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执行蒙特利尔议定书
多边基金执行委员会
第五十五次会议
2008 年 7 月 14 日至 18 日，曼谷

项目提案：中国

本文件由基金秘书处就以下各项目提案提出的评论和建议构成：

<u>气雾剂</u>

- 计量吸入器行业淘汰各类氟氯化碳消费的行业计划 工发组织

<u>熏蒸剂</u>

- 国家淘汰甲基溴（第二阶段，第三次付款） 意大利和工发组织

<u>加工剂</u>

- 淘汰消耗臭氧层物质加工剂应用（第二阶段）和相应四氯化碳生产的行业计划：2008 年度方案 世界银行

<u>化工生产剂</u>

- 淘汰甲基溴生产行业计划：2008－2010 年工作方案（第二阶段） 工发组织

项目评价表 — 非多年期项目
中国

项目名称	双边/执行机构
计量吸入器行业淘汰各类氟氯化碳消费的行业计划	工发组织

国家协调机构	国家环境保护总局 国家食品药品监督管理局

最新报告的项目所涉消耗臭氧层物质的消费数据

A： 第 7 条数据（ODP 吨，2006 年，截至 2007 年 10 月）

CFC	12,414.9		

B： 国家方案行业数据（ODP 吨，2006 年，截至 2007 年 10 月）

ODS	气雾剂	计量吸入器			
CFC-11	98.9	46.0			
CFC-12	370.0	276.5			
CFC-114					
共计	468.9	322.5			

仍符合供资条件的氟氯化碳消费量（ODP 吨）	423.2

本年度业务计划拨款	供资（美元）	淘汰 ODP 吨
	13,000,000	250

项目名称：	
企业使用的消耗臭氧层物质消费量（ODP 吨）：	340.5
将淘汰的消耗臭氧层物质消费量（ODP 吨）：	322.5
将采用的消耗臭氧层物质消费量（ODP 吨）：	暂缺
项目期限（月）：	40
最初申请金额（美元）：	18,850,502
最终项目成本（美元）：	
增支费用：	16,299,000
应急费用（10%）：	420,400
增支经营费用：	1,989,502
项目费用总额：	
地方所有权（%）：	100
出口部分（%）：	无
申请的赠款（美元）：	18,708,902
成本效益值 （美元/公斤）：	58.01
执行机构支助费用（美元）：	1,403,168
项目向多边基金申请的总费用（美元）：	20,112,070
对应资金是否已确认（是/否）：	是
是否包括了项目监测阶段目标（是/否）：	是

秘书处的建议	供个别审议

项目说明

1. 工发组织代表中华人民共和国（中国）政府提交了关于淘汰用于生产计量吸入器的322.5 ODP 吨各类氟氯化碳的行业计划（《计量吸入器行业计划》），供执行委员会第五十五次会议审议。提交的项目费用总额为 18,850,502 美元，外加给工发组织的 1,413,788 美元的机构支助费用。一旦该项目获得核准，中国将再无其他符合供资条件的氟氯化碳消费。

背景

2. 工发组织在第五十三次会议上代表中国政府提交了关于淘汰用于生产计量吸入器的280.9 ODP 吨各类氟氯化碳的行业计划，费用总额为 22,316,189 美元，外加机构支助费用1,673,714 美元。委员会组建了一个非正式联络小组，以便讨论计量吸入器行业计划费用高昂所涉问题，以及一些计量吸入器厂家 2006 年末期开始生产和中国政府今后仍然能够申请必要用途豁免等实情。执行委员会审议后，将项目提案的审议工作推迟至第五十四次会议，并请中国政府和工发组织再次提交订正的项目提案时考虑工业合理化和成本效益（第 53/23 号决定）。

3. 重新提交第五十五次会议的《计量吸入器行业计划》涉及执行委员会先前提出的问题。考虑到项目提案的复杂性，以及为了便于执行委员会审议项目提案，秘书处根据提交给第五十三次会议的文件编写了本文件（UNEP/OzL.Pro/ExCom/53/28）。本文件由下述部分组成：

（a） 项目概述，简要说明工发组织为解决委员会第五十三次会议提出的问题（即氟氯化碳消费、干粉吸入器的生产、工业合理化以及资本和运营费用）开展的活动；

（b） 计量吸入器生产设施分析，考虑工发组织收集的补充和/或订正信息（即 ExCom/53/28 号文件第 6 段的更新内容）；

（c） 2009 年后生产计量吸入器所需氟氯化碳的数量；

（d） 替代技术的选择；

（e） 技术援助活动；

（f） 资本和运营费用；

（g） 成本效益；以及

（h） 秘书处的一项建议。

项目概述

4. 根据《计量吸入器行业计划》，中国有 38 家计量吸入器生产厂家，拥有 104 份生产许可证。拥有 36 份许可证的 16 个生产厂家 2007 年[1]报告了产量，而 18 个厂家当年没有报告产量。其余 5 个厂家由跨国公司所有（其中的一家 2005 年停产）。

5. 工发组织在订正的《计量吸入器行业计划》中涉及到执行委员会第五十三次会议提出的问题，具体如下：

（a） 氟氯化碳消费：根据工发组织通过实地走访以及对发票和生产、销售及库存报告的审查所收集的补充信息，用于生产计量吸入器的氟氯化碳消费量从 280.9 ODP 吨增至 341.0 ODP 吨，其中有 322.5 ODP 吨符合供资条件；

（b） 干粉吸入器：国家食品药品监督管理局审议了开始在一个或多个计量吸入器生产厂家生产干粉吸入器的可行性，得出的结论是：这样的选择在目前不可行，原因如下：必须对干粉吸入器适用新的注册程序；生产干粉吸入器需要购买和安装新的生产线；剂量装置将需要进口，安装生产剂量装置的设备需要大量资源，并且涉及到专利权；中国市场上干粉吸入器的现行价格约为计量吸入器的五倍；一家外国企业正在中国建立干粉吸入器生产设施，以占据干粉吸入器的利基市场（另一个新的干粉吸入器生产商在市场上似乎没有地位）。

（c） 工业合理化：鉴于中国没有强制企业关并的文书，有人提议为全部 77 份生产许可证中的 44 个颁发奖金，以此实现计量吸入器行业的工业合理化：

（一） 对于基准年无产量的生产厂家来说，将为每份许可证支付 20,000 美元，作为对放弃其生产许可证的部分补偿；及

（二） 对于基准年产量非常低（不到 5 ODP 吨氟氯化碳）的厂家来说， 将为现有的每份许可证支付 20,000 美元，作为对注册或放弃其生产许可证的一部分补偿，另外还将支付 50,000 美元，以示对销毁设备和放弃生产的奖励，或者作为一次性资本和经营费用；

（三） 中国政府和工发组织认为，采用这种办法，可以借助市场力量实现工业合理化，因为一些计量吸入器生产厂家今后将面临着为其使用氟氯化碳的生产线转产筹措资金的难题，并且将不得不考虑放弃作为独立的计量吸入器生产商。其他厂家可能决定通过基金以外的其他筹资渠道支付其生产线转产的费用。此举的结果是，中国的计量吸入器生产设备减少，生产能力却提高，而且经济和技术上的可行

[1] 16 家企业持有另外 22 份许可证，但没有生产。

性都提高。拟议的办法还旨在根据执行委员会第 53/23 号决定提高行业计划的成本效益。

（d） 资本和经营费用：计量吸入器的资本和经营费用估计如下：

（一） 资本费用根据工厂的氟氯化碳消费量进行计算：对于氟氯化碳年消费量低于 5 ODP 吨的工厂（10 家），每条生产线为 50,000 美元；氟氯化碳年消费量介于 5 至 50 ODP 吨（2 家工厂）的生产线为 200,000 美元；氟氯化碳年消费量介于 50 至 100 ODP 吨（3 家工厂）的生产线为 680,000 美元；以及年消费量超过 100 ODP 吨的一家工厂为 1,320,000 美元；

（二） 购买专利的费用将部分主要支付给大型生产厂家，小厂从基金得到的补偿非常有限，或者得不到基金的补偿；

（三） 现已计算了一年期的经营节余额。

6. 考虑到上述各点后，订正的《计量吸入器行业计划》的总费用是 18,850,502 美元，比提交第五十三次会议的项目总费用少 3,465,687 美元，如下表 1 所示：

表1. 中国《计量吸入器行业计划》总成本摘要

费用项目	**费用总额（美元）**		
	第五十五次会议	**第五十三次会议**	**差额**
技术援助	1,100,000	1,100,000	-
专利费	2,600,000	-	(2,600,000)
2007 年在产许可证档案（*）	6,435,000	7,020,000	585,000
2007 年未在产许可证档案	880,000	3,485,000	2,605,000
工厂对现有设施的改造	4,260,000	5,560,000	1,300,000
生产鉴定（每条生产线）	720,000	680,000	(40,000)
培训方案（每条生产线）	440,000	412,500	(27,500)
经营费用	1,989,502	3,502,689	1,513,187
应急费用	426,000	556,000	130,000
共计	**18,850,502**	**22,316,189**	**3,465,687**

（*） 包括生产工艺研究、质量研究、药理学研究、毒物学研究、特别安全试验和临床试验。

7. 本文件附有工发组织提交的《计量吸入器行业计划》副本。

秘书处的评论和建议

评论

计量吸入器生产设施分析

8. 秘书处在审查《计量吸入器行业计划》所提供的信息时注意到：

（a） 用于计量吸入器生产的氟氯化碳消费量从 2004 年的 152.1 ODP 吨增至 2007 年的 340.5 ODP 吨。目前医生们越来越多地使用计量吸入器治疗哮喘病和慢性阻塞性肺病（COPD）患者，以取代传统治疗方法；

（b） 中国的 7 家计量吸入器生产企业也正在生产药用气雾剂。[2]其中一些厂家已获得供资，以便将其药用气雾剂生产线转换为非氟氯化碳推进剂、提供技术援助及开展培训方案。这些企业具备不同的计量吸入器生产线和许可证；

（c） 如下文表 2 所示，在过去三年中，三家跨国公司[3]一直在生产计量吸入器。这些企业未就转产问题申请资本和经营费用：

表 2. 跨国公司的计量吸入器生产情况

编号	公司名称	产品	有效成分	2005 年 CFC（公斤）	2006 年 CFC（公斤）	2007 年 CFC(公斤)
1	阿斯利康制药有限公司	B04	布地奈德	3,494.0	4,538.0	
1	阿斯利康制药有限公司	B13	硫酸特布他林	7,460.0	8,665.0	
3	北京圣德莱宝制药有限公司	B15	沙丁胺醇	745.9		730.0
3	北京圣德莱宝制药有限公司	B01	二丙酸倍氯米松	180.3		
31	潍坊中狮制药有限公司	B01	二丙酸倍氯米松	-	-	57.0
31	潍坊中狮制药有限公司	B15	沙丁胺醇	1,350.0	900.0	597.0
31	潍坊中狮制药有限公司	B16	沙丁胺醇（悬浮液）	-	-	70.7
共计				**13,230.2**	**14,103.0**	**1,454.7**

工发组织表明，上述企业申请的供资数额已考虑到其生产量较低。

（d） 如下文表 3 所示，三家生产企业仅从 2006 年开始生产计量吸入器，并且其生

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[2] 这 7 家企业是：北京海德润制药有限公司（第 2 号）；广州东康药业有限公司（第 8 号）；贵阳德昌祥药业有限公司（第 9 号）；黑龙江唐龙制药有限公司（第 16 号）；蓬莱诺康药业有限公司（第 19 号）；上海医药（集团）有限公司（第 28 号）；以及无锡山禾集团（第 32 号）。

[3] 另一家跨国公司，葛兰素史克（天津）制药有限公司，已自 2005 年开始停止生产使用氟氯化碳的二丙酸倍氯米松计量吸入器。

产量在 2007 年出现大幅下降：

表3. 仅从2006年开始生产计量吸入器的生产企业

编号	公司名称	产品	有效成分	2006 年 CFC（公斤）	2007 年 CFC（公斤）
2	北京海德润制药有限公司[4]	B15	沙丁胺醇	6,424.0	214.0
2	北京海德润制药有限公司	B22	盐酸异丙肾上腺素	2,915.0	-
2	北京海德润制药有限公司	B23	异丙托溴铵	27.0	325.0
14	河南新星药业股份有限公司[5]	B11	华山参	300.0	-
38	江苏天际药业有限公司	B12	利巴韦林喷剂	4,202.0	-
共计				**13,868.0**	**539.0**

（e） 如下文表 4 所示，在 5 家生产企业中，有的于 2007 年首次生产一些计量吸入器，有的在停产几年后于 2007 年重新开始生产。在中国，有些企业已开始生产其他计量吸入器：

