3,499.0	78,808	1.311%
Ribavirin (B12)	7,395.0	679,756	2.772%
Sodium cromoglicate (B14)	7,541.5	443,724	2.827%
Beclomethasone dipropionate (B01)	23,048.0	993,589	8.639%
Isoprenaline hydrochloride (B22)	47,324.0	3,795,736	17.737%
Salbutamol (suspension) (B16)	85,396.2	4,919,968	32.007%
Salbutamol (solution) (B15)	90,650.0	6,840,887	33.976%
Total	**266,804.2**	**17,871,870**	**100.000%**

Essential use exemptions for CFCs

7. Through its decision 51/34, the Executive Committee requested, *inter alia,* that countries with MDI manufacturing plants should be advised of the timing for when to begin considering the need for essential use exemptions beyond the 2010 phase-out date, and that the preparation of a nomination for essential use exemptions might begin in 2007 for submission to the Parties for their consideration in 2008. According to the project proposal, the Government of China has issued quotas for CFC production of 550 ODP tonnes of CFCs for each year in 2008 and 2009, while current consumption in the sector is about 300 ODP tonnes. After the end of 2009, MDI manufacturers will have to use stockpiled CFCs. On this basis, the Secretariat asked whether the Government of China would be requesting essential use exemptions for CFCs for the production of MDIs.

8. UNIDO advised that the CFC/halon accelerated phase-out plan for China allowed for the production of 550 ODP tonnes of pharmaceutical aerosol grade CFCs annually until 2009. The conversion of all CFC-based MDI production lines should be partially completed by the end of 2010 if the MDI Sector Plan is approved by the Executive Committee at its 53rd Meeting. Due to the complexity of conversion in this sub-sector, conversion of some production lines might not be completed by the end of 2010. For a transitional period, CFCs that are currently being stockpiled will be used. In order to protect the ozone layer, the Government of China is currently not planning to apply for essential use exemptions. However, if for unforeseen reasons this situation changes, the Government will report back to the Executive Committee.

Selection of alternative technologies

9. According to the project proposal, major stakeholders involved in the production of CFC-MDIs in China have only a preliminary idea of an action plan for the phasing-out of CFCs in this sub-sector. There are still many outstanding issues to be resolved before the introduction of HFA-MDIs. On this basis, the Secretariat pointed out to UNIDO that it might be advisable to consider the feasibility of stockpiling pharmaceutical grade CFCs for a period of time (i.e., two to four years) until the outstanding technological issues have been resolved before proceeding with the implementation of the MDI Sector Plan.

10. UNIDO stated that some manufacturing plants have conducted studies on alternative technologies. Currently, the main issue is related to patent rights, which, in China, cover almost all MDIs using HFA as propellant. There are other plants that have not yet finalized their studies on CFC-replacement technologies. On this basis, CFCs are being stockpiled and will be used in 2010 and beyond. Should these difficulties continue to exist, the project implementation timetable will be adjusted and the issue will be reported to the Executive Committee.

Technical assistance activities

11. The Secretariat pointed out that the levels of funding being requested for all studies for the preparation of technical dossiers[4] are the same, irrespective of the production levels of each MDI, and whether or not the MDI is currently being produced. Furthermore, an additional US $1.1 million is being requested for technical assistance activities (the same amount as requested for the Pharmaceutical Aerosol Plan), which includes workshops, training programmes, public awareness, consultants, study tours, legislative support activities, auditing CFC consumption for pharmaceutical aerosol manufacturers, development of a monitoring and information system and several other technical assistance activities. An additional US $680,000 is being requested for validation of equipment and production processes at the 17 production lines in operation.

12. UNIDO responded that none of the MDI manufacturing plants are considering giving up their production license. The same procedure must be followed by all plants to change their licenses for HFA-MDI production, regardless of whether the production actually takes place. The actual cost is much higher than the US $195,000 being requested for each of the 36 licenses for MDIs that are currently produced, or the US $85,000 for each of the 41 licenses for MDIs that are not being produced. Plants that have no production will have to use more funding on preparing the technical dossier. Furthermore, the content of the training programmes, the trainees to be trained, the target groups for the awareness activities, the legislative activities, the experts to be recruited and the audits to be conducted will all be different from those of the Pharmaceutical Aerosol Plan. Only the MIS experience could be borrowed for this project. China's Drug Administration Law requires equipment validation before any drug production line can operate. It is part of capital costs for production-line conversion.

[4] Over US $10.5 million is being requested for the preparation of technical dossier for registration of 77 products: 36 that were in production in 2006 (at US $195,000/product) and 41 that were not produced in 2006 (at US $85,000/product).

Capital and operating costs

13. In regard to the funding for the conversion of the 15 manufacturing plants with current production of CFC-MDIs, the Secretariat noted that capital and operating costs amounting to US $914,715, production validation and training costs amounting to US $202,500 and costs for technical dossiers for registration amounting to US $975,000, are being requested for the conversion of three manufacturing plants that commenced production of MDIs for the first time in 2006 (i.e., plants Nos. 2, 14, 38). Considering that the project proposal suggests a cut-off date of 30 November 2004, which is when the preparatory assistance project for the MDI sector was approved, conversion of these lines would not be eligible for funding. UNIDO indicated that, according to Article 29 of the Drug Administration Law, any manufacturing plant developing a new medicine must submit relevant data and samples to the drug supervision and administration department under the State Council. This means that the production lines of plants, which began commercial production in 2006 were in fact established between 2002 and 2003, as it takes three to four years on average from the project start date to get approval from the relevant authorities. Furthermore, some established manufacturing plants were relocated and therefore had no production in 2004 and 2005.

14. The Secretariat also noted that, based on their current consumption of CFCs, three similar replacement production lines have been proposed for all manufacturing plants, irrespective of the baseline production equipment and installed capacity at each manufacturing plant. For many of the production lines, this would result in a capacity increase from their current capacity level and/or a technology upgrade:

(a) An MDI production line at a cost of US $220,000 is being requested for each of the eleven manufacturing plants with CFC consumption below 10 ODP tonnes.[5] Based on current production output, the level of funding being proposed will represent a technology upgrade and/or a capacity increase at the plant level;

(b) An MDI production line at a cost of US $748,000 is being requested for each of three manufacturing plants with CFC consumption between 10 and 100 ODP tonnes[6] The replacement costs proposed is almost US $350,000 more that the level of funding already approved for MDI manufacturing plants with similar levels of CFC consumption in other countries;

(c) An MDI production line at a cost of US $1,452,000 is being requested for one facility with CFC consumption of more than 100 ODP tonnes[7]. The replacement cost proposed is similar to that of manufacturing plants with similar capacity that have already been approved in other countries.

15. UNIDO pointed out that, although in most cases the facilities at the manufacturing plants are currently underutilised, their capacity is higher.

[5] Four plants (Plants No. 37, 9, 14 and 25) have annual CFC consumption below 1,000 kg; five plants (Plants No. 8, 24, 15, 32 and 38) have CFC consumption between 1,500 and 4,900 kg, and only two plants (Plants No. 2 and 36) has CFC consumption of over 7,300 kg.

[6] These manufacturing plants are: Plant No. 18, with an annual CFC consumption of 63.8 ODP tonnes; Plant No. 19, with a CFC consumption of 28.9 ODP tonnes; and Plant No. 28, with a CFC consumption of 19.4 ODP tonnes.

[7] Plant No. 21.

16. Operating costs are almost three times the operating costs for the MDI projects for Bangladesh, Egypt and Iran, which had recently been approved by the Executive Committee. UNIDO indicated that prices used in the proposal to calculate the incremental operating costs were based on market quotations. The incremental costs of the canister and the valve account for almost 87 per cent of the total operating costs, since these items are imported. The calculation of operating costs also took into consideration a 30 per cent reduction in the amount of HFA as compared to CFCs.

Industrial rationalization and cost-effectiveness

17. In reviewing the MDI Sector Plan, the Secretariat developed an indicative table associating each unitary cost proposed in the Plan with each of the 15 manufacturing plants currently producing MDIs (Annex I attached). In this analysis, the total request for technical assistance (US $1,100,000) was divided by the total amount of CFCs to be phased out and pro-rated among the 15 manufacturing plants on the basis of their total CFC consumption. Responding to this issue, UNIDO said that industrial rationalization is not suitable for the medicine production industry in China. The license of every drug is an important component of the plant's assets. Each license is obtained by each enterprise through heavy investment. Relevant government authorities cannot cancel licenses or make changes to the information contained in the license. Therefore, it is not feasible to combine production lines through a Government administrative ruling. Furthermore, a production licence cannot be cancelled because of low or even zero production over a selected period of time.

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

(a) The overall cost-effectiveness (CE[8]) of the MDI Sector Plan of US $79.45/kg (based on a CFC consumption of 280.9 ODP tonnes including 14.1 ODP tonnes used by transnational corporations) is about two times the CE of the MDI projects recently approved by the Executive Committee for Bangladesh (US $36.39/kg); Iran (US $36.61/kg) and Egypt (US $36.98/kg);

(b) The most cost-effective enterprises are the two largest producers of MDIs (Plants No. 18 and 21), with a CE of US $35.29/kg and US $34.44/kg, respectively. The combined production of these two plants represents 65 per cent of total MDIs produced and 69 per cent of total CFC consumed in the MDI sector;

(c) Three manufacturing plants (Plants No. 36, 19 and 28) have a CE value between US $81.00/kg and US $98/kg; seven plants have a CE value between US $114/kg and US $972.00/kg; and three plants have a CE value between US $1,631/kg and US $6,904/kg. Based on these values, the long-term sustainability of all of these enterprises is in doubt;

(d) Contrary to the practice of formulating several of the national sectoral phase-out plans approved for China and several other Article 5 countries, industrial rationalization has not been considered in the MDI Sector Plan.

[8] 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.

19. An additional US $4,265,000 is being requested for technical dossiers for registration of MDIs that have a license but that were not produced in 2006. This funding has not been considered in the above analysis.

Proposal by the Secretariat

20. Taking into consideration the above issues and observations, and consistent with the current policies and guidelines of the Fund, the Secretariat proposed to UNIDO to consider the following alternative methodology for determining the incremental cost of the MDI Sector Plan:

(a) Funding for an MDI transition strategy that will, among other things: review and enforce policies and regulations governing the MDI sub-sector including: adaptation of the ODS licensing system; assessing the request for essential use exemptions beyond the 2010 phase-out date; developing policies to manage stocks of pharmaceutical-grade CFC if needed; further consideration of the development of an action plan for industrial rationalization; implementation of education campaigns for major stakeholders including the general public; and information dissemination. Considering the number of manufacturing plants involved and the number of active ingredients in MDIs, the cost of the transition strategy would be US $200,000;

(b) Funding for the development of HFA-MDIs for the four most important active ingredients, namely, salbutamol (both solution and suspension presentations), beclomethasone, isoprenaline, and cromoglicate. The cost of product development would be US $3,400,000 (estimated at US $1,000,000 for the development of salbutamol in both solution and suspension presentations and US $800,000 for each of the other three active ingredients, similar to the levels approved for Egypt and Iran);

(c) Funding of a technical assistance programme for addressing the remaining ten active ingredients, representing less than 5 per cent of total CFC consumption for the production of MDIs. The cost of the technical assistance programme would be US $180,000, calculated on the basis of the current price of CFC-12 of US $3.43/kg and the current CFC consumption of 12,850 kg over a four-year period;

(d) Capital costs required for the conversion of the 15 manufacturing plants with current production of CFC-MDIs. The total capital costs would be US $3,410,000 calculated as follows:

(i) US $50,000 for the eight production facilities with CFC consumption below 10 ODP tonnes, calculated on the basis of a new small production line with a pressure tank required for the use of HFA propellant;

(ii) US $400,000 for three facilities with CFC consumption between 10 and 100 ODP tonnes. This cost is based on a recent quotation for a new production line in one MDI manufacturing plant in Egypt that was recently approved by the Executive Committee;

(iii) US $1,500,000 for the only plant with a CFC consumption of more than 100 ODP tonnes. This cost is also based on a recent quotation for a new production line in one MDI manufacturing plant in Egypt that was recently approved by the Executive Committee;

(iv) Ten per cent contingency over the total capital costs;

(e) Operating costs of US $1,120,000 calculated over a one-year period, on the basis of a total CFC consumption of 252,937 kg, which excludes 13,868 kg of CFCs used by the three enterprises that commenced production of MDIs only in 2006[9];

(f) Funding at a total cost of US $1,990,000 for the project implementation and monitoring unit, which will be responsible, among other things, for:

(i) Assisting in the preparation of 17 technical dossiers (at US $30,000 each) for active ingredients[10] which are currently being produced in plants that commenced production of MDIs prior to 2006 (the total cost for this activity is US $510,000);

(ii) Validating the facilities of the 12 plants that commenced production of MDIs prior to 2006 and are currently in operation (at US $30,000 per plant). The main activities include validation of workshops, of installation, of facilities and equipment, of facility operation and performance, and of products (the total cost for this activity is US $360,000);

(iii) Training 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 $340,000, estimated at 10 per cent of the capital cost);

(iv) Providing specific technical assistance addressing active ingredients that are not currently being produced, and those manufacturing plants that only commenced production in 2006 (the total cost for this activity is US $100,000);

(v) Establishing a monitoring unit, including the development of relevant management, monitoring and verification systems, and management of stockpiles if necessary (the cost of this activity is US $680,000, estimated at 20 per cent of the capital cost).

[9] The level of operating costs is calculated on the basis of the average operating costs of the MDI projects for Bangladesh, Egypt and the Islamic Republic of Iran already approved by the Executive Committee.

[10] The active ingredients are: sodium cromoglicate, beclomethasone dipropionate, isoprenaline hydrochloride and salbutamol in solution and in suspension.

21. In summary, the total level of funding proposed for the complete phase-out of CFCs in the MDI sector in China is US $10,300,000, with the following distribution:

Transition strategy	US $200,000
Product development/technical assistance	US $3,580,000
Capital costs	US $3,410,000
Operating costs	US $1,120,000
Project implementation and monitoring unit	US $1,990,000

22. 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 sub-sector and in accordance with relevant decisions and guidelines of the Multilateral Fund.

23. To the proposal by the Secretariat, UNIDO responded as follows:

(a) When looking into the details of centralized development of new medicines and substitute technologies, major legal, liability, ownership and market implications have to be considered. There is no authority in China that can assume the implications, risks and responsibilities related to the development of new drugs for commercial manufacturing plants with diverse ownership structures and market shares;

(b) The cost of the project proposal as originally prepared was US $29.5 million. This cost did not include the funding required to purchase patent rights, which are valid in China for several of the MDIs. In order to reduce the level of grant to be requested from the Multilateral Fund, the Government of China put pressure on the manufacturing plants to increase their counterpart contribution;

(c) Although the project proposal is more expensive than any other MDI project approved so far, it should be noted that no other country has so many producers, production lines, active ingredients and licenses as China. Also, the actual CFC consumption in this sector is much higher than the CFC consumption reported in the proposal, as various manufacturing plants do not have adequate accounting and recording systems able to demonstrate exact consumption levels;

(d) Nevertheless, the Government of China has agreed to reduce, to the bare minimum, the cost associated with product development and registration for those plants that did not produce MDIs in 2006. These enterprises will have to find resources to offset the proposed reduction of the grant. The revised budget proposed is as follows:

Development and registration of products	US $8,965,000
Modification to production facilities	US $5,560,000
Production validation	US $680,000
Staff training	US $412,500
Incremental operating cost	US $3,502,689
Technical assistance and transition strategy	US $1,100,000
Contingency (applied to capital costs only)	US $556,000
Total	**US $20,776,189**

24. The Secretariat notes that the revised project cost is US $1,540,000 less than the project cost as submitted. The Secretariat further notes 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 there are unresolved cost-related issues with UNIDO. However, being aware that this is the last CFC phase-out plan for China, the complexity of the proposal, its major implication on 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 submitted the project for consideration by the Executive Committee.

RECOMMENDATION

25. 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
Foam	IBRD

(II) LATEST ARTICLE 7 DATA (ODP Tonnes)			Year: 2005	
CFC: 13123.8	CTC: 1060.3	Halons: 4516.5	MB: 601.5	TCA: 186.6

(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		2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
Maximum Allowable Consumption (ODP Tonnes)	CFC		14,143.	13,830.	10,500.	9,000.	7,000.	400.	0.		
Project Costs (US$)	Project Costs		9,940,000.	12,570,000.	10,903,000.	10,903,000.	3,320,000.	2,676,000.	1,767,000.	1,767,000.	53,846,000.
	Support Costs		886,600.	1,115,300.	961,270.	961,270.	282,800.	240,840.	159,030.	159,030.	4,766,140.
Total Funds Approved in Principle (US$)	Project Costs	0.	9,940,000.	12,570,000.	10,903,000.	10,903,000.	3,320,000.	2,676,000.	1,767,000.	1,767,000.	53,846,000.
	Support Costs	0.	886,600.	1,115,300.	961,270.	961,270.	282,800.	240,840.	159,030.	159,030.	4,766,140.
Total Funds Released by the ExCom (US$)	Project Costs	9,940,000.	12,570,000.	10,903,000.	10,903,000.	3,320,000.		0.	0.	0.	47,636,000.
	Support Costs	886,600.	1,115,300.	961,270.	961,270.	282,800.		0.	0.	0.	4,207,240.
Total Funds Requested for Current Year (US$)	Project Costs						2,676,000.		1,767,000.		4,443,000
	Support Costs						240,840.		159,030.		399,870

(V) SECRETARIAT'S RECOMMENDATION:	For blanket approval

PROJECT DESCRIPTION

26. On behalf of the Government of the People's Republic of China (China), the World Bank has submitted to the 53rd Meeting of the Executive Committee a request for approval of the 2008 annual implementation programme (AIP) for the CFC-11 phase-out in the polyurethane (PU) foam sector in the China. The World Bank also requests the release of a seventh funding tranche, that is, US $1,767,000 plus agency support costs of US $159,030, to finance the 2008 AIP. In addition, the World Bank requests also the release of the sixth tranche of US $2,676,000 and support costs of US $240,840; the associated AIP for 2007 has been approved at the 52nd Meeting, but funding could not be approved because the preconditions had not been met at that time. In addition, the World Bank submitted the multi-year overview tables, which is provided as Annex II to this document.

Background

27. The CFC-11 phase-out in the polyurethane foam sector in China was approved at the 35th Meeting of the Executive Committee, with the World Bank as the implementing agency and the State Environmental Protection Agency (SEPA) as the national implementing operating agency. The implementation of the CFC-11 phase-out in the polyurethane foam sector supports the Government of China in meeting its Montreal Protocol obligations, including the complete phase-out of the controlled use of CFCs by 2010. In order to achieve these targets, a series of investment, non-investment, technical assistance and capacity building activities will be, and are being, implemented by China with the assistance of the World Bank. The total funds approved in principle for the plan amounted to US $53,846,000 plus agency support costs of US $4,766,140.

28. The original "Agreement for the China CFC 11 PU Foam Sector" between China and the Executive Committee was approved at the 35th Meeting of the Executive Committee. Subsequently, at the 44th Meeting both parties entered into another more broad agreement, which supersedes partially the agreement of the 35th Meeting, namely the agreement for the CFC/CTC/Halon Accelerated Phase-out Plan (APP). The latter agreement also foresees, among other objectives, a phase-out of CFC-11 production at the end of June 2007. This phase-out has been achieved.

Status of the plan

29. The foam sector plan agreement also included, in addition to maximum allowable consumption targets, targets for the activities, particularly related to phase-out of CFC-11. It is stipulated that for compliance with the agreement, CFC phase-out contracts need to have been signed amounting to at least 50 per cent of the current year targets and 100 per cent of the previous year targets. In the recent past, it became increasingly difficult for China to identify eligible enterprises on a case-by-case basis because of the specific verification requirements. Being made aware of the related issues, the Executive Committee, in its decisions 51/28 and 52/34, decided on the eligibility of enterprises with capacity established after July 1995 under Multi-Year Agreements, and clarified the definition of "phase-out contract" within the Agreement. With these clarifications, China could modify the implementation modalities accordingly, and has now reported the following overall status regarding the signing of contracts:

- As of end of September 2007, contracts for a total of 10,740.38 tonnes of CFC-11 phase-out were awarded. These fall into the following main groups:

(a) Eleven industrial consolidation phase-out contracts for 7,094.08 tonnes;

(b) Ninety-one individual contracts to foam enterprises for 2,746.296 tonnes; and

(c) Four provincial contracts for 900 tonnes for the 2002-2007 annual programmes.

30. With this status on signed contracts, and assuming that those contracts will be subsequently implemented, China has fully met its obligation regarding the signing of phase-out contracts, to which 10,651 ODP tonnes have been attributed. China will have to continue to provide monitoring and verification, as applicable, for its consumption targets, on the implementation of the annual work programme, and on the progress of its activities relating to the phase-out contracts signed.

Verification of consumption

31. The PU foam sector plan foresees a maximum consumption of 6,885 ODP tonnes of CFC-11 for 2006; the APP foresees a consumption of only 6,318 ODP tonnes. The latter target became therefore the binding one for China under both the PU foam sector plan and the APP.

32. The consumption in the PU foam sector is verified by using the overall CFC-11 consumption of China as a starting point, and deducting from it the verified consumption in other sectors using CFC-11. The results are shown in the table below:

CFC-11 production and consumption	**CFC-11 (ODP tonnes)**
CFC-11 2006 production as verified under the CFC production Sector	6,959.421
CFC-11 export as reported by SEPA and verified by the World Bank	74.030
National CFC-11 Consumption	6,885.391
Pharmaceutical aerosol (Non-MDI)	98.87
MDI	236.70
Refrigeration servicing sector (chillers)	210.00
Tobacco sector	21.27
CFC-11 for the PU foam sector (difference between above):	6,318.551

33. The level of sector consumption calculated in the verification is therefore slightly higher than the maximum allowable consumption under the APP agreement. The difference is 551 kg, or 0.00872%.

Report on the 2006 Annual Work Plan and preliminary report on the 2007 Annual Work Plan

34. The implementation of the foam sector plan includes a number of government-related and awareness activities

(a) In order to meet the target of the Agreement on Accelerated Phase-out (APP agreement), China has stopped CFC production since 1 July 2007. Bans on the use of CFC-11 in all use sectors, such as tobacco, refrigeration, and foam have been promulgated and the CFC-11 use in these sectors is prohibited from July 2007 and January 2008, respectively. The control of CFC production, import/export and of the consumption in other sectors enable the foam sector to

control its national CFC-11 consumption limit within the agreed targets. On 25 June 2007, SEPA promulgated the "Ban on CFC use as blowing agents in the foam sector", which will apply from 1 January 2008.

(b) Enterprises and research institutes were encouraged to conduct research and development on substitute technologies. Development and revision of product standards is ongoing. Studies and research were and are being undertaken to promote the use of new and existing blowing agents and technologies for foam production. Seminars and workshops were organized to disseminate study results to enterprises. Recommendations on substitute technologies from experts and specialists were also collected and disseminated.

35. The main thrust of the implementation of the foam sector plan in 2006 was in the enterprise and provincial phase-out activities:

(a) In the 2006 Annual Programme, the provincial approach was adopted and contracts with each of the provinces of Shandong, Jiangsu, Zhejiang, and Guangdong accounting for 900 tonnes of CFC-11 phase-out were signed. With the contracts, the phase-out target of 600 tonnes has been met leaving a 300 tonnes surplus; and

(b) The provincial contracts will facilitate CFC-11 phase-out through the following activities:

(i) public awareness;

(ii) surveys of enterprises, polyol suppliers and CFC-11 dealers in their respective jurisdictions;

(iii) training and technical assistance provided by local and national foam experts to CFC-11 using enterprises in order to assist them in changing over to non-CFC-11 technologies;

(iv) supply of CFC substitutes for formulation and trial production;

(v) training and technical assistance for the relevant local authorities; and

(vi) enforcement of policies banning the use of CFC-11 for foam production, and monitoring of enterprises to ensure that no CFCs are used and traded, including registration which blowing agents are being used.

36. The report regarding the progress achieved so far in the 2007 Annual Programme informs that seven individual contracts accounting for 195.6 tonnes of CFC-11 phase-out have been signed with total grant of US $554,320. With the surpluses of previous years, the 2007 phase-out target of 551 tonnes has been met. The fund for individual projects is used for procurement of either CFC-free equipment or substitute chemicals.

Verification of activities

37. The World Bank carries out annual verification of CFC-11 consumption in a sample of the activities under the sector plan.

(a) In July 2006, a consultant of the World Bank verified consumption in the Nanjing Hongbaoli sub-project relating to the 2005 annual programme. All CFC equipment has been dismantled, two of the eleven small enterprises involved with this sub-project have closed, two are producing non-CFC foam and others have converted to non-foam production; and

(b) In September 2007, the Bank visited 14 individual projects with CFC-11 phase-out contracts signed during 2007, relating to the phase-out target for the 2005 annual programme. The 14 projects constitute about 28 per cent of the 2,500 ODS phase-out and 18 per cent of the total conversion contracts (78) under the 2005 annual programme. The World Bank also verified the CFC-11 consumption in one of the four provincial projects (Shandong) under the 2006 annual programme. This verification constitutes 39 per cent of the 600 ODP phase-out and 25 per cent of the total phase-out contracts (4) under the 2006 annual programme. Detailed verification reports have been submitted.

Work plan for 2008

38. According to the requirement of the CFC/CTC/Halon Accelerated Phase-out Plan (APP), approved by the Executive Committee in December 2004, the maximum allowable CFC consumption for 2008 will be 550 ODP tonnes, to be achieved through CFC production and import control. The maximum allowable CFC-11 consumption limit in PU foam sector in 2008 will be zero.

