



COVER PAGE

Country: Moldova

UNDAF Outcome(s)/Indicator(s): By 2011, public institutions with support of CSOs are better able to ensure good governance, rule of law and promotion of human rights

Expected Outcome(s)/Indicator (s): Management of environmental and natural resources is improved in compliance with international/EU standards

Expected Output(s)/Annual Targets: A sound MDI transition strategy is developed so that Moldova can meet its obligations under the Montreal Protocol in completely phasing out CFCs

Implementing partner: Ministry of Environment and Natural Resources

Responsible parties: United Nations Development Programme

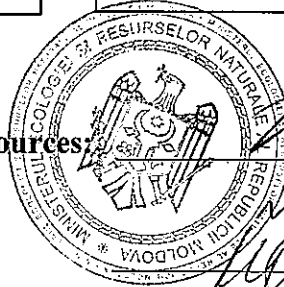
PROJECT SUMMARY

Through this Technical Assistance approved by the Multilateral Fund for the Implementation of the Montreal Protocol, UNDP aims to assist the Government of Moldova to implement a project in MDI sector in order to develop a sound transition strategy.

Programme Period: 2007-2011  
 Programme Component: \_\_\_\_\_  
 Project Title: MOL/ARS/54/TAS/20 "MDI Transition Strategy"  
 Project ID: 00064071  
 Project Duration: 18 months  
 Management Arrangement: NEX

Total Budget \$30,000  
 Allocated resources:  
 • Government N/A  
 • Regular N/A  
 • Other:  
   o Donor: Montreal Protocol, \$30,000  
   o Donor \_\_\_\_\_  
 • In kind contributions \_\_\_\_\_  
 Unfunded budget: \_\_\_\_\_

Agreed by Minister of Ecology and Natural Resources:



19.01.2009

*Violeta Ivanov*  
National Coordinator

Agreed by UNDP:

*[Signature]*

**PROJECT COVER SHEET**

<b>COUNTRY:</b>	MOLDOVA	<b>IMPLEMENTING AGENCY:</b>	UNDP
<b>PROJECT NAME</b>	MDI Transition Strategy		
<b>PROJECT IN CURRENT BUSINESS PLAN</b>	YES		
<b>SECTOR COVERED</b>	MDI		
<b>PROJECT IMPACT</b>	0.0 ODP tons		
<b>PROJECT DURATION</b>	18 months		
<b>TOTAL PROJECT COST</b>	US\$ 30,000		
<b>LOCAL OWNERSHIP</b>	100 %		
<b>EXPORT COMPONENT</b>	N/A		
<b>REQUESTED GRANT</b>	US\$ 30,000		
<b>COST-EFFECTIVENESS</b>	Not Applicable – TAS		
<b>AGENCY SUPPORT COSTS</b>	2,700		
<b>STATUS OF COUNTERPART FUNDING</b>	N/A		
<b>NAT. COORDINATING AGENCY</b>	National Ozone Office under the Ministry of Ecology and Natural Resources		
<b>PROJECT MONITORING MILESTONES INCLUDED</b>	Included in Document		
<b>BENEFICIARY ENTERPRISE</b>	Not Applicable		

***PROJECT SUMMARY***

Through this Technical Assistance approved by the Multilateral Fund for the Implementation of the Montreal Protocol, UNDP aims to assist the Government of Moldova to implement a project in MDI sector in order to develop a sound MDI transition strategy.

## Submission background

While developed as a part of the TPMP project document for Moldova, MDI component was not submitted for the consideration at the 52<sup>nd</sup> meeting of the Executive Committee and in line with the decision 52/42:

*“Secretariat also noted that the information provided for the development of a transition strategy to non-CFC MDIs included in the TPMP project did not fully demonstrate the need for such a strategy. At its 51st Meeting the Executive Committee decided that requests for transition strategies should be fully demonstrated and documented through the submission of detailed information for the previous three years on CFC and non-CFC MDIs and dry-powder inhalers (decision 51/34). The Secretariat was subsequently informed that this project component will not be requested at this time. With the remaining funding available from the preparation of the TPMP project, UNDP will gather additional information on the MDI sub-sector, and submit a request for the preparation of the transition strategy to a future meeting of the Committee if necessary”.*

Therefore, following the Executive Committee decisions 45/54, 51/34 and 52/42, the current project document was specifically developed to provide as much of the required information as possible to demonstrate the need for the MDI transition strategy in Moldova.