表4. 固定生产企业仅在2007年生产的计量吸入器

编号	企业名称	产品	有效成分	2007 年 CFC（公斤）
11	哈尔滨圣泰制药股份有限公司	B14	色甘酸钠	127.0
22	山东力诺科锋制药有限公司	B22	盐酸异丙肾上腺素	30.0
22	山东力诺科锋制药有限公司	B04	布地奈德	70.0
31	潍坊中狮制药有限公司.	B01	二丙酸倍氯米松	57.0
31	潍坊中狮制药有限公司	B16	沙丁胺醇（悬浮液）	70.7
32	无锡山禾集团第一制药有限公司	B15	沙丁胺醇	3,200.0
35	广东同德药业有限公司	B15	沙丁胺醇	3,420.0
35	广东同德药业有限公司	B16	沙丁胺醇（悬浮液）	2,650.0
共计				**9,624.7**

工发组织表明，上述企业申请的供资数额已考虑到其生产量较低。

（f） 如下文表 5 所示，目前中国生产的计量吸入器中只有 13 种不同的有效成分。[6]

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[4] 由于环境问题，1999 年该企业搬迁到新址；2005 年下半年开始试生产氟氯化碳-计量吸入器，并于 2006 年全面投产。1996 年至 1998 年期间氟氯化碳消费量在 3,567 公斤至 4,459 公斤之间。

[5] 2001 年和 2003 年，该企业用于生产 B11 的各类氟氯化碳消费量分别为 300 公斤和 150 公斤。

[6] 工发组织表示，1997 年生产了 100,000 件异丙托溴铵计量吸入器（B23），氟氯化碳总消费量为 1,414 公斤；2001 年（32,000 件计量吸入器）和 2003 年（16,000 件计量吸入器）生产了华山参计量吸入器（B11）；富马酸酮替芬计量吸入器（B09）的许可证于 1995 年获得批准，但是没有 2004 年之前该产品生产量的资料；硫酸沙丁胺醇计量吸入器（B25）于最近获得核准，投入应用。

需要说明的是：

（一） 二丙酸倍氯米松（B01）、硫酸特布他林（B13）、色甘酸钠（B14）、沙丁胺醇—溶液（B15）和悬浮液（B16），以及盐酸异丙肾上腺素（B22）计量吸入器的生产总量占 2007 年生产总量的 97 %以上。这五种有效成分在哮喘和慢性阻塞性肺病的治疗过程中发挥着非常重要的作用；

（二） 计量吸入器中布地奈德（B04）、二甲基硅氧烷（B05）、富马酸酮替芬（B09）、利巴韦林（B12）、沙美特罗羟萘甲酸盐（B17）、异丙托溴铵（B23）和止喘灵（B24）这七种不同有效成分的氟氯化碳消费量总量占总消费量的 3.0%以下；以及

（三） 仅从 2006 年开始生产将富马酸酮替芬（B09）、沙美特罗羟萘甲酸盐（B17）和异丙托溴铵（B23）作为有效成分的计量吸入器，氟氯化碳消费总量为 1,308.0 公斤（2007 年增至 1,606 公斤）。

表 5. 目前在中国生产的计量吸入器的有效成分

产品	有效成分	CFC 消费量（公斤）			CFC 百分比*
		2005 年	2006 年	2007 年	
B17	沙美特罗羟萘甲酸盐		10.0	10.0	0.00%
B05	二甲基硅氧烷	22.2	70.0	100.0	0.03%
B24	止喘灵	30.0	130.8	320.0	0.09%
B23	异丙托溴铵	-	27.0	325.0	0.10%
B09	富马酸酮替芬	-	1,271.0	1,271.0	0.37%
B12	利巴韦林	1,851.0	7,395.0	3,443.0	1.01%
B04	布地奈德	6,273.5	8,037.0	4,069.0	1.20%
B14	色甘酸钠	6,902.0	7,541.5	13,591.0	3.99%
B13	硫酸特布他林	7,460.0	8,665.0	16,612.7	4.88%
B22	盐酸异丙肾上腺素	40,647.2	47,324.0	43,452.0	12.76%
B01	二丙酸倍氯米松	16,796.6	23,048.0	59,954.0	17.61%
B15	沙丁胺醇（溶液）	69,905.3	91,650.0	85,378.0	25.07%
B16	沙丁胺醇（悬浮液）	93,793.1	85,396.2	111,968.7	32.88%
共计		**243,680.9**	**280,565.5**	**340,494.4**	**100.0%**

(*) 占 2007 年氟氯化碳总消费量的百分比。

2009 年后计量吸入器生产中使用氟氯化碳的要求

9. 工发组织就潜在的必要用途豁免问题与中国政府进行了深入讨论。秘书处最初提出该问题时，工发组织表示，“如果该行业计划能获得执行委员会第五十三次会议的核准，预计将在 2010 年底之前能完成部分计量吸入器生产线转产工作。该行业转产工作中存在诸

多困难，因此可能有一些生产线无法在 2010 年底之前完成转产。过渡时期将使用目前正在积累的库存。为保护臭氧层，中国目前不准备申请必要用途豁免”。现在这一情况已发生变化。根据经修订的《计量吸入器行业计划》，2007 年至 2011 年期间氟氯化碳消费量将逐年上升，从 341 ODP 吨增至 748.3 ODP 吨这一最高水平，然后将逐年下降，并在 2014 年之前实现完全淘汰。2008 年至 2014 年期间，氟氯化碳的累计消费总量将高达 3,332.3 ODP 吨。解释为何在 2014 年之前需要继续消费时，工发组织指出，鉴于目前的专利情况及技术所有者不愿向中国提供其可负担的技术援助，该国政府和工发组织认为，先前拟议的淘汰计划要求过高，并且无法实施。

10. 根据中国政府与执行委员会之间关于停止氟氯化碳生产协定，2008 年和 2009 年可生产的各类氟氯化碳总量为 1,100 ODP 吨。[7]为解决其他的氟氯化碳需求（2,232.3 ODP 吨），该国政府正计划对现有生产协定做出修正。

11. 根据《计量吸入器行业计划》，2007 年至 2011 年期间该国将不会限制氟氯化碳消费量的增长。仅在 2012 年，通过执行项目将前一年的消费量削减约 100 ODP 吨。但考虑到重新配置 HFA-134a 推进剂以替代将二丙酸倍氯米松和沙丁胺醇作为有效成分的计量吸入器已是众所周知的，因此如果该项目获得第五十五次会议的核准，预计将提前实现至少这两种计量吸入器的转换，其氟氯化碳消费量占中国消费总量的 75%以上。倘若如此，2010 年后所需的各类氟氯化碳数量将大幅下降。工发组织在答复中表明，诸如技术提供者的援助有限以及对计量吸入器的需求日益加大等问题减缓了项目的执行进度。但工发组织正在计划，首先开始转换含有这些有效成分的计量吸入器，可能在 2011 年完成。此阶段无法开展进一步降低 2010 年淘汰日期后对各类氟氯化碳的需求的工作，虽然在执行过程中将始终遵循这一要求。

替代技术的选择

12. 根据《计量吸入器行业计划》，所有氟氯化碳-计量吸入器均可转换为氢氟烷烃推进剂。该提案报告，“在将氟氯烷烃作为推进剂用于计量吸入器方面，尚有许多问题有待解决”。在最初提出该问题时，工发组织表明，“主要问题与专利权有关。如本提案所述，在中国有效的专利权涉及几乎所有使用氢氟烷烃作为推进剂的计量吸入器。其他生产企业尚未完成其用于替代各类氟氯化碳技术的研究”。工发组织指出，自最初提交《计量吸入器行业计划》以来，中国的计量吸入器生产企业已经意识到了淘汰其氟氯化碳消费量的迫切性。因此，多数企业已开始就淘汰该行业中各类氟氯化碳方面的问题开展研究。

技术援助活动

13. 秘书处指出，虽然未在产许可证技术档案编制工作的费用已从 85,000 美元降至 20,000 美元（根据提交至第五十三次会议的提案所载的申请），但非投资类活动方面申请

[7] 根据中国政府与执行委员会之间就各类氟氯化碳/四氯化碳/哈龙加快淘汰计划签署的一份协议，2008 年和 2009 年，中国可分别出口 100 ODP 吨和 50 ODP 吨的各类氟氯化碳。

的供资总额却高达 1,173.5 万美元，其中包括：

（a） 用于 80 种产品注册的技术档案编制工作的 731.5 万美元：33 种 2007 年在产（195,000 美元/产品），44 种[8]2007 年未生产（20,000 美元/产品）；

（b） 用于提供技术援助，诸如讲习班、培训方案、公共宣传、顾问、考察旅行、立法支助活动、审计药用气雾剂制造商的氟氯化碳消费量、建立一项信息管理系统，以及多项其他技术援助活动的 110 万美元；

（c） 向 18 条生产线中的各条生产线提供 40,000 美元，用于鉴定设备及生产工序，以及其他方面的支出，共计 720,000 美元；以及

（d） 向一项有限制专利支付赔偿 260 万美元。需要指出的是，提交至第五十三次会议的《计量吸入器行业计划》并未包含这一申请。

资本和经营费用

14. 《计量吸入器行业计划》项目正提议为目前正在生产氟氯化碳-计量吸入器的 16 家生产企业的转产供资。并已向所有生产企业提议开展类似的生产线替代工作，不论各家生产企业的基准生产设备和已安装的生产能力如何。除规模最大的生产企业（第 21 号企业）以外，提议的供资将导致目前的生产能力提高。特别是：

（a） 7 家企业的氟氯化碳年消费量为 0.55 ODP 吨（第 2、9、11、16、22、25 和 37 号企业），另外 3 家企业的消费量低于 4.2 ODP 吨（第 8、24 和 32 号企业）。其中每家企业会获得 50,000 美元；

（b） 两家企业（第 35 和 36 号企业）的氟氯化碳年消费量介于 6.1 至 9.8 ODP 吨之间，其将分别获得 200,000 美元；

（c） 两家企业（第 19 和 28 号企业）的消费量介于 21.7 至 26.1 ODP 吨之间，另外一家企业（第 18 号企业）的消费量为 73.3 ODP 吨，其将分别获得 680,000 美元；以及

（d） 一家企业（第 21 号企业）的氟氯化碳年消费量为 175.2 ODP 吨，其将获得 1,320,000 美元。

15. 秘书处还表示，虽然增支经营费用已从 3,502,689 美元（12.47 美元/公斤）降至 1,989,502 美元（7.08 美元/公斤），但与孟加拉国（4.06 美元/公斤）、埃及（5.64 美元）、伊朗（3.59 美元/公斤）和墨西哥（2.70 美元/公斤）已获得核准的计量吸入器项目的经营费用相比，其仍然很高。

[8] 不久，44 种产品中的 3 种将会被淘汰。

16. 工发组织表示，生产量较低的计量吸入器生产企业在基准年度的生产力甚至相对较高（即 500 万至 800 万桶/年），并且由于市场原因，其未被充分利用。但这些企业申请的供资却最低，因此成了停止生产及破坏设备的一个刺激因素。为降低供资总额，经营费用已从 350 万美元降至 200 万美元以下。如果阀门生产实现本地化并且其产量达到合理水平，则可在降低其价格的情况下对计算经营费用时所用的阀门价格做出估算。

成本效益

17. 如前一次提交《计量吸入器行业计划》，秘书处对该提案进行了一次详细的审查。为此，秘书处制订了一份表格，将该《计划》提出的单位费用同 16 家目前正在开展经营的生产企业逐一联系起来。在分析中，将技术援助（1,100,000 美元）和专利（2,600,000 美元）的申请总额除以即将淘汰的氟氯化碳总量，并根据 16 家目前正在开展经营的企业 2007 年的氟氯化碳消费量在其间按比例分配。

18. 基于上述分析，秘书处做出了如下附加评论：

（a） 根据 322.475 ODP 吨的氟氯化碳消费量，提交的整体成本效益值（CE）为 58.46 美元/公斤。《计量吸入器行业计划》的整体成本效益值为 20.00 美元 / 公斤，该值高于孟加拉国（38.08 美元/公斤）、伊朗（36.61 美元/公斤）、埃及（36.36 美元/公斤）和墨西哥（37.75 美元/公斤）已核准的计量吸入器项目的成本效益值；

（b） 秘书处意识到，执行委员会尚未建立计量吸入器次级行业中各项目的成本效益阈值。但秘书处将已计算出的企业一级成本效益值与生产企业的潜在可持续性进行了联系。因此，它指出：