39. China has promulgated the “Ban on CFCs use as blowing agents in the foam sector” banning CFC-11 consumption in the foam sector from 1 January 2008. Since it will take industrial consolidation projects three to four years and individual project one and half years to be completed, SEPA is aware that the conversion projects in the 2004-2007 annual programmes may not be completely implemented by the end of 2007. However, in order to meet the APP phase-out targets, all CFC-11 equipment in the projects in the 2004- 2007 annual programmes will be disposed of or converted to non-CFC ones by the end of 2007.

40. The flexibility authorized by the Executive Committee in terms of the eligibility for grant and the implementation modality enabled China to fulfil its CFC-11 phase-out obligation for the foam sector of 10,651 ODP tonnes. 24 enterprises with estimated baseline CFC-11 consumption of 500 ODP tonnes have submitted their application to the Project Management Office before the deadline for any new projects, of August 2007. SEPA will sign phase-out contracts with these enterprises if their eligibility is confirmed. For those that arrived after the deadline, their CFC-11 phase-out will be addressed through the provincial approach.

41. In addition to the four provinces that have signed contracts with SEPA, more provinces and municipalities with significant foam production will be identified, and contracts signed. It is planned that those will not be considered as contributing to the targets of the agreement in terms of phase-out contracts.

42. Since good substitute technologies (in both technical and economic terms) are crucial to the success of sustained ODS phase-out, SEPA will continue to organize, and support financially, where necessary, the research projects aimed at improving the existing technologies or even develop a new substitute technology.

43. The following activities are proposed for 2008:

(a) Implementation workshops to familiarize beneficiaries with the implementation procedure;

(b) Performance verification and consultant services;

(c) *Survey on blowing agents used in the foam sector in China*. For the rigid foam sub-sector in China, the main blowing agent substitutes are HCFC-141b, water, pentane, and in a few cases, HFC-245fa. Among these, HCFC-141b is the most widely used. In order to gather more detailed data on the use of these chemicals, a survey will be carried out on how well they are used by enterprises as well as problems encountered;

(d) *Technical study tours on substitute technologies*. There are several non-ODS alternative substitute technologies, which are presently not widely used. Two technical study tours are planned under the 2008 annual programme to study the experience of industry in Europe and North America with a view to promoting the use of non-ODS technologies in the foam sector in China. Technical experts, technicians from enterprises, and staff from the project management office will be part of the mission; and

(e) *Monitoring of CFC phase-out in the foam sector*. SEPA will increase the monitoring activities to ensure sustained phase-out in the foam sector. Inspection will be conducted on site, therefore portable CFC detectors, laptop computers and digital cameras will need to be procured.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

44. The verification indicated a consumption above the target approved in the APP agreement for the foam sector. When assessing the significance of this over-consumption, it is important to look at both the figures as well as the methodology used to determine them. The methodology deducts known consumption in sectors and exports from a known total, but without exact knowledge if the deductions represent all areas of consumption outside the sector. In addition, certain leakage (spillage, accounting, evaporation) might also take place. This leads to the observation that some minor uncertainty even in verified numbers has to be accepted, at least in cases where a sector consumption is verified on the basis of several other verifications, leading to a situation where inherent uncertainties are adding up.

45. The Secretariat believes therefore that the result of the verification identifying less than 0.1 per cent above the allowed consumption for the sector, can be viewed as having fulfilled the

condition of the APP agreement, taking into account some uncertainties in reporting and verification.

46. The report on the implementation of the 2006 annual plan was found to be detailed and with a large amount of information. The activities largely followed the pattern established in the past years. A new feature was the verification of the consumption of the one region in China, Shangdong Province where the consumption was determined through assessment of the sales of CFC-11 producers in the different regions. The verification appears to be successful, although the methodology used might not be easily transferable. Other parts of the verification of the sector plan focussed on enterprise level verification. The Annual plan for the following year mainly addresses activities in regions and a number of studies, and demonstrates the advanced status of the implementation of this sector plan. According to information submitted by the World Bank regarding their current level of expenditures under the plan, more than 80 per cent of the funds approved so far have been used.

RECOMMENDATION

47. The Fund Secretariat recommends blanket approval of the 2007 and 2008 tranches of the Plan for CFC phase-out in the Polyurethane Foam Sector in China with associated support costs at the funding level shown in the table below:

	Project Title	Project Funding (US$)	Support Cost (US$)	Implementing Agency
(a)	Plan for CFC-11 phase-out in the polyurethane (PU) foam sector in the China (2007 tranche)	2,676,000	240,840	World Bank
(b)	Plan for CFC-11 phase-out in the polyurethane (PU) foam sector in the China (2008 tranche)	1,767,000	159,030	World Bank

SECTOR PLAN FOR HALON PHASE-OUT: 2008 ANNUAL PROGRAMME

PROJECT DESCRIPTION

Background

48. The China Halon Sector Plan was approved at the 23rd Meeting of the Executive Committee in November 1997 in decision 23/11. This is the first sector phase-out plan and it addresses both halon consumption and production. US $61.6 million has been approved to date of the US $62 million approved for the overall plan. The 2008 annual work plan is the second to last tranche of this multi-year agreement. The last tranche will be submitted next year.

49. In accordance with the Executive Committee's approval of the Sector Plan for Halon Phase-out (decision 23/11) and the CFC/CTC/Halon Accelerated Phase-out Plan in China (decision 44/59), China is requesting, through the World Bank, the release of the eleventh tranche of US $300,000 for the implementation of the 2008 annual programme, and US $22,500 in support costs (at a rate of 7.5 per cent). Details of the annual programme are provided in the request submitted by the World Bank that is available on the Multilateral Fund's intranet. The 2008 annual programme includes the following elements:

(a) US $300,000 to be used for technical assistance activities to support the halon phase-out programme and ensure that existing fire protection requirements can be met. These include the following activities:

  (i) Establishing a certification system to enable the development of certification requirements for halon recycling centres;

  (ii) Training personnel;

  (iii) Conducting a performance audit; and

  (iv) Conducting a study tour to the United States and/or Australia to gain experience on halon banking management.

(b) Halon recycling and banking:

  (i) Continuing to process the pilot project on halon-1211 recycling in Guangdong province;

  (ii) Preparing a draft plan for a national halon banking system;

  (iii) Continuing to collect (through recycling stations) halon from non-essential users and those older than 10 years;

  (iv) Establishing halon-1301 recycling centres and strengthen their capacity to initiate halon-1301 reclamation;

  (v) Issuing related polices on halon recycling and conduct a survey of halon fire fighting systems and extinguishers;

(vi) Conducting training courses for local fire fighting offices; and

(vii) Conducting public awareness activities on halon recycling and management.

50. There are neither any remaining halon-1211 production facilities nor consumption in China, as defined by the Montreal Protocol. Of the 71 halon fire extinguisher manufacturers and the 22 halon-1211 system manufacturers, 61 extinguisher and 14 system manufacturers were funded under the sector plan. An additional four fire extinguisher manufacturers were found to be producing under licenses from provincial governments. Their licenses have been withdrawn and the companies have changed to use of substitutes at their own cost.

51. Actual halon-1301 production was within the 1,000 ODP tonne total with production recorded in 2006 as 995 ODP tonnes. Halon-1301 consumption was 205 ODP tonnes (20.5 metric tonnes) lower than the planned level of 1,000 ODP tonnes. Several halon technical assistance programmes are still under implementation from initial approvals dating back to 2002. Four technical assistance activities were added for consideration in the 2007 programme including:

(a) The investigation and verification of feedstock applications of halon-1301;

(b) A study on testing technology and equipment for superfine dry powder extinguishing agents;

(c) Requirements and approval procedures for the installation of gaseous extinguishing systems;

(d) A study on evaluation methods and the requirement for disposal technology for halon systems.

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

Plan for unused funds

52. As requested in decision 50/29(c), the World Bank provided the following table to outline how funds would be used that had been approved for the halon phase-out project but that had not been allocated or disbursed. The value of these funds amounted to US $13 million.

53. The World Bank indicated that the budget was tentative and, as the funding from the Executive Committee is based on agreed performance targets which have all so far been met, China reserves the right to adjust the budget as needed. The Bank provided information with an indicative budget as included in the following table.

Table 1

INDICATIVE BUDGET 2007-2015

Period	Activity	Tentative allocation	Comments
2008	CO_2 fire extinguisher penalty	US $1,200,000	To be managed under the halon account.
2007-2008-2009	Halon-1301 system manufacture conversion	US $600,000	Remaining manufacturers as per SP and surveys
2009	Closure of the halon-1301 production for controlled consumption	US $520,000	Closure of Halon-1301 production for consumption
2007-2010	TA activities, training and awareness activities	US $1,100,000	
2009-2010	Halon sector closure activities, PCR, audits, Bank reporting and verifications etc.	US $300,000	
2008-2015	Central and provincial halon banking and management activities	US $7,780,000	Activities to be supported in 31 provinces and larger cities and municipalities
2010-2015	Halon management, supervision activities, monitoring and controlling feedstock uses of halons and preventing illegal halon production and export and other activities as needed	US $1,500,000	
Total		**US $13,000,000**	

54. Table 1 shows, *inter alia*, that China proposes extending the halon sector plan until 2015 from its original completion date of 2010. The Bank, upon being asked how this could be implemented, advised that it was presently reviewing the post 2010 situation. It indicated that since funding had been provided based on a performance agreement between the Executive Committee and China that all the funds would remain with the country provided that all conditions in the agreement had been met. Similar arrangements had been made in the Bank's Grant Agreement with China without any return of funding. The Bank further advised that its legal department was reviewing the issue of post-2010 implementation for the halon sector plan.

55. The Fund Secretariat requested an updated table with annual allocations. The World Bank indicated that China was presently preparing an updated table and it would be submitted during the week of the dispatch of documents. The Executive Committee may wish to consider requesting China and the World Bank to continue to report on the use of these remaining funds until they are expended.

Prohibition against exports of recovered/reclaimed halon to developed countries

56. The Secretariat noted that decision 23/22(g) states that in view of the fact that the project is expected to fund extensive recycling facilities, and related funds for necessary capacity building are being provided solely to allow China to meet it reduction obligations, China will endeavour to prevent exports to developed countries of recovered/reclaimed halon. Since the unallocated funds are largely intended for recovery, recycling and reclamation activities, the Secretariat enquired as to how China would meet the provision of the agreement.

57. The World Bank indicated that the condition was put in place to avoid unfair competition with halon recyclers in other countries. However, it noted that in 2008, ten years after the approval of the sector plan, the conditions have changed and that the Executive Committee might consider removing this condition and allowing such export if needed for critical uses in developed countries. The Executive Committee may wish to consider this option in the context of the UNEP study on challenges associated with halon banking in developing countries, approved in decision 52/27.

Halon-1301 as a feedstock

58. In approving the 2007 tranche of the halon sector plan at its 50th Meeting, the Executive Committee requested the World Bank and the Government of China to continue monitoring and reporting on the annual amount of halon-1301 and, if applicable, halon-1211 being produced and/or used as feedstock, as well as to explore the possibility of verifying those amounts. Halon-1301 is used for producing pesticides, pesticide intermediates and pharmaceutical intermediates starting in 2003.

59. A total of 277.02 metric tonnes of halon-1301 were produced in 2005 and 400 metric tonnes in 2006. At the end of 2006, there was a stockpile of 283 metric tonnes. The ten enterprises that used halon-1301 as a feedstock for pesticide and pharmaceutical intermediate production in 2006 (with a total consumption of 300 metric tonnes of halon-1301) are subject to the following measures:

(a) All feedstock users have been verified and an in-house consultant verifies their applications;

(b) Only halon-1301 sold to these 10 enterprises is accepted for the use of halon produced in China;

(c) The halon producer is required to sell halon only for feedstock to these 10 approved enterprises—the company reports its production, domestic and export sales and stock on a monthly basis so that the stockpile is monitored, along with the halon-1301 production;

(d) Sales and consumption of halon-1301 will be initiated following the approval of a regulation by the State Council; and

(e) Halon-1301 consumers/users are also required to report on their stockpile of halon-1301, its procurement, consumption and the production of final products on a quarterly basis with random site visits to be conducted as needed.

60. In responding to a question about the conclusions of the auditors, the World Bank indicated that the monitoring mechanism set up by China and the Bank is identical to the procedure used for CTC feedstock and process agent applications. The feedstock users are registered by the Government of China and must report their procurement and uses of halon-1301 as feedstock. China conducts random spot checks to ensure that the halon-1301 is used as feedstock by the companies. These procedures for accounting and monitoring are consistent with the recommendations made by the auditors to establish such systems.

RECOMMENDATIONS

61. The Executive Committee may wish to:

(a) Approve the request for funding for the China halon phase-out work programme for 2008, at the amount of US $300,000 plus support costs for the World Bank of US $22,500 after taking into account any decision related to the extension of halon sector plan activities post-2010 taken in the context of the Overview of Issues Identified during Project Review (UNEP/OzL.Pro/ExCom/53/15);

(b) Consider requesting China and the World Bank to continue to report on the use of remaining unused funds until they are expended; and

(c) Consider the request of China to remove condition (g) of decision 23/22 requiring China to endeavour to prevent exports to developed countries of recovered/reclaimed halon in the light of the UNEP study on challenges associated with halon banking in developing countries, approved in decision 52/27.

PHASE-OUT THE PRODUCTION AND CONSUMPTION OF CTC FOR PROCESS AGENT AND OTHER NON-IDENTIFIED USES (PHASE I): 2008 ANNUAL PROGRAMME

Introduction

62. The World Bank is submitting to the 53rd Meeting of the Executive Committee, on behalf of the Government of China, the 2008 annual programme of the sector plan for phasing out the production and consumption of CTC and the consumption of CFC-113 for process agent (25 applications) under phase I. This with the understanding that the request for the release of funding amounting to US $3 million plus the associated support cost of US $225,000 will be submitted to the 54th Meeting with the submission of the verification of the implementation of the 2007 annual work programme. The 2008 work programme is not attached but could be made available upon request.

Background

63. At its 38th Meeting in November 2002, the Executive Committee approved, in principle, US $65 million for the Agreement with the People's Republic of China to phase-out the production and consumption of CTC, and the consumption of CFC-113 as process agents (phase I), and disbursed the first tranche of US $2 million at the meeting to start implementation. China has committed to complying with the Montreal Protocol phase-out schedule for the controlled CTC production and consumption (25 applications) and the consumption of CFC-113 as a process agent by implementing the Agreement. Subsequently the Executive Committee approved the 2003 to 2007 annual work programmes at a total funding level of US $61 million. The production of CTC for controlled use and as feedstock for CFC production was reduced from 64,152 ODP tonnes in 2001 when the phase-out plan was developed to 28,470 ODP tonnes in 2006. The consumption of CTC as a process agent for the 25 applications under phase I came down from 5,049 ODP tonnes in 2002 to 461 ODP tonnes in 2006 and CFC-113 consumption was reduced from 17.2 ODP tonnes in 2002 to zero in 2006.

64. The reduction targets and the associated funding levels for 2007 and 2008 are set out in the table below.

Table 1

TARGETS AND FUNDING OF THE 2007 AND 2008 ANNUAL PROGRAMMES

Consumption	
CTC for 25 process agent application	
2007	493 ODP tonnes
2008	493 ODP tonnes
Impact	0
CFC-113 for process agent application	
2007	0
2008	0
Impact	0
Production	
CTC	
2007	*18,782 ODP tonnes
2008	**8,188 ODP tonnes
Impact	10,594 ODP tonnes
Total MLF funding approved in principle	US $65 million
Total funding released by the MLF by July 2007	US $61 million
Level of funding requested	US $3 million

*The 2007 target for CTC maximum allowable production and imports for CTC use as process agent and feedstock for CFC production as a result of the approval of phase II of the CTC sector plan.

**This is the target for both phase I and phase II, which includes 7,341 ODP tonnes which is 15 per cent of the baseline plus 10 per cent for BDN and 847 ODP tonnes as feedstock for 550 ODP tonnes of CFC production in 2008.

Project Description

65. The submission of the World Bank starts with Part A which contains a summary of the results from the implementation of the four annual work programmes from 2003 to 2006, as well as a progress report on the implementation of the 2007 annual programme. The status of implementation of the programme is summarised in the following tables, one on production and the other on consumption.

Table 2

SUMMARY OF IMPLEMENTATION ON CTC PRODUCTION PHASE-OUT (PHASE I) BY AUGUST 2007

Year	Number of CTC producers	CTC producers closed in the year	Remaining number of CTC producers	CTC producers with production quotas
2003	16	0	16	14
2004	17 (1 new added)	5	12	9
2005	12	1	11	8
2006	12 (1 new added)	2	10	6
2007	13 (3 new added)	0	13	[0]
2008	13	0	13	[0]

Table 3

STATUS OF PHASE I ENTERPRISES ODS PHASE-OUT ACTIVITIES UP TO 30 JUNE 2007

PA Applications	Original number of PA enterprise	Remaining enterprise using CTC/CFC-113	Converted to non-ODS	ODS PA production closed
CR	8 (including one newly identified)	3	0	5
CP-70	12	0	1	11
CSM	3	1 (emission control)	0	2
Ketotifen	1	0	1	0
Endosulphan	2 (newly identified)	0	0	2
PTFE	6	0	6	0

66. The Government of China has continued to implement a number of policies to assist the implementation of the CTC sector plan. The "Circular on Implementing Carbon Tetrachloride (CTC) Production Quota-License System" placed all CTC producers including the newly erected chloromethane plants under control. The "Circular on CTC Consumption Quota-License System", issued in May 2003, required CTC dealers and consuming enterprises to register and apply permits both for selling and buying the controlled substance and submit quarterly reports to SEPA. In 2004 the Government issued the "Circular on Management Procedures for Site Supervision of CTC Production Enterprises", which introduced the same peer monitoring system used in the CFC production phase-out plan. The supervision included the newly established chloromethane producers.

67. In managing the chloromethane plants, the Government made a distinction between those built before and those built after January 2005. While there is no production quota for all of them, those built before January 2005 could sell to consumers using their consumption quota, and those built afterwards cannot sell CTC and have to either destroy it or use it as feedstock for non-ODS production.

68. As can be seen in Table 3 above, since 2005 there were only 3 CR producers and 1 CSM producer still consuming CTC while the other enterprises have been closed, or converted to non-ODS technologies. Since 2006, consumption of CFC-113 as a process agent has been terminated.

69. The chlorosulphonated polyofin (CSM) project in Jilin Province, the only emission control project under phase I, continues to struggle with the imported technology. Modifications have been made without much improvement. Meanwhile, the enterprise entrusted several universities or research institutes to seek substitute technologies to replace CTC consumption. If all efforts fail, the plant will have to cut its CSM operation to meet the CTC consumption target for 2010 set by the Agreement.

70. Tables II-1 to II-5 in Annex II of the submission provide the details of the activities on an enterprise level for each of the applications, with information on the number of the application,

name of the enterprise, name of the product, capacity, CTC/CFC-113 consumption between 2001-2005, level of production between 2001-2005 and status of the plant. Annex V of the submission provides a list of the contracts that have been signed between SEPA and the enterprises, with specifics such as the name of the enterprise, the baseline, nature of the contract, year of contract and status of the plant (producing or closed).

71. Under the technical assistance programme, out of a total of 27 activities since 2003, 20 have been completed and seven are still under implementation. Details are provided in Annex VI of the submission. Among those planned for 2007 is the verification of new feedstock, new process agents and dealers, CTC sales online application and approval which aims at collecting CTC sales information on time and preventing over-purchase and unauthorized sales.

72. Part B of the submission contains the proposed 2008 annual programme and covers the planned targets and the activities proposed to be undertaken to achieve these targets. The targets have been adjusted to reflect the impact of the accelerated phase-out plan and phase II of the sector plan. CTC production for controlled uses for both phase I and phase II of the sector plan and for feedstock use in CFC production should not exceed 8,188 ODP tonnes (7,341 + 847), and the consumption of CTC as process agents under phase I should not exceed 493 ODP tonnes in 2008. The consumption of CFC-113 as a process agent would be zero, as stipulated in the Agreement under phase I.

73. The new "ODS management regulation" has been under development since 2004 and would serve as a solid legal basis for sustainable ODS phase-out. The submission anticipates its approval by the State Council in the second half of 2008.

74. The five technical assistance activities planned for 2008 include:

(a) *Survey of CTC residues.* The aim of the TA is to investigate the management status of CTC residues at each CTC producer, including residue amounts, CTC content and disposal method;

(b) *Verification of CTC lab users.* This TA is to identify all the CTC lab users and corresponding CTC procurement, consumption and production situation, which will provide solid support for future phase-out of CTC lab uses; and

(c) *CTC management Studying Tour to India:* This TA aims to learn and exchange CTC management experience from India, including the management for feedstock users, substitute technologies for phasing out ODS process agents consumption, etc.

75. The US $3 million of the 2008 annual programme is planned for financing TA activities in the 2007 and 2008 work programmes.

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

76. The 2007 annual programme is proceeding as planned and the only problem remains to be the Jilin CSM emission control project which continues experiencing difficulty in absorbing the technology imported. However there seems to be a plan to control the CTC consumption by cutting back on CSM production if all current efforts to change the situation fails.

77. The proposed 2008 annual work programme provides clear targets which are consistent with those in the Agreement and a plan of action which intends to continue the momentum and the implementation structure that has been built in the past five years.

RECOMMENDATION

78. The Secretariat recommends that the Executive Committee approves the 2008 work programme of the China sector plan for phasing out the production and consumption of CTC and the consumption of CFC-113 as a process agent (25 applications) under phase I, at US $3.0 million and associated support cost at US $225,000, noting that the request for funding and support costs will be submitted by the World Bank to the 54th Meeting together with a verification report on the implementation of the 2007 annual programme.

PHASE-OUT THE PRODUCTION AND CONSUMPTION OF CTC FOR PROCESS AGENT AND OTHER NON-IDENTIFIED USES (PHASE II): 2008 ANNUAL PROGRAMME

Introduction

79. The World Bank is submitting to the 53rd Meeting of the Executive Committee, on behalf of the Government of China, the 2008 annual programme of the sector plan for phasing out the production and consumption of CTC for process agent and other non-identified uses (phase II). This is with the understanding that the request for the release of the third tranche of funding amounting to US $10 million plus the associated support cost of US $0.75 million will be submitted to the 55th Meeting with the submission of the verification of the implementation of the 2007 annual work programme. The proposed 2008 annual work programme is not attached but could be made available upon request.

Background

80. At its 47th Meeting in 2005, the Executive Committee approved, in principle, the sector plan for phasing out the production and consumption of CTC for process agent and other non-identified uses in China (phase II) at a total level of funding of US $46.5 million plus support costs of US $3,487,500 for the World Bank. The Committee approved the Agreement for phase II of the sector plan at the 48th Meeting. The Committee has disbursed a total of US $35 million to implement the 2006 and 2007 annual work programmes. The CTC reduction targets and fund disbursement schedule under the agreement are reproduced below.

Table 1

ALLOWABLE CTC PRODUCTION AND CONSUMPTION IN PA II AND AGREED FUNDING

	Baseline (2003)	2006	2007	2008	2009	2010
1. Max allowed CTC production for consumption under the MP	29,367	7,341*	7,341	7,341	7,341	4,471
2. Max allowable CTC consumption as per the Montreal Protocol control measures	55,891	8,383	8,383	8,383	8,383	0
3. Max allowable CTC consumption for Phase I	5,049	493	493	493	493	220
4. Max allowable CTC consumption for Phase II	5,411	6,945**	6,945	6,945	6,945	994[1]
5. Non identified CTC consumption	3,300	945	945	945	945	-
6. Max allowable amount of CTC used in process agent applications listed in the interim table A-bis of decision XVII/8 and in potential future process agent applications as identified and reported by China in its annual verification reports***	NA	14,300	14,300	14,300	14,300	0****
Multilateral Fund funding (in US $ thousands)						**TOTAL**
7. MLF Funding for Phase II		25,000	10,000	10,000	1,500	46,500
8. Agency support costs for Phase II		1,875	750	750	112.5	3,487.5

Notes: 1. provided emissions are accepted by the Parties as eligible, under decision X/14

* The allowed CTC production for consumption includes the additional production of 10 per cent of base level allowed for basic domestic need from 2005 to 2009 and 15 per cent from 2010

** The Bank will verify consumption by companies and applications covered by the PA II Sector Plan (Row 4). The annual verification will cover a random selection of at least 30 per cent of all enterprises covering at least 30% of the PA II consumption,

*** These figures are subject to reconfirmation at the 50th Executive Committee Meeting. The CTC use figures for the years 2007, 2008 and 2009 will be reviewed by the Executive Committee and may be amended. China will verify the annual amount of the CTC amounts used in those applications consistent with the procedures established for CTC feedstock uses and endorsed by Executive Committee at its 48th Meeting.

**** The amount of CTC used will be reduced to zero, or any insignificant levels of emissions which might be approved by the Parties, by 1 January 2010.

Project description

81. The submission of the World Bank for the 2008 annual work programme under phase II contains a number of elements in common with the 2008 annual programme under phase I, and therefore the summary for phase II will only cover those elements which are specific to the second phase.

82. As for targets, the 2007 programme for phase II would ensure:

(a) National annual CTC consumption control target for 13 process agent applications will not exceed 6,945 ODP tonnes; and

(b) National annual CTC consumption control target for process agent applications, other than phase I and phase II, will not exceed 6,600 ODP tonnes, which has been revised from 14,300 ODP tonnes as originally planned.

83. A status report of the 2007 programme as of June 2007 is provided in the following table.

Table 2

STATUS OF 2007 PLANNED ACTIVITIES (AS OF JUNE 2007)

Type of activities	Planned	Actual situation	CTC Reduction planned	CTC Reduction achieved
New policies and regulations	None	None	NA	NA
Production reduction	5 contracts	Five contracts signed (incentive contract for CTC producers)	2009 MT	2009 MT
Consumption reduction	9 contracts	0	0 MT	0 MT
TA activities	4	One has been done (performance audit), one was cancelled (technical assessment), one will be done under CTC/PAI sector plan (verification of new PA).	NA	NA
Training activities planned	1 (5 workshops)	One workshop completed (three will be done under CTC/PAI sector plan)	NA	NA

84. The following table gives further details by process agent application on the progress on the phase-out activities by the enterprises.