The following reasons to have the MDI transition strategy were considered during the compilation of the required information:

- Ensure orderly transition to new products and most importantly ensure that the patients will have available equally effective alternative products at a reasonable cost (compared to CFC MDI products) and on time to guarantee that when the CFC MDI supply stops alternatives are sustainably available, registered and approved by the local regulatory entity. This includes possible contingency plans in case that registration and approval is a long process and there is a risk of a shortage of alternative products by the time CFC MDIs are out of the market.
- Facilitate the transition to new products by providing training and targeted awareness activities to ensure acceptance of the alternative products (in some cases they will be HFA MDI and in others DPI) by the patients and by the doctors
- Update the legislation to ensure that when the transition takes place no CFC MDI products will be imported and sold.

## Part I. Situation analysis

### 1. Asthma statistics and economic situation:

In general, the trends of both CFC and non-CFC MDIs imports are increasing over time. The available data indicates that 85,000 units of such medical products were in use in 2003 and this number increased up to 140,000 units in 2007.

The evolution of asthma and chronic obstructive pulmonary diseases (COPD) in the country, including tuberculosis, has had an increase due to economic crisis, insufficient financing of the health system and lack of medicines.

#### 1.1. Number of patients with asthma and COPD:

While there is no statistics that is separately provided for COPD in the Republic of Moldova, since it forms a part of general reporting on all types of bronchitis and pulmonary emphysema, the number of patients suffering from asthma is steadily growing over years. Compared to the base 2003, this number increased by 8% in 2007.

Years	Number of patients with asthma
2003	6,940
2004	7,186
2005	7,371
2006	7,501
2007	7,525

#### Conclusions:

- number of asthma cases is steadily growing, and the data for COPD is not separately available and needs to be further analyzed
- the country's economic situation continues to deteriorate
- the medical care system is not sufficiently financially supported.

### 2. National legislation:

The Republic of Moldova does not produce ODS and ODS-containing products in MDI sector.

The national legislation that controls the activities in the sector does not specifically regulate import/export of CFC MDIs products. There is only one Regulation that controls the imports of medical products (including CFC-MDIs) in the Republic of Moldova - *the Law on Pharmaceutical Activity # 1456 - XII, which was adopted in May 25, 1993*. The

regulation is outdated and considers CFC MDIs during imports in bulk with other medicines/medical products.

Conclusions:

- Specific regulations which would control the use of CFC MDI are lacking

## **2. Supply of anti-asthma/COPD inhalers and other medical products:**

Aerosol products containing CFCs for MDI applications are still being imported into the country. Although some companies have already started the substitution of some CFC-based MDIs independently, the country feels that there should be a coordination strategy for the gradual and informed phase-out of imported CFCs-based MDIs from the country market, including the appropriate supporting measures.

The situation with the supply of MDIs and their non-CFC equivalents in Moldova in brief can be described by the following factors:

- CFC MDIs, HFA MDIs and DPIs are present on the market;
- Growing number of HFA MDIs is being supplied on the market, exceeding 90% of the market share in 2006, but at the same time not exceeding 55% share in 2007;
- CFC MDIs imports through 2003-2005 were slowly decreasing with a slump down to 5% of the market in 2006. However, the imports reached more than 45% in 2007;
- HFA MDIs imports were increasing from 2003 till 2006 with a sharp decrease in 2007;
- DPIs take negligible market share.

<b>Market share %/years</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
CFC %	96.5	75.7	64.8	4.7	45.5
HFA%	3.5	24.3	35.2	95.3	54.1
DPI%	0	0	0	0	0.41

The 2006 sharp slump in the imports of MDIs were dictated by difficulties in getting access to inexpensive CFC MDIs from the traditional supplier located in Ukraine. The acute need to substitute usual CFC MDIs was compensated by sharply increased imports from a single source. However, in 2006 that adaptive action in fact meant the resultant increase in the medicine costs of around 30% up in unit prices with adverse effects on the purchasing power of the target population.

An economically wise import planning can be observed the following year with inexpensive CFC-based MDIs gaining more and more importance. The two sources of

inexpensive MDIs are Russia (70%) and China (20%) with these two sources being new to Moldova.