（一） 中国成本效益值最高的企业是两家最大的计量吸入器制造商（第 18 号和 21 号企业），其成本效益值分别为 32.93 美元/公斤和 26.76 美元/公斤。这两家企业的总产量占中国计量吸入器总产量的 74%和计量吸入器行业中氟氯化碳总消费量的 77%；

（二） 3 家生产企业（第 19、28 和 35 号企业）的成本效益值介于 67 美元/公斤至 99 美元/公斤之间；6 家企业（第 2、8、11、24、32 和 36 号企业）的成本效益值介于 178 美元/公斤至 788 美元/公斤之间；3 家企业（第 9、16 和 25 号企业）的成本效益值介于 1,128 美元/公斤至 1,619 美元/公斤之间；还有 2 家企业（第 22 号和 37 号企业）的成本效益值介于 5,140 美元/公斤至 5,145 美元/公斤之间。根据上述数值，所有这些企业的长期可持续性值得怀疑；

（三） 在中国目前生产计量吸入器的各企业中，未向已具备许可证但未在 2007 年生产的计量吸入器注册的技术档案拨付 880,000 美元。

工发组织表示，将鼓励成本效益值（绝对值）较高的那些计量吸入器生产企业通过采取《计量吸入器行业计划》提议的方法，停止其计量吸入器生产活动。

秘书处的提案

19. 根据秘书处在审查工发组织再次提交的《计量吸入器行业计划》过程中提出的问题和意见，向尚不确定是否符合供资条件的一些项目提供经费的申请，以及多边基金在计量吸入器行业获得的经验，秘书处提议工发组织采用以下替代方法，确定中国计量吸入器行业的增支费用。该方法符合多边基金现行的政策和指导原则，并且只有在秘书处提出的相关问题获得充分解决时，才可采用。

过渡战略

20. 中国政府制订的《计量吸入器行业计划》确定了若干构成部分，其考虑到了计量吸入器行业氟氯化碳向非氟氯化碳替代品过渡的过程。这些部分包括，审查并强制执行管理该行业的政策和条例；审议 2010 年淘汰日期后的必要用途豁免申请；必要时制订与氟氯化碳淘汰工作相关的政策以管理药用等级氟氯化碳储存，并采取消耗臭氧层物质许可证制度来控制计量吸入器行业的氟氯化碳消费量；进一步考虑制订一项工业合理化计划；针对主要有关利益方开展教育活动；并进行公共宣传和信息传播。考虑到计量吸入器中的有效成分种类繁多，过渡战略的费用将达到 300,000 美元。

产品开发

21. 通过《计量吸入器行业计划》所载的信息，以及一些有效成分方面的出版文献所载的有限信息，还不能确定这些成分在中国是否作为药用气雾剂或计量吸入器进行销售。这些有效成分包括：利巴韦林、二甲基硅氧烷、富马酸酮替芬、盐酸异丙肾上腺素、华山参和止喘灵。

22. 目前中国生产的计量吸入器中有 13 种有效成分，其中 4 种成分在哮喘和慢性阻塞性肺病的治疗过程中发挥着非常重要的作用。这些成分为色甘酸钠、倍氯米松、盐酸异丙肾上腺素，以及沙丁胺醇－溶液和悬浮液。这些计量吸入器的生产总量占目前中国氟氯化碳消费总量的 97%以上（如上文表 5 所示）。

23. 为确定氢氟烷烃计量吸入器的开发费用，提议向色甘酸钠、倍氯米松和盐酸异丙肾上腺素产品开发提供总额为 2,400,000 美元（即每种有效成分为 800,000 美元，与埃及和伊朗核准的供资数额相当）的资金。另外，提议向沙丁胺醇（溶液和悬浮液形式）产品开发供资 1,200,000 美元。氢氟烷烃计量吸入器开发工作的职权范围与工发组织针对埃及和伊朗项目提案制订的范围相当。

24. 为解决剩余的 9 种有效成分（占计量吸入器生产中氟氯化碳总消费量的 3%以下），提议供资 600,000 美元作为技术援助，计算的依据为目前 CFC-12 的价格（3.43 美元/公斤），

以及当前 6 年期内氟氯化碳的消费量（9,540 公斤），在此期间将完全淘汰用于计量吸入器生产的各类氟氯化碳。

25. 与氢氟烷烃技术开发相关的总费用将达到 4,200,000 美元。

成本和经营费用

26. 秘书处提议，按如下数额供资，用于目前正在生产氟氯化碳计量吸入器的 16 家企业的转产：

（a） 50,000 美元用于 12 处氟氯化碳消费量低于 10 ODP 吨的生产设施。估算的依据为，30,000 美元用于一条新生产线，另外 20,000 美元用于一个使用氢氟烷烃推进剂所必需的小型压力罐；

（b） 400,000 美元用于 3 处氟氯化碳消费量介于 20 ODP 吨和 100 ODP 吨之间的设施。费用的计算依据为，埃及计量吸入器项目中一条新完成的生产线的最新报价；

（c） 2,000,000 美元仅用于氟氯化碳消费量高于 100 ODP 吨的企业。费用的计算依据为，埃及、伊朗和墨西哥的生产线费用；

（d） 因此，与符合供资条件的企业转产相关的资本总费用高达 4,180,000 美元，包括 10%的应急费用。

27. 经营费用的计算依据为，氟氯化碳的消费总量为 322,475 公斤，及每公斤价格为 4.43 美元（是孟加拉国、埃及和伊朗核准经营费用的平均值）。因此，经营费用达到 1,430,000 美元。

项目执行和监测机构

28. 为向中国计量吸入器行业氟氯化碳向氢氟烷烃推进剂过渡的工作提供便利，并考虑到分布在该国各地一些企业生产的计量吸入器中的有效成分种类繁多，秘书处提议，建立一个项目执行和监测机构，费用总额为 2,380,000 美元。除其他事项外，该机构负责：

（a） 协助编制 16 家生产企业目前生产的 32 种有效成分的技术档案（每种 20,000 美元，总费用为 640,000 美元）；

（b） 鉴定目前在产的 16 家生产企业（每家企业 30,000 美元）。主要活动包括：鉴定车间、设施和设备安装、设施运作和运行情况，以及产品（总费用为 480,000 美元）；

（c） 对生产企业的相关工作人员进行培训。该培训属于技术培训以外的培训，后者由设备供应商来提供，其属于资本费用中的一部分（培训费用为 420,000

美元，估计占资本费用的 10%）；并

（d） 建立监测机构，包括制订相关的管理、监测和核查制度，并在必要时对库存进行管理。（费用总额为 840,000 美元，估计占资本费用的 20%）。

供资概要

29. 为完全淘汰中国计量吸入器行业的各类氟氯化碳，拟议的供资数额为 12,490,000 美元，分配情况如下：

过渡战略	300,000 美元
产品开发	4,200,000 美元
成本费用	4,180,000 美元
经营费用	1,430,000 美元
项目执行和监测机构费用	2,380,000 美元

30. 中国政府可根据多边基金的相关决定和指导原则，在其认为有助于完全淘汰计量吸入器行业各类氟氯化碳的活动中灵活使用《计量吸入器行业计划》提供的资金。

31. 工发组织对上述提案做出的答复为：中国有许多生产企业生产使用不同有效成分的计量吸入器，尽管第 5 条国家可根据一项核准的项目拥有有限的企业（1 个或 2 个）生产计量吸入器。对于中小型企业而言，每种产品和许可证都是企业的一项重要资产。在编制《计量吸入器行业计划》时已考虑到了这些问题及中国的具体状况。因此，根据成本效益值对项目进行评估将得出错误的结论。

32. 此外，工发组织表示，经修订的《计量吸入器行业计划》已证实了淘汰计量吸入器行业氟氯化碳消费量所需各项活动的实际费用。计算此费用时采用一个恰当的计算方法。考虑到秘书处的提案，已削减了正在同时生产计量吸入器和非计量吸入器药用气雾剂的企业的成本费用。下文表 6 对工发组织提出的修订项目做了说明：

表6. 工发组织提出的《计量吸入器行业计划》的订正总费用

费用项目	总费用（美元）		
	执行委员会第五十五次会议	执行委员会的五十三次会议	差额
技术援助	1,100,000	1,100,000	-
专利费用	2,600,000		(2,600,000)
2007 年在产许可证技术档案	6,435,000	7,020,000	585,000
2007 年未在产许可证技术档案	880,000	3,485,000	2,605,000
工厂对现有设施的改造	4,204,000	5,560,000	1,356,000
生产鉴定（每条生产线）	640,000	680,000	40,000
培训方案（每条生产线）	440,000	412,500	(27,500)
经营费用	1,989,502	3,502,689	1,513,187
应急费用	420,400	556,000	135,600
共计	**18,708,902**	**22,316,189**	**3,607,287**

33. 秘书处注意到，修订后的项目费用比起初提交至执行委员会第五十三次会议的项目费用低 3,607,287 美元。秘书处还注意到，根据第 41/80 号决定，不应将中国的《计量吸入器行业计划》提交执行委员会审议，因为与工发组织尚未就供资数额达成协议。但是，考虑到这是中国的最后一项氟氯化碳淘汰计划，再加上提案的复杂性、提案对 2010 年后必要用途潜在申请的重大影响，以及中国政府为减少其氟氯化碳消费量以期在 2010 年 1 月 1 日前完全淘汰各类氟氯化碳所需的额外援助，秘书处决定将该项目提交执行委员会审议。

建议

34. 谨建议执行委员会根据上述评论和意见审议《计量吸入器行业计划》。

项目评价表 – 多年期项目

中国

(一) 项目名称	机构
甲基溴	联合国工业发展组织 - 意大利

(二) 最新第7条数据 (ODP吨)			年: 2006	
CFC: 12414.9	CTC: 774.4	Halons: 161	MB: 300.4	TCA: 279.9

(三) 最新国家方案行业数据 (ODP吨)						Year: 2006							
物质	气雾剂	泡沫塑料	哈龙	制冷		溶剂	加工剂	计量吸入器	实验室用途	甲基溴		烟草膨里	总计
				生产	维修					检疫和装运前消毒处理	非检疫和装运前消毒处理		
CFC	468,8	6.318,6		493,8	3.287,			280,9				21,3	10.870,4
CTC							356,5		534,6				891,1
哈龙			795,										795,
甲基溴										568,2	310,		878,2
TCA						279,9							279,9

(四) 项目数据			2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total
蒙特利尔议定书的消费限量		MB	1.102,1	1.102,1	1.102,1	881,7	881,7	881,7	881,7	881,7	881,7	881,7	881,7	881,7	881,7	0,	
最大允许消费量 (ODP吨)		MBR	1.087,8	1.087,8	1.087,8	880,	723,8	570,6	390,	250,	209,	176,	150,	100,	50,	0,	
项目费用 (美元)	联合国工业发展组织	项目费用		4.086.600,				1.200.000,	1.800.000,	1.300.000,	600.000,	500.000,	500.000,	500.000,	302.742,		10.789.342,
		支助费用		306.495,				90.000,	135.000,	97.500,	45.000,	37.500,	37.500,	37.500,	22.706,		809.201,
	意大利	项目费用				4.000.000,											4.000.000,
		支助费用				470.000,											470.000,
原则核准资金总额 (美元)		项目费用		4.086.600,		4.000.000,		1.200.000,	1.800.000,	1.300.000,	600.000,	500.000,	500.000,	500.000,	302.742,		14.789.342,
		支助费用		306.495,		470.000,		90.000,	135.000,	97.500,	45.000,	37.500,	37.500,	37.500,	22.706,		1.279.201,
执行委员会发放资金总额 (美元)		项目费用		4.086.600,		4.000.000,		1.200.000,	0,	0,	0,	0,	0,	0,	0,		9.286.600,
		支助费用		306.495,		470.000,		90.000,	0,	0,	0,	0,	0,	0,	0,		866.495,
本年申请资金总额 (美元)		项目费用							**1.800.000,**								0,
		支助费用							**135.000,**								0,

(五) 秘书处的建议：	一揽子核准

项目说明

35. 工发组织代表中国政府提交了一份关于中国甲基溴淘汰计划第二阶段第二次付款执行情况的进度报告，并且请求支付项目的第三次付款（2008 年工作方案）：1,800,000 美元的费用，外加给工发组织的机构支助费用 135,000 美元。目前正在意大利政府的援助下实施这一项目。

背景

36. 执行委员会第四十四次会议原则上核准了中国消费行业的国家甲基溴淘汰计划，供资总额为 14,789,342 美元（包括之前第四十一次会议为工发组织核准、用以淘汰 389 ODP 吨甲基溴的金额）。此外，会议还核准了中国政府和执行委员会签署的一份协定（第 44/30 号决定）。其后，执行委员会已核准了该项目的头两次付款，总额为 5,200,000 美元，外加给意大利政府（470,000 美元）和工发组织（90,000 美元）的支助费用 560,000 美元。