Table 3

SUMMARY OF IMPLEMENTATION OF PHASING OUT CTC AS PROCESS AGENT (PHASE II) AS OF AUGUST 2007

Application	Annual consumption (MT)		No. of Production Lines		Actions
	2003	**2006**	**2003**	**2007**	
Cyclodime	152.85	98.18	9	9	Closure contract will be signed in 2007 with Liyang Guanghua. 7 stopped production and use of CTC*.
CPP/CEVA	2,730.40	2543.94	15	10	2 newly identified added. 7 closed and dismantled. 4 stopped production*.
MIC	574.54	1295.90	6	6	Substitute technology is being developed.
MPB	679.95	650.85	3	3	1 stopped production*. 2 will stop their production by the end of 2007.
Imidacloprid	264.81	168.80	4	1	1 multi-functional production line not used for Imidacloprid production any more.. 1 converted. 1 closed and dismantled.
Buprofenzin	316.87	262.96	3	1	1 closed and dismantled. 1 converted.
Oxadiazon	57.00	5.00	3	1	1 stopped. 1 multi-functional production line not used for production of Oxadiazon any more.
CNMA	136.12	270.00	1	1	
Mefenacet	6.93	0.00	1	0	1 converted.
DCBT	0.00	0.00	0	0	
Total	**4,919.47**	**5,295.63**	**45**	32	

*Enterprises which stopped production without dismantling is still counted as production lines in 2007.

85. The targets for the 2008 programme remain the same as those for 2007 and the maximum allowable CTC consumption, other than those covered under phases I and II, has been reduced from 14,300 ODP tonnes to 6,600 ODP tonnes. The details are shown in the table below:

Table 4

TARGETS UNDER 2008 ANNUAL PROGRAMME

Target	National annual CTC Consumption in the PA Sector (Phase II)						
Indicators			**2008 (year of Program)**	**Reduction**	**Funding US$ million**	**Key actions required**	**Key dates**
		(ODP tons)					
CTC consumption	PAII enterprises		6,945	0	9	1. Issue CTC consumption quotas. 2. Sign CTC consumption phase-out contracts.	1. By March 31, 2008 2. By Sept 30, 2008
	Total		**6,945**	**0**	**9**		
Max allowable amount of CTC used in process agent applications listed in the interim table A-bis of Decision XVII/8 and in potential future process agent applications as identified and reported by China in its annual verification reports			**6,600**	0	0	1. Issue CTC consumption quotas.	1. By March 31, 2008

86. Of the US $10 million requested for the 2008 plan, US $1 million is planned for funding technical assistance activities as shown below:

Table 5

PLANNED FUNDING OF TECHNICAL ASSISTANCE ACTIVITIES

Technical assistance activities				
Proposed Activity	**Target group**	**Funding (US$ Million)**	**Actions Required**	**Key Dates**
1. Training of personnel involved in implementation of phase-out activities.	PAII and new PA enterprises	0.1	1. TOR to be agreed with World Bank 2. Training of PAII enterprises 3. Training of new PA enterprises	1. April 2008 2. June 2008 3. August 2008
2. Technical assessment meeting for conversion and emission control projects	Projects to implement conversion or emission control	0.3	1. TOR to be agreed with the Bank 2. Several technical assessment meetings	1. April 2008 2. By Dec. 2008
3. Technical consulting services of experts		0.3	1. TOR to be agreed with the Bank 2. Selection of experts 3. Service Contract signed with experts Travel costs of experts will be included	1. April, 2008 2. May, 2008 3. June, 2008
4. Other TA		0.3		
Total for TA activities		1		
Total annual funding		10		

87. The submission has four annexes: Annex I provides a list of CTC producers and their status; Annex II contains information on PA enterprises under phase II, which has four tables providing details on ODS consumption for each application between 2001-2006, production lines of each application, list of PA enterprises in the sector plan, and CTC consumption for each

sub-sector and enterprises. Annex III is a list of policies implemented and Annex IV is a list of TA activities.

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

88. The World Bank's submission contains revised targets on the maximum allowable consumption for CTC process agent applications not covered under Phases I and II from 14,300 ODP tonnes stipulated under the Agreement of Phase II to 6,600 ODP tonnes for both 2007 and 2008. The World Bank advises that it is the decision of the Government of China to revise the target from 14,300 ODP tonnes to 6,600 ODP tonnes for 2008 and 2009 in response to the decision of the Executive Committee at the 52nd Meeting to "defer to its 53rd Meeting consideration of the need to adjust the ceiling of 14,300 ODP tonnes of the Phase II agreement for CTC applications not covered by Phases I and II of the sector plan."

89. Otherwise, phase II of the sector plan has proceeded well in 2007 and been achieving its target. The proposed 2008 programme has targets consistent with the Agreement and a plan of action to achieve them.

RECOMMENDATION

90. The Secretariat recommends that the Executive Committee:

(a) Amends the maximum allowable amount of CTC used in process agent applications listed in the interim table A-bis of Decision XVII/8, and in potential future process agent applications as identified and reported by China, from the 14,300 ODP tonnes currently included in the Agreement of Phase II of the sector plan from to 6,600 ODP tonnes in 2008 and 2009;

(b) Approves the 2008 annual work programme of Phase II of the sector plan for phasing out CTC production and consumption for process agents at US $10 million, and the associated support cost at US $750,000, with the understanding that the request for funding and support costs will be submitted by the World Bank to the 55th Meeting together with a verification report on the implementation of the 2007 annual programme.

SECTOR PLAN FOR CFC PRODUCTION PHASE-OUT: 2008 ANNUAL PROGRAMME

I. Introduction

91. The World Bank is submitting to the 53rd Meeting of the Executive Committee on behalf of the Government of China the request for the approval of the 2008 annual work programme of the Agreement for the China CFC production sector. This is with the understanding that approval of funding of US $7.5 million plus US $562,500 as support cost for the implementation for the 2008 programme will be requested at the first meeting of that year based on satisfactory performance of the programme in 2007, as per the Agreement. The 2008 work programme is not attached but could be made available upon request.

II. Background

92. Since its approval by the Executive Committee in 1999, the China Production Sector Phase-Out Agreement has been successfully implemented between 1999 and 2007 to reduce the number of CFC-producing plants from 37 in 1999 to six in 2007, and the level of CFC production from 50,351 ODP tonnes in 1997 to 7,400 ODP tonnes in 2007 (to be verified in the second half of 2007). CFC production in China was terminated by 1 July 2007 with only one facility remaining to produce no more than 550 ODP tonnes of CFCs for the production of MDIs in 2008 and 2009.

93. The table below sums up the key data from the China CFC production sector plan and from the 2007 and 2008 work programmes.

Table 1

Country	People's Republic of China
Project title:	Sector Plan for CFC production phase-out in China
Year of plan	2008
# of years completed	9
# of years remaining under the plan	2
Ceiling for 2007 CFC production (in ODP tonnes)	7,400 ODP tonnes
Ceiling for 2008 CFC Production (in ODP tonnes)	550 ODP tonnes
Total funding approved in principle for the CFC sector plan	US $150 million
Total funding released from MLF as of December 2007	US $135 million
Total funding disbursed from World Bank to China (as of Oct. 2007)	US $104.5 million
Level of funding requested for 2008 Annual Plan	US $7.5 million

III. Project description

94. The submission has two parts: Part A is a summary report on the implementation by China of the Sector Phase-Out Agreement since its approval in 1999, including progress achieved in the implementation of the 2007 annual programme as of August 2007; and Part B is the proposed 2008 work programme. The following are the most salient features of the summary report.

95. Implementation of the China Production Sector Phase-Out Agreement between 1999 to 2007 has reduced the number of CFC-producing plants from 37 in 1999 to six in 2007, and CFC production from 50,351 ODP tonnes in 1997 to 7,400 ODP tonnes in 2007 (which will be verified in the second half of 2007). The annual production each year has been confirmed by both a national audit of the annual programme conducted by the China National Audit Office and an international verification of the production commissioned by the World Bank. Starting from the 2004 annual programme, implementation of the CFC production closure programme began to establish linkages with other related sector plans under implementation in China. For instance the verification under this programme will provide monitoring of China's compliance on the production of CFC-13 according to the relevant Montreal Protocol control schedule. In 2005 the only CFC-113 producing plant was closed, thus completing the phase-out of that controlled substance.

96. Under the 2007 Annual Programme, three kinds of phase-out activities have been carried out as per the accelerated phase-out plan (APP) agreement namely, production reduction activities, closure activities and CFC stockpiling. Firstly, to reduce production from 13,091 ODP tonnes in 2006 to 7,400 ODP tonnes in 2007, five production reduction contracts were signed to remove 5,755.49 ODP tonnes of CFC production. The total CFC production quota issued by SEPA in 2007 was 6,305.49 ODP tonnes, below the control target of 7,400 ODP tonnes as per the CFC agreement. The remaining producer's quota will be limited at 550 ODP tonnes for MDI uses in 2008 and 2009. Therefore China has realized the accelerated CFC production phase-out two and a half years ahead of the Montreal Protocol schedule and the original CFC phase-out agreement with the MLF.

97. Secondly, for the five total closure contracts, all CFCs remaining in the production system have been purged and accounted for in the quota calculation for the first half of 2007. All residue materials have been properly disposed of, and remaining CTC feedstock has been handled according to the CTC sales and consumption licensing system. All key equipment has been dismantled and destroyed by the end of July 2007 with on-site supervision of SEPA officials, and the concerned parties. All the total closure activities, including the preparation of all verification documents and the completion report are expected to be ready by the end of 2007.

98. Thirdly, according to the requirement of the APP plan, China has stockpiled a total of 500 ODP tonnes of CFC-11 and 3,000 ODP tonnes of CFC-12 in 2006 and 2007 as the national stock to meet the demand for CFCs in the refrigeration servicing sector, pharmaceutical aerosols sector and MDIs sector for the years 2008-2018. Contracts have been signed between FECO/SEPA and the four CFC11/12 producers for funding the CFC storage facility and production cost in September 2007. The control and management mechanism for stockpiled CFCs is under development and will be put into operation. The sales and uses of stockpiled CFCs will be under strict monitoring and supervision.

99. Annex I includes 13 tables which provide a brief history of the results of each of the seven annual programmes implemented to date covering names of enterprises, CFC type, capacity, production level and the status of the plant (closed or producing) in 2007. The result of implementing the 2007 programme will be verified by the World Bank and reported to the first meeting of the Executive Committee in 2008.

100. The progress report on the 2007 annual programme continues to list the policy controls that have been enacted by the Government of China, such as the circular on Implementing the Quota System for CFC Production issued by SEPA and the State Administration of Petroleum and Chemical Industry on 31 May 1999, the circular on Strengthening Management of ODS Import and Export issued in April 2000, and the circular on Control Mechanism of Import and Export of ODS promulgated in December 1999. Imports of CTC, a key feedstock for CFC production, were banned in April 2000. As an attempt to discourage illegal CFC production, the National Development and Reform Commission, the central planning authority, has listed CFC production as an obsolete production technology in 2004. This will prevent anyone planning to set up a CFC production plant from obtaining bank loans or approval from local authorities. During 2007 the Government continued to implement the Regulation on Implementing Site Supervision to CFC Production Enterprises, issued by SEPA in December 2001. Under this regulation, technical professionals from the remaining CFC producers are contracted by SEPA as supervisors to be placed in the plants of peer producers to carry out year-round on-site mutual monitoring. This has proved to be an effective monitoring mechanism.

101. An update is provided on the implementation of the technical assistance programme under which a total of 55 activities were planned, of which 44 were either completed or on-going and 11 cancelled. There is also an update on three other activities previously reported as special initiatives under the flexibility clause namely, the establishment of the HCFC-134a production in two phases, screening of alternatives to methyl bromide in soil fumigation, and the China convention compliance centre. Annex III includes nine tables on the annual TA programmes between 1999-2007, which present the information on each of the technical assistance activities planned, including title of the activity, implementing agency, contract date, completion date planned and status of implementation.

102. Part B of the World Bank's submission is a description of the components of the 2008 programme, which include policy actions, production reduction to be achieved by producing enterprises, and technical assistance activities. According to the accelerated phase-out programme (APP), China will not produce more than 550 ODP tonnes of CFC in 2008 for MDI production, maintain its CFC exports below 100 ODP tonnes and ensure that its CFC-13 production does not exceed 15 per cent of the baseline of 26.7 ODP tonnes.

103. At the enterprise level, the following activities will be implemented in 2008:

(a) *CFC Production quotas.* "Zhejiang Quhua" the remaining producer will be issued a production quotas in 2008 for no more than 550 ODP tonnes.

(b) *Management of National CFC stock.* According to the APP plan, China has built up a stockpile of 3,500 ODP tonnes of CFC-11 and CFC-12 in 2006 and 2007 to meet the demand of CFCs in the refrigeration servicing sector, pharmaceutical aerosols sector and MDIs sector for the years 2008-2018. Three contracts have been signed with each of the 4 CFC-11 and CFC-12 producers. Two contracts

were signed with each producer for setting up the necessary storage capacity for CFCs in 2006 and in 2007 respectively. The third contract with each producer covered the cost of production of the 3,500 mt.

(c) SEPA is requesting the four former CFC11/12 producers to sell out their own stocks (of CFC-11/12) by the end of 2007. This would ensure that the producers only have the national stockpile and all sales by the four companies would be controlled by the CFC sales licensing system.

(d) SEPA has drafted a management and supervision system for the national stock, which will be used until the approval of the ODS Management Regulation by the State Council. A national plan for the annual sales from the national stock from 2008 to 2018 has also been developed based on data provided by the concerned ministries and associations. The plan will be updated periodically based on the future demands and on experiences gained.

(e) The consumption of CFCs will be strictly controlled and monitored through issuing of the consumption license to pharmaceutical aerosol and MDI companies. Each of the four producers who have the national stock will report the sales data, the users and remaining stock on a monthly basis to SEPA who will visit the four companies periodically.

(f) The CFC sales price from the national stock will be determined by the producers, but under strict supervision by SEPA, who has the responsibility to ensure that prices are reasonable and do not create chaos in the market or incentives for illegal production. For example, the price of pharmaceutical aerosol products will be monitored. If it is found that the patients cannot afford the prices of the pharmaceutical aerosol drugs due to the high prices of CFCs, SEPA and other relevant government departments would have the right to intervene and control the CFC prices.

104. The current policy framework will continue to facilitate the implementation of the 2008 work programme.

105. The submission of the World Bank includes an updated list of HCFC producing enterprises in China as per the Agreement. A new plant started in March 2006 which is added to the list from last year and the total number of producers is 19.

106. The US $7.5 million for implementation of the 2008 programme is currently planned for funding the remaining unfunded commitment from the 2007 work programme, work related to the setting up of the CFC national stockpiles, and the technical assistance activities.

IV. SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

107. The progress report on the results to-date of the 2007 annual work programme indicates the achievement of the targets for the year, with the achievement of the complete phase-out of CFC production by 1 July 2007, two and a half years ahead of the requirement of the Montreal Protocol and the Agreement. That phase-out, however, still needs to be confirmed by the verification to be commissioned by the World Bank towards the end of this year. SEPA has also set up a national stockpile of CFC to meet the needs of the country between 2008-2018. All the CFC producing plants, except the one which will remain in production, have purged their plants of all remaining CFCs and CTC and have prepared for the final closure.

108. The 2008 work programme proposes a series of actions that would ensure that CFC production would not exceed 550 ODP tonnes, sets up the CFC national stock to cover the remaining consumption between 2008-2018 and a management system for the national CFC stocks.

RECOMMENDATION

109. The Secretariat recommends that the Executive Committee:

(a) Commends the Government of China and the World Bank for completing the CFC production phase out in China two and a half years ahead of the Montreal Protocol control schedule; and

(b) Approves the 2008 work programme of the China CFC production closure programme at US $7.5 million and associated support cost of US $562,500, noting that the request for funding and support costs will be submitted by the World Bank to the 54th Meeting together with a verification report on the implementation of the 2007 annual programme.

PROJECT EVALUATION SHEET – MULTI-YEAR PROJECTS

China

(I) PROJECT TITLE	AGENCY
Refrigeration servicing sector CFC phase-out plan	Japan, UNEP, UNIDO

(II) LATEST ARTICLE 7 DATA (ODP Tonnes)			Year: 2005	
CFC: 13123.8	CTC: 1060.3	Halons: 4516.5	MB: 601.5	TCA: 186.6

(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**
				Manufac-turing	**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			2004	2005	2006	2007	2008	2009	2010	Total
Maximum Allowable Consumption (ODP Tonnes)		CFC	25,300.	18,750.	13,500.	7,400.	550.	550.	0.	
Project Costs (US$)	Japan	Project Costs	1,000,000.	3,000,000.						4,000,000.
		Support Costs	130,000.	390,000.						520,000.
	UNIDO	Project Costs	550,000.		700,000.	700,000.	700,000.	785,000.		3,435,000.
		Support Costs	41,250.		52,500.	52,500.	52,500.	58,880.		257,630.
	UNEP	Project Costs		450,000.						450,000.
		Support Costs		58,500.						58,500.
Total Funds Approved in Principle (US$)		Project Costs	1,550,000.	3,450,000.	700,000.	700,000.	700,000.	785,000.		7,885,000.
		Support Costs	171,250.	448,500.	52,500.	52,500.	52,500.	58,880.		836,130.
Total Funds Released by the ExCom (US$)		Project Costs	2,000,000.	3,450,000.	0.	700,000.	0.	0.		6,150,000.
		Support Costs	205,000.	448,500.	0.	52,500.	0.	0.		706,000.
Total Funds Requested for Current Year (US$)		Project Costs					700,000			700,000
		Support Costs					52,500			52,500

(V) SECRETARIAT'S RECOMMENDATION:	For blanket approval

PROJECT DESCRIPTION

110. On behalf of the Government of the People's Republic of China (China), UNIDO as the lead implementing agency, has submitted to the 53rd Meeting of the Executive Committee a funding request for the fourth tranche of the refrigeration servicing sector CFC phase-out plan for China, at a total cost of US $700,000 plus agency support costs of US $52,500. The request was accompanied by a report on project implementation during 2006, and an annual implementation plan for 2008. The submission also contained a verification report for the CFC-12 consumption for China in 2006. In addition, UNIDO submitted the multi-year overview tables, which is provided as Annex III to this document.

Background

111. The refrigeration servicing sector CFC phase-out plan for China was approved at the 44th Meeting of the Executive Committee, with UNIDO as lead agency and Japan as cooperating bilateral agency. Subsequently, the Agreement was amended to also include UNEP as a cooperating implementing agency. The implementation of this refrigeration servicing sector CFC phase-out plan supports China in meeting its Montreal Protocol obligations, including the complete phase-out of the controlled use of CFCs prior to 2010. In order to achieve these targets, a series of investment, non-investment, technical assistance and capacity-building activities will be, and are being, implemented by China with the assistance of the agencies. The total funds approved in principle for the plan amounted to US $7,885,000 plus agency support costs of US $836,130.

112. UNIDO submitted a verification of the 2006 consumption in the refrigeration-servicing sector. Under the Agreement between China and the Executive Committee, the Article 7 consumption of CFC-12 in China has to be independently verified. In contrast, the consumption in the refrigeration servicing sector needs confirmation through monitoring and auditing activities undertaken by China. The verification of the consumption of CFC-12 was based on results of the production sector verification. The figure for CFC production obtained by that verification was amended by a verification of exports and imports, resulting in the verification of consumption. The imports of CFC to China in 2006 were zero. With exports of 537.3 ODP tonnes, the consumption of CFC-12 in China was 5,421.0 ODP tonnes in 2006. This consumption is 216 ODP tonnes below the limit of 5,637 ODP tonnes specified in the Agreement between China and the Executive Committee.

113. Regarding the implementation of the annual plan in 2006, China demonstrated its consumption in the refrigeration servicing sector by using its verified Article 7 data as a starting point, and deducting from it the consumption in the different sectors. China also deducted a quantity of 1,550 ODP tonnes for stockpiles. The calculated consumption for the service sector is 2,956.3 ODP tonnes. The Agreement with the Executive Committee specifies a maximum sector consumption of 3,790 ODP tonnes for 2006, 833.7 ODP tonnes more than the actual consumption.

114. In 2006, a number of technical assistance activities were carried out. The most prominent achievements are the operation of the Monitoring and Management Information System (MIS), and reporting using that system, e.g. through which monitoring of the training of and CFC recovery and recycling activities was conducted. The quarterly newsletter reflecting the progress of MAC refrigeration servicing sector project was published as an awareness raising tool.

Publications such as posters and calendars were printed and distributed to the public. A code of good practices was prepared and 6,000 copies published, of which more than 4,000 copies have been distributed to target group.

115. The activities related to training of trainers and technicians, and delivery of equipment for training were an important feature of the 2006 implementation plan. Regional training centres for all sectors except MAC were equipped; the training equipment needs in the MAC sector had been addressed in previous tranches. SEPA completed selection of training centres for non-MAC training in 2006 (non-MAC refers to the Domestic, Industrial, Commercial Refrigeration and Chiller sectors). All the 15 training centres had been identified, the tender for procurement will be conducted in the fourth quarter of 2007, and the three training workshop for trainers (22-25 trainers) are to be conducted in early 2008. In the MAC sector, 1,097 technicians were trained through 60 workshops at the end of 2006. The implementation continued in 2007 with 1,797 technicians trained in 99 workshops from January to August, and about 1,300 additional technicians to be trained in the remainder of the year 2007.

116. Activities related to refrigerant recovery and recycling were also implemented in 2006. A tender for 269 recovery machines and 273 refrigerant identifiers was conducted in December 2006; the contract was awarded in March and the equipment delivered in May 2007. The bidding for 420 recovery and recycling machines was conducted in March 2007 for delivery in September 2007. Savings from the procurement will be used for purchasing equipment in the future. In some cities, the local governments opened an incentive scheme subsidising about 40 per cent of the cost of R&R equipment. The subsidy provided amounted to e.g. in Xian to some RMB 3,000 per enterprise.

117. A number of government actions were carried out. SEPA is preparing the ODS Management Bylaw, which includes all requirements for CFC recovery and recycling in refrigeration servicing processes, and prohibits venting of CFCs. SEPA and the Ministry of Communication are negotiating issuance of a Notice on obliging the MAC servicing station to recover refrigerant. SEPA and the Ministry of Commerce are preparing a Notice requiring vehicle disposal stations to recover CFCs from retired vehicles. A number of studies are presently under preparation or carried out, namely “Management Regulations of Recovery & Dismantling Retired Vehicle”, a “Study on the management policies and measures of recovery of refrigerant in the MAC servicing sector”, and a “Study on the operation mechanism of reclamation centres, as well as destruction of heavily contaminated and mixed ODS residue”.

118. For 2008, a number of new and ongoing activities are foreseen. The MIS system will be maintained, and will continue to operate with the primary objective of monitoring the training and CFC recovery and recycling activities in the MAC sector. It is also expected that data reports on CFCs recovered and recycled, in particular in MAC and automobile disposal sectors, will be collected. The public awareness activities will include the issuance of publication materials, such as posters, calendars, brochures for distribution to the public, and providing information about CFC recovery, recycling and reclamation on related media. It is expected that the study on the mechanism for operating the reclamation centre and for destruction of ODS residue, the last of those studies presently under preparation or implementation, will be finalized in 2008. For the training of technicians, the identification of adequate training centres to undertake technician training in non-MAC sectors will continue. It is planned to train approximately another 1,000 technicians across all sectors. Finally, preparatory work for the establishment of reclamation centre is foreseen, with commissioning planned for the middle of 2009.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

119. As part of discussions regarding aspects of the verification, UNIDO provided the Secretariat with the data submitted by China to the Ozone Secretariat. The verification report is fully consistent with the Article 7 data provided.

120. The Secretariat sought additional information from UNIDO regarding the monitoring of consumption in the servicing sector. UNIDO provided an official statement by the State Environmental Protection Agency (SEPA), pointing out that because of the Accelerated Production Sector Phase-out Plan (APP) approved at the 44th Meeting, China decided to stockpile about 3,500 ODP tonnes CFC-11 and CFC-12 in 2006 and 2007 to meet the future CFC demand post July 2007 when production has ceased. Based on a demand estimate of the pharmaceutical, MDI and refrigeration servicing sectors, China stored 1,550 ODP tonnes of CFC-12 as a national stockpile in 2006 and is planning to store another 1,450 ODP tonnes of CFC-12 and 500 ODP tonnes of CFC-11 in 2007. The national stockpile is under strict, direct government supervision and its accumulation had been agreed with four CFC-12 manufacturers who will receive reimbursement by the government for the storage cost. As a provision in the contracts, it is strictly forbidden to use any of this stockpile before 2008. Verification of the opening and closing stockpiles will be conducted under the Sector Plan for CFC Production Phase out in China. The Secretariat therefore concluded that China fulfils the monitoring provision under its Agreement with the Executive Committee for its stockpile of CFCs.

121. The sector plan is addressing all sub-sectors of the refrigeration servicing sector. The report on activities shows a close adherence to the plan and good progress in the implementation, which is fully in line with that expected from a successful project. Minor delays are not likely to be critical. The mix of policy, technical assistance and industry related activities appears balanced and strategic.

