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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Forty-fourth Meeting
Prague, 29 November-3 December 2004

PROJECT PROPOSAL: ROMANIA

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

Aerosol

- Phase-out of CFC-12 in the manufacture of pharmaceutical aerosols by conversion to HFC-134a propellant at MEBRA, Brasov

UNIDO

**PROJECT EVALUATION SHEET
ROMANIA**

PROJECT TITLES**BILATERAL/IMPLEMENTING AGENCY**

(a) Phase-out of CFC-12 in the manufacture of pharmaceutical aerosols by conversion to HFC-134a propellant at MEBRA, Brasov	UNIDO
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NATIONAL CO-ORDINATING AGENCY

NOU, Ministry of Environment

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT**A: ARTICLE-7 DATA (ODP tonnes, 2003 as of October 2004)**

CFC	362.1		
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B: COUNTRY PROGRAMME SECTORAL DATA (46.54 ODP TONNES IN 2003)

ODS Name	Sub-sector/quantity	Sub-sector/quantity	Sub-sector/quantity	Sub-sector/quantity.
CFC	46.54			

CFC consumption remaining eligible for funding (ODP tonnes)

99.3

CURRENT YEAR BUSINESS PLAN ALLOCATIONS		Funding US \$	Phase-out ODP tonnes
	(a)	204,776	46.54

PROJECT TITLE:	Mebra
ODS use at enterprise (ODP tonnes):	46.54
ODS to be phased out (ODP tonnes):	46.54
ODS to be phased in (ODP tonnes):	
Project duration (months):	26
Initial amount requested (US \$):	204,776
Final project cost:	
Incremental Capital Cost (US \$)	75,000
Contingency (10%) (US \$)	7,500
Incremental Operating Cost (US \$)	521,646
Total Project Cost (US \$)	604,146
Local ownership (%):	100
Export component (%):	n/a
Requested grant (US \$):	204,776
Cost-effectiveness (US \$/kg):	4.4
Implementing agency support cost (US \$):	18,430
Total cost of project to Multilateral Fund (US \$):	223,206
Status of counterpart funding (Y/N):	Y
Project monitoring milestones included (Y/N):	Y

SECRETARIAT'S RECOMMENDATION

Blanket approval at the costs indicated above

PROJECT DESCRIPTION

1. The Government of Romania has submitted a project proposal for the phase-out of CFC-12 in the manufacture of pharmaceutical aerosols by conversion to HFC-134a propellant at MEBRA, Brasov (terminal aerosol sector project) for consideration by the Executive Committee at its 44th Meeting.
2. Implementation of this project will result in the phase-out of 46.5 ODP tonnes of CFC-12, and the complete phase-out of CFCs in the aerosol sector in the country.
3. In 1999, the use of CFCs in the production of cosmetic aerosols and insecticides was banned in Romania, except for the production of pharmaceutical aerosols. As reported in the country programme update for Romania approved at the 43rd Meeting of the Executive Committee (UNEP/OzL.Pro/ExCom/43/48 and Add.1), in 1998, the only manufacturer of cosmetic aerosols in Romania (Farmec-Cluj, Napoca) was converted to the use of hydrocarbon aerosol propellant (HAP).
4. Production of pharmaceutical aerosols for skin burns treatment commenced in 1980. At that time, the company was owned by a transnational corporation. In 1994, the company was bought by national stakeholders. Current production (based on average production for the last three years) is 587,220 cans of aerosols.
5. The existing aerosol production line comprises one product filler, one single head crimper/gasser and one propellant delivery pump. After product filling, manual valve insertion and a simultaneous crimping/gassing operation, the cans are put into the water test tank (locally made) and then packed.
6. HAPs are the preferred replacement for CFCs. However, HAPs available in Romania contain impurities (sulphur compounds and olefins), which cannot be removed to obtain the high purity grade required in the production of pharmaceutical aerosols. The company explored various sources of supply of imported hydrocarbons produced in neighboring countries. However, these were also either high in impurities or producers could not provide the required documentation for their use in the production of pharmaceutical aerosols. Therefore, the company selected HFC-134a as the replacement propellant.
7. The use of HFC-134a technology will not require substantial changes to the pharmaceutical aerosol filling and propellant storage and handling facilities because of the non-flammable nature of the substance. Therefore, conversion entails the replacement of the existing semi-automatic propellant crimping/gassing unit with a new indexing unit with a gasser and a new crimping unit. Technical assistance will be provided for the performance and supervision of engineering designs, installation of equipment, and commissioning of the plant and training.
8. The total capital cost is US \$86,900 and the incremental operating costs are US \$521,646 (net present value for 4 years). However, the enterprise is requesting US \$204,776, corresponding to the maximum amount allowable under the cost effectiveness threshold value of US \$4.40/kg.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

