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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fiftieth Meeting
New Delhi, 6-10 November 2006

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 in the China pharmaceutical aerosol sector — World Bank

Halon

- Sector plan for halon phase-out: 2007 annual programme — World Bank

Process agent

- Phase-out of the production and consumption of CTC for process agent and other non-identified uses (phase I): 2007 annual programme — World Bank
- Sector plan for phase-out of ODS process agent applications (phase II) and corresponding CTC production: 2007 annual programme — World Bank

Production

- Sector plan for the CFC production phase-out: 2007 annual programme

Solvent

- ODS phase-out in China solvent sector: 2007 annual programme — UNDP

PROJECT EVALUATION SHEET – MULTI-YEAR PROJECTS
CHINA

PROJECT TITLE	BILATERAL/IMPLEMENTING AGENCY
Sector plan for phase-out of CFCs in the China pharmaceutical aerosol sector	World Bank

NATIONAL CO-ORDINATING AGENCY:	State Environment Protection Administration

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2005, AS OF OCTOBER 2006)

CFC	-		

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

ODS	Aerosol	Foam	Ref.	ODS	Solvents	Process agent	Fumigant
CFC-11	101.98						
CFC-12	374.264						

CFC consumption remaining eligible for funding (ODP tonnes)	

CURRENT YEAR BUSINESS PLAN: Total funding: US $5,375 million: Total phase-out: 345.0 ODP tonnes

PROJECT DATA		2006	2007	2008	2009	2010	Total
CFC (ODP tonnes)	Montreal Protocol limits	**4,471.5**	4,471.5	4,471.5	4,471.5	Tbd	
	Annual consumption limit	**8,385.57**	8,385.57	8,385.57	8,385.57	Tbd	
	Annual phase-out from ongoing projects	**485.1**	485.1	0	0	0	485.1
	Annual phase-out newly addressed						
	Annual unfunded phase-out						
TOTAL ODS CONSUMPTION TO BE PHASED OUT		**485.1**	**485.1**	**0**	**0**	**0**	**485.1**
Total ODS consumption to be phased-in (HCFCs)							
Project cost as originally submitted (US $)							
Final project costs (US $):							
Funding for World Bank		**12,680**	0	0	3,247	0	15,927
Total project funding		**12,680**	**0**	**0**	**3,247**	**0**	**15,927**
Final support costs (US $):							
Support cost for World Bank		**951**	0	0	244	0	1,195
Total support costs		**951**	**0**	**0**	**244**	**0**	**1,195**
TOTAL COST TO MULTILATERAL FUND (US $)		**13,631**	**0**	**0**	**3,491**	**0**	**17,122**
Final project cost effectiveness (US $/kg)							

FUNDING REQUEST: Approval of funding for the first tranche (2006]) as indicated above.

SECRETARIAT'S RECOMMENDATION	Pending

PROJECT DESCRIPTION

1. On behalf of the Government of China, the World Bank has submitted a sector plan for phase-out of CFC consumption in China's pharmaceutical aerosol sector (Pharmaceutical Aerosol Plan), at a total cost to the Multilateral Fund of US $15,926,838, plus agency support costs of US $1,194,513, for consideration by the Executive Committee at its 50th Meeting. A copy of the Pharmaceutical Aerosol Plan as submitted by the World Bank is attached to the present document.

Project summary

2. According to the proposal, there are 39 pharmaceutical aerosol enterprises in China, with 48 production lines and 63 pharmaceutical aerosol products (42 skin aerosol products and 21 cavity aerosol products). The average CFC consumption for the production period 2003-2005 has been estimated at 485.1 ODP tonnes of CFC-11 and CFC-12. Of all the production facilities, 32 enterprises with 22 production lines would be eligible to receive assistance from the Multilateral Fund. Thus, the total amount of CFCs that will be phased out through the Pharmaceutical Sector Plan has been estimated at 464.4 ODP tonnes.

3. The Pharmaceutical Aerosol Plan proposes the replacement of CFC propellants by HFC-134a. The total cost of the Pharmaceutical Aerosol Plan has been based on the following unitary costs:

Cost Item	Unitary Cost (US $)	Units	Total Cost (US $)
Technical assistance	1,100,000	1	1,100,000
Screening substitutes	43,750.00	63	2,756,250
Technical dossier for skin aerosols	75,000.00	42	3,150,000
Technical dossier for cavity aerosols	93,750.00	21	1,968,750
Plant modifications (skin aerosol line)	63,750.00	14	892,500
Plant modifications (cavity aerosol line)	38,750.00	8	310,000
Production validation (per production line)	37,500.00	22	825,000
Training programme (per production line)	17,500.00	22	385,000
Operating cost	3,536,824	1	3,536,824
Contingency	1,492,432.00	1	1,492,432
Adjustment (foreign ownership)	(489,918.00)	1	(489,918)
Total			15,926,838

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

4. The Secretariat undertook a thorough analysis of the project proposal and provided detailed comments and observations to the World Bank. The main issues raised by the Secretariat's review can be summarized as follows:

(a) Date of establishment of production lines;

(b) Assistance for pharmaceutical products which are not currently being produced;

(c) Industrial rationalization;

(d) Selection of alternative propellant and production line modifications;

(e) Issues related to technical assistance;

(f) Cost-effectiveness; and

(g) Level of funding proposed.

5. A summary of the issues raised by the Secretariat and responses received from the World Bank are presented below.

Date of establishment of production lines

6. In reviewing the information presented in the Pharmaceutical Aerosol Plan, the Secretariat noted that eight of the 39 enterprises identified were established after the cut-off date of 25 July 1995, as shown in Table 1 attached. The total CFC consumption of these enterprises is 2.682 ODP tonnes (representing 0.55 per cent of the total CFC consumption in pharmaceutical aerosols) and the total amount of funding being requested is US $2,050,000. On the basis of decision 17/7 (i.e., in the light of technological advances, not to consider any projects to convert any ODS-based capacity installed after 25 July 1995), these enterprises are not eligible for funding.

7. The World Bank responded by stating that substitute technologies were not available in the pharmaceutical sector in China in 1995. In fact, pharmaceutical aerosols were specifically excluded from the CFC ban in China's 1997 ODS regulation. According to the World Bank, decision 17/7 applied to the foam, refrigeration and general aerosol sectors, not the pharmaceutical aerosol sector. For this reason, the Executive Committee had not approved a single pharmaceutical aerosol project before 1995.

8. The Secretariat wishes to note, however, that the Executive Committee has approved the following five investment projects for the phase-out of CFCs used in the production of pharmaceutical aerosols in three countries, as shown in the table below. The issue of availability of substitute technologies prior to 1995 was not raised in any of these projects:

Country	Project	ODP Tonnes	CE (US $/kg)	Date of Approval
India	Aerosol Conversion at Midas Care Pharmaceuticals	25.20	4.40	Mar-98
India	Aero Pharma aerosol conversion	36.00	1.74	Nov-93
India	Terminal umbrella project in the aerosol sector	132.50	4.40	Nov-02
Macedonia	Phase-out of CFC-11 and CFC-12 in the manufacture of aerosols by conversion to HFC and hydrocarbon propellants at Alkaloid A.D.	25.00	4.40	Dec-00
Romania	Phase-out of CFC-12 in the manufacture of pharmaceutical aerosols by conversion to HFC-134a propellant at MEBRA, Brasov (terminal aerosol sector project)	46.50	4.40	Dec-04

Assistance for pharmaceutical products which are not currently being produced

9. The Secretariat pointed out that 14 enterprises included in the Pharmaceutical Aerosol Plan have no reported CFC baseline consumption, as shown in Table 2. For these enterprises, US $2,832,500 (equivalent to 18 per cent of the total cost of the Pharmaceutical Aerosol Plan) is

being requested solely for screening of substitutes (at US $43,750 per product) and for the preparation of technical dossiers (at US $75,000 for each skin aerosol and US $93,750 for each cavity aerosol). At its 16th Meeting, the Executive Committee decided that ODS consumption should be calculated on the basis of either the year, or an average of the three years, immediately preceding project preparation. Therefore, the enterprises in question are not eligible for financial assistance from the Multilateral Fund.

10. The World Bank recognized that not all of the companies in the project proposal have yearly production planning for all the pharmaceutical aerosol applications. However, China's Drug Administration Law makes it mandatory to submit any alteration to an approved drug to the drug regulation agency before it can be produced at a later date. Funding for screening substitutes and tests for registration for these enterprises is needed since the phase-out of CFCs in pharmaceutical aerosols can only be ensured when the enterprises have completed their substitute screening and registration processes. Furthermore, if left alone, some companies might resume production with CFCs and could undermine the phase-out programme.

11. Based on the rules of the Multilateral Fund, the Secretariat concludes that only 16 enterprises are eligible for funding (as shown in Table 3), since they were established prior to 25 July 1995, have CFC baseline consumption and are currently using CFCs (i.e., 418.34 ODP tonnes after considering the foreign ownership component of two of the enterprises).

Industrial rationalization

12. In reviewing the CFC consumption by type of aerosol produced by each of the 16 enterprises eligible for funding (Table 4), the Secretariat noted that:

(a) CFC consumption for the manufacture of 12 pharmaceutical aerosols is very small, ranging from 3 kg per year to 797 kg per year;

(b) Except for one enterprise (No. 24 with a total CFC consumption of 273.3 ODP tonnes represents 56.3 per cent of the total CFC consumption in the sector), the number of aerosol cans produced varies from less than one can per day to a maximum of 4,505 cans per day. This production is very small; and

(c) The total amount of CFCs used for the production of the 6 cavity aerosol products is only 6.494 ODP tonnes/year (i.e., less than 1.5 per cent of the total amount of CFCs used by these enterprises), with a total production of 208,384 cans per year (less than 3.0 per cent of the total production of cans).

13. In response to the Secretariat's analysis, the World Bank said that small production amounts for some of the companies did not reflect the importance of the product. The small CFC consumption for the manufacture of 12 pharmaceutical aerosols was due to market and clinical demands, frequency of use and price, which made production output vary considerably. Furthermore, the data presented in the proposal was based on actual production by the enterprises, which could be expanded at any time once the legally prescriptive conditions and capacity for production were achieved.

14. In addition to its observations with regard to the distribution of CFC use among companies, the Secretariat pointed out that, contrary to the practice in formulating several of the

national sectoral phase-out plans approved for China and all other Article 5 countries, industrial rationalization had not been considered in the Pharmaceutical Aerosol Plan. The World Bank responded that China had changed, and industrial rationalization was no longer a matter of dictating a single measure, but rather a matter of entering into voluntary agreements with the various companies.

Selection of alternative propellant and production line modifications

15. The Pharmaceutical Aerosol Plan proposes to replace CFCs with HFC-134a. Except for those cavity pharmaceutical aerosols that are applied to the mouth (and which represents a very small percentage of the overall pharmaceutical aerosols in China), expert advice available to the Secretariat indicates that other products could be converted using hydrocarbon propellants. This conclusion, which was questioned by the World Bank, is based on documented evidence of HC propellant use in pharmaceutical aerosol products available worldwide,[1] and on the Secretariat's experience with projects for the conversion of pharmaceutical aerosols funded by the Multilateral Fund in at least three Article 5 countries, where several pharmaceutical aerosols are currently being produced with HC propellants.[2]

16. The Pharmaceutical Aerosol Plan estimated the capital costs for the conversion of the 22 production lines from CFCs to either HFC-134a propellant at US $1,202,500, or to hydrocarbon (HC) propellant at US $7,920,000. The cost analysis for the conversion to HFC-134a propellant was based on a unitary cost of US $63,750 for each of the 14 lines used for the production of skin aerosol products and a unitary cost of US $38,750 for each of the 8 lines used for the production of cavity aerosol products. The cost analysis in the Pharmaceutical Aerosol Plan for the conversion to HC propellant was based on a unitary cost of US $360,000 for each of the 22 production lines (which includes US $190,000 for the replacement of the existing production lines).

17. However, this cost analysis fails to acknowledge that there is no need to replace the entire production line when replacing CFC with HC propellant and that within the level of funding that has been approved in aerosol projects (including pharmaceutical aerosols) safety equipment to properly handle HC can be installed, and technology transfer for the reformulation of the aerosol products and training can be provided. HC technology would yield operating savings of US $745,000 for a two-year period (assuming US $1.00/kg of HC, compared to the actual price of US $7.38/kg of HFC-134a), whereas the Pharmaceutical Aerosol Plan is requesting US $3,536,824 as incremental operating costs for HFC-134a technology. Furthermore, the proposal to replace the production lines (at a cost of US $190,000 per line), would imply an increase of the production capacity for the majority of the lines.

[1] A few examples of these products are the following: hydrocortisone acetate and pramoxine hydrochloride topical aerosol foam for anal use; topical corticosteroids used as anti-inflammatory and antipruritic agents; several anti-fungi aerosols for treatment of tinea pedis (athlete's foot), tinea cruris (jock itch) and tina corporis due to T. rubrum, T. mentagrophytes and E. flocossum, exclusive of nails and hair area; betamethasone valerate for the treatment of corticosteroid-responsive scalp dermatoses; first aid antiseptic liquid bandage spray; aerosol formulation containing beclomethasone dipropionate; and topical anaesthetic spray containing benzocaine as active ingredient).

[2] These products include: pain relief and muscle relaxant which uses methyl salicylate and allied chemicals; local anaesthetic having a chemical like lidocaine; pharmaceutical product for skin burns relief and remedy having antiseptics and anaesthetics; povidone iodine (broad spectrum antiseptic and antifungal); antisceptic air freshener containing BKC; medicinal body deodorant; and wound dressing aerosol which contains cetrimide; dental products containing lidocaine and other chemicals to stop bleeding; and rubbing alcohol spray for massage containing isopropyl alcohol.

18. In response, the World Bank enumerated the benefits of the chosen HFC-134a technology including that HFC-134a is produced in China, and shares more similarities with CFCs, entailing fewer changes in the production line and facilitating the process of registering substitutes. With regard to altering production equipment, the World Bank pointed out that there are many differences in equipment types and models in the pharmaceutical aerosol production lines in China. Given the advances in pharmaceutical manufacturing machines, it would be impractical to purchase the low-level equipment needed to replace the current combination of automatic and semi-automatic production lines, particularly since the principle of the programme is to maintain the original scale and level of production without enlarging or reducing the production capacity.

19. With regard to the capital cost savings represented by HC technology, according to the World Bank, after the replacement of CFCs the quantity of HC used in each aerosol must be determined according to the result from the substitute-screening test. Assuming that the proportions of drug solution and propellant were almost unchanged, the low density of hydrocarbons would require the volume of tanks to be increased by more than 50 per cent, thus increasing costs by about 30 per cent.

20. Finally, the World Bank stated that the price of aerosol-grade HC on the domestic market is about US $1.56 kg, and went on to say that price was not the only factor in determining the best substitute. The World Bank expressed the view that, according to its cost assessment of the various substitutes, the proposal for funding was based on the least costly option.

Issues related to technical assistance

21. In reviewing the unitary costs proposed in the Pharmaceutical Aerosol Plan, the Secretariat noted that US $1.1 million has been requested for technical assistance activities, which include workshops, training programmes, public awareness activities, consultants, study tours and other unidentified activities. An additional US $9,085,000 has been requested for the following activities, which are also related to technical assistance: US $2,756,250 for screening substitutes, US $5,118,750 for the preparation for technical dossiers for registration; US $825,000 for production validation; and US $385,000 for staff training. In many cases, this would constitute double counting since similar activities are requested more than once (i.e., toxicological evaluations and tests, studies on quality, training for sales staff).

22. Furthermore, the Secretariat pointed out that the levels of the funding being requested for screening substitutes and for the preparation of technical dossiers are the same, irrespective of the production levels of each product, i.e., US $118,750.00 for the production of 323 cans per year for one skin aerosol product, while a similar amount is requested for 5,306,667 cans per year for another skin aerosol product. The eligibility for the preparation of technical dossiers for registration has to be further demonstrated. For instance, only those CFC-based pharmaceutical aerosols for which a technical dossier had been prepared prior to July 1995 might be considered eligible for funding. The level of incremental funding could only be assessed on the basis of the costs actually paid for the technical dossier.

23. Similarly, the request for production validation is the same irrespective of the production output and nature, i.e., US $37,500 for a production line of 79 cans per year or for a production line of 5,306,667 cans per year. Here too, the eligibility of the request for production validation

has to be further demonstrated. Only those CFC-based production lines that have already been validated might be considered eligible for funding.

24. In response to the double-counting issue raised by the Secretariat, the World Bank stated that the training under the technical assistance programme includes: the protection of the ozone layer; the implementing procedures and requirement for the Fund-supported ODS phase-out programme; instruction for purchasing, financing and reporting; auditing requirements; and policy. However, the training conducted for each enterprise consists of the introduction of substitutes or substituting techniques at the production lines.

25. With regard to the preparation of technical dossiers, the World Bank clarified that obtaining approval from the drug regulation agency usually takes three to four years. Therefore, the research and development of pharmaceutical aerosol applications approved in July 1999 must have started in 1995 or before. Due to the particularity of drug administration regulations, the proposal suggests that 1 July 1999 may be specified as the cut-off date in China's pharmaceutical sector. Furthermore, when one application is produced by several enterprises, the production process is often different, and thus the technical dossier must be finished independently, which is why 24 technical dossiers must be submitted by 16 enterprises for the 20 applications.

26. Finally, with regard to the cost of screening and product validation, the World Bank advised that, since the substitute screening and tests for registration are required by law, the necessary procedures for the CFC conversion programme are independent of the quantities of an aerosol being manufactured. Finally, due to the specificity of drugs, the cost of technical activities carried out to meet legal requirements is very high, and there is no direct relation with the level of production of pharmaceutical aerosols or the CFCs consumption.

Cost-effectiveness

27. In reviewing the Pharmaceutical Aerosol Plan, the Secretariat developed a table associating each unitary cost proposed in the Plan to each of the 16 eligible enterprises (Table 5). In this analysis, the total requests for technical assistance (US $1,100,000) and operating costs (US $3,536,824), were divided by the total amount of CFCs to be phased out (i.e., 465.355 ODP tonnes) and pro-rated among the 16 enterprises eligible for funding on the basis of their total CFC consumption.

28. Based on this analysis, the Secretariat noted that the overall cost-effectiveness (CE) of the project as submitted is US $34.30/kg, which is almost 8 times the CE threshold for the aerosol sector established by the Executive Committee at its 16th Meeting (i.e., US $4.40/kg). The CE of the seven "most cost-effective" enterprises ranges from US $11.94/kg to US $57.65/kg. Four enterprises have a CE value between US $109.12/kg and US $645.86/kg. The five "least cost-effective" enterprises have CE values between US $1,151.81/kg and US $40,278.84/kg.

29. The Secretariat's analysis also shows that the most cost-effective enterprise is the largest producer of pharmaceutical aerosols in China (plant No. 24), with a CE of US $11.70/kg. US $2,081,879 of the total cost for the conversion of the enterprise (US $3,198,809) is operating costs associated with HFC-134a technology. If the enterprise was to be converted to HC, and the associated operating savings were not discounted from the total cost, the CE of the conversion would be US $3.56/kg.

30. In response to the Secretariat's observations, the World Bank admitted that the CE of the project is high. However, as this is a new sector, the Bank disagreed that the threshold of US $4.40/kg for general aerosol could be applied, particularly since cost elements not relevant to general aerosols are necessary for pharmaceutical aerosols. The Executive Committee has not yet discussed, nor decided on polices and guidelines for the pharmaceutical aerosol sector.

31. Also according to the World Bank, the method used to calculate the CE is inapplicable to pharmaceutical aerosols. Although substitute screening and tests for registration are the key points to ensure the phase-out of CFCs, they belong to the scope of the technical activity. By subtracting these two costs, and the cost for the use of a substitute (at US $5,593,869), the overall CE value is between US $6.45 US $6.71 per kg.

32. The Secretariat further notes that the five pharmaceutical aerosol projects that have been funded by the Fund had a CE equal to or below the CE threshold of US $4.40/kg for the aerosol sector. The projects covered all eligible costs associated with the replacement of CFCs to either HC or HFC-134a propellants, including capital costs, operating costs/savings, activities relative to technology transfer and training.

Level of funding proposed

33. Taking into consideration that only 1.4 per cent of the total eligible CFC consumption is for the production of the cavity aerosol products for which HFC-134a might be required, it would appear that CFCs could be replaced by HC for the production of the majority of pharmaceutical aerosol products. On the basis of the level of CFC consumption at the enterprise level (from 13 kg per year to a maximum of 273,333 kg per year), and based on the experience gained in the Multilateral Fund for the conversion of aerosol production lines, and consistent with the current policies and guidelines of the Multilateral Fund, the Secretariat concluded that the total incremental cost of the Pharmaceutical Aerosol Plan should be based on the CE threshold value for the aerosol sector plus additional support (possibly 20 per cent of the total cost) for technical assistance activities.

34. The World Bank responded that, while the project is not as cost-effective as the Secretariat might want, all of the costs are incremental and eligible and should be considered as such. It reiterated that the pharmaceutical aerosol sector includes components that are not relevant to the general aerosol sector, hence the CE for that sector should not be applied. Finally, the 1995 cut-off date should not be applied, since the technology was not available in China at that time.