RECOMMENDATION

122. The Fund Secretariat recommends blanket approval of the fourth tranche of the project, with associated support costs, at the funding levels shown in the table below:

	Project Title	Project Funding (US $)	Support Cost (US $)	Implementing Agency
	Refrigeration servicing sector CFC phase-out plan (fourth tranche)	700,000	52,500	UNIDO

PROJECT EVALUATION SHEET – MULTI-YEAR PROJECTS

China

(I) PROJECT TITLE	AGENCY
ODS phase-out in China solvent sector: 2008 annual programme	UNDP

(II) LATEST ARTICLE 7 DATA (ODP Tonnes)			Year: 2005	
CFC: 13123.8	CTC: 1060.3	Halons: 4516.5	MB: 601.5	TCA: 186.6

(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

Continuation of project evaluation sheet – multi-year projects

China

(IV) PROJECT DATA		2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Total
Maximum Allowable Consumption (ODP Tonnes)	CFC	3,300.	2,700.	2,200.	1,700.	1,100.	550.	0.	0.	0.	0.	0.	
	CTC	110.	110.	110.	55.	0.	0.	0.	0.	0.	0.	0.	
	TCA	621.	613.	605.	580.	502.	424.	339.	254.	169.	85.	0.	
Project Costs (US$)	Project Costs	6,750,000.	6,955,000.	6,330,000.	5,755,000.	5,555,000.	5,680,000.	5,055,000.	5,480,000.	1,480,000.	1,480,000.	1,480,000.	52,000,000.
	Support Costs	675,000.	695,500.	633,000.	431,625.	416,625.	426,000.	379,125.	411,000.	111,000.	111,000.	111,000.	4,400,875.
Total Funds Approved in Principle (US$)	Project Costs	6,750,000.	6,955,000.	6,330,000.	5,755,000.	5,555,000.	5,680,000.	5,055,000.	5,480,000.	1,480,000.	1,480,000.	1,480,000.	52,000,000.
	Support Costs	675,000.	695,500.	633,000.	431,625.	416,625.	426,000.	379,125.	411,000.	111,000.	111,000.	111,000.	4,400,875.
Total Funds Released by the ExCom (US$)	Project Costs	6,750,000.	6,955,000.	6,330,000.	5,755,000.	5,555,000.	10,735,000.	5,480,000.	0.	0.	0.	0.	47,560,000.
	Support Costs	675,000.	695,500.	633,000.	431,625.	416,625.	805,125.	411,000.	0.	0.	0.	0.	4,067,875.
Total Funds Requested for Current Year (US$)	Project Costs								1,480,000.	0.			1,480,000.
	Support Costs								111,000.	0.			111,000.

(V) SECRETARIAT'S RECOMMENDATION:	For blanket approval

PROGRESS REPORT ON IMPLEMENTATION OF THE SOLVENT SECTOR PLAN FOR ODS PHASE-OUT IN CHINA FOR 2006/2007, 2008 ANNUAL IMPLEMENTATION PROGRAMME AND REQUEST FOR FUNDING OF THE NINTH TRANCHE

PROJECT DESCRIPTION

123. On behalf of the Government of China, UNDP as the implementing agency has submitted the 2007 Annual Progress Report and Annual Implementation Programme for 2008 for the Solvent Sector Plan for ODS Phase-out in China for consideration by the Executive Committee at its 53rd Meeting. The total cost of the 2008 annual implementation programme as submitted is US $1,480,000 plus support costs for UNDP of US $111,000. This funding is included in UNDP's 2007 business plan.

Background

124. The solvent sector plan for China was approved in principle at the 30th Meeting of the Executive Committee at a total cost of US $52 million plus support costs for UNDP. Funds totalling US 47,560,000 plus support costs of US $4,067,875 for UNDP have been approved for the first eight annual tranches from 2000 to 2007 inclusive.

125. The phase-out is being achieved through a combination of investment activities targeting specific enterprises and a technical assistance programme for smaller enterprises managed through a voucher system. Consumption limits are being maintained through regulation of production and imports. The reductions in production are controlled under China's production sector phase-out plans for CFCs and CTC. The use of CTC as a cleaning solvent has been prohibited since 1 June 2003 and the use of CFC-113 as a solvent has been prohibited since 1 January 2006. The only ODS solvent with remaining consumption is methyl chloroform (1.1.1 TCA) which, under the Plan, will be completely phased out by 1 January 2010.

Phase-out from investment projects and activities

126. Phase-out has been completed under all ODS reduction contracts entered into between 2001 and 2005 and also for activities for smaller enterprises under a voucher system that operated between 2003 and 2006. The selection and availability of suitable alternative cleaning technologies has led to delays in final acceptance procedures for one enterprise manufacturing military components and in a number of smaller enterprises enrolled in the voucher scheme. FECO/SEPA has been assisting these enterprises, and acceptance procedures for all enterprises are expected to be completed by early 2008.

127. SEPA and UNDP continued to implement enterprise-level ODS phase-out activities through retroactive re-imbursement contracts initiated in 2006 and 2007. The final group of 26 enterprises that signed contracts for reimbursement for CFC-113 phase-out have completed their activities and have been verified by an independent accounting company.

128. TCA is the only remaining ODS solvent in use in China. Reimbursement projects for 12 and 15 enterprises were initiated in 2006 and 2007 respectively. Five of the 12 enterprises in the 2006 programme will complete their phase-out of TCA in 2007 and the remaining seven in

2008. A small TCA phase-out (2.3 ODP tonnes) will be realized in 2007 from the current year's projects and the remainder in future years.

129. A summary of progress with the phase-out of ODS solvents through investment activities is indicated in Table 3 of UNDP's project submission, as reproduced below:

Table 3: Phase-out through 2000 – 2007 ODS Reduction Contracts, Voucher System, Retroactive Reimbursement and Self-Phase-out Mechanisms

			CFC-113 (ODP tonnes)	TCA (ODP tonnes)	CTC (ODP tonnes)	No. of Enterprises	Funding (US$ 1,000)
2000	Contracts for future phase out	Planned	372.8	10	0	20	$5,000
		Signed	378.5	10.2	8.4	16	$4,133
	Phase out Achieved	2000 Contracts	-	-	-		
	Total 2000 phase out		**0**	**0**	**0**		
2001	Contracts for future phase out	Planned	524	10	0	20	$5,505
		Signed	541.6	10.6	0	21	$4,361
	Phase out Achieved	2000 Contracts	340.1	9.8	8.4		
		2001 Contracts	54.1	-			
	Total 2001 phase out		**394.2**	**9.8**	**8.4**		
2002	Contracts for future phase out	Planned	500	25	55	40	$5,830
		Signed	535.8	43.2	17.9	32	$4,004
	Phase out Achieved	2000 Contracts	38.4	0.4	-		
		2001 Contracts	-	-			
		2002 Contracts	291.3	41.7			
	Total 2002 phase out		**329.7**	**42.1**	-		
2003	Activities for future phase out	Planned	600	78	55	140	$5,255
		Signed	417.7	19.1	0	87	$5,105
	Phase out Achieved	2001 Contracts	331.1	7.3			
		2002 Contracts	-	-	-		
		2003 Contracts	49.3	9.8			
	Total 2003 phase out		**380.4**	**17.1**	-		
2004	Activities for future phase out	Planned	550	78	0	141	$4,000
		Signed	414.2	23.8	3.2	141	$4,156
	Phase out Achieved	2001 Contracts	156.4	3.3			
		2002 Activities*	108.6	1.5	17.9		
		2003 Activities	-	-			

			CFC-113 (ODP tonnes)	TCA (ODP tonnes)	CTC (ODP tonnes)	No. of Enterprises	Funding (US$ 1,000)
		2004 Activities *	26.4	-	3.21		
	Total 2004 Phase Out		**291.4**	**4.8**	**21.1**		
2005	Activities for future phase out	Planned	550	85	0	20	$4,280
		Signed	156.7	0	0	20	$2,711
	Phase out Achieved	2002 Activities *	126.3	-			
		2003 Activities	368.4	9.3	0		
		2004 Activities	303	13.6			
	Total 2005 Phase Out		**797.7**	**22.9**	**-**		
2006	Activities for future phase out	Planned	360	30	0	33	$3,340
		identified	245	48.4	0	33	$2,532
	Phase out Achieved	2004 Activities	84.8	10.2	-		
		2005 Activities	156.7				
		2006 Activities	245	9.2			
	Total 2006 phase out*		**486.5**	**19.4**			
2007	Activities for future phase out	Planned	0	60.4	0	15	$1,520
		Identified	**0**	**60.4**	0	**15**	**$1,520**
	Phase out Achieved	2002 Activities	9.6				
		2006 Activities		34.9			
		2007 Activities		2.3			
	Total 2007 phase out*		**9.6**	**37.2**			
	Phase out Targets		3,300	452	110		
Eight Year Cumu -lative Total	Phase out Planned		3,456.8	376.4	110	429	
	Actual Phase out signed/identified		2,689.5	215.7	29.5		
	Actual Phase-out achieved		**2,689.5**	**153.3**	**29.5**	**365**	

* From retroactive reimbursement and gradual self-phase-out activities
Note: Phase out achieved figures in 2007 are estimated quantities expected to be achieved by 31 December 2007

130. Cumulative phase out achieved under the China Solvent Sector Plan up to 2007 is 2,689.5 ODP tonnes of CFC-113, 153.5 ODP tonnes of TCA and 29.5 ODP tonnes of CTC. Consistent with advice in previous reports, China and UNDP have indicated that the difference between the planned and actual phase out is due to:

(a) Delays in recording phase-out which has actually occurred until all administrative procedures necessary to declare a project complete have been undertaken; and

(b) Gradual phase-out during implementation prior to project completion, which results in national level reductions in consumption being greater than the recorded enterprise level phase-out.

Technical assistance activities

Combating Illegal ODS activities

131. Under the cooperative project to address emerging illegal production consumption and import/export undertaken by SEPA's Bureau of Environmental Supervision, four cases of illegal methyl bromide production were revealed between October 2006 and July 2007. The programme continues to receive funding from the solvent sector plan. A project implementation coordinating group will be established under this programme between September and December 2007 to conduct a thorough check of enterprises with suspected illegal ODS activities. In January 2007, mid-term investigation under the Sky Hole Patching Initiative was undertaken by SEPA and the General Administration of Customs of China, during which 9 illegal cases were revealed. Fifty ODS fast-detecting instruments have been provided to the Customs Service to strengthen capabilities for on-site detection.

Ozone friendly provinces/cities demonstration project

132. Of the 12 provinces/cities that signed agreements in October 2005 to implement legislative and administrative actions to complete the phase-out of chlorofluorocarbons and halons by June 2006, seven had completed their legislative and public awareness actions by June 2006. All 12 provinces/cities have published notices on phase-out and co-ordinating mechanisms have been established. The national auditing procedure has been successfully achieved in 11 of the provinces/cities. The assessment of the final province/city will take place in September 2007.

Research Programme on TCA Substitutes and Technology in the Solvent Sector

133. Under the programme initiated in 2006 to identify specialized substitutes for TCA, a report was completed by the China Information Centre of Cleaning Technology in May 2007 and investigations across the country have commenced. The project is expected to be completed in 2008.

Public awareness and training

134. In May 2007, representatives from enterprises, local government environmental agencies, nearly twenty associations, and other community groups participated in a seminar to improve cooperation on ODS phase-out and relevant policies between SEPA, regional environmental agencies, industry associations and relevant community groups. During 2007 the second of two workshops was undertaken by SEPA and UNDP to brief enterprises on project management and verification processes for TCA phase-out projects.

Verification of 2006 ODS consumption limits

135. The 2006 national consumption of CFC-113, TCA and CTC is presented in Table 4 of the report, reproduced below:

Table 4 ODS Solvent Consumption for the Year 2006 (ODP tonnes)

	CFC-113 (ODP tonnes)	TCA(ODP tonnes)	CTC(ODP tonnes)
Consumption control target	0	339	0
Production	-	77.864	-
Import	-	202.054	-
Export	-	-	-
Solvent consumption	0	279.918	0

National Level Consumption

136. Information on ODS solvent production was obtained from World Bank verification reports on CFCs, TCA and CTC, from data reported by the TCA manufacturers to FECO/SEPA and "the Audit Report of China TCA Production Phase-out Sector Plan Project" issued by the China National Audit Office. Information on import and export of each type of ODS solvent was acquired from the Administration Office of ODS Imports and Exports, which was jointly set up by the Ministry of Commerce, SEPA, and the General Administration of Customs. The annual national consumption of each type of ODS solvent is obtained by deducting export from the total of production and import.

137. Based on official data and statistics on China CFC production and import and export obtained by SEPA and verified as above, the total national consumption of CFC-113, TCA and CTC in 2006 has met the phase-out targets specified in Table 1 of the Agreement. CFC-113 and TCA production figures (nil and 77.864 ODP tonnes respectively) are identical to the audited data reported in the relevant 2006 Production Sector Plan reports presented to the 51st Meeting of the Executive Committee by the World Bank.

138. According to information from the General Administration of Customs and the Administration Office of ODS Import and Export, imports of CFC-113 and TCA in 2006 were nil and 202.054 ODP tonnes respectively. Exports of TCA were also indicated as nil. Therefore, the total consumption of CFC-113 in 2006 was nil and the total consumption of TCA was 279.018 ODP tonnes, which meets the control target of 339 ODP tonnes set out in the Agreement.

139. CTC production for solvent use was also indicated in the World Bank CTC sector plan report as nil. There are no records of imports and during the field verification exercise no evidence of CTC use was discovered. Thus CTC consumption has also been verified as zero.

Enterprise-level consumption

140. On behalf of SEPA and UNDP, the National Audit Office of the People's Republic of China (CNAO) carried out a performance verification on 2006 activities, including field

verifications, at 18 participating enterprises that had completed phase-out and an additional two that were currently implementing TCA phase-out contracts. The verifications followed agreed terms of reference, and provided specialized training for the verifiers and contracted the services of two solvent sector experts to assist in providing technical reports.

141. The verification confirmed that the actual consumption that had been phased out was equal to or greater than the reductions for which the contracts had been issued. It also reported on disposal of equipment, noting that five enterprises had disposed of the old equipment while 12 had retrofitted it for use with non-ODS solvents. Two other enterprises did not have equipment, and one enterprise is not required to dispose of its equipment until 31 December 2007 and is still using it.

142. The verification examined the economic and technical effects of the substitute technologies and found that costs had been reduced for 14 of the 18 enterprises that had completed conversions and that production quality had not been adversely affected for 17 of the 18 enterprises.

143. In regard to financial management, the verification found that enterprises needed to be made more aware of regulatory requirements and obligations associated with participation in phase-out contracts, particularly the need for presentation of documentary evidence to ensure verification of consumption and the keeping of adequate records of grants received. Specific measures were identified and recommended.

Unspent balances from previous tranches

144. The total funding released by the Executive Committee, the funds disbursed or committed by the Implementing Agencies and the unspent balances from funds released, are indicated in the table below for the complete period 2000-2006 and for 2007 to date:

Year	Funding released by ExCom (US $)	Value of contracts signed (US $)	Funds disbursed (US $)	Funds committed but not disbursed (US $)	Balance uncommitted (US $)
2000-2006	$42,080,000	$36,708,692	$27,508,607	$9,200,085	$5,371,308
2007	$5,480,000	$6,679,940	$56,576	$6,623,364	($1,199,940)
Total	$47,560,000	$43,388,632	$27,565,183	$15,823,449	$4,171,368

145. Under retroactive contracts, payment does not take place until phase-out has been completed. Additionally, SEPA and UNDP delay payment to beneficiaries until pre-disbursement scrutiny has been undertaken, in order to verify the levels of consumption and the authenticity of procurement and contractual services. These two factors contribute to the large uncommitted balance.

146. SEPA continues to prefer to retain such savings at this stage to cover any unforeseen requirements later in the project and to ensure sufficient funding to cover all beneficiaries. A total amount of US $43.4 million (91%) of contractual agreements for phase-out have been signed against US $47.6 million released by the Executive Committee. Actual disbursement of

US $27.6 million has been effected as of September 2007 (58% against the US $47.6 million released and 64% against contracts signed). Committed but undisbursed funds amount to US $15.8 million (33% against funds released and 36% against contracts signed). Overall, only 8.8% of the fund released remains uncommitted.

The 2008 annual implementation programme

147. The 2007 Annual Implementation Programme will continue to implement and complete the TCA phase-out activities initiated in 2006 and 2007. New activities will be introduced to phase out 85 ODP tonnes of TCA, contributing to the achievement of the 2008 consumption control limits. For 2008, phase-out activities at the enterprises level will be achieved through direct phase-out and the retroactive reimbursement mechanism. To ensure that phase-out activities can be completed by the end of 2009, activities will be initiated early in 2008.

148. Necessary technical assistance activities, legislative measures, monitoring and enforcement mechanisms are also included in the 2008 Annual Implementation Programme. Such activities are now becoming more important in terms of sustaining phase-out of CTC and CFC-113 and eventually TCA.

149. The technical assistance activities and Government actions proposed in 2008 are indicated in the following tables:

Technical assistance activities in the 2008 AIP

Activity		Description
Public Awareness	Objective	Introduce and publicize nationwide ODS phase-out in the solvent sector to attract attention and participation; maintaining and updating solvent website
	Target group	Industries, local EPBs (Environment Protection Bureau), distributors and solvent consumers
	Outcome	Public awareness and interest in participation increased
Training on TCA new phase-out project	Objective	Address inquiries on project procedures
	Target Group	TCA consumption enterprises that participate in the ODS Reduction Project
	Outcome	Promotion of enterprises' understanding of MP, MLF procedures, requirements of the project and performance verification, improved financial management, preliminary selection of alternative technologies
Supervision and monitoring of the phase-out Project	Objective	Ensure successful implementation of ODS phase-out project and verify the qualification of the enterprise
	Target Group	Recipient enterprises and potential enterprises who have applied phase out project and will sign contracts with SEPA
	Outcome	All enterprises participating in the project being qualified, executive procedures being strictly followed by each enterprise
Study on TCA Substitute Technologies in Dope Industry	Objective	To find the appropriate TCA substitute technologies in Dope industry for consumption enterprises completing TCA phase out smoothly
	Target Group	Reach institutes and dope manufacturing enterprises
	Outcome	Appropriate substitute technologies gained in dope industry
Training and workshops for TCA Substitute Technologies	Objective	Introduce alternative technologies and TCA substitutes
	Target Group	Recipient enterprises, experts, IEAs (Intermediate implementing agencies) and administrations
	Outcome	Information on substitutes and alternative technologies updated for relevant stakeholder

Activity		Description
Preliminary Investigation on Consumption of HCFC and Formulate Phase out Strategy in Solvent Sector	Objective	Investigate total consumption of HCFC in solvent sector and formulate the most effective strategy for phasing out HCFC
	Target Group	Research institute and HCFC consumption enterprises in solvent sector
	Outcome	Current HCFC consumption status, effective substitutes and strategy for HCFC phase out in solvent sector
International Study on OD Solvent Phase out Management and Effective Substitute	Objective	Learning the advanced technologies and managerial experience to control and phase out OD solvent to ensure effective monitoring and enforcement on OD solvent phasing out
	Target Group	Experts, administrative officer
	Outcome	New or advanced international technologies for substitute OD solvents and managerial experience gained to control and monitoring phasing activities
Continuation of Combating Illegal Production, Trade as well as Consumption	Objective	Establish effective system and methods to monitoring and control the illegal production, trade and consumption
	Target Group	Enterprises with illegal activities
	Outcome	Effective mechanism established to tackle illegal ODS related cases
Performance Verification	Objective	Verify the performance of ODS phase-out activities at both national and enterprise level in the year of 2007 by an independent entity
	Target Group	National consumption and industry consumption of ODS solvents
	Outcome	Assessment of the performance of ODS phase-out at both national and enterprise level
Implementation of TCA Quota & Licenses System (training, workshop and supervision)	Objective	Through training and supervision, control and reduce TCA in production, distribution and consumption
	Target Group	TCA producer, distributors and consumers
	Outcome	Information obtained on production, distribution and consumption of TCA and control measures applied

Government actions in the 2008 AIP

Policy/Activity Planned	Schedule of Implementation
Monitoring of CTC and CFC-113 solvent ban and TCA consumption enterprises who have complete the phase out	Throughout the year
Continue to implement regulation on management of TCA through quota and license system to control production, distribution and consumption of TCA	Throughout the year
Combating illegal production and trade	Throughout the year
Public Awareness	Throughout the year
Continue identification and monitoring of enterprises who have undertaken phase-out on their own initiatives, verify phase-out and implement reimbursement of phase-out costs; continue identification of enterprises that choose to undertake gradual phase-out, finalize agreement, signing reduction contracts, verify annual phase-out and monitor issuance of usage certification.	Throughout the year

2008 Budget

150. The total amount requested for the 2008 annual implementation programme is US $1,480,000 plus support costs of US $111,000 for UNDP. Prior to 2005, funding was requested at the first meeting of the year. However, commencing with the 2006 tranche, UNDP and China are now requesting approval of funding at the last meeting of the preceding year, together with submission of the annual report on implementation of the previous tranche. The breakdown of expenditure is indicated below:

ACTIVITY	Planned Expenditures (US $)
Enterprise-level phase-out activities -Reduction contract and retroactive reimbursement phase-out mechanism	**860,000**
Technical Assistance - Public awareness ($50,000) - Training on TCA new phase-out project ($30,000) - Supervision and monitoring of the phase-out project ($50,000) - Study on TCA substitute technologies in Dope Industry ($80,000) - Training and workshop on TCA substitutes ($40,000) - Investigate HCFC consumption and formulate phase out strategy in solvent sector ($100,000) - International study on OD solvent phase out management and effective substitute ($90,000) - Combating illegal production, trade and consumption ($70,000) - Implementation of TCA quota & licenses system ($40,000) - Performance verification ($60,000) - International and national technical experts ($10,000)	**620,000**
TOTAL	**1,480,000**

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

151. TCA is now the only ODS solvent for which consumption in China, as defined under the Montreal Protocol, is permitted under the sector plan Agreement. Verified TCA production figures are available from the World Bank TCA production sector report and are consistent with the Agreement. The verification of imports and potential exports of TCA confirms that the production, import and export figures held by the ODS Import and Export Control Office - jointly set up by SEPA, the Ministry of Commerce and the General Administration of Customs - were accurately reported in project documentation and conform to the limits in the Agreement. Consistent with practice in previous years, the verification process does not extend to the examination of the origin of the figures held by the Import and Export Control Office. On the basis of the information provided, China has met the TCA control measures contained in the Agreement for the solvent sector phase-out plan and has not produced or consumed CFC-113 or CTC.

152. China has reported country programme data for 2006. The figures are consistent with those in the project document, and indicate that consistent with the requirements of the Agreement there was nil consumption of CTC for solvent uses in 2006. The verification report showed that investigations had not discovered any non-compliance. UNDP subsequently advised that in line with the ban on CTC use as solvent, the licensing and quota systems regulating CTC consumption and production and the CTC sales registration system, all relevant suppliers and enterprises are required to report periodically on their CTC consumption or lack thereof. Both regular and irregular site verifications are conducted each year by SEPA. Through this management system, CTC production, consumption and circulation within China is strictly controlled. Visits were also made to certain enterprises considered to be suspicious and more detailed information was gathered. UNDP reported China's view that, with the policy measures

and regular investigation and detection activities in place, the control of ODS use as solvents has been quite effective, including the assurance that no CTC was diverted to solvent use.

153. Consistent with information provided to the Secretariat by UNDP in the previous year's report, the current report places major emphasis on combating illegal production and import. Now that the consumption of CFC-113 and CTC has been phased out, and TCA consumption has been reduced below 254 ODP tonnes (corresponding to 2,540 metric tonnes), the prevention or detection of illegal activities is taking on added significance. The 2007 report and the audit report contained therein addresses and describe in detail the current regulatory systems, including quotas that govern imports and exports and the measures being taken to enforce and promote awareness of the regulations.

154. In regard to phase-out performance, consistent with previous reports, the verification exercise undertaken at the enterprise level continues to indicate that the uptake of phase-out projects by industry does not result in phase-out quantities equal to the total reductions in consumption at the national level. It also shows that there are still challenges to be overcome in both attracting enterprises to participate in the funded phase-out programme and in administering the programme itself. However the verification report findings and the actions of SEPA and UNDP also indicate that the issues raised in the verification report are being actively addressed.

155. In addition to the national acceptance procedures at the enterprise level UNDP indicated that together with SEPA it had, since 2006, initiated a vigorous investigation and confirmation procedure for each enterprise participating in phase-out activities. To ensure accountability, reimbursements are based on this investigation and confirmation process. UNDP said that this extends the time required for disbursement but assists in providing an assurance that Fund resources are being properly applied.

156. As for the previous annual report, the original proposal from UNDP did not include information on the use of CTC as a feedstock at the plant level as required in clause (c) of the Agreement. UNDP subsequently provided the required data which indicated that a total of 461.43 ODP tonnes of CTC was used as a process agent for the uses approved as process agents at the time the agreement was concluded. This conforms to the limit of 5,500 ODP tonnes specified in the Agreement.

157. Following a request for clarification of financial obligations and disbursements UNDP provided the following additional details on use of approved funds and targets for disbursement of the 2007 tranche:

Funding Released by ExCom (US$)	Value of Contracts Signed (US$)	Funds disbursed as of Dec. 2006 (US$)	Funds committed but not disbursed (US$)	Year and amount of payment of funds not disbursed (US$)	Balance of funds not disbursed or uncommitted (US$)
Previous Tranches （2000-2006）					
$42,080,000	**$34,913,257**	**$27,490,219**	**$7,423,038**		**$7,166,743**
Investment Activities	27,773,977	23,220,621	4,553,356	$2,793,359 (2007) $375,297 (2008) $1,384,700 Savings	
Non-Investment Activities	7,139,280	4,269,598	2,869,682	$290,000 (2007) $3,205,590 (2008)	
2007 AIP					
$5,480,000	**$7,098,678**	**$56,953**	**$7,041,725**		**($1,618,678)**
Investment Activities	1,529,962	-	1,529,962	$305,993 (2007) $1,223,969 (2008)	
Non-Investment Activities	5,568,716	56,953	5,511,763	$35,000 (2007) $5,476,763 (2008)	
Total					
$47,560,000	**$42,011,935**	**$27,547,172**	**$14,464,763**		**$5,548,065**

158. The values for all the categories of commitment and expenditure in the additional table provided by UNDP differed from those in the project submission. In particular the indicated total of uncommitted funds rose from US $4,171,368 to US $5,548,065. UNDP advised that this was because errors in compilation of the financial information had been discovered and corrected, and also that additional corrections were introduced to reflect varying exchange rates for the local currency in which disbursements are made.

