MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEF SEC PROJECT ID: 3043
COUNTRY: Republic of Moldova
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of the Republic of Moldova
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES):
DURATION: 48 months
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: December 2005
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	542 350
PDF A*	
Sub-Total GEF	542 350
CO-FINANCING**	
GEF	
Government	147 000
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	147 000
Total Project Financing:	689 350
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

(Enter Name, Position, Ministry)
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GEF Political Focal Point
Minister of Ecology and Natural Resources of the Republic of Moldova
Ms. Violeta Ivanov,
GEF Operational Focal Point
Ministry of Ecology and Natural Resources

Date*: (Month, day, year)*
[October 31, 2005]
Endorsement letter (attached Annex A)

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

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DateNovember 25, 2005

LIST OF ACRONYM

AF = Agency for Forestry "Moldsilva"
ASM= Academy of Sciences of Moldova
BCH = Biosafety Clearing House
BG = Botanical Gardens (Research Institute):
CBD = Convention on Biological Diversity
CCD = Customs Control Department
CCS = Customs Control Services
CEP = Concept of Environmental Policy of the Republic of Moldova
CGPI = Chair of genetics and plant improvement –
CGR = Center for Genetically Resources
CP = Cartagena Protocol on Biosafety
DNA = Desoxyribonucleic Acid
DVB = Department of Vegetal Biology
EAPEH = European Action Plan on Environment Hygiene
EC = European Commission
EGPRSP = Strategy for Economic Growth and Poverty Reduction
EU = European Union
FNRB = First National Report on Biodiversity
GDP = Gross Domestic Product
GEF = Global Environmental Facility
GEL = Genetic Expertise Laboratory of the Standardization and Metrology Services:
GMOs = Genetically Modified Organisms
GRI = Genetic Research Institute
HRI = Horticulture Research Institute
LC = Licensing Chamber
MAFI = Ministry of Agriculture and Food Industry
MEC = Ministry of Economy and Commerce
MERN = Ministry of Ecology and Natural Resources
MEYS = Ministry of Education, Youth and Sport
MHCSP = Ministry of Health Care and Social Protection
MJ = Ministry of Justice
MRI = Microbiology Research Institute
NACHE = National Action Plan on Health and Environment
NBC = National Biosafety Committee
NBF = National Biosafety Framework
NBP = National Biosafety Policy
NBTC = National Biosafety Testing Center
NCC = National Coordination Committee
NEA = National Executing Agency
NFP CP and BCH = National Focal Point for the Cartagena Protocol on Biosafety and the BCH
NGOs = Nongovernmental Organizations
NIE = National Institute of Ecology-
NRCPHC = National Research Center for Preventive Health Care-
NSAPBC = National Strategy and Action Plan in the field of Biodiversity Conservation
NSB = National Statistical Bureau
NPM = National Project Manager
NSPICR = Northern Station for Project Implementation and Chemical Research:
NSSD = National Strategy for Sustainable Development – "Moldova 21"
NTRAC = National Testing and Risk Assessment Center

NVWRI = National Viticulture and Wine Research Institute –
OPs = GEF Operational Programs
PPRI = Plant Physiology Research Institute:
PPRI = Plant Protection Research Institute -
PSC = Project Steering Committee
RICS = Research Institute for Corn and Sorghum:
SAU = State Agricultural University of Moldova:
SEI = State Ecological Inspectorate
SMPU = State Medical and Pharmacological University „Nicolae Testemitanu"
SMS = Standardization and Metrology Services
SUM = State University of Moldova:
TOR = Terms of Reference
UNDP = United Nations Development Program
UNEP = United Nations Environmental Program
WB = World Bank
ZRI = Zoological Research Institute:

A. PROJECT SUMMARY

A decade ago, the Republic of Moldova proclaimed its independence and stepped on the path of radical changes that led to the formation of a market economy in the mid 90s while changes became irreversible. As a result of the reforms, the Republic of Moldova achieved some progress: reform of the property structure, introduction of the national currency, reform of the banking-financial system, agricultural reform, and the creation of the legal and institutional framework to ensure the functioning of the market economy.

At the same time, it is worth mentioning that alongside with these economic progresses, poverty is a serious problem in the Republic of Moldova, which is caused by both internal and external factors. Moldova is affected by the lack of its own energy resources and the increase of their prices up to the global standards, the Transnistrian conflict in 1992 as well as a number of natural disasters that led to the halving of GDP. Floods of 1992 and 1994 and the draughts in 2000 should be mentioned in this context as well.

Agriculture has a significant importance for the republic of Moldova given that the productive sector of national economy will have agricultural and food character and more than half of the population of the country has directly or indirectly the agro-industrial activity as the major source of existence.

Environmental problems in Moldova are related to the excessive use of the recyclable natural resources, on one hand – by the global deterioration of the quality of environment. The reduction of the recycling capacities of the resources and the environment pollution affects human security.

Large import-export relations with Russia, Ukraine, and Romania, as well as lack of efficient mechanism for custom control for GMOs for economical agents and private persons create a fruitful base for the possible introduction of GMOs in Moldova as food and feed products, agriculture products, and seeds.

Such, the Republic of Moldova is exposed to the introduction of GMOs in the country. 9 samples of soybean products collected in the market in Moldova have been sent to an independent laboratory in the UK at the end of 2004 for GMO testing. The quantitative and qualitative analyses have been provided in order to identify the presence of GMOs in the samples, and the quantity of the GMOs (in %). In 7 of samples the GMOs have been detected, and in 5 of the samples GMOs constitute more than 5%.

The Republic of Moldova undertakes actions to consider the *Agenda - XXI (Rio-de-Janeiro,1992)* principles for the sustainable development. The *Strategy for Economic Growth and Poverty Reduction (2004-2006)* (EGPRSP) adopted by the Law *nr. 398-XV 02.12.2004, M.O. nr.5-12 of 14.01.2005* integrates the approach to sustainable development .

Being a Party to the *Convention on Biodiversity Conservation* (CBD) since 1995 (Parliament Decision No. 457-XIII of 16.05.1995), Moldova completed its *National Strategy and Action Plan in the field of Biodiversity Conservation* (NSAPBC), adopted by the Resolution of the Moldovan Parliament no. 112-XV of 27 April 2001 (published in Moldova's official gazette *Monitorul official al Republicii Moldova* nos. 90-91 of 2 August 2001). Investigations of flora highlighted the possibility of using about 150 aromatic species, 200 medicinal plant species, 80 fodder plant species from spontaneous flora; about 43 species represent the forebears of agricultural plants in the country.

The conservation of genetic varieties as a component part of biodiversity is done in two ways: *in-situ* and *ex-situ. Natural* protected areas that covered the most representative natural ecosystems constitutes 66 467,3 ha or 1,96% of the territory. However, this not ensures the needed area for biodiversity conservation and protected areas are very sensitive one to the adverse impact provoked from the possible GMOs using in the environment. The process of autochthonous biodiversity conservation usually is very passive and some varieties are being lost. The use of biotechnologies and genetic engineering is at a very beginning of its way in the Republic of Moldova. Some biotechnological methods are used in agriculture, medicine and environmental protection (production of food and fodder proteins, vitamins, active biological substances, multiplication of endangered species etc.).

As provided for by the Convention, National Strategy and Action Plan in the field of Biodiversity Conservation, the Moldovan Government provides for the development of a comprehensive urgent actions package to ensure the national biodiversity and biosafety. It was considered necessary to improve the existing environmental legislation by adding elements of ensuring the biological security of the country, regulating the GMOs uses respecting the Convention and the respective protocol. The package includes actions related to the biodiversity conservation :

- Protection of representative natural areas;
- Protection of natural habitats;
- Conservation of the natural heritage of unique natural objects, important zones for the reproduction of spontaneous flora and wild animal species;
- Regulation of biological resources use;
- Integration of the biodiversity conservation requirements onto the activities of the national economy sectors.

and to the biosafety needs:

- *Regulation of imports and exports of organisms produced using transgenic methods;*
- *Establishment of an adequate legal and institutional framework;*
- *Training of experts and establishing of a laboratory to control GMOs;*
- *Development of special public awareness raising programs to disseminate information on the risks connected with use of GMOs.*

Since the Moldovan Parliament ratifiying the *Cartagena Protocol on Biosafety (CP)* by Law no. 1381-XV of 11 October 2002, biosafety has become a national priority in the field of environmental protection actions. The new Concept of environmental Protection, as well as the "Strategic Plan: Republic of Moldova- EU" considers it important to promote harmonization of the national legislation with the Cartagena protocol and the EU Directives in the following aspects:

- contained use of genetically modified micro-organisms;
- GM food and feed regulates the placing on the market;
- traceability and labeling of GMOs;
- assistance for developing national strategies and best practices to ensure co-existence.

Moldova has already adopted the *National Law on Biosafety* no. 755-XV of 21 December 2002 (published in *Monitorul official al Republicii Moldova* no. 75 of 13 June 2003) – the country's main law in the field of biosafety, which regulates all activities regarding creation, testing, production, use and marketing of genetically modified organisms (GMOs). Any activities of that kind are subject to authorisation by the *National Biosafety Committee (NBC)*. The National Biosafety Committee was set up by Government Resolution no. 603 of 20 May 2003 (published in *Monitorul official al Republicii Moldova* no. 91-96 of 30 May 2003). Additionally all activities involving high risks (III and IV class of risks) are subject to licensing in conformity with the Moldovan *Law on Licensing of*

Certain Activities no. 451-XV of 30 July 2001, Section on licensing of certain activities in the sphere of genetics and microbiology. *Regulation on authorisation of the activities regarding testing, production, use or marketing of GMOs* was approved by the Government Decision no. 1153 of 25 September 2003. Other related laws and regulations covering specific sectors or industries should be amended and harmonized with the provisions of the Cartagena Protocol, with consideration of Moldova's current situation and specifics, peculiarities of its national economy, special activity requirements and suggestions submitted by stakeholders during follow-up on the work already performed in that direction.

The *UNEP-GEF Project no. GF/2716-02-4520 "Development of the National Biosafety Framework (NBF) for the Republic of Moldova"* has been implemented under the Moldovan Ministry of Ecology and Natural Resources during the 2002-2004. The *National Biosafety Framework* (NBF) for the Republic of Moldova was prepared, thanks to the support given by the mentioned project.

The task of the national biosafety system is to provide for an indispensable level of biological security with respect to release and use of genetically modified organisms by:

- assessing possible negative effects during deliberate release into environment;
- establishing monitoring system;
- planning emergency actions to deal effectively with accidents;
- establishing systems to provide consent and certification on each stage of experiments and deliberate release into the environment;
- establishing a competent authority with the mandate to provide advice, decisions and control on registration, consent for GMO release and codes of practice;
- developing information system;
- establishing international co-operation;
- training personnel and public participation.

The circumstances listed above had a negative impact on the national economy during a decade, generating serious problems, including economical decrease, degradation of natural resources, and the phenomenon of poverty. The identification and becoming aware of these problems is a condition of absolute need for the implementation of the *National Biosafety Framework in Moldova*, in order to develop an efficient and comprehensive policy, regulatory system, institutional and decision making mechanism appropriate to implement requirements of the Cartagena Protocol, to strengthen mechanisms for public awareness, training and participation in the decision-making.

The NBF provides a useful guide and aims at developing the appropriate level of biosafety with respect GMOs release and use, given both the risks associated with their use in food and feed and the possible negative ecological implications of the release of such organisms into the environment.

In addition, Moldova is also implementing the UNEP-GEF project "Capacity Building for Effective Participation in the BCH" by establishing their national node for the BCH and also by training decision-makers and stakeholders to use and benefit from the BCH.

The implementation of the National Biosafety Framework requires a substantial effort in capacity building. GEF support is therefore considered crucial in facing the following needs:

- The development of related Biosafety/Environment policy;
- Development of a regulatory system. Special attention should be addressed to the sectorial regulation framework;
- Administrative arrangements. Risk assessment and risk management capacity building
- Enforcement mechanism and monitoring. Preparing special regulations, guidelines, manuals etc.;
- Training of the stakeholders representatives, particularly in the areas of risk assessment and risk management; strengthening the institutions serving as centers of excellence, expertise and reference laboratories for monitoring;

- Testing and monitoring;
- Increasing public awareness on issues relating to the use of GMOs, including providing information and answers to the media and NGOs;
- Development of information resources in the form of various databases (on experts, biosafety programs, research activities etc.).

The main purpose of the project "Support the Implementation of the National Biosafety Framework of the Republic of Moldova" is to help Moldova to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol and have a National Biosafety Framework fully operational by:

- The implementation of the Moldova's legislative framework on the safe use of biotechnology through improvement of the Biosafety law, development of sectorial regulations, guidelines and manuals;
- The preparation of specific technical guidelines;
- The strengthening of appropriate institutional structures for risk assessment and decision making;
- The development and implementation of policies for biosafety;
- The training of decision makers, scientists, and administrative and technical staff on legal and technical matters;
- The reinforcement of the existing infrastructures (laboratories) to strengthen monitoring;
- The setting up of a mechanism for monitoring and enforcement;
- The strengthening of communication and information exchange relating to biosafety both at the national level as well as through the BCH
- Systems for strengthening public awareness, education and participation in decision making on GMOs.