RECOMMENDATION

35. Pending.

Table 1 – List of enterprises established after 25 July 1995

No.	Name	Lines	CFC (kg)	Skin Products	Cavity Products
17	Shandong Bencao Pharmaceutical Co., Ltd	1	428	-	A26, A38
26	Huayi Pharmaceutical Co., Ltd	1	380		A41
28	Heilongjiang Tianlong Pharmaceutical Co., Ltd	2	300	A23, A25, A29	A15, A40
29	Guizhou Hongyu Pharmaceutical Co., Ltd	1	1,231	A36	A01
30	Sanpu Pharmaceutical Co., Ltd	0	13	-	A04
33	Sanjing Pharmaceutical Co., Ltd of Harbin Pharmaceutical Group	1	145	A23	A18, A21, A44
34	Hubei Lishizhen Medical Group Co., Ltd	1	137	A37	-
35	Shannxi Fengwuchendayaotang Pharmaceutical Factory Co., Ltd	1	48	-	A31
	Total	**8**	**2,682**		

Table 2 – List of enterprises with no CFC consumption

No.	Name	Ownership %	Skin Products	Cavity Products
2	Beijing Haiderun Pharmaceutical Co., Ltd	100	A25, A28, A30	
3	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd	100	A09, A23	A40
4	Externally Applied Agent Factory of Guangzhou Baiyunshan Pharmaceutical Co., Ltd	100	A23	
6	Beijing Double-Crane Modern Pharmaceutical Technology Co., Ltd	100	A25	
8	Xinyi Pharmaceutical General Factory of Shanghai Pharmaceutical Group Co., Ltd	100	A24, A35	A06
10	Shanghai Fuxingzhaohui Pharmaceutical Co., Ltd	100	A42	
15	Harbin Hengcang Pharmaceutical Co., Ltd	100	A25	
22	Hangzhou Sino-US Huadong Pharmaceutical Co., Ltd	75	A23	
25	Chongqing Kerui Pharmaceutical Co., ltd	100	A10	A12
31	Guangzhou Dongkang Pharmaceutical Co., Ltd.	100	A16	
36	Harbin Guangji Pharmaceutical Factory	100	A29	
37	Nantong Zhongbao Pharmaceutical Co., Ltd	100		A20
38	Xian Lisheng Pharmaceutical Co., Ltd	100	A25	
39	Anshan No.1 Pharmaceutical Factory	100		A38

Table 3 – List of enterprises eligible for funding

No.	Name	Ownership %	Lines	Total CFC (kg)	Eligible CFC (kg)	Skin products	Cavity products
1	Wuxi Shanhe Group No.1 Pharmaceutical Co., Ltd	100	2	823	823	A10, A23	
5	Guiyang Dechangxiang Pharmaceutical Co., Ltd	100	1	13	13		A07
7	Beijing Tongrentang Technology Development Corporation	100	1	14	14	A35	A21, A34
9	Fujian Nanshaolin Pharmaceutical Co., Ltd	100	1	10,684	10,684	A22, A33	
11	Penglai Nuokang Pharmaceutical Co., Ltd	100	1	3,491	3,491	A23	
13	Hubei Nanyang Pharmaceutical Co., Ltd	70	1	49,393	34,575	A29	
14	Shenyang Jingcheng Pharmaceutical Co., Ltd	50	1	57,717	28,859	A17	
16	Pharmaceutical Factory of Hunan Bencao pharmacy Co., Ltd	100	1	1,300	1,300	A16	

No.	Name	Ownership %	Lines	Total CFC (kg)	Eligible CFC (kg)	Skin products	Cavity products
18	Shandong Jewim Pharmaceutical Co., Ltd BlueBox	100	1	12,080	12,080	A23	A38, A39
19	Suizhou Pharmaceutical Co. Ltd of Wuhan Jianmin Group	100	1	13	13	A14, A19	
20	Guizhou Antai Pharmaceutical Co., Ltd	100	1	20,827	20,827	A02, A08	
21	Guizhou Xinyi Pharmaceutical Corporation	100	1	229	229	A13	
23	Xinjiang Biochemistry Pharmaceutical Co., Ltd	100	1	2,592	2,592		A05
24	Yunnan Baiyao Group Corporation	100	1	273,333	273,333	A45	
27	Zhanjiang Xintongde Pharmaceutical Co., Ltd	100	1	29,397	29,397	A11, A22, A23, A27, A32	A38, A40
32	Shanghai Yishengyuan Pharmaceutical Co., Ltd	100	1	112	112	A11, A23	
	Total		**17**	**462,018**	**418,342**		

Table 4 – Production outputs by type of products manufactured by the 16 eligible enterprises

Application ID No.	Type of Aerosol	Plant ID No.	CFC (Kg/Year)	Cans/Year	Cans/Day*
A39	Cavity	18	3	79	<1
A14	Skin	19	6	323	1
A19	Skin	19	7	377	1
A07	Cavity	5	13	100	<1
A34	Cavity	7	14	1,267	5
A22	Skin	27	36	1,516	6
A23	Skin	1	106	3,435	13
A16	Skin	32	112	4,845	19
A13	Skin	21	229	8,333	32
A38	Cavity	18	392	10,328	40
A10	Skin	1	717	23,232	89
A22	Skin	9	797	3,636	14
A16	Skin	16	1,300	58,333	224
A08	Skin	20	1,773	49,377	190
A05	Cavity	23	2,592	50,000	192
A40	Cavity	27	3,480	146,610	564
A23	Skin	11	3,491	100,600	387
A32	Skin	27	5,583	235,209	905
A33	Skin	9	9,851	44,935	173
A23	Skin	18	11,685	307,873	1,184
A02	Skin	20	19,053	530,622	2,041
A23	Skin	27	20,334	856,662	3,295
A29	Skin	13	49,393	1,171,333	4,505
A17	Skin	14	57,717	968,533	3,725
A45	Skin	24	273,334	5,306,667	20,410
Total			**462,018**	**9,884,225**	

(*) Based on 8-hour 260 working days per year.

Table 5 – Analysis by the Fund Secretariat of the submitted cost of the Pharmaceutical Aerosol Plan for all eligible enterprises

No	Name	CFC eligible	TAS	Screen	Dossier	Plant mod.	Validate	Training	Operating Cost	Contingency	Total Cost	CE
1	Wuxi Shanhe Group No.1 Pharmaceutical Co., Ltd	823	1,950	87,500	150,000	127,500	75,000	35,000	6,268	48,322	531,540	645.86
5	Guiyang Dechangxiang Pharmaceutical Co., Ltd	13	31	87,500	187,500	38,750	37,500	17,500	99	36,888	405,768	31,212.91
7	Beijing Tongrentang Technology Development Corporation	14	33	131,250	262,500	63,750	37,500	17,500	107	51,264	563,904	40,278.84
20	Guizhou Antai Pharmaceutical Co., Ltd	20,827	49,337	87,500	150,000	63,750	37,500	17,500	158,632	56,422	620,640	29.80
32	Shanghai Yishengyuan Pharmaceutical Co., Ltd	112	265	87,500	150,000	63,750	37,500	17,500	853	35,737	393,105	3,509.87
9	Fujian Nanshaolin Pharmaceutical Co., Ltd	10,684	25,309	87,500	150,000	63,750	37,500	17,500	81,376	46,294	509,229	47.66
11	Penglai Nuokang Pharmaceutical Co., Ltd	3,491	8,270	87,500	150,000	63,750	37,500	17,500	26,590	39,111	430,220	123.24
27	Zhanjiang Xintongde Pharmaceutical Co., Ltd	29,397	69,638	306,250	562,500	63,750	37,500	17,500	223,906	128,104	1,409,149	47.94
13	Hubei Nanyang Pharmaceutical Co., Ltd	34,575	81,904	43,750	52,500	63,750	37,500	17,500	263,346	56,025	616,275	17.82
14	Shenyang Jingcheng Pharmaceutical Co., Ltd	28,859	68,362	43,750	37,500	63,750	37,500	17,500	219,805	48,817	536,984	18.61
16	Pharmaceutical Factory of Hunan Bencao pharmacy Co., Ltd	1,300	3,080	43,750	75,000	63,750	37,500	17,500	9,902	25,048	275,529	211.95
18	Shandong Jewim Pharmaceutical Co., Ltd BlueBox	12,080	28,616	131,250	262,500	63,750	37,500	17,500	92,009	63,313	696,438	57.65
19	Suizhou Pharmaceutical Co. Ltd of Wuhan Jianmin Group	13	31	87,500	150,000	63,750	37,500	17,500	99	35,638	392,018	30,155.21
21	Guizhou Xinyi Pharmaceutical Corporation	229	542	43,750	75,000	63,750	37,500	17,500	1,744	23,979	263,765	1,151.81
23	Xinjiang Biochemistry Pharmaceutical Co., Ltd	2,592	6,140	43,750	93,750	38,750	37,500	17,500	19,742	25,713	282,846	109.12
24	Yunnan Baiyao Group Corporation	273,333	647,492	43,750	75,000	63,750	37,500	17,500	2,081,879	296,687	3,263,558	11.94
	Total	418,342	991,000	1,443,750	2,583,750	1,033,750	637,500	297,500	3,186,357	1,017,361	11,190,967	26.75

SECTOR PLAN FOR HALON PHASE-OUT: 2007 ANNUAL PROGRAMME

PROJECT DESCRIPTION

36. 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 tenth tranche of US $400,000 for the implementation of the 2007 annual programme and US $30,000 in support costs. 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 2007 annual programme includes the following:

(a) US $400,000 to be used for technical assistance activities in order to support the halon phase-out programme and ensure that existing fire protection requirements can be met including:

(i) A study on test methods for water mist fire extinguishing systems;

(ii) Establishment of an engineering construction standard for HFC-23 fire extinguishers; establishment of a standard for the design, construction and acceptance of dry powder fire extinguishers;

(iii) Design of an integrated control technology for fire detection;

(iv) Training of personnel; and

(v) A performance audit.

(b) Zero halon-1211 production or consumption; 100 metric tonnes of halon-1301 production excluding 20 metric tonnes of production for export and a ceiling of 100 metric tonnes for consumption; and

(c) Five to nine contracts are to be signed for the conversion or closure of halon-1301 systems manufacturers.

37. There are no remaining halon-1211 production facilities in China. There are no fire-fighting equipment manufacturers currently in operation, with 61 having received funding and 15 closed without contracts or funding including 4 that were not identified in the original proposal. The Government of China will continue to implement tradeable production quotas and strengthen the ban on installation of new halon extinguishers for non-essential uses through a gradual tightening of the definition of essential uses. The Government of China will also take actions to support the halon recovery and recycling activities and to prevent unnecessary emission of halon-1211.

38. Actual halon-1211 and 1301 production and consumption in 2005 was lower than planned resulting in production of 2,492 ODP tonnes less than planned (2,142 ODP tonnes of halon-1211 and 350 ODP tonnes of halon-1301) and consumption of 2,872 ODP tonnes less than planned as shown in the following table:

	Planned (metric tonnes)	Actual (metric tonnes)	Difference (metric tonnes)	Difference (ODP tonnes)
Halon-1211 Production	1,990	1,276	714	2,142
Halon-1211 Consumption	1,890	1,046	844	2,532
Halon-1301 Production	200	165	35	350
Halon-1301 Consumption	150	131	34	340

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

CO_2 fire extinguishers

39. The audit report confirms that China has achieved the targets of the 2005 work programme. Therefore, funds for the 2007 work programme can be released. However, there remain three issues that may warrant the Executive Committee's consideration concerning allocating funds through the flexibility clause for CO_2 fire extinguishers and halon-1301 as a feedstock.

40. At its 47th Meeting, the Executive Committee approved the 2006 tranche of the halon sector plan and requested the Government of China and the World Bank to consider a cumulative audit of the halon plan as part of the 2006 work programme. According to the Bank, a review was undertaken and included in the annual programme. However, this review did not apparently provide information on the number of CO_2 extinguishers produced in the year 2005.

41. Under the original decision approving the China halon plan, China was required to produce 3.59 million extinguishers in 2005 (decision 23/11, paragraph E). A financial penalty was associated with not achieving this target. However, the requirement was waived at the 44th Meeting and replaced with the following:

> "Instead, in case of any shortfall, the equivalent amount of this refund will remain in China for capacity building to help China to comply with the Montreal Protocol commitments for activities in the China Convention Compliance Centre (decision 44/59, Annex XVII of document UNEP/OzL.Pro/ExCom/44/73, footnote 1)".

42. China has indicated that 2.255 million CO_2 extinguishers were reported to be produced in 2004, but the 2005 investigation was still ongoing as of September 2006. The Fund Secretariat asked when the investigation was expected to be completed, but the Bank did not provide an answer.

43. The Fund Secretariat also notified the World Bank that a refund of US $4,111,800 would result from a calculation assuming the same level of CO_2 production in 2005 as reported for 2004. This level of refund is lower than the US $860,000 left to be approved for the entire halon sector plan including the US $400,000 requested at this meeting. The Bank responded that it could not answer the question before the 2005 survey had been completed and a full report provided.

Implementation of decision 47/50 on allocating funds through the flexibility clause

44. At its 47th Meeting, the Executive Committee decided that "…the disbursement information should be provided cumulatively and data concerning actual or planned commitments could also be provided, as appropriate. The information should also specify how the relevant flexibility clause in the agreement was implemented and/or how to allocate unused funds from previous tranches..." (decision 47/50(b)(i)). The Bank was requested to provide the information required in decision 47/50 about the use of the flexibility clause. However, the Bank indicated that China was not requesting flexibility to use the funds for the plan. It should be noted however that US $11.4 million had not been transferred by the World Bank to China and around US $19.6 million of the amount approved for China had not been disbursed as at 31 July 2006. Therefore, there could be large plans for which the flexibility clause might need to be used based on the size of these balances.

Halon-1301 as a feedstock

45. In approving the 2006 tranche of the halon sector plan at its 47th Meeting, the Executive Committee encouraged the Government of China to limit its production of halon-1301, for the purpose of feedstock, to the levels allowed under the agreement to avoid any future unintentional consumption that would be in violation of the agreement with the Executive Committee and to seek to use more effective non-ODS alternatives if possible. Halon-1301 is used for producing pesticides, pesticide intermediates and pharmaceutical intermediates starting in 2003. A total of 277.02 metric tonnes of halon-1301 was produced in 2005.

46. Most of the consumption (112 of the total 277 metric tonnes) of halon-1301 as a feedstock is consumed by the Bayer CorpScience Hangshou Company and at least four other companies. According to the technical review, China has given CRI (the halon-1301 producer) the following guidelines for selling halon-1301 as raw materials to pesticide producers namely that: "the halon-1301 should not have the possibility of harming the ozone layer; the production data on halon-1301 sold as feedstock must be reported to SEPA; and all original files should be kept for auditing purposes".

47. The technical auditors noted that most of the production equipment (two pipe reactors, bromination cauldron, water cooler, bromine stripping tower and bromine feed-in tanks) had been renewed in 2004 and the plant is in good technical shape with a production capacity of 600 metric tonnes. They indicated that it is more difficult to control whether halon-1301 to be used as fire extinguishing agent is being phased out according to the plan since the same production lines producing halon for fire extinguishers are also producing the halon for feedstock.

48. 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 reports the feedstock uses to the Ozone Secretariat. The Bank stated that it had visited one of the feedstock users and verified the process used in China and the figures reported by the companies. The Bank indicated that since the system in place requires financial support, it did not know how the monitoring system would work after 2009.

Exports

49. A total of 32 metric tonnes of halon-1301 (320 ODP tonnes) were exported in 2005. Seven metric tonnes (70 ODP tonnes) of this amount were for supply to Taiwan.

50. The total halon-1211 and 1301 exports to Israel (270.6 ODP tonnes) and India (119.7 ODP tonnes) reported in the audit do not correspond to the zero consumption reported by those countries pursuant to Article 7.

RECOMMENDATION

51. The Executive Committee may wish to consider the above in the context of approving the China halon phase-out work programme for 2007.

PHASE-OUT OF THE PRODUCTION AND CONSUMPTION OF CTC FOR PROCESS AGENT AND OTHER NON-IDENTIFIED USES (PHASE I): 2007 ANNUAL PROGRAMME

PROJECT DESCRIPTION

Introduction

52. The World Bank is submitting, to the 50th Meeting of the Executive Committee, the 2007 annual programme of the sector plan for phasing out the production and consumption of CTC for process agent and other non-identified uses (25 applications under phase I) on behalf of the Government of China. This is with the understanding that the request for the release of the sixth tranche of funding amounting to US $5 million plus the associated support cost of US $0.375 million will be submitted to the 51st Meeting with the submission of the verification of the implementation of the 2006 annual work programme. The 2007 work programme is not attached but could be made available upon request.

Background

53. 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 levels of CTC production and consumption (25 applications) by implementing the Agreement. Subsequently, between March 2003 and March 2006, the Executive Committee approved the 2003 to 2006 annual work programmes at a total funding level of US $56 million. The production of CTC for controlled use and as a feedstock for CFC production was reduced from 64,152 ODP tonnes in 2001 when the phase-out plan was developed to 33,080 ODP tonnes in 2005. 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 485.02 ODP tonnes in 2005.

54. The reduction targets and the associated funding levels for 2006 and 2007 are shown in the table below.

Table 1

Targets and Funding of the 2007 Annual Programme

Consumption	
CTC for 25 PA application	
2006	493 ODP tonnes
2007	493 ODP tonnes
Impact	0
CFC-113 for process agent	
2006	10.8 ODP tonnes
2007	Zero ODP tonnes

Impact	10.8 ODP tonnes
Production	
CTC	
2006	*28,618 ODP tonnes
2007	**18,782 ODP tonnes
Impact	9,880 ODP tonnes
Total MLF funding approved in principle	US $65 million
Total funding released by the MLF by July 2006	US $56 million
Level of funding requested	US $5 million

* The 2006 target for CTC maximum allowable production and imports for CTC use as process agent and feedstock for CFC production was adjusted from 32,044 ODP tonnes to 28,618 ODP tonnes 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.

Project Description

55. The submission of the World Bank starts with Part A which contains a summary of the results from the implementation of the three annual work programmes from 2003 to 2005, as well as a progress report on the implementation of the 2006 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 of the CTC production phase-out (phase I) as of August 2006

Year	No. of Producers	Target in Agreement	Actual Production	Reduction	Actions
		(ODP tonnes)			
2001	14	64,152	64,152	0	Baseline established
2003	15	61,514	59,859	2,638	Closure of one CTC producer(CTC4) Production cut by four producers two new CM producers set up (CTC14 & CTC15)**
2004	12	54,857	50,194	6,657	Closure of four producers (CTC3,7,10 &17) Production cut by four producers one new CM producer set up (CTC 16)**
2005	11	38,686	33,080	16,171	Closure of one producer (CTC6) Production cut by three producers
2006*	9	28,618	To be verified	10,068	Closure of one producer and two lines(CTC5, lines at CTC11 and CTC8), production cut by three producers

* Results in 2006 to be verified.
** CTC14, 15 and 16 were established after the 2001 baseline and not eligible for funding.

Table 3

Summary of implementation of phasing out CTC and CFC-113 as a process agent (phase I) as of August 2006

ODS	Application	Annual consumption (ODP tonnes)			No. of Plants		Actions
		2003	2004	2005	2001	2005	
CTC	CR	965	1,963.52	210.5	8	3	Four plants closed in 2004 and one plant closed in 2005, three under contract for closure in 2009
	Endosulfan	359	0	0	2	2	Both closed in 2005
	CSM	1,338	1,343.5	230.4	3	1	Two closed and dismantled, one for emission control
	CP-70	694	225.4	0	12	0	11 closed and 1 converted to non-ODS
	Ketotifen	6	0	0	1	0	Converted to non-ODS technology
	Total	**3,382**	**3,532.5**	**440.93**			
CFC-113	PTFE	21.5	13.5	4	6	0	One plant merger, and five converted to non-ODS

56. The Government of China has continued to implement a number of policies to assist the implementation of the CTC sector plan. Specifically since 2003 a strict control was introduced on the construction and expansion of new CTC production facilities. The "Circular on Implementing Carbon Tetrachloride (CTC) Production Quota-License System" placed all CTC producers, including the newly erected chloromethane (CM) plants, under control. The three new CM producers were not eligible for production quota but could buy quotas from the existing CTC producers.

57. 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 control was extended to all CTC consumers, which included the 25 applications covered by the Agreement, other new process agent applications, non-ODS feedstock applications and solvents.

58. 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.

59. In 2006 SEPA signed production reduction contracts with three CTC producers and closure contracts with one CTC distiller and two dedicated CTC production lines. These contracts were intended as the vehicle to ensure the achievement of the production target in the Agreement. Annex IV contains four tables which provide the production phase-out contracts between SEPA and the CTC producers in each of the 2003, 2004, 2005 and 2006 annual programmes.

60. On the consumption side, SEPA continued to use closure and conversion to achieve the reduction targets for CTC and CFC-113 in 2006 under phase I of the sector plan. As a result of the 2006 annual programme, there will be three chlorinated rubber (CR) producers and one chlorosulphonated polyefin (CSM) producer which will remain in production and consume CTC from phase I of the sector plan. Tables II-1 to II-5 in Annex II 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 2001-2004, level of production between 2001-2004 and status of the plant. Annex V provides a list of the contracts that have been signed between SEPA and the enterprises.

61. There is an update on the CSM project in Jilin Province which is the only emission control project under phase I, but which has not faired well so far. The characteristic of the project is a drying screw expeller which is specially designed and imported to reduce CTC emissions in the drying process. The drying screw expeller was put into operation at the end of 2004 as planned. After the half year's test operation, it was found that the performance of the drying screw expeller could not meet the design requirements. The enterprise has entrusted several universities or research institutes to seek substitute technologies to replace the CTC consumption. If all efforts fail, the CTC consumption target for 2010 set by the Agreement may not be met.

62. The World Bank submission reports progress on a number of on-going activities under the technical assistance programme. Study on CTC incineration technologies and management under the 2004 AP and the verification of new CTC feedstock applications and dealers under 2005 AP are completed. For 2006, a domestic survey of non-ODS producers and CTC dealers under PAII is planned. SEPA is also planning an on-line monitoring system for CTC production which aims at collecting CTC production data more accurately and promptly by installing on-site on-line monitoring instruments which can replace site supervisors. The terms of reference is being prepared and is expected to be submitted for the World Bank's approval before December 2006.

63. A new technical assistance (TA) to assess the quality of CR products using CTC as process agent and aqueous CR products will be added to the 2006 annual program. Two to three CR enterprises are still using CTC as a process agent and must completely phase-out CTC before 31 December 2009. Several enterprises have been working to develop aqueous CR products in recent years. This TA intends to analyze technical indexes and quality of CR products, make comparisons, examine the impact on the paints sector of the phase-out of CTC for CR product, and make feasibility appraisal on conversion proposals of CR product.

64. Part B of the submission contains the proposed 2007 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 17,075 MT (18,782 ODP tonnes), and the consumption of CTC for process agents under phase I should not exceed 493 ODP tonnes in 2007. The consumption of CFC-113 for process agents would be zero, as stipulated in the Agreement under phase I.

65. On the policy level, the Government plans to continue implementing the controls discussed in the preceding paragraphs both for the production and consumption of CTC. Furthermore, a new "ODS management regulation" has been under development since 2004. This draft consists of six chapters covering the management and monitoring of ODS production, consumption, use, sale, import and export and the related legal liabilities. By July 2006, the first round of collecting comments and opinions has been completed. The draft has been revised in

August 2006 and will be submitted to the meeting of the ministers of SEPA for review. Then, the draft will be submitted to the Regulation Department of the state council for further review. At the same time, a hearing will be conducted. After the review of the Regulation Department, the draft will be submitted to the meeting of the state council for final approval. It is foreseen that this Regulation would serve as a solid legal basis for sustainable ODS phase-out.

66. At the enterprise level, SEPA will sign one to two closure contracts and four production reduction contracts with CTC producers, resulting in closure contracts with Shanghai Chlor-Alkali and Quzhou Jiuzhou (residual distilling enterprise). In addition, there will be four production reduction contracts with co-producers to buy back their CTC production quotas to ensure achievement of the Agreement's targets. As these CM production facilities will remain in production, the facilities will not be dismantled.

67. The three CM producers without production in the baseline year (Wuxi Greenapple, Shandong Jinling and Shandong Dongyue) will establish their own disposal facilities for their surplus CTC co-products. This is vital to successfully implement the sector plan. In order to support and encourage them to set up conversion facilities to convert co-produced CTC as early as possible, the Chinese Government plans to provide some MLF funding to support the operational cost of the CTC conversion. On the consumption side, quotas will be assigned to each remaining eligible PA enterprise to ensure that the maximum allowable consumption limit in 25 applications does not exceed the Agreement's targets.

68. Table 8 in Part B provides targets for the 2007 annual programme and includes data on production, consumption, a comparison of 2006 and 2007 data, the reduction to be achieved, the level of funding for each category of activity, and monitoring indicators for key actions and dates. Table 9 provides a break-down of funding by policy action and enterprise activities under two categories of production and consumption, with key actions and dates of completion. Table 10 gives details on the technical assistance programme in 2007, with funding, action and dates of completion. The submission has six annexes: Annex I with two tables on gross production and status of CTC producers; Annex II with five tables on ODS consumption status; Annex III with one table on policies implemented; Annex IV with four tables on CTC production phase-out status; Annex V with one table listing contracts with process agent enterprises; and Annex VI with four tables on status of TA activities.

69. The submission estimates a total cost of US $18 million to implement the 2007 annual programme, out of which US $5 million will be from 2007 annual programme and US $8 million from the unallocated balance of the 2006 annual programme of phase I. The balance of US$ 6 million will be charged to the 2007 annual programme of phase II of the sector plan.

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

70. The approval of the second phase of the sector plan at the 47th Meeting of the Executive Committee in March 2006 results in adjustment of the maximum allowable CTC production and imports for controlled use as process agents under both phases and as feedstock for CFC production from 32,044 ODP tonnes to 28,618 ODP tonnes in 2006. This was reflected in decision 48/25, under which the Executive Committee decided "to approve the revision of the

maximum CTC production target in the 2006 annual work programme of the CTC sector plan (phase I) to 28,618 ODP tonnes". This is the sum of 21,276 ODP tonnes for CFC production (from the accelerated phase-out plan, APP) and 7,341 ODP tonnes allowed under the Montreal Protocol (15 per cent of the baseline plus 10 per cent of baseline for basic domestic needs). However the World Bank maintains that the target should remain at 32,044 ODP tonnes, as included in the APP.

71. The approval of phase II has no impact on the CTC consumption target for phase I in 2006. From what is reported on the progress in the implementation of the 2006 targets up to August 2006, there have been a number of activities such as closures and production cuts at the enterprise level to achieve the reductions required.