159. Additionally, in its report to the 50th Meeting on the 2006 annual implementation plan, the cumulative balance of uncommitted funding for the overall project was indicated as US $3,710,000. This has increased to US $5,548,065 in the latest data indicated above. UNDP advised that additional commitments may be made during the remainder of 2007 and will redress this figure. Also, at a level of less than 12 per cent of funds released, the overall uncommitted balance has been reserved by China to date to meet unforeseen activities that might be required towards the end of the phase-out schedule. China is therefore keen that this uncommitted balance and savings not be programmed at this stage, to ensure sufficient funding to cover all beneficiaries.

160. There are no issues arising from the proposed 2008 annual implementation plan.

161. The data for tables eight and nine of the multi-year overview tables was not received in time with sufficient quality to enable their inclusion in Annex IV to this document. Tables eight

and nine of the multi-year overview tables will be posted on the intranet of the Secretariat latest two weeks before the Meeting.

RECOMMENDATION

162. The Fund Secretariat recommends that the Executive Committee notes the report from the Government of China and UNDP on the implementation of the solvent sector plan for ODS phase-out in China for 2006/2007 and verification of 2006 performance. The Fund Secretariat also recommends blanket approval of the 2008 annual implementation plan for the solvent sector in China and funding for the eighth tranche of the project with associated support costs at the level shown in the table below:

	Project Title	Project Funding (US$)	Support Cost (US$)	Implementing Agency
	ODS phase-out in China solvent sector: 2008 annual programme	1,480,000	111,000	UNDP

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

No*	Company Name	Product No. (B)	CFC 2006 (kg)	Can 2006	$License cost**	$Capital cost	$Prod validation	$Train-ing	$Opera-ting cost	$Other TAS***	$Total cost	CE ($/kg)
37	Zigong Chenguang Pharmaceutical	5	70	2,020	195,000	220,000	40,000	27,500	467	289	483,256	6,903.65
9	Guiyang Dechangxiang Pharmaceutical	24	131	10,898	195,000	220,000	40,000	27,500	2,091	540	485,131	3,703.29
14	Henan Xinxin Pharmaceutical (Group)	11	300	30,000	195,000	220,000	40,000	27,500	5,652	1,237	489,389	1,631.30
25	Pharmaceutical Factory of Shanxi Medical University	01, 16	708	35,554	390,000	220,000	40,000	27,500	7,311	2,919	687,730	971.37
8	Guangzhou Dongkang Pharmaceutical	15, 22	1,560	124,800	390,000	220,000	40,000	27,500	24,055	6,432	707,987	453.84
24	Shandong Lunan Beite Pharmaceutical	04,17, 25	3,320	114,560	585,000	220,000	40,000	27,500	25,359	13,688	911,547	274.56
15	Henan Zhongfu Pharmaceutical	15	2,205	150,000	195,000	220,000	40,000	27,500	29,485	9,091	521,076	236.32
32	No.1 Pharmaceutical of Wuxi Shanhe Group	15, 22	4,840	313,689	390,000	220,000	40,000	27,500	62,059	19,955	759,514	156.92
38	Jiangsu Tianji Pharmaceutical	12	4,202	466,982	195,000	220,000	40,000	27,500	87,172	17,324	586,996	139.69
2	Beijing Haiderun Pharmaceutical	15, 22, 23	9,366	851,400	585,000	220,000	40,000	27,500	161,891	38,615	1,073,006	114.56
28	Shanghai Pharmaceutical (Group)	04, 09, 12, 16	19,434	1,132,455	780,000	748,000	40,000	27,500	227,444	80,124	1,903,068	97.92
19	Penglai Nuokang Pharmaceutical	07, 14, 15, 16, 22	28,928	2,552,299	975,000	748,000	80,000	27,500	486,790	119,266	2,436,556	84.23
36	Chongqing Kerui Pharmaceutical	16	7,377	448,800	195,000	220,000	40,000	27,500	89,573	30,414	602,487	81.67
18	Jinan Weiming Pharmaceutical	22	63,786	4,832,300	195,000	748,000	80,000	27,500	937,297	262,981	2,250,778	35.29
21	Jewim Pharmaceutical	01, 14, 15, 16	120,578	6,704,000	780,000	1,452,000	40,000	27,500	1,356,043	497,126	4,152,669	34.44
	Grand Total		266,805	17,769,757	6,240,000	6,116,000	680,000	412,500	3,502,689	1,100,000	18,051,189	67.66

* There was no production of CFCs in plants Nos. 2, 14, 38 prior to 2006

** An additional US $4,265,000 is being requested for licenses of MDIs which are not currently produced.

*** The request of US $1.1 million for technical assistance is distributed among eligible plants based on their 2006 CFC consumption

Annex II - Overview Tables for Multi-Year Agreements

China

(1) PROJECT TITLE: CFC Phaseout in the Polyurethane Foam Sector in China

(2) EXECUTIVE COMMITTEE APPROVALS AND PROVISIONS

Code	Agency	Excom Provision	Fulfilled? (Yes/No)	Comments
CPR/FOA/35/INV/380	IBRD	Approved in accordance with the agreement between the Government of China and the Executive Committee.		
CPR/FOA/38/INV/396	IBRD	China be requested to report its Article 7 data, as much as possible, on time (i.e. by 30 September of each reporting year) and endeavour also to report its consumption broken down by substance to the Fund Secretariat to enable verification of CFC-11 consumption both at the national and sectoral level as required under the Agreement		
CPR/FOA/41/INV/405	IBRD	The World Bank was requested to ensure, as a matter of priority, that as indicated in the 2004 annual programme, a system is put in place that would provide satisfactory verification of CFC phased out in on going and new project in the polyurethane foam sector as well as the annual CFC consumption in the sector in 2003 and subsequent years.		
CPR/FOA/44/INV/424	IBRD			
CPR/FOA/47/INV/434	IBRD			
CPR/FOA/52/INV/???	IBRD			

(3) ARTICLE 7 DATA (ODP TONNES)

Substances	Baseline	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
CFC	57,818.7	75,290.8	47,089.	51,076.4	55,414.2	42,983.4	39,123.6	33,922.6	30,621.2	22,808.8	17,902.5	13,123.8	12,475.8
CTC	38,220.6	-15.4	-100.1	110.	85,628.4	110.	28,923.4	15,305.4	3,294.4	20,019.9	3,885.8	1,060.3	842.5
Halons	34,186.7	33,714.	33,115.	35,731.	22,207.	18,602.	14,780.	10,409.	6,604.2	4,959.2	2,238.9	4,516.5	795.
Methyl Bromide	1,102.1	372.	720.	1,356.	1,960.2	1,598.4	2,100.6	1,567.8	1,087.8	1,008.	688.8	601.5	878.2
TCA	721.2	291.5	544.5	671.7	759.	647.1	757.6	465.4	380.8	336.8	370.2	186.6	279.9

(4) LATEST COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES) **Year: 2006**

Chemical	Aerosol	Foam	Fire Fighting	Refrigerating		Solvent	Process Agent	MDI	Lab Use	Methyl Bromide		Tobacco fluffing	stock	Total Sector Consumption
				Manufacturing	Servicing					QPS	Non QPS			
CFC	468.9	6,318.6		493.8	3,342.4	0.	0.	280.9				21.3	1,550.	12,475.8
CTC							356.5		486.					842.5
Halons			795.											795.
Methyl Bromide										568.2	310.			878.2
TCA						279.9								279.9

(5) PHASE-OUT (ODP TONNES)

Substances		2001	2002	2003	2004	2005	2006	2007	2008	Total	Decision
CFC	Maximum Allowable Consumption (Agreement; per substance if valid)		14143	13830	10500	9000	7000	400	0		
	Compliance Action Target (MOP)										
	Consumption Reported in Implementation Report submitted										
	Consumption Reported in the Verification Report										
	IBRD										
	Reduction Under Plan			313	3330	1500	2000	6600	400	14143	
	Approved Phase-Out	2000	2500	2500	2500	600				10100	
	Actual Phase-Out	2000	2721	2500	1335	0				8556	
	Remaining Phase-Out to be Achieved										

(6a) PROJECT COSTS (US$)

Calendar year		2002	2003	2004	2005	2006	2007	2008	2009	Total
IBRD	Funding as per Agreement	9,940,000	12,570,000	10,903,000	10,903,000	3,320,000	2,676,000	1,767,000	1,767,000	53,858,000
	Support Costs as per Agreement	886,600	115,300	961,270	961,270	282,800	240,840	159,030	159,030	2,561,480
	Funds Approved (Inventory)	9,940,000	12,570,000	10,903,000	10,903,000	3,320,000				47,636,000
	Estimated Disbursement in Previous Progress Report	8,114,370	8,168,440	3,887,370	971,790	70,000				21,211,970
	Funds Disbursed in Current Progress Report	9,940,000	12,570,000	10,903,000	8,805,600	360,000				25,650,500
	Funds Obligated in Current Progress Report				2,097,400	2,960,000	2,676,000			7,733,400
	Estimated Disbursement in Current Progress Report				2,097,400	2,368,000	1,503,000			5,968,400
	Disbursement as per Annual Plan				2,097,400	2,368,000	1,503,000			5,968,400
	Funds Requested							1,767,000		1,767,000
	Support Costs Requested							132,525		132,525
	Comments									

(6b) SUBMISSION SCHEDULES (planned and actual)

Submission Year as per Agreement		2002	2003	2004	2005	2006	2007	2008
IBRD	Planned Submission	Dec-2001	Nov-2002	Dec-2003	Dec-2004	Nov-2005	Nov-2006	Nov-2007
	Tranche Number	I	II	III	IV	V	VI	VII
	Revised Planned Submission						Mar-2007	
	Date Approved	Dec-2001	Nov-2002	Dec-2003	Dec-2004	Nov-2005	July-2007	

(7) INFORMATION ON POLICIES FROM COUNTRY PROGRAMME AND VERIFICATION REPORTS

		Country Programme 2005		
TYPE OF ACTION / LEGISLATION		**(Yes/No)**	**Since when (Date)**	**Verification**
1.	**REGULATIONS:**			
1.1	**Establishing general guidelines to control import (production and export) of ODSs**			
1.1.1	**ODS import/export licensing or permit system in place for import of bulk ODSs**			
1.1.1.1	ODS import licensing system in place for import of bulk ODSs	Yes	01/01/2000	
1.1.1.2	ODS export licensing system in place for export of bulk ODSs	Yes	01/01/2000	
1.1.1.3	Permit System in place for import of bulk ODSs	Yes	01/01/2000	
1.1.1.4	Permit System in place for export of bulk ODSs	Yes	01/01/2000	
1.1.2	**Regulatory procedures for ODS data collection and reporting in place**			
1.1.2.1	Regulatory procedures for ODS data collection in place	Yes	01/01/1992	
1.1.2.2	Regulatory procedures for ODS data reporting in place	Yes	01/01/1992	
1.1.3	**Requiring permits for import or sale of bulk ODSs**			
1.1.3.1	Requiring permits for import of bulk ODSs	Yes	01/01/2000	
1.1.3.2	Requiring permits for sale of bulk ODSs	Yes	01/01/2000	
1.1.4	Quota system in place for import of bulk ODSs	Yes	01/01/2000	
1.2	**Banning import or sale of bulk quantities of:**			
1.2.1	**Banning import of bulk quantities of:**			
1.2.1.1	CFCs	No		
1.2.1.2	Halons	No		
1.2.1.3	CTC	No		
1.2.1.4	TCA	No		
1.2.1.5	Methyl Bromide	No		
1.2.2	**Banning sale of bulk quantities of:**			
1.2.2.1	CFCs	No		
1.2.2.2	Halons	No		
1.2.2.3	CTC	No		
1.2.2.4	TCA	No		
1.2.2.5	Methyl Bromide	No		
1.3	**Banning import or sale of:**			
1.3.1	**Banning import of:**			
1.3.1.1	Used domestic refrigerators using CFC	No		
1.3.1.2	Used freezers using CFC	No		
1.3.1.3	MAC systems using CFC	Yes	01/01/2002	
1.3.1.4	Air conditioners using CFC	Yes	01/01/2005	
1.3.1.5	Chillers using CFC	Yes	01/01/2005	
1.3.1.6	CFC-containing aerosols except for metered dose inhalers	No		
1.3.1.7	Use of CFC in production of some or all types of foam	No		
1.3.2	**Banning Sale of:**			
1.3.2	**MAC systems using CFC**			
1.3.2.1	Used domestic refrigerators using CFC	No		
1.3.2.2	Used freezers using CFC	No		
1.3.2.3	MAC systems using CFC	Yes	01/01/2002	
1.3.2.4	Air conditioners using CFC	Yes	01/01/2005	
1.3.2.5	Chillers using CFC	Yes	01/01/2005	
1.3.2.6	CFC-containing aerosols except for metered dose inhalers	No		
1.3.2.7	Use of CFC in production of some or all types of foam	No		
2.	**ENFORCEMENT OF ODS IMPORT CONTROLS**			
2.1	Registration of ODS importers (Yes/No)	Yes	01/01/2000	
D:	**Qualitative assessment of the operation of RMP**			
	The ODS import licensing scheme functions:			
	The CFC recovery and recycling programme functions:			

(8) IMPLEMENTATION DETAILS (2002-2007)

	Completed tranche covered by report submitted (2002-2006)								Tranche currently implemented (2007 preliminary data)				
	Activities			Budget				Explanation	Activities		Budget		Explanation
	Planned (annual)	Actual (annual)	Cumulative achievement as compared to overall plan	Planned (annual)	Actual (annual)	Cumulative achievement as compared to overall plan	Carryover		Planned	Actual	Planned	Actual	CFC to be captured by contracts. Additional funding from future tranches to be usec
Convension (MT)	10,100	10,545	104%	47,636,000	42,272,000	0.887396087	5,364,000	CFC-11 captured by contracts signed	551	195.58	2,676,000	5,873,200	
Group Consolidation Project	NA	7094											
Individual ent. Pre-95	NA	1410											
Indvidual ent. Post-95	NA	1,141											
Provincial Phaseout	0	900											
technical Assistance	30	24							5	5	330,000	330,000	one TA completed, one is ongoing, three are under
Training of personnel in implementation of phaseout activities [number trained]	5	4	80%	1,422,000	1,458,235			30 TA planned and 24 completed	1	0			
PU foam products standard formulation and revision (% completed)	5	3	60%						1	0			
Performance audits (just write 100% if you are exactly in plan)	4	4	100%						1	100%			
Public Awareness	7	6	100%						1	0			
Consultant Service (same)	5	4	80%						1	0			
Studies	4	3	75%						0				
Unforeseen Activities	NA		NA						NA	NA			

*Refers to latest revision of overall plan

(9) ANNUAL PLAN SUBMITTED COMPARED TO OVERALL PLAN-2008

	Activities		Budget		Explanation
	Planned (future tranche)	Cumulative achievement as compared to overall plan [%]*	Planned (future tranche)	Cumulative achievement as compared to overall plan [%]*	
Convension (MT)	500	100	2,500,000		
Group Consolidation Project					
Individual ent. Pre-95					
Indvidual ent. Post-95	500 (estimated and beyond the phaseout target per the agreement				
Provincial Phaseout					
Technical assistance	6		760,000		
Implementation workshops	1				
Technical study tours on substitute technologies	1				
Performance audits (just write 100% if you are exactly in plan)	1				
Consultant services (same)	1				
Survey on blowing agents used in the foam sector in China	1				
Monitoring of CFC-11 phaseout	1				
Unforeseen Activities	NA		NA		

*Refers to latest revision of overall plan

OVERVIEW TABLES FOR MULTI-YEAR AGREEMENTS
CHINA
Annex III

(1) PROJECT TITLE: **Refrigeration Servicing**

(2) EXECUTIVE COMMITTEE APPROVALS AND PROVISIONS

CODE	AGENCY	EXCOM PROVISION	Fulfilled? (Yes/No)	Comments
CPR/REF/44/INV/420	Japan	Approved in accordance with the Agreement between the Government of China and the Executive Committee.		n/a
CPR/REF/47/INV/438	Japan			
CPR/REF/45/TAS/426	UNEP			n/a
CPR/REF/44/INV/419	UNIDO	Approved in accordance with the Agreement between the Government of China and the Executive Committee, and subsequently adjusted at the 45th Meeting of the Executive Committee		n/a
CPR/REF/51/INV/450	UNIDO			n/a

Source: Inventory

(3) ARTICLE 7 DATA (ODP TONNES)

Substances	Baseline	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
CFC	57,818.7	75,290.8	47,089.0	51,076.4	55,414.2	42,983.4	39,123.6	33,922.6	30,621.2	22,808.8	17,902.5	13,123.8	-
CTC	38,220.6	-15.4	-100.1	110.0	85,628.4	110.0	28,923.4	15,305.4	3,294.4	20,019.9	3,885.8	1,060.3	-
Halons	34,186.7	33,714.0	33,115.0	35,731.0	22,207.0	18,602.0	14,780.0	10,409.0	6,604.2	4,959.2	2,238.9	4,516.5	-
MBR	1,102.1	372.0	720.0	1,356.0	1,960.2	1,598.4	2,100.6	1,567.8	1,087.8	1,008.0	688.8	601.5	-
TCA	721.2	291.5	544.5	671.7	759.0	647.1	757.6	465.4	380.8	336.8	370.2	186.6	-

Source: A7 Data from the Ozone Secretariat

(4) LATEST COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES) **Year:** 2005

Substances	Aerosol	Foam	Halon	Refrigeration		Solvent	Process Agent	MDI	Lab Use	Methyl Bromide		Tobacco Fluffing	Total
				Manufacturing	Servicing					QPS	Non-QPS		
CFC	476.2	6,193.3		1,058.2	4,434.8	546.1	3.2	286.0				128.0	13,125.8
CTC							485.0		575.3				1,060.3
Halons			4,446.5										4,446.5
MBR										850.9	620.2		1,471.1
TCA						186.6							186.6

Source: Country Programme Data

(5) PHASE-OUT (ODP TONNES)

Substances	Calendar year	2004	2005	2006	2007	2008	2009	2010	Total	Decision
CFC	Maximum Allowable Consumption (Agreement; per substance if valid)	25,300.0	18,750.0	13,500.0	7,400.0	550.0	550.0	0.0		
	Compliance Action Target (MOP)									N/A
	Consumption Reported in Implementation Report submitted									
	Consumption Reported in the Verification Report			5,421.0						
	Japan									
	Reduction Under Plan		511.0						511.0	
	Approved Phase-Out (Inventory)	0.0	511.0						511.0	
	Actual Phase-Out (Current Progress Report)	0.0	511.0						511.0	
	Remaining Phase-Out to be Achieved									
	UNIDO									
	Reduction Under Plan			782.0	793.0	680.0	531.0	605.0	3,391.0	
	Approved Phase-Out (Inventory)	0.0			782.0				782.0	
	Actual Phase-Out (Current Progress Report)	0.0		1,309.9					1,309.9	
	Remaining Phase-Out to be Achieved			1,775.3						

Source: Agreement, Inventory, Progress Report, MOP Report, Project Document (Annual Plan) and Verification Reports.

(6a) PROJECT COSTS (US$)

Calendar year	2004	2005	2006	2007	2008	2009	Total
Japan							
Funding as per Agreement	1,000,000	3,000,000					4,000,000
Support Costs as per Agreement	130,000	390,000					520,000
Funds approved (Inventory)	1,000,000	3,000,000					4,000,000
Estimated Disbursement in Previous Progress Report	586,400	1,000,000					1,586,400
Funds Disbursed in Current Progress Report	1,000,000	709,004	2,146,562				3,855,566
Funds Obligated in Current Progress Report	0	137,100					137,100
Estimated Disbursement in Current Progress Report	0	1,000,000	2,855,566				3,855,566
Disbursement as per Annual Plan			n/a				
Funds Requested			0				
Support Costs Requested			0				
[Comments]							
UNEP							
Funding as per Agreement		450,000					450,000
Support Costs as per Agreement		58,500					58,500
Funds approved (Inventory)		450,000					450,000
Estimated Disbursement in Previous Progress Report		304,462					304,462
Funds Disbursed in Current Progress Report		316,345	60,000				376,345
Funds Obligated in Current Progress Report		904					904
Estimated Disbursement in Current Progress Report		133,655	60,000				193,655
Disbursement as per Annual Plan							
Funds Requested							
Support Costs Requested							
[Comments]							
UNIDO							
Funding as per Agreement	550,000		700,000	700,000	700,000	785,000	3,435,000
Support Costs as per Agreement	41,250		52,500	52,500	52,500	58,880	257,630
Funds approved (Inventory)	1,000,000			700,000			1,700,000
Estimated Disbursement in Previous Progress Report	420,000						420,000
Funds Disbursed in Current Progress Report	385,454		325,500				710,954
Funds Obligated in Current Progress Report	3,099		441,400				444,499
Estimated Disbursement in Current Progress Report	3,000		328,100				331,100
Disbursement as per Annual Plan							
Funds Requested				700,000			
Support Costs Requested				52,500			
[Comments]	Transferred US $450,000 to UNEP						

Source: Agreement, Inventory, Progress Reports and Project Document (Annual Plan)

(6b) SUBMISSION SCHEDULES (planned and actual)

Submission year as per agreement	2004	2005	2006	2007	2008	2009
Japan						
Planned submission as per Agreement	Dec-04	Nov-05				
Tranche Number	I	II				
Revised Planned Submission (As per Submission						
Date Approved	Dec-04	Nov-05				
UNEP						
Planned submission as per Agreement		Nov-05				
Tranche Number		I				
Revised Planned Submission (As per Submission						
Date Approved		Apr-05				
UNIDO						
Planned submission as per Agreement	Dec-04		Nov-06	Nov-07	Nov-08	Nov-09
Tranche Number	I		III	IV		
Revised Planned Submission (As per Submission			Mar-07	Nov-07		
Date Approved	Dec-04		Mar-07			

Source: Agreement, Inventory and Final ExCom Report Decisions

(7) INFORMATION ON POLICIES FROM COUNTRY PROGRAMME AND VERIFICATION REPORTS

TYPE OF ACTION / LEGISLATION		Country Programme - 2005		Verification
		(Yes/No)	Since when (Date)	Report (Yes/No)
1.	**REGULATIONS:**			
1.1	***Establishing general guidelines to control import (production and export) of C***			
1.1.1	ODS import/export licensing or permit system in place for import of bulk ODSs			
1.1.1.1	ODS import licensing system in place for import of bulk ODSs	Yes	2000	yes
1.1.1.2	ODS export licensing system in place for export of bulk ODSs	Yes	2000	yes
1.1.1.3	Permit System in place for import of bulk ODSs	Yes	2000	yes
1.1.1.4	Permit System in place for export of bulk ODSs	Yes	2000	yes
1.1.2	Regulatory procedures for ODS data collection and reporting in place			
1.1.2.1	Regulatory procedures for ODS data collection in place	Yes	1992	yes
1.1.2.2	Regulatory procedures for ODS data reporting in place	Yes	1992	yes
1.1.3	Requiring permits for import or sale of bulk ODSs			
1.1.3.1	Requiring permits for import of bulk ODSs	Yes	2000	yes
1.1.3.2	Requiring permits for sale of bulk ODSs	Yes	2000	yes
1.1.4	Quota system in place for import of bulk ODSs	Yes	2000	yes
1.2	***Banning import or sale of bulk quantities of:***			
1.2.1	Banning import of bulk quantities of:			
1.2.1.1	CFCs	No		
1.2.1.2	Halons	No		yes
1.2.1.3	CTC	No		
1.2.1.4	TCA	No		
1.2.1.5	Methyl Bromide	No		
1.2.2	Banning sale of bulk quantities of:			
1.2.2.1	CFCs	No		
1.2.2.2	Halons	No		
1.2.2.3	CTC	No		
1.2.2.4	TCA	No		
1.2.2.5	Methyl Bromide	No		
1.3	***Banning import or sale of:***			
1.3.1	Banning import of:			
1.3.1.1	Used domestic refrigerators using CFC	No	2007	
1.3.1.2	Used freezers using CFC	No	2007	
1.3.1.3	MAC systems using CFC	Yes	2002	
1.3.1.4	Air conditioners using CFC	Yes	2005	
1.3.1.5	Chillers using CFC	Yes	2005	
1.3.1.6	CFC-containing aerosols except for metered dose inhalers	No		
1.3.1.7	Use of CFC in production of some or all types of foam	No		
1.3.2	Banining sale of:			
1.3.2.1	Used domestic refrigerators using CFC	yes	2007	
1.3.2.2	Used freezers using CFC	yes	2007	
1.3.2.3	MAC systems using CFC	Yes	2002	
1.3.2.4	Air conditioners using CFC	Yes	2005	
1.3.2.5	Chillers using CFC	Yes	2005	
1.3.2.6	CFC-containing aerosols except for metered dose inhalers	No		
1.3.2.7	Use of CFC in production of some or all types of foam	No		
2.	**ENFORCEMENT OF ODS IMPORT CONTROLS**			
2.1	Registration of ODS importers (Yes/No)	Yes	2000	
D: QUALITATIVE ASSESSMENT OF THE OPERATION OF RMP				
The ODS import licensing scheme functions				
The CFC recovery and recycling programme functions				