Brief description of national institutional arrangements:

According to the provisions of the Cartagena Protocol and the Law on Biosafety, the *Ministry of Ecology and Natural Resources* (MERN) was appointed the national authority in charge of their implementation. The relevant institutional framework established at the national level to ensure implementation of the *Law on Biosafety*, comprised of:

- *Ministry of Ecology and Natural Resources;*
- *The National Biosafety Committee;*
- *The National Focal Point for the Cartagena Protocol on Biosafety and the BCH* (NFP CP and BCH)
- *The National Task Force for Cartagena Protocol on Biosafety and the BCH*

The National Biosafety Committee operates as the interdepartmental authority and consists of 14 members. *The National Authority on Biosafety - the Ministry of Ecology and Natural Resources* is the national environmental authority, which has the function to ensure fulfillment at the national level of the responsibilities resulting from provisions of the international legal acts regarding implementation of biosafety measures on GMO use. *The National Focal Point for the Cartagena Protocol on Biosafety and the BCH*- is a nominated person responsible for ensuring the relations with the Secretariat of the CBD and the CP, and to promote the requirement on Biosafety at national level. *The National Task Force for Cartagena Protocol on Biosafety and the BCH* – is a CP implementation body composed of 8 members from various governmental bodies, research and civil society, with responsibility to help the NFP in the implementation of the CP.

The National Biosafety Testing Center (NBTC) has been established for the purpose of assessment of risks for public health and the environment, testing of GMOs and products obtained thereof, and monitoring of the relevant activities.

The **overall goal** of the project is that by 2009 the Republic of Moldova has a workable and

transparent national biosafety framework, in line with its national development priorities and international obligations

Specific Objectives: **To support the Implementation of the objective of the Cartegena Protocol on Biosafety in the signatory countries**

Objective for Component A: Enforce a comprehensive National Biosafety policy as basis for the development of the adequate national regulatory regime and institutional framework

Objective for Component B: Strengthen the national regulatory regime in line with the Cartagena Protocol, NBF, and biosafety policy

Objective for Component C: Strengthen the national administrative system for handling requests, which includes administrative processing, risk assessment and management, and decision-making in compliance with the Cartagena Protocol requirements and NBF

Objective for Component D: Consolidate a fully functional system for monitoring and enforcement in line with Cartagena Protocol and NBF

Objective for Component E: Consolidate a fully functional system for public awareness and participation in the decision-making process, in line with Cartagena Protocol and NBF

Project Outcomes

Component A: A comprehensive National Biosafety policy is enforced and used as the basis for the development of an adequate national regulatory regime and institutional framework

- **Outcome A.1:** Strengthened national Biosafety policy to guide the implementation of the Cartagena Protocol, National Biosafety Framework, National Biodiversity Strategy, and other national and international requirements
- **Outcome A.2:** Strengthened public and political support for Biosafety policy implementation

Component B: Strengthened, national regulatory regime, in line with Cartagena Protocol, NBF, and the National Biosafety Policy

- **Outcome B.1:** The National Biosafety Law reviewed, amended and harmonized in line with the provisions of the Cartagena Protocol, other international requirements (EU) related the inspection, monitoring and control of GMOs and related institutional setting-up, as well as with the requirements for specific information needed for the BCH and the GMO register
- **Outcome B.2:** Branch legislation revised and amended for the purpose of its harmonization with the Cartagena Protocol, national Biosafety policy and law
- **Outcome B.3:** Secondary regulations and guidelines, required by the law, developed and in force ensuring implementation of the Law

Component C: Strengthened and fully operational administrative system for handling of requests, in compliance with the Cartagena Protocol requirements

- **Outcome C.1** Functional risk assessment system in place
- **Outcome C.2:** Strengthened capacities and tools for a functional decision-making system and system for administrative processing, including emergency response procedures

Component D: Consolidated and fully functional system for monitoring and enforcement

- **Outcome D.1:** Monitoring, inspection and control procedures and capacities built and in place

- **Outcome D.2:** Strengthened facilities and capacities for laboratory testing of GMOs
- **Outcome D3:** Requirements for packaging, labeling, storage and transportation, transboundary or transit movement control of GMOs established. Strengthened capacity on import/export/transit of LMOs

Component E: Consolidated and fully functional system for public awareness and participation in the decision-making process in line with CP

- **Outcome E.1:** Strategy for public awareness in place and an efficient mechanism for public consultations developed and implemented to ensure public participation in decision-making as a component of the Biosafety strategy
- **Outcome E.2:** Increased public awareness, Best practices on Public participation learned and disseminated

Estimated budget (in USD)

GEF: Project Cost: USD 542, 350

Co-financing: Moldova government: USD 147, 000

In cash: USD 0

In kind: USD 147, 000

Total: USD 689, 350

Information on Project proposer:

Ministry of Ecology and Natural Resources is the national environmental authority, and also is the national competent Biosafety authority which has the function to ensure fulfillment at the national level of the responsibilities resulting from provisions of the international legal acts regarding implementation of biosafety measures, authorization issuing, risk assessment/management, monitoring and control on the GMOs use in the country.

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B - COUNTRY OWNERSHIP

B1. Country eligibility

The Republic of Moldova ratified the Convention on Biological Diversity by the Resolution of the Moldovan Parliament no. 112-XV of 27 April 2001 and the Cartagena Protocol by the Resolution of the Moldovan Parliament no. 1381-XV of 11 October 2002.

B2. Country Driveness

State Project linkage to national priorities, action plans and programmes:

The project is fully consonant with a range of national policy and strategic documents. The *National Strategy and Action Plan in the field of biological diversity conservation* (approved by Parliamentary Decision no. 112-XV of 27 April 2001) is to implement the commitments made by Moldova as a signatory party to the Convention on biological diversity, consequences of GMO use. The major goal of the Strategy on biodiversity conservation is the conservation, rehabilitation, reconstruction and efficient use of the biodiversity and landscape to ensure the sustainable social-economic development of the Republic of Moldova. The objectives of the Strategy can be achieved through consequent well-targeted actions, establishing deadlines and funding amount. The National Strategy and Action Plan attaches special importance to transparency and preventive actions in use of GMOs. A comprehensive package of immediate measures has been provided for to ensure biosafety in Moldova:

- *Regulation of imports and exports of transgenic organisms;*
- *Creation of the relevant legislative and institutional framework;*
- *Capacity building via staff training;*
- *Establishment of a testing laboratory to exercise control over GMOs; and*
- *Development of special public awareness raising programs to disseminate information on the risks connected with use of GMOs.*

The Cartagena Protocol on Biosafety was ratified by the Republic of Moldova as an integral part of the Convention on Biological Diversity by the Law no. 1381-XV of 11 October 2002. *The National Biosafety Framework* was elaborated in a framework of the UNEP/GEF project "Development of the National Biosafety Framework for the Republic of Moldova"(2002-2004), and it is in conformity with the Protocol provisions.

The new *Concept of Environmental Policy of the Republic of Moldova* (CEP) was adopted by the Parliament Decision nr 605-XV of 2 November 2001, and has adjusted the major environmental objectives to the social and economic changes in the country as well as the regional and global programs focusing on environment protection. The environmental policy's main objectives are: (i) prevention and mitigation of adverse impact of economic activities upon the environment, natural resources and public health in the context of sustainable national development; and (ii) ensuring a safe environment for the country, including biological safety. The Environmental policy priorities for the Republic of Moldova are focused on the Regulation on environmental impacts, pollution prevention and rehabilitation of the environment.

The policy of the Republic of Moldova in the field of environment protection is an urgent necessity; it is required to consolidate the country's course towards sustainable development and European integration, towards intensification of international collaboration in that sphere. As of today, the Republic of Moldova has ratified 18 International Environmental Conventions, and compliance with their provisions requires a detailed review of the legislative and regulatory framework and its harmonization with the relevant EU Directives. The *Action Plan "Republic of Moldova – European Union* " was signed in the framework of the VII-th Meeting of the Council for Cooperation: The Republic of Moldova- European Union in Brussels on 22.02.2005. It was developed with the aim of

making use of the opportunities offered by the new EU policy in respect of its future neighbors.

The *Strategy for Economic Growth and Poverty Reduction (2004-2006)* adopted by the Law *nr. 398-XV 02.12.2004, M.O. nr.5-12 of 14.01.2005*, states the importance of biodiversity conservation as one of the main factors for poverty reduction and economic growth in the country. The EGPRSP recognizes the linkage between the quality of natural resources, socio-economic welfare and stability, invoking the necessity to eliminate the contributing factors to natural resource degradation. The EGPRSP highlights the priorities for the period 2005-2008 and puts the emphasis on the implementation of the following objectives: (i) prevent and reduce the degradation of natural resources and increase efficiency of their use; (ii) maintain the quality of the environment as a factor that ensures health and quality of life; (iii) create an effective natural disaster monitoring, prevention and damage compensation system.

The *National Strategy for Sustainable Development – "Moldova 21"* (NSSD) for the next 20 years was launched in November 2000 with the UNDP financial and logistic support. The National Strategy for Sustainable Development of the Republic of Moldova in the 21 century reaffirms the commitment to sustainable development and represents the first complex and long-term programme for the social-economic development of the country based on new principles:

- Development of a market economy with a social focus, based on private and public property and engaged in free competition which implies the creation of a competitive economic system and adequate to the principles, standards, tools and institutions of developed countries;
- Creation of an open civil society based on democracy, decentralization of the public system and support to the civil society;
- Development focus on the improvement of the life quality, investment in the human capital;
- Promotion of a new security concept – economic, social, food and environmental.

National Report on the Implementation of AGENDA 21 in the Republic of Moldova, approved by the National Preparatory Committee (established by the Government Decision No. 967 of 10.09.2001) for the Johannesburg Summit, May 30, 2002

In accordance with the European Action Plan on Environment Hygiene (EAPEH), the *National Action Plan on Health and Environment* (NACHE) was approved by the decision No. 287 of the Government of the Republic of Moldova on June 19, 2001. This Plan gives details of the concept on the measures required for health in relation with environment. Priorities include the stage aimed at achieving medical and environmental stability, stopping the deterioration of the environment and health. The adjustment of the legal, methodological and organization framework is also important, which should create new conditions, aimed at fostering the activity in health and environment protection.

The major objective of the agricultural activities of the last 50 years was the property reform, the creation of the adequate institutional and economic conditions for the creation of the production and functioning structures of the economic entities in the agro-industrial sector, the diversification of the economic relations under the market economy conditions, restructuring of the services system, provision of information, advisory assistance and the improvement of knowledge of the new producers of the agro-industrial sector.

The main objectives of the agricultural and food policy in view of integration into the EU market are the considerable increase of the efficiency and productivity of labor in this economic sector and the adjustment of the requirements for the quality of food products to the European standards with the solution of the following problems:

- Ensure food security of the population
- Increase the efficiency of the labor force

- Increase the favorable conditions for the economic, social and ethnic-cultural development of the rural population
- Efficient use and conservation of natural resources and environment protection

Considering the importance of agriculture and agribusiness for Moldova's national economy and in view of the objective to enter the international market of agricultural products, the Government has approved *the National Concept for natural farming, production and distribution of environmentally clean and non-GMO food* (Government Resolution no. 863 of 21.08.2000). The document declares that use of gene engineering is considered inadmissible for the purposes of ecological agricultural production.

The *UNEP-GEF Project no. GF/2716-02-4520 "Development of the National Biosafety Framework (NBF) for the Republic of Moldova"* was implemented under the Moldovan Ministry of Ecology and Natural Resources. The above project was carried out from 2002 with support from UNEP-GEF, and was completed on 10 Dec. 2004.

UNDP-GEF Project MOL/03/G31 "National Self-assessment of Capacity Building Needs for Global Environmental Management " (2003-2005) provides the support for the identification through a country-driven consultative process of priorities, needs, and constraints for capacity building in order to reinforce the synergetic effect and meet obligations under the three Rio global environmental Conventions (UN Framework Convention on Climate Change, the UN Convention on Biological Diversity, and the UN Convention to Combat Desertification) towards the protection of global environment. The *National Action Plan on Building Capacities for the Integrated Implementation of the Environmental Conventions of Rio de Janeiro for the period 2005-2010* is being drafted now. It stresses the measures for further development of policies, regulatory framework, institutional settings, monitoring and research and development in the field of biodiversity and biosafety.

The sub-project *"Support for the Development of the National Biosafety Framework for the Republic of Moldova, co-financed by the British Embassy in Chisinau* - the Global Opportunities Fund (Environment Fund) is to supplement the UNEP activities held under the project "Development of the National Biosafety Framework for the Republic of Moldova". The two additional components covered from UK funds were: (a) work to harmonise Moldavian legislation with EU legislation; (b) training for Moldovan practitioners, including visits to the UK and study of the UK experience of biotechnologies (techniques and practices).

Moldova is in the process of implementing the UNEP-GEF project "Capacity Building for Effective Participation in the BCH" by establishing their national node for the BCH and also by training decision-makers and stakeholders to use and benefit from the BCH.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area. It is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private

sector stakeholders."

It is therefore most relevant to the implementation of GEF Operational Programs (OPs) 1-4 and 13.

C2. PROJECT DESIGN

Details are shown in the log frame, which is attached as Annex B.

C2.A BACKGROUND AND CONTEXT

The Republic of Moldova participated in the Global Project on "Development of National Biosafety Frameworks". In order to design its **National Biosafety Framework**, Moldova carried out the following activities:

A review of the current situation regarding Biosafety Framework in Moldova and to identify key stakeholders has been completed. Therefore the following surveys were made during the project: survey and analysis of existing national policy, legislative and institutional framework; branch policies and regulatory system related to biosafety; system for handling of notifications and authorization procedures; international, regional and sub-regional cooperation; biotechnology uses and production; research and development, risk assessment/ risk management; monitoring, inspection and control; public information and educational capacities and public access to decision making; identification of main stakeholders and civil society. The final output of the Project's Phase 1 was the creation of a Biosafety web-page, where the most important information on biosafety in Moldova, EU and CP CBD was made publicly available (www.biosafety.md).

Special workshops were organized to review the findings of the survey phase, to identify gaps, needs and priorities for Moldova's NBF. A survey and analysis of the gaps, inadequacies and weaknesses of the national legislative and institutional frameworks, research and development, risk assessment / risk management, international, regional and sub-regional cooperation, biotechnology use and production have been provided. Gaps and priorities in regulation and institutional frameworks have been identified. A survey on the current situation of information exchange and databases infrastructure related to the Biosafety Clearing House (BCH) and identifications of building capacity needs has been provided. A series of workshops was targeted at different GMO regulation administrative levels and stakeholders (inspectors, risk assessment experts, ministries, researchers, farmers, business, NGOs, mass-media, etc.).