72. As per the request of the Executive Committee in decision 48/25 when approving the 2006 annual tranche for CTC phase I, there is an update on the further actions that have been undertaken to reduce the emission level by the CSM plant, which was experiencing difficulty in applying the imported technology to reduce CTC emission. However the update does not give any assurance of success and this could impact on the achievement of the target in the Agreement in 2010.

73. The Government of China has put in place rather strict controls on both CTC production and consumption, including the requirement for all the dealers and consumers of CTC to register and obtain permits, and for all the producers including the new chloromethane producers to produce under a permit. Furthermore, the Government has introduced the same on-site peer monitoring mechanism for the CTC producers that has been successfully applied in the case of the CFC producers. Furthermore, the new regulation on ODS which is being developed will provide strong legal grounds for enforcing and sustaining the phase-out.

74. The proposed 2007 annual work programme provides clear targets which are consistent with those from the Agreement and a plan of action which intends to continue the momentum and the implementation structure that has been built in the past four years.

RECOMMENDATIONS

75. In light of the uncertainty associated with the emission control project for the CSM application at the enterprise in Jilin Province and its likely implication on compliance with the Agreement, the World Bank is requested to provide an update on the project in the 2008 annual work programme.

76. In view of the disagreement on the maximum allowable CTC production and imports for process agent uses and as a feedstock for CFC production for 2006, the Secretariat is not in a position to make a recommendation at this time.

SECTOR PLAN FOR PHASE-OUT OF ODS PROCESS AGENT APPLICATIONS (PHASE II) AND CORRESPONDING CTC PRODUCTION: 2007 ANNUAL PROGRAMME

PROJECT DESCRIPTION

Introduction

77. The World Bank is submitting to the 50th Meeting of the Executive Committee the 2007 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), on behalf of the Government of China. This is with the understanding that the request for the release of the second tranche of funding amounting to US $10 million plus the associated support cost of US $0.75 million will be submitted to the 51st Meeting with the submission of the verification of the implementation of the 2006 annual work programme. The proposed 2007 annual work programme is not attached but could be made available upon request.

Background

78. 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 disbursed at the meeting US $15 million plus support costs of US $1.125 million and another US $10 million plus US $0.75 million as support cost at its 48th Meeting to the World Bank for the implementation of the 2006 annual work programme. Furthermore the Committee approved the Agreement for phase II of the sector plan at the 48th Meeting. The CTC reduction targets and fund disbursement schedule under the agreement are reproduced below.

Table 1

Allowable CTC Production and Consumption in Phase II and Agreed funding

	Baseline (2003)	2006	2007	2008	2009	2010
1. Max allowed CTC production for consumption under the MP	29,367	7,386*	7,386	7,386	7,386	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 phase 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 per cent of the phase 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

79. The submission of the World Bank for the 2007 annual work programme under phase II contains considerable common elements for the 2007 annual programme under phase I, and therefore the summary for phase II will only cover those elements which are specific to the second phase.

80. On progress on the 2006 work programme, it is reported that project implementation mechanism for phase II of the sector plan, as a supplement for the project implementation manual of China's ODS production sector, has been developed by SEPA and cleared by the World Bank in September 2006. This mechanism includes, among other things, eligibility of projects for grant compensation, participants and main responsibilities, implementation strategy, and project implementation modality (including closure, conversion, emission control and retroactive financing).

81. As for targets, the 2006 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 those in phase I and phase II will not exceed 14,300 ODP tonnes.

82. In 2006, a total of 9 CTC phase-out contracts have been signed, including five closure contracts with (CPP/CEVA) enterprises, two conversion contracts with two MIC enterprises, one closure contract with one buprofenzin enterprise and one retroactive financing contract for conversion with an imidacloprid enterprise, which completed CTC conversion in 2005. Two imidacloprid enterprises, Suhua Group and Hisun Chem, have dismantled their production lines and committed to stop using CTC. The Suhua Group, which produces oxidiazon and mefenacet and other products on a multi-functional production line will submit a commitment document to stop using CTC for this line and not to apply for funding. Another mefenacet producer, Changlong Chem., will also commit to converting the production to a non-ODS process at its own cost. SEPA will also not issue a CTC consumption quota for those applications.

83. Of the technical assistance activities planned in 2006, two are particularly interesting. The first one is a domestic investigation of new process agent consumers other than those covered by phase I and phase II. Beijing University of Chemical Technology (BUCT) has been selected to undertake this project. Of the 62 new process agent companies with CTC consumption in 2005, 46 were visited by the end of August 2006. The remaining companies would have been visited by September 2006. The purpose of the investigation is to clarify the number of applications and enterprises and the actual CTC consumption in 2005 for reporting back to the 50th Meeting of the Executive Committee as per the phase II Agreement.

84. The second one is a study of CTC consumption and emissions in the production of CPP/CEVA. As the Parties have not defined the emission control levels for process agent applications for Article 5 countries, it is not clear whether the 994 ODP tonnes of CTC reserved for these applications under phase II is technically feasible for the CPP/CEVA enterprises and if it will be accepted by the Parties. Therefore, the Chinese Government feels it is essential to study the details of CTC consumption and emissions in CPP/CEVA production. The terms of reference is under preparation. A consultant will be selected to perform the task.

85. The targets for 2007 annual programme remain the same as for those in 2006, which are explained in paragraph 5 above. To contain the consumption of CTC within the targets for the applications under phase II, another nine contracts will be signed in 2007 with consuming enterprises for closure, conversion, emission control and retroactive funding for those industries which have already completed their phase-out activities. Of the US $10 million requested, US $6 million will be allocated to CTC producers for reducing production, US $3 million to CTC consuming enterprises, and US $1 million for technical assistance activities. The 2007 annual programme presents the annual phase-out targets, policy actions, and technical assistance activities in tables 2, 3 and 4 with details on targets, expenditure level and key dates for completion.

86. The submission has three annexes: Annex I provides a list of CTC producers and their status; Annex II contains information on process agent enterprises under phase II which has four tables providing details on ODS consumption for each application between 2001-2005, the production lines of each application, the list of process agent enterprises in the sector plan, and CTC consumption for each sub-sector and enterprise; and Annex III covers a list of policies implemented.

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

87. The World Bank's submission includes the following two clarifications for the annual programme:

(a) Seven applications in Table A-bis of decision XVII/8 are considered by China as feedstock uses for non-ODS chemicals. These applications are No. 49, 57, 63, 64, 65, 66 and 67; and

(b) In this annual programme, "new PA" refers to all CTC uses except those in phase I, phase II, lab uses and potential applications using CTC as feedstock (including the above-noted seven applications).

88. In response to the comments of the Secretariat, the World Bank confirmed that, until the Meeting of the Parties and TEAP reclassifies these seven applications as feedstock, China will treat them consistent with the other applications in Table A-bis under decision XVII/8. Otherwise, phase II of the sector plan has taken off the ground since its approval towards the end of 2005 on the momentum built up during phase I of the sector plan. The survey of the unknown CTC process agent applications is reportedly going well and the result is likely to be submitted to the 50th Meeting as per the request in the Agreement for phase II.

RECOMMENDATIONS

89. The Secretariat recommends that the Executive Committee approves the 2007 annual work programme with the understanding that:

(a) The seven applications from Table A-bis under decision XII/8 of the Parties to the Montreal Protocol, which China has contested should be included in the national annual CTC consumption control target for process agent applications, other than those in phase I and phase II, which should not exceed 14,300 ODP tonnes per year for 2006 and 2007; and

(b) The request for funding and support costs for the 2007 annual work programme will be submitted by the World Bank to the 51st Meeting together with a verification report on the implementation of the 2006 annual programme.

SECTOR PLAN FOR CFC PRODUCTION PHASE-OUT: 2007 ANNUAL PROGRAMME

PROJECT DESCRIPTION

Introduction

90. The World Bank is submitting to the 50th Meeting of the Executive Committee the request on behalf of the Government of China for the approval of the 2007 annual work programme of the Agreement for the China production sector. This is with the understanding that approval of funding of US $24 million plus US $1.8 million as support cost for the implementation for the 2007 programme will be requested at the first meeting of that year based on satisfactory performance of the programme in 2006, as per the Agreement. The 2007 work programme is not attached for reasons of economy but could be made available upon request.

Background

91. Since its approval by the Executive Committee in 1999, the China Production Sector Phase-Out Agreement has been successfully implemented between 1999 to 2006 to reduce the number of CFC-producing plants from 37 in 1999 to six in 2006, and the CFC production from 50,351 ODP tonnes in 1999 to 13,500 ODP tonnes in 2006 (to be verified in the beginning of 2007). It is expected that CFC production in China would be terminated by July 2007 with the implementation of the 2007 annual programme.

92. The table below sums up the key data of the China CFC production sector plan and those of the 2006 and 2007 work programmes.

Table 1

Country	Peoples Republic of China
Project title:	Sector Plan for CFC production phase-out in China
Year of plan	2007
# of years completed	8
# of years remaining under the plan	3
Ceiling for 2006 CFC production (in ODP tonnes)	13,500 ODP tonnes
Ceiling for 2007 CFC Production (in ODP tonnes)	7,400 ODP tonnes
Total funding approved in principle for the CFC sector plan	US $150 million
Total funding released from MLF as of December 2006	US $111 million
Total funding disbursed from World Bank to China (as of September 2006)	US $91.5 million
Level of funding requested for 2007 Annual Plan	US $24 million

Project description

93. The submission has two parts:

(a) 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 2006 annual programme as of August 2006. The following are the most salient features of the summary report:

(i) Implementation of the China Production Sector Phase-Out Agreement between 1999 to 2005 has reduced the number of CFC-producing plants from 37 in 1999 to six in 2006, and CFC production from 50,351 ODP tonnes in 1999 to 13,500 ODP tonnes in 2006 (which will be verified at the beginning 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 Government bought back 550 ODP tonnes of CFC-113 production quota and signed the contract to close and dismantle the only CFC-113 producing plant. Implementation of the 2006 annual programme continues to rely on a combination of administrative measures and tradable production quotas, because the reduced number of producers and continued market demand make it increasingly difficult to rely solely on voluntary production quotas to reduce CFC production. The Government will limit the CFC export to 400 ODP tonnes in 2006 as required in the agreement for the accelerated phase-out programme (APP). Annex I includes 12 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 2006. The result of implementing the 2006 programme will be verified by the World Bank and reported to the first meeting of the Executive Committee in 2007;

(ii) The progress report on the 2006 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 CFC production from obtaining bank loans or approval from local authorities. During 2006 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 designated 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; and

(iii) An update is provided on the implementation of the technical assistance programme under which a total of 40 activities were initiated out of the 51 planned and 11 cancelled. One technical assistance programme which was started in 2006 was an attempt to develop a strategy to monitor and manage the increasing use of ODS as feedstock applications in China. Annex III includes eight tables according to annual work programmes, 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.

(b) Part B of the World Bank's submission is a description of the components of the 2007 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 7,400 ODP tonnes of CFCs by 1 July 2007 and will terminate CFC production after that, apart from the 550 ODP tonnes allowed each year between 2008-2009 for MDI production. China will also ensure that its CFC-13 production should not exceed 15 per cent of the baseline of 26.7 ODP tonnes by 1 January 2007.

(i) Five total closure contracts are expected to be signed with five CFC producers by the end of May 2007. One partial closure contract will be signed with the only remaining CFC producer. The producer's quota will be limited to 550 ODP tonnes for MDI uses in 2008 and 2009. For the five total closure contracts, all CFCs remaining in the production system will be purged and accounted for in the quota calculation for the first half of 2007. All residue materials will be properly disposed of. All remaining CTC feedstock will be handled according to the CTC sales and consumption license system. All key equipment will be dismantled and destroyed. All the closure activities, including the preparation of the necessary documents and the completion report will be ready by the end of September 2007. The verification of the production in the first half of 2007 together with the verification of the complete closure of plants will be carried out in October 2007; and

(ii) In accordance with the Accelerated Phase-out Plan and the Refrigeration Service Sector Plan, a total of approximately 2,500 MT of CFC-11 and CFC-12 will be stockpiled for critical applications and the refrigeration service sector after production ceases.

94. The current policy framework will continue, especially the regulation of production quotas, which will be monitored by the on-site peer supervision of the producing plants. In addition, a number of bans for achieving the target of 2007 are prepared now and will be issued in the last four months of 2006 or the earlier part of 2007, which include:

(a) The public notice of the ban for CFCs used in home appliances and the import and export of these CFC-based appliances will be issued in September or October 2006 jointly by five ministries (SEPA, NDRC, GAC, MOC, AQSIQ) and will be effective by 1 January 2007;

(b) The ban on the consumption of CFC-11 in the tobacco sector will be issued and effective by 1 January 2007;

(c) The ban on the production of CFCs except for MDI uses will be issued and effective by 1 July 2007; and

(d) The ban on the consumption of CFCs in the foam sector will be issued and effective by 1 January 2008.

95. The submission of the World Bank includes an updated list of HCFC producing enterprises in China as per the Agreement. In 2005 there were three new HCFC plants added to the list, namely plants 16, 17, and 18, which brought the total number of HCFC producers to 18. In 2006, plant 2 changed its name from “Zhonghao New Chemical Materials Co. Ltd” to “Changshu 3F Zhonghao New Chemical Materials Co. Ltd” and plant 3 changed its name from “Jiangsu Changhu Elf Atochem 3F Co. Ltd to “ARAKEMA (Changshu) Fluorochemical Co. Ltd”.

96. US $23 million out of the US $24 million for implementation of the 2007 programme is currently planned for compensating the enterprises for closing and reducing CFC production and the remaining US $1 million is planned for technical assistance although reallocation could happen once implementation starts.

SECRETARIAT’S COMMENTS AND RECOMMENDATIONS

COMMENTS

97. The 2007 annual work programme will complete the CFC production sector plan although there will be two more funding tranches to be disbursed. China will be allowed to produce up until 1 July 2007 a total of 7,400 ODP tonnes of CFCs and should then terminate all CFC production after that, except for 550 ODP tonnes each year in 2008 and 2009 reserved for MDIs. China should also ensure that its CFC-13 production complies with the control schedule of the Montreal Protocol by reducing production by 1 January 2007 to 15 per cent of the baseline.

98. The 2007 work programme proposes a series of actions that would make these targets achievable, such as the signing of the complete plant closure contracts no later than May 2007 with five of the remaining plants and limiting the validity of the quota to the first half of 2007. One CFC producer is expected to remain in production while the other five will be dismantled in

September 2007. All this will be verified by the World Bank in the second half of the year and reported to the Executive Committee in the context of the 2008 annual work programme.

99. A series of regulative measures are being planned by the Government to sustain the CFC production phase-out. But most important is the new regulation on ODS management, which is being proposed for endorsement by the State Council and which will be the tool to enforce and sustain the phase-out. The on-site supervision by peer CFC producers instituted by SEPA has proved to be an effective tool for monitoring CFC production and will continue in 2007.

RECOMMENDATIONS

100. The Secretariat recommends that the Executive Committee:

(a) Requests that the production target for CFC-13 be separately listed within the overall CFC production limit for 2007 since it has a different control schedule under the Montreal Protocol;

(b) Requests the World Bank to provide further details on the proposed scheme for controlling CFC exports for 2006 and 2007 through five CFC producers in the revised 2007 work programme to be submitted together with the verification of the 2006 annual work programme at the 51st Meeting; and

(c) Approves the 2007 work programme of the China CFC production closure programme, noting that the request for funding and support costs will be submitted by the World Bank to the 51st Meeting together with a verification report on the implementation of the 2006 annual programme.

PROJECT EVALUATION SHEET – MULTI-YEAR PROJECTS
CHINA

PROJECT TITLE	BILATERAL/IMPLEMENTING AGENCY
ODS phase-out in China solvent sector: 2007 annual programme	UNDP

NATIONAL CO-ORDINATING AGENCY:	State Environmental Protection Administration (SEPA)

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2005, AS OF OCTOBER 2006)

CFC	-	CTC	-
TCA	-		

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

Substance	Aerosols	Foams	Refrigeration	Substance	Solvents	Process Agent	Fumigant
CFC-113					546.10		
TCA					186.59		
CTC					-		

CFC consumption remaining eligible for funding (ODP tonnes)	N/A

CURRENT YEAR BUSINESS PLAN: Total funding US $5,891,000: total phase-out 169.3 ODP tonnes

PROJECT DATA		2000 2004	2005	2006	2007	2008	2009	2010	Total
CFC-113	Annual consumption limit	N/A	550	**0**	0	0	0	0	N/A
(ODP tonnes)	Annual phase-out	N/A	550						N/A
TCA	Annual consumption limit	N/A	424	**339**	254	169	85	0	N/A
(ODP tonnes)	Annual phase-out	N/A	85	**85**	85	84	85	0	N/A
CTC	Annual consumption limit	N/A	0	**0**	0	0	0	0	N/A
(ODP tonnes)	Annual phase-out	N/A	0	**0**	0	0	0	0	N/A
TOTAL ODS CONSUMPTION TO BE PHASED OUT									
Annual CFC phase-out target in the Solvent Sector (ODP) tonnes		N/A	635	85	85	84	85	0	N/A
Final project costs (US $):									
Funding for UNDP		31,345,000	5,680,000	5,055,000	5,480,000	1,480,000	1,480,000	1,480,000	52,000,000
Total project funding		**31,345,000**	**5,680,000**	**5,055,000**	**5,480,000**	**1,480,000**	**1,480,000**	**1,480,000**	**52,000,000**
Final support costs (US $):									
Support cost for UNDP		2,851,750	426,000	379,125	411,000	111,000	111,000	111,000	4,400,875
Total support costs (US $)		**2,851,750**	**426,000**	**379,125**	**411,000**	**111,000**	**111,000**	**111,000**	**4,400,875**
TOTAL COST TO MULTILATERAL FUND (US $)		**34,196,750**	**6,106,000**	**5,434,125**	**5,891,000**	**1,591,000**	**1,591,000**	**1,591,000**	**56,400,875**
Final project cost effectiveness (US $/kg)									

FUNDING REQUEST: Approval of funding for the eight tranche (2007) as indicated above.

SECRETARIAT'S RECOMMENDATION	Blanket approval

PROGRESS REPORT ON IMPLEMENTATION OF THE SOLVENT SECTOR PLAN FOR ODS PHASE-OUT IN CHINA FOR 2005/2006, 2007 ANNUAL IMPLEMENTATION PROGRAMME AND REQUEST FOR FUNDING OF THE EIGHT TRANCHE

PROJECT DESCRIPTION

101. On behalf of the Government of China, UNDP has submitted to the 50th Meeting of the Executive Committee the 2006 annual progress report and annual implementation programme for 2007 for the solvent sector plan for ODS phase-out in China. Funding for the 2007 annual implementation programme of US $5,480,000 plus support costs of US $411,000 is requested. This funding is included in UNDP's 2006 business plan.

Background

102. The solvent sector plan for China was approved in principle at the 30th Meeting at a total cost of US $52 million plus support costs for UNDP. Funds totalling US $45,736,875 (including support costs) have been approved for the first seven annual tranches from 2000 to 2006 inclusive.

103. 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 was prohibited on 1 January 2006 onwards. 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

104. SEPA and UNDP continued to implement enterprise-level phase-out activities through ODS reduction contracts initiated between 2003 and 2005, through retroactive reimbursement and through agreements for gradual self-phase-out as well as activities for smaller enterprises under a voucher system initiated in 2003.

105. Phase-out is complete for all 2001 and 2002 ODS reduction contracts. Two contracts are pending national acceptance and payment. Verification was undertaken by sampling 30 per cent of the enterprises.

106. Twelve enterprises that signed reduction contracts in 2004 submitted project completion reports in 2005 for complete phase-out of 87.79 ODP tonnes of CFC-113 and 2.15 ODP tonnes of TCA. However, differences between reported and verified consumption were identified at the first three enterprises verified in 2006. SEPA is now requiring independent verification of all twelve enterprises prior to reimbursement. This will be completed in 2006.

107. Phase II of the voucher system, initiated in 2004, also uses a reimbursement mechanism. A total of 225 enterprises are continuing with the project for a total phase-out of 610 ODP tonnes of CFC-113 and 27.8 ODP tonnes of TCA. A sample of 34 enterprises was audited to confirm

the reported consumption and achievement of phase-out. Project completion reports were expected in September 2006 and the national acceptance procedure is planned for completion in November 2006.

108. Contracts for procurement of equipment for 20 enterprises manufacturing liquid crystal displays were issued in September 2005 and all equipment has now been delivered, installed and tested. National acceptance procedures will be conducted before the end of 2006.

109. In view of the ban on use of CFC-113 as of January 2006, the final group of retroactive reimbursement contracts was initiated with 26 enterprises, for a potential phase-out of 340 ODP tonnes of CFC-113. Applications were required to be submitted by 14 September. An independent accounting company will verify the qualification requirements and completion of phase-out. National acceptance will be conducted by the end of 2006.

110. Action was initiated in 2006 to extend the retroactive reimbursement programme to users of TCA. Following awareness activities to attract participation, by early September enterprises with a total consumption of 10.4 ODP tonnes had applied. Total consumption of 30 ODP tonnes is predicted by the application deadline of 30 September 2006. Contracts are planned for signature in November 2006 with completion of conversion in mid-2008.

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

Table 3: Phase-out achieved through 2000 – 2006 ODS reduction contracts,voucher system, and retroactive reimbursement and self-phase-out mechanisms

			CFC-113 (ODP T.)	TCA (ODP T.)	CTC (ODP T.)	No. of Enterprises	Funding (US $1,000)
2000	Contracts for future phase-out	Planned	372.8	10	0	10 – 20	5,000
		Signed	378.4	10.1	8.36	16	4,132
	Phase-out achieved	On-going projects	-	7.4	-		
	TOTAL 2000 PHASE-OUT		-	**7.4**	-		
2001	Contracts for future phase-out	Planned	524	10	0	10 – 20	5,505
		Signed	541.6	10.6	0	21	4,361
	Phase-out achieved	On-going projects	54.1	-			
		2000 contracts	340.1	9.8	8.36		
	TOTAL 2001 PHASE-OUT		**394.2**	**9.8**	**8.36**		
2002	Contracts for future phase-out	Planned	500	25	55	20 – 40	5,830
		Signed	535.8	43.2	17.94	32	4,004
	Phase-out achieved	On-going projects	291.3	41.7			
		2000 contracts	38.4	0.4	-		
		2001 contracts	-	-			
	TOTAL 2002 PHASE-OUT		**329.7**	**42.1**	-		
2003	Activities for future phase-out	Planned	600	78	55	120-140	5,255
		Signed	417.7	19.1	0	87	5,100
	Phase-out achieved	On-going projects	-	-	-		
		2001 contracts	336.3	7.3			
		2002 contracts	-	-	-		
		2003 activities *	142.1	37.9			
	TOTAL 2003 PHASE-OUT		**478.4**	**45.2**	-		

			CFC-113 (ODP T.)	TCA (ODP T.)	CTC (ODP T.)	No. of Enterprises	Funding (US $1,000)
2004	Activities for future phase-out	Planned	550	78	0-		4,000
		Identified	737.8	54		302	4,729
	Phase-out achieved	2001 contracts	205.3	3.3			
		2002 activities*	108.6	18.3	16.5		
		2003 activities	-	-			
		2004 activities*	49.4	9.8			
	TOTAL 2004 PHASE-OUT		**363.3**	**31.4**	**16.5**		
2005	Activities for future phase-out	Planned	550	85	0		4,280
		Identified	156.7				4,200
	Phase out Achieved	2002 activities *	427.2	24.9	1.44		
		2003 activities	463.8	36.7	0		
		2004 activities	256.4	11.9			
	TOTAL 2005 PHASE-OUT		**1,147.4**	**73.5**	**1.44**		
2006	Activities for future phase-out	Planned	(360)	(30)	0		3,340
		Identified	340+	10.5+	0	40	3,222
	Phase-out achieved	2003 activities	21.7	-27.2			
		2004 activities	(254.2)	(5.3)			
		2005 activities	(156.7)				
		2006 activities	(300)	(5)			
	TOTAL 2006 PHASE-OUT*		**(732.6)**	**-17**			
Seven Year Cumulative Total	Phase-out planned		3,456.80	316	110		
	Phase-out targets		3,300	367	110		
	Phase-out achieved by completion of on-going projects and signed contracts		3,108	167	26.3		
	ACTUAL PHASE-OUT ACHIEVED		**(3,445.6)**	**(192.4)**	**26.3**		

* From retroactive reimbursement and gradual self-phase-out activities
\+ phase-out achieved as of September 2006
Figures in brackets ( ) indicate anticipated phase-out as of December 2006

112. 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;

(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.