Source: Country Programme and Verification Report

(8) IMPLEMENTATION DETAILS

	Completed tranche covered by report submitted								Tranche currently implemented (preliminary data)				
	Activities			Budget				Explanations	Activities		Budget		Explanations
	Planned (annual)	Actual (annual)	Cumulative achievement as compared to overall plan [%]*	Planned (annual)	Actual (annual)	Cumulative achievement as compared to overall plan [%]*	Carryover		Planned	Actual	Planned	Actual	
Customs Training								This table considers all costs for all sources of funds (UNEP, JAPAN and UNIDO)					
Train the Trainers													
Training of Customs Officers													
Good Practices in Refrigeration				1,422,500	1,422,500	100.0%							
Train the Trainers Workshops	8	5	62.5%										
Training of Technicians by Trained Trainers	5,593	2,894	51.7%										
Strengthening vocational schools													
Refrigeration Service investment component				3,892,500	2,572,500	66.1%							
Recovery & Recycling, establish R&R Centers	569	500	87.9%										
Service equipment supply other than R&R	365	365	100.0%										
PMU & Monitoring	1	1	100.0%	985,000	1,003,811	101.9%							
Unforeseen Activities													

*Refers to latest revision of overall plan

(9) ANNUAL PLAN SUBMITTED COMPARED TO OVERALL PLAN

	Activities		Budget		Explanations
	Planned (future tranche)	Cumulative achievement as compared to overall plan [%]*	Planned (future tranche)	Cumulative achievement as compared to overall plan [%]*	
Customs Training					This table considers all costs for all sources of funds (UNEP, JAPAN and UNIDO)
Train the Trainers					
Training of Customs Officers					
Good Practices in Refrigeration			151,000	9.60%	
Train the Trainers					
Training of Technicians by Trained Trainers	1,007	15.3%			
Strengthening vocational schools					
Refrigeration Service investment component			500,000	1	
Reclaim Centre	2	50%			
Service equipment supply other than R&R					
PMU & Monitoring	1	100.0%	20,000	8.33%	
Public Awarness	n/a	n/a	10,000	4.17%	
Contingency	n/a	n/a	19,000	5.69%	

*Refers to latest revision of overall plan

Annex IV - Overview Tables for Multi-Year Agreements

China

(1) PROJECT TITLE: Solvent

(2) EXECUTIVE COMMITTEE APPROVALS AND PROVISIONS

Code	Agency	Excom Provision	Fulfilled? (Yes/No)	Comments
CPR/SOL/42/INV/410	UNDP			
CPR/SOL/45/INV/429	UNDP	An amendment to the 2005 annual implementation programme was approved to reallocate US $2 million in savings from previous tranches of the solvent sector plan to purchase and install equipment for the purification of nPB subject to the following conditions; HEP-2 produced by China would not be made available for export; an annual production quota would be imposed on HEP-2 to meet the requirement for solvent use only; China would ensure that HEP-2 was only supplied to enterprises involved in the China solvent sector plan; the Import and Export Office of China would monitor and ensure that no HEP-2 was exported by China; and the implementing agency of the China solvent sector plan, UNDP, would include in its annual audit verification plan that no HEP-2 was exported.		
CPR/SOL/47/INV/435	UNDP			
CPR/SOL/50/INV/446	UNDP			
CPR/SOL/30/INV/355	UNDP	Approved in principle a total of US $52 million in funding for the phased reduction and complete phase out of consumption of CFC-113, TCA and CTC used as cleaning solvents. This is the total funding that would be available to China from the Fund for total elimination of solvent use of these ODSs. The agreed level of funding would be paid out in installments. China commits that in exchange for the funding approved, it will eliminate its total non-exempt CFC-113 and TCA consumption as well as its total CTC consumption for solvent use in accordance with the schedule provided in the agreement approved at the 30th ExCom Meeting (Annex IV of document UNEP/OzL.Pro/ExCom/30/41). Funds will be provided on the basis of annual work programmes as indicated in the agreement. Payments are conditioned upon completion of the agreed consumption decreases, being verified and maintained China agrees to ensure accurate monitoring of the phase out, and to provide annual reports at the last calendar year meeting of the Committee. China has maximum flexibility in using the agreed funds to meet the reduction requirements agreed. If China does not meet the redu		
CPR/SOL/33/INV/373	UNDP	Approved on the understanding that: (a) n-propyl bromide produced by China would not be made available for export; (b) an annual production quota would be imposed on n-propyl bromide to meet the requirement for solvent use only; (c) China would control the sale of n-propyl bromide only to enterprises involved in the conversion projects under the China Solvent Sector Plan; (d) the Import and Export Office of China would monitor and ensure that no n-propyl bromide was exported by China; (e) the implementing agency of the China Solvent Sector Plan, UNDP would include in its annual audit plan verification that no n-propyl bromide was exported; and (f) no further financial assistance would be sought from the Multilateral Fund for the final conversion to zero ODP alternatives.		
CPR/SOL/36/INV/390	UNDP	Approved on the understanding that no disbursement would occur until after the required information on the use of carbon tetrachloride as a process agent was provided.		
CPR/SOL/40/INV/403	UNDP	The Government of China was requested to return the funding of US$2 million reallocated under Decision 33/46 for uses as originally approved in the solvent sector plan		

(3) ARTICLE 7 DATA (ODP TONNES)

Substances	Baseline	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
CFC	57,818.7	75,290.8	47,089.	51,076.4	55,414.2	42,983.4	39,123.6	33,922.6	30,621.2	22,808.8	17,902.5	13,123.8
CTC	38,220.6	-15.4	-100.1	110.	85,628.4	110.	28,923.4	15,305.4	3,294.4	20,019.9	3,885.8	1,060.3
Halons	34,186.7	33,714.	33,115.	35,731.	22,207.	18,602.	14,780.	10,409.	6,604.2	4,959.2	2,238.9	4,516.5
Methyl Bromide	1,102.1	372.	720.	1,356.	1,960.2	1,598.4	2,100.6	1,567.8	1,087.8	1,008.	688.8	601.5
TCA	721.2	291.5	544.5	671.7	759.	647.1	757.6	465.4	380.8	336.8	370.2	186.6

(4) LATEST COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES) **Year: 2006**

Chemical	Aerosol	Foam	Fire Fighting	Refrigerating		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

(5) PHASE-OUT (ODP TONNES)

Substances		2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Total	Decision
CFC	Maximum Allowable Consumption (Agreement; per substance if valid)	3300	2700	2200	1700	1100	550	0	0	0	0	0		
	Compliance Action Target (MOP)													
	Consumption Reported in Implementation Report	3246	2674.4	2192.3	1676.7	1099.4	549.3	0						
	Consumption Reported in the Verification Report	0	2674.4	2196	1676.7	1099.4	549.3	0						
	IBRD													
	Reduction Under Plan													
	Approved Phase-Out													
	Actual Phase-Out													
	Remaining Phase-Out to be Achieved					0	0	0						
	UNDP													
	Reduction Under Plan		600	500	500	600	550	550					3300	
	Approved Phase-Out	372.8	524	500	500	600	550						3046.8	
	Actual Phase-Out	373	524	500	500	600	550						3047	
	Remaining Phase-Out to be Achieved	3300	2674.4	2196	1676.7	1099.4	549.3	0						
CTC	Maximum Allowable Consumption (Agreement; per	110	110	110	55	0	0	0	0	0	0	0		
	Compliance Action Target (MOP)													
	Consumption Reported in Implementation Report	110	110	110	55	0	0	0						
	Consumption Reported in the Verification Report	0	59.6	27.3	5.5	0	0	0						
	IBRD													
	Reduction Under Plan													
	Approved Phase-Out													
	Actual Phase-Out													

	Remaining Phase-Out to be Achieved	0	0	0	0	0	0	0						
	UNDP													
	Reduction Under Plan				55	55							110	
	Approved Phase-Out			55	55	55							165	
	Actual Phase-Out			55	55	55							165	
	Remaining Phase-Out to be Achieved	110	59.6	27.3	5.5	0	0	0	0					
TCA	Maximum Allowable Consumption (Agreement; per	621	613	605	580	502	424	339	254	169	85	0		
	Compliance Action Target (MOP)													
	Consumption Reported in Implementation Report	571	457.5	380.6	336.8	370.2	186.6	279.9						
	Consumption Reported in the Verification Report		457.5	380.6	336.8	370.2	186.6	279.9						
	UNDP													
	Reduction Under Plan		8	8	25	78	78	85	85	85	84	85	621	
	Approved Phase-Out	10	10	25	25	78	170	85					403	
	Actual Phase-Out	10	10	25	25	78	170	0					318	
	Remaining Phase-Out to be Achieved	571	457.5	380.6	336.8	370.2	186.6	279.9	0					

(6a) PROJECT COSTS (US$)

Calendar year		**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**
UNDP	Funding as per Agreement	6,750,000	6,955,000	6,330,000	5,755,000	5,555,000	5,680,000	5,055,000	5,480,000	1,480,000	1,480,000	1,480,000	52,000,000
	Support Costs as per Agreement	675,000	695,500	633,000	431,625	416,625	426,000	379,125	411,000	111,000	111,000	111,000	4,400,875
	Funds Approved (Inventory)	6,750,000	6,955,000	6,330,000	5,755,000	5,555,000	10,735,000	5,480,000					47,560,000
	Estimated Disbursement in Previous Progress Report			1,086,097	2,877,500	1,944,250	3,757,250						9,665,097
	Funds Disbursed in Current Progress Report	6,750,000	6,955,000	6,330,000	5,755,000	1,312,986							27,102,986
	Funds Obligated in Current Progress Report												
	Estimated Disbursement in Current Progress Report					3,393,611	3,283,000	1,096,000					7,772,611
	Disbursement as per Annual Plan	6,750,000	6,955,000	6,330,000	5,755,000	1,312,986							27,102,986
	Funds Requested	6,750,000	6,955,000	6,330,000	5,755,000	5,555,000	10,735,000	5,480,000	1,480,000				49,040,000
	Support Costs Requested	675,000	695,500	633,000	431,625	416,625	805,125	411,000	111,000				4,178,875
	Comments												

(6b) SUBMISSION SCHEDULES (planned and actual)

Submission Year as per Agreement		**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
UNDP	Planned Submission	Mar-2000	Mar-2001	Mar-2002	Jul-2003	Apr-2004	Apr-2005	Nov-2006	Nov-2007	Nov-2008	Nov-2009	Nov-2010
	Tranche Number	I	II	III	IV	V	VI and VII	VIII				
	Revised Planned Submission											
	Date Approved	Mar-2000	Mar-2001	Mar-2002	Jul-2003	Apr-2004	Apr-05 and	Nov-2006				

(7) INFORMATION ON POLICIES FROM COUNTRY PROGRAMME AND VERIFICATION REPORTS

		Country Programme 2005		
TYPE OF ACTION / LEGISLATION		**(Yes/No)**	**Since when (Date)**	**Verification Report(Yes/No)**
1.	REGULATIONS:			
1.1	Establishing general guidelines to control import (production and export) of ODSs			
1.1.1	ODS import/export licensing or permit system in place for import of bulk ODSs			
1.1.1.1	ODS import licensing system in place for import of bulk ODSs	Yes	01/01/2000	Yes
1.1.1.2	ODS export licensing system in place for export of bulk ODSs	Yes	01/01/2000	Yes
1.1.1.3	Permit System in place for import of bulk ODSs	Yes	01/01/2000	Yes
1.1.1.4	Permit System in place for export of bulk ODSs	Yes	01/01/2000	Yes
1.1.2	Regulatory procedures for ODS data collection and reporting in place			
1.1.2.1	Regulatory procedures for ODS data collection in place	Yes	01/01/1992	Yes
1.1.2.2	Regulatory procedures for ODS data reporting in place	Yes	01/01/1992	Yes
1.1.3	Requiring permits for import or sale of bulk ODSs			
1.1.3.1	Requiring permits for import of bulk ODSs	Yes	01/01/2000	Yes
1.1.3.2	Requiring permits for sale of bulk ODSs	Yes	01/01/2000	Yes
1.1.4	Quota system in place for import of bulk ODSs	Yes	01/01/2000	Yes
1.2	Banning import or sale of bulk quantities of:			
1.2.1	Banning import of bulk quantities of:			
1.2.1.1	CFCs	No		Yes
1.2.1.2	Halons	No		Yes
1.2.1.3	CTC	No		Yes
1.2.1.4	TCA	No		No
1.2.1.5	Methyl Bromide	No		
1.2.2	Banning sale of bulk quantities of:			
1.2.2.1	CFCs	No		Yes
1.2.2.2	Halons	No		Yes
1.2.2.3	CTC	No		Yes
1.2.2.4	TCA	No		No
1.2.2.5	Methyl Bromide	No		
1.3	Banning import or sale of:			
1.3.1	Banning import of:			
1.3.1.1	Used domestic refrigerators using CFC	No		Yes

1.3.1.2	Used freezers using CFC	No		Yes
1.3.1.3	MAC systems using CFC	Yes	01/01/2002	Yes
1.3.1.4	Air conditioners using CFC	Yes	01/01/2005	Yes
1.3.1.5	Chillers using CFC	Yes	01/01/2005	Yes
1.3.1.6	CFC-containing aerosols except for metered dose inhalers	No		Yes
1.3.1.7	Use of CFC in production of some or all types of foam	No		Yes
1.3.2	Banning Sale of:			
1.3.2	MAC systems using CFC			
1.3.2.1	Used domestic refrigerators using CFC	No		Yes
1.3.2.2	Used freezers using CFC	No		Yes
1.3.2.3	MAC systems using CFC	Yes	01/01/2002	Yes
1.3.2.4	Air conditioners using CFC	Yes	01/01/2005	Yes
1.3.2.5	Chillers using CFC	Yes	01/01/2005	Yes
1.3.2.6	CFC-containing aerosols except for metered dose inhalers	No		Yes
1.3.2.7	Use of CFC in production of some or all types of foam	No		Yes
2.	ENFORCEMENT OF ODS IMPORT CONTROLS			
2.1	Registration of ODS importers (Yes/No)	Yes	01/01/2000	Yes
D:	Qualitative assessment of the operation of RMP			
	The ODS import licensing scheme functions:			Very Well
	The CFC recovery and recycling programme functions:			Satisfactorily

PROJECT COVER SHEET – MULTI-YEAR PROJECTS

COUNTRY: China

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

NATIONAL CO-ORDINATING AGENCY: State Environmental Protection Administration (SEPA)
State Food and Drug Administration (SFDA)

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT
A: ARTICLE-7 DATA (ODP TONNES, 2005, AS OF SEMPTEMBER 2006)

Annex A, Group I	13,549.81	Annex B, Group II	963.936
Annex A, group II	1,176.9	Annex E, MeBr	

B: COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES, 2005, AS OF SEPTEMBER 2006)

ODS	Foam	Refrigeration	Aerosol
CFC-11	6,085.29	606.38	101.96
CFC-12	108.00	4,598.03	374.26

CFC consumption remaining eligible for funding (ODP tonnes)	423.2

CURRENT YEAR BUSINESS PLAN: Total funding: US$ 3,225,000 total phase-out: 101 ODP tonnes.

PROJECT DATA		**2007**	**2008**	**2009**	**2010**	**Total**
CFCs (ODP tonnes)	Montreal Protocol limits	8,672.8	8,672.8	8,672.8	0	n.a.
	Annual consumption limit	7,400	550	550	0	n.a.
	Annual phase-out newly addressed	0	0	280.9	0	280.9
TOTAL ODS CONSUMPTION TO BE PHASED OUT		0	0	280.9	0	280.9
Total ODS consumption to be phased-in (CFCs)		0	0	0	0	0
Project costs (US $):						22,316,189
Support costs (US $))						1,673,714
TOTAL COST TO MULTILATERAL FUND (US $)						**23,989,903**
Project cost effectiveness (US $/kg): 79.45						

FUNDING REQUEST: Approval of the MDI Sector CFCs Phase out Plan for China and its total project funding of **US$ 22,316,189** plus support cost of **US$1,673,714** as indicated above.

EXECUTIVE SUMMARY

This sector plan will assist China to phase out all CFC consumption of MDI sector in China. The funding request targets the eligible consumption of 280.9 ODP tonnes (236.7 tonnes of CFC11, 40.9 tonnes of CFC12 and 3.3 tonnes of CFC114). 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 of MDI manufacturing enterprises in China, and covers all enterprises and production lines. The sector plan proposes a mix of approaches including change to other type of pharmaceutical products, (for example to DPI, if mature MDI substitutes are not available), conversion to non-ODS substitute processes where economically feasible, and closure of production where other approaches are not feasible. The sector plan will include 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.

Prepared by: SFDA/SEPA and the UNIDO **Date: 20 August 2007**

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, that is 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 phaseout.** 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 (SEPA) 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 SEPA. There are nine special working groups in the IOC, which consist of staff from SEPA 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 ten 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).

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 SEPA, the Aerosol Newsletter (a professional magazine of China's aerosol sector), organized 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, SEPA 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, SEPA 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 MDI Sector. As the leading agency for the implementation of Montreal Protocol, SEPA 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 SEPA and SFDA. The first draft of MDISP was completed in April 2007 endorsed at a national workshop in August 2007.
6. **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: (1) data survey and analysis, (2) current regulations and policies governing the sector, (3) technical options, (4) strategy of phase out and policy framework, (5) incremental costs analysis, (6) operating mechanism, and (7) action plan. Upon approval of this Sector Plan with the requested funding of US$ 22,316,189 (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 280.9 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

7. The first pharmaceutical aerosols were from sulfamido compound aerosols 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 Pharmaceutics Factory, Wuxi First Pharmaceutics Factory and Chongqing Seventh Pharmaceutics Factory. However, during the first 20 years after the initiating stage of the production, i.e. until the 1980s, the development of medicinal aerosol in China was comparatively slow due to the scarcity of can, valve and satisfactory metering device. Great progress was made along with the solutions of all these technical problems after 1980s. Up to 2006, 104 MDI production licences were approved in China. These are used by 38 producers manufacturing 25 types of CFC MDIs, based on 22 chemical active 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 with registration licences but no production
Currently produced CFC-based MDI products	40	17	17	

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

B Asthma and COPD in China

9. 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.

10. 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).
11. 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.
12. 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.
13. Development of anti-asthma drugs is targeting the inflammatory factors as leukotriene, the platelet-activating factor - thromboxane A2, cytokines, phospholipase A2-inhibitor, tachykinin, in view of the complicated mechanism of the occurance. 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.
14. 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 south China, with a highest 3.03% in Fujian province and 2.53% in Guangzhou. North and inland region of China is lower, with 0.5% in Shandong province and 0.11% in the Tibet autonomous region.

C Treatment of Asthma and COPD in China

15. Based on old habits of treatment, some doctors and patients still many times choose less effective oral medicine or injections instead of MDI to relieve or cure asthma. Some patients also take Chinese traditional medicine. 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.
16. The of asthma treatment was 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:

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

Drug type	Drug Delivery	Drug Name	Remarks
Theophyllines	Oral	Aminophylline	
		Controlled (Sustained)Released Theophylline	
	Intravenous	Aminophylline	
		Doxofylline	
		Bis 2-Hydroxylpropylene Theophylline	
Anticholinergic drugs	Inhalation	Ipratropium Bromide	
		Atropine oxybromide	
		Tiotropium bromide	
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	

17. 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.
18. For the time being, 26 provinces (including municipalities directly under the central government) have their own asthma alliances. The activities to propagate the standard treatment and to develop the doctor training programme with the help of asthma control organizations should 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.
19. 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% percents of the asthma drug was sold in hospitals. The market has been increasing steadily from 2004 to 2006.

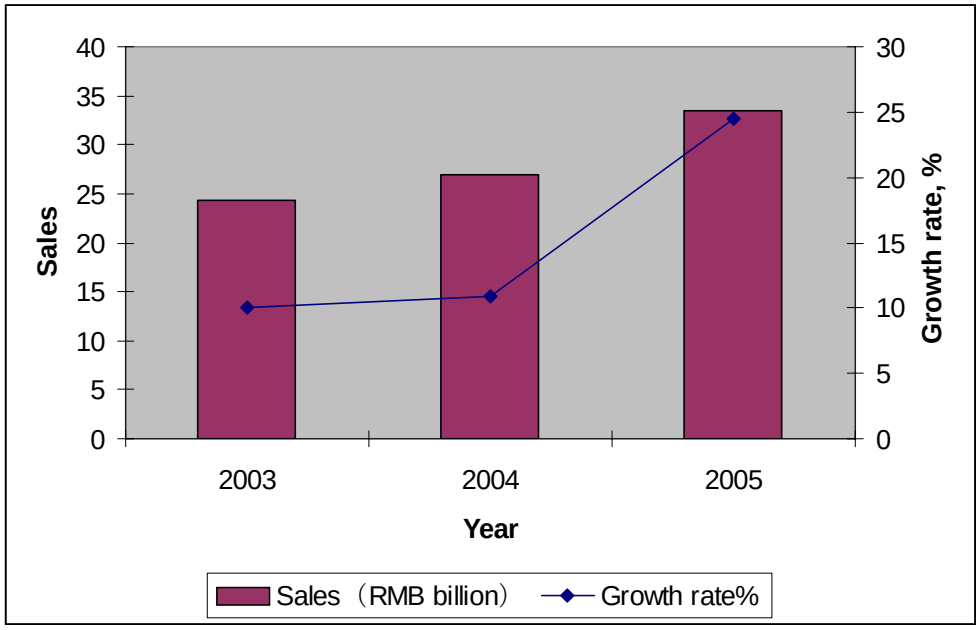

Fig. 1: The Sales of MDI Products in China

20. It is expected that MDI will be used more and more to treat the asthma.

D Production process of MDIs

21. As other medicines, MDIs should be registered at SFDA prior the start of their production. The detailed registration process is described in Section A, chapter III.
22. The MDI production process is simply described on the following figure.

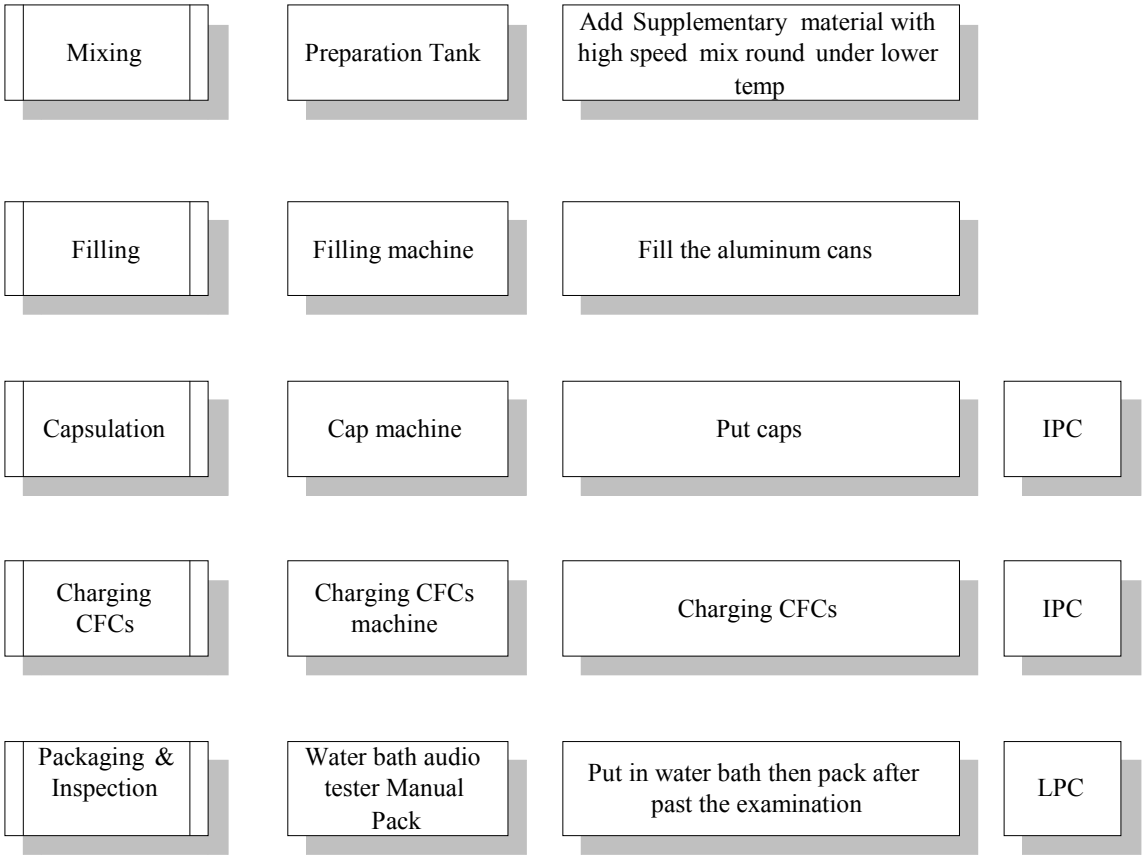

Fig. 2 The production process for Salbutamol Aerosol (suspension)

E Date Survey

23. NICPBP was entrusted by SFDA, SEPA and UNIDO to carry out MDI sector investigation and prepare the sector plan to phaseout CFCs in the MDI sector of China.
24. The date survey process is shown in following figure 3.
25. The data survey was planned to be conducted by the following ways:

A. Search 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.

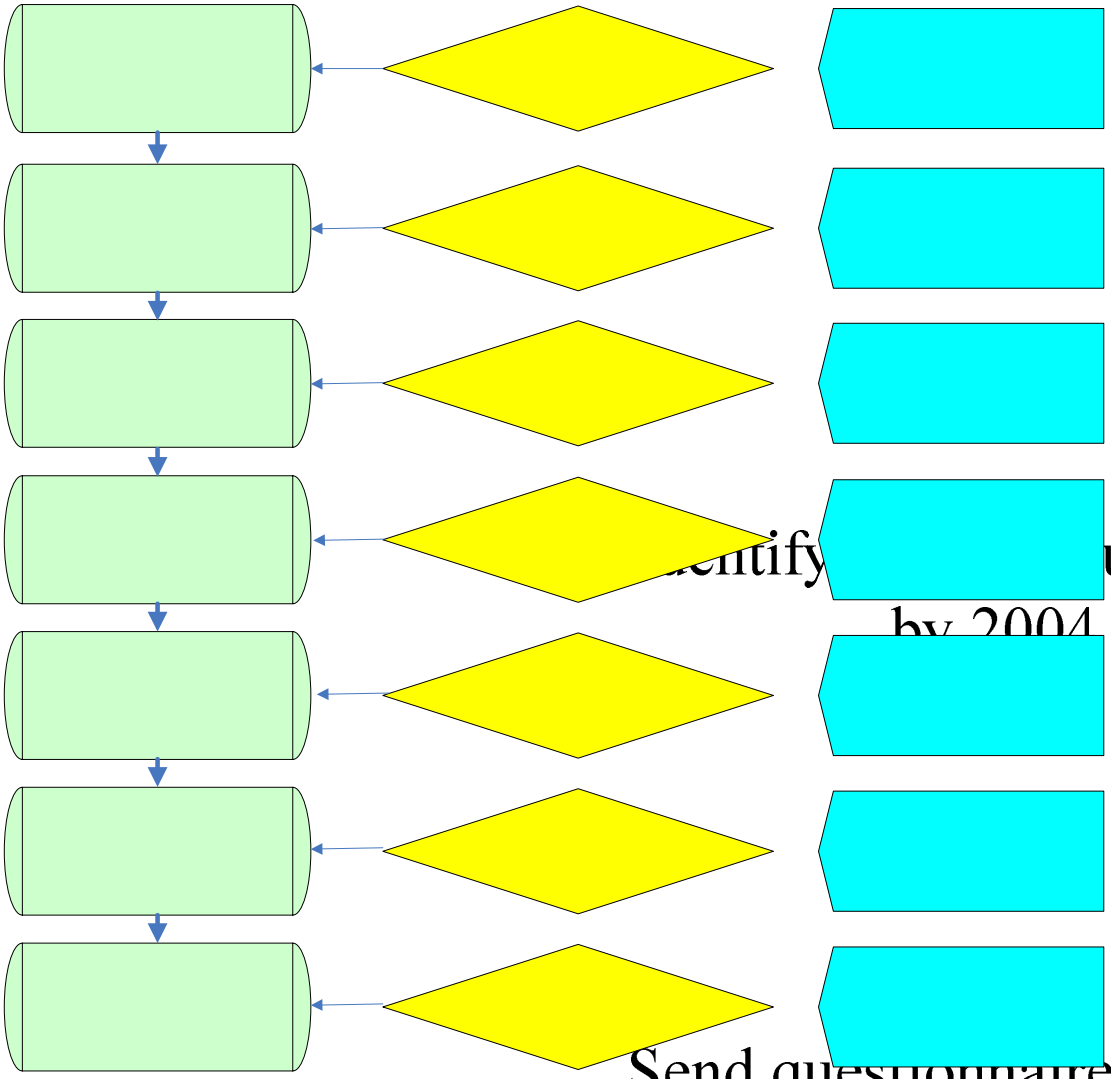

Fig. 3 Data survey process

26. The actual chronology of events was as follows:

a. SFDA and NICPBP identified all MDI producers;

b. SFDA, SEPA and NICPBP prepared a questionnaire to collect the consumption, production and technical data under supported of UNIDO;

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

d. Up to the November 2004, SFDA received feedback from 57 companies;

Workshop for initially survey in 2004 and 2006

e. In August 2004, SEPA, 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.