Key components of the NBF Concept have been identified. The concept of the structure of the NBF final document has been elaborate. Draft of the "National Biosafety Framework for the Republic of Moldova "has been elaborated. The National Biosafety Framework for the Republic of Moldova was discussed with various stakeholders such as central and local public administrators, researchers, farmers, consumers associations, business and private sector, students, NGOs, representatives of mass-media and press, agricultural consultants and civil society at a series of workshops in Chisinau and in different districts of Moldova. A series of guidelines and drafts of legislations, brochures and books have been developed and published.

A summary of the background and context to the project is attached in Annex **C** as well as a copy of the draft National Biosafety Framework, accomplished as result of mentioned project **Annex D**.

C2.B Current situation (in the country with respect to the NBF)

Biosafety policy

The Republic of Moldova ratified the *Convention on Biological Diversity in 1995*. As provided for by that Convention, the Moldovan *Ministry of Environment and Natural Resources* has developed in collaboration with experts from various institutions and organizations the *National Strategy and Action Plan in the area of biodiversity conservation in the Republic of Moldova*. The *National Strategy and Action Plan in the area of biodiversity conservation* as well as the *First National Report on Biodiversity* (FNRB) (approved by Resolution of the Moldovan Government no. 112-XV of 27 April 2001) provide for the development of a comprehensive urgent actions package to ensure national biosafety.

The major goal of the Strategy on biodiversity conservation is the conservation, rehabilitation, reconstruction and efficient use of the biodiversity and landscape to ensure a sustainable social-economic development of the Republic of Moldova. The objectives of the Strategy can be achieved through consequent well-targeted actions, establishing deadlines and funding amount. The National Strategy and Action Plan attaches special importance to transparency and preventive actions in use of GMOs. A comprehensive package of immediate measures has been provided for to ensure biosafety in Moldova:

- *Regulation of imports and exports of transgenic organisms;*
- *Creation of relevant legislative and institutional framework;*
- *Capacity building via staff training;*
- *Establishment of a testing laboratory to exercise control over GMOs; and*
- *Development of special public awareness raising programs to disseminate information on the potential risk connected with the use of GMOs.*

Regulatory regime for biosafety

As a party to the Convention on Biological Diversity, the Republic of Moldova is in the process of implementing the requirements of the *Cartagena Protocol on Biosafety*. Based on the Convention on Biological Diversity and the Cartagena Protocol, the Ministry of Environment and Natural Resources has developed the *National Biosafety Law* no. 755-XV promulgated by the Moldovan Parliament on 21 December 2002.

The law has been harmonized to the new *EC Directive 2001/18/EC* on release of GMOs into the environment and came into effect on 13 June 2003. This Law regulates all activities involving production, reproduction, testing and contained use of GMOs; intended release into the environment and market release of GMOs; accidental release of GMOs into the environment; intended release into the environment and market release of processed products containing processed or unprocessed GMOs; all GMO trials, including laboratory, clinical, field and industrial trials; imports and exports of GMOs and their derivatives; accidental transboundary movement of GMOs; storage, burial or elimination of GMOs and/or their derivatives, elimination of waste produced by modern biotechnologies.

The National Biosafety Law establishes certain labelling requirements to marketed products. In particular, the label and/or accompanying documentation must provide information regarding the presence of GMO components. For products containing GMOs, it is required by law to make the respective indication both on the label and in the accompanying documentation.

The law puts the *National Biosafety Committee* in charge of choosing the competent public authorities or scientific institutions to perform risk assessment. Risk assessment should be based on scientific approach and transparency. Such risk assessment should concentrate on identification and assessment of negative impact of GMOs and/or their derivatives on human health and the environment.

The Regulation on authorization of activities connected with production, testing, use and distribution of GMOs (Government Resolution no. 1153 of 25.09.2003) has been drafted in line with the provisions of the Law on Biosafety and provides for authorization of GMO-related activities via issuance of licenses to provide the holder's right to perform certain activities subject to compliance with the license (authorization) terms and conditions. The Regulations require authorization of the following activities:

- contained use of GMOs;
- deliberate release of GMOs into the environment;
- deliberate market release of GMOs and products made thereof;
- imports/exports of GMOs and/or products made thereof.

The national legislation includes a number of laws, which regulate the spheres indirectly connected with the issues of biosafety and food safety and which can influence decision-making to a certain extent, although they do not have provisions directly relating to the above issues. These laws include: Laws on animal breeding, horticulture, plant protection, medicines, and others (a total of 12 laws). Furthermore, the category of legislation acts indirectly related to the issues of biosafety includes a number of Parliamentary Resolutions and Government Decisions.

System for handling request for permits

The National Biosafety Committee was set up by Government Resolution no. 603 of 20 May 2003 (published in *Monitorul official al Republicii Moldova* no. 91-96 of 30 May 2003). Moldova's Biosafety Committee is an inter-ministerial body with the powers to authorise, coordinate and control activities regulated by the National Law on Biosafety, including activities connected with GMOs.

The *National Biosafety Testing Center* has been established by the Inter-ministerial Resolution no. 18 of 10 February 2004. The Center will monitor imported GMOs, test GMOs and their derivatives, and perform assessment of risks for human health and environment.

The actual authorization procedures require the following actions:

To obtain an authorization to perform activities connected with contained use, deliberate release in the environment or market release, the notifier must submit the following documents to the National Committee:

a) an application specifying the merchant's name and legal status, registered office;
b) a special notification for each activity;
c) an environmental risk assessment report for the environment and human health accompanied
d) a short notification information format.

Upon registration of the notification, the National Committee informs the public and starts public consultations, requests opinions from the national authorities for the environment, economy, agriculture and food industry, health care and protection of consumer rights. At the same time it transfers the summary file to a competent research institution for the purposes of risk assessment. Based on the accumulated information, the National Committee decides to issue the authorization or to reject the application, giving the applicant the substantiating argumentation.

Within 90 days upon issuance of the confirmation for being in receipt of the notification the National Committee must make one of the following decisions:

- To issue an authorization for the notified activities;
- To prohibit practice of the notified activities;
- To request additional information; or
- To extend the period required for decision-making for the time required to assess additional information.

Systems for monitoring of environmental effects and enforcement

Monitoring of GMO-related activities is the task of the National Biosafety Committee. The national legislation does not specify the exact control authorities with the function of performing inspection and control of GMO-related activities. Monitoring objectives, general rules and procedures for development of a monitoring plan are specified in Appendix 5 (2) to *Regulations on authorization of activities connected with production, testing, use and distribution of GMOs.*

Although not a single application has been registered as yet regarding authorization of GMO-related activities, the relevant Moldovan authorities take certain actions by way of monitoring. The Ministry of Agriculture and Food Industry developed *Regulations regarding imports and exports of seeds and seedlings* approved by Government Decision no. 360 of 27.03.02. There is an urgent need to complete the existing legislation framework and enforcement system and to specify responsibilities and duties of the governmental inspection bodies with the GMOs monitoring and inspection functions.

Public Information and participation

To ensure transparency of the NBC activities, a special procedure on consultations with the public has been included in the Biosafety law. The National Biosafety Committee should take into consideration the comments received from the public. Public hearings may be organized depending on the comments.

The Committee shall be guided by national legislation and international agreements to ensure public participation – Art. 39. This includes doubtless the *Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*. Based on the information in the submitted notification, the National Biosafety Committee, acting in conformity with Government Decision no. 1153 of 25.09.2003, Paragraph 29 and 30, must inform the public about the information provided in the notification within 10 days upon its receipt and start consultations; consider the received comments and questions and place the notification documentation within the same time on the official web page of the National Environmental Authority. In decision-making document regarding the notified activity, the Committee must consider comments in the nature of advisory received from the public within 30 days after the day of information dissemination. Depending on the received comments, the Committee may organize public hearings regarding any aspect of the issues being considered.

To ensure detailed implementation of the above provisions, the Minister of Ecology and Natural Resources issued Order 19 of 10.02.2004 *on Regulations on Information and Public Consultations on Genetically Modified Organisms* establishing procedures for regulation of public access to information regarding GMOs and mechanisms for influencing the discussion and drafting of decisions.

Biotechnology R&D institutional capacity

A number of laboratories and research units, whose activities have indirect relevance to new biotechnologies, operate within the framework of research institutes, including:

1. In the Academy of Sciences of Moldova:

. • *Genetic Research Institute:* Laboratory for molecular genome structure and gene formulation; Laboratory for genome instability and genetic engineering; Laboratory for non-traditional amelioration technologies; Laboratory for ontogenetics and cell engineering; Laboratory for induced genetic variability;

. • *Microbiology Research Institute:* Laboratory of enzymology; Laboratory for microbial products;

. • *Botanical Gardens (Research Institute):* Laboratory for embryology and biotechnology;

. • *Plant Physiology Research Institute:* Laboratory of ontogenesis biochemistry; Laboratory for cell structure and ultrastructure;

2. In the universities:

. • *State University of Moldova:* Chair of vegetal biology;
. • *State Agricultural University of Moldova*: Chair of genetics and plant improvement;

3. In Ministries and State Departments:

. • *Department of Standardization and Metrology:* Genetic expertise laboratory;
. • *National Wine and Viticulture Research Institute:* Laboratory of sparkling wines;
. • *Institute for Maize and Sorghum Research*: Laboratory of biochemistry, physiology and biotechnology;
. • *Northern Station for Project Implementation and Chemical Research:* Research laboratory;
. • *Institute of Fruit Trees Research*

A network of institutions subordinated to the Ministry of Agriculture and Food Industry carries out scientific research in the agricultural and food sector. These include 11 research institutes and 3 branches, 2 scientific research and production centers, 2 scientific research stations, and State Agrarian University of Moldova. Those institutions carry out research within the framework of technical and scientific research programs with co-participation of certain subdivisions within the Moldovan Academy of Sciences. Activities of state institutions in the field of agricultural research and development are coordinated by the respective subdivision within the Ministry of Agriculture and Food Industry. The following branch research institutes should be mentioned in connection with biotechnology research and agricultural plant selection: *Institute of Maize and Sorghum Research, Institute of Fruit Trees Research, Institute of Crop Science, and National Institute of Wine and Viticulture* within the Ministry of Agriculture and Food Industry.

Extensive research in the sphere of molecular biology and gene engineering is conducted in the laboratories of the *Genetics Research Institute of the Academy of Sciences, Laboratories of the State Moldavian University, State Agrarian University*. The laboratory for molecular genome structure and gene formulation has identified, isolated and cloned the regulatory sequences for certain reproductive system gene promoters of several superior plants (tomatoes, corn, melandrium). It has established the primary structure for those sequences and identified the homology of these regulatory element nucleotide sequences with genes of other organisms.

The research has resulted in the identification, cloning and characterization of the primary structure of the genes specific for reproductive processes in tomato and maize; identification and characterization of spontaneous and cultivated forms of plants based on the molecular analysis of the genome; creation of a library of molecular markers to test genotypes characterized by valuable economic indices; identification and localization of the genetic factors of plant resistance to thermal stress at the level of chromosomes and loci; elucidation of some regularities of the genetic control of quantitative indices in maize and tomato; production of the maize lines used as efficient haploid inducers; development of techniques to yield tomato transgenic plants through the use of exogenic DNA via interspecific hybridization and methods of pollen and haploid breeding of tomato and maize; development of the procedure of molecular diagnosis of some human viral diseases including hepatitis.

More than 1000 new cultivars of tomato, maize, durum winter and soft wheat, *triticales* etc. have been obtained. Naturally occurring biological regulators belonging to the class of steroidal glycosides have been isolated from plant resources and studied both chemically and biologically. Fifty new varieties and hybrids of maize, winter durum wheat, *triticale*, vegetable bean, peanut and gladiolus have been produced; 15 varieties have been registered in the Republic of Moldova.

Strengthen national infrastructure (reference laboratories) as needed for risk assessment and monitoring

With the entry into force of the Biosafety Law, the Ministry of Environment and Natural Resources in agreement with the Ministry of Education designated the reference laboratory of the State Moldavian

University, as the *National Biosafety Testing Center (NBTC)*. The laboratory should provide expertise with respect to those products, which are within their competence. The reference laboratory will also provide technical support to the biosafety system, risk assessment procedures and will be involved in the training activities.

Under this project, the reference laboratory, involved in research on GMO and equipped with basic instruments for DNA isolation, characterization and electrophoresis, will be strengthened with additional equipment needed (e.g. Quantitative PCR) to meet the requirements of the Cartagena Protocol to carry out inspections on GMOs and related products as follows:

- GMOs involved in transboundary movement
- Living modified plants released to the environment
- GMOs used in containment,
- Food products containing GMOs or where appropriate, products thereof (as referred to in Article 20(3c), Annex I (i) and Annex III (5) of the Cartagena Protocol)

The list of the equipment requested under this project is presented in Annex E.

C2.C PROJECT RATIONALE

The Republic of Moldova ratified the Cartagena Protocol on Biosafety by Law no. 1381-XV of 11 October 2002 and is in the process of its implementation. This project "Implementation of the National Biosafety Framework (NBF) for the Republic of Moldova" aims to support Moldova in meeting the obligations foreseen under the Protocol by providing the required capacity building for establishment of the legal and regulatory structures required to implement the Protocol. In particular, with respect to the requirements coming from Articles 1 and 2 of the Cartagena Protocol, the Republic of Moldova needs to set up a comprehensive framework for biosafety and to put in place appropriate legal and regulatory systems to assess any adverse effects on the environment and human health and ensure their adequate protection in the field of safe transfer, handling, and use of GMOs by means of proper infrastructure and use of human potential. Relevant regulations, based on the Cartagena Protocol on Biosafety and the EU Directives, will assure proper implementation of the National Biosafety Law.