<u>进度报告</u>

37. 经与中国政府商定，项目第二阶段的重点是淘汰用于烟草和农产品（即番茄、黄瓜和草莓等作物）行业的土壤熏蒸及商品熏蒸的甲基溴。所选替代技术包括：用于烟草行业的浮盘系统、用于农产品行业的土壤害虫生物控制以及用于商品行业的磷化氢熏蒸。

38. 现已在烟草行业实施了下列活动：开展技术援助方案，编制和分发培训材料和协议，建立技术专家小组，为培训者和农民制订培训方案，建立温室、为其配备设备并进行升级。为补充通过基金提供的资金，国家烟草专卖局在温室、聚苯乙烯盘和其他辅助设备上额外投资 5,500 万美元，用于使用浮盘系统的烟苗生产。

39. 关于将甲基溴用于土壤熏蒸，意大利、西班牙和日本均已开展了若干关于使用设备和甲基溴替代技术的培训方案。工作计划是在 2007 年 9 月才获得核准的，因此，甲基溴淘汰活动的执行工作始于 2008 年的栽培季节。商品行业开展了一些技术援助方案，包括制订磷化氢熏蒸协议，训练培训员和仓库管理员，采购和安装设备以及建立长期技术援助和监测系统。商品领域的甲基溴消费量已于 2006 年底之前被全部淘汰。

40. 进出口许可证制度已于 2004 年 1 月 1 日起生效。禁止使用甲基溴商品应用的条例于 2006 年 9 月发布，并于 2007 年 1 月 1 日起施行。2007 年 5 月 21 日，发布了一份关于实行甲基溴生产许可证和配额制度的通知。甲基溴的进出口由“消耗臭氧层物质进出口管理办公室”负责监测。为甲基溴增加了两个新的协调制度编码，以便在海关统计数据和管理工作中准确无误地识别所有的甲基溴用途。关于甲基溴生产，2008 年 1 月实行的甲基溴销售条例要求三个甲基溴生产商中，每个生产商都要获得生产许可证、为检疫和装运前消毒处理用途签发的熏蒸认证、 交货单、运输序列和应用类型，并留下记录。

41. 在迄今为中国核准的供资总额（9,286,600 美元）中，工发组织（作为牵头执行机构）

已支付 7,731,598 美元（不包括机构支助费用）。中国政府各机构一旦提交相关进度报告，工发组织将再支付 1,555,002 美元。

2008 年工作方案

42. 尽管商品行业的甲基溴用途已被淘汰（2006 年），烟草行业的也即将于 2008 年被淘汰，当前，有些活动仍处于执行过程中。在商品行业，这类活动包括继续实行 2006 年制订的技术援助和监测制度，以控制采用有效和安全的方式使用磷化氢，向技术和管理人员提供最新支持，并监测比较各种替代技术的处理成本。在烟草行业，这类活动包括完成温室的安装（拟议于 2008 年 8 月之前）及执行长期技术援助和培训方案，以使技术人员不断更新知识，巩固替代技术和持续淘汰甲基溴。

43. 关于甲基溴用作土壤熏蒸剂，将为农民提供设备和农用物资，以淘汰其在各区域和若干作物（主要是草莓、黄瓜、西红柿和姜等作物）中的消费。2007 年开始的培训方案将继续进行，以便农民正确使用各种替代技术。

秘书处的评论和建议

评论

44. 中国政府估算的 2007 年甲基溴消费量是 389.5 ODP 吨，这已经比《议定书》规定的当年最大允许消费量 881.6 ODP 吨少 492.1 ODP 吨，比中国政府和执行委员会通过协定确定的允许消费量 570.6 ODP 吨少 181.1 ODP 吨。

45. 考虑到目前为止在甲基溴消费量削减方面取得的重大成果，秘书处希望能获得更多信息，以了解中国政府为避免重新使用甲基溴、以及为避免把为检疫和装运前消毒处理（即非受控用途）进口/生产的甲基溴用于土壤和/或商品熏蒸而采取的措施和/或建立的机制。工发组织表示，已经在完全淘汰了甲基溴的商品和烟苗行业建立了长期技术援助和监测制度，以确保实施的替代技术的可持续性。国家粮食局和国家烟草专卖局都是建制良好且非常重要的国家机构，均致力于在各自领域淘汰甲基溴。它们有自己的体系、管理和财政资源，并且一直在努力淘汰甲基溴。至于甲基溴淘汰活动刚刚开始的农产品行业，除提供设备和技术援助外，淘汰方案计划还执行长期技术援助和监测制度，以确保替代技术的长期可持续性。

46. 秘书处注意到在中国的烟草行业实施浮盘系统需要大量浮盘，便询问工发组织，中国政府有无考虑购买一些机器以便在当地生产浮盘。工发组织表示，国家烟草专卖局严格控制烟苗及其生产，并向各地区发放烟草生产配额。当地的烟草公司根据生产配额编制种植计划，并计算所需秧苗和浮盘。在此基础上，烟草公司启动了一个全国性竞标，以在市场上购买所需浮盘。生产浮盘的机器由各工厂购买。生产浮盘的技术非常简单，价格也低，通常一个浮盘的寿命是三年，因此，浮盘需求量有所增加并不会影响工厂的生产。

建议

47. 基金秘书处建议按下表所列供资额一揽子核准国家甲基溴淘汰项目的第三次付款和相关支助费用。

	项目名称	项目供资（美元）	支助费用（美元）	执行机构
(a)	国家淘汰甲基溴（第二阶段第三次付款）	1,800,000	135,000	工发组织

对四氯化碳行业计划（第二阶段）
2007 年加工剂用途四氯化碳消费情况的核查

导言

48. 世界银行代表中国政府报请第五十五次会议发放 1,000 万美元的 2008 年供资付款和 750,000 美元的支助费用，用于实施中国四氯化碳行业计划第二阶段的 2008 年工作方案。执行委员会第五十三次会议核准了 2008 年工作方案，但暂不支付资金，以待世界银行提交对 2007 年该行业计划第二阶段四氯化碳消费情况的核查报告。下文概述了核查报告，也可应要求提供报告全文。

对 2007 年四氯化碳行业计划第二阶段的四氯化碳消费情况的核查

49. 核查工作于 2008 年 4 月至 5 月实施，由世界银行为前几年核查工作签约的同一名顾问负责。核查小组视察了该行业计划第二阶段涉及到的 15 家四氯化碳消费企业。

50. 该名顾问在进行核查时采用了下列方法：

（a） 从企业管理人员那里了解企业的历史、企业的身份、使用四氯化碳作为加工剂生产产品的企业活动以及 2007 年的四氯化碳消费/购买情况，如果企业已关闭，则了解停止四氯化碳相关生产方面的活动；

（b） 审查四氯化碳的定购单和运入企业仓库的四氯化碳的每日调度记录，以核定四氯化碳购买量；

（c） 核对四氯化碳存货记录，包括存放于仓库以及留存于生产系统中的四氯化碳数量，以核定四氯化碳的期初库存量和期末库存量；

（d） 核定四氯化碳消费量=四氯化碳购买量+四氯化碳期初库存量-四氯化碳期末库存量；

（e） 审查每日生产日志、产品包装/转移记录以及产品仓库内外的每日调度记录，以核定产量和销售量；

（f） 审查产品目录，以核定产品期初库存量和期末库存量；

（g） 审查企业的每日生产日志，以核定生产天数；

（h） 审查与 2007 年购买的四氯化碳有关的所有增值税发票，交叉核对财务记录；并

（i） 视察生产场地，如果企业已关闭，则视察已拆除的场地，并拍照。

51. 关于各被视察公司的报告包括一份关于公司历史的说明、其主要生产线以及重点核查的生产线。提交的核查结果显示了 2007 年企业的四氯化碳期初库存量、购买量、消费量、其他用途以及期末库存量，包括产品在内。核查报告指出了所涉产品的生产天数以及制造的每单位产品与所消费四氯化碳之间的比值。报告末尾提出了视察中遇到的问题和困难、2007 年企业的四氯化碳实际购买量以及从国家环保总局获得的四氯化碳配额。

52. 顾问进行实地视察后得出结论，15 家企业根据国家环保总局签发的总配额 3,474.6 ODP 吨，购买了共计 3,066.25 ODP 吨的四氯化碳。本文件的附件二载有对这 15 家企业的核查结果概述，其中包括关于企业名称、使用四氯化碳的产品、产量、四氯化碳购买量、四氯化碳消费量、四氯化碳期初库存量和期末库存量以及生产线状况（运营中或已关闭企业）的数据。

53. 世界银行提交的文件包含三个附件：附件一载有 2007 年第二阶段的核查记录和关闭活动；附件二载有进行核查视察时拍摄的照片；附件三载有关于关闭工厂的文件。

秘书处的评论

54. 四氯化碳行业计划第二阶段协定中规定的、用于四氯化碳消费情况核查的方法要求“将由世行核查各公司的消费情况和包括在行业计划第二阶段之内的各项用途。年度核查将从所有企业中随机选择至少 30%的企业，至少占第二阶段消费的 30%。”第五段列明了核查结果。核查的抽样符合《协定》的要求，可以证实国家环保总局报告的总消费量是有效的。国家环保总局报告的、顾问核实的 2007 年第二阶段四氯化碳总消费量为 5,175 ODP 吨，低于《协定》为 2007 年规定的四氯化碳最大允许消费量 6,945 ODP 吨。

建议

55. 秘书处建议执行委员会：

（a） 注意到 2007 年四氯化碳行业计划第二阶段的四氯化碳消费情况核查报告；

（b） 核准支付 1,000 万美元和 750,000 美元的支助费用，用于实施四氯化碳行业计划第二阶段的 2008 年工作方案。

淘汰甲基溴生产行业计划：2008－2010 年工作方案（第二阶段）

导言

56. 工发组织代表中国政府向第五十五次会议提交了淘汰甲基溴生产行业计划的涉及 2008－2010 年的第二阶段的工作方案，并请求为执行工作方案发放 300 万美元，外加 225,000 美元的机构资助费用。呈件包括关于 2005－2007 年行业计划第一阶段取得成就的核查，这是中国政府与执行委员会关于发放行业计划第二阶段资金的协定所规定的强制性核查。核查报告和 2008－2010 年工作方案均未随附，但如要求可予提供。

背景

57. 在 2005 年的第四十七次会议上，执行委员会原则上核准总共拨款 980 万美元，协助中国遵守《蒙特利尔议定书》的关于控制用途甲基溴生产的管制时间表，同时发放了 200 万美元的第一次付款，用于 2005－2007 年期间执行行业计划的第一阶段。以下表格来自涉及行业计划的《协定》，列出了甲基溴生产的年度减产目标和资金发放时间表。

年份	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	共计
受控用途甲基溴最大年度允许生产量（ODP 吨）	621.0	600.0	570.6	390.0	250.0	209.0	176.0	150.0	100.0	50.0	0.0*	-
项目费用（千美元）	3,000	0	0	3,000	0	0	2,000	0	0	1,790	0	9,790
机构费用（千美元）	225	0	0	225	0	0	150	0	0	134	0	734
多边基金赠款总额（千美元）	3,225	0	0	3,225	0	0	2,150	0	0	1,924	0	10,524

* 除检疫和装运前消毒处理外，原料和关键用途有待缔约方的核准。

58. 《协定》规定，“资金将在工发组织提出呈件后，在执行委员会接受对已列明以往数年减产目标的核查后，在上述年份中的第二次会议上予以核准。”

对 2005 年至 2007 年甲基溴生产的核查

59. 2008 年 4 月，由中国的两名顾问组成的小组进行了核查。其中一名成员虽然没有核查甲基溴生产的直接经验，但具有化工行业方面的广泛经验，另一成员的专业是财务会计。

60. 核查的目的是确认受控用途的甲基溴生产没有超过《协定》规定的最高允许限量，即：2005 年 621 ODP 吨，2006 年 600 ODP 吨，2007 年 570.6 ODP 吨。