Country of CFC MDI origin in 2007	Sub-market shares for various sources (% of total)
Russia	71.6
China	20.4
Others	8.0
Total	100.0

**Conclusions:**

- Imports of CFC and HFA MDIs are prone to significant fluctuations,
- As a result, the availability of affordable MDI is subject to abrupt fluctuations in quantity and price,
- The planning of anti-asthma/COPD medicines imports is weak, and it economically impacted the population in 2006.
- Two inexpensive sources of CFC MDI were discovered as a supply diversification option, namely Russia and China, with Russia accounting for around 70% of sub-market share for CFC-MDIs; however there is still no plan to ensure a smooth transition to alternative products.

**3. Price dynamics for anti-asthma medical products:**

On average, the price for CFC MDIs is less expensive. For instance, in 2007, the mean price for HFA MDIs was recognizably more than double that of CFC-MDIs. This was a determining factor behind increasing demand for CFC MDIs and thus, more imports of the latter category of medical products.

If one to compare the lowest reported prices per unit between the most demanded CFC and HFA MDIs, it is possible to notice a minimum 33% price difference between the products supplied from Russia (CFC) and Poland (HFC). If a future consideration is given to the newly discovered source from China (50% the costs of the cheapest HFC MDI in 2007), the imports from China may increase.

Overall, only 2 items in the list of HFA-based MDIs out of 7 product brands are imported at prices from around 33% to 110% higher than the cheapest CFC MDIs. For CFC MDIs, 5 items out of 8 products listed are cheaper than the two cheapest HFA-MDI brands mentioned above.

**Conclusions:**

- Average mean prices for CFC MDIs at least 50% cheaper if compared with those for HFA MDIs

- CFC-based MDIs products, while in their majority cheaper than HFA MDIs, has a greater variety, thus, providing more flexible choices in terms of future imports planning
- When importing from China, despite import distances, considerable savings can be expected which is an important factor for unstable economy

#### **4. Institutional capacity to control the transition:**

The health authorities experienced problems during the compilation of the MDI consumption data, and multiple consultations from NOO-Moldova were required in order to manage the process in a coordinated manner.

Institutional capabilities to proactively and knowledgably plan the imports of CFC and non-CFC MDIs for anti-asthma/COPD treatment in order to ensure more stable imports from predictable sources is lacking. A multi-year planning with a due consideration given to current developments on the market may not be considered as an established practice.

When making a decision on selecting the MDI supply sources, due to bad economic conditions, it is traditional to consider cheaper sources, thus, adjusting the supplies to both the demand and current purchasing power.

#### **Conclusions:**

- the health authorities are not aware of the implications of the Montreal Protocol on the world production of CFC MDIs
- the imports planning is sensitive to cheaper MDIs sources
- taking into account future closure of more CFC MDI lines, need of some producers to evacuate stocks and possible lack of CFC pharmaceutical grade, more distortions in the market (in quantities, price and quality) are expected.

## Part II. MDI transition strategy

The national strategy on replacement of CFC-based MDI with alternatives should include the following:

- Better study and analysis of current MDI market consumption, supply sources and future trends;
- Analysis of alternative products and their effects and health benefits;
- Cooperation with the main importers and representatives of medical establishments towards organization and taking measures to shifting to affordable alternative medications, including timeframes for the import substitution and individual and group agreements with suppliers and distributors;
- Development of a multi-year national planning on imports and ensuring a smooth shift towards alternatives;
- Adopting a wide, informed and participatory decision-making process;
- Through training and targeted awareness activities, to increase confidence and ensure acceptance of the alternative products by the patients and by the doctors
- Extended and targeted work with asthma associations and delivering of trainings in yearly family-based financial planning to ensure better transition to HFC MDIs

Actions could include adjustments made to the legal framework, such as a modification of CFC Import Licensing System to include import of MDI and controlling MDI supplies under humanitarian aid.