Biosafety policy

The most important gaps of the current political framework have been identified:

- Political framework and strategies in the biosafety sphere are not very clearly determined or not sufficiently detailed;
- There is no integration of biosafety into other related strategies or policies.

As mentioned in the above, the principal document, which currently determines the policies and strategy in the field of Biosafety in the Republic of Moldova, is the National Strategy and Action Plan in the field of Biodiversity Conservation. Annual action plans are developed based on this document. In this context it is necessary to include the activities making possible completion of an integral National Biosafety Plan in the action plans for the next 2-3 years.

Regulatory regime for biosafety

In this context, the Law on Biosafety should be amended to bring it in compliance with the National Biosafety Framework concept. To these regulatory needs it would be necessary to introduce certain amendments to the Biosafety legislative framework regarding the following:

- Division of powers and functions of state authorities regarding:
  a) the process of examination and decision making;
  b) involvement of new institutional components – technical biosafety committees of the relevant ministries and departments, and development of their statutes;
- Procedures and methodologies for monitoring, inspection and control of the authorized GMO-

related activities;

- Introduction of a new chapter regarding the Biosafety Clearing House and Biosafety Register;
- Development of procedures and methodologies for testing and risk assessment/ management of biotechnology risks.

For an efficient application of the Biosafety Law it would be necessary to harmonize the current sectoral legislation with the law, as well as to develop a package of new regulations, which would ensure enforcement and implementation of this law. An Action Plan for amending branch regulations will be elaborated. To this end it would be necessary to develop detailed regulations, guidelines and manuals covering the necessities for workable Testing Laboratory; procedures and methodologies for risk assessment in situations of contained use; operation of technical committees within the relevant ministries and institutions and Technical Committee of the National Biosafety Committee; procedures and methodologies and requirements for packaging, labeling, storage and transportation; monitoring of the GMO activities; establishment of the state GMO inspection system (guidelines for relevant branches inspectorates); contents and maintenance of the National GMO Register including providing information to the BCH; approximation of customs procedures to the international requirements regarding GMO transboundary movement; simplify GMO imports/exports customs procedures with the neighboring countries and in the region; regulations regarding confidential information etc.

System for handling request for permits

According to the concept of the National Biosafety Framework, the decision-making system will be facilitated by a number of the national governmental authorities, depending on the intended use of GMOs.

The following regulations for internal use, guidelines and procedures will be developed to ensure implementation of the National Biosafety Framework: procedures for submission of notifications to the National Committee; preliminary examination of the submitted application; consultation with branch technical committees and the National Testing and Risk Assessment Center for assessment of potential risks for the environment and human health; as well as procedures for forwarding the application documentation package and the Opinion of the National Biosafety Committee to the National Environmental Authority for approval; issuance (or refusal) of authorization by the National Biosafety Committee; procedures for public consultation and public hearings.

The decision-making methods and procedures are supposed to be similar for situations of contained use, deliberate release into the environment and placing on the market of GMOS and products derived from GMOs.

Systems for monitoring of environmental effects and enforcement

To ensure *monitoring, inspection and control*, the State Inspectorates and Agencies with the relevant functions within the *Ministry of Ecology and Natural Resources, Ministry of Agriculture and Food Industry (MAFI), Ministry of Health Care and Social Protection* (MHCSP) will have the obligation to: perform monitoring, inspection and control of GMOs in situations of contained use, release to the environment and placing on the market; control the notifier's compliance with technical requirements and standards specified in the authorization; impose penalties according to the applicable laws in case of non-compliance with applicable standards; initiate the procedure for authorization withdrawal in exceptional situations.

For transportation of GMOs or products derived from such organisms, especially in *transboundary or transit movement*, it is necessary to develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements.

The national authorities in the field of environment, standards and metrology, and health care would have the task to develop methodologies for *transportation, labeling and packaging of GMOs*. The following actions will be taken to ensure fulfillment of these tasks:

. • *State Ecological Inspectorate* (SEI) (border-crossing offices) and the *Customs*

Control Department (CCD) will have the functions of border monitoring, inspection and control over compliance with the requirements for transportation, labeling and packaging of GMOs;

- Inside the country the functions of monitoring, inspection and control over transportation, labeling and packaging will be exercised by inspectorates within the *Ministry of Health Care and Social Protection, Standardization and Metrology Service (SMS), and State Ecological Inspectorate.*

The following actions are suggested to ensure control over *GMO imports/exports/transit*: to vest the function to perform customs procedures in respect of GMOs with the customs offices at border-crossing points; to establish inspection, control and monitoring services within the customs office to ensure control over imports/exports/transit of GMOs; to include a special section in the customs declaration for the transported goods for the purpose of declaration of presence or absence of GMOs; to ensure that information about transboundary movement of GMOs is provided promptly to the national and international biosafety institutions.

To comply with the requirements of the Convention and the Protocol, the following activities would be carried out to facilitate *testing and risk assessment*: provision of the *National Testing and Risk Assessment Center* (NTRAC) with the required analytical laboratory equipment; facilitate NTRAC for national and international accreditation; training of NTRAC specialists in the field of testing and assessment of risks presented by GMO-related activities; development of GMO sample databanks and access to reference material; development and approval of methodologies for testing and assessment of risks for the environment and human health; development of procedures for provision of testing and risk assessment services and for calculation of their costs.

Public information and participation

To implement the standards ensuring public participation in the field of biosafety, regarding the issue of risks connected with use of GMOs, the National Biosafety Committee must:

- ensure public access to decision-making process;
- ensure public awareness via mass media, seminars, books, brochures, etc.;
- create a special web page, inform the public about it and ensure its regular updates;
- establish permanent contacts and collaboration with the relevant accredited NGOs and other stakeholders with the purpose of involving them into the decision-making process and into the process of adequate public information;
- develop capacities to implement traceability and transparency;
- inform the public regarding the problems and risks associated with use of GMOs via mass media, workshops, publications, etc.;

Public information and consultations can be ensured via identification of the interested parties and development of their Register with due consideration of the fact that this category may include any party accredited in this field. Provisions of Government Decision no. 1153 of 2003 and Order of the Ministry of Ecology and Natural Resources no. 19 of 2004 must be implemented to this end. The process of information and consultation should be performed with assistance of the relevant nongovernmental sector.

In the absence of GEF contribution, the baseline scenario is as follows:

a. Implementation of Protocol

The scenario of the Cartagena Protocol implementation in Moldova in the absence of additional funding could be as follows:

In accordance with the National Biosafety Framework document, the development of the national biosafety policy should be one of the Government's priority activities, because it ensures the required

development of the regulatory, handling, monitoring and inspection mechanisms in accordance with the requirements of the Cartagena Protocol. The necessity to postpone the activities connected with the policy elaboration, approval, awareness raising, and enforcement would have a negative impact on the development of a comprehensive and functional biosafety framework and the national measures to meet the nation's obligations to the international community.

In the absence of additional financial support, the process of drafting, discussion and approval of industry regulations with the aim of their harmonization with the national Biosafety policy, Biosafety law, National Biosafety Framework and development of a second tier regulations, guidelines and manuals for public officers, farmers, researchers, local public administrators, business, private sector, etc. could be ineffective and time-consuming - in view of the current poor national capacities, low awareness, and lack of consensus between the government and the public, etc.

As regards the Cartagena Biosafety Protocol provisions, the existing national procedures for handling, risk assessment, decision-making, monitoring and registration have to be improved and made acceptable for business, private firms, farmers and consumers. Targeted information support, administrative framework, development and enforcement of procedures require additional funding to develop and put in place within the relevant period of time a comprehensive handling system, complete with the web-page and IP support for decision-making.

It should be mentioned that currently the GMO monitoring, inspection and control systems have not yet been developed in Moldova due to insufficient national capacities and practices. There is a critical need to assist the governmental efforts connected with the development of laboratory testing capacities, databases, GMO information exchange mechanisms, monitoring and reporting procedures as well as the emergency alert system and the BCH[1].

In view of the lack of national consensus between the public sector and the civil society as well as low understanding and awareness on the part of various stakeholders and target population groups, the lack of efficient public information and feedback practices, there is an urgent need to put in place the mechanisms for public access to biosafety information, public participation in the decision-making in the sphere of Biosafety and GMO use. Additional financing could ensure beneficial support for the successful implementation of the requirements stipulated in Article 20 of the Protocol regarding public participation.

b. The economic situation

The lack of a comprehensive Biosafety system in Moldova can cause certain difficulties which can affect the nation's economic development. It is true, for example, in the case of the imports and exports procedures regarding agricultural GMO crops, food and feed products obtained from GMOs. The complete lack or inefficiency of the national system for handling, risk assessment and monitoring could make possible deliberate release or unauthorized entry of GMOs into the country from abroad through exports. On the other hand, exports from Moldova could be blocked by the EU, OMM countries, or the countries where the national Biosafety system is in place. The absence of a comprehensive regulatory and handling system in connection with GMOs could produce a negative impact on the sustainable economic development in agriculture, block the farmers, researchers,

[1] The BCH project, which has just started its operational phase and is expected to finish by the end of 2006, is run in parallel to the implementation project and complements it. According to its MoU, the BCH project covers:

- Creation of the National BCH Center and Network consisting of a freely accessible National BCH Web-based Info Center and a set of stakeholder workstations. Procurement of equipment and software
- Development of the structure and content of the National Biosafety data and information compatible with BCH
- Interoperability and data exchange with the BCH Central Portal through the interoperability protocols and minimum standards (national database/XML) – "push/pull technology",
- Training and workshops for key stakeholders will cover data management, identification of and access to information for decision-making process, etc.

business circles access to the new biotechnologies and plant varieties with the potential to increase the agricultural production and effectiveness, and to contribute to poverty reduction.

Insufficient GMO laboratory-testing capacities will result in an inadequate level of monitoring, control and inspection, emergency alerting, risk assessment, etc.

At the same time, low-income consumer groups will not have the opportunity to buy food or feed containing GMOs at low price, thus supporting their needs and living standards.

Farmers wishing to grow GMOs on their private land will not be able to get approvals for GMO imports to grow, if the handling, risk assessment, authorization and monitoring systems are not in place. This could aggravate the situation with poverty in the rural area and vulnerable population groups.

c. Environmental and Development Viewpoint

If we consider that the two main crops grown in Moldova are corn and wheat (each covering 25% of the total arable land), the cultivation of these crops on small plots (1.5 ha per land owner on the average) could be affected by GMOs introduced in the country (in case of deliberate release). The traditional crops could be contaminated with GMOs via cross-pollination or via mixture of crops during harvest, transportation or storage.

Another potential factor of influence on the traditional biodiversity in agriculture is the possibility of penetration or permission to grow GMO soybeans. It should be mentioned that a neighboring country Romania grows 80% of its soybeans as GMO.

It is very important to maintain GMO-free areas in Moldova in the organic farming area, in accordance with the *Concept for agricultural organic production*.

Furthermore, GMO-free areas have to be maintained for experimental lots and seed stock production fields of the Research institutes operating within the Academy of Sciences and the Ministry of Agriculture for all kinds of crops (grain crops, corn, horticultural crops, grapes, etc.) in order to preserve and protect the gene collections and domestic crop varieties.

A possible negative effect on the natural biodiversity in the country could be produced by the release of the GM rape seeds (Brassica) into the environment and the possible cross pollination with the wild charlock (Synapsis arvensis) in the natural ecosystems. An unpredictable effect on the resistance and viability of this weed could provoke an expansion of this species and substitution of other species, affecting the natural structure and functionality of the ecosystems.

EXPECTED PROJECT OUTPUTS BY COMPONENT

Component A	**The National Biosafety Policy for Moldova** A comprehensive National Biosafety policy (NBP) is enforced and used as basis for the development of an adequate national regulatory regime and institutional framework **by 2009**
Outputs	**Output A.1:** Strengthened national Biosafety policy, drafted as a National Biosafety Action Plan (NBSP) to guide the implementation of the Cartagena Protocol, National Biosafety Framework, National Biodiversity Strategy, and other national and international requirements **Action A.1.1:** Developed Draft National Biosafety Action Plan, used as a policy paper in conformity with national and international requirements **Action A.1.2:** A macroeconomic assessment survey provided, quantifying economic benefits and incremental risks/costs associated with the implementation of the National Biosafety Action Plan to the national economy and social development in Moldova