61. 中国有 3 家甲基溴生产厂，这些生产厂的概况如下：

公司名称	连云港死海溴化物有限公司	昌邑市化工厂	临海市建新化工有限公司	**共计**
地址	江苏连云港	山东昌邑	浙江临海	
所有权	合资：以色列 60%/中国 40%	私有	私用	
历史	初步设备于 1977 年建立。1995 年，60%的资本来自以色列一公司，生产能力增加到 4,000 公吨/年。	初步设备于 1992 年建立，生产能力为 500 公吨/年。产品主要用于农业和检疫和装运前消毒处理。	1989 年投产的甲基溴生产线，生产能力 800 吨。1999，生产能力增加到 2,400 公吨。产品多用于检疫和装运前消毒处理。	
生产能力	4,000 公吨/年	1,500 公吨/年	2,400 公吨/年	7,900 公吨/年
2002-2004 年生产(公吨)	2,582 2,023 1,920	149 176 241	828 794 308	

2002－2003 年生产数据来自 Wakim 审计报告。2004 年生产数据来自国家环保总局/工发组织调查报告。

62. 核查组走访了所有三个工厂，此前，核查组曾通过为这一工作专门设计的调查问卷收集了这些工厂的数据。根据报告，核查组在每一地点采取以下步骤，检查了以下内容：

- 通过记录单核查保留记录制度；
- 工厂现状和表观业务情况；
- 日生产日志、原材料记录、甲醇和二溴的原料消耗数据以及甲基溴产品；
- 通过年度产品库存记录确认甲基溴库存是否与年度生产和销售数据相符；
- 通过原料库存记录计算甲醇和二溴的积累库存变化，以确认与整体以及每一生产周期的甲基溴生产相符；以及
- 每小时的生产日志，包括厂内流量数据以及容器容量的改变以核查原料的单位消耗比率。据报告，这一比率与生产量相符，尽管由于跑漏、生产厂操作条件以及其他因素，这一比率被认为高于行业的规范。

63. 核查组作为取样分析了每一生产周期中 4 周的数据。同一周的原料消耗与消耗臭氧层物质的生产之间也相符。

64. 为核查受控用途的甲基溴生产、检疫和装运前消毒处理和原料，核查组报告采取了以下步骤对销售记录进行检查：

- 关于检疫和装运前消毒处理：在中国，只有发有许可证的熏蒸公司才可从事检疫和装运前消毒处理。此外，每一检疫和装运前消毒处理必须取得国家质量监督检验检疫总局（国家质检总局）的授权。核查组根据买主登记时使用的名称和国家质检总局颁发的授权书，评估了检疫和装运前消毒处理用途的甲基溴销售情况。

- 关于受控用途：只有农业货物经销者、农户、粮库和烟草公司等有照买家才有权购买甲基溴。核查组根据买家名称和可查阅的许可证评估了受控用途甲基溴的销售情况。

- 关于原料：只有药品制造商、化学品制造者和香水制造者才有权用甲基溴为原料。核查组根据买家名称和可查阅的许可证评估了原料用途甲基溴的销售情况。

- 关于进口和出口：核查组检查了结关单据、进出口合同和发票，随后向消耗臭氧层物质进口/管理办公室核证了进出口许可证，以核查每笔甲基溴进出口的用途。

65. 核查组随后讨论和核查中查出的问题。例如，连云港死海公司将运抵的甲基溴随即打包，随后在货物运输之前进行存货登记。因此，运输中的损失没有反映出来，从而造成仓库与车间记录之间的不对应。其他两个业务规模小的生产厂没有符合标准的保留记录制度。其中一个生产厂不对其原料进行秤量，只作估计。因此，原料的消耗到最终的生产都不准确。

66. 核查组提出了若干建议，其中包括政府有必要制订方案以便进一步管制分类产品的生产和销售，同时执行实行一项消耗臭氧层物质的具体管理制度。关于各生产厂，核查组建议，每项销售必须包括签署销售合同，而检疫和装运前消毒处理用途或原料用途的甲基溴供应商必须提供成分的熏蒸处理证书。必须改进生产管理制度，确保正确秤量原料的重量，销售分类必须更准确，不同用途应签署不同的合同。

67. 核查组的结论是，没有发现三家生产厂超出甲基溴受控物质用途的生产配额，三家生产厂年度生产总量如下：

ODS（吨）	**最高允许生产量**	**管制配额**	**实际生产**
2005 年	1,035	1,030	730.739
2006 年	1,000	1,000	985.085
2007 年	951	900	686.275

68. 以下为根据用途和向臭氧秘书处报告的数据分列的甲基溴生产情况：

		2005 年	**2006 年**	**2007 年**
核查的数据	受控用途	730.739	985.085	686.275
	检疫和装运前消毒处理	1,356.271	1,313.611	1,534.736
	原料	1,098.364	992.955	1,461.426
	共计	**3,185.368**	**3,291.651**	**3,682.437**
报告的数据	受控用途	730.115	985.088	*
	检疫和装运前消毒处理	1,357.753	1,313.615	*
	原料	1,097.500	992.953	*
	共计	**3,185.368**	**3,291.656**	*

关于 2005－2007 年行业计划执行情况的进度报告

69. 2005－2007 年以及 2008 年期间，在与三家甲基溴生产厂签署赔偿合同方面取得了进展。今后，将根据甲基溴生产厂的业绩和所发表的年度审计报告，与这些厂家谈判签署合同问题。环境保护部（环保部）在与甲基溴厂家协商后，并根据中国与执行委员会达成的《协定》，确定了生产配额。下表列出了 2005－2008 年期间的配额。

年份	**2005 年**	**2006 年**	**2007 年**	**2008 年***
配额（ODS 吨）	1,030	1,000	900	640
年水产限量	1,035	1,000	951	650

70. 环保部在所有与甲基溴检疫和装运前消毒处理用途有关的问题上均与国家质量监督检验检疫总局（国家质检总局）进行合作。环保部和国家质检总局正在联合制订与甲基溴检疫和装运前消毒处理用途有关的政策。国家质检总局负责开展能力建设方案，同时亦负责数据的收集、监测以及发放甲基溴检疫和装运前消毒处理熏蒸的授权与核证。

71. 由环保部代表，与海关总署和商务部派代表组成的环保部“消耗臭氧层物质进出口管理办公室”，负责监测包括甲基溴在内的所有消耗臭氧层物质的进口和出口。所有官方数据均由该办公室核证和加以综合。继调查结果和建议提出后，环保部和海关总署商定，为甲基溴增加两种商品海关编码。因此，甲基溴将具有三种商品海关编码，分别是：(a) 消耗臭氧层物质、(b) 检疫和装运前消毒处理以及 (c) 原料。这样做将在海关总署的统计数字和管理中明确标示出出口的甲基溴用途。根据上述改变，环保部、海关总署和“消耗臭氧层物质进出口管理办公室”将于 2008 年对海关官员进行进一步的培训和开展一项调查。,

72. 关于甲基溴生产行业，环保部与“消耗臭氧层物质进出口管理办公室”共同开展了以下各项活动：

项次	方案	现状
1	与海关当局一道调查甲基溴进出口数据	2007 年 11 月 16 日完成
2	根据调查结果修订协调编码制度	分别就消耗臭氧层物质、检疫和装运前消毒处理及原料商定了三项商品海关编码。
3	为管理和使用新的商品海关编码，对海关和甲基溴进出口经销商进行培训。	正在进行中，预计于 2008 年 9 月完成。

73. 为管理中国的甲基溴生产、消费和贸易，颁布了以下政策：

(a) 通过环保部发布《通知》，自 2003 年 7 月 1 日起，禁止 1,1,1－三氯乙烷和甲基溴生产设备的建造、扩建和整修；

(b) 2004 年 5 月 21 日起开始执行甲基溴水产许可证和配额管理制度；

(c) 甲基溴（包括检疫和装运前消毒处理）进出口许可证自 2004 年 1 月 1 日起生效。自 2004 年起，禁止受控用途甲基溴的出口，但不包括检疫和装运前消毒处理；

(d) 2006 年 9 月环保部发布通知，禁止粮食熏蒸行业销售和使用甲基溴；以及

(e) 继在环保部、农业部、国家质检总局、公安部、国家林业局和国家安全生产监督管理总局举行的第一次会议上提出和讨论后，中国甲基溴生产监督计划开始实施。该计划要求生产商须获得买主经签字的声明，表明购买甲基溴的用途以及只允许一次实际的运销。

74. 进度报告介绍了行业计划第二阶段的拟议工作方案，其中载有由各有关利益方开展的行业淘汰、政府政策工作、公众认识和技术援助方面的 15 项活动。总预算估计为 300 万美元。

秘书处的评论

75. 这是对甲基溴审查进行的第一次核查，秘书处确认，工发组织遵循了 2000 年 通过的核查消耗臭氧层物质生产淘汰的准则。秘书处还注意到，中国政府实行了政策措施管理因存在双重意图、受控用途和检疫和装运前消毒处理而变得复杂的甲基溴生产。中国世界上有三种用途，第三种用途是作原料用途。

76. 秘书处想要就工发组织的核查提出的问题是，在没有双重用途的复杂因素的情况下，核查消耗臭氧层物质生产淘汰所运用的办法是否足以能够核查带有像四氯化碳和甲基溴这样复杂因素的消耗臭氧层物质的核查。由于无法通过外表确定这些消耗臭氧层物质的用途，确保所生产物质分销售与原意相符的唯一途径是在最终用户一级进行核查。世界银行在核查印度和中国的四氯化碳生产时就是这样做的，世界银行采取了两种方式。就印度的四氯

化碳行业计划而言，世界银行除了核查四氯化碳的生产商和进口量之外，还核查原料用户的四氯化碳消费量。在减去用作原料的生产量之后，剩余的四氯化碳便是受控用途。就中国的情况而言，世银对四氯化碳的生产商进行核查，并在取样的基础上对受控用途的最终用户进行核查。事实上，两国四氯化碳生产和消费的核查报告均已提交本次会议。

77. 工发组织认为，甲基溴生产核查不同于中国和印度的四氯化碳核查，原因是印度和中国四氯化碳行业计划均包括四氯化碳生产和消费，而中国甲基溴行业计划则仅限于甲基溴生产，不包括消费。尽管如此，不存在核查甲基溴消费的要求，这也是实际情况。

78. 工发组织认为，实施最终用户核查费用会很高，原因是根据工发组织的数据，中国有 180 项检疫和装运前消毒处理用途和 90 家甲基溴原料用户。尽管如此，世界银行开创的四氯化碳核查的先例，不能证明需要对这两种用途进行核查。秘书处建议，工发组织可选择若干大的甲基溴原料用户，这些用户在甲基溴原料消费量中占了很大的比例，同时选择若干小的用户，因而能够对该国总的消费情况有个很好的了解。事实上，环保部已在对甲基溴原料用户进行调查/审计，至年底即将完成，能够成为第一次甲基溴最终用户核查。

79. 关于 2008－2010 年行业计划的拟议的第二阶段，为 2008 年建议的目标与《协定》中的目标相符，因此，可以预测将相应地制订 2009－2010 年的目标。参与制订行业计划的各机构实力雄厚，对于成功的执行关系重大。

80. 环保部拟订了继续加强对中国甲基溴生产、进出口、销售和消费进行管制的计划。秘书处确信，环保部将考虑核查组的建议，并进一步加强对三家甲基溴生产厂的甲基溴生产和销售的管理。

建议

81. 由于有多边基金核查具有双重用途的消耗臭氧层物质生产的先例，秘书处并不认为工发组织进行的对于甲基溴生产的核查业已完成，原因是核查并未确定原料和检疫和装运前消毒处理用途的甲基溴生产数量。因此，秘书处无法建议在本次会议期间发放供资的下一次付款。秘书处建议对现有核查提供补充，在取样的基础上审查一组合理数量的甲基溴原料用途用户或受控用途用户，以便如同上文段落所述，对不同用途的甲基溴生产作出确认。工发组织应向第五十六次会议重新提交经修订的核查报告。

