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

PROJECT PROPOSAL: MEXICO

This document consists of the comments and recommendation of the Fund Secretariat on the following project proposal:

Aerosol

• Phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs) in Mexico	UNIDO

PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT
MEXICO

PROJECT TITLE(S)	BILATERAL/IMPLEMENTING AGENCY
Phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs) in Mexico	UNIDO

NATIONAL CO-ORDINATING AGENCY	SEMARNAT

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

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

CFCs	(441.3)		

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

ODS	Subsector/quantity	Subsector/quantity	Subsector/quantity	Subsector/quantity
CFCs	MDI/75.5			
	Ref. Servicing/352.2			

CFC consumption remaining eligible for funding (ODP tonnes)	

CURRENT YEAR BUSINESS PLAN ALLOCATIONS	Funding US $ million	Phase-out ODP tonnes
	537,500	13.3

PROJECT TITLE:	
ODS use at enterprise (ODP tonnes):	70.9
ODS to be phased out (ODP tonnes):	97.0 (*)
ODS to be phased in (ODP tonnes):	n/a
Project duration (months):	26
Initial amount requested (US $):	3,826,264 (**)
Final project costs (US $):	
Incremental Capital Cost:	884,243
Contingency (10 %):	88,424
Incremental Operating Cost:	133,785
Transition Strategy	40,000
Total Project Cost:	2,716,453 (**)
Local ownership (%):	100% (***)
Export component (%):	<1%
Requested grant (US $):	2,716,453 (**)
Cost-effectiveness (US $/kg):	38.31(***)
Implementing agency support cost (US $):	203,734
Total cost of project to Multilateral Fund (US $):	2,920,187
Status of counterpart funding (Y/N):	Y
Project monitoring milestones included (Y/N):	Y

* Including 26.1 ODP tonnes by a multi-national corporation.

** Excluding deduction as per decision 52/30.

*** Based on the MDI manufacturing plant covered by the project.

SECRETARIAT'S RECOMMENDATION	For individual consideration

PROJECT DESCRIPTION

1. On behalf of the Government of Mexico, UNIDO has submitted the national strategy for the phase-out of CFC propellants in metered-dose inhalers (MDIs) in Mexico together with an investment project proposal for the phase-out of 97.0 ODP tonnes of CFCs used in the manufacture of MDIs for consideration by the Executive Committee at its 53rd Meeting. The total funding requested in the original submission for the national strategy is US $129,000 and for the investment project is US $3,697,264, plus total support costs of US $286,970 for UNIDO. The adjustment to the project to avoid double counting for CFC consumption that had already been covered under the national phase-out plan for Mexico has been estimated at US $26,300.

Background

2. At its 52nd Meeting, the Executive Committee considered a request submitted by UNIDO for the preparation of an MDI phase-out project in Mexico at the amount of US $50,000. The request was submitted with the supporting data required under decision 51/34(c), according to which such requests were to be considered by the Executive Committee on a case-by-case basis. Following a discussion, the project preparation request was approved, with a series of conditions (decision 52/30).

Sector background

3. CFC-MDIs have been produced in Mexico by Laboratorios Salus since 1999, containing the following three active ingredients: salbutamol, beclomethasone dipropionate, and sodium cromoglicate. Production of salbutamol and beclomethasone MDIs represents 99 per cent of the enterprise's total MDI production. About 70 per cent of MDIs produced by this company are for the Mexican Social Health system and other government medical health services. The remaining 30 per cent production is for the local market. The production levels of these MDIs are shown in the table below:

Active ingredient	2004		2005		2006	
	MDIs	CFC (tonnes)	MDIs	CFC (tonnes)	MDIs	CFC (tonnes)
Salbutamol	1,746,347	40.35	2,136,750	37.34	2,902,704	58.60
Beclomethasone	655,005	15.13	542,527	9.48	575,246	11.61
Cromoglicate	73,909	1.71	38,736	0.68	34,664	0.70
Total	2,475,261	57.19	2,718,013	47.50	3,512,614	70.91

4. Ipatropium bromide CFC-MDIs are also produced in Mexico by one transnational corporation. In 2006, about 26 tonnes of CFCs were used by this company. In June of 2004, this company introduced tiotropium bromide dry powder inhaler (DPI) to provide significant and sustained improvements in lung function for patients with chronic obstructive pulmonary disease (COPD).