Policy measures

113. In June 2002, SEPA announced rules establishing ODS solvent consumption certificates, which imposed controls on ODS consumption on the basis of ODS supply and demand. In March 2003, SEPA issued a nationwide ban on use of CTC as solvents as of 1 June 2003. On 7 December 2004, SEPA issued a nationwide ban on the use of CFC-113 as a solvent to take effect from 1 January 2006.

114. In September 2006, SEPA/FECO announced regulations for a quota and licensing system for TCA production, consumption and distribution. Enterprises will be required to apply for licenses during October each year. FECO will control the total quantities to be produced and

consumed and will release quotas as appropriate between 1 November and 30 December each year.

Technical assistance activities

Essential solvent uses

115. A final report of the technical assistance activity entitled "Strategy and Study on Essential Usage of ODS" by the College of Environmental Science of Peking University was commenced in April 2004 was issued in March 2006. The report indicates that essential use exists primarily in enterprises consuming solvents in the manufacture of products for the military sector.

Illegal ODS activities

116. The cooperative project to address emerging illegal production consumption and imort/export undertaken by SEPA's Bureau of Environmental Supervision established in May 2004 has been working effectively since its inception. Six cases of illegal ODS production were revealed in 2006. The management system for monitoring illegal ODS production, consumption and trade underwent national acceptance in July 2005.

117. An emergency response mechanism to investigate illegal ODS activity has been established in several key provinces/cities. In 2006 two workshops were conducted on combating illegal ODS activities. A total of 208 trainees participated. Related material was added into the national training programme for inspection officers. Thirty-one sets of ODS detection equipment were purchased and distributed for nationwide use.

118. In order to release data in a timely manner on ODS production, consumption, trade, import and export, to carry out statistical work and analysis, and to effectively reveal and combat illegal ODS related activities, SEPA/FECO has established an on-line system for trade licenses. Assessment of the project will be undertaken before the end of 2006.

119. To complement the on-going project to combat ODS related illegal activities an additional technical assistance project was commenced to improve the capacity of China's customs authorities, including procurement of detection equipment, training for key customssupervision staff and investigation of illegal activities.

Ozone friendly provinces/cities demonstration project

120. Twelve provinces/cities signed agreements in October 2005 to implement legislative and administrative actions to complete the phase-out of chlorofluorocarbons and halons by June 2006. The 12 provinces/cities have met the target. Assessment of the associated phase-out activities commenced in August 2006 and is expected to be completed before the end of this year.

121. During the phase-out period SEPA held three coordinating meetings and sent a research group to Europe and the United States to investigate and research policies on phase-out and reclamation of CFCs and halons in developed countries. In addition, under this sub-project, six issues of the periodical "News Briefing on Accelerating the Phase-out of ODS, Establishing

Ozone Friendly Provinces/Cities" were published and a column was developed for the website www.ozone.org.cn.

Research programme on TCA substitutes and technology in the solvent sector

122. In view of the need to encourage industries to participate in the TCA phase-out programme, in August 2006 an independent research institution was contracted to identify specialized substitutes for TCA and to identify alternative technologies that can be applied effectively to each individual industry.

Public awareness and training

123. To facilitate and promote TCA phase-out activities in 2006, 25 media outlets were selected in partnership with FECO to publicize the phase out project and to promote the notice of participation across the country. The website http://solvent.ozone.org.cn was initiated in July 2006, from which detailed information about the project and related application forms can be downloaded.

124. To overcome deficiencies in reporting and verification of consumption, training will be given to participating enterprises in October 2006 on verification of consumption, requirements for project management, the implementation process, the performance audit and research on substitutes.

125. FECO officials now attended industrial association seminars to encourage enterprises to participate in phase-out activities. The association approach is becoming more and more helpful in the implementation of the projects and has produced positive results.

Verification of 2005 ODS consumption limits

126. The 2005 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 2004 (ODP tonnes)

	CFC-113 (ODP tonnes)	TCA (ODP tonnes)	CTC (ODP tonnes)
Consumption control target	**550**	**424**	**0**
Production	549.304	77.883	-
Import	-	108.708	-
Export	-	-	-
Solvent consumption	**549.304**	**186.591**	**0**

127. Consistent with the verification process in previous years, UNDP included the China solvent sector plan project in its regular annual management and financial audit undertaken in 2006 by the National Audit Office of the People's Republic of China (CNAO). The audit was conducted in conformity with the provisions of the project document, international auditing standards, relevant Chinese auditing standards and the principles and procedures prescribed for

the United Nations with respect to funds obtained from or through UNDP. The audit included examination of accounting records, tests of internal control systems and other procedures considered necessary for due performance of this audit.

National level consumption

128. The audit confirmed that official government import and export data indicate nil imports or exports of CFC-113 in 2005. Based on the World Bank's production sector verification report for 2005, the total consumption of CFC-113 was found to be below the 2005 consumption control target of 550 ODP tonnes.

129. According to the data reported by the producers and the 2006 report of CNAO Foreign Loan & Financial Aids Projects Audit Centre No 43, TCA production in 2005 was 77.883 ODP tonnes. According to information from the General Administration of Customs and the Administration Office of ODS Import and Export, import of TCA in 2005 was 108.708 ODP tonnes. Therefore, the total consumption of TCA is 186.591 ODP tonnes, which meets the control target of 424 ODP tonnes set out in the Agreement, while consumption of CTC used as a solvent has also been verified as zero.

Enterprise-level consumption

130. SEPA and UNDP commissioned an independent accounting firm, Beijing Zhong Tian Hua Zheng Certified Public Accountants Co. Ltd., to undertake a performance verification at 41 recipient enterprises under the 2005 annual implementation programme as well as the technical assistance activities undertaken under the solvent sector phase-out plan and the national consumption limits, through verification of TCA production, import and export quantities of CFC-113 and TCA. As recommended in decision 42/13, a careful selection process was carried out to ensure that the 41 enterprises constituted a representative sample.

131. The verified CFC-113 consumption of the enterprises was substantially lower than the consumption reported by the enterprises in the original contracts. However it was confirmed that by June 30th, 2006, 39 of the 41 enterprises had ceased ODS solvent consumption. Several enterprises failed to provide documents proving the disposal of the old ODS equipment, due to inappropriate management.

132. The verification found that enterprises participating in the retroactive reimbursement project had relatively strong accounting and management systems and production procedures. Several of those participating in the voucher system phase II did not have satisfactory management and accounting systems, but appeared capable of carrying out and completing their projects.

Policy enforcement

133. The audit concluded that the verification process found no non-compliance with the SEPA ban on the use of CTC for solvent purposes first promulgated on 1 June 2003.

Audit recommendations

134. To overcome a lack of clear understanding of the requirements of phase-out projects, it is suggested that intermediate executing agencies (IEAs) and the participating enterprises should be trained in advance.

135. Inconsistency between invoice consumption figures and actual enterprise consumption amount is not rare. Therefore, it is recommended that verification of the amount phased out should be based on a number of relevant indicators, not only the invoice amount.

136. Pre-training of the intermediate executing agencies is necessary to guarantee the quality and progress of the phase-out programmes.

137. Lack of awareness of the project at national level, including the bans on use and the overall phase-out schedule, had led to hesitation and suspicion about the project. More activities are needed to promote public awareness and to ensure the effectiveness of implementation.

Unspent balances from previous tranches

138. The total funding released by the Executive Committee, the amount of fund disbursed or committed by the implementing agencies and the unspent balance from fund released, as of 31 December 2005 are indicated in the table below.

Total Amount Approved (US $)	Amount Disbursed / Committed (US $)	Uncommitted / Undisbursed Balance (US $)	Year of Commitment of Unspent Balance
42,080,000	20,534,485	21,545,515	2006-2008

139. The above does not include US $9 million targeted to be disbursed in 2006.

140. FECO/SEPA and UNDP decided that vigorous pre-disbursement scrutiny is needed to verify the levels of consumption and the authenticity of procurement and contractual services. Additionally, the retroactive payment is further delayed until the verification process is completed. These are the two main factors contributing to the large uncommitted balance.

141. FECO/SEPA is also keen to ensure that such savings not be programmed at this stage, but are saved to cover any unforeseen expenditures later in the project and to ensure sufficient funding to cover all beneficiaries.

The 2007 annual implementation programme

142. The 2007 Annual Implementation Programme will continue to implement and complete the phase-out activities initiated in 2005 and 2006. New activities will be initiated to phase out 85 ODP tonnes of TCA, contributing to the achievement of 2007 consumption control limits. For 2007, 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 initiated in 2006 can be completed by the end of 2008, activities will commence early in 2007.

143. Necessary technical assistance activities, legislative measures, monitoring and enforcement mechanisms are also included in the 2007 Annual Implementation Programme.

Such activities are now becoming more important in terms of sustaining phase-out of CTC and CFC-113.

144. The technical assistance activities and Government actions proposed in 2007 are indicated in the following tables:

Technical assistance activities in the 2007 AIP

Activity		Description
Public awareness	Objective	Introduce and publicize nationwide ODS phase-out in solvent sector to attract attention and participation maintaining and updating solvent website
	Target group	Solvent consumers in both formal and informal enterprises
	Outcome	Public awareness and interest in participation increased
Workshops for TCA substitute and alternative technology	Objective	Introduce alternative technologies and TCA substitutes
	Target group	Recipient enterprises, EIAs and administrations
	Outcome	Enterprises being assisted on possible TCA substitutes, foundation of future work being established
Training on TCA new phase-out project, alternative technologies and implementation mechanism	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. Preliminary selection of alternative technologies.
Compilation of a collection of successful and proved TCA substitute technologies	Objective	Gathering the experience of TCA users successful in phasing out of TCA and suggestions from experts to guide the TCA consumption enterprises for technology substitution
	Target group	Target TCA users and recipient TCA users
	Outcome	Knowledge gained by enterprises on substitute technologies
Continuation of the TCA substitute and alternative technology project	Objective	Find the most effective substitutes for TCA in most of the TCA consumption fields
	Target group	TCA consumption enterprises that have signed contracts with SEPA
	Outcome	TCA consumption enterprises being guided from the research results to select most appropriate ODS alternative technology
Continuation of the programme against illegal import, production and consumption of ODS	Objective	Ensure effective monitoring and enforcement on ODS usage, selection of appropriate and effective technologies, clear understanding of MLF procedures, ensure workplace and worker safety recipient
	Target group	Local EPB, customs authorities and AQSIQ
	Outcome	Effective mechanism established to tackle illegal ODS related cases
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 contract with SEPA
	Outcome	Every enterprise will meet the project's requirements both in qualification and consumption and executive procedures
Performance verification	Objective	Verify the performance of ODS phase-out activities at both national and enterprise level in the year of 2006 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
Policy training for local authorities in China	Objective	Establish and promote the on line training system and continue to conduct face to fact training to local governments
	Target group	Officials from local EPBs, customs and supervision departments
	Outcome	Improvement in capacity of policy enforcement with regard to ozone protection

Government actions in the 2007 AIP

Policy/Activity Planned	Schedule of Implementation
Monitoring of CTC and CFC-113 solvent ban	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
Promulgate bans on production and consumption of TCA in 2010	End of 2007
Public awareness	Throughout the year
Continue identification and monitoring of enterprises who have undertaken phase-out at their own initiatives, verify phase-out and implement reimbursement of phase-out costs	Activities will be continued and emphasis will be raised in 2007
Continue identification of enterprises that choose to undertake gradual phase-out, finalize agreement, verify annual phase-out and monitor issuance of usage certification	

2007 Budget

145. The total amount requested for the 2006 annual implementation programme is US $5,480,000 plus support costs of US $411,000 for UNDP. Prior to 2005, funding was requested at the first meeting of the year. However, commencing with the 2006 tranche, UNDP and China now request approval of funding at the last meeting of the preceding year. UNDP indicated that funding for the additional tranche for the 2006 AIP was included in its 2005 business plan approved at the 48th Meeting. The breakdown of expenditure is indicated below:

Activity	Planned Expenditures (US $)
Enterprise-level phase-out activities -Retroactive reimbursement and gradual self phase-out mechanism	**4,391,000**
Technical assistance - Public awareness (US $130,000) - Workshop on TCA substitutes (US $50,000) - Training on TCA new phase-out project (US $80,000) - Compilation of a collection of TCA substitute technologies (US $50,000) - Programme against illegal trades (cooperation with AQSIQ) (US $200,000) - Supervision and monitoring of the phase-out project ($100,000) - Implementation of TCA quota & licenses system ($150,000) - Performance verification ($100,000) - Policy training for local authorities in China (US $129,000) - International and national technical experts (US $100,000)	**1,089,000**
TOTAL	**5,480,000**

SECRETARIAT'S COMMENTS AND RECOMMENDATIONS

COMMENTS

146. Compliance with the consumption limits specified in the sector plans agreement is dependent firstly on the level of production of CFC-113 in China. This amount is verified as part of production sector phase-out plans. The other relevant factors are TCA production and imports and exports of TCA and CFC-113. The audit of these quantities confirms that the production and 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. Consistent with practice in previous years, the verification audit process does not extend to 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 CFC-113 and TCA control measures contained in the agreement for the solvent sector phase-out plan.

147. It has been reported that, consistent with the requirements of the agreement there was nil consumption of CTC for solvent uses in 2005. The verification report indicated that through investigation, no non-compliance was discovered. UNDP subsequently advised that to ensure sustainability of the phase-out in CTC for solvent use, the terms of reference of the performance verification include undertaking spot checks of previously identified CTC solvent consumers, to confirm the non-existence of such illegal consumption. Similar activities will be carried out to detect illegal use of CFC-113 as of 1 January 2006, however such random checks can only be carried out in a limited scope due to the availability of resources to undertake such investigations.

148. The Secretariat sought clarifications concerning the measures that had been taken to implement decision 42/13 (b) concerning the focussing of audit and verification activities at the national level in combined missions of national and international experts, and the establishment of an effective monitoring system to prevent diversion of CTC for solvent use.

149. UNDP indicated China's view that emphasis should be placed on the enforcement of the regulations and preventive actions through technical assistance activities to combat illegal ODS activities, which have a wider scope than the China solvent sector phase-out plan alone. Future actions under the China solvent sector phase-out plan may include allocation of additional resources to combat illegal ODS activities and to strengthen capacities to enforce the regulations.

150. UNDP further added that specific actions to combat illegal ODS activities to control unofficial import currently in progress through the technical assistance programme include:

(a) A SEPA 'hotline' and website for reporting illegal production, consumption and trade of ODS;

(b) A cooperative investigation mechanism between FECO and the Bureau of Environmental Supervision (BES) of SEPA;

(c) Under this mechanism, six cases of illegal ODS production were revealed in 2006;

(d) An emergency response mechanism established by BES in several key provinces/cities in collaboration with local Government authorities;

(e) The second technical assistance project for combating illegal trade to train customs authorities and provide ODS detecting instruments; and

(f) Provisions for strict punishment under related laws including fines, closure and dismantling of equipment.

151. As occurred with 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

485 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.

152. In regard to phase-out performance, consistent with previous reports, the verification exercise undertaken at the enterprise level indicate that the uptake of phase-out projects by industry does not provide phase-out quantities equal to the total reductions in consumption at the national level. It also indicates 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 proposed actions of SEPA and UNDP also indicate that the issues raised in the verification report are being actively addressed.

153. It is clear that a great deal of effort is being directed towards attracting enterprises to participate in funded phase-out activities. It is also evident from UNDP's report that particular emphasis is being placed on ensuring that funds are being administered in an appropriate manner and that enterprise claims are fully verified prior to disbursement of funds. This extends the time required for disbursement. However it appears to be time well spent and provides an assurance that Fund resources are being properly applied.

154. 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 Executive Committee (US $)	**Value of Contracts Signed (US $)**	**Funds Disbursed as of December 2005 (US $)**	**Funds Committed but not disbursed (US $)**	**Year and Amount of Payment of Undisbursed Amount (US $)**	**Balance Undisbursed or Uncommitted (US $)**
Previous Tranches					
37,025,000	**34,320,698**	**18,914,114**	**15,406,584**		**2,704,302**
Investment Activities	31,270,343	17,238,517	14,031,826	$5,572,215 (2006) $7,608,392 (2007) $851,219 Savings	
Non-Investment Activities	3,050,355	1,675,597	1,374,758	1,330,210 (2006) 44,548 (2007)	
2006 AIP					
5,055,000	**4,049,302**	**n/a**	**4.049,302**		**1,005,698**
Investment Activities	2,069,070	n/a	2,069,070	582,529 (2006) 1,486,541 (2007)	
Non-Investment Activities	1,980,232	n/a	1,980,232	1,740,582 (2007) 239,650 savings	
Total					
42,080,000	**38,370,000**	**18,914,114**	**19,455,886**		**$3,710,000**

155. UNDP indicated that contracts with a value of US $38.37 million had been entered into by the end of September 2006. However because the contracts have been signed by SEPA, and not by UNDP, they cannot be recorded in UNDP's financial record, even as obligations, until disbursement by SEPA has taken place. The low disbursements reported by UNDP are due in large part to the time that elapses between the contracting of an activity by SEPA and the recording of financial obligation and disbursement in the UNDP financial system. While there is an uncommitted balance of US $3.7 million, plus about US $1 million in savings, it is estimated that the total amount of contracts signed will be approximately $42 million by the end of 2006, leaving only US $80,000 uncommitted out of the total approved funding of $42,080,000.

156. There are no issues arising from the proposed 2007 annual implementation plan.

RECOMMENDATIONS

157. 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 2005/2006 and verification of 2005 performance. The Fund Secretariat also recommends blanket approval of the 2007 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: 2007 annual programme	5,480,000	411,000	UNDP

Sector Plan for Phaseout of CFCs Consumption in China Pharmaceutical Aerosol Sector

State Environmental Protection Administration

State Food and Drug Administration

and

National Institute for the Control of Pharmaceutical and Biological Products

August 4, 2006

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Summary

This sector plan aims to assist China to phase out CFCs consumption in its pharmaceutical aerosol sector excluding MDIs applications. The funding request targets the consumption of 485.089 ODP MT CFCs. The sector plan was prepared on the basis of a detailed analysis of eligible aerosol applications in China. It proposes conversion to non-ODS substitute aerosol where mature substitutes are available. Before new non-CFCs production starts, manufacturers are allowed to use stockpiled CFCs to maintain production to meet clinical demand. The sector plan will be implemented through two biennial programs starting in 2007. The sector plan includes policy actions to ensure that the phase-out proceeds on schedule. An action plan indicating annual CFC phase-out targets is included in the proposal and the first biennial program for 2007-2008 is submitted along with this sector plan.

Pharmaceutical Aerosol Manufacturers:	**39**
Eligible Manufacturers:	**32**
Applications by Eligible Manufacturers:	**24** Skin Aerosol Applications
	16 Cavity Aerosol Applications
CFCs Baseline Consumption(Average of 2003-2005):	**485.089 ODP MT**
ow. CFCs Consumption Requested for MLF Grant:	**464.355 ODP MT**
Project Duration:	**4 years**
Project Incremental Cost:	**US$15.927 million**
Requested MLF Funding:	**US$ 15.927 million**
IA Support Cost	**US$ 1,195 million**
Total cost to the MLF	**US$ 17.122 million**
Cost Effectiveness:	**US$ 32.83/kg ODP**
National Coordinating Agency:	**SFDA and SEPA**

CHAPTER 1 Introduction

1. Background

1. The Government of China ratified the Montreal Protocol on Substances that Deplete the Ozone Layer in 1991 and finalized China Country Program for Ozone Depleting Substances Phase-out in January 1993. This Country Program was submitted to the 9th Executive Committee (ExCom) of the Multilateral Fund of the Montreal Protocol in March 1993 and was updated by China in November 1999. From 1997 to 2006, several phase-out sector plans have been developed and implemented, reaffirming China's commitment to meeting its obligations for phase-out of ODS consumption with the support of MLF.

2. Funding of US$ 135,000 was approved at the 43rd ExCom meeting in July 2004 to prepare *the Sector Plan for Phase-out of CFCs Consumption in China Pharmaceutical Aerosol Sector (non-MDIs)*. As the leading agency for the implementation of Montreal Protocol, the State Environmental Protection Administration of China (SEPA), in cooperation with the State Food and Drug Administration (SFDA), selected National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) to prepare this sector plan.

2. Objectives

3. The main objectives of this sector plan include the following:

   a Identify all CFCs-based pharmaceutical aerosol manufacturers, their aerosol applications and CFCs consumption;

   b Design a technical scheme for phaseout of CFCs consumption in China pharmaceutical aerosol sector based on available non-ODS substitutes;

   c Develop a CFCs Phaseout Action Plan to meet the requirement of *China Accelerated Phase-out Plan(APP);*

   d Request MLF funding consistent with the MLF policies and guidelines to phase out CFCs in the sector[1];

   e Develop new CFCs phase-out policies for pharmaceutical aerosol sector; and

   f Develop a monitoring and management system to ensure successful implementation of the CFC phase-out in the pharmaceutical aerosol sector and rational utilization of MLF funds.

CHAPTER 2 Sector Profile

1. Background

4. China pharmaceutical aerosol industry started fairly late. In 1964, Shanghai Institute of Pharmaceutical Industry, in cooperation with Shanghai Sine Pharmaceutics Factory, Wuxi First Pharmaceutics Factory and Chongqing Seventh Pharmaceutics Factory, developed and produced Pingchuan (Anti-asthmatic), the first aerosol product in China. The period from 1964 to the 1980s saw comparatively slow development of China pharmaceutical aerosol sector due to the bottleneck of development of containers, valves and metered-dosed charging equipment. However, after those problems were solved, great progress has been achieved in the sector.

2. Sector Survey

[1] As substitute technology was not available in 1990s, it is proposed that the cutting off date should be July 1, 1999 after which Article 5 Parties had the obligation to freeze CFCs production and consumption (see paragraph 45).

5. NICPBP was selected to carry out the sector survey and to prepare the sector plan for China pharmaceutical aerosol sector. The survey covered both non-MDIs and MDIs pharmaceutical aerosol manufacturers. To collect data, an investigation questionnaire was jointly prepared by SFDA, SEPA and NICPBP.

6. In June 2004, SFDA sent the questionnaire to pharmaceutical aerosol manufacturers in China. By November 2004, SFDA had received feedback from 57 enterprises.

7. In August 2004, SEPA, NICPBP and SFDA verified three aerosol manufacturers by site visit, namely, S&P Pharmaceutical Industry Co. Ltd., Xinjiang Biochemical Pharmaceutical Co. and Xinjiang Pharmaceutical Factory.

8. In September 2005, SFDA and NICPBP visited 40 pharmaceutical aerosol manufacturers to collect data.

9. In March 2006, SFDA requested again that its provincial Food and Drug Administration Bureaus confirm the list of aerosol manufacturers and their aerosol products.

10. In April 2006, pharmaceutical manufacturers were invited to attend a meeting in Beijing to learn the CFCs phaseout for the sector. At the meeting, they confirmed their data of aerosol products. The meeting also provided information on the process for phasing out CFC and the requirements for new registrations of aerosol products.

11. In April 2006, NICPBP visited eight pharmaceutical manufacturers. Therefore, total 51 manufacturers have been investigated by site visit. For the other 11 manufacturers without aerosol production, NICPBP had collected by sending questionnaires their relevant information including product approval numbers. So total 62 pharmaceutical aerosol manufacturers were investigated. It is confirmed by NICPBP that the survey covered all the CFCs-based non-MDIs pharmaceutical aerosol manufacturers.