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

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

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

Annex II

CHINA PROCESS AGENT SECTOR PLAN

PHASE II

2007 CTC Consumption Verification Report

The World Bank

10 May 2008

CHINA PROCESS AGENT SECTOR PLAN

PHASE II

2007 CTC Consumption Verification Report

The World Bank

May 10, 2008

I SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PROJECT COVER SHEET – MULTI-YEAR PROJECTS

COUNTRY: China, People's Republic

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

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

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

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

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

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

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

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

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

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

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

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

EXECUTIVE SUMMARY

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

Contents

Chapter I Introduction

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

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

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

Chapter II Sector Baseline

A Development of MDI in China

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

Table 1. Basic information on production licences and producers

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

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

B Asthma and COPD in China

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

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

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

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

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

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

C Treatment of Asthma and COPD in China

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

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

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

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

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

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

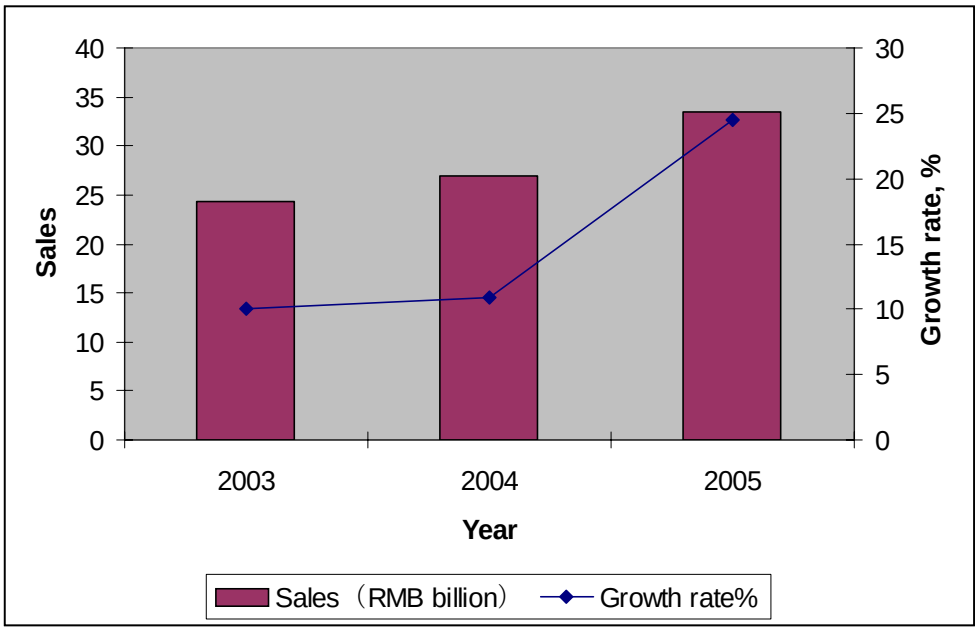

Fig. 1: The Sales of MDI Products in China

D Production process of MDIs

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

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

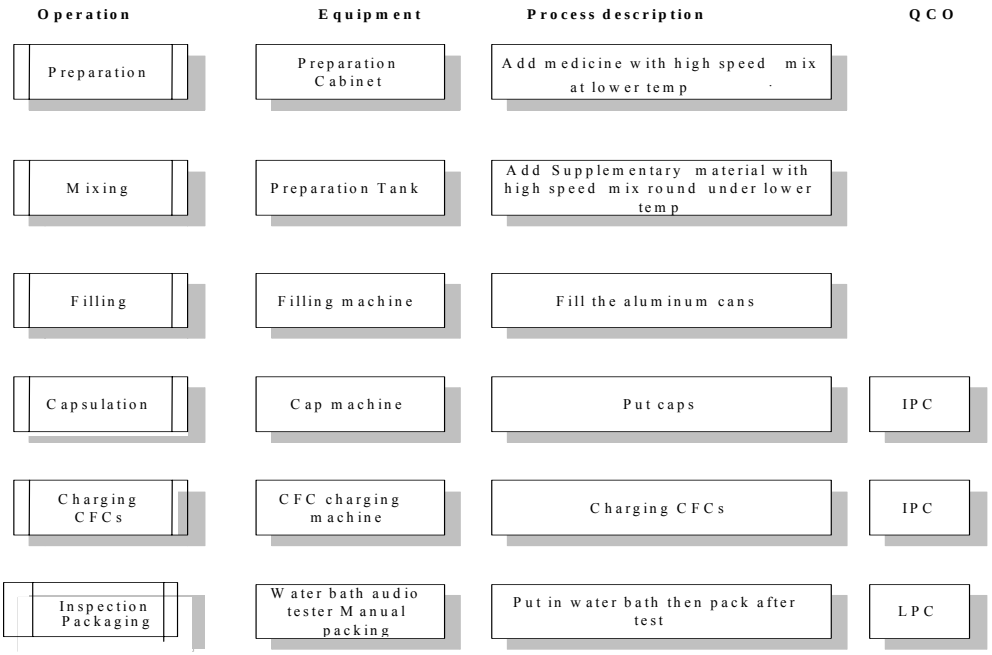

Fig. 2: The production process for Salbutamol Aerosol (suspension)

E Data Survey

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

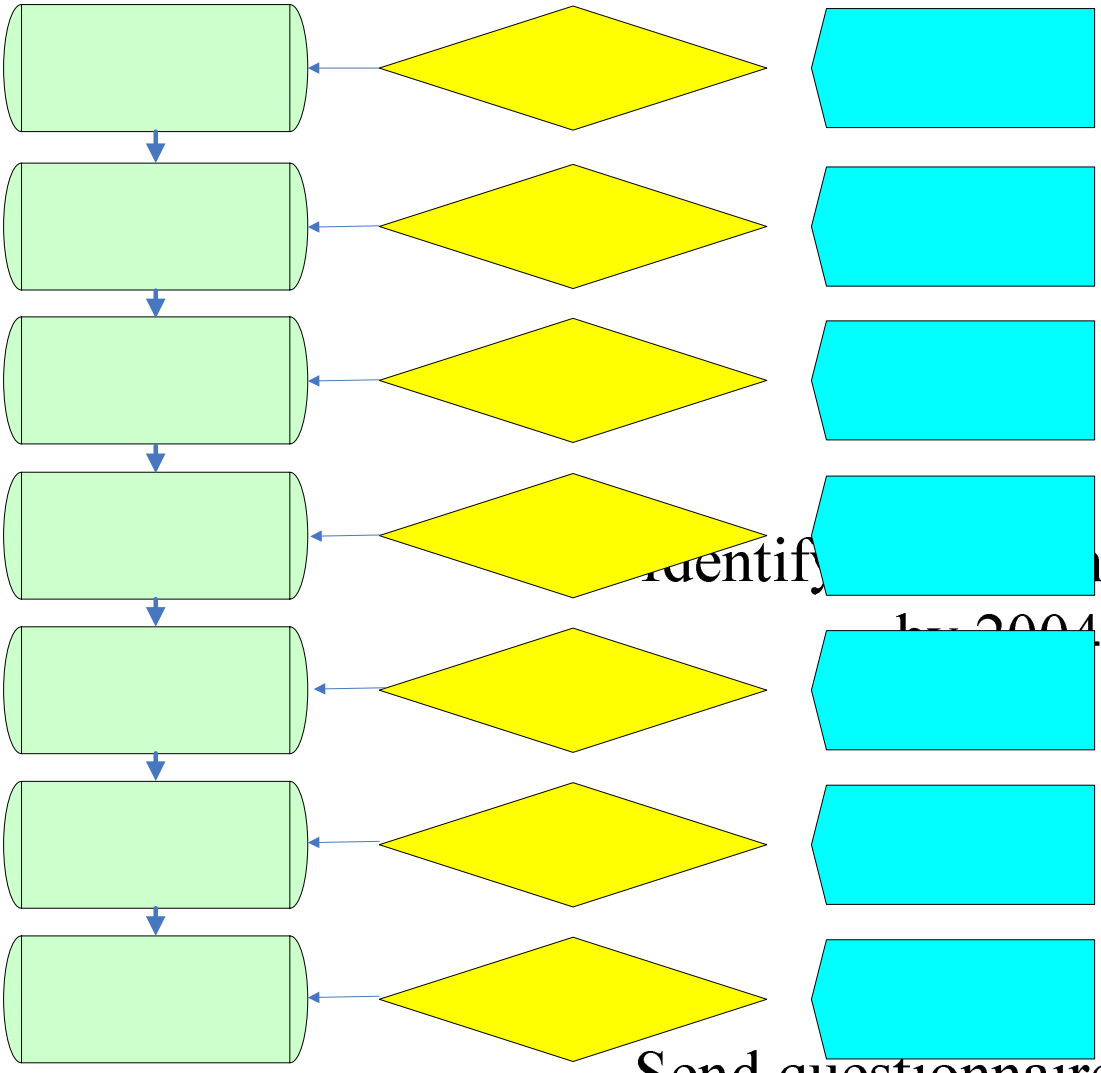

Fig. 3: Data survey process

28) The actual chronology of events was as follows:

a) SFDA and NICPBP identified all MDI producers;

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

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

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

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

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

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

Workshop for initially survey in 2004 and 2006

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d) The flow chart of verification is shown below:

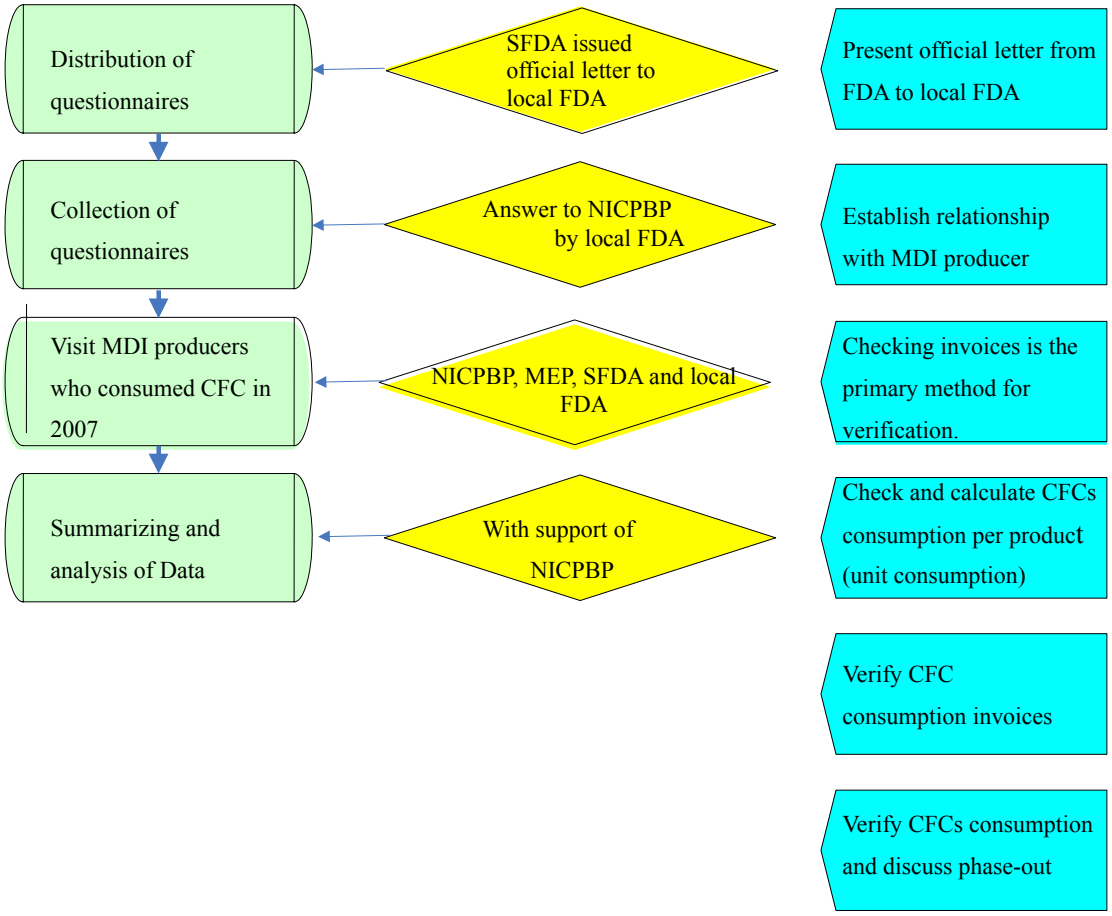

Fig. 4: Flow Chart of Verification

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

F Enterprise information, CFC Consumption in the MDI Sector

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

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

Table 3. Products and CFC Consumption by enterprises

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

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

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

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

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

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

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

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

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

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

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

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

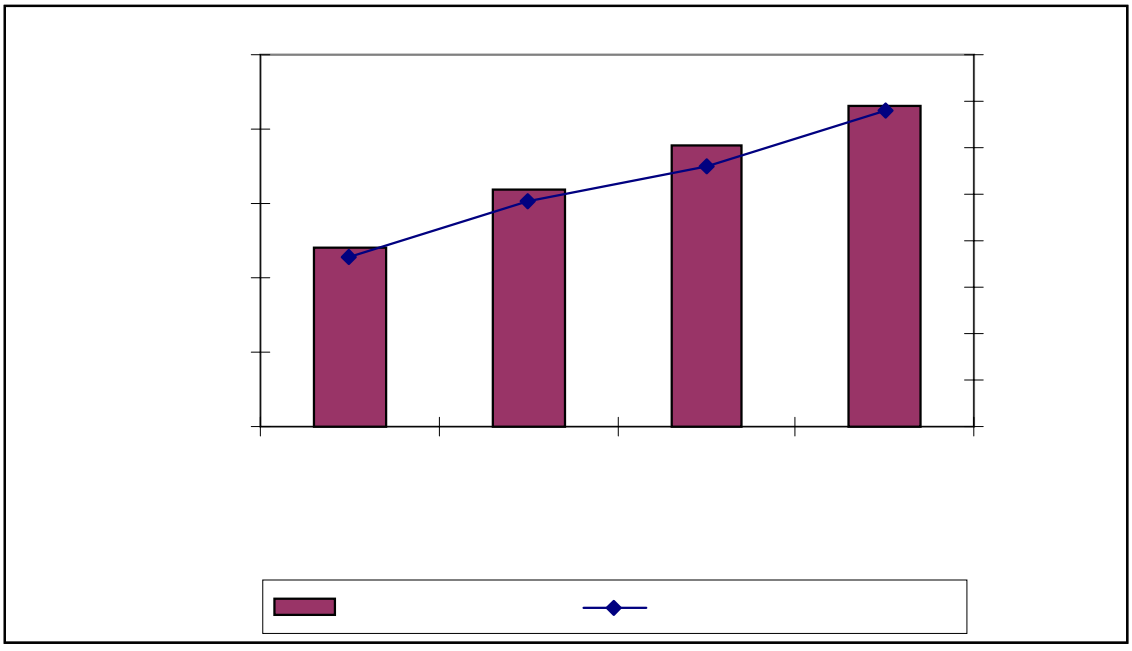

Fig. 5: CFC Consumption and MDI production during 2004 - 2007

Table 6. General Information of the MDI Manufacturing Enterprises

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

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

Note:

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

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

Table 7. Summary of information of enterprises for 2007

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

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

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

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

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

A Regulatory framework for Drug, especially for MDI

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

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

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

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

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

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

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

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

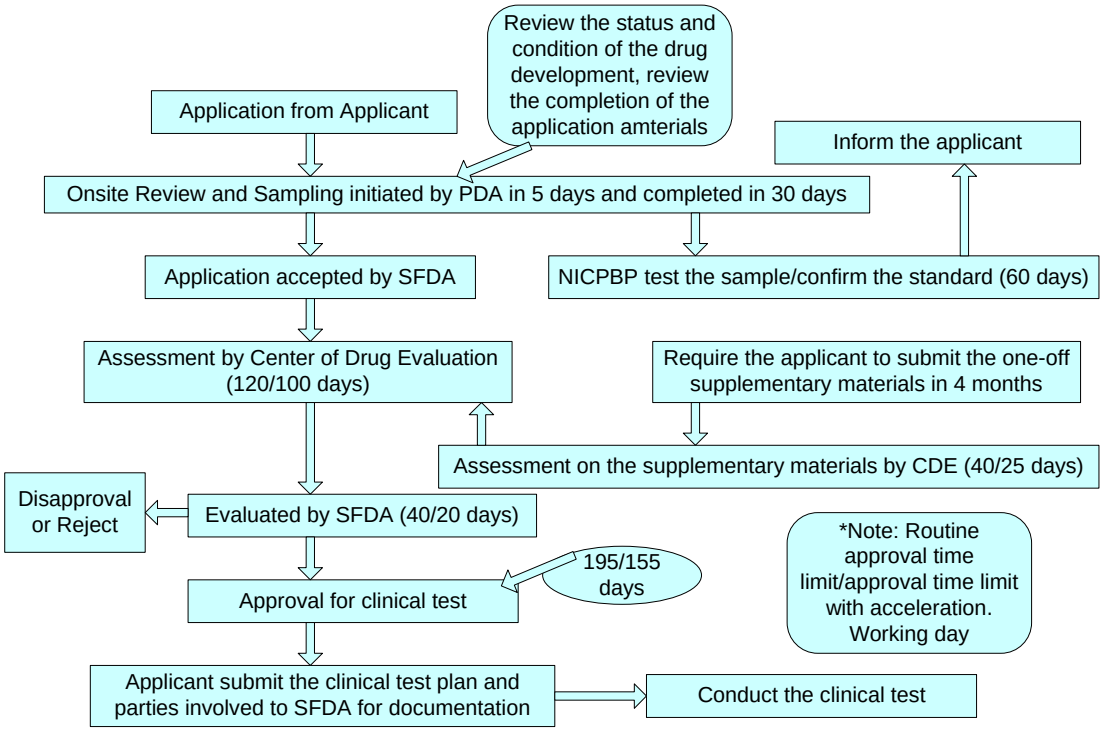

Fig. 6: Approval Procedure for Clinical Test of the New Drug

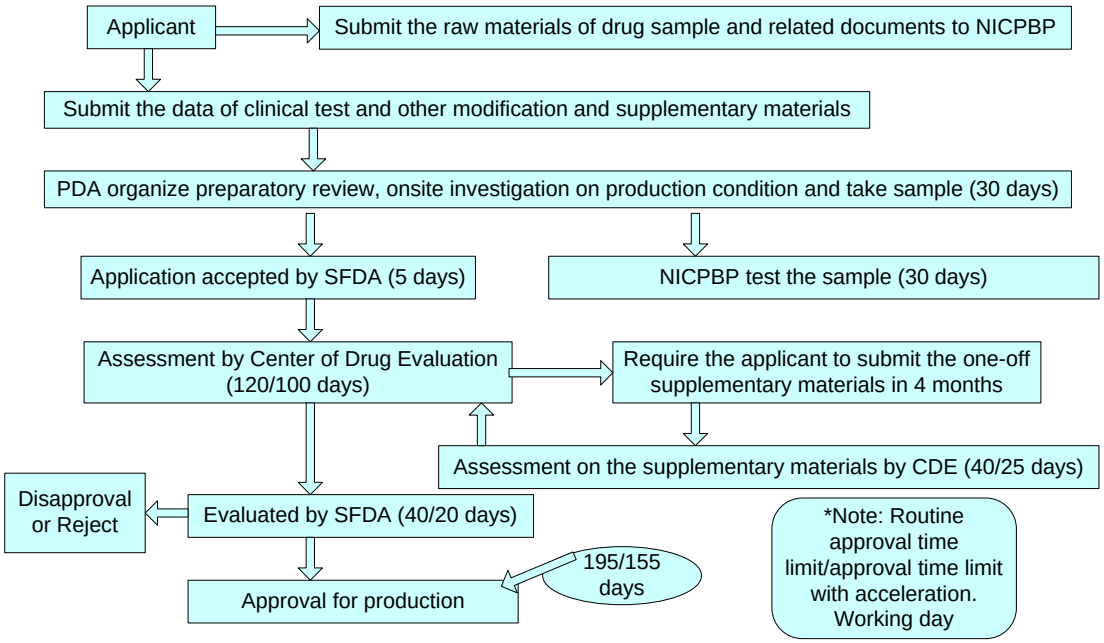

Fig. 7: Approval Procedure for the Production of New Drug

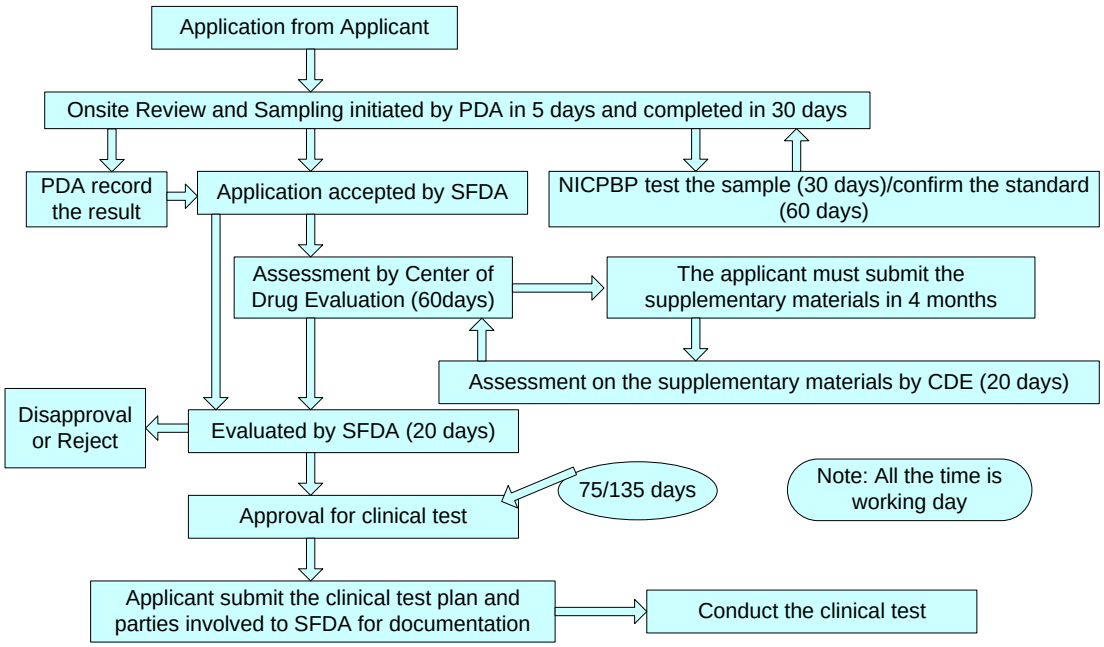

Fig. 8: Approval Procedure for Clinical Test for Change to Existing Drug

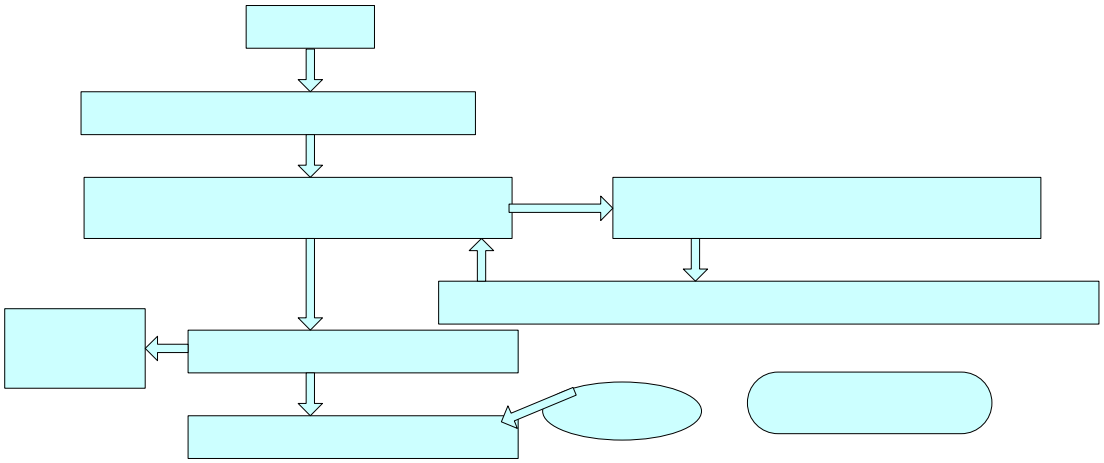

Fig. 9: Approval Procedure for Production for Change to Existing Drug

B Policies Related to CFC Phase out

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

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

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

Chapter IV Technical Options

A Potential Ways to Phase out CFCs in the MDI Sector

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

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

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

Table 8. Comparison of Different Types of Asthma Treatment Drugs

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

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

B DPI Production

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

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

C Alternative excipient - Hydrofluoroalkanes (HFA)

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

Table 9. Comparison of Properties between Fluoroalkanes and CFCs

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

Table 10. Advantages and Disadvantages of using HFA for MDIs

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

D Alternative Technologies

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

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

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

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

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

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

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

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

E Policy and Patent Issues

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

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

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

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

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

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

b. co-solvent and surfactant as well.