	Action A.1.3: A 4-day Workshop with key decision-makers, NCC members, parliamentarians, and public to discuss the Draft NBP, for feedback and proposals for the strategy and the economical assessment conclusions. The workshop will involve 40 participants from the Parliament, government, sectorial bodies, stakeholders, public, NGOs, farmers etc. **Action A.1.4:** Consultation of the NBAP with the main decision-makers of the government in the pre-approval process **Action A.1.5:** Submit Draft NBAP to the Government for approval as a National Biosafety Policy. **Output A.2:** Strengthened public and political support for Biosafety policy implementation **Action A.2.1:** Training on Biosafety policy for decision makers, NCC members, parliamentarians, public, etc. A 2-day training on the consultative process to establish dialogue and receive feedback for improvement of the strategy for 20 participants. **Action A.2.2:** Meetings with specific groups of stakeholders in different districts and communities. 5 one-day workshops (Northern, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of farmers, local politicians and authorities, consumers etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy. Total number of participants attracted – about 125 persons
Component B	**The National Regulatory Regime (Legislation)** Strengthened national regulatory regime in line with CP, NBF and biosafety policy **by 2010**
Outputs	**Output B.1:** The National Biosafety Law reviewed, amended and harmonized with the provisions of the Cartagena Protocol, other international requirements related the institutional set up for the inspection, monitoring and control of GMOs, as well as with the legal requirement for information needed for the BCH and GMOs Register **Action B.1.1**: Set-up an Expert Task force and prepare an Action plan for reviewing, amending and harmonizing the National Biosafety Law to meet the requirements of the Cartagena Protocol and the NBF **Action B.1.2**: Revision and amendment of the Biosafety law by expert Task force in order to comply with the national biosafety policy and international obligations **Output B.2:** Branch legislation revised and amended for the purpose of its harmonization with the Cartagena Protocol, national Biosafety policy and law **Action B.2.1:** Draft suggestions and amendments to harmonize branch laws related to the the requirements of the Cartagena Protocol, Biosafety policy and Biosafety law and international requirements **Action B.2.2:** A 1-day Workshop for 30 participants to discuss these amendments and their complementation to the laws related to the national biosafety regulations **Output B.3:** Secondary regulations and guidelines, required by the law, developed and in force ensuring implementation of the Law **Action B.3.1a:** Drafting secondary regulations and guidelines required for the implementation of the Biosafety Law and NBF **Action B.3.1b:** Develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement **Action B.3.2** Organize a 4-day training workshop for 50 participants such as members of the Expert Task force, decision makers from related governmental bodies and parliamentarians, legal experts, politicians and NGO representatives to elaborate on the Action plan, national and branch regulations, secondary level regulation, recommendation from the Task force, and startegies to promote consensus on the biosafety requirements for branch regulation, secondary regulations

	Action B.3.3 Discuss and consolidate recommendations on the national Action plan, national and branch regulations, secondary level regulation at the two-day training workshop organized for the Expert Task Force, government officers, legal experts, politicians and NGO representatives (50 participants)
Component C	**Administrative system for handling requests (comprising administrative processing, RA/RM, and decision-making etc)** Moldova has a functional national administrative system for handling requests and decision-making as well as performing risk assessment and management associated to LMOs **by 2009**
Outputs	**Output C.1:** Functional risk assessment system in place **Action C.1.1:** Update national Roster of experts for Risk Assessment **Action C.1.2:** Development of clear national procedures and guidelines for Risk assessment. **Action C.1.3** Establishment of Technical committees for risk assessment as well as a body for decision making with members from national authorities related to agriculture and food industry, health care, and from the Academy of Sciences of Moldova **Action C.1.4:** Development of a check-list for Risk Assessment practitioners **Action C.1.5:** Conducting a 5-day training workshop on Risk assessment for 30 decision-makers, researchers, experts and personnel (training provided by invited external experts) **Output C.2:** Strengthened capacities and tools for a functional decision-making system and system for administrative processing **Action C 2.1:** Development of administrative procedures for handling notifications and requests for permits, including a manual for the administrative handling of requests **Action C 2.2:** Development of an administrative database **Action C 2.3:** Development of an administrative **s**ystem to track dossier, and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities **Action C 2.4 :** Development of administrative procedures and an operational manual for the submission, examination and consultation of notifications and decision making **Action C 2.5:** Development of an administrative system for the protection of confidential information **Action C.2.6:** Establishment of an electronic National GMOs Register **Action C.2.7:** Two three-day training workshops on notification handling and decision making process in compliance with international obligations organised for decision-makers from involved ministries and departments (for 30 participants) **Action C.2.8:** Development of guidelines and rules for emergencies and remediation, including TORs for responsible persons, definition of emergency response procedures, identification of the Authority and staff to be contacted. **Action C.2.9:** One-day training workshop for emergency operations and risk management for all stakeholders and officials. (20 participants)
Component D	**The National Systems for Monitoring and Enforcement** Consolidated and fully functional national system for "follow-up" activities, namely monitoring of environmental effects and enforcement **by 2010**
Outputs	**Output D.1:** Monitoring, inspection and control procedures and capacities built and in place **Action D.1.1:** Clarify responsibilities and duties of different agencies to enable them to carry out their responsibilities for monitoring, inspection and control **Action D.1.2:** A four-day training course on monitoring, inspection and control procedures for 30 trainers: officials of different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services, Standards and Metrology, selected on the basis of their background and current duties **Output D.2:** Strengthened facilities and capacities for laboratory testing

	Action D.2.1: Procurement of accessories and essential reagents needed for the operation of the purchased main GMO testing equipment carried out. **Action D.2.2**: Two four-day capacity-building training courses on laboratory testing and risk assessment research methodologies for 10 laboratory researchers and technicians **Output D.3:** Establishment of requirements for packaging, labelling, storage and transportation, transboundary or transit movement control of GMOs. Strengthened capacity on the control of import/export/transit of GMOs **Action D.3.1:** Establishment of procedures for custom control on import/export/transit of GMOs **Action D.3.2:** Three-day training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement. Training targetted for stakeholders, officials, custom services, inspections, risk management personnel, relevant businessmen, farmers, researchers public, ONGs etc. (40 participants)
Component E	**The National Mechanisms for Public Awareness, Education and Participation** Consolidated and fully functional system for public awareness and participation in decision-making **by 2010**
Outputs	**Output E.1:** Strategy for public awareness in place, together with an enhanced and efficient mechanism for public consultations developed and implemented, to ensure public participation in decision-making, as a component part of the Biosafety strategy **Action E.1.1:** Development of guidelines and manuals on public consultations and participation **Action E.1.2:** Two three-day workshops on the importance of public consultations and information exchange, including explanation of legislation, systems for public participation etc, for biosafety for 70 government officials, journalists, scientists and NGO representatives, consumers associations, farmers, press, civil society etc. **Output E.2:** Increased public awareness, Best practices on Public participation learned and disseminated **Action E.2.1:** Improvement of the national biosafety website, including the establishment of a public participation/dialogue platform **Action E.2.2:** Production and dissemination of outreach materials, training materials, workshop summaries, technical manuals, publications in mass media, educational videos, brochures, etc.

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

Details shown in log-frame, attached as an annex B.

Planned activities to achieve outcomes

- **COMPONENT A . THE NATIONAL BIOSAFETY POLICY FOR MOLDOVA (TOTAL COSTS: USD 62,710.00; GEF: USD 41, 710. 00; GOVERNMENT: USD 21, 000.00)**

Action A.1.1: Elaboration of Draft National Biosafety Action Plan, as a policy paper in conformity with national and international requirements
Total costs: USD 30,000.00 (GEF: USD 20,000. 00; Government: USD 10,000.00)

Action A.1.2: Conduct a Macroeconomic assessment survey, quantifying the economic benefits and incremental risks/costs associated with the implementation of the National Biosafety Action Plan to the national economy and social development in Moldova
Total costs: USD 7,500.00 (GEF: USD 5,000. 00; Government: USD 2,500.00)

Action A.1.3: Organize a four-day workshop with key decision-makers, NCC members, parliamentarians and public, to discuss the Draft NBP for feedback and proposals for the strategy, and the economic assessment conclusions. The workshop will involve 40 participants from the parliament, government and sectorial bodies, stakeholders, public, NGOs, farmers etc.

Total costs: USD 5750.00 (GEF: USD 4240. 00; Government USD 1,500.00)

Action A.1.4: Organize a consultation on the NBAP with the main decision-makers of the government in the pre-approval process
Total costs: USD 4,000.00 (GEF: USD 2,000. 00; Government; USD 2,000.00)

Action A.1.5: Submitting the Draft NBAP to the Government for approving
Total costs: USD 6,000.00 (GEF: USD 3,000. 00; Government; USD 3,000.00)

Action A.2.1: Training on Biosafety policy for decision makers, NCC members, parliamentarians, public, etc
A 2-day training on the consultative process to obtain feedback and suggestion to improve the strategy (20 participants)
Total costs: USD 3260.00 (GEF: USD 2260. 00; Government; USD 1,000.00)

Action A.2.2: Organize a Meeting with specific groups of stakeholders in different districts and communities. 5 one-day workshops (Northern, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of farmers, local politicians and authorities, consumers etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy. Total number of participants attracted – about 125 persons
Total costs: USD 6,210.00 (GEF: USD 5,210. 00; Government USD 1,000.00)

COMPONENT B. THE NATIONAL REGULATORY REGIME (LEGISLATION) (TOTAL COSTS: 70, 020.00; GEF: 50, 020. 00; GOVERNMENT: 20, 000.00)

Action B.1.1: Setting-up an Expert Task force and prepare an Action plan for reviewing, amending and harmonizing the National Biosafety Law to meet the requirements of the Cartagena Protocol and the NBF
Total costs: USD 4,000.00 (GEF: USD 3 000, 00; Government: USD1, 000.00)

Action B.1.2:
Revising and amending the Biosafety Law by an Expert Task Force in order to comply with the national biosafety policy and international obligations
Total costs: USD 4,000.00 (GEF: USD 3,000. 00; Government: USD 1,000.00)

Action B.2.1: Elaboration of the Draft suggestions and amendments to harmonize branch laws related to the national biosafety with the requirements of the Cartagena Protocol, Biosafety policy and Biosafety Law and international requirements
Total costs: USD 25,500.00 (GEF: USD 18,000.00; Government: USD 7,500.00)

Action B.2.2: Organize a 1-day Workshop for 30 participants to discuss the above amendments and completion to the law related to the national biosafety regulations
Total costs: USD 1,990.00 (GEF: USD 1,490. 00; Government: USD 500.00)

Action B.3.1a: Elaboration of the Drafts for secondary regulations and guidelines required for the implementation of the Biosafety Law and NBF
Total costs: USD 19,500.00 (GEF: USD 15,000. 00; Government: USD 4,500.00)

Action B.3.1b: Elaboration of regulations specifying requirements for transportation, labeling and packaging and to harmonize these at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement
Total costs: USD 2,500.00 (GEF: USD 2,000. 00; Government: USD 500.00)

Action B.3.2
Organize a 4-day training workshop for 50 participants, comprising members of the Expert Task Force, decision makers from branch governmental bodies and parliamentarians, legal experts, politicians and NGO representatives on discussion on development of branch regulations, the national Action plan, secondary level

regulation elaboration of the Task force and on ways to promote consensus regarding the biosafety requirements for branch regulation, secondary regulations
Total costs: USD 4,550.00 (GEF USD 3550. 00; Government USD 1,000.00)

Action B.3.3
Conduct a 2-day workshop to discuss recommendations received and reflect these in the national Action plan , national and branch regulations, and secondary level regulation. The 50 target participants will include members of the Expert Task Force, government officers, legal experts, politicians and NGO representatives.
Total costs: USD 4980.00 (GEF: USD 3,980. 00; Government; USD 1,000.00)

Component C. ADMINISTRATIVE SYSTEM FOR HANDLING REQUEST, INCLUDING RISK ASSESSMENT AND RISK MANAGEMENT, ADMINISTRATIVE PROCESSING AND DECISION-MAKING (TOTAL COST: USD 96,130.00; GEF: USD 65,130. 00; Government: USD 31,000.00)

C.1 Risk assessment and risk management

Action C.1.1: Updating of Roster of experts for Risk Assessment
Total costs: USD 7,500.00 (GEF: USD 5,000. 00; Government: USD 2,500.00)

Action C.1.2: Preparing national procedures and guidelines for Risk assessment.
Total costs: USD 6,000.00 (GEF: USD 3,000. 00; Government: USD 3,000.00)

Action C.1.3 Establishing a Technical committee for risk assessment and opinion for decision making with members from national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova
Total costs: USD 4,500.00 (GEF: USD 3,000. 00; Government: USD 1,500.00)

Action C.1.4: Preparation of check-lists for Risk Assessment practitioners
Total costs: USD 4,500.00 (GEF: 3,000. 00; Government: 1,500.00)

Action C.1.5: Organize a Five-day training workshop on Risk assessment for 30 decision-makers, researchers, experts and personnel (training provided by the invited external experts)
Total costs: USD 11,240.00 (GEF: USD 9,240. 00; Government: USD 3,000.00)

C.2 Administrative processing, including guarding confidential information, emergency measures, and decision-making

Action C 2.1: Establishment of administrative procedures for handling notifications and requests for permits, including a manual for the administrative handling of requests
Total costs: USD 7,000.00 (GEF: USD 5,000. 00; Government: USD 2,000.00)

Action C 2.2: Preparation of an administrative database
Total costs: USD 7,500.00 (GEF: USD 5,000. 00; Government: USD 2,500.00)

Action C 2.3: Establishment of administrative **s**ystems to track dossier, and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities
Total costs: USD 7,500.00 (GEF: USD 5,000. 00; Government: USD 2,500.00)

Action C 2.4: Establishment of administrative procedures and an operational manual for the submission, examination, consultation on notifications and decision-making
Total costs: USD 9,000.00 (GEF: USD 6,000. 00; Government: USD 3,000.00)

Action C 2.5: Establishment of an administrative system for the protection of confidential information
Total costs: USD 4,500.00 (GEF: USD 3,000. 00; Government: USD 1,500.00)

Action C.2.6: Establishment of an electronic National GMOs Register
Total costs: USD 7,500.00 (GEF: USD 5,000. 00; Government: USD 2,500.00)

Action C.2.7: Organize two 3-day training workshops on notification handling and decision making process in compliance with international obligations organized for decision-makers from involved ministries and departments for 30 participants
Total costs: USD 12,850.00 (GEF: USD 8,850. 00; Government: USD 4,000.00)

Action C.2.8: Preparation of guidelines and rules for handling emergencies including emergency response plan, and remediation, development of TORs for responsible persons.
Total costs: USD 4,000.00 (GEF: USD 3,000. 00; Government: USD 1,000.00)

Action C.2.9: Organize a 1-day training workshop for emergency operations for all stakeholders, officials, and risk management personnel (20 participants)
Total costs: USD 1,540.00 (GEF: USD 1,040. 00; Government USD 500.00)