12. The sector survey indicates that Chinese pharmaceutical aerosol manufacturers only have conceptual ideas on the CFCs substitutes and conversion technology.

3. Sector Profile

13. Pharmaceutical aerosol product comprises the propellant compatible with the drug, a container capable of withstanding vapor pressure of propellant and a valve system. Propellants used in China pharmaceutical aerosol sector are mainly CFCs including CFC-11 and CFC-12. CFC-11 is used as a dispersant while CFC-12 as a propellant. Containers are made of glass, aluminum, stainless steel and plastic, but glass and aluminum containers are more often seen. Valves are often made of plastic, rubber, aluminum and stainless steel. Valves have to be inert with formulations in the canisters.

14. Pharmaceutical aerosols can be grouped by dispersing system into three types, namely, solution type, suspension type and emulsion type. China pharmaceutical aerosols can also be divided by medical usage into three groups – i) aerosol absorbed through skin (Skin Aerosol hereinafter), which is also called as external-use aerosol in China. ii) aerosol absorbed through cavity and mucosa, e.g. oral, nasal and vaginal cavity (Cavity Aerosol hereinafter) and iii) aerosol inhaled through respiratory tract (MDIs). The first two groups are referred to as non-MDIs aerosols, which are addressed in this sector plan. China will submit another sector plan for MDIs sector separately at a later stage. Table 2-1 is the survey summary of the non-MDIs sector.

Table 2-1 Summary of China Pharmaceutical Aerosol Sector

	Eligible for MLF Grant*	**Not Eligible for MLF Grant**	**Total**
CFCs Baseline Consumption (MT)	464.355	20.733	485.089
Number of Manufacturers	32	7	39

Number of Production Lines	35	6	41
Number of Production Lines with Baseline Consumption	22	5	27
Number of Skin Aerosol Applications	24	3	-
Number of Cavity Aerosol Applications	16	4	-
Number of Skin Aerosol Products	42	3	45
Number of Cavity Aerosol Products	21	4	25

* Aerosol manufacturers with production lines established before cutting-off date (July 1, 1999).

3.1 Aerosol Applications

15. **Skin Aerosol Applications.** Skin Aerosols are used for wound surface protection, cleaning, sterilization, topical anesthesia and homeostasis etc. They are requested to have no stimulation effect. The surface coverage (thin film) provided by those aerosols should have good permeability. SFDA has issued 51 drug production approval numbers (i.e. drug specifications), relating to 25 applications (see table 2-2). Out of the 25 applications, 10 are chemicals applications which are as same as those in foreign countries; 15 are Traditional Chinese Medicine (TCM) Applications, of which 12 are proprietary applications owned by Chinese manufacturers. There are total 30 manufacturers with registration numbers for Skin Aerosol products.

16. **Cavity Aerosol Applications.** SFDA has issued 24 registration approval numbers for Cavity Aerosols, relating to 19 applications (see table 2-2), among which 8 are chemicals applications and 11 TCM applications. There are four nasal aerosol applications, mainly peptides and protein drugs, which exert general action, obviate gastrointestinal and hepatic first-pass action and improve bioavailability. There are two vaginal aerosol applications, mainly with tropical therapy for virginities and with contraception purpose. There are 13 oral aerosol applications, mainly with local action for the treatment of pharyngitis. Total 18 pharmaceutical manufacturers have registration numbers for cavity aerosol products.

Table 2-2 China Pharmaceutical Aerosol Applications

Application ID	Application Name	CFCs Baseline (kg)	Number of Manufact.	Manufacturer Name(#ID)
1) Skin Aerosol Application (total 25 applications)				
A02	Ice Cape Jasmine Distress Aerosol	19,053	1	Guizhou Antai Pharmaceutical Co., Ltd (#20)
A08	Compound Salicylic Acid and Clortrimazol Aerosol	1,773	1	Guizhou Antai Pharmaceutical Co., Ltd (#20)
A09	Compound ethyl chloride aerosol	0	1	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd (#03)
A10	Compound Chlorobutanol Aerosol	717	2	Wuxi Shanhe Group No.1 Pharmaceutical Co., Ltd. (#01); Chongqing Kerui Pharmaceutical Co., ltd. (#25)
A11	Compound Methyl Salicylate and Diphenhydramine Aerosol	0	2	Zhanjiang Xintongde Pharmaceutical Co., Ltd. (#27), Nantong Zhongbao Pharmaceutical Co., Ltd.(#37)
A13	Compound Cape jasmine Aerosol	229	1	Guizhou Xinyi Pharmaceutical Corporation (#21)
A14	Compound lithospermi aerosol	6	1	Suizhou Pharmaceutical Co. Ltd of Wuhan Jianmin Group (#19)
A16	Haobai Damp Impairment Aerosol	1,412	2	Hunan Bencao Pharmaceutical Co., Ltd. (#16); Shanghai Yishengyuan Pharmaceutical Co., Ltd. (#32)
A17	Hongyao Aerosol	57,717	1	Shenyang Jingcheng Pharmaceutical Co., Ltd. (#14)
A19	Keshangtong Aerosol	7	1	Suizhou Pharmaceutical Co. Ltd of Wuhan Jianmin Group (#19)
A22	Dolicaine chlorhexidine aerosol	833	2	South shaolin Pharmaceutical Co., Ltd in Fujian. (#09);

Application ID	Application Name	CFCs Baseline (kg)	Number of Manufact.	Manufacturer Name(#ID)
				Zhanjiang Xintongde Pharmaceutical Co., Ltd. (#27)
A23	Dolicaine chlorhexidine aerosol	35,616	10	Wuxi Shanhe Group No.1 Pharmaceutical Co., Ltd. (#01); Guangdong Baiyunshan Hejigong Pharmaceutical Co., Ltd. (#03); Guangdong Baiyunshan Externally Applied Agent Factory (#04); Penglai Nuokang Pharmaceutical Co., Ltd. (#11); Shandong Jingwei Pharmaceutical Co., Ltd. (#18); Hangzhou Sino-US huadong Pharmaceutical Co., Ltd. (#22); Zhanjiang Xingtongde Pharmaceutical Co., Ltd. (#27); Heilongjiang Tianlong Pharmaceutical Co., Ltd. (#28); Nantong Zhongbao Pharmaceutical Co., Ltd. (#37); Anshan No.1 Pharmaceutical Factory (#39);
A24	Lidocaine aerosol	0	1	Sine Pharmaceutical Factory of Shanghai Pharmaceutical Group Co., Ltd. (#08)
A25	Molsidomine Aerosol	0	6	Beijing Haiderun Pharmaceutical Co., Ltd. (#02); Beijing Double-Crane Modern Pharmaceutical Technology Co., Ltd. (#06); Sine Pharmaceutical Factory of Shanghai Pharmaceutical Group Co., Ltd. (#08); Harbin Hengcang Pharmaceutical Co., Ltd. (#15); Heilongjiang Tianlong Pharmaceutical Co., Ltd. (#28), Harbin Guangji Pharmaceutical Factory. (#36);
A27	Ruxiang Rheumatism Aerosol	0	1	Zhanjiang Xingtongde Pharmaceutical Co., Ltd. (#27)
A28	Shangle Aerosol	0	1	Beijing Haiderun Pharmaceutical Co., Ltd. (#02)
A29	Huoxianqutong Aerosol	49,530	3	Hubei Nanyang Pharmaceutical Co., Ltd. (#13), Heilongjiang Tianlong Pharmaceutical Co., Ltd. (#28), Hubei Lishizhen Medical Group Co., Ltd. (#34)
A30	Shiyang Aerosol	0	1	Beijing Haiderun Pharmaceutical Co., Ltd. (#02)
A32	Diclofenac Sodium Aerosol	5,583	1	Zhanjiang Xingtongde Pharmaceutical Co., Ltd. (#27)
A33	Methyl Salicylate aerosol	9,851	1	Fujian Nanshaolin Pharmaceutical Co., Ltd. (#09)
A35	Sunshangsuxiaozhitong Aerosol	0	1	Beijing Tongrentang Technology Development Corporation. (#07)
A36	Wanjinxiang Aerosol	38	1	Guizhou Hongyu Pharmaceutical Co., Ltd. (#29)
A37	Xiangbingqutong Aerosol	13	1	S & P Pharmaceutical Industry Co., Ltd.(#30)
A42	Lidocaine Hydrochloride Aerosol	0	1	Shanghai Fuxingzhaohui Pharmaceutical Co., Ltd. (#10)
A45	Yunnan Baiyao Aerosol	273,334	1	Yunnan Baiyao Group Corporation. (#24);
	Subtotal	**455,712**		
2) Cavity Aerosols Application (total 19 applications)				
A01	Bao Fu Kang foam	1,193	1	Guizhou Hongyu Pharmaceutical Co., Ltd.(#29)
A03	Beclometasone Tubinaire (Beconase)	20,390	1	Glaxo SmithKline (Tianjin) Pharmaceutical Co., Ltd.(#12)
A04	Beclometasone Aerosol	0	1	Guangzhou Dongkang Pharmaceutical Co., Ltd.(#31)
A05	Xanthiun and Magnolia flower Aerosol	2,592	1	Xinjiang Biochemistry Pharmaceutical Co., Ltd.(#23)
A06	Fluconazol Aerosol	0	1	Sine Pharmaceutical Factory of Shanghai Pharmaceutical Group Co., Ltd.(#08)
A07	Fudekang foam	13	1	Guiyang Dechangxiang Pharmaceutical Co., Ltd.(#05)

Application ID	Application Name	CFCs Baseline (kg)	Number of Manufact.	Manufacturer Name(#ID)
A12	Compound Chlorobutanol Aerosol	0	1	Chongqing Kerui Pharmaceutical Co., ltd.(#25)
A15	Isoconeazole Nitrate Aerosol	0	1	Heilongjiang Tianlong Pharmaceutical Co., Ltd. (#28)
A18	Jinlan aerosol	0	1	Anshan No.1 Pharmaceutical Factory. (#39)
A20	Stomatitis spraying agent	48	1	Shannxi Fengwuchendayaotang Pharmaceutical Factory Co., Ltd. (#35)
A21	Huanxiong Aerosol	0	2	Beijing Tongrentang Technology Development Corporation. (07); Anshan No.1 Pharmaceutical Factory. (#39)
A26	Qiweiqingyan Aerosol	293	1	Shandong Bencao Pharmaceutical Co., Ltd. (#17)
A31	Shuanghuanglian Aerosol	145	1	Sanjing Pharmaceutical Co., Ltd of Harbin Pharmaceutical Group. (#33)
A34	Suxiaojiuxin Aerosol	14	1	Beijing Tongrentang Technology Development Corporation.(#07)
A38	Nitroglycerin Aerosol	528	4	Shandong Jewim Pharmaceutical Co., Ltd. (#18); Zhanjiang Xintongde Pharmaceutical Co., Ltd. (#27); Xian Lisheng Pharmaceutical Co., Ltd.(#38); Shandong Bencao Pharmaceutical Co., Ltd.(#17)
A39	Isosorbide Dinitrate Aerosol	3	1	Shandong Jewim Pharmaceutical Co., Ltd.(#18)
A40	econazole nitrate aerosol	3,780	3	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.(#03), Zhanjiang Xingtongde Pharmaceutical Co., Ltd. (#27); Heilongjiang Tianlong Pharmaceutical Co., Ltd. (#28)
A41	Rapid recovery of throat aerosol	380	1	Huayi Pharmaceutical Co., Ltd. (#26)
A44	Yinhuangpingchuan Aerosol	0	1	Anshan No.1 Pharmaceutical Factory (#39)
	Subtotal	**29,377**		
	Total	**485,089**		

Table 2-3 Overviews of Pharmaceutical Aerosol Manufacturers

ID	Name of Enterprise	Chinese Share (%)	Lines	Date of Line.	Cap. (can/ hour)	CFCs Baseline (kg)	Baseline CFCs for SA[1] (kg)	Baseline CFCs for CA[1] (kg)	Total Prodt. Quantity[2] (can)	SA Prodt. Quantity (can)	CA Prodt. Quantity (can)	SA App. ID	CA App. ID
01	Wuxi Shanhe Group No.1 Pharmaceutical Co., Ltd	100%	2	1965	2000	823	823	0	26,667	26,667	0	A10, A23	-
02	Beijing Haiderun Pharmaceutical Co., Ltd	100%	2	1978	-	0	0	0	0	0	0	A25, A28, A30	-
03	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd	100%	1	1983	-	0	0	0	0	0	0	A09 A23	A40
04	Externally Applied Agent Factory of Guangzhou Baiyunshan Pharmaceutical Co., Ltd	100%	1	1959	-	0	0	0	0	0	0	A23	-
05	Guiyang Dechangxiang Pharmaceutical Co., Ltd	100%	1	1979	600	13	0	13	100	0	100	-	A07
06	Beijing Double-Crane Modern Pharmaceutical Technology Co., Ltd	100%	1	1980	-	0	0	0	0	0	0	A25	-
07	Beijing Tongrentang Technology Development Corporation	100%	1	1981	1800-3600	14	0	14	1,267	0	1,267	A35	A21,A34
08	Xinyi Pharmaceutical General Factory of Shanghai Pharmaceutical Group Co., Ltd	100%	1	1969	0	0	0	0	0	0	0	A24,A25	A06
09	Fujian Nanshaolin Pharmaceutical Co., Ltd	100%	1	1985	3000	10,684	10,684	0	48,571	48,571	0	A22, A33	-
10	Shanghai Fuxingzhaohui Pharmaceutical Co., Ltd	100%	1	1988	-	0	0	0	0	0	0	A42	-
11	Penglai Nuokang Pharmaceutical Co., Ltd	100%	1	1986	2000	3,491	3,491	0	100,600	100,600	0	A23	-
13	Hubei Nanyang Pharmaceutical Co., Ltd	70%	1	1991	1000	49,393	49,393	0	1,171,333	1,171,333	0	A29	-
14	Shenyang Jingcheng Pharmaceutical Co., Ltd	50%	1	1992	2000	57,717	57,717	0	968,533	968,533	0	A17	-
15	Harbin Hengcang Pharmaceutical Co., Ltd	100%	1	1992	-	0	0	0	0	0	0	A25	-
16	Pharmaceutical Factory of Hunan Bencao pharmacy Co., Ltd	100%	1	1993	800-1000	1,300	1,300	0	58,333	58,333	0	A16	-
17	Shandong Bencao Pharmaceutical Co., Ltd	100%	1	1997	1500	428	0	428	56,720	0	56,720	-	A26,A38
18	Shandong Jewim Pharmaceutical Co., Ltd BlueBox	100%	1	1993	500-600	12,080	11,685	395	318,281	276,314	41,967	A23	A38,A39
19	Suizhou Pharmaceutical Co. Ltd of Wuhan Jianmin Group	100%	1	1993	2000	13	13	0	700	700	0	A14, A19	-
20	Guizhou Antai Pharmaceutical Co.,	100%	1	1983	500-600	20,827	20,827	0	580,000	580,000	0	A02, A08	-

ID	Name of Enterprise	Chinese Share (%)	Lines	Date of Line.	Cap. (can/ hour)	CFCs Baseline (kg)	Baseline CFCs for SA[1] (kg)	Baseline CFCs for CA[1] (kg)	Total Prodt. Quantity[2] (can)	SA Prodt. Quantity (can)	CA Prodt. Quantity (can)	SA App. ID	CA App. ID
	Ltd												
21	Guizhou Xinyi Pharmaceutical Corporation	100%	1	1993	500-600	229	229	0	8,333	8,333	0	A13	-
22	Hangzhou Sino-US Huadong Pharmaceutical Co., Ltd	75%	1	1993	-	0	0	0	0	0	0	A23	-
23	Xinjiang Biochemistry Pharmaceutical Co., Ltd	100%	1	1994	2500	2,592	0	2592	50,000	0	50,000	-	A05
24	Yunnan Baiyao Group Corporation	100%	1	1995	5000	273,333	273,333	0	5,306,667	5,306,667	0	A45	
25	Chongqing Kerui Pharmaceutical Co., ltd	100%	1	1975	-	0	0	0	0	0	0	A10	A12
26	Huayi Pharmaceutical Co., Ltd	100%	1	1996	500	380	0	380	70,000	0	70,000	-	A41
27	Zhanjiang Xintongde Pharmaceutical Co., Ltd	100%	1	1987	3600	29,397	25,917	3,480	1,240,000	1,036,667	203,333	A11, A22, A23,A27, A32,	A38, A40
28	Heilongjiang Tianlong Pharmaceutical Co., Ltd	100%	2	1996	1500-2000	300	0	300	33,333	0	33,333	A23, A25, A29	A15,A40
29	Guizhou Hongyu Pharmaceutical Co., Ltd	100%	1	1998	1500	1,230	38	1,193	76,933	2,800	74,133	A36	A01
31	Guangzhou Dongkang Pharmaceutical Co., Ltd.	100%	1	1987	-	0	0	0	0	0	0	-	A04
32	Shanghai Yishengyuan Pharmaceutical Co., Ltd	100%	1	1983	600-800	112	112	0	4,845	4,845	0	A16	-
37	Nantong Zhongbao Pharmaceutical Co., Ltd	100%	1	1990	-	0	0	0	0	0	0	A11, A23	-
39	Anshan No.1 Pharmaceutical Factory	100%	1	1990	-	0	0	0	0	0	0	A23	A18, A21, A44
30	Sanpu Pharmaceutical Co., Ltd	100%	0	2002	-	13	13	0	1,700	1,700	0	A37	-
33	Sanjing Pharmaceutical Co., Ltd of Harbin Pharmaceutical Group	100%	1	2003	1200	145	0	145	15,210	0	15,210	-	A31
34	Hubei Lishizhen Medical Group Co., Ltd	100%	1	2004	100	137	137	0	86,667	86,667	0	A29	-
35	Shannxi Fengwuchendayaotang Pharmaceutical Factory Co., Ltd	100%	1	2003	1800	48	0	48	6,000	0	6,000	-	A20
36	Harbin Guangji Pharmaceutical Factory	100%	1	NA	-	0	0	0	0	0	0	A25	-
38	Xian Lisheng Pharmaceutical Co., Ltd	100%	1	NA	-	0	0	0	0	0	0	-	A38
12	Glaxo SmithKline (Tianjin) Pharmaceutical Co., Ltd	0%	1	1991	1300-2000	20,390	0	20,390	1,216,000	0	1,216,000	-	A03
	Total		41			485,089	455,712	29,377	11,446,793	9,678,730	1,768,063		
	Eligible for MLF Fund		**35**			**464,355**	**455,561**	**8,794**	**10,121,216**	**9,590,363**	**530,853**		

ID	Name of Enterprise	Chinese Share (%)	Lines	Date of Line.	Cap. (can/ hour)	CFCs Baseline (kg)	Baseline CFCs for SA[1] (kg)	Baseline CFCs for CA[1] (kg)	Total Prodt. Quantity[2] (can)	SA Prodt. Quantity (can)	CA Prodt. Quantity (can)	SA App. ID	CA App. ID
	Not Eligible for MLF Fund		6			20,733	150	20,583	1,325,577	88,367	1,237,210		

1: SA: Skin Aerosol, CA: Cavity Aerosol; 2: Production quantity of baseline year.(average of 2003-2005).

3.2. CFCs Historical Consumption and Forecast for Future CFCs Consumption.

3.2.1. CFCs Consumption for Skin Aerosol

17. Table 2-4 shows the annual CFCs consumption data from 1996 to 2005 for Skin Aerosol. Baseline consumption is based on the average CFCs consumption of 2003 to 2005.

Table 2-4 CFCs Consumption for Skin Aerosol (1996-2005)

Year	CFC-11 Consumption (kg)	CFC-12 Consumption (kg)	Total (kg)
1996	30,519	117,596	148,116
1997	32,274	145,891	178,166
1998	33,834	133,219	167,054
1999	31,884	148,851	180,736
2000	43,007	165,436	208,443
2001	90,215	236,591	326,807
2002	124,551	296,296	420,847
2003	127,041	342,803	469,844
2004	97,120	347,122	444,242
2005	97,940	355,109	453,049
Baseline Level Average of 03-05	107,367	348,345	455,712

Chart 2-1 Annual CFC-11 Consumption for Skin Aerosol (1996-2005)

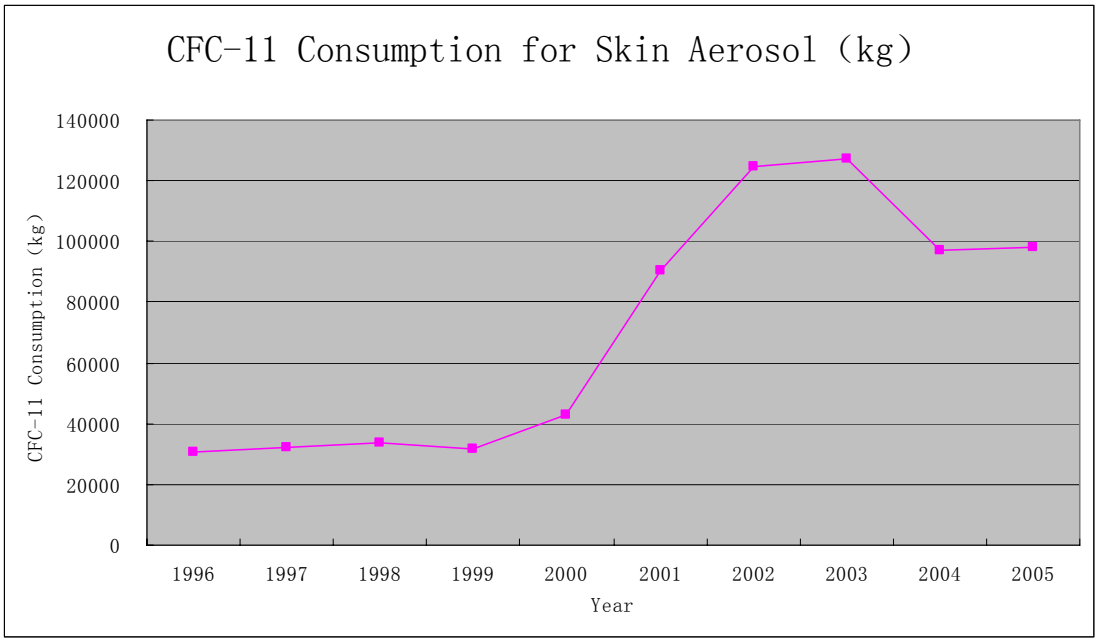


Chart 2-2 Annual CFC-12 Consumption for Skin Aerosol (1996-2005)

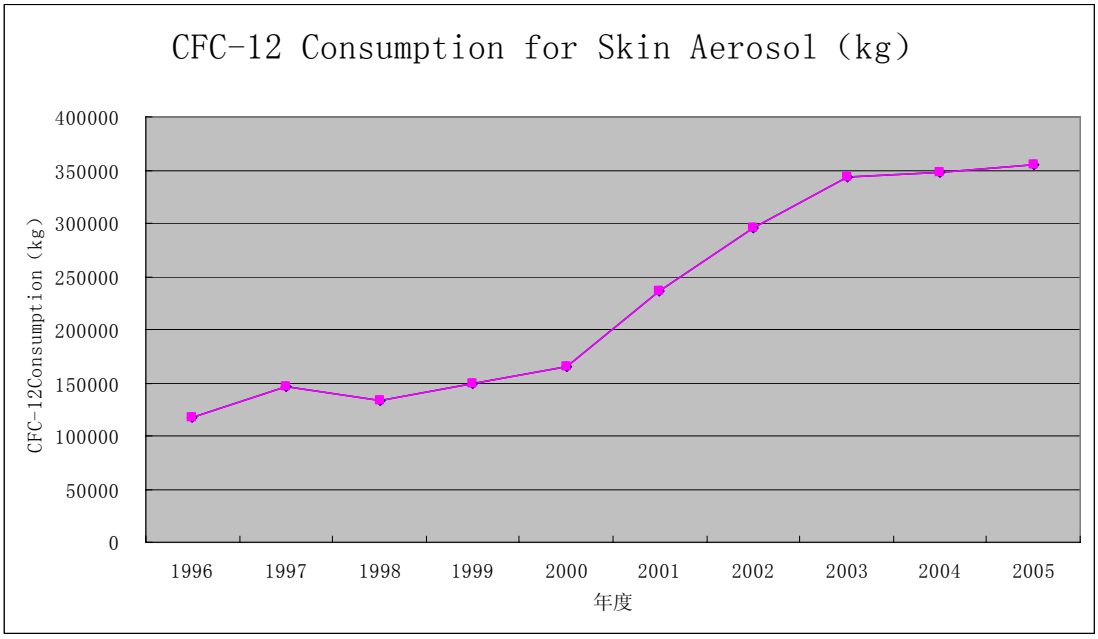
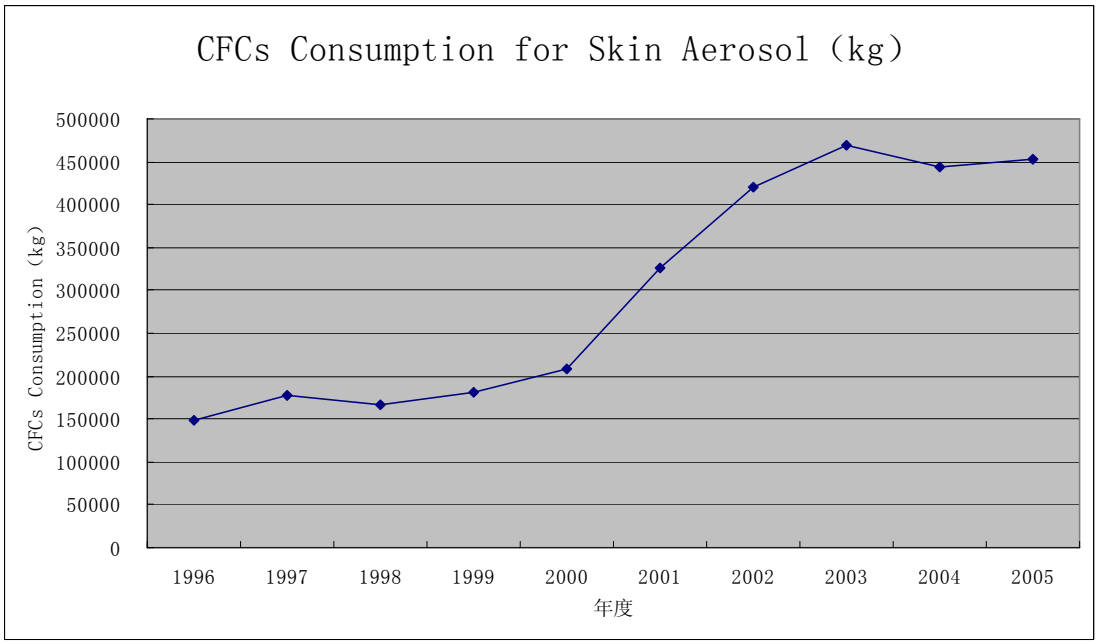


Chart 2-3 Aggregated Annual CFCs Consumption for Skin Aerosol (1996-2005)



3.2.2. CFCs Consumption for Cavity Aerosol

18. Table 2-5 shows annual CFCs consumption for Cavity Aerosol from 1996 to 2005. Baseline Consumption is based on the average CFCs consumption of 2003- 2005.