5. Non-CFC-MDIs are also being imported into Mexico by three multinational companies with the following active ingredients: sodium cromoglicate, budesonide, beclomethasone dipropionate, fluticasone, salbutamol sulphate, combined salbutamol/beclomethasone and salmeterol xinafoate. In 2006, over 2.4 million non-CFC MDIs were imported by these companies.

National strategy for the phase-out of CFC-based MDIs

6. The Government of Mexico has prepared a national strategy for the phase-out of CFC-based MDIs that takes into account sufficient time and resources for the education of health professionals, patients and their families in the replacement of CFC-MDIs. The strategy was developed in coordination and with the participation of major stakeholders.

7. The national strategy will, among other things, ensure that the health and safety of patients is safeguarded during the transition, and that importers and manufacturers fulfil their obligation to withdraw CFC-MDIs from the market in a timely manner. It will also develop an educational training package to facilitate communication with patients. The estimated cost of the transition strategy is US $129,000, with the following breakdown:

Activity	Cost (US $)
Legal/medical advisors	11,000
Education and communication activities	82,000
Project technical support	36,000
Total	**129,000**

8. The Government of Mexico is proposing to launch a first batch of non-CFC-based MDIs 26 months after the MDI phase-out investment project has been approved by the Executive Committee.

Project description

9. The company has a single production line with a capacity of 57,000 units per day, or around 6.9 million units annually. The current actual demand is for the production of 25,000 units per day in a single shift operation. The CFC-MDI formulation technology was based on the enterprise's own research work. The aerosol filling technology was obtained from Pamasol, an aerosol filling equipment supplier.

10. MDI production at Laboratorios Salus is based on the pressure filling manufacturing process using a Pamasol Macromat machine with an estimated maximum output of 45 canisters per minute. The company has decided to convert three of their CFC-based MDIs to HFC-134a technology, requiring the installation of two Macromat machines that will be capable of both single- and two-stage filling. The total capital cost associated with the installation of the two production lines has been estimated at US $1,452,061. The transition from CFC-MDIs to HFA-MDIs will be implemented in two phases. In phase I, salbutamol MDIs will be converted to HFA technology with the phase-out of over 80 per cent of the current consumption of CFCs. Phase II will address beclomethasone and cromoglicate MDIs so achieving the complete phase-out of CFCs.

11. The proposed modifications for the new HFC-134a-based MDIs, by active ingredient, are shown in the table below, with associated technology transfer costs. For HFA-cromoglicate MDIs, Laboratorios Salus is proposing to develop the product in-house, with the assistance of an international expert. An additional US $50,000 is being requested for stability tests and travelling.

Active ingredient	Proposed modifications	Technology transfer cost (US $)
Salbutamol	Pressure filled, HFA/ethanol formulation with surfactant. Double-stage filling	715,000
Beclomethasone	Pressure filled, HFA/ethanol formulation as a solution in two presentations. Double-stage filling	1,085,000
Cromoglicate	Pressure filled, HFA formulation. Single-stage filling	81,750
Total cost		**1,881,750**

12. Incremental operating costs, calculated on the basis of the difference in prices between CFCs and HFC-134a, and the increased costs of the canister, metering valve and actuator, have been estimated at US $191,453 for a one-year period.

Total cost of the project

13. The total cost of the phase-out of CFCs used in the manufacture of MDIs in Mexico has been estimated at US $3,826,264, with a cost-effectiveness of US $52.15/kg (calculated on the basis of the 70.9 ODP tonnes of CFCs consumed by Laboratorios Salus and excluding the 26.1 ODP tonnes consumed by a transnational corporation). The project cost breakdown is presented below:

MDI transition strategy	US $129,000
Capital costs	US $1,574,061
Technology transfer	US $1,931,750
Operating costs	US $191,453

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

14. The Secretariat reviewed the national strategy for the phase-out of CFCs in MDIs in Mexico and the investment phase-out project in light of:

(a) The policy papers on MDIs considered by the Executive Committee at its 37th, 49th and 51st meetings;

(b) The MDI phase-out projects so far approved for Cuba at its 41st and 46th meetings, Egypt at its 50th meeting, Iran at its 52nd meeting and Uruguay at its 43rd meeting, and;

(c) The national phase-out plan (NPP) for Mexico approved by the Executive Committee at its 42nd Meeting at a cost of US $8,794,500 plus agency support costs of US $659,588 for UNIDO. The NPP also included an Agreement between the Government of Mexico and the Executive Committee.