### Budget for actions:

Table: Planned expenditures

Description	US\$
National Consultant in MDIs	8,000
Technical assistance	8,000
Promotion, printing	4,000
Workshops	8,000
<b>Sub-Total</b>	<b>28,000</b>
Contingency	2,000
<b>Total</b>	<b>30,000</b>

### Monitoring Milestones

TASK	MONTH
(a) Project document submitted	1
(b) Project document signature	3
(c) Contracts Awarded	7
(d) Begin importers consultations efforts	9
(e) Training/Seminars	9
(f) Strategy developed	12
(g) HOP signature	18



SIGNATURE PAGE

Country: Moldova

UNDAF Outcome(s)/Indicator(s):

*(Link to UNDAF outcome. If no UNDAF, leave blank)*

Expected Outcome(s)/Indicator (s):

*(Those that are linked to the project, are extracted from the CP and are linked to the SRF/MYFF goal and service line)*

Expected Output(s)/Indicator(s):

*(Those that are linked to the project, are extracted from the CP and are linked to the SRF/MYFF goal and service line)*

Implementing partner:  
*(designated institution)*

Republic of Moldova

Other Partners:  
*(formerly implementing agencies)*

Ministry of Environment

Programme Period: _____
Programme Component: _____
Project Title: MDI Transition Strategy
Project Code: _____
Project Duration: _____

Total budget:	USD 30,000
Allocated resources:	_____
• Government	_____
• Regular	_____
• Other: <i>(including in-kind contributions)</i>	_____
<input checked="" type="checkbox"/> Donor MLF	_____
<input type="checkbox"/> Donor	_____
<input type="checkbox"/> Donor	_____
Unfunded budget:	_____

Agreed by (Government): \_\_\_\_\_

Agreed by (Implementing partner): \_\_\_\_\_

Agreed by (UNDP): \_\_\_\_\_

**Total Budget and Work Plan**  
**MLF project reference number: MOL/ARS/54/TAS/20**  
**MDI Transition Strategy**

MLF Outcome/Atlas Activity	Responsible Party	Source of Funds	ERP/Atlas Budget Description	Amount 2008-09 (USD)	Dept. ID	Oper. Unit	Funds	Implementing Agency	Donor ID
ACTIVITY 1 Development of MDI transition strategy	Ministry of Ecology and Natural Resources	MLF	71200 Technical assistance	8,000	t.b.d.	t.b.d.	63030	t.b.d.	10009
			71300 National Consultant	8,000	t.b.d.	t.b.d.	63030	t.b.d.	10009
			72100 Service contract - workshops, promotion, printing	14,000	t.b.d.	t.b.d.	63030	t.b.d.	10009
			<b>TOTAL UNDP 2008-2009</b>	<b>30,000</b>					

Annex. Imports of CFC, non-CFC MDIs and DPIs to Moldova (units). Costs to patient and total costs are provided for 2007 (US\$)

Nr. d/o	Product	Active Ingredient	Brand/Manufacturer/ Country	Technology (CFC- MDI/HFA- MDI/DPI)	Imports per Year (MDI)					Price to patient in 2007, US\$	Sub-total expenditures in 2007, US\$
					2003	2004	2005	2006	2007		
1	Astmopent aerosol 0,75 mcg/doze -20 ml	Orciprenaline sulphate	Glaxo Smith Kline Pharmaceuticals SA, Poland	CFC-MDI	-	800	1031	-	0	7.1	0.00
2	Becloforte aerosol 250 mcg/doze-200 doze 15 ml	Beclomethasone dipropionate	Glaxo Wellcome Operations, UK	CFC-MDI	9790	1653	2200	100	1480	8.4	12432.00
3	Berovent-MF aerosol 200 mcg/doze-300 doze	Fenoterol hydrobromide	Mikrofarm, Ukraine	CFC-MDI	440	320	540	-	0	2.6	0.00
4	Cameton aerosol 30 g	Chlorbutanolhydrate	Microfarm, Ukraine	CFC-MDI	64709	22020	7200	-	0	2	0.00
5	Cameton aerosol 30 g	Chlorbutanolhydrate	Moschimfarm-preparati, Russia	CFC-MDI	3200	5568	-	-	35704	2.1	74978.40
6	Cromal-5 aerosol 5 mg/doze-112 doze	Sodium cromoglycate	Cipla Ltd, India	CFC-MDI	-	-	2000	-	0	28.6	0.00
7	Inflacort inhaler 50 mcg/doze 200 doze	Budesonide	Bilim Pharmaceuticals, Turkey	CFC-MDI	-	-	700	700	0	14	0.00
8	Inflacort inhaler 200 mcg/doze 200 doze	Budesonide	Bilim Pharmaceuticals, Turkey	CFC-MDI	-	-	700	500	110	30.2	3322.00
9	Salbutamol-MF aerosol 100 mcg/doze 200 doze	Salbutamol sulphate	Mikrofarm, Ukraine	CFC-MDI	3918	6720	11000	2000	0	2.3	0.00
10	Serevent aerosol 25 mcg/doze-60 doze	Salmeterol xinafoate	Laboratoires Glaxo Wellcome, France	CFC-MDI	41	530	7735	2050	0	21	0.00