Table 2-5 CFCs Consumption for Cavity Skin Aerosol (1996-2005)

Year	CFC-11 Consumption (kg)	CFC-12 Consumption (kg)	Total (kg)
1996	1,137	2,924	4,061
1997	550	1,445	1,995
1998	1,614	6,125	7,739
1999	2,285	9,926	12,211
2000	2,058	9,881	11,939
2001	2,909	13,210	16,119
2002	1,867	10,425	12,292
2003	3,826	20,437	24,263
2004	8,228	32,471	40,699
2005	4,015	19,155	23,170
Baseline Level (average of 03-05)	**5,356**	**24,021**	**29,377**

Chart 2-4 CFC-11 Consumption for Cavity Aerosol (1996-2005)

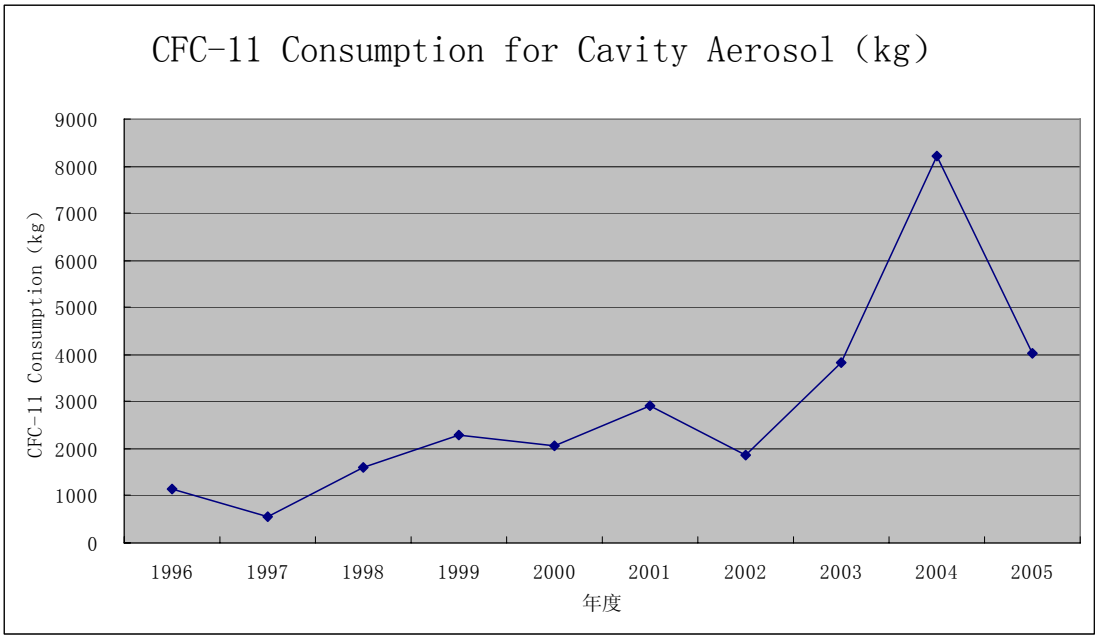


Chart 2-5 CFC-12 Consumption for Cavity Aerosol (1996-2005)

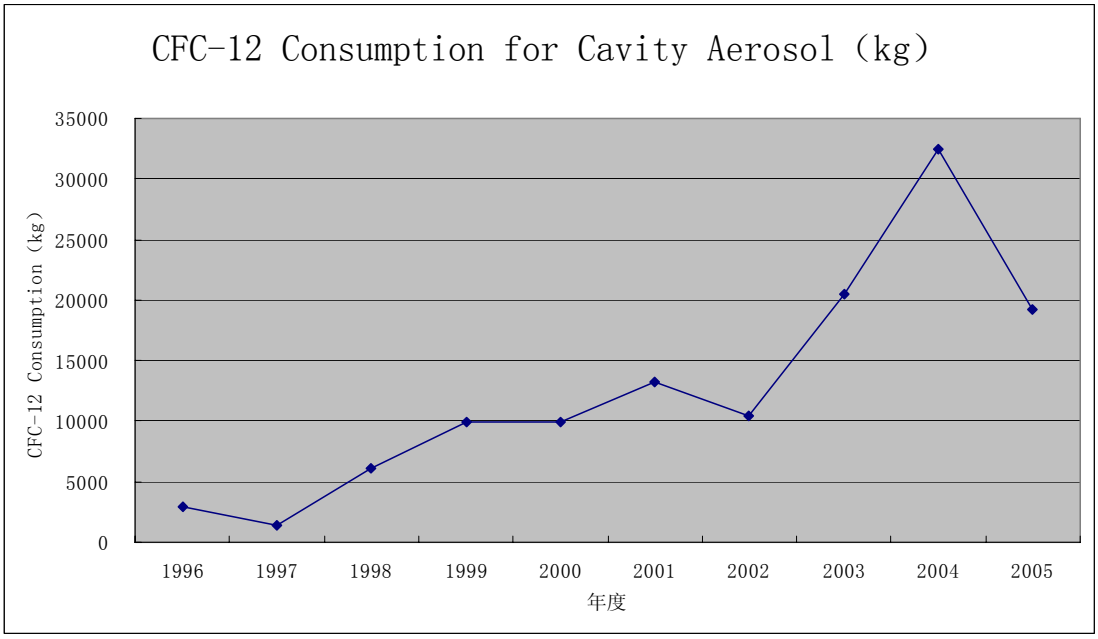
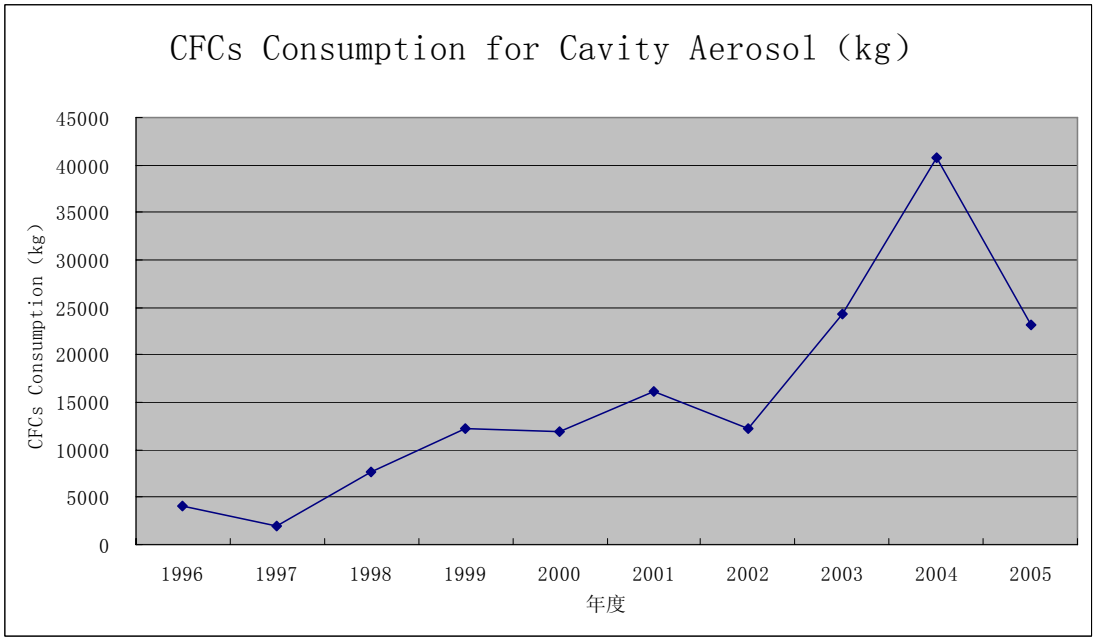


Chart 2-6 Aggregated Annual CFCs Consumption for Cavity Aerosol (1996-2005)



3.2.3. Forecast for CFCs Demand.

a) CFCs Demand Prediction for Skin Aerosol

19. CFCs consumption for Skin Aerosol increased from 1996 to 2005. Predicted by the tendency linear equation below, CFCs consumption for Skin Aerosol would reach at 700 tons in 2010.

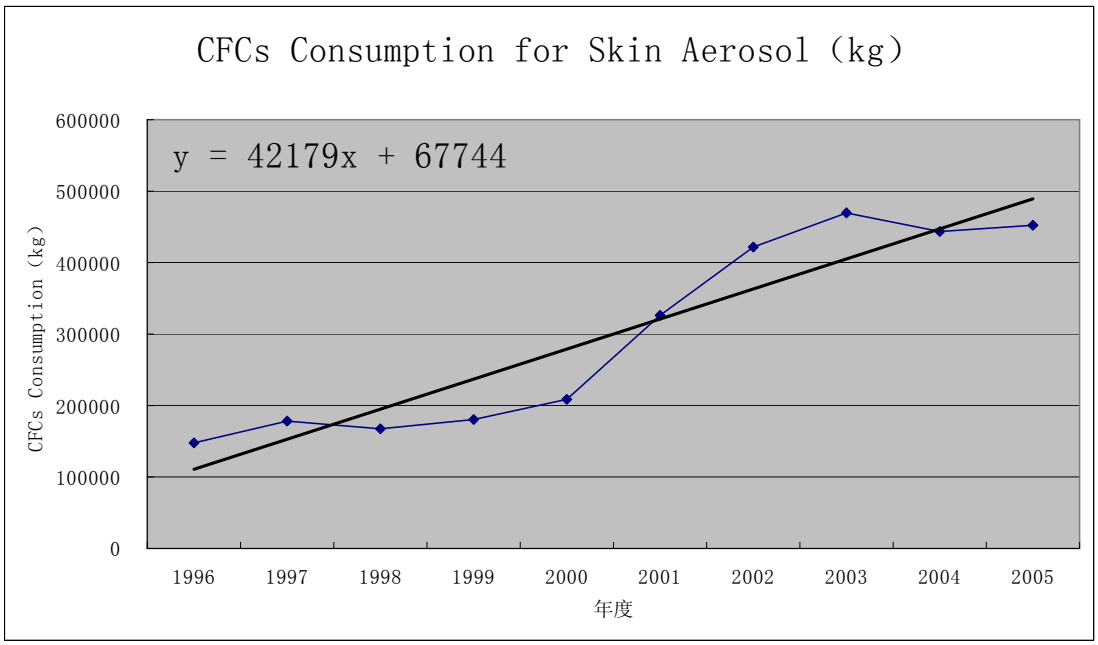
Y=42179X+67744

Where

X: The certain year minus 1995

Y: Annual CFCs consumption at a certain year;

Chart 2-7 Tendency Linear Equation for CFCs Demand Prediction for Skin Aerosol

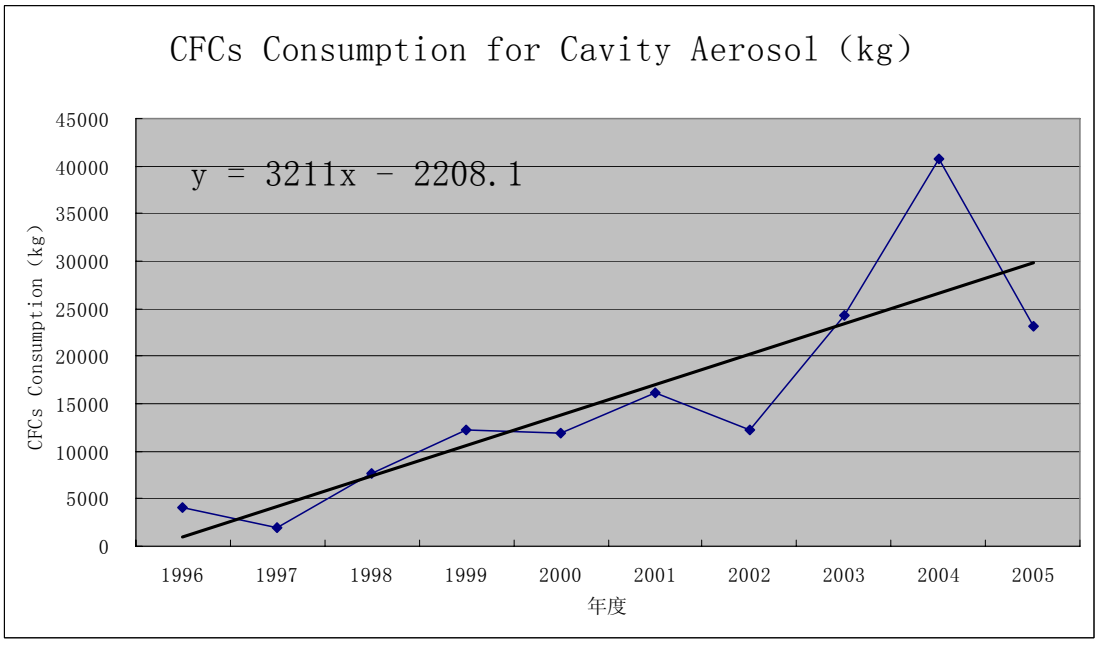


b) CFCs Demand Prediction for Cavity Aerosol

20. CFCs consumption for Cavity Aerosol increased from 1996 to 2005. Predicted by the tendency linearity equation below, CFCs consumption for Cavity Aerosol would be about 37 tons in 2010.

Y=3211X-2208.1
Where
X: The certain year minus 1995
Y: Annual CFCs consumption at a certain year;

Chart 2-8 Tendency Linear Equation for CFCs Demand Prediction for Cavity Aerosol



CHAPTER 3 Sector Polices

21. **Existing Policies** CFCs are used as excipients for pharmaceutical aerosol products. Replacement of CFCs with non-CFCs excipients or with different dosage form is subject to Chinese relevant laws, regulations and policies which mainly include the following:

1. Drug Administration Law of the People's Republic of China (effective since December 1, 2001)

22. This Law is enacted to strengthen drug administration, to ensure drug quality and safety for human beings, to protect the health of people and their legitimate rights and interests in the use of drugs. Article 2 of this law stipulates that all institutions and individuals engaged in research, production, distribution, use, or drug administration in the People's Republic of China shall abide by this Law. Some clauses related to the pharmaceutical aerosol sector plan include, but not limited to:

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

24. **Control over Drugs**. Article 29 stats 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 regulatory 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 administrative 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 regulatory department under the State Council.

25. Article 31 states that "A drug manufacturer may produce the drug only after an approval number is granted to it."

2. Provisions on Drug Registration issued by SFDA (No. 17, effective since May 1, 2005)

26. Article 8 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, add new indication shall be treated as a new drug application."

27. "Application for a drug already with national standards means application for production of a drug for which SFDA has already issued formal standards. Supplemental application means an application for the change, addition, or cancellation of any item or contents in the existing registration approval of a new drug, drug already with national standards, or import drug."

3. Notice of Stopping Using Chlorofluorocarbons (CFCs) as Excipients for Pharmaceutical Aerosol issued by SFDA on June 22, 2006.

In order to cooperate with China Accelerated Phaseout Plan - to stop CFCs production by June 30, 2007 - SFDA issued the following policy. As per this notice,

28. (i) China is to stop using CFCs as excipients for external-use aerosol production since July 1, 2007. CFCs-based external-use aerosols products in storage are allowed to be circulated and used until the

expiration of their validity periods. China is to stop using CFCs as excipients for MDIs aerosol production since January 1, 2010. CFCs-based MDIs aerosols products in storage are allowed to be circulated and used until the expiration of their validity periods. SFDA will introduce special provisions for the transitional period from July 2007 to December 2009(see Chapter 5).

29. (ii) China is to stop importing CFCs-based external-use aerosols since July 1, 2007. CFCs-based external use aerosol products imported before this date are allowed to be circulated and used until the expiration of their validity periods. China is to stop importing CFCs-based MDIs aerosol since January 1, 2010. CFCs-based MDIs aerosol products imported before this date are allowed to be circulated and used until the expiration of their validity periods.

30. (iii) China is to stop approval of registration for external-use aerosols with CFCs as excipients from July 1, 2007 (including application for the imported CFC-based external use aerosol products). China is to stop approval of registration for MDIs aerosol products with CFCs as excipients (including application for the imported CFC-based MDIs aerosol products) since January 1, 2010.

31. (iv) Should any pharmaceutical manufacturer change excipients or dosage form of aerosols, it shall submit such applications in accordance with Provisions on Drug Registration.

CHAPTER 4 Technical Analysis

32. As CFCs propellants are degrading the ozone layer, researchers are studying on CFCs-free pharmaceutical aerosol. There are mainly two approaches to replace CFCs: i) to identify CFCs substitutes; ii) to use alternative delivery system, such as compressed-air spray, ultrasonic spray, two-phase system, self-pressurized system and dry powder inhaler. Presently, there are four commonly used CFCs substitutes: Hydrofluoroalkane (tetrafluoroethane HFA 134a and heptafluoropropane HFA 227), Dimethyl ether (DME), Hydrocarbon (isobutane) and compressed gas (e.g carbon dioxide). Substitute propellants being used in foreign countries comprise tetrafluoroethane HFA-134a, heptafluoropropane HFA-227 and DME.

1. Potential Substitutes

1) Hydrofluroalkane

33. Compared with CFCs, Hydrofluoroalkane has similar properties, poorer chemical stability and less polarity. Table 4-1 indicates the physical and chemical properties of Hydrofluoroalkane and its impact on the atmosphere in comparison to CFCs.

Table 4-1 Properties of Hydrofluoroalkane and CFCs

Item	Trichlorofluoromethane (CFC-11)	Dichlorodifluoromethane (CFC-12)	Dichlorotetrafluoroethane (CFC-114)	Tetrafluoroethane (HFA-134a)	Heptafluoroethane (HFA-227)
Molecular Formula	$CFCl_3$	CF_2Cl_2	CF_2ClCF_2Cl	CF_3CFH_2	F_3CHFCF_3
Vapor Pressure (Psig/20℃)	-1.8	67.6	11.9	4.71	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	0.7	0	0
GWP*	1	3	3.9	0.22	0.7
Atmospheric Life Cycle (year)	75	111	7200	15.5	33

*Ozone Depleting Potential/ Global Warming Potential relative to CFC-11

2). Dimethyl Ether (DME)

34. Table 4-2 shows the properties of DME (CH3OCH3). DME is flammable and has low acute and chronic toxicity. It is mainly used as CFCs substitute for external-use aerosols. One of DME's advantages is that it can be dissolved homogeneously with water at a certain proportion.

Table 4-2 Properties of DME

Molecular formula	CH_3OCH_3
Molecular weight	46.07
Boiling point	-24.9℃
Vapor pressure	6kg/cm^2
Density	0.66g/ml
Water solubility	35.5%
Flammability Limits in Air, Vol %	3.4~26.7%
Damage on ozone layer	-

3). Hydrocarbon

35. Table 4-3 lists the physical properties of Hydrocarbon (mainly including isobutane, propane, and n-butane). Despite with good stability and low density, Hydrocarbon is toxic, inflammable and explosive, thus entailing high safety standard for production. Hydrocarbon is commonly blended with Hydrofluoroalkane as propellant.

Table 4-3 Physical Properties of Hydrocarbon

Chemical Name	Formula	Molecular Weight	Flashing Point (℃)	Boiling Point (℃)	Vapor Pressure (gauge pressure, kPa, 21.1℃)	Liquid Density [21.1℃ (g/cm^2)]	Flammability Limit in Air [% (ml/ml)]	
							Min.	Max.
Propane	CH3(CH2)CH3	44.1	-104.4	-42.1	744.8	0.50	2.2	9.5
Isobutane	CH(CH3)3	58.1	-32.8	-11.7	214.3	0.56	1.8	8.4
N-butane	CH3(CH2)2CH3	58.1	-73.9	-0.5	116.4	0.58	1.9	3.5

4). Compressed Gas.

36. Table 4-4 lists the physical properties of compressed gas (mainly including carbon dioxide, nitrogen and nitrogen monoxide). In comparison with DME and HFA, Compressed Gas is more chemically stable and inflammable but has lower boiling point after liquefaction and higher vapor pressure at normal atmospheric temperature, thus requiring that packaging containers should withstand higher pressure (e.g. small steel cylinder as the packaging container). If un-liquefied compressed gas is filled in the container, pressure within the container falls rapidly and continuous injection cannot be maintained. Presently, compressed gas is basically not used for aerosol products, but for spray products.