Essential use exemptions for CFCs

15. The Secretariat pointed out that in its decision 51/34, the Executive Committee requested, *inter alia*, that countries with MDI manufacturing plants should be advised of the timing on which to begin considering the need for essential use exemptions beyond the 2010 phase-out date, and that the preparation of a nomination for essential use exemptions might begin in 2007 for submission to the Parties for their consideration in 2008. According to the project proposal, it is estimated that the conversion will be completed by February 2011, more than a year after the mandatory date for the complete phase-out of CFCs. However, the need for essential use exemptions for CFCs, or for stockpiling pharmaceutical aerosol-grade CFCs for a short period of time (i.e., one to two years) has not been considered either in the project proposal or the strategy. UNIDO reported that the Government of Mexico is intending to stockpile pharmaceutical aerosol-grade CFCs, which are already available in the country, to be used by Laboratorios Salus during the conversion process to HFA technology. The Government of Mexico would consider in 2008 whether or not to request an essential use exemption for CFC-MDIs after 2010 and would inform the Parties to the Montreal Protocol accordingly.

Selection of alternative technology

16. The implementation of DPI technology was not considered to be a feasible alternative to CFC-MDI production in Mexico as it would necessitate a suitable DPI device, new production manufacturing and packaging lines, and result in a significant increase in operating costs. Noting, however, that several DPIs are currently available on the market in Mexico, the Secretariat sought further clarification on this issue. UNIDO indicated that the question of DPIs as an alternative technology had been discussed with Laboratorios Salus and rejected as a viable replacement for CFC-MDIs for the following reasons:

(a) The development of a new DPI for a single active ingredient, including design, prototyping, manufacture of sample mould tooling, testing and optimization, formulation development, and equipping a new production line would cost about US $8 million and take four to five years to implement. Based on the DPIs currently available, the incremental operating costs of a new DPI would be around US $4.00/unit, or US $16 million for an annual production of 4 million DPIs;

(b) For comparison purposes, the cost of a DPI in Mexico is about US $27 while the cost of a HFA-MDI with the same active ingredient is US $16;

(c) Furthermore, DPIs do not represent a satisfactory therapeutic alternative to the pressurised MDI for all patients or for all active ingredients. For example, children five years old and under, patients with severe asthma, and elderly COPD patients may not always be able to achieve adequate breathing flow to ensure optimal medication delivery from DPIs.

Adjustment from the funding approved for the NPP for Mexico

17. In addressing decision 52/30 (b), UNIDO deducted US $26,300 from the total project cost, calculated on the basis of a CFC consumption of 5 ODP tonnes and at US $5.26/kg. However, on the calculation of this adjustment, the Secretariat notes, as follows:

(a) In accordance with the strategic planning of the Multilateral Fund (decision 35/57), the Government selected Option 1 as the starting point for determining the sustained reduction in CFC consumption in Mexico. Accordingly, the NPP for Mexico was approved for the phase-out of 1,669 ODP tonnes, representing the total remaining CFC consumption eligible for funding. The NPP indicated that about 5.0 ODP tonnes of CFCs were used in the manufacturing of MDIs; and that this consumption was to remain until 2009 and would be phased out in 2010 within the funding requested for the NPP;

(b) In 2004, at the time the Executive Committee approved the NPP for Mexico, the CFC consumption for production of MDIs by Laboratorios Salus was 57.2 ODP tonnes;

(c) The cost of the NPP for Mexico (as well as for the majority of the NPPs for non-LVC countries) was calculated using a cost-effectiveness value of US $5.00/kg of CFCs used in the refrigeration servicing sector, plus the cost-effectiveness threshold applied to each manufacturing sector where CFCs were still used, plus additional funding for monitoring and reporting.