COMPONENT D. THE NATIONAL SYSTEMS FOR MONITORING AND ENFORCEMENT. (TOTAL COSTS: USD 87,790.00; GEF: USD 66,790.00; GOVERNMENT: USD 21,000.00)

Action D.1.1: Clarifying the responsibilities and duties of different agencies to enable them to carry out their responsibilities for monitoring, inspection and control
Total costs: USD 8,000.00 (GEF: USD 6,000. 00; Government: USD 2,000.00)

Action D.1.2: Organize a 4-day training course on monitoring, inspection and control procedures for 30 trainers: officials of different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services, Standards and Metrology, selected on the basis of their background and current duties
Total costs: USD 6,460.00 (GEF: USD 4,820. 00; Government: USD 1640.00)

Action D.2.1: Procurement of accessories to equipment and relevant reagents required for the operation of the purchased main GMO detection equipment necessary for the testing laboratory
Total costs: USD 48,400.00 (GEF: USD 38,400. 00; Government: USD 10,000.00)

Action D.2.2: Organize two 4-day capacity-building training courses on laboratory testing and risk assessment research methodologies for 10 laboratory researchers and technicians
Total costs: USD 10,080.00 (GEF: USD 6,720. 00; Government: USD 3,360.00)

Action D.3.1: Establishing the procedures for custom control over import/export/transit of GMOs
Total costs: USD 8,000.00 (GEF: USD 6,000. 00; Government: USD 2,000.00)

Action D.3.2: Organize a 3-day Training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement. Training focused for stakeholders, officials, custom services, inspections, personnel responsible for risk management, businessmen, farmers, researchers, the public, NGOs etc. (40 participants).
Total costs: USD 6,850.00 (GEF: USD 4,850. 00; Government: USD 2,000.00)

Component E. The National Mechanisms for Public Awareness, Education and Participation (Total costs: USD 117,500.00; GEF: USD 92,500. 00; Government: USD 25,000.00)

Action E.1.1: Preparation of guidelines and manuals for public consultations and participation
Total costs: USD 10,000.00 (GEF: USD 10,000. 00; Government: USD 0)

Action E.1.2: Organize two 3-day workshops on the importance of public consultations and information exchange, including explanation of legislation, systems for public participation etc, for biosafety for 70 government officials, journalists, scientists, NGO representatives, consumers associations, farmers, press, civil society etc.
Total costs: USD 22,500.00 (GEF: USD 16,500. 00; Government: USD 6,000.00)

Action E.2.1: Improvement of the national biosafety website, including setting a public participation e-platform
Total cost: USD 15,000.00 (GEF: USD 10,000. 00; Government: USD 5,000.00)

Action E.2.2: Preparation and dissemination of outreach materials, training materials, workshop summaries, technical manuals, publications in mass media, educational videos, brochures, etc.

Total costs: USD 70,000.00 (GEF: USD 56,000. 00; Government: USD 14,000.00)

Total Component A-E, Project activities: Total costs (TOT: USD 434,150.00: GEF: USD 316,150.00; Government: USD 118,000.00)

Component F, project coordination: Total costs (TOT: USD 159, 200.00: GEF: USD 132,200.00; Government: USD 27, 000.00)

Component G, other project support: Total costs (TOT: USD 96, 000: GEF: USD 74, 000.00; Government: USD 2,000.00)

Project management, including institutional set-up, staffing etc.

	Project coordination	GEF contribution	Government contribution
	National Project Manager (NPM)	38400	
	Two Project Assistants	38 400	
	One staff (half time) in charge of monitoring and evaluation issues and financial reporting	14 400	
	National Coordination Committee (NCC) Meetings, NCC travels	20 000	12 000
	Equipment and premises component (expendable and non-expendable equipment)	5 000	10 000
	Miscellaneous and others	12 000	5 000
	Audit	4 000	
	Total: project coordination	***132 200***	***27 000***
	Other project support Printing of reports and published work	10 000	2 000
	Translation	4 000	
	Communication costs	10 000	
	Technical support	70 000	
	Total: project support	***94 000***	***2 000***
	Total	**226, 200.00**	**29, 000.00**

Total costs (TOT: USD 689, 350.00: GEF: USD 542, 350. 00; Government; USD 147, 000.00)

Summary table of planned training activities in Moldova

Subject	**Duration**	**Number of participants**	**Type participants**	**Budgetary estimates**
Action A.1.3: Workshop with key decision-makers and public to discuss the Draft NBP, feedback and proposals to the strategy and the economic assessment conclusions.	4 days	40 participants	Parliament, government, decision-makers, NCC members, sectorial bodies, stakeholders, public, NGOs,	1.Venue rent- 4dx200$=800$ 2.Consumables-40pX9,25$X1d=370$ 3.Coffee break-4dX40pX4$=640$ 4.Lunch- 4dX40p.X13$=2080$ 5.Car rent 6dX50$=300$ 6.Per diem/participants- 10 parX.30$X4d=1200$ 7.Travel/participants to seminar-

			farmers ,public etc.	10pX10$=100$ 8.Honorarium for experts- 5 expX50$X4d=500$ **Subtotal Workshop=6090$** 9. *All taxes=410$ **TOTAL=6500$**
Action A.2.1: Meetings with specific groups of stakeholders in different districts and communities. (Northern, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy	5 one-day workshops	Total about 125 persons	farmers, local politicians and authorities, consumers	1 Venue rent-5dx100$=500 2.Consumables25pX8$X5d=1000$ 3.Coffee break-5dX25pX4$=500$ 4.Lunch- 5dX25p.X13$=1625$ 5. Car rent-5dX100 $=500$ 6. Per diem/experts-3expX.30$X5d=450$ 7.Honorarium for experts- 3expX30$X5d=450$ **Subtotal Workshop=5020$** 8.All taxes=190$ **TOTAL= 5210$**
Action B.2.2: Workshop to discuss these amendments and completion of the laws related to the national biosafety regulations	one-day	30 participants	Parliament, government, decision-makers, sectorial bodies, stakeholders, public, NGOs, farmers etc.	1.Venue rent- 1dx150$=150$ 2.Consumables-30pX8$X1d=240$ 3.Coffee break-1dX30pX4$=120$ 4.Lunch- 1dX30p.X13$=390$ 5.Car rent-1dX50$=50$ 6. Per diem/participants - 5parX.30$X1d=150$ 7.Travel/participants to seminar 5par.x10$=50$ 8.Honorarium for experts- 5expX50$X1d=250$ **Subtotal Workshop=1400$** 9..All taxes=90$ **TOTAL= 1490$**
Action B.3.2 A training workshop to discuss the Action Plan of Task Force on national and Branch regulations, secondary regulation and on promotion of consensus regarding biosafety requirements	Four- days	50 participants	Task force, decision makers from branch governmental bodies, parliamentarians , legal experts, politicians and NGO representatives	1.Venue rent- 4x200$=800$ 3.Consumables-50pX8$X2d=800$ 4.Coffee break-4dX50pX4$=800$ 5.Lunch- 4dX50p.X13$=2600$ 6.Car rent-4dX50$=200$ 7. Per diem/participants - 10par.X30$X3d=900$ 8. Travel/participants to seminar-10parx10=100$ 9.Honorarium for experts- 5expX50$X4d=1000$ **Subtotal Workshop=7200$** 10 All taxes=330$ **TOTAL=7530$**
Action C.1.5:	Five- days	30	decision-	1.Venue rent- 5dx150$=750$

Training workshop on Risk assessment (training provided by the invited external experts)		participants	makers, researchers, experts and personnel	2.Consumables 30pX10$X1d=300$ 3.Coffee break-5dX30pX4$=600$ 4.Lunch- 5dX30p.X13$=1950$ 5.Car rent -5dX50$=250$ 6.Honorarium for experts- 4expX50$X5d=1000$ 7. for external expert: -travel= 600$ -hotel costs=80$ X7d=560$ -per diem 171$X8d=1368$ - fee 250$x6d=1500$ **subtotal expert -=4028$** **Subtotal Workshop=8880$** 8.All taxes=360$ **TOTAL= 9240$**
Action C.2.7: Training workshops on notification handling and decision making process in compliance with international obligations	two 3 -day	30 participants	decision-makers from involved ministries and departments	1.Venue rent 2x3dx150$=900$ 2.Consumables 30pX8$X2x3d =1440$ 3.Coffee break2x3dX30pX4$ =900$ 4.Lunch- 2x3dX30p.X13$=2340$ 5.Car rent-2x3dX50$=300$ 6. Per diem/participants - 5parX.30$X2x3d=900$ 7 Travel/participants to seminar 5parx10$=50$ 8. Honorarium for experts- 5expX50$X2x3d=1500$ **Subtotal Workshop=8330$** 9.All taxes=520$ **TOTAL= 8850$**
Action C.2.8: Training workshop for emergency operations	one-day	20 participants	all stakeholders, officials, risk management staff	1.Venue rent- 1dx150$=150$ 2.Consumables-20pX8$X1d=160$ 3.Coffee break-1dX20pX4$=80$ 4.Lunch- 1dX20p.X13$=260$ 5. Car rent-1dX50$=50$ 6.Honorarium for experts- 5expX50$X1d=250$ **Subtotal Workshop=950$** 7.All taxes=110$ **TOTAL= 1040$**
Action D.1.2: Training course on monitoring, inspection and control procedures	A four- day	30 trainers	officials from different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services,	1.Venue rent- 4dx150$=600$ 2.Consumables-30pX8$X1d=240$ 3.Coffee break-4dX30pX4$=480$ 4.Lunch- 4dX30p.X13$=1560$ 5.Car rent 4dX50 $=200$ 6.Per diem/participants - 5par.X.30$X4d=600$ 7.Travel/participants to seminar

			Standards and Metrology, selected on the basis of their background and current duties	5parx10$=50$ 8.Honorarium for experts- 4expX50$X4d=800$ **Subtotal Workshop=4530$** 9.All taxes=290**$** **TOTAL= 4820$**
Action D.2.2: Capacity-building training courses on laboratory testing and risk assessment research methodologies	two 4 -day	10 participants	Laboratory researchers and technicians	1.Consumables10pX8$X2x4d=640$ 2Equipment rent-2x4dx200$=1600$ 3.Coffee break-2x4dX10pX4$=320$ 4.Lunch- 2x4dX10p.X13$=1040$ 5.Car rent-8dX50$=400$ 6 .Honorarium for experts- 5expX50$X2x4d=2000$ **Subtotal Workshop=6000$** 7.All taxes=720**$** **TOTAL= 6720$**
Action D.3.3: Training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement	Three -days	40 participants	Stakeholders, officials, custom services, inspections, risk management staff, businessmen, farmers, researchers public, NGOs etc	1.Venue rent- 3dx150$=450$ 2.Consumables-40pX10$X1d=400$ 3.Coffee break-3dX40pX4$=480$ 4.Lunch- 3dX40p.X13$=1560$ 5.Car rent-3dX50$=150$ 6.Per diem/participants - 10parX.30$X3d=900$ 7. Travel/participants to seminar- 10par.x10=100$ 8.Honorarium for experts- 4expX50$X3d=600$ **Subtotal Workshop=4640$** 9.All taxes=210$ **TOTAL= 4850$**
Action E.1.2: Workshops on the importance of public consultations and information exchange, including explanation of legislation, systems for public participation etc, for biosafety	two 3-day	70 participants	Government officials, journalists, scientists and NGO representatives, consumers' associations, farmers, press, civil society etc	1.Venue rent- 2x3dx200$=1200$ 2.Consumables- 70pX8$X2x3d=3360$ 3.Coffee break- 2x3dX70pX4$=1680$ 4.Lunch- 2x 3dX70p.X13$=5460$ 5.Car rent-2x3dX50$=300$ 6.Per diem/participants – 15pX30$X2x3d=2700$ 7. Travel/participants to seminar- 15px10$=150$ 8.Honorarium for experts- 4expX50$X\2x3d=1200$ **Subtotal Workshop=16050**$ 9.All taxes=450**$** **TOTAL= 16500$**
Subtotal workshops				**69,090.00**
Taxes*				**3,360.00**

Bank fees**			**1,210.00**
TOTAL Workshops			**73,960.00**

C.3 Sustainability

- **Institutional sustainability**

Moldova has officially committed itself to meet the obligations of the Cartagena Protocol on Biosafety by its ratification on 4th March 2003. This commitment was strengthened by the elaboration of the NBF and the approval of the *National Biosafety Law* no. 755-XV, promulgated by the Moldovan Parliament on 21 December 2002.

Based on this Law, an institutional set up for biosafety is currently in place to advise the Government. It comprises a National Biosafety Committee, with a multi-stakeholder representation, and a Biosafety National Focal Point, promoting stakeholders cooperation, consultation and participation in decision-making. The reference GMOs testing laboratory, already designated, will be fully operational once it is equipped and the staff is appropriately trained (in quantitative and qualitative analysis). Furthermore, an institutional coordination mechanism between different institutions for biosafety is in place and run by the Competent Authority, namely the Ministry of Ecology and Natural Resources.

The NCC, already established during the Development project, will be retained for the present project. This will ensure continuity between the two phases of development and the implementation of the NBF as well as efficiency in steering activities at financial, technical and operational level. The capacity built during the development project can be further enhanced by this project, and therefore ensure sustainability.

- **Financial and political sustainability**

According to the Biosafety Law, Moldova has specific budget allocations and a fee based system to ensure financing of the biosafety activities beyond the life of the project. The fee is expected to cover the costs of the biosafety administration, the functioning of the references laboratories and the costs of risk assessment.

As political support is needed to maintain biosafety as priority for the country, the involvement of high-level decision-makers is considered key to success. In order to create the much needed involvement, the project plans a series of meetings and training activities to involve parliamentarians and government officials in the elaboration of the National Biosafety Action Plan and in integrating biosafety considerations into existing sectoral policies. This will guarantee political and financial sustainability to the implementation and regular functioning of the entire national biosafety framework beyond project life.