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

Table 11. MDI related patents in China

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

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

Chapter V Phase-out Strategy and Policy Framework

A Objectives

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

B CFC Consumption Phase-out Schedule

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

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

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

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

** Except the essential use agreed by the parties.

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

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

C Transitional Arrangement and Need for Essential Use Exemption

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

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

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

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

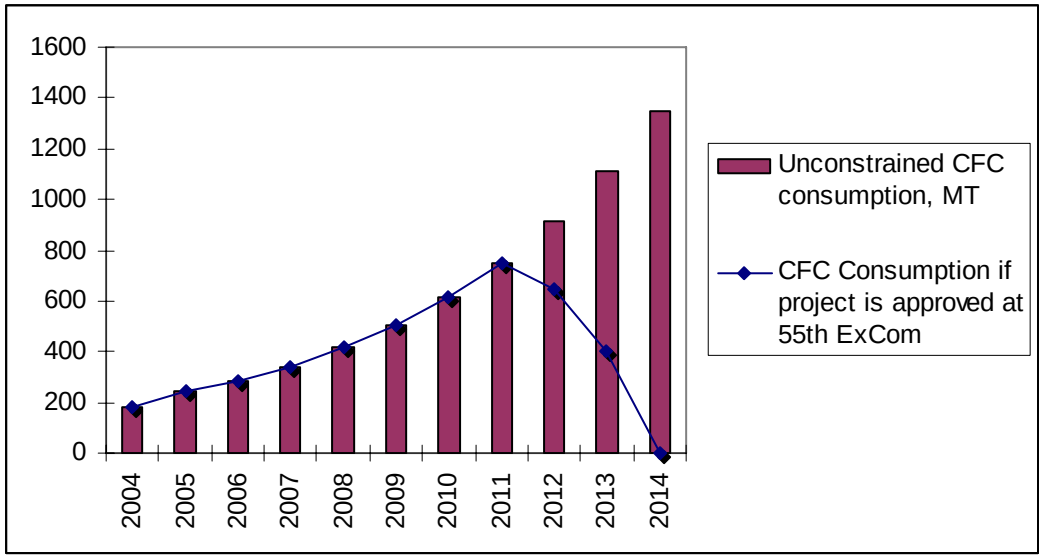

Fig. 10: Unconstrained growth and proposed CFC phase out schedule in China's MDI sector

D CFC production during 2008-2013

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

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

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

Table 14. Planned CFC demand and related production in China

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

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

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

E Policies and Measures

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

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

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

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

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

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

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

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

Chapter VI Incremental Cost Calculation

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

A Incremental Costs Identified

Incremental Cost at Enterprise Level

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

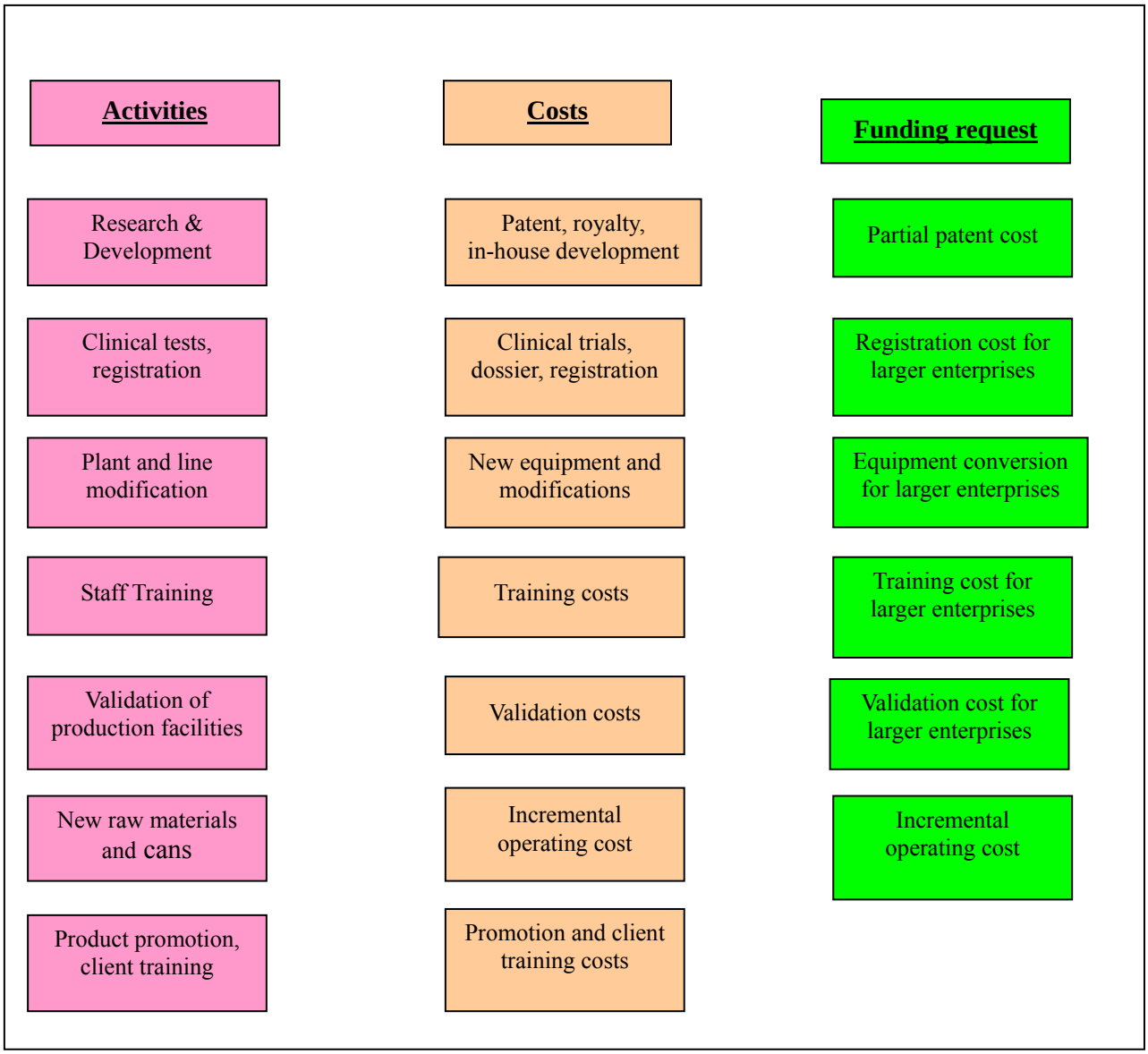

Fig. 11: The relationship between conversion activities at enterprise level to the incremental cost items requested from MLF

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

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

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

Incremental Cost for Technical Assistance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C Basic Assumptions for the Incremental Cost Calculation

Eligibility Criteria for Incremental Cost Calculation

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

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

i) in 1995 no alternative technology was available;

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

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

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

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

Key Assumptions for Incremental Operating Cost Calculation

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

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

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

D Incremental Investment Cost for Conversion of MDI manufacturers

Preparation of Technical Dossier Required for non-CFC MDI Registration

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 18. Cost of Preparation of Technical Dossier for Registration

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

Patent Cost

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

Cost of Modification of Existing Production Facilities

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

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

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

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

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

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

Table 19. Cost of Modification of Existing Facilities

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

Validation Process

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

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

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

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

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

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

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

(1) Validation for Changing Excipient (Alternative Propellant)

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

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

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

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

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

(3) Validation of Production Equipment

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

(4) Validation of Production Process

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

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

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

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

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

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

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

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

(5) Validation for Personnel and Other Relevant Items

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

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

(6) Validation for Change in Dosage Form

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

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

Table 20. Cost of Production Validation

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

(7) Staff Training

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

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

Table 21. Cost for Staff Training

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

E Incremental Operating Cost

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

Table 22. Price difference for HFA products and CFC products

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

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

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

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

Table 23. Enterprise level IOC Calculation

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

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

F Contingency of incremental capital cost

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

G Technical Assistance (TA)

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

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

H Summary

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

Table 24. Summary of incremental costs

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

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

Chapter VII Operating Mechanism

A Agreement between MEP and UNIDO

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

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

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

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

B Roles and Responsibilities

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

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

I. UNIDO

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

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

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

II. MEP

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

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

II. SFDA

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

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

k) Ensure adequate clinical supply of MDI products.

IV. SWG

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

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

V. DIA

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

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

C Auditing and Reporting

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

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

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

D Destruction of CFC Equipment and Certification

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

Chapter VIII Action Plan

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

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

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

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

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

Appendix 1

Chinese Producers and Varieties of MDI Products

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

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03	Beijing Shengdelaibao Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H11020197	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B19	Isopropyl Scopolamine Bromide Aerosol	H11022168	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B23	Ipratropium Aerosol	H11021801	
04	Beijing Double-Crane Modern Medicinal Technology Co., Ltd.	B23	Ipratropium Aerosol	H11021802	
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250ug/200 sprays)	H20056231	
05	GlaxoSmithKline (Tianjin) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (50ug/200 sprays)	H20056259	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H44023113	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H44023121	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B20	Clenbuterol Hydrochloride Aerosol	H44025373	
07	Guangzhou Baiyunshan Hejigong Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H44023123	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H44024063	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H44020217	
08	Guangzhou Dongkang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H44020226	

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09	Guiyang Dechangxiang Pharmaceutical Co., Ltd.	B24	Zhichuanling Aerosol	Z52020225	yes
10	Harbin Guangji Pharmaceutical Factory	B15	Salbutamol Aerosol (liquid)	H23020561	
10	Harbin Guangji Pharmaceutical Factory	B16	Salbutamol Aerosol (suspension)	H23020684	
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H23023413	
11	Harbin Hengcang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020333	
12	Harbin Huili Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	H19980105	
13	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H33021444	
14	Henan Xinxin Pharmaceutical (Group) Co., Ltd.	B11	Physochlaina infundibulris Kuang Aerosol	z41022146	yes
15	Henan Zhongfu Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H41021424	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H23020369	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020370	
16	Heilongjiang Tianlong Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H23020371	
17	Jilin Xiuzheng Pharmaceutical (Group) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H22023411	
18	Jinan Weiming Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H37020653	
18	Jinan Weiming Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (28mg,0.2%(g/g)	H37020653	

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18	Jinan Weiming Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37020655	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	H37023690	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H20003867	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37020545	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37020544	
19	Penglai Nuokang Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37020549	
20	Qiqihar Pharmaceutical Factory	B15	Salbutamol Aerosol	H23022108	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250μg/100 sprays)	H20059866	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol (250μg/200 sprays)	H20059867	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37022928	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B14	Sodium Cromoglicate Aerosol	H37022929	

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21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H19983227	
21	Jewim Pharmaceutical (Shandong) Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H37022817	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37022314	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B18	Isosorbide Dinitrate Aerosol	H37022845	
22	Shandong Linuo Kefeng Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37023560	
23	Shandong Lukang Cisen Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37021846	
23	Shandong Lukang Cisen Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H37022070	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B04	Budesonide Aerosol	H20030987	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B17	Salmeterol Xinafoate Aerosol	H20052614	
24	Shandong Lunan Beite Pharmaceutical Co., Ltd.	B25	Salbutamol Sulfate Aerosol	H20060409	
25	Pharmaceutical Factory Shanxi Medical University	B01	Beclomethasone Dipropionate Aerosol	H14020317	
25	Pharmaceutical Factory Shanxi Medical University	B16	Salbutamol Aerosol (suspension)	H14020757	
25	Pharmaceutical Factory Shanxi Medical University	B18	Isosorbide Dinitrate Aerosol	H14023848	
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B08	Compound Ipratropium Aerosol (5ml)	H20046117	

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26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B08	Compound Ipratropium Aerosol (10ml)	H20046118	
26	Shanghai Boehringer-Ingelheim Pharmaceutical Co., Ltd.	B23	Ipratropium Aerosol (Atrovent Aerosol, 10ml)	H20033863	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B02	Beclomethasone Dipropionate Aerosol (suspension)	H31021090	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H31021094	
27	Shanghai Fuxing Zhaohui Pharmaceutical Co., Ltd.	B16	Salbutamol Aerosol (suspension)	H31020802	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B01	Beclomethasone Dipropionate Aerosol	H31020770	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B04	Budesonide Aerosol	H20010552	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B07	Compound Isoprenaline Hydrochloride Aerosol (suspension)	H31022807	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B09	Ketotifun Fumarate Aerosol	H31022604	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B10	Carbochromen Aerosol	H31022283	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B12	Ribavirin Aerosol	H10970349	

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28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B14	Sodium Cromoglicate Aerosol	H31020681	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B15	Salbutamol Aerosol (liquid)	H31020606	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B16	Salbutamol Aerosol (suspension)	H31020560	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B17	Salmeterol Xinafoate Aerosol	H20010548	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B20	Clenbuterol Hydrochloride Aerosol	H31022809	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B21	Bromhexine Hydrochloride Aerosol	H31022607	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B22	Isoprenaline Hydrochloride Aerosol	H31021141	
28	Sine Pharma Laboratory of Shanghai Pharmaceutical (Group) Co., Ltd	B22	Isoprenaline Hydrochloride Aerosol	H31022858	
29	Tianjin Century Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol	H12020083	
29	Tianjin Century Pharmaceutical Co., Ltd.	B22	Isoprenaline Hydrochloride Aerosol	H12020084	
30	Tonghua Baishan Pharmaceutical Co., Ltd.	B06	Compound Danshen Aerosol	Z10950049	yes
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B01	Beclomethasone Dipropionate Aerosol	H37022152	
31	Weifang Zhongshi Pharmaceutical Co., Ltd.	B15	Salbutamol Aerosol (liquid)	H37023628	

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