11	Salbutamol susp. for inhalat. 100 mcg/doze-90 doze	Salbutamol sulphate	"Altaivitamin" SAI, Russia	CFC-MDI	-	-	-	-	1568	2.1	3292.80
12	Salbutamol susp. for inhalat. presurizate 100 mcg/doze 12 ml	Salbutamol sulphate	"Moshimfarmpreparat" în numele N. A. Semasco, Russia	CFC-MDI	-	-	-	-	9906	2.3	22783.80
13	Salbutamol susp. for inhalat. presurizate 100 mcg/doze-200 doze	Salbutamol sulphate	Shandong Jewim Pharmaceutical Co, Ltd, China	CFC-MDI	-	-	-	-	13000	1.6	20800.00
14	Beclomethason susp. for inhalat. presurizate 50 mcg/doze-200 doze	Beclometazon	Shandong Jewim Pharmaceutical Co, Ltd, China	CFC-MDI	-	-	-	-	700	3.5	2450.00
15	Beclomethason susp. for inhalat. presurizate 250 mcg/dozã-200 doze	Beclometazon dipropionate	Shandong Jewim Pharmaceutical Co, Ltd, China	CFC-MDI	-	-	-	-	1200	7.4	8880.00
	<b>Total</b>				82098	37611	33106	5350	63668		148939.00
16	Salbutamol susp. for inhalat. presurizate 100 mcg/dozã-200 doze	Salbutamol sulphate	Glaxo SmithKline Pharmaceuticals, Poland	Non CFC (HFA 134a)	-	-	-	-	60640	3.1	187984.00
17	Berotec N sol. for inhalat. presurizate 100 mcg/doze 200 doze	Fenoterol hydrobromide	Boehringer Ingelheim International GmbH (producãtor Boehringer Ingelheim Pharma GmbH&Co.KG), Germany	Non CFC (HFA 134a)	3014	6548	4320	3524	4363	9.2	40139.60
18	Flixotide 125 mcg/ 120 doze evohaler	Fluticasone propionate	Glaxo Smith Kline Pharmaceuticals SA, Poland	Non CFC (HFA 134a)	-	282	3170	2650	1370	30.3	41511.00
19	Flixotide 50 mcg/ 120 doze evohaler	Fluticasone propionate	Glaxo Smith Kline Pharmaceuticals SA, Poland	Non CFC (HFA 134a)	-	500	1630	1690	1160	47	54520.00
20	Flixotide 50 mcg/ 250 doze evohaler	Fluticasone propionate	Glaxo Smith Kline Pharmaceuticals SA, Poland	Non CFC (HFA 134a)	-	250	950	1330	2170	15.2	32984.00

21	Ventolin CFC free 100 mcg/doză 200 doze	Salbutamol sulphate	Poland Glaxo SmithKline Pharmaceuticals SA (Glaxo Wellcome Group), Poland	Non CFC (HFA 134a)	-	4500	7923	12206	5448	3.5	19068.00
22	Berodual N sol. for inhalat. presurizate 200 doze 10 ml	Ipratropium bromide;	Boehringer Ingelheim International GmbH (producer) Boehringer Ingelheim Pharma GmbH&Co.KG, Germany	Non CFC (HFA 134a)	-	-	-	200	500	9.2	4600.00
	<b>Total</b>				3014	12080	17993	108800	75651		<b>380806.60</b>
23	Seretide Discus pulb. For inhalat. 50/100 mcg-60 doze	Salmeterol xinafoate; Fluticasone propionate	Glaxo Operations UK Limited, UK	DPI	-	-	-	-	330	56.6	18678.00
24	Seretide Discus pulb. for inhalat. 50/250 mcg-60 doze	Salmeterol xinafoate; Fluticasone propionate	Glaxo Operations UK Limited, UK	DPI	-	-	-	-	210	71.7	15057.00
25	Seretide Discus pulb. for inhalat. 50/500 mcg-60 doze	Salmeterol xinafoate; Fluticasone propionate	Glaxo Operations UK Limited, UK	DPI	-	-	-	-	30	101.8	3054.00
	<b>Total</b>				0	0	0	0	570		<b>36789.00</b>