18. Therefore, the adjustment to the NPP for Mexico would be US $285,950, calculated on the basis of the 2004 CFC consumption of 57.2 ODP tonnes by Laboratorios Salus, and a cost-effectiveness value of US $5.00/kg. Accordingly, incremental operating costs were recalculated on the basis of 2004 consumption, resulting in a value of US $133,785.

Scope and cost of the transition strategy

19. Several HFC-134a-based MDIs and DPIs have already been introduced and are currently being used in Mexico, the locally-owned MDI manufacturing enterprise has already selected the HFC-134a technology and a detailed project proposal has been fully developed and submitted for approval by the Executive Committee. On this basis, the cost of the national strategy was agreed at US $40,000, which will allow for the implementation of the main activities proposed.

Technical and cost issues related to the production facility

20. Laboratorios Salus currently has a production line with a capacity of 45 cans/minute, purchased in 1994. According to the project proposal, the existing equipment cannot be retrofitted. The Secretariat noted that conversion of salbutamol and beclomethasone MDIs to HFA technology could be achieved using the same two-stage filling process currently available at the enterprise. However, production of cromoglicate HFA-MDI (representing only one per cent of total MDI production) would require a more complex process which is not currently available. Therefore, a new production line with two filling machines installed in a double configuration is being proposed. In order to compensate for a technology upgrade and capacity increase, UNIDO agreed to establish one production line capable of both single- and two-stage filling, allowing both types of formulations to be used. The revised cost of the production line is US $972,668. Laboratorios Salus will purchase additional filling equipment if it wishes to increase its production output to meet the level of actual capacity.

Counterpart contribution

21. In addressing the request by the Executive Committee (decision 52/30 (a)) on commitments for significant counterpart funding from the beneficiary enterprise, a letter indicating the level of contribution from Laboratorios Salus was attached to the project proposal. The total contribution by Laboratorios Salus is US $1,250,000 with the following breakdown: 10 per cent of the pilot production of salbutamol, beclomethasone and cromoglicate HFA MDIs (US $90,000); in-house reformulation and product development for cromoglicate MDIs (US $150,000); laboratory equipment for trials and testing, including cascade impactor, spray checking machine and laser particle counter (US $350,000); analytical tests and validation for the new production area (US $120,000); technical engineering support, including training of staff, preparation of dossiers, partial contribution to the transition strategy and project management (US $130,000); building modifications, including propellant facilities (US $110,000); and clinical tests (US $300,000). The Secretariat has not assessed the accuracy of the estimated costs proposed by the enterprise.

Agreed level of funding

22. The Secretariat and UNIDO concluded their discussions on cost-related issues, and agreed on the following level of funding for the project for the phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs) in Mexico:

Capital cost (including contingency)	US $972,668
Technology transfer costs	US $1,570,000
Operating costs (one year)	US $133,785
Total cost	US $2,676,453
MDI transition strategy	US $40,000
Adjustment required under decision 52/30 (b)	(US $285,950)

23. UNIDO informed the Secretariat that the Government of Mexico has decided to distribute the US$ 285,950 as the adjustment required under decision 52/30 (b) as follows: US $85,950 from the MDI project and US $200,000 for the NPP for Mexico. The Secretariat notes that as the total funding available under the NPP has already been allocated to UNIDO by the Executive Committee, US $200,000 would have to be returned to the Multilateral Fund.

RECOMMENDATION

24. The Executive Committee might wish to consider:

(a) Approving the national transition strategy for the phase-out of CFC MDIs and the project for the phase-out of CFC consumption in the manufacture of aerosol MDIs in Mexico at the amount of US $2,630,503 plus agency support costs of US $197,288 for UNIDO, having taken into account a deduction of US $85,950 of the total US $285,950 to eliminate double-counting of funds provided under the national phase-out plan;

(b) Noting that UNIDO will return the remaining US $200,000 plus agency support costs of US $15,000 of the adjustment required under decision 52/30(b) from the

national phase-out plan (NPP) for Mexico to the 54th Meeting, and on the understanding that no further funding would be provided for CFC-MDI conversion in Mexico.

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