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 SEPA, SFDA and NICPBP in Beijing and visited several major producers in Hangzhou, Shanghai and Wuxi to verify the data.

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

k. In June 2007, SEPA, 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.

F Enterprise information, CFC Consumption in the MDI Sector

27. Currently there are totally 25 types of MDIs (including three Chinese traditional medicine) produced in China by 38 companies (including 5 with foreign ownership). In the period 2003-2006 23 companies produced 17 types of MDIs using CFCs. Due to market reasons 8 types of MDIs were not produced during 2003-2006. The companies and their CFC consumptions are listed as follows:

Table 3 Products and CFC Consumption by enterprises

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

Company Code	Company Name	Product Code	Product Name (active ingredient)	CFC Consumption (g/can)	CFC Consumption (kg), 2004	CFC Consumption (kg), 2005	CFC Consumption (kg), 2006
06	GlaxoSmithKline (Chongqing) Co., Ltd.*	B26	Beclomethasone Dipropionate Aerosol	13.1			
06	GlaxoSmithKline (Chongqing) Co., Ltd.*	B01	Beclometasone Dipropionate Aerosol	19.8			
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	12.5	2,370.0	2,010.0	1,341.0
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	12.5	250.0	400.0	219.0
09	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	B24	Zhichuanling Aerosol	12.0	393.6	30.0	130.8
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	22.5	172.1	179.5	0.0
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	B11	Huashanshen Aerosol	9.8	0.0	0.0	300.0
15	Henan Zhongfu Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	14.7	670.3	1,380.3	2,205.0
16	Heilongjiang Tanglong Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	13.9	27.8	0.0	
18	Jinan Weimin Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	13.2	22,560.1	29,676.2	33,652.0
18	Jinan Weimin Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol	13.2	24,492.6	26,574.2	30,134.0
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol (solution)	11.3	12,219.0	12,395.0	16,025.0
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol	11.3	12,028.0	10,618.0	12,769.0

Company Code	Company Name	Product Code	Product Name (active ingredient)	CFC Consumption (g/can)	CFC Consumption (kg), 2004	CFC Consumption (kg), 2005	CFC Consumption (kg), 2006
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	20.9	7.5	7.4	41.7
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B14	Sodium Cyomoglicate Aerosol	25.3	0.0	0.0	50.5
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	20.9	0.0	0.0	41.7
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B16	Salbutamol Aerosol (suspension)	17.2	37,405.7	79,163.9	70,000.0
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	23.2	7,288.5	16,526.3	22,950.0
21	Jewim Pharmaceutical (Shandong)Co., Ltd.	B15	Salbutamol Aerosol (solution)	16.2	2,947.4	9,801.2	20,250.0
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B14	Sodium Cyomoglicate Aerosol	16.9	2,109.9	6,902.0	7,378.0
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	49.4	3,459.0	2,344.5	3,210.0
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B25	Salbutamol Aerosol Compound Salbutamol Sulfate Aerosol	22.4			100.0
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	3.3			10.0
25	Pharmaceutical Factory of Shanxi Medical University	B16	Salbutamol Aerosol (suspension)	19.5	1,003.0	858.0	689.0

Company Code	Company Name	Product Code	Product Name (active ingredient)	CFC Consumption (g/can)	CFC Consumption (kg), 2004	CFC Consumption (kg), 2005	CFC Consumption (kg), 2006
25	Pharmaceutical Factory of Shanxi Medical University	B01	Beclomethasone Dipropionate Aerosol (suspension)	19.5	62.0	90.0	19.0
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
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
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B12	Ribavirin Aerosol	15.0	0.0	1,851.0	3,193.0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B09	Ketotifun Fumarate Aerosol	20.1	0.0	0.0	1,271.0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B04	Budesonide Aerosol	20.9	198.0	435.0	289.0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B22	Isoprenaline Hydrochloride	15.6	165.0	200.0	165.0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B01	Beclometasone Dipropionate Aerosol	23.3	0.0	0.0	79.0

Company Code	Company Name	Product Code	Product Name (active ingredient)	CFC Consumption (g/can)	CFC Consumption (kg), 2004	CFC Consumption (kg), 2005	CFC Consumption (kg), 2006
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B14	Sodium Cyomoglicate Aerosol	21.9	0.0	0.0	113.0
28	Shanghai Pharmaceutical (Group) Co., Ltd Prescription Drug Business Unit	B17	Salmeterol Xinafoate Aerosol	15.0	33.6	0.0	0.0
29	Tianjin Century Pharmaceutical Co.,Ltd.	B22	Isoprenaline Hydrochloride Aerosol		0.0	0.0	0.0
29	Tianjin Century Pharmaceutical Co.,Ltd.	B15	Salbutamol Aerosol	9.8	0.0	0.0	0.0
31	Weifang Zhongshi Pharmacy Co.,Ltd.	B15	Salbutamol Aerosol (solution)	11.6	3,150.0	1,350.0	900.0
31	Weifang Zhongshi Pharmacy Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	15.0	0.0	0.0	0.0
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B15	Salbutamol Aerosol	11.5	7,570.0	6,755.0	4,840.0
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	B22	Isoprenaline Hydrochloride Aerosol	11.5	1,470.0	1,245.0	0.0
36	Chongqing Kerui pharmacy Co.,Ltd.	B16	Salbutamol Aerosol (suspension)	16.8	5,550.0	7,530.0	7,376.5
37	Zigong Chengguang Pharmaceutical Co.,Ltd.	B05	Dimethicone Aerosol	25.2	307.1	22.2	70.0
38	Jiangsu Tianji Pharmaceutical Co.,Ltd.	B12	Ribavirin Spray	9.0			4,202.0

Table 4 CFC Consumption of MDI Sector in China 2004 - 2006 (unit: tons ODP)

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

* There are 15 domestic companies which have registered MDI products but have no production during 2003-2006.

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

Table 5 Production of CFCs MDI in China 2004 - 2006

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

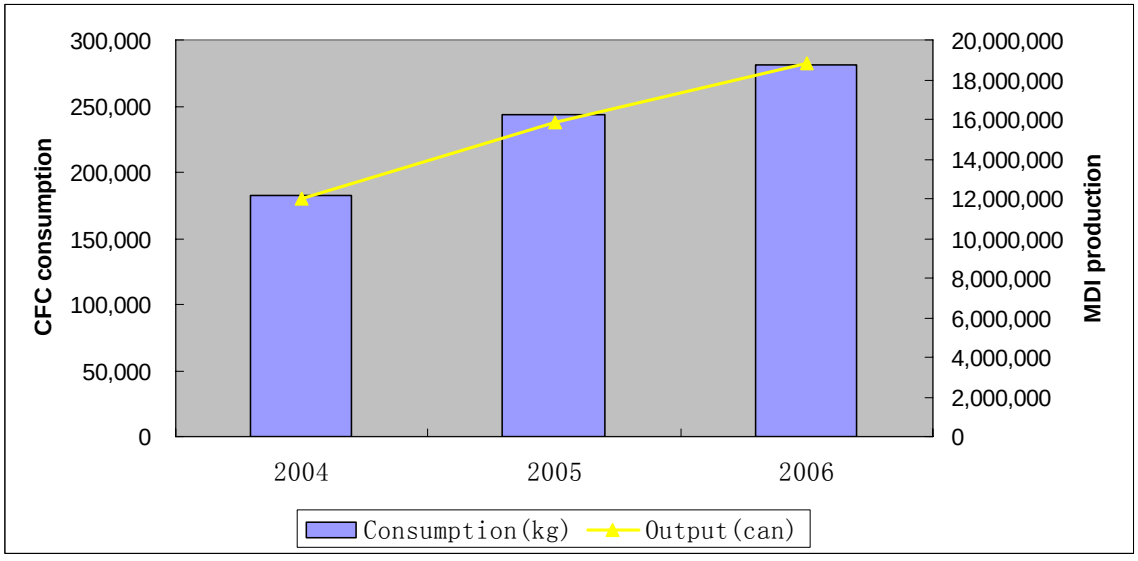

Fig. 4 CFC Consumption and MDI production during 2004 - 2006

Table 6 General Information of the MDI Manufacturing Enterprises

Company Code	Company Name	Year of Establishment	Chinese share of ownership	No. of Production Lines	Number of Licenses	Type	CFC Consumption 2006 (kg)	2006 Output (ampul)
1	AstraZeneca Pharmaceutical Co., Ltd.	1992	0%	1	4	B04, B13	13,203	1,084,726
2	Beijing Haiderun Pharmaceutical Co., Ltd.	1978	100%	1	3	B15, B22, B23	9,366	851,400
3	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	1991	0%	1	7	B01,B12,B14, B15	0	0
4	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	1991	100%	0	3	B19, B23, B23	0	0
5	GlaxoSmithKline (Tianjin) Co., Ltd.	1991	0%	1	2	B01	0	0
7	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.*	1994	100%	0	4	B01, B15,B20, B22	0	0
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1988	100%	1	3	B01,B15, B22	1560	124,800
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	1979	100%	1	1	B24	131	10898
10	Harbin Guangji Pharmaceutical Factory*	n.a.	100%	0	2	B15, B16	0	0
11	Harbin Hengcang Pharmaceutical Co., Ltd.	1993	100%	1	2	B14,B15	0	0
12	Harbin Huili Pharmaceutical Co., Ltd.	1998	100%	0	1	B17	0	0
13	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.*	1994	100%	0	1	B01	0	0
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	1982	100%	1	1	B11	300	30000
15	Henan Zhongfu Pharmaceutical Co., Ltd.	1992	100%	1	1	B15	2,205	150,000 -
16	Heilongjiang Tianlong	1997	100%	2	3	B14,B15	0	0

Company Code	Company Name	Year of Establishment	Chinese share of ownership	No. of Production Lines	Number of Licenses	Type	CFC Consumption 2006 (kg)	2006 Output (ampul)
	Pharmaceutical Co., Ltd.							
17	Jilin Xiuzheng Pharmaceutical (Group) Co., Ltd.*	n.a	100%		1	B01	0	0
18	Jinan Weiming Pharmaceutical Co., Ltd.	1979	100%	2	3	B15, B22	63,786	4,832,300
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	1993	100%	2	5	B07, B14, B15, B16, B22	28,928	2,552,299
20	Qiqihar Pharmaceutical Factory*	n.a	100%		1	B15	0	0
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	1993	100%	1	6	B01, B14, B15, B16	120,578	6,704,000
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	1991	100%		3	B15, B18, B22	0	0
23	Shandong Lukang Cisen Pharmaceutical Co., Ltd.	1992	100%		2	B01, B22	0	0
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	2001	100%	1	3	B04,B17,B25	3,320	114,560
25	Pharmaceutical Factory of Shanxi Medical University	1994	100%	1	3	B01, B16,B18	708	35,554
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	1990	100%	0	3	B08, B23	0	0
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	1988	100%		3	B02, B15, B16	0	0
28	Shanghai Pharmaceutical (Group) Co., Ltd Sine Pharma Laboratory	1982	100%	1	14	B01, B04, B07,B09,B10,B12 B14, B15, B16, B17 ,B21,B22	19,434	1,132,455
29	Tianjin Century Pharmaceutical Co., Ltd.	1981	100%	1	2	B15, B22	0	0
30	Tonghua Baishan Pharmaceutical Co., Ltd.	2001	100%		1	B06	0	0
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	1993	0%	1	4	B01,B15, B16	900	3280

Company Code	Company Name	Year of Establishment	Chinese share of ownership	No. of Production Lines	Number of Licenses	Type	CFC Consumption 2006 (kg)	2006 Output (ampul)
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	1965	100%	1	2	B15, B22	4,840	313,689
33	Xi'an Lisheng Pharmaceutical Co., Ltd.*	n.a.	100%		1	B15	0.	0
34	Xinjiang Pharmaceutical Factory	1975	100%	1	1	B15	0	0
35	Zhanjiang New Ton Tex Pharmaceutical Co., Ltd.	1987	100%	1	2	B15, B16	0.	0
36	Chongqing Kerui Pharmaceutical Co., Ltd.	1975	100%	1	4	B15,B16,B20,B22	7,377	448,800
37	Zigong Chenguang Pharmaceutical Co., Ltd.	1981	100%	1	1	B05	70	2,020
38	Jiangsu Tianji Pharmaceutical Co., Ltd.	1992	100%	1	1	B12	4,202	466,982
	Total						**280,908**	**18,677,763**

Note:

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

28. The summary of information on enterprises for the year 2006 is as follows:

Table 7 Summary of information of enterprises for 2006

	Producers	Number of Licences	Number of Licences in production
Number of MDI producers	38	104	40
Of which producing CFC-MDI ownership by domestic	15	51	36
Of which with idling capacities ownership by domestic	18	36	0
Of which producing CFC-MDI with foreign ownership	4	17	4
Of which doesn't exist	1	*	*
Consumption (tons):			
CFC-11	236.7		
CFC-12	40.9		
CFC-114	3.3		
Total consumption	280.9		
Of which consumed by five foreign companies	14.1		
Of which consumed by 15 domestic companies*	266.8		

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

29. 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, SEPA began to conduct public awareness raising activities on CFCs phase out. Currently, a large amount of imported DPI and CFC-free MDIs are on the Chinese market.
30. 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 form one enterprise got approval from SFDA for clinical tests. All the other enterprises have no clear ideas on the ways to phase out CFCs.

Chapter III Regulation and Policy for the MDI Sector and CFC Phaseout

A Regulatory framework for Drug, especially for MDI

31. 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 the 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)

32. 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 is 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 an other 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 occurs 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.

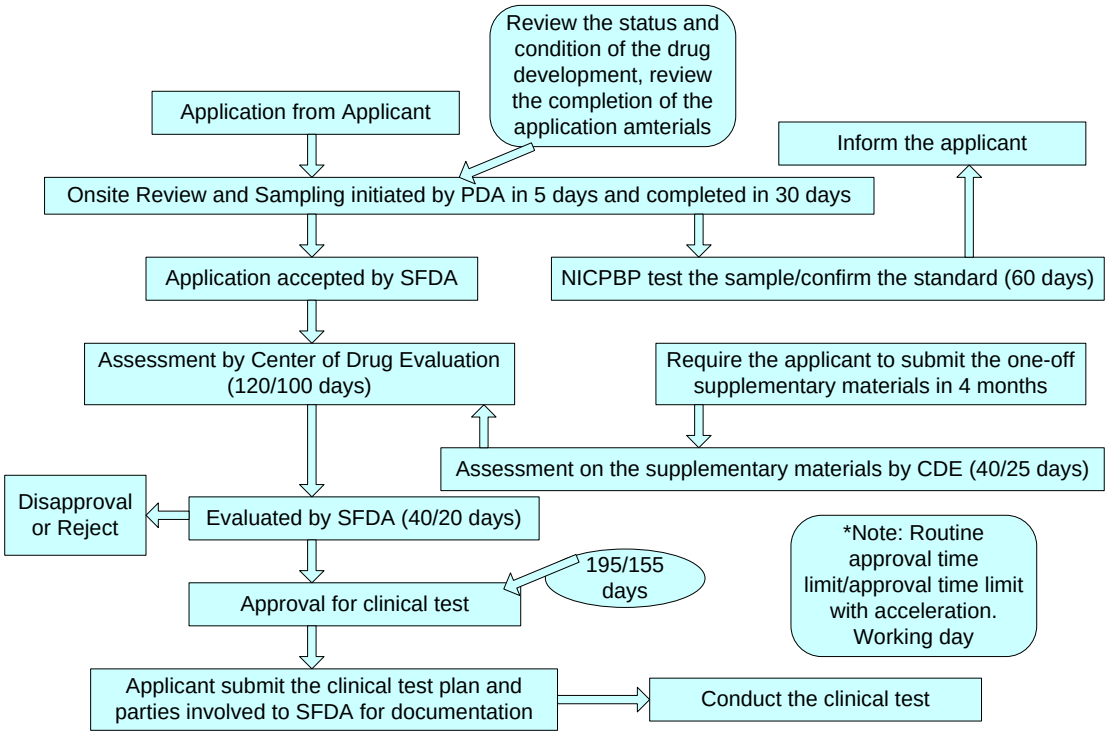

Fig. 5 Approval Procedure for Clinical Test of the New Drug

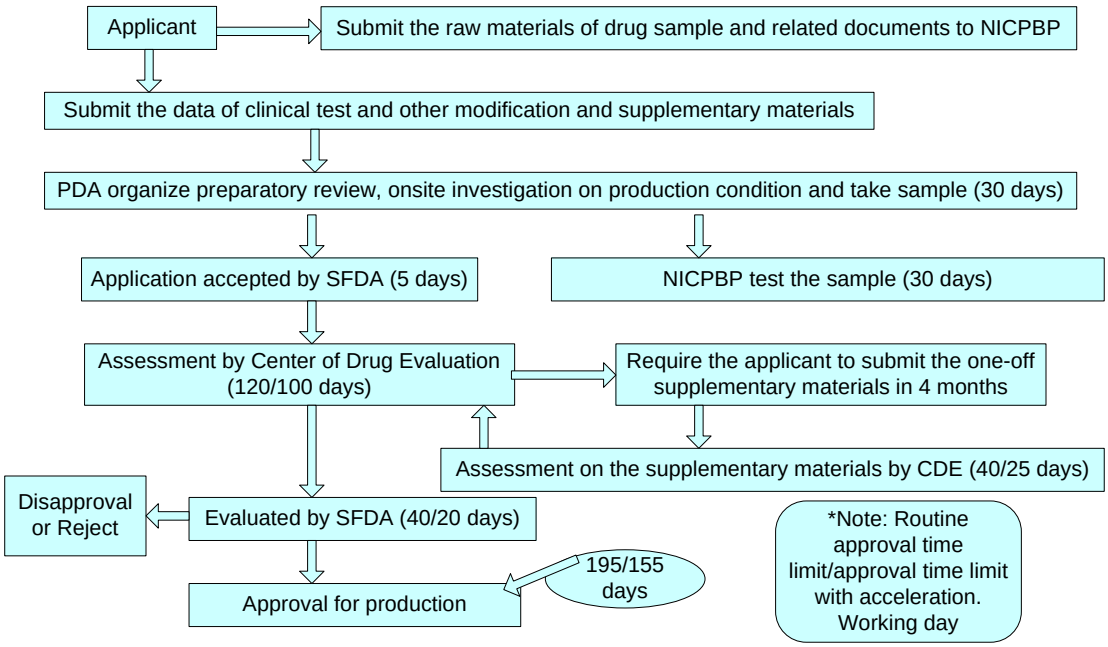

Fig. 6 Approval Procedure for the Production of New Drug

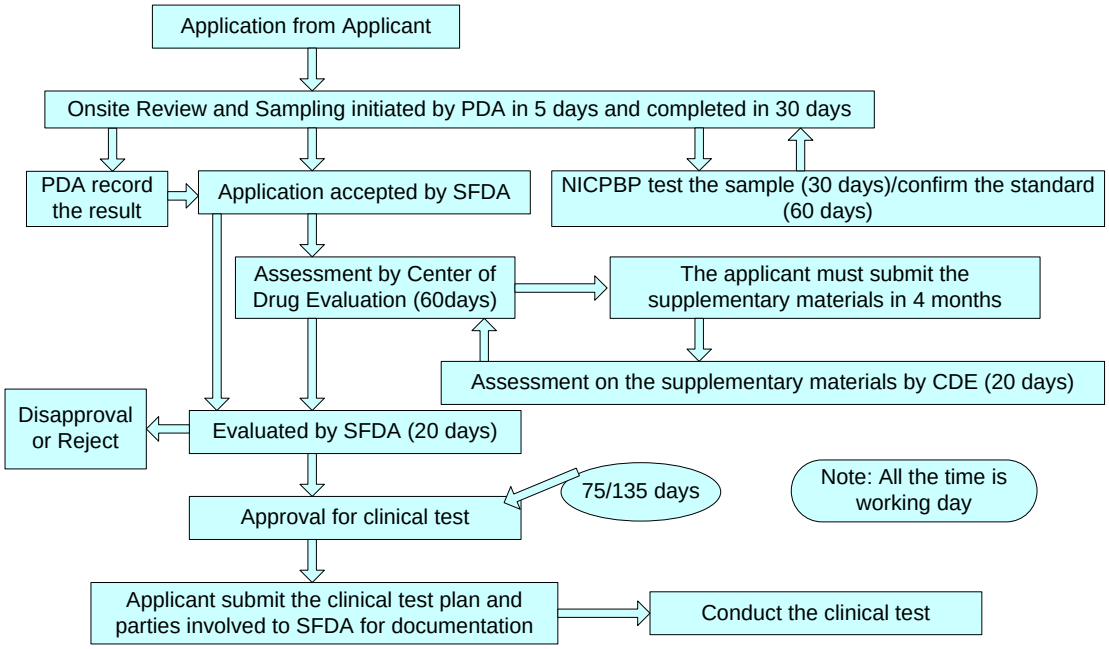

Fig. 7 Approval Procedure for Clinical Test for Change to Existing Drug

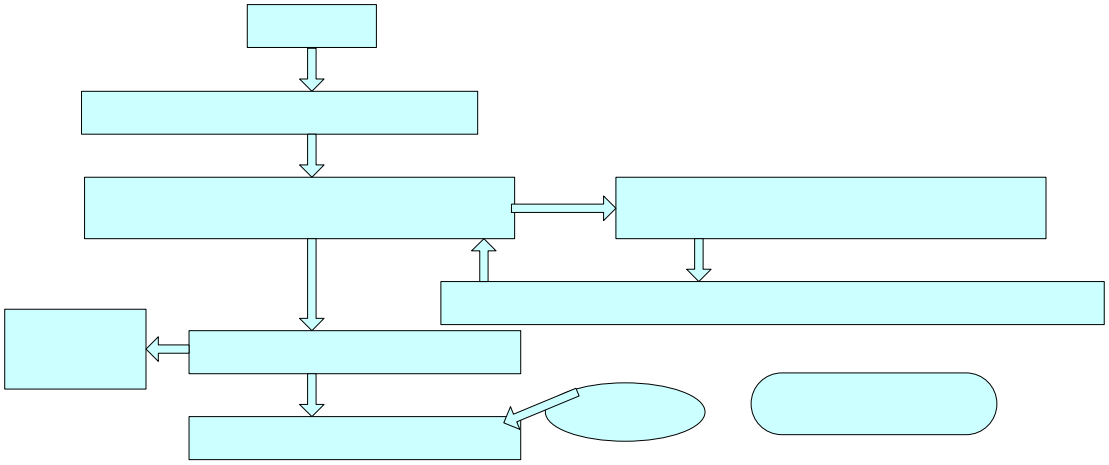

Fig. 8 Approval Procedure for Production for Change to Existing Drug

B Policies Related to CFC Phaseout

33. **Notice on Terminating the Use of Chlorofluorocarbons (CFCs) as Excipient for Medical Aerosols** (Guo Si Yao Jian Zhu No. [2006] 279): This notice issued by SFDA on 22 June 2006, specified 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. China will stop using CFCs as pharmaceutical excipient in the production of metered dose inhalant aerosols from 1 January 2010, and the CFC based metered inhalant aerosol produced before 1 January 2010 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 Phaseout CFCs in the MDI Sector

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

1) find the substitute excipient to replace CFCs,

2) adopt other drug delivery system to 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.
Nebulisers	1. No special breathing coordination required. 2. Works with patients using mechanical ventilation. 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.