- **Operational sustainability**

Once the regulatory regime is amended and completed, laws, regulations as well as the enforcement system will ensure the operation of the handling, monitoring and risk assessment systems.

To be cost effective, operational sustainability will be addressed by using existing enforcement mechanisms, but to be strengthened by additional appropriate training. In this respect, a series of workshop and trainings will be organized during the project execution that will contribute to increased understanding of operational process and will ensure sustainability. In addition, participants from different groups of stakeholders, namely responsible institutions, non-governmental and private sectors, farmers, politicians, decision-makers, researchers, local communities, general public, youth

and women will also be involved in the public awareness and training activities. A greater general awareness and appreciation of biosafety will also enhance sustainability.

- **Environmental sustainability**

Development of this project will improve the sustainability of social and economic development, which will have a positive impact on the environment through the promotion of biodiversity conservation, resulting from the harmonization of the National Biosafety policy with several existing national policies. These include the policies on Agriculture, Environmental Protection, Environmental Security and Nature Conservation, Research and Development, etc. Recognizing that the quality of the environment is intrinsically related to the quality of the environment, the project activities will also contribute to measures to address environmental health whilst at the same time, contribute to poverty reduction in the country.

Main Risks associated with the implementation of this project can be described in the following general categories: need to amend and complete current legislative framework; capacity building; public information and participation.

Mitigation measures: sustainability of the project activities will be determined by a growing interest and the responsibilities taken by the decision-makers and the public in the field of biosafety. In order to minimize the above risks, the project will organize a series of public awareness meetings, training workshops and debates as well as consultations with main stakeholders. In addition brochures and manuals will be prepared to improve the understanding of the biosafety needs of the country and provide operational guidance beyond the project life.

Detailed identification of the risks and related risk - management measures is presented in the logframe, Annex B.

Replicability

The project benefits from the lessons learned through the demonstration projects. It will not only make use of the technical manuals, methodologies, training tools, approaches and structures developed so far, but will also adopt/adapt those produced from the demonstration projects. Additionally, this project will have a strong potential of replicability within the country; at district and community levels, and outside the country, especially in countries from the region like Romania, Ukraine, Georgia, Armenia etc. Under this project, Moldova intends to improve its website and use it as a main vehicle for project information and dissemination and to post the main project outcomes (manuals, guidelines, books, explicative dictionary, brochures, training materials, etc) for use by the wider audience, such as teachers and students, academia, etc. thus promoting replicability.

Two meetings of the national project coordinators of the demonstration countries were carried out in January 2004 and in March 2005. Judging by the success of these meetings in terms of 1) getting insight to other countries day-to-day practices, 2) promoting exchange of information and 3) sharing of lessons learned - another similar initiative is being considered for 2006. This NPC meeting will be extended to this project.

The Monitoring and Evaluation plan (Annex F) of the project includes indicators to measure potential of replication.

C. 5 Stakeholder involvement

Stakeholder involvement in Moldova started with the implementation of the "Development of the National Biosafety Framework in the Republic of Moldova" project, which helped to identify the

main stakeholders whose invaluable contributions were of great assistance in more precise identification of project goals and activities.

The main stakeholders include governmental organisations, such as the *Ministry of Ecology and Natural Resources, Ministry of Agriculture and Food Industry, Ministry of Economy and Commerce* (MEC), *Ministry of Health Care and Social Protection, Ministry of Education, Youth and Sport* (MEYS), *Ministry of Justice (MJ), Customs Control Services (CCS), Standardization and Metrology Services SMS)*, *National Statistical Bureau (NSB), Agency for Forestry "Moldsilva" (AF), Licensing Chamber* (LC) etc. Staff from these ministries and departments will provide their expertise and infrastructure to the project.

Furthermore, the stakeholders will include the *Academy of Sciences* and research institutes. There are several research institutions in Moldova, such as the *Institute of Genetics, Institute of Plant Physiology, and Institute of Microbiology* within the Academy of Sciences as well as several industry-specific institutes (*Institute of Wine and Viticulture, Institute of Vegetable Crops, Institute of Maize and Sorghum*), the *State University of Moldova* and the *State Agrarian University*, which conduct scientific research in the field of biotechnology, tissue cultivation methods, virus-free plant reproduction, production of specific microbiological samples, etc. The scientific community will play an important role in the implementation of the National Biosafety Framework by providing scientific expertise for formulation of the implementation regulations.

Other stakeholder groups include food industry companies directly involved with food safety issues, broader business community desiring to enter global markets and therefore having to comply with international market requirements in respect of biosafety, farmers and farmer associations who should be made aware of such issues as the possibility of biological contamination and its possible consequences for marketability of their products, local public administration authorities in charge of ensuring compliance with laws, regulations and standards at the local level, communities, consumer associations, associations of women and youth, NGOs, and in particular the environmentalists.

Efforts to improve public awareness on biosafety issues during implementation of the project "Development of the National Biosafety Framework in the Republic of Moldova" led to more active NGO involvement in the decision-making process and improvement of the NBF. Informed decisions regarding implementation of the NBF will take into consideration comments and suggestions submitted by NGOs and public concerns. The NBC will consider and use the suggestions submitted during public discussions, consultations and round table discussions.

Table 1: Major Stakeholders and their Participation

STAKEHOLDERS	**Type of involvement**
Parliamentarians, decision-makers:	
The Parliament of the Republic of Moldova adopts laws and ensures uniformity of the legal and regulatory framework in all the country, approves principal directions for the country's domestic and foreign policies, including those in the sphere of biosafety, facilitates and directs the activities of the National Committee for Ecology and Territorial Development.	Examination and adopting of policy and legislation
Parliamentary Commission for Public Administration, Ecology and Territorial Development is the executive body of the Parliament, in charge with the environmental issues, including the Biosafety concerns	
Ministries and Departments:	
National Biosafety Authority - Ministry of Ecology and	Preparing legislation and implementing guidelines

Natural Resources is the national environmental and natural resources authority responsible for: (i) development and implementation of policies and strategies regarding environment and natural resources; (ii) development of draft laws and regulations, standards, requirements, other regulatory documents; (iii) implementation of environmental management, monitoring and control; (iv) development of biodiversity protection strategies and actions jointly with other stakeholders. It also has the function to ensure fulfillment at the national level of the responsibilities resulting from provisions of the international legal acts regarding implementation of biosafety measures regarding GMO use.

National Focal Point for the Cartagena Protocol and the National BCH Focal Point – person in duty with the Cartagena Protocol Secretariat reporting and exchange of information, and the BCH responsibilities in the country, and to ensure the Central BCH portal with the specific information regarding GMOs.

Cartagena Protocol and BCH Task Force – appointed by the Minister of Ecology and Natural Resources – assist the NFP in their activity to ensure the CP implementation.

National Biosafety Committee- is a decision making body, responsible for authorization issuing, monitoring and risk assessment in the field of Biosafety.

The Ministry of Health Care and Social Protection is the national authority in charge of public health, responsible for management of public health care and sanitary-epidemiological activities, sanitary control and monitoring, including the adverse risks from the GMOs and Products. Is responsible for risk assessment and monitoring of the GMOs placing to the market

Ministry of Agriculture and Food Industry is responsible for: (i) quality testing and control in respect of pesticides and fertilizers and their monitoring in soil, feed and agricultural products, ensuring of public food security regarding quality, amounts and availability of agricultural products; (ii) supervision over compliance of certified agricultural products in agriculture and food industry with the requirements of applicable laws and regulations; (iii) control over observance of ecological restrictions in agriculture and agroindustry. Is responsible for deliberative release into the agriculture and the environment

Other Ministries that will be involve in the implementation of NBF:
Ministry of Economy and Commerce – socio-economical assessment form resulting from the possible use of GMOs
Ministry of Education, Youth and Sport – educational and public awareness issues related to GMOs and biotechnologies
Ministry of Justice – legislative assessment and expertise of regulations related GMOs

Agencies and Services:
Customs Control Services- procedures for custom control and monitoring, transboundery movement of GMOs

Standardization and Metrology Services – standards for laboratory testing, food quality, labeling and control
National Statistical Bureau – elaboration of statistical databases and analyses for GMOs
Agency for Forestry "Moldsilva" – deliberative release into the environment, risk assessment

Licensing Chamber- licencing of activities linked with the GMOs related to Class 3 and 4 of risks

Inspection, Control and Monitoring bodies

Ministry of Ecology and Natural resources:

State Ecological Inspectorate

Ministry of Agriculture and Food Industry*:*

State Phytosanitary Quarantine Inspectorate,

State Seed Inspectorate,

State Veterinary Inspectorate
State Committee for Testing of Plant Varieties

Ministry of Health Care and Social Protection:
National Research Center for Preventive Health Care

Minister of Interior Affairs:
Customs Control Services

Identification of procedures for monitoring, inspection and control. Preparation of guidelines, manuals and brochures

Local public administration authorities and communities

Local monitoring, control, inspection and BCH exchange of information related to GMOs; public awareness and risk assessment to the local and community scales for deliberative release and placing to the market

Public awareness and public participation

Preparing instructions for risk assessment

Scientific community (including academic institutions):

Academy of Sciences of Moldova:

Genetic Research Institute and the Center for Genetically Resources: contained use of GMOs, testing and risk assessment on genetical resources biodiversity
Microbiology Research Institute: contained use of GMOs, testing and risk assessment on microbiological biodiversity
Botanical Gardens (Research Institute): contained use of GMOs, testing and risk assessment on floristical biodiversity
Plant Physiology Research Institute: risk assessment issues on agriculture biodiversity
Zoological Research Institute: risk assessment on faunistical biodiversity

Research bodies within the universities:

State University of Moldova:
Department of vegetal biology with the *National Biosafety Testing Center* which has been established for the purpose of assessment of risks for public health and the environment, testing of GMOs and products obtained therefrom, and monitoring of the relevant activities.
State Agricultural University of Moldova:
Chair of genetics and plant improvement – contained use, deliberative release and risk assessment on agriculture
State Medical and Pharmacological University „Nicolae Testemitanu" – risk assessment on human health

Research bodies within the Ministries and Departments:

Ministry of Ecology and Natural Resources:
National Institute of Ecology- risk assessment upon natural ecosystems and biodiversity

Ministry of Agriculture and Food Industry:
Plant Protection Research Institute - risk assessment for agriculture and biodiversity

National Viticulture and Wine Research Institute – risk assessment of contained use and microbiology

Research Institute for Corn and Sorghum: risk assessment and monitoring for deliberative release into the environment and agriculture

Horticulture Research Institute- risk assessment and monitoring for deliberative release into the environment and agriculture

Northern Station for Project Implementation and Chemical Research: Research laboratory- risk assessment and monitoring for deliberative release into the environment and agriculture

Ministry of Health Care and Social Protection:
National Research Center for Preventive Health Care- monitoring, control and risk assessment related to placement

to the market and human health Standardization and Metrology Services: *Genetic expertise laboratory*- standards and accreditation for GMOs testing and control, contained use, food quality, placing to the market, labelling	
Education and training : Ministry of Education: *State University of Moldova* *State Pedagogical University* *State Pedagogical University from Tiraspol* *State Pedagogical University Balti* *Ecological College* Ministry of Health Care and Social Protection: *State Medical and Pharmacological University of Moldova „N. Testemitanu"* *Ministry of Agriculture and Food Industry:* *State Agrarian University* UTA Gagauzia: *Komrat State University* Private: *University of Ecology and Socio-Humanitarian Sciences*	Education, public awareness, training
Private business representation (producers, importers, exporters, etc.) *(Names of organisations involved and specific role)* „UniAgroProtect" , Republican Union of Agricultural Producers Associations „Agrocerealiere" Association of exporter of cereals products Union of Sugar Producers from Moldova Association of Producers of Horticultural Plant Materials "Timpul" Republican Club of Businessmen Chamber for Commerce and Industry of the Republic of Moldova MEPO - Organization for Export Promotion from Moldova « MTI Maize Technologies International » LTD, Pascani, Chisinau	Participation in the formulation and consultation of National Biosafety Policy and regulations Involvement in the National Biosafety Committee sessions and decision-making Participation in the Biosafety Steering Committee and stakeholders consultation Involvement in public awareness workshops, debates, publication and dissemination of information among the private business Involvement in and feedback on monitoring and awareness process Practise control and compliance with the established authorized procedures for GMOs
Civil society (consumers associations , NGOs) **Public associations:** Federatia Nationala a Fermierilor "ProruralInvest" National Consumers Association National Center for Bioethics	Participation in the public monitoring and decision making process Public awareness and public participation

NGOs :
"Eco-TIRAS"
"Miscarea Ecologista"
"Biotica"
"Biosecuritate"
"Pelican" - Transnistria
« Terra-nostra »
« Medicii pentru ecologie » - Dubasari
« Habitat»- Rezina

C6. MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This process will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs (Annex F, C.6a) and project impact (Annex F, C6.b) will be measured according to the indicators developed in the project log frame (Annex B), and using this specific Monitoring and Evaluation Plan. The general and specific objectives of the project, and the list of its planned outcomes, provide the basis for this monitoring and evaluation plan. The project manager, with the assistance of the NCC, will be in charge of the monitoring and evaluation component of the project and will take action whenever needed so as to guarantee that the M&E activities and the relevant indicators adequately reflect the progress and needs of the project.

The Monitoring and Evaluation plan is detailed in Annex F.

The M&E plan should cover the general and specific objectives of the project, its planned outcomes and outputs, and should look at:

i. The **efficiency** (in terms of time, resource inputs and costs) with which project activities were carried out;
ii. The **effectiveness** (quality, quantity and timeliness) with which project outputs were achieved;
iii. The **impacts** of project outcomes.

The monitoring and Evaluation plan includes a list of indicators and means of verification (Table 2), reporting and monitoring responsibilities (Table 3), and key information on reporting requirements (Table 4).