Table 4-4 Physical Properties of Compressed Gas

Chemical name	Molecular Formula	Molecular Weight	Boiling Point (℃)	Vapor Pressure (gauge pressure, kPa, 21.1℃)	Inflammability
Carbon dioxide	CO_2	44.0	-78.3[1]	5767	No
Nitrogen monoxide	N_2O	44.0	-88.3	4961	No
Nitrogen	N_2	28.0	-195.6	3287[2]	No

1: Sublimation; 2: Critical temperature: -147.2

37. During past few years, Boeheringer, Fisons, 3M, Glaxo and Riker have obtained relevant formulation patents which cover propellant system including components, co-solvent, hydrocarbon surfactant and fluoro-surfactant. It is reported that a few issues have to be solved for Hydrofluoroalkane being employed as propellants for pharmaceutical aerosol sector.

i) **Co-solvent with Low Boiling Point.** Both tetrafluoroethane and heptafluoropropane have higher vapor pressure and are in gaseous state under normal atmospheric temperature. Presently, no Hydrofluoroalkane has the same high boiling point as CFC-11 does. Therefore, it brings challenges to design formulation and production process. One of solutions is to seek proper solvent without toxicity or irritation but with certain volatility and good compatibility with Hydrofluoroalkane. Commonly used co-solvents include low-molecular-weight alkane (e.g propane and butane) and low-molecular-weight alcohols (e.g ethanol and isopropanol).

ii) **Surfactant Selection.** Surfactant is to disperse medicament particles and lubricate the valve. As Hydrofluoroalkane has smaller 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 co-solvent which can dissolve surfactant.

iii) **Drug Characteristics.** Some medicaments easily form solvate in 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 the suspended aerosol.

iv) **Valve Selection.** As Hydrofluoroalkane is less chemically stable than CFCs, valve components (e.g airproof rubber and its additive should be compatible with propellants. 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.

v) **Alternative Actuator.** In case medicament can not be formulated into suspended aerosol, it is generally made into solution aerosol. In general, solution aerosol has poorer atomization effect. Decreasing vapor pressure of the canister results in bigger atomized particles sizes. Though increasing the pressure can reduce the particle sizes, 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.

2. Preliminary Analysis

Table 4-5 Comparison of CFCs Substitutes

	Advantage	Disadvantage	Remarks
DME	Very soluble in water. In aqueous solutions, the propellant is hydrolytically stable over a wide pH range. Zero ODP.	Acute and chronic toxicity. May cause anesthetic effects. May irritate eyes, skin, and mucous membranes. Flammable.	DME is a flammable chemical. If using it as the CFCs substitute, Chinese pharmaceutical manufacturers have to renovate their workshops substantially or may have to relocate to other places. The incremental cost is likely to be astronomical.
Hydrocarbon	Low cost of Hydrocarbon; Zero ODP; Negligible greenhouse effect; Excellent solvent. Low GWP.	Highly flammable; Aftertaste; Unknown toxicity following inhalation; Low level density. Potential reaction and interaction with TCM. High conversion cost.	Hydrocarbon is a flammable chemical. If using it as the CFCs substitute, Chinese pharmaceutical manufacturers have to renovate their workshops substantially or may have to relocate to other places. The incremental cost is likely to be astronomical.
HFA	Low inhalation toxicity; High chemical stability; High purity; Zero ODP;	Poor solvents; GWP lower than CFC's; High cost of HFA. Low conversion cost.	HFA is known to be used by foreign manufacturers as CFCs substitutes.
Compressed Gas	Low inhalation toxicity; High chemical stability ; High purity; Inexpensive; Zero ODP.	Require use of a non-volatile co-solvent; Produce course droplet spray; Pressure falls during use;	Use of compressed gas propellant is typically restricted to applications where spray characteristics are not critical;

3. Conclusion

38. Based on the above technical analysis, it is tentatively concluded that

a. Ideal CFCs substitutes should possess properties such as similar physical properties, insignificant damage to the atmosphere, similar toxicity, good thermodynamic property, non-inflammability and economical feasibility.

b. In comparison with DME and Hydrocarbon, the properties of HFA are similar to those of CFCs.

Besides, international experience shows that HFA is the substitute being widely used in foreign countries. HFA-134a is chemically stable, requiring less modification on existing equipment and associated facilities.

c. The properties of DME and Hydrocarbon are not similar to those of CFCs. Exploring the conversion to DME or Hydrocarbon is more technically difficult, though the two chemicals are cheaper than HFA. Especially for Traditional Chinese Medicine Applications, there is no international experience for Chinese manufacturers.

d. Compressed gas is often used for spray products but not for aerosol products.

e. It is assumed that the majority of Chinese pharmaceutical aerosol manufacturers, after screening a variety of substitutes, are likely to use the HFA as CFCs substitute.

CHAPTER 5 Phaseout Strategy

1. Principle.

39. The phaseout of CFCs in China pharmaceutical aerosol sector should not impose any significant negative impact on the clinic demand for aerosol products. In other words, the principle of the strategy is to phase out CFCs rather than the pharmaceutical aerosol products.

2. Two priority Issues.

40. **a. Substitute Selection**. Out of 44 aerosol applications, Chinese manufacturers have 26 Traditional Chinese Medicinal Aerosols, for which no experience can be borrowed from the abroad. Thus selection of suitable substitutes for those TCM aerosols will be challenging. Based on international experience, HFA-134a, HFA-227, DME, hydrocarbon (isobutane) and compressed gas (carbon dioxide) are deemed as potential CFCs substitutes. However, each CFCs substitute has different chemical and physical properties. Each aerosol application is different in terms of production process and formulation. Therefore, selection of suitable CFCs substitute or conversion technology (such as alternative delivery system) is the key issue for CFCs phase-out in China pharmaceutical aerosol sector. The pharmaceutical aerosol manufacturers will have to screen CFCs substitutes or conversion technology first, then determine conversion plan which covers new formulations and production process.

41. **b. Preparation for Technical Dossier for Registration**. In accordance with relevant laws and regulations, replacement of CFCs with alternative excipients is subject to the approval of the government agencies. Manufacturers have to prepare technical dossier stipulated by the regulations so as to have their CFCs-free products registered at SFDA. The preparation for registration should be immediately initiated after the completion of the substitute selection

3. New Policies Proposed.

42. **a. Policies over Transition Period (July 1, 2007~December 31, 2009).** China will stop using CFCs as excipients for external-use aerosols since July 1, 2007. Given the limited timeframe, pharmaceutical aerosol manufacturers have to use CFCs in storage before they can obtain from SFDA the approval numbers for their new products. However, using of CFC in storage would be under stringent supervision of the government. SFDA will make transitional arrangement within the framework of Country Program. 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. SEPA plans to establish a license system to control CFCs consumption for those aerosol manufacturers.

43. **b. Supervision after 2010.** After 2010, SFDA will monitor non-CFCs aerosol products so as to guarantee its safety and efficacy of clinical application.

4. Phaseout Schedule.

44. China plans to implement the CFCs phaseout for pharmaceutical aerosol sector in three stages.

    a. The first stage is to develop sector policies and to screen substitutes (January-December, 2007);

    b. the second stage is to complete registration for new aerosol products (January 2007-June 2009);

    c. In parallel, the third stage is to start new production after the completion of facility modification, production validation and staff training (July, 2007-December 2009).

CHAPTER 6 Cost Analysis

1. Basis for Cost Calculation

45. **Cutting-off Date.** The cutting-off date of July 25, 1995 should not be applied to the pharmaceutical sector as substitute aerosol technology in 1990s was not available. It is proposed that the cutting off date should be July 1, 1999 after which Article 5 Parties had the obligation to freeze CFCs production and consumption. China will not request MLF fund for seven manufacturers with production lines established after the cutting-off date. Those enterprises have to use their own funding to phase out CFCs consumption.

46. **Eligible Incremental Cost.** Cost calculation covers Technical Assistance (TA), preparation for technical dossier for registration of new aerosol products, modification on the existing facilities, production validation, staff training and two years (and not four years as used as default until the ExCom establishes guidelines for new sectors and sub-sectors)) of Incremental Operation Cost. For eligible manufacturers with baseline consumption, both Incremental Capital(IC) and Incremental Operation Cost (IOC) are considered as eligible Incremental Cost. A few eligible manufacturers have not been in production for years. However, as long as they have aerosol product approval numbers issued by SFDA, they have legal rights to resume production depending on the market demand. Therefore, for those manufacturers without the baseline consumption, only cost for substitute screening and cost for preparation for technical dossier for registration purpose are considered as eligible incremental cost.

47. **Reasons to Use HFC-134a for Cost Calculation.** Cost analysis is based on the sector survey and the literature review on international experience. It is estimated that from technical perspective, majority of Chinese pharmaceutical aerosol manufacturers may use HFA (e.g. HFA-134a, HFA-227) as CFCs substitute after screening a variety of substitutes. Besides, conversion to HFA is more financially feasible in China because in case of conversion to DME or Hydrocarbon, Chinese manufacturers have to renovate their workshops substantially or relocate to other places to meet safety standards. As CFCs has high chemical stability, it is not mandatory that the existing workshops meet national anti-explosive standards or safety standards. If converted to hydrocarbon and DME production, the existing facilities and the workshops would have to be replaced to meet the area hazard classification as per Chinese regulations. Storage vessels, pipe system and valves would have to be installed according to Chinese safety regulations, which might not in all cases be possible without relocation of workshops. As the filling takes place in special enclosed clean rooms, use of hydrocarbon as propellant would require changes to the ventilation system and enclosure as well. Consequently, the conversion cost to Hydrocarbon or DME would be very prohibitive.

48. In Chinese market, HFA-227 is slightly more expensive than HFA-134a. Besides, only limited experience on the conversion to HFA-134a is available when the sector plan is under preparation. Therefore, the Incremental Cost calculation is based on the conversion to HFA-134a. In case any Chinese pharmaceutical aerosol manufacturer selects other substitutes (e.g. DME, Hydrocarbon or others) in the future, it is the manufacturer which has to raise sufficient counterpart funding for the renovation or the relocation of its workshops.

2. Technical Assistance (TA)

49. In order to implement the sector plan smoothly, it is necessary to undertake TA activities 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 for government agencies such as local Food and Drug Administration Bureaus and

Environmental Protection Bureaus on the implementation of the phaseout policies;

c. Public awareness promotion including training activities;

d. Recruitment of individual consultants to provide technical support for phaseout activities. Recruitment of consultant firms to provide technical support such as review test data and appraise feasibility study reports etc.;

e. Development of a MIS system.

f. Auditing for CFCs consumption annually for pharmaceutical aerosol manufacturers

g. Study tours to learn international experience.

h. Other TAs as necessary.

3. Incremental Cost for Manufacturers.

3.1. Substitute Screening

50. Presently, due to lack of testing data, Chinese pharmaceutical manufacturers are not able to decide which substitute is the best one for their aerosol products, particularly for those producing Traditional Chinese Medicine aerosol products. MLF Funding is requested to allow those enterprises to screen potential substitutes as mentioned in Chapter 4. The objective of the screening is to identify the best substitute or alternative delivery system for their pharmaceutical aerosol products. Due to business confidentiality and potential property rights which may arise from the conversion, manufacturers should screen substitutes by themselves. In case some manufacturers do not have such capacity, they may have to engage qualified institutions to do the screening. After the screening, manufacturers should submit feasibility study reports for the conversion to non-CFCs production, which consists of screening on formulations and production processes, preliminary evaluation on drug quality and stability, pharmacology comparison test, preliminary evaluation on toxicology and preliminary analysis on the manufacturing equipment. Those study reports will furnish technical basis to develop phase-out policies and to make arrangement for the transitional period. These reports may also provide technical reference for those non-eligible manufacturers so as to facilitate CFCs phase-out in the whole sector.

51. If suitable CFCs alternatives can not be identified for an application, it would be necessary to use alternative delivery system, such as compressed air spray, ultrasonic spray, two-phase system, self-pressurized system and dry powder inhaler. Such alternative delivery system would have to follow the same screening procedures as that for aerosol products.

52. In case some manufacturers are not able at all to identify suitable substitute or alternative delivery system, their study reports may also be used as technical basis for exemption applications for essential use after January 1, 2010.

53. The cost for each item of the tests is shown in table 6-1. There are 63 aerosol products owned by 32 manufacturers, so the total cost adds up to USD 2,756,250.

Table 6-1 Cost for Screening Substitutes

Item	Activity	Cost (USD)
Screening for Formulations and Production Process	Test for Formulation and Production Process	12,500
Evaluation on Quality and Stability	Evaluation on Quality-related Factors	6,250
	Preliminary Stability Test	6,250
Pharmacodynamics Comparative Test		6,250
Preliminary Toxicology Evaluation		6,250
Pre-analysis on Major Equipment		6,250

Subtotal	43,750
Number of Products	63
Total Cost (US$)	**2,756,250**

3.2. Preparation of Technical Dossier for CFCs-Free Aerosol Registration Application

54. As any change in excipients or delivery system may have consequence for the safety and efficacy, *China Drug Administration Law* and *Provisions of Drug Registration* require that pharmaceutical aerosol manufacturers apply for new registration. For the registration purpose, manufacturers have to prepare technical dossier in accordance with relevant national regulations, Table 6-2 lists the dossier for application for change of excipients already with National Standards; Table 6-3 lists the dossier for Drug Registration Application with New Excipients; Table 6-4 lists the dossier for Drug Registration Application for Change in Dosage Form.

Table 6-2 Dossier for Application for Change of Excipients with National Standards

No.	Document Name
1	photocopy of drug approval certificate and appendix
2	supporting 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	Sample of drug
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

Table 6-3 Dossier for Drug Registration Application with New Excipients

No	Document Name
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 pharmacodynamics influence on to-be-applied drug

No	Document Name
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

Table 6-4 Dossier for Drug Registration Application for Change in Dosage Form.

No.	Document Name
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 documents & 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

55. Cost for preparation for the technical dossier will depend on applications, selected propellants and production process. It can not be accurately calculated at the currant stage. Therefore, Table 6-5 is the best estimation based on the past experience. Six key items are included for the estimation, though there are other items not included. Compared with the Skin Aerosol, cost for dossier preparation for Cavity Aerosol is more costly because the requirement for the latter is more stringent.

56. In accordance with relevant regulations, each manufacturer has to make registration for their aerosol

products based on its formulation and production process, though some products may also be produced by multiple manufacturers. Therefore, enterprises have to make registration application for total 42 Skin Aerosol products and 21 Cavity Aerosol products.

Table 6-5 Cost for Preparation for Technical Dossier for Registration

No.	Name of the data	Cost for Skin Aerosol Product (USD$)	Cost for Cavity Aerosol Product (USD$)
1	Study on Pharmacy	6,250	6,250
2	Study on Production Process	12,500	12,500
3	Study on Quality	6,250	6,250
4	Pharmacological Study	18,750	25,000
5	Toxicological Study	18,750	25,000
6	Special Safety Test	125,00	18,750
	Subtotal	75,000	93,750
	Number of Products	42	21
	Subtotal	**3,150,000**	**1,968,750**
	Total	**5,118,750**	

3.3. Modification on Existing Facilities

57. The requested incremental cost for modification on existing facilities is based on the assumption that these manufacturers will convert to a non-flammable propellant such as HFA-134a. As HFC-134a is not compatible with hermetic materials of the existing facilities, it is needed to modify or replace existing pumps, pipes, hermetic components for pipes, valves and filling&charging equipment and associated instruments.

58. Based on the sector survey, existing production lines can be divided into two groups, one is automatic (Type A), while the other is semi-automatic (Type B). Modification cost is showed in Table 6-6.

Table 6-6 Modification Cost for Existing Facilities

Items	Type A (USD)	Type B (USD)
1.1 Storage Vessel for Propellant	15,000	15,000
1.2 Pipes and Hermetic Components(for pipes, valves, filling& charging equipment)	10,000	10,000
1.3 Pumps	12,500	12,500
1.4 Detecting Leakage Equipment	25,000	N.A
1. 5 Labor Cost	1,250	1,250
Total Cost for One Line with Baseline Consumption	63,750	38,750
Number of Lines with Baseline Consumption	14	8
Subtotal	892,500	310,000
Total	**1,202,500**	

59. In the case of conversion to Hydrocarbon, estimated modification cost based on initial assessment for enterprises would be as follows:

Table 6-7 Modification Cost for One Production Line Converted to Hydrocarbon*

Item	Cost (USD)
1.1. Replacement of Existing Filing Line	150,000
1.2 Piping and Valves	40,000
1.3. Hydrocarbon Storage Tank	30,000

Item	Cost (USD)
1.4. Replacement of Electrical Installation and Grounding of Filling Line:	20,000
1.5. Aerosol Lid Control	5,000
1.6. Clean Room Modification and Ventilation System:	20,000
1.7. Gas Detection System:	15,000
1.8. Fireproof Facility	30,000
1.9. Installation	20,000
1.10: Safety Certification:	30,000
Subtotal	**360,000**
Number of Lines with Baseline Consumption	22
Total	**7,920,000**

* Cost for workshop relocation is not taken into accounted.

3.4. Production Validation

60. *Provisions on Quality Management for Pharmaceutical Production* (SFDA #9, effective August 1, 1998) was issued by SFDA in 1998. Article 57 stipulates that validation for pharmaceutical production shall consist of validation for workshop, validation for installation of facilities and equipment, validation for facility operation and performance and validation for products. Article 58 states that re-validation shall be carried out in case of change of main quality related factors such as production process, quality control method, main excipients and production facility,

61. In accordance with *Guidance of Validation for 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, new production technology and new product application may be introduced. Therefore, it is necessary to carry out prospective validation before commercial production. The purpose of prospective validation is to evaluate and confirm the reproducibility and reliability of production process. Concurrent validation is to obtain data from the actual process operation, so as to prove that it fulfills the expected requirements. Retrospective validation is to collect statistics data and make trend analysis after normal production for a certain period of time, thus discovering the worst conditions for the process operation and indicating the risk of potential malfunction. Revalidation includes compulsive validation, alterant validation and regular validation.

A. Validation for Changing Excipient (Alternative Propellant)

62. Changing of excipients has to conduct prospective validation, concurrent validation, retrospective validation and revalidation. The validation include 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

a) Validation for Workshop, Public Utility System and Computer System

63. Validation of workshop is to confirm that 1) reconstructed workshops shall be in compliance with design standards; 2) the flow of people and materials shall be reasonable;3) workshop cleanliness shall be up to the level of 300,000. Validation of public utilities consists of six items, namely, heating, ventilation, air conditioning, discharging system, cooling system and propellant supply system. 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.

b) Validation for Production Equipment

64. 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.

c) Validation for Production Process

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

(ii) Validation of cleaning effect of containers: various impurities placed into the container shall be totally removed after cleaning.

(iii) 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.

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

(v) Validation items for the product inspection time 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.

(vi) Validation item for spray inspection include the performance of spray and elimination of samples that don't spray or don't spray constantly.

(vii) Against product quality standard, validation items for metered aerosols comprise appearance, active ingredient per actuation, times of actuation per canister, shot weight per actuation, spray distribution, microbes, etc. Validation for non-metered aerosol includes appearance, spray speed, shot weight per actuation 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.

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

d) Validation for Personnel and Other Relevant Items

65. Validation for personnel consists of establishment of filing system for each person engaged in aerosol production, including records for training, health and safety and personnel performance, etc. Validation for other relevant items includes document record, instrument calibration, preventative maintenance, production areas, and area for changing clothes, and waste cleansing and sterilization.

B. Validation for Change in Dosage Form

66. 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, which are part of production process validation. 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. Validation items for non-metered aerosol includes appearance, spray speed, shot weight per actuation 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.

67. There are 22 production lines which had aerosol production during the baseline year. Cost for production validation is detailed in Table 6-8.

Table 6-8 Cost for Production Validation

No.	Validation	Contents	Cost (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.	18,750
3	Others	Workshop; Public Utilities; Computer System; Others	6,250
		Subtotal for One Production Line	37,500
		Number of Production Lines with Baseline Consumption	22
		Total	**825,000**

3.5. Staff Training

68. Due to the introduction of new substitute, 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 sales.

Table 6-9 Staff Training Cost

	Production Staff	Sales Staff
Number of Trainees	20	40
Unit Cost (US$/person)	125	375
Subtotal (US$)	2500	15,000
Subtotal for One Production Lines(US$)	17,500	
Number of Production Lines with Baseline Consumption	22	
Total	**385,000**	

3.6. Incremental Operating Cost

69. The calculation is based on the data collected from manufacturers during the survey undertaken by NICPBP, SFDA and SEPA. Baseline production data is shown in Table 2-3. Calculation of IOC is based on the ExCom guidelines and using Incremental Operating Cost for a period of two years.

70. For the new production, the propellant, valve and canister etc. have to be changed. Table 6-10 shows the prices of CFCs and HFA-134a in 2005, which is consistent with the baseline year.

Table 6-10 Price of Propellant

	Baseline Consumption (MT)	Price (USD/MT)
CFC-11	112.723	1,643
CFC-12	365.964	2,366
CFCs Weighted Price		2,196
HFC-134a Price		7,380

71. The total production quantity of baseline year is 10,121,216 pieces of aerosol products, of which 9,590,363 are of skin aerosols. The average CFCs consumption for skin aerosol products is 47.50 gram/canister, while that for cavity aerosol is 16.57gram/canister. Literature reviews indicates that on average, HFA aerosols uses 30% less propellant than CFCs aerosols. Therefore, it is assumed that after conversion, the average HFA-134a consumption for skin aerosol products is 33.25 gram/canister, while that for cavity aerosol is 11.60 gram/canister. Calculation for Incremental Operation Cost is shown in Table 6-11.

72. Due to the price difference of HFA-134a and CFCs, it is proposed that those manufacturers be financed with two years of Incremental Operation Cost only (USD 3,536,824) (and not four year as per the general rules until the Excom decides). The IOC will be allocated to eligible pharmaceutical aerosol manufacturers based on their baseline year production.

3.7. Contingency

73. Contingency is calculated as 10% of the TA and total Incremental Capital(IC).

3.8. Deduction Due to Foreign Share

74. Out of 32 eligible manufacturers, there are three joint ventures (#13, #14, and #22) with foreign shares (i.e. British Virgin Islands and USA). Funding for these enterprises is prorated according to Chinese share. Total USD 489,918 will be deducted (see Annex I).

Table 6-11 Incremental Operation Cost

I. IOC for Skin Aerosol							
Items	Before Conversion(CFCs as propellant)		After Conversion(HFA-134 a as propellant)		IOC for One Piece of Aerosol	Skin Aerosol Production Quantity	IOC for Skin Aerosol
		Unit Cost (US$/can)		Unit Cost (US$/can)			
1. Propellant		0.10433		0.24523	0.14090		
Price(USD/g)	*0.00220*		*0.00738*				
Average Propellant Consumption(g/can)	*47.50*		*33.25*				
2. Canister		0.16875		0.19125	0.02250		
3 Valve		0.04813		0.05188	0.00375		
Subtotal		**0.32120**		**0.48835**	**0.16715**	**9,590,363**	**1,603,058**
II. IOC for Cavity Aerosol							
Items	Before Conversion(CFCs as propellant)		After Conversion(HFA-134 a as propellant)		IOC for One Piece of Aerosol	Cavity Aerosol Production Quantity	IOC for Cavity Aerosol
		Unit Cost (US$/can)		Unit Cost (US$/can)			
1. Propellant		0.03638		0.08552	0.04914		
Price(USD/g)	*0.00220*		*0.00738*				
Average Propellant Consumption(g/can)	*16.57*		*11.60*				
2. Canister		0.16875		0.19125	0.02250		
3 Valve		0.12250		0.47500	0.35250		
Subtotal		**0.32763**		**0.75177**	**0.42414**	**530,853**	**225,156**
III. Total IOC for one year							**1,828,214**

IOC(discount @7%)		**Cumulative**
IOC for one year	1,828,214	1,828,214
IOC for 2nd year	1,708,611	**3,536,824**
ICO for 3rd year	1,596,833	5,133,657
IOC for 4th year	1,492,367	6,626,024

Summary: Incremental Cost

No.	Components	Cost (USD)	
A	**Technical Assistance**	**1,100,000**	
B	**Incremental Capital Cost (Manufacturer Conversion Cost**	**10,287,500**	
B.1	Screening Substitutes		2,756,250
B.2	Cost for Preparation for Technical Dossier for Registration Application		5,118,750
B.3	Modification on Existing Facilities		1,202,500
B.4	Validation		825,000
B.5	Staff Training		385,000
C	**IOC of Two Years (discount rate@7%)**	**3,536,824**	
D	**Contingency (10% of A+B+C)**	**1,492,432**	
	Subtotal (A+B+C+D)		16,416,757
E	**Deduction Due to Foreign Share**	**- 489,918**	
	Total(A+B+C+D+E)	**15,926,839**	
	Total Requested Funding	**15,926,839**	

Chapter 7 Operation Mechanism

75. This Chapter explains the procedures for establishing funding arrangements and operating mechanisms for project management, coordination, supervision and evaluation as well as the responsibilities of various institutions involved in implementation of this Sector Plan.