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

B Alternative excipient - Hydrofluoroalkanes (HFA)

36. HFA have similar properties as CFCs, however their chemical stability and polarity are slightly lower than that of CFCs. The table 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℃)	92.4	484	88.9	569(20℃)	3.99
Boiling point (℃)	-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 circle of the atmosphere (year)	75	111	7200	15	33

Table 10 Advantages and Disadvantages of using HFA for MDIs

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

C Alternative Technologies

37. In recent years, international MDIs 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.

38. In contrast with the above, the results of our sector investigation show that Chinese MDI manufacturing enterprises possess only preliminary idea instead of actual action plans on the process of CFCs replacement. It is reported that many issues still have to be resolved for introduction of Hydrofluoroalkane as propellants for MDIs:

- **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).

- **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.

- **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 have crystalline transformation and promote crystal growth. Thus, drug characteristics should be taken into account in formulation design, particularly in the design for suspended aerosols.

- **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.

- **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 increase of initial speed. Thus, it is needed to design new actuators, which can both crash the particles and reduce the initial speed.

D Policy and Patent Issues

39. Phaseout 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. The preparation of the technical dossier required for the re-registration, in which a lot of 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.

40. The patent issue is also a big obstacle to conduct CFC phaseout in MDI sector.
41. 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.

42. 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 below:

Table 11 MDI related patent 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

E Transitional Arrangement

43. Due to limited time before 1 January 2010 when the use of virgin CFCs have to be stopped in MDI manufacturing, it will be very difficult for quite a few MDI producers to complete the drug re-registration process. Thus, some CFC should be stockpiled to be used 2010 onwards.
44. For some enterprises, which have more than one applications, if the re-registration can not be completed before 1 January 2010 for some drugs, stockpiled CFC is also needed for the production of those applications.
45. Another concern is the high GWP of HFAs, even though, HFA used for MDI propellant is estimated to account for less than 0.02% of global greenhouse gas emission in 2010. The International Pharmaceutical Aerosol Confederation (IPAC) is persuading the parties to the Kyoto Protocol to allow maintaining the continuous use of HFA in MDI sector.

Chapter V Phase-out Strategy and Policy Framework

46. China will meet the phase out schedule of CFCs for protection of the Ozone layer and compliance with Montreal Protocol as indicated below. The phase out of CFCs in the MDI sector 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.
47. MDI sector plan is the last sector plan for phase out CFCs in China. China will insure that the domestic sale of freshly produced CFCs after 2008 will be limited to the MDI sector only. China will 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, Criteria) to set up future CFCs production plan.

A Objectives

48. The main objectives of this plan are:

    1) To ensure that the phase out of CFCs in China's MDI sector meets the requirements stipulated in the Montreal Protocol and in Accelerated CFC Phase out Plan and/or other Agreements;
    2) To maintain the phase-out momentum and to avoid risk in compliance with the Montreal Protocol for phase-out of CFCs;
    3) To encourage new alternatives in China's MDI sector to improve technology innovation, and to maintain MDI production at the level to meet the clinical demands.

B Phase-out Schedule

49. CFCs consumption in MDI sector: China will make efforts to phaseout CFCs consumption for MDI sector by end of 2009. The phase-out control targets for CFC consumption in MDI sector are listed in Table 12.

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

	2006	2007	2008	2009	2010
Maximum Allowable CFCs consumption					
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.

50. CFCs production during 2008-2010: the CFCs productions for domestic sale are limited for MDI sector and possible essential use only during 2008-2010. Based on the current survey, the maximum consumption for the whole MDI sector will be 300 MT/annul (including CFC-11/CFC-12) during 2007-2009; however, considering ongoing conversion consumption requirement after 2009, the maximum consumption quota issued for the sector will be 550 tons and 550 tons in 2008 and 2009 respectively.

C Policies and Measures

51. ***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 SEPA, and (5) all transaction and trade process must be entered into the information management system.
52. ***Issue CFCs consumption ban for MDI sector***. The National Leading Group of Ozone Layer Protection under the State Council will issue the ban on CFCs consumption to ensure that all the 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.
53. ***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.

54. ***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 phaseout in MDI sector.
55. ***Policies Ranging over the Transition Period (after 2010)***. China will stop using CFCs as excipients for MDI as of 1 January 2010. That means that there are no virgin CFCs produced for the MDI sector. After this date, given the limited timeframe, MDI manufacturers have to use stockpiled CFCs before they can obtain from SFDA the approval numbers for their new products. However, using of stockpiled CFCs would be under stringent supervision of the government. SFDA will make transitional arrangement. When receiving the application form the manufacturers for using CFCs in storage during the transition period, SFDA and SEPA will review and approve the applications.
56. ***Public awareness and education***. China will continue to strengthen the education and training for enterprises, public, and those who are responsible for implementation of ODS policies, especially stakeholders in the MDI sector.
57. ***Supervision after 2010***. After 2010, SFDA and SEPA will monitor non-CFCs aerosol products so as to guarantee its safety and efficacy of clinical application.

Chapter VI Incremental Cost Calculation

58. The incremental costs for the MDI sector have been calculated taking into consideration:

1) MLF guidelines,
2) Activities identified for conversion of CFCs based technologies to no-CFC based ones;
3) Remaining eligible consumption of CFCs in the sector;
4) Enterprise level incremental conversion costs for all the identified eligible enterprises, according to their activities:
5) Identified Technical Assistance activities

A Incremental Cost Identified

Incremental Cost at Enterprise Level

59. The conversion activities at enterprise level include seven items:

1) Research & Development of non-CFC MDIs (including technology screening and formulation development);
2) Registration of the new products;
3) Modification of existing facilities;
4) Training to meet the new production requirements;
5) Validation of new production process ;
6) Incremental operating cost of materials and utilities for production;
7) Promotion of new products on the market.

60. 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:

1) Cost for Research & Development of non-CFC MDIs (including technology screening and formulation development), and
2) Cost for marketing and promotion of new products.

The relationship between conversion activities at enterprise level and the IC requested from MLF are shown as follows:

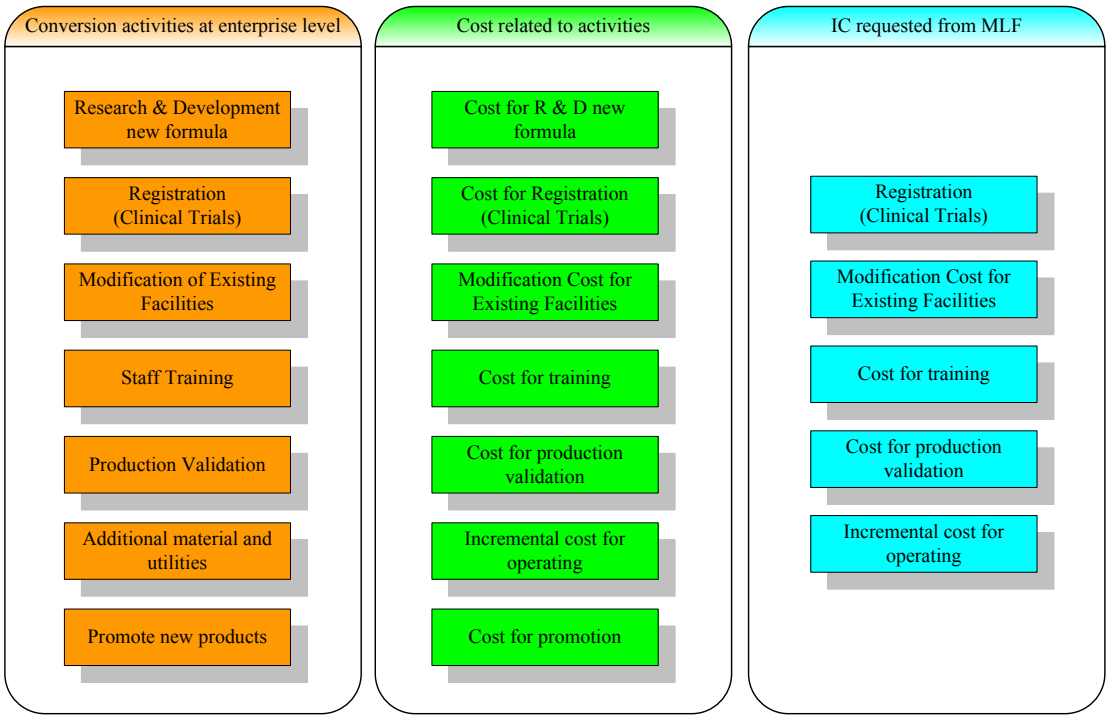

Fig. 9 The relationship between conversion activities at enterprise level to the incremental cost items requested from MLF

61. ***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 may be required based on their annual production. Therefore, it is very difficult to estimate the cost for Research & Development of the new formulation of MDIs.
62. ***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 to 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

63. 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 Basic Assumptions for the Incremental Cost Calculation

Eligibility Criteria for Incremental Cost Calculation

64. There are three factors impacting eligibility: (1) the installation date of the production facility; (2) ownership of the company; (3) export ratio of MDI production; and (4) idle production facilities.

i. **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:
   1) in 1995 no alternative technology was available;
   2) 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.

ii. **Ownership of the company.** There were four enterprises with foreign ownership in 2006, which were not considered in the calculation of the incremental costs. The baseline consumption (2006) of these enterprises with foreign ownership is 14.1 ODP tonnes ODP.

iii. **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. Therefore, the deduction of export ratio of MDI production is considered in the deduction of ownership of the said companies.

iv. **Idle production facilities.** A few eligible manufacturers have not been in production for years. However, as long as they have MDI product approval numbers issued by SFDA, they have legal rights to resume production depending on the market demand. Therefore, for those manufacturers, which had no CFC consumption in 2006, only the cost for preparation of technical dossier for registration purposes are considered as eligible incremental cost.

Key Assumptions for Incremental Operating Cost Calculation

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

i. **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 sector survey and the literature review of international experience, HFC-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 in case of conversion to DPI or other dosage forms, the whole production facility would have to be changed and the registration of the new drug at SFDA would take much more time and would cost much more than the replacement of propellant. It is also to be noted that DPI cannot be universally used for all patients, since a certain group of patients cannot inhale DPIs.

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

C Incremental Investment Cost for Conversion of MDI manufacturers

Preparation of Technical Dossier Required for non-CFC MDI Registration

66. On the basis of preliminary screening tests, the aerosol 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 use 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:

1) the excipient was already approved in China for medical applications;
2) 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).

67. Table 13 lists the content of the dossier for application for change of excipient to a new one, already within the National Standards.

Table 13 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

Table 14 lists the content of dossier for Drug Registration Application for the Use of New Excipients.

Table 14 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

68. Table 15 lists the dossier for Drug Registration Application for Change in Dosage Form.

Table 15 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

69. 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 17 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.
70. 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, enterprises have to make re-registration application 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 36 licenses in production in 2006 the US$ 195,000 will be requested from MLF, as detailed in Table 16. For licenses not in production in 2006 only the most important activities will be compensated at the level of US$ 85,000, the remaining will be borne by the enterprises.

Table 16 Cost of Preparation of Technical Dossier for Registration

No.	Application Materials	For Licences in Production in 2006 (US$ $)	For Licences Not in Production in 2006 (US$ $)
1	Study of Production Process	12,500	7,500
2	Study of Quality	7,500	7,500
3	Pharmacological Study	20,000	0
4	Toxicological Study	20,000	0
5	Special safety Test	15,000	0
6	Clinical Test	120,000	70,000
	Subtotal	*195,000*	*85,000*
	Number of License with Production in 2006	36	41
	Sub - Total	7,020,000	3,485,000
Grand Total		**10,505,000**	

Cost of Modification of Existing Production Facilities

71. The requested incremental cost for modification of existing facilities shown in Table 17 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.
72. Based on information in Table 7, Section F in Chapter II, currently, 17 enterprises produced CFC based MDIs in baseline year 2006, among which only 15 enterprises with 17 production lines are of 100% Chinese ownership. The cost of conversion of these 17 production lines in the 15 Chinese enterprises will be requested from the MLF.
73. The cost for converting/replacing of the drug mixing tank, piping, valves, sealings, labour etc. for the enterprise with annual CFC consumption of
    - more than 100 tonnes, will be calculated at USD 800,000/line.
    - 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.
    - less than 10 tonnes, the compensation for these changes are calculated as USD 100,000/line.
74. The cost of conversion/replacement of filling/crimping line equipment is also classified into three categories:
    - USD 520,000 for those with production more than 5 million cans/year;
    - USD 260,000 for those with production less than 5 million and more than 1 million cans/year;
    - USD 100,000 for those with production less than 1 million cans/year.

Table 17 Cost of Modification of Existing Facilities

Company Code	Company Name	CFC Consumption 2006 (kg)	2006 Output (can)	Cost for Mixing Tank and Related (US$)	Cost for Filling/ Crimping Line (US$)	Total (US$)
2	Beijing Haiderun Pharmaceutical Co., Ltd.	9,366	851,400	100,000	100,000	200,000
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1560	124,800	100,000	100,000	200,000
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	131	10898	100,000	100,000	200,000
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	300	30000	100,000	100,000	200,000
15	Henan Zhongfu Pharmaceutical Co., Ltd.	2,205	150,000 -	100,000	100,000	200,000
18	Jinan Weiming Pharmaceutical Co., Ltd.	63,786	4,832,300	420,000	260,000	680,000
19	Penglai Nuokang Pharmaceutical Co.,Ltd.	28,928	2,552,299	420,000	260,000	680,000
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	120,578	6,704,000	800,000	520,000	1,320,000
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	3,320	114,560	100,000	100,000	200,000
25	Pharmaceutical Factory of Shanxi Medical University	708	35,554	100,000	100,000	200,000
28	Shanghai Pharmaceutical (Group) Co., Ltd Sine Pharma Laboratory	19,434	1,132,455	420,000	260,000	680,000
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	4,840	313,689	100,000	100,000	200,000
36	Chongqing Kerui Pharmaceutical Co., Ltd.	7,377	448,800	100,000	100,000	200,000
37	Zigong Chenguang Pharmaceutical Co., Ltd.	70	2,020	100,000	100,000	200,000
38	Jiangsu Tianji Pharmaceutical Co., Ltd.	4,202	466,982	100,000	100,000	200,000
	Grand Total	**280,908**	**18,677,763**			**5,560,000**

Validation Process

75. *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.

76. 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.
77. 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.
78. 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.
79. 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.
80. 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 malfunction.
81. Revalidation includes compulsive validation, alternate validation and regular validation

Validation for Changing Excipient (Alternative Propellant)

82. Changing of excipients requires prospective validation, concurrent validation, retrospective validation and revalidation. The validation includes:

    i) validation of workshop;
    ii) validation of public utilities;
    iii) validation of computer system;

iv) validation of production equipment;
v) validation of production process;
vi) validation of personnel;
vii) validation of other relevant items.

i. Validation of Workshop, Public Utility System and Computer System

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

ii. Validation of Production Equipment

d. 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.

iii. Validation of Production Process

e. Validation items for dispensing preparation includes: temperature of liquid product in compound vessels, particle sizes and homogenization of the drug liquid.
f. Validation of cleaning effect of containers: various impurities placed into the container should be totally removed by cleaning.
g. 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.
h. Validation items for weighing equipment include weighing accuracy and elimination of under-weighed and over-weighed samples.
i. 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.
j. Validation item for spray inspection include the performance of spray and elimination of samples that don't spray or don't spray constantly.
k. 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.

l. 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.

iv. Validation for Personnel and Other Relevant Items

m. 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.

n. 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.

Validation for Change in Dosage Form

83. 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.

84. There are 17 eligible production lines in 15 eligible enterprises, which had MDI production in 2006. Cost for production validation is detailed in Table 18.

Table 18 Cost of Production Validation

SN	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 with baseline production		17
	Grand Total, Validation		**680,000**

Staff Training

85. 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 19 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$)			*27,500*
Number of Eligible Enterprises			15
Grand Total, Training (US$)			**412,500**

D Incremental Operating Cost

86. The calculation is based on the consumption, production and cost data collected from manufacturers during the survey undertaken by NICPBP, SFDA, SEPA and UNIDO. Calculation of IOC is based on the ExCom guidelines and using Incremental Operating Cost for a period of one year. In this project, IOC is calculated based on the CFC consumption

and production output of the year preceding the submission of the document, i.e. in 2006. The price differences for HFA products and CFC products are shown in Table 20.

Table 20 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		0.16875		0.19507
Valve		0.04813		0.19287
Subtotal for packaging		0.21688		0.38793

87. The foreign ownership enterprises were excluded in the process of IOC calculation.
88. Literature reviews indicate that on average, HFA MDI uses 30% less propellant than a CFC MDI.
89. The calculation for each enterprises based on the above parameters is shown below in Table 21. The total IOC is US$3,502,689.

Table 21 Enterprise level IOC Calculation

Company Code	Company Name	Year of Establ.	CFC Consumption in 2006, (kg)	IOC, Propellant, US$	Output in 2006, (cans)	IOC, Can, US$	Total IOC (US$)
2	Beijing Haiderun Pharmaceutical Co., Ltd.	1978	9,366	16,259	851,400	145,632	161,891
8	Guangzhou Dongkang Pharmaceutical Co., Ltd.	1988	1,560	2,708	124,800	21,347	24,055
9	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	1979	131	227	10,898	1,864	2,091
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	1982	300	521	30,000	5,132	5,652
15	Henan Zhongfu Pharmaceutical Co., Ltd.	1992	2,205	3,828	150,000	25,658	29,485
18	Jinan Weiming Pharmaceutical Co., Ltd.	1979	63,786	110,732	4,832,300	826,565	937,297
19	Penglai Nuokang Pharmaceutical Co., Ltd.	1993	28,928	50,219	2,552,299	436,571	486,790
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	1993	120,578	209,323	6,704,000	1,146,719	1,356,043
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	2001	3,320	5,764	114,560	19,595	25,359
25	Pharmaceutical Factory Shanxi Medical University	1994	708	1,229	35,554	6,082	7,311
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	1982	19,434	33,737	1,132,455	193,706	227,444
32	No.1 Pharmaceutical Co., Ltd. of Wuxi Shanhe Group	1965	4,840	8,402	313,689	53,657	62,059
36	Chongqing Kerui Pharmaceutical Co., Ltd.	1975	7,377	12,806	448,800	76,767	89,573
37	Zigong Chenguang Pharmaceutical Co., Ltd.	1981	70	122	2,020	346	467
38	Jiangsu Tianji Pharmaceutical Co., Ltd.		4,202	7,295	466,982	79,877	87,172
Grand Total, IOC			**266,804**	**463,172**	**17,769,757**	**3,039,517**	**3,502,689**

E Contingency of incremental capital cost

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

F Technical Assistance (TA)

91. 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 aerosol manufacturers, 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.

G Summary

92. 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 280.9 ODP tonnes/year CFCs in the MDI sector of China .

Table 22 Summary of incremental costs

Item	Incremental Cost (US$)
Preparation of Technical Dossiers Required for non-CFC MDI Registration	**10,505,000**
Modification of Existing Production Facilities	**5,560,000**
Production Validation	680,000
Staff Training	412,500
Incremental Operating Cost	3,502,689
Technical Assistance	1,100,000
Contingency*	556,000
Total	**22,316,189**
Implementing Agency Support Cost	**1,673,714**
Total Funding Requested	**23,989,903**
Cost Effectiveness, US$/kg	**79.45**

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

Chapter VII Operating Mechanism

A Agreement between SEPA and UNIDO

93. Following approval of the Sector Plan by the ExCom, SEPA and UNIDO will sign an agreement, which will indicate that UNIDO entrusts SEPA to implement the Sector Plan under UNIDO's supervision. According to the Agreement, UNIDO will disburse grants to SEPA 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.
94. 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.
95. After signing the Agreement with UNIDO, SEPA 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.
96. Based on the satisfactory progress report of SEPA and verified achievement of the phase-out target. UNIDO will disburse funds to a special account; ODS Special Account set up in SEPA after receiving SEPA's funding request.

B Roles and Responsibilities

97. The MDI Sector Plan will be executed by SEPA, acting on behalf of Chinese Government. The daily work will be done by FECO, one affiliated institution of SEPA. SEPA and SFDA will jointly set up the SWG, whose office will be located in FECO. SWG will be responsible for preparing the Work Plan. SEPA 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.
98. Roles and Responsibilities of each institution involved are described as follows.

UNIDO

99. 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 SEPA and SFDA;
b) Supervise SEPA, SFDA and the recipient companies to complete this Sector Plan;
c) Provide necessary technological and managerial support to SEPA and SFDA for the implementation of this Sector Plan;
d) Pay the fund of the Sector Plan to SEPA 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.

SEPA

100. Will through PMO, be responsible for overall project management and coordination for the implementation of the Sector Plan. SEPA 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.

SFDA

101. Will cooperate with SEPA 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 SEPA;

d) Coordinate the relationships among SEPA, SWG, DIA and counterpart enterprises;

e) Help SEPA to realize the CFC phase out target indicated in the Sector Plan,

f) Monitor the destruction of CFC equipment at the recepient 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 SEPA so that they can be issued and enter into force subsequently;

h) Design CFCs phase-out policies in MDI sector, in cooperation with SEPA;

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.

SWG

102. Will, with the backstopping of SEPA 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, SEPA/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 SEPA/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.

DIA

103. 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 Audit and Reporting

104. 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 SEPA, SFDA and UNIDO. UNIDO will report to ExCom on the progress of implementation and financial status of the project.
105. UNIDO will audit each year's project implementation. UNIDO will supervise implementation of the Work Plan, including spot check of project records and periodic check on enterprises.
106. SEPA will be responsible for conducting local annual audits according to regulations set for the ODS Special Account.

D Destruction of CFC Equipment and Certification

107. 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 SEPA and enterprises. SEPA 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

108. This Chapter presents the Action Plan and schedule for implementing CFCs phase-out for China's MDI sector. The proposed Action Plan is summarized in table 23.

Table 23 Phase-out Targets and Funding Request from 2007 to 2010 in Action Plan

	2006 (Baseline)	2007 (Estimate)	2008	2009	2010
CFC Consumption Targets					
Maximum Allowable CFC Consumption/Production under the Accelerated CFC Phase out Plan (except for essential use consumption)			550	550	0
CFCs Consumption (newly produced CFCs)	280.9	310	310*	310*	0
CFCs from Stockpiled CFCs	0		0	0	n.a.**
Funding Request(USD'000)					
Enterprise-Level Activities	n.a.	21,216,189			
Technical Assistance Activities	n.a.	1,100,000			
Support Cost (7.5%)	n.a.	1,673,714			
Total MLF Cost	n.a.	23,989,903			
Actions					
Enterprise-Level Activities	n.a.		(1) sign CFC phase out contract with SFDA/SEPA	(1) Modification of Existing Facilities	
			(2) Identify alternatives by mid 2008.	(2)Validation and New Production	
			(3) Start Registration Application.	(3) Workshops, Trainings	
Technical Assistance Activities			(1) Workshops on alternatives, new processes, technical requirements, consumption quota, contract issues etc.;	(1) Workshops on alternatives;	(1) Workshops on new products and technical standards.
			(2) Survey on technical standards and other issues.	(2) Survey of conversion issues as necessary.	

	2006 (Baseline)	2007 (Estimate)	2008	2009	2010
Policies and measures			(1) Issue and enforce consumption quota licenses to MDI producers;	(1) Enforcement of quotas and verification audit of CFCs consumptions	(1) Enforcement of quotas and verification audit of CFCs consumptions
			(2) Issue ban on use of CFCs for MDI production.	(2) Preparation of Progress Reports covering all sector plan activities.	(2) Preparation of Progress Reports covering all sector plan activities.
			(3) Verification audit of CFCs consumptions		
Indicators					
			(1) All eligible MDI producers signed contract for CFC phaseout.	(1) CFC production and CFC consumption quota are lower than 550 tones ODP respectively.	(1) CFC production and fresh CFC consumption quota for MDI are 0 ODP tonnes.
			(2) Consumption quota system is established.	(2) several TA activity contracts are signed.	
			(3) Relevant TA activity contracts are signed.	(3) 5 producers completed conversion.	
			(4) National CFC production and CFC consumption quota are lower than 550 tones ODP respectively.		
			(5) Ban on use of CFCs for MDI production is issued.		

* Maximum quota will be issued to allowed MDI producers stockpile CFCs as needed during the conversion.

** Use of stockpiled CFCs required in the ongoing process of conversion.

Appendix 1

Chinese Producers & 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	
03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H11020197	

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
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	
09	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	B24	Zhichuanling Aerosol	Z52020225	yes

Company Code	Company Name	Product Code	Product Name	Approval No.	Traditional Chinese Medicine
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	