D FINANCING

D1. Incremental cost assessment

Table 5 (below) provides a summary of baseline and incremental costs by output/component as well as information on GEF financing and national co-funding. A detailed incremental cost analysis, and global and domestic benefits and related schematic representation are presented in Annex G together with an incremental cost matrix. The total baseline expenditure amounts

to USD 122,200. The increment has been estimated at USD 689,350.The national contribution in kind amounts to USD 147,000. The remaining total of USD 542,350 is requested from GEF.

Table 5. Summary incremental cost analysis

Activity	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing (in kind contributions)
National Biosafety strategy	15 000	77,710	62,710	41,710	21,000
National Biosafety legislation	103 600	173,620	70,020	50,020	20,000
Handling of requests	2 800	98,930	96,130	65,130	31,000
Monitoring of environmental effects and inspections	0	87,790	87,790	66,790	21,000
Public awareness and participation	800	118,300	117,500	92,500	25,000
Project coordination and management		159,200	159,200	132, 200	27,000
Other project support		96,000	96,000	94,000	2,000
TOTAL	122 200	811,550	689,350	**542, 350**	**147,000**

D2. BUDGET and PROJECT IMPLEMENTATION PLAN

The implementation plan for the project is based on the log frame (Annex B) and using a 48-month timeframe – as shown in Annex H.

The detailed budget of the project is shown in Annex I. A summary of the budget by components with co-financing details and staff costs are shown in Tables 6 and 7 respectively (below).

Table 6: Project Budget by Components.

	Component	GEF (US $)	Government (US $)	Total (UD $)
1	Biosafety strategy	41,710.00	21,000.00	62,710.00
2	Regulatory regime	50,020.00	20,000.00	70,020.00
3	Handling applications	65,130.00	31,000.00	96,130.00
4	Monitoring and Inspection	66,790.00	21,000.00	87,790.00
5	Public participation and information	92,500.00	25,000.00	117,500.00
6	Project coordination	132, 200.00	27,000.00	159,200.00
7	Other project support	94, 000.00	2,000.00	96,000.00
	TOTAL	**542,350.00**	**147,000.00**	**689,350.00**

Table 7: Staff costs – not directly linked to a specific activity

Personnel	GEF	National Co-financing	TOTAL
National Project Manager 48 months	38 400		38 400
One project assistant for general issues (full time) 48 months	19 200		19 200
One project assistant for training (full time) 48 months	19 200		19 200
Financial Officer 48 months	14 400		14 400
National Coordination Committee Meetings (16 meetings)	10 000	6 000 (in-kind)	16 000
Travel for NPC, Staff and NCC members	10 000	6 000 (in-kind)	16 000
TOTAL	**111 200,00**	**12 000,00**	**123, 200.00**

Equipment and operating costs:

Office equipment and operating costs (Total USD: 46,000; GEF: USD **31,000;** Government: USD 15,000) cover the purchase of computers, software upgrades, maintenance etc. as well as office utilities, stationery and communication costs. This amount is shared between GEF and the country: GEF covers ca 70% and government ca 30%.

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out over four years. The implementation plan is provided in Annex H.

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on an UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the CP-carried out through the development and implementation of National Biosafety Frameworks projects respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in Moldova, where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

E2. CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IMPLEMENTING AGENCIES, EXECUTING AGENCIES, AND THE GEF SECRETARIAT (WHERE APPROPRIATE)

E2.a National Co-ordinating Committee

The National Executing Agency (NEA), namely the Ministry of Ecology and Natural Resources, will establish a National Co-ordinating Committee (NCC) to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex J.

E2.b National Project Manager

The National Project Manager will be appointed by the National Executing Agency, namely the Ministry of Ecology and Natural Resources, after consultation with UNEP, for the duration of the National Project. The National Project Manager shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Management Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPM are in Annex J.

E2.c UNEP Steering Committee

The Steering Committee provides guidance and direction to the implementation of the project. It is chaired by UNEP, and comprises representatives of the National Executing Agency, namely the Ministry of Ecology and Natural Resources, and two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, whenever technical and scientific issues related to the implementation of the MSP are to be addressed, the representative of STAP as well as experts selected in their personal capacity will be invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

ANNEXES (in separate files)

ANNEX A	Endorsement letter
ANNEX B	Project Log Frame
ANNEX C	Background and context
ANNEX D	Summary of the Biosafety Framework
ANNEX E	Provisional list of equipment for laboratory
ANNEX F	Monitoring plan
ANNEX G	Incremental cost assessment
ANNEX H	Implementation Plan
ANNEX I	Detailed Project Budget
ANNEX J	Draft TOR for the National Executing Agency, National Project Committee, National Project Manager

TABLES

TABLE 1	**MAIN STAKEHOLDERS AND ROLES**
TABLE 2	**INDICATORS AND MEANS OF VERIFICATION (IN ANNEX F)**
TABLE 3	**REPORTING AND MONITORING RESPONSIBILITIES (IN ANNEX F)**
TABLE 4	**INFORMATION ON REPORTING REQUIREMENTS (IN ANNEX F)**
TABLE 5	**INCREMENTAL COST**
TABLE 6	**PROJECT COST BY COMPONENTS (SUMMARY BUDGET)**
TABLE 7	**STAFF COST**

Annex B: **NATIONAL BIOSAFETY FRAMEWORK IMPLEMENTATION PROJECT FOR THE REPUBLIC OF MOLDOVA**

LOGFRAME

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Project goal: To support the Implementation of the objective of the Cartegena Protocol on Biosafety in the signatory countries **Overall Project Objective: Implementation of the National Biosafety Framework in the Republic of Moldova**	A workable, comprehensive and transparent NBF is approved by the Government of Moldova, and implemented in line with the Cartagena Protocol by 2009	The Parliament Decision published in Official Gazette Publications in National newspapers; BCH web page	Changes in the national priorities resulting from changes in the national political situation due to new political forces coming to power after the Parliamentary Elections of 2005; NBF and the national regulations and secondary regulations rejected by the Government, Parliament; Negative press and public attitude	Public awareness-raising activities to achieve the level of awareness that commitment to biosafety remains a national priority irrespective of the fact, which political forces are in power; Ensure public consultation process; Involve mass-media; Publication of the Draft NBF Concept in Internet, newspapers Ensure approval of Draft NBF
Component A: The National Biosafety Policy for Moldova				
Objective for Component A: Enforced comprehensive National Biosafety policy as the basis for the development of the adequate national regulatory regime and institutional framework	National Biosafety Policy (NBP) as part of the National Strategy and Action Plan in the field of Biodiversity Conservation approved by the Government By 2009	Moldova's national biosafety policy formalized as a part of a broader policy in the field of Biodiversity conservation; The Government Decision published in Official Gazette; Published in national newspapers; BCH web page	Biosafety policy not approved due to change of government and political instability; National Biosafety Policy rejected by the Government; Negative press and public attitude; Polarization of the debate on Biosafety policy; Lack of political commitment to a policy	Public awareness-raising activities; Ensure public consultation and involving process; Involve mass-media; Publication of the Draft NBP in Internet, newspapers; Ensure inter-ministerial consultation and submitting approval of Draft National Biosafety Action Plan; Promote cooperation and exchange of information throughout government structure; Develop tools and training for translation of policy into practice;

Summary	Indicators	Means of verification	Risks and constraints	Risk management
				Promote national consensus on Biosafety
Outcome A.1: Strengthened national Biosafety policy to guide the implementation of the Cartagena Protocol, National Biosafety Framework, National Biodiversity Strategy, and other national and international requirements	Moldova's National Biosafety Action Plan approved as part of the broader national biodiversity policy.	Moldova's national biosafety policy formalized as a part of a broader policy in the field of Biodiversity; The Government Decision published in Official Gazette; Publications in National newspapers; BCH web page Project quarterly progress reports	Biosafety policy not approved due to change of government and political instability; National Biosafety Action Plan rejected by the Government; Negative press and public attitude; Polarization of the debate on Biosafety policy; Lack of political commitment to a policy	Public awareness-raising activities; Ensure public consultation and involving process; Involve mass-media; Publication of the Draft National Biosafety Action Plan in Internet, newspapers; Ensure inter-ministerial consultation and submitting approval of Draft National Biosafety Action Plan
Action A.1.1: Develop the Draft National Biosafety Action Plan, as a policy paper in conformity with national and international requirements	Policy taskforce and terms of reference formally approved by 2006 Key components of the NBP identified and published by 2007; Draft NBAP elaborated and published on web-page, newspapers	Official communication by Ministry of Ecology and Natural Resources Formal submission of NBP to the BCH Draft NBP published on Webpage and newspapers Project quarterly progress reports	Negative attitude of the decision-makers from the different governmental departments to the economical survey conclusions; Negative public attitude	Public awareness actions; Publishing a series of popular articles in press to explain the key components of the Draft NBP; Workshop with key decision-makers and public to discuss the Draft NBP

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Action A.1.2: A Macroeconomic assessment survey provided, quantifying economic benefits and incremental risks/costs associated with the implementation of the National Biosafety Action Plan to the national economy and social development in Moldova	Study team, terms of reference, and methodology formally approved by july 2006 Economical assessment survey conclusions published by 2007; Economical assessment survey as a support document to the Draft NBAP circulated among key decision-makers of the Government during the pre-approval process	Official communication by National Coordinator Survey report published in newspapers, web-page; Information note; distributed to the key decision makers during consultation process;	Negative attitude of the decision-makers from different governmental departments to the economical survey conclusions; Negative public attitude	Public awareness actions; Publishing a series of popular articles in press to explain the main conclusions of the economical assessment of the NBAP; Workshop with decision-makers to discuss the economical assessment conclusions
Action A.1.3: 2 days Workshop with key decision-makers and public to discuss the Draft NBP and the economical assessment conclusions. The workshop will involve 50 participants form the parliament, government, sectorial bodies, stakeholders, public, NGOs, farmers etc.	Workshop methodology and program communicated by National Coordinator Suitable workshop presentators and participants identified and approved 50 trained participants Materials disseminated through the participants	Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press	Lack of recognition of Biosafety as an important issue; Poor interest and understanding of Biosafety issues by stakeholders	Public awareness actions; Publishing a series of popular articles in press; Distributing a series of brochures and materials
Action A.1.4: Consultation of the NBAP with the main decision-makers of the government in the pre-approval process	Draft NBAP published; Draft NBAP distributed to the ministries and departments; Notes from different decision-maker regarding Draft NBAP received	Comments from the main governmental bodies, interested organizations, business and NGOs for gained and an evaluation of proposals made by NPC Draft NBAP published on web-page for consultation On-line forum to dialogue with the public available	Negative opinion notes from ministries and departments given regarding the Draft NBAP approving; Government changes could influence on the consultation process	Promote cooperation and exchange of information throughout governmental structure; Promote national consensus; Awareness actions

Summary	Indicators	Means of verification	Risks and constraints	Risk management
		Feedback and proposals for improvement pf the Draft analyzed		
Action A.1.5: Submit Draft NBAP to the Government for approval	Draft NBAP, (two languages) with the economical assessment, and opinions of National Authority, and relevant ministries and departments submitted to the State Chancellery of the Government for approving; NBAP approved by the Government Decision; Government Decision published	Official communication by Ministry of Ecology and Natural Resources made Formal submission of NBP to the BCH Government Decision published in official Gazette; Published on web-page	Approval process prolonged; NBAP not approved	Promote national consensus; Awareness actions; Public involvement and lobbing
Outcome A.2: Strengthened public and political support for Biosafety policy implementation	Clearly defined procedure for policy implementation; Mechanisms for regular reporting and supervising of policy implementation	Manuals and guidelines explaining the reporting and supervising procedures published and available Decision makers and politicians awared and trained Consultation with main stakeholders done Consensus reached Public and private business attracted to the policy formulation and implementation Press, web-site and media involved Communications by MERN to the Parliament and Government Project quarterly progress reports	Resistance from special interest groups; Lack of information; Bureaucratic inertia; Lack of government commitment	Promote public awareness and consensus building; Conflict resolution training; Promote information collection, analysis and exchange

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Action A.2.1: Training on Biosafety policy for decision makers, NCC members, parliamentarians, public, etc 20 participants, 2 days long training for feedback and proposals for the strategy	Workshop methodology and program communicated by National Coordinator Suitable workshop speakers and participants identified and approved 20 policy makers and decision makers, NCC, public trained with the Biosafety policy implementation methods; Press release published; Report of training workshop published in web-page;	Press release published in press; Report of training workshop published in web-page Workshop program and training materials Training certificates Participants' evaluation of workshop	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Action A.2.2: Meetings with specific groups of stakeholders in different districts and communities . 5 one-day workshops (Northern, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of farmers, local politicians and authorities, consumers etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy. Total number of participants attracted – about 125 persons.	Workshop methodology and program communicated by National Coordinator Suitable workshop speakers and participants identified and approved 125 participants awared and consulted Local public authority, farmers, consumers, community, students, NGOs and public trained with the Biosafety policy implementation methods; Press release published; Report of training workshop published in web-page	Press release published in press Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press	Resistance from special interest groups Lack of information Resource persons are not appropriate	Careful identification and planning of the meeting tools and activities, including identification of moderator and resource persons, as well as and feedback mechanism Promote information collection, analysis and exchange

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Component B: The National Regulatory Regime (Legislation)				
Objective for Component B: Strengthen the national regulatory regime in line with Cartagena Protocol, NBF, and biosafety policy	A national regulatory regime approved and enforced as`a comprehensive and operational regulatory regime, and at the same time, reflecting Biosafety policy and NBF components in line with Cartagena Protocol and other international obligations. Biosafety legislation improved and amended; Sectoral legislation developed and approved; Secondary implementing legislation developed and approved; Guidelines and internal manuals available	Official