9. The Secretariat noted that:

- (a) On the basis of Decision 35/57, the remaining CFC consumption eligible for funding in Romania is 145.8 ODP tonnes;
- (b) If the project is approved, the remaining CFC consumption eligible for funding would be 99.3 ODP tonnes (145.8 ODP tonnes minus 46.5 ODP tonnes); and
- (c) 2003 CFC consumption in the refrigeration-servicing sector is about 325 ODP tonnes.

10. Based on the above observations, the Secretariat sought confirmation that UNIDO had explained the concept of remaining eligible consumption to the Government of Romania and that Romania wished to allocate 46.5 ODP tonnes to the aerosol sector. The Government of Romania submitted a letter to the Secretariat confirming the CFC consumption in the aerosol sector to be 46.5 ODP tonnes.

11. According to the technical reviewer of the project, hydrocarbons are a better choice of propellant for the application than HFC-134a because they are better solvents and produce a more compatible suspension system. The reviewer further indicated that the solubility of HFC-134a and the active ingredients in pharmaceutical sprays are critical, and the project's success will depend upon the ability to formulate the pharmaceutical sprays using HFC-134a.

12. In addition to the above-mentioned technical disadvantages, the cost of production of HFC-134a-based pharmaceutical aerosols is much higher, as evidenced in the level of operating costs being requested (about US \$165,000 per year or US \$522,000 for four years). Hence, the long-term sustainability of the project is in doubt. Taking into consideration the outstanding technical and economic issues associated with the use of HFC-134a propellant, the Secretariat suggested that UNIDO explore with the enterprise other potential suppliers of high-quality HAPs (mainly in Europe) before committing to retrofit the aerosol production line to HFC-134a propellant.

13. Subsequently, UNIDO informed the Secretariat that the selection of the technology had been discussed at length with the enterprise's management and all advantages and disadvantages of the use of each substitute propellant were explained in detail. UNIDO provided the enterprise with a list of several European HAP suppliers to be approached. However, the company decided to select HFC-134a technology because, in addition to its inability to find pharmaceutical-grade HAP or the respective documentation needed to certify the new aerosol product based on its use, it had already run tests with the HFC-134a propellant and was quite satisfied with the results obtained.

14. The Secretariat further discussed the issue of the selection of an HFC propellant in Romania in light of the agreement reached by the European Commission to regulate the use of fluorinated gases (HFCs) used in refrigeration, air conditioning, fire-fighting and other industry processes by 2012. Subsequently, UNIDO raised this issue with the management of Mebra (the aerosol manufacturing plant) who indicated that the company was aware of the European Commission regulation on HFCs; however, the company selected HFC-134a as an alternative propellant since there were no other propellants that meet the norms imposed by the National Agency of Medicines (i.e., HFC-134a is the only propellant certified by the Drug Master File for medical aerosols containing antibiotics).

15. The Secretariat and UNIDO discussed technical and cost issues regarding the replacement of the propellant pump, which can be used with either CFC or HFC-134a propellant (and hence is not eligible). Subsequently, UNIDO adjusted the capital costs of the project to US \$82,500, after removing the request for the pump.

16. The revised project cost is US \$604,146. However, the enterprise is requesting US \$204,776, corresponding to the maximum amount allowable under the cost-effectiveness threshold value (US \$4.40/kg). The Executive Committee has already approved aerosol projects based on alternative HFC propellants.

RECOMMENDATION

17. The Fund Secretariat recommends blanket approval of the project with associated support costs at the funding level shown in the table below on the understanding that no additional funds will be requested from the Multilateral Fund for the phase-out of CFCs in the aerosol sector in Romania.

	Project Title	Project Funding (US\$)	Support Cost (US\$)	Implementing Agency
(a)	Phase-out of CFC-12 in the manufacture of pharmaceutical aerosols by conversion to HFC-134a propellant at MEBRA, Brasov	204,776	18,430	UNIDO