1. Umbrella Grant Agreement

76. China and the World Bank have signed an Umbrella Grant Agreement in December 1997. The Agreement sets forth the terms and conditions under which grant resources approved by the ExCom in sector approaches in China would be carried out. This Agreement includes provisions that allow the Bank to disburse funds to China based on performance indicators, and will also be extended to the pharmaceutical aerosol sector.

2. Funding Arrangements

77. MLF Approval: it is anticipated that funds for this Sector Plan would be approved in two steps:

    a The Government, through the World Bank, will request that the ExCom consider this overall sector plan and agree to fund the phase-out with tranches, provided that China meets agreed annual phase-out targets for the previous year. At the same time, the Government will also apply for approval of the First Biennial Program, presently proposed to cover activities in the calendar years from 2007 to 2008, which will be submitted to the ExCom as a separate document.

    b From 2007 onwards, another Biennial Programs will be submitted to the last ExCom meeting of 2008, setting out the annual targets and funding requests. The amount of annual funding request would be consistent with the funding amounts indicated in the overall sector plan. The ExCom would be asked to release funds at the levels agreed to in the sector plan based on achievement of previous phase-out targets, so that the next Biennial Program could start in the following January. In general, approval of funds would be based on achievement of agreed ODS phase-out targets.

78. In case China fails to reach the phase-out targets for a given year, i.e., if CFCs consumption for pharmaceutical Aerosol Sector exceeds the agreed targets or the phase-out amount contracted is less than that required to meet the target, the Bank and China would agree on remedial actions before applying for the next funding. The remedial actions proposed would be to bring the program back on track in the coming year, and would be further subject to ExCom approval. Other conditions as stated in the Umbrella Grant Agreement would also apply.

79. The Biennial Program would contain the following sections:

    a Sector phase-out schedule, including phase-out activities, manufacturers involved, phase-out approaches adopted and the phase-out timetable arranged;

    b Status of all activities of previous year(s) and any agreed remedial actions if necessary, for the current year;

    c Objectives of Biennial Program – phase-out targets and funding requirements for activities in the following year;

    d Description of activities in the Biennial Program, including phase-out activities for the manufacturers involved, any new policies to be taken up, and technical assistance activities;

    e Performance indicators of the Biennial program.

80. The World Bank would approve the technical assistance consistent with the Biennial Program, based on agreed Terms of reference for each TA (including the funding level of TA) in that year’s Biennial Program.

3. Disbursement Mechanism

81. MLF disbursement to the World Bank: Upon approval of the Biennial Program by the ExCom, the Multilateral Fund will transfer the funding to the World Bank account.

82. World Bank disbursement to China: There would be four disbursements into the ODS Phase-out Account at SEPA for each Biennial Program. The Government would be allowed to request these four disbursements at any time during the year, provided that the disbursement conditions have been met. In any particular year, disbursement to China will start only when the Bank receives grants for that Biennial Program from the MLF. Disbursement conditions and amounts to be disbursed are as follows:

    a ***First disbursement*** – funds for technical assistance and DIA's agency fees. ***Condition:*** Approval of the Biennial Program by the ExCom and release of funding to the World Bank.

    b ***Second disbursement –*** 50% of funds allocated for manufacturer activities and 50% of China's management fees.

    Conditions:

    I) 30% of all contracts covering target phase-out amount of the current year's Biennial Program have been signed by government with manufacturers;

    II) Progress report on this sector plan implementation is satisfactory to the Bank; and

    III) Any other conditions as specified in the current Biennial Program.

    c ***Third disbursement*** – 30% of funds allocated to manufacturer activities and 30% of China's management fees.

    Conditions*:*

    I) 100% of all contracts covering target phase-out amount and TA contracts of the current year's Biennial Program have been signed;

    II) The government reports the actual consumption does not exceed the consumption target set for the previous year (not applicable to the first implementation program);

    III) A Progress report should be provided to the Bank, which is satisfactory to the Bank;

    IV) the Biennial Program implementation should be considered satisfactory to the Bank; and

    V) Any other conditions as specified in the current Biennial Program.

    d ***Fourth disbursement*** – 20% of funds allocated to manufacturer activities and 20% of China's management fees.

    Conditions:

    I) Performance audit of the previous year's Biennial Program is acceptable to the Bank;

    II) Progress report on sector plan implementation is satisfactory to the Bank; and

    III) Any other conditions as specified in the current Biennial Program.

83. In the event that any phase-out target is not met, the Bank will suspend further disbursements to China. Disbursements will resume only after China and the Bank agree on and carry out remedial actions.

84. The grant funds will be allocated to manufacturers in consistence with the MLF funding approved for the sector. Manufacturers would sign ODS reduction contracts with SEPA.

85. The contracts will stipulate, among others, (a) Date and amount of ODS phase-out in applications; (b)

the disposal equipment list, if any; (c) and agreed disposal dates.

4. Management and Coordination

86. The Government would be responsible for implementing this Sector Plan. PMO will manage and coordinate execution of each Biennial Program. In addition, SFDA and SEPA will select a qualified firm as a Domestic Implementing Agency (DIA) to help manage day-to-day activities at manufacturer level. The World Bank will supervise overall implementation of this Sector Plan, replenish the ODS IV project account, report implementation progress to the ExCom and submit future funding requests to the ExCom.

A) State Food and Drug Administration

87. State Food and Drug Administration (SFDA) will play an important role in the preparation and execution of the yearly program. Responsibilities of SFDA include the following

(i) To establish CFCs phase-out policies for pharmaceutical aerosol sector;

(ii) To organize local FDAs to impalement phase-out policies and undertake irregular spot check to the pharmaceutical aerosol manufacturers

(iii) To supervise CFCs consumption of pharmaceutical aerosol manufacturers;

(iv) To ensure adequate clinical supply of pharmaceutical aerosol products.

B) Foreign Economic Cooperation Office (FECO)

88. FECO is a management department to implement the environmental protection projects financed by the organizations of the United Nations and international or regional financial organizations. It hosts the project management office (PMO) for ODS projects. Responsibilities of FECO include the following:

a To supervise PMO activities,

b The financial division of FECO manages the ODS IV phase-out special account,

I) prepare and submit withdrawal applications to WB for advance deposit;

II) review the application of disbursement from beneficiaries according to the manufacturer contracts and TA contracts and make disbursement,

III) keep financial records and account details,

IV) Provide financial information on the ODS IV account to the audit agency and assist the work of the audit agency.

c On behalf of SEPA, sign the ODS phase-out contracts, including manufacturer contracts and TA project contracts;

d On behalf of SEPA, handover the ownership of all the equipment purchased under the ODS project to the manufacturers after the project commissioning.

C) *Project Management Office (PMO)*

89. PMO is the National Ozone Unit (NOU) of China with full responsibility to implement the international and national policies and regulations, and manage the information concerning the ozone layer protection. It is also in charge of the project selection, development and submission to the Multilateral Fund. Once the ExCom approves project, the PMO will coordinate, manage and monitor its implementation. PMO consists of the staff from Pollution Control Department, International

Cooperation Department of SEPA and FECO. It is responsible for the routine management of all the activities of ODS phase-out consistent with the MP and reports to the Leading Group on key issues. PMO is set up in the FECO of SEPA. Its responsibilities are as follows:

a. To coordinate with related line ministries, industrial departments and related industrial association to jointly prepare the sector plans for completely phasing out ODS in a given sector, including the implementation mechanism and the policies in favor of ODS phase-out to ensure healthy development of industries;

b. To select the domestic implementing agents (DIA) and endorse procurement agents selected;

c. To organize and implement sector plans strictly in accordance with the agreement signed between the Chinese Government and the ExCom;

I) review of the Biennial Programs prepared by the special working groups (SWG) and submit the Biennial Programs to the ExCom through the World Bank for approval,

II) review of the work plans prepared by the SWGs,

III) approval of project documents prepared and submitted by SWGs,

IV) review of progress reports submitted by SWGs,

V) helping SWGs to solve problems encountered during project implementation,

VI) Coordinating SWGs on ODS data reporting, policy formulation, training, and information exchange.

d. To supervise SWGs' activities and provide with necessary working conditions,

e. To communicate and reach an agreement with the World Bank on the important issues during the implementation of projects,

f. To cooperate with audit agency to carry out audit,

g. To assist the World Bank and the ExCom in necessary project evaluation.

h. To be responsible for implementation of Technical Assistant Projects (TAs)

I) To define the demand on TA projects;

II) To review all of the TORs of TA projects written by the SWG;

III) To review the selection of consultants for TA projects;

IV) To authorize disbursement to all the technical assistant project;

V) To evaluate the results of technical assistant projects and determine if further improvement is necessary.

D) ***Local Environmental Protection Bureau(EPB) and Local Food and Drug Administration(FDAs)***

90. Local EPB and FDAs are bureaus with jurisdiction over the geographical areas where the project manufacturers are located. The responsibilities of local FDAs and EPBs are the following:

a. To implement the ODS phase-out policies in the region;

b. To assist to resolve the issues in the region during the implementing of the project with the request of the SFDA and SEPA;

c. To assist to verify the ODS consumption of the manufacturers, attend the project commissioning with the request of the SEPA and SFDA;

d. To supervise the disposal of the ODS equipment, if any;

e. To supervise the manufacturers to comply with ODS quota system;

f. To attend the training with the request of SFDA and SEPA.

E) ***Domestic Implementation Agent (DIA)***

91. A DIA will be competitively selected by PMO for the Sector Plan (SP) after it is approved. The DIA will assist PMO in managing the implementation of SPs and Biennial Programs. Staffs from DIA usually work with staff from PMO in the SWGs. Under the guidance of PMO, DIA will carry out the following activities:

a. Overall management --

I) Assist SWGs in project preparation and implementation;

II) Keep all project preparation and implementation documentation for audit by the audit agency during annual performance audit and for the annual verification by the Bank,

III) Input data into (monitoring and information system) MIS in a timely manner and generate various project progress reports; and

IV) Review project implementation status and report identified problems to SWGs.

b. During project Preparation --

I) Prepare work plan with SWGs for each Biennial Program;

II) Assist SWGs in publicizing the sector plan;

III) Assist SWGs in training manufacturers, local experts, and general contractor(s) if needed;

IV) Review project application submitted by manufacturers;

V) Assist SWGs to organize experts to help manufacturers in preparing project proposals and feasibility study,

VI) Assist SWGs to organize experts to help manufacturers in evaluating project proposals and feasibility study; Assist SWGs to organize experts to provide technical support to manufacturers during project implementation

VII) Supervise expert activities and verify its working load and cost, and report to the SWGs accordingly; and

VIII) Assist SWGs in project appraisal.

c. During project implementation --

I) Prepare ODS phase-out contracts and its annexes;

II) Review project implementation status and verify the progress report submitted by beneficiary manufacturers and general contractor through plant visits;

III) Review of payment applications submitted by beneficiary manufacturers, and submission of applications to sector team;

IV) Assist PMO to select the procurement agency and review the procurement organized by the procurement agency in conform with the agreed procedures;

V) Assume responsibility for supervising equipment destruction and maintain relevant data and information;

VI) Assist PMO in selecting general contractors for sub-projects, if needed, including:

- Advertise the procurement notices in specified newspaper;

- Organize local experts to prepare bidding document for general contractor and submit to PMO for approval;
- Invite bids, organize bid opening and bid evaluation;
- Prepare bid evaluation reports and submit to PMO for approval;
- Prepare contract for general contractor and sign the contract with the winning bidder together with FECO and manufacturers;

VII) Review payment requests from project beneficiaries and general contractors, and prepare disbursement requests to FECO;

VIII) maintain project documentation and coordinate sector teams to provide all information necessary for financial and performance audit, and assist audit agency whenever necessary,

IX) Organize necessary training for manufacturers,

X) Assist PMO in implementing TA projects.

d. Reporting

I) reporting on technical, financial, procurement, and management problems occurred during project implementation in a timely manner, and submission of reports to PMO with recommendations to solve problems;

II) compilation of progress reports on manufacturer activities;

III) preparation of project completion reports and commissioning report and,

IV) input of information into the MIS in a timely manner on the status of implementation of manufacturer projects.

92. The World Bank plays a major role in assisting developing countries to meet their obligations as Parties to the Montreal Protocol. The Bank partners with developing countries in its role as an implementing agency for the Multilateral Fund. The World Bank and China began their partnership on Montreal Protocol program in 1993 to help China meet its national phase-out obligations. The WB is responsible for a range of activities specified in the project document along the lines of the following:

a. assisting China in preparation of the Biennial Programs;

b. verifying for the Executive Committee that consumption of the substances have been eliminated in accordance with the targets;

c. providing a verification report to the Executive Committee bringing evidence that the targets have been met and associated annual activities have been completed as indicated in the Biennial Program;

d. ensuring that achievements in previous Biennial Program are reflected in future Biennial Programs and will serve as the progress report;

e. Reporting on the implementation status of all previous years' Biennial programs activities will be included in Biennial Program.

f. carrying out supervision missions;

g. helping China to set up an operating mechanism to allow effective and transparent implementation of the Biennial Program;

h. co-coordinating the activities of the co-coordinating Implementing Agencies, if any;

i. ensuring that disbursements made to China are based on the use of the indicators; and

j. Providing China with the necessary policy, management and technical support.

5. Monitoring and Evaluation

93. PMO is the core organization for monitoring the implementation of Biennial Programs with the responsibility for reporting to the World Bank. PMO will be responsible for tracking the implementation of policy measures and the technical assistance activities; submit progress reports to the Bank every quarter. PMO will also report on specific issues if requested.

94. DIA will oversee the progress of Biennial Programs, and submit written reports to PMO quarterly.

95. The implementation status of all activities in Biennial Programs will be reported to ExCom once a year during preparation of following year's Biennial Program, and at other times if specifically requested.

96. There are two means for monitoring and evaluating the implementation of ODS PA phase-out plan.

A) Verification

97. The Bank will conduct an independent verification annually to verify CFCs consumption and conversion activities. The Bank will supervise the implementation of Biennial Programs and will have access to any ongoing or completed manufacturers for spot checks of the records of projects, including random factory visits. The Bank will also carry out such additional verifications as are required by the ExCom.

B) Audit

98. There will be an annual financial audit of the ODS Phase-out Account at SEPA, conducted by an independent audit agency acceptable to the Bank, and a performance audit, also by an independent audit agency acceptable to the Bank.

Chapter 8 Action Plan

99. This Chapter presents the Action Plan and schedule for implementing CFCs phase-out for the pharmaceutical aerosol sector. This is a rolling plan where the impact of a Biennial Program can be spread over subsequent years. Every Biennial Program will provide detailed progress of all program activities of previous years, including policy implementation, manufacturer activities and technical assistance activities. The proposed Action Plan is summarized in table 8-1.

Table 8-1 Phase-out Targets and Funding Request from 2007 to 2010 in Action Plan

Line		Baseline (average of 03-05)	2007	2008	2009	2010
1	CFCs Consumption (newly produced CFCs)	485.089	485.089	0	0	0
2	CFCs from Stockpiled CFCs	0	0	1/	1/	1/
3	Total CFCs Consumption	485,089	485.089	0	0	0
Funding Request(US$'000)						
4	Enterprise-Level Activities[1]		11,780		3,047	
5	Technical Assistance Activities		900		200	
6	Support Cost		951		244	
7	Total MLF Cost		13,631		3,491	

1/. Use of stockpiled CFCs as needed during the conversion.

1. Biennial Program

1). 2007-2008 Biennial Program: The following activities will be covered under this program:

a Substitute screening. To support manufacturers to identify substitutes for their aerosol products before the first half year of 2007.

b Registration Application. To support the registration for new CFCs-free aerosol products.

c Modification of Existing Facilities, Validation and New Production.

d Workshops, trainings and public awareness promotion.

e Development of a MIS system and other TA activities as necessary.

f Verification on CFCs consumption;

3). 2009-2010 Biennial Program: This will be submitted to the last ExCom meeting of 2008. It will consist of the following, but not limited to:

a Registration Application. To support the registration for new CFCs-free aerosol products.

b Modification of Existing Facilities, Validation and New Production.

c Workshops, Trainings and public awareness promotion.

d Verification on CFCs consumptions, including final verification of all phase out targets under the sector plan.

e Project Completion Report covering all sector plan activities will be prepared.

Implementation Schedule

Stage	Activities
Start-up	To complete policy development and substitute screening
Registration Application	To complete registration for new aerosol products. Registration application for new aerosol, if possible, will be initiated in the first year.
Production	To complete modification on the existing facilities, validation for production process and training for staff.
Commissioning	To undertake project commissioning organized by SFDA and attended by SEPA, the World Bank and DIA. All the original record, report and related documents should be retained.

Table 8-2 Implementation Schedule

Year / Process	2007				2008				2009				2010			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Start-up	X	X	X	X												
Registration Application	X	X	X	X	X	X	X	X	X	X						
Production	X	X	X	X	X	X	X	X	X	X	X	X				
Acceptance													X	X	X	X

Annex I. Incremental Cost for Pharmaceutical Aerosol Manufacturers

Enterp. ID	Enterprise Name	Chinese Share (%)	Line Type	CFCs Baseline (kg)	SA Prodt. Quantity (can)	CA Prodt. Quantity (can)	Incremental Capital (USD '000)					IOC	Subtotal	Adjusted Total
							Substitute Screening	Dossier Preparation	Modification	Validation	Training			
01	Wuxi Shanhe No.1	100%	A, B	823	26,667	0	88	150	102.5	75	35	8.62	459	459
02	Beijing Haiderun Pharmaceutical Co., Ltd	100%	-	0	0	0	131	225	0	0	0	0.00	356	356
03	Guangzhou Baiyunshan Hejigong	100%	-	0	0	0	131	243.75	0	0	0	0.00	375	375
04	Externally Applied Agent Factory of Guangzhou Baiyunshan	100%	-	0	0	0	44	75	0	0	0	0.00	119	119
05	Guiyang Dechangxiang Pharmaceutical Co., Ltd	100%	A	13	0	100	44	93.75	63.75	37.5	17.5	0.08	256	256
06	Beijing Double-Crane Modern Pharmaceutical Technology Co., Ltd	100%	-	0	0	0	44	75	0	0	0	0.00	119	119
07	Beijing Tongrentang	100%	B	14	0	1,267	131	262.5	38.75	37.5	17.5	1.04	489	489
08	Xinyi Pharmaceutical General Plant	100%	-	0	0	0	131	243.75	0	0	0	0.00	375	375
09	Fujian Nanshaolin Pharmaceutical Co., Ltd	100%	A	10,684	48,571	0	88	150	63.75	37.5	17.5	15.71	372	372
10	Shanghai Fuxingzhaohui	100%	-	0	0	0	44	75	0	0	0	0.00	119	119
11	Penglai Nuokang Pharmaceutical Co., Ltd	100%	A	3,491	100,600	0	44	75	63.75	37.5	17.5	32.53	270	270
13	Hubei Nanyang Pharmaceutical Co., Ltd	70%	A	49,393	1,171,333	0	44	75	63.75	37.5	17.5	378.77	616	431
14	Shenyang Jingcheng Pharmaceutical Co., Ltd	50%	A	57,717	968,533	0	44	75	63.75	37.5	17.5	313.20	551	275
15	Harbin Hengcang Pharmaceutical Co., Ltd	100%	-	0	0	0	44	75	0	0	0	0.00	119	119
16	Pharmaceutical Plant of Hunan Bencao	100%	B	1,300	58,333	0	44	75	38.75	37.5	17.5	18.86	231	231
17	Shandong Bencao Pharmaceutical Co., Ltd	100%	B	428	0	56,720	88	187.5	38.75	37.5	17.5	46.54	415	415
18	Shandong Jewim Pharmaceutical Co.,	100%	A	12,080	276,314	41,967	131	262.5	63.75	37.5	17.5	123.79	636	636
19	Suizhou Pharmaceutical Co. Ltd.	100%	B	13	700	0	88	150	38.75	37.5	17.5	0.23	331	331
20	Guizhou Antai Pharmaceutical Co., Ltd	100%	A	20,827	580,000	0	88	150	63.75	37.5	17.5	187.56	544	544
21	Guizhou Xinyi	100%	A	229	8,333	0	44	75	63.75	37.5	17.5	2.69	240	240
22	Hangzhou Sino-US Huadong	75%	-	0	0	0	44	75	0	0	0	0.00	119	89

Enterp. ID	Enterprise Name	Chinese Share (%)	Line Type	CFCs Baseline (kg)	SA Prodt. Quantity (can)	CA Prodt. Quantity (can)	Incremental Capital (USD '000)					IOC	Subtotal	Adjusted Total
							Substitute Screening	Dossier Preparation	Modification	Validation	Training			
23	Xinjiang Biochemistry Pharmaceutical Co., Ltd	100%	A	2,592	0	50,000	44	93.75	63.75	37.5	17.5	41.03	297	297
24	Yunnan Baiyao Group Corporation	100%	A	273,333	5,306,667	0	44	75	63.75	37.5	17.5	1716.02	1,954	1,954
25	Chongqing Kerui Pharmaceutical Co., ltd	100%	-	0	0	0	88	168.75	0	0	0	0.00	256	256
26	Huayi Pharmaceutical Co., Ltd	100%	B	380	0	70,000	44	93.75	38.75	37.5	17.5	57.44	289	289
27	Zhanjiang Xintongde Pharmaceutical Co., Ltd	100%	A	29,397	1,036,667	203,333	306	562.5	63.75	37.5	17.5	502.07	1,490	1,490
28	Heilongjiang Tianlong Pharmaceutical Co., Ltd	100%	A,B	300	0	33,333	219	412.5	102.5	75	35	27.35	871	871
29	Guizhou Hongyu Pharmaceutical Co., Ltd	100%	A	1,230	2,800	74,133	88	168.75	63.75	37.5	17.5	61.73	437	437
31	Guangzhou Dongkang Pharmaceutical Co.	100%	-	0	0	0	44	93.75	0	0	0	0.00	138	138
32	Shanghai Yishengyuan Pharmaceutical Co., Ltd	100%	B	112	4,845	0	44	75	38.75	37.5	17.5	1.57	214	214
37	Nantong Zhongbao Pharmaceutical Co., Ltd	100%	-	0	0	0	88	150	0	0	0	0.00	238	238
39	Anshan No.1 Pharmaceutical Plant	100%	-	0	0	0	175	356.25	0	0	0	0.00	531	531
30	Sanpu Pharmaceutical Co., Ltd	100%	-	13	1,700	0	0	0	0	0	0	0	0	0
33	Sanjing Pharmaceutical Co., Ltd of Harbin Pharmaceutical Group	100%	A	145	0	15,210	0	0	0	0	0	0	0	0
34	Hubei Lishizhen Medical Group Co., Ltd	100%	A	137	86,667	0	0	0	0	0	0	0	0	0
35	Shannxi Fengwuchendayaotang	100%	A	48	0	6,000	0	0	0	0	0	0	0	0
36	Harbin Guangji Pharmaceutical Factory	100%	-	0	0	0	0	0	0	0	0	0	0	0
38	Xian Lisheng Pharmaceutical Co., Ltd	100%	-	0	0	0	0	0	0	0	0	0	0	0
12	Glaxo SmithKline (Tianjin)	0%	A	20,390	0	1,216,000	0	0	0	0	0	0	0	0
	Eligible for MLF Fund						**2,756**	**5,119**	**1,203**	**825**	**385**	**3,537**	**13,824**	**13,334**
													Deduction	**-490**