15 May 2008

Dear Ms. Kaarina Immonen,

Subject: Project approved at the 54th Executive Committee Meeting - Montreal Protocol.

We are pleased to inform you that the following project was approved for Moldova at the 54th Meeting of the Executive Committee of the Multilateral Fund, held in Montreal in April 2008. This project was prepared with the assistance of the Government of Moldova, National Ozone Office, and in cooperation with Mr. Vasile Filatov of your staff.

MLF Reference*	Project Title	US\$
MOL/ARS/54/TAS/20	MDI Transition Strategy	30,000

Note\*: Please indicate this reference number in the cover sheet of the project document and in the ATLAS short project title.

Please find the following important clarifications related to this project.

1. Implementation Modality. We are suggesting that this project will be implemented through the NEX modality.

2. Project Document Format. We are attaching herewith the MDI Transition Strategy document that was approved by the Executive Committee. It is important to annex this document without any change to the document that will be signed between UNDP and the Government. No outputs, activities or inputs can be added, modified or deleted in the attached document that was approved by the Executive Committee. If changes are needed, this may be done in a subsequent project revision after consultation with this office.

3. Entering the Budget into ATLAS. Your office is requested to enter the budget into ATLAS, using the Annual Work Programme Table that is provided on page 9 of the project document. The Multilateral Fund guidelines do not give us flexibility to shift funds between specific budget categories.

4. Support Cost. The General Management Support Services (GMS) fee received by UNDP in relation to these projects is managed centrally at BDP-HQ, and should NOT be part of the project budget. In ATLAS, please therefore leave the F/A field % at zero. GMS, covering management support rendered by your office, will be credited directly to your XB income at 3 percent based on delivery. Implementation Support Services (ISS) should be charged to the project budget, following the 2004 UNDP guidelines on Cost Recovery Policy (including use of the Universal Price List).

LN  
Ms. Kaarina Immonen  
Resident Representative.  
UNDP – Chisinau, Moldova



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This would have to be applied for services provided other than project management. In this connection it should be noted however that charging budget lines for administrative actions undertaken by UNDP would be against Multilateral Fund (MLF) guidelines and procedures. As such, at the end of the year, the project would have to be credited back by the ISS amounts that were charged to the project budget using the Universal Price List. This exercise will be carried out by MPU HQ.

5. Government Counterpart. Just as a reminder, kindly note that the National Ozone Focal Point in your country is Mr. Anatol Tarita (environment@ozon.mldnet.com). While he may not be the one to sign the project document on behalf of the Government, kindly make sure that he is copied on every correspondence related to this matter.

6. Over-Expenditures. We wish to remind you that over-expenditures are absolutely not allowed in Montreal Protocol projects. Please therefore ensure that total expenditures never exceed the budget total.

7. Executive Committee Condition. The Executive Committee has approved this project without specific conditions.

More information on these decisions can be obtained from the National Ozone Focal Point.

Based on the above points, kindly finalize the project documentation and enter the proposal into ATLAS. Please inform Mr. Maksim Surkov using the "email notification" feature within ATLAS. After this last clearance from us, you are then authorized to sign the project document on behalf of UNDP. Please do not send the budget to KK before the project document has been signed. Once the project document has been signed please send the budget to "Commitment Control" and send a copy of the cover page and request for ASL to MPU (attn. Ms. Loise Nganga, loise.nganga@undp.org).

Thank you very much for your important partnership in the implementation of this programme. Elimination of Ozone Depleting Substances constitutes one of the Service Lines under UNDP's "Energy and Environment for Sustainable Development" Practice.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suelly Carvalho', written over the typed name.

Dr. Suelly Carvalho, Chief  
Montreal Protocol Unit  
GEF PTA - Chemicals  
Environment and Energy Group  
Bureau for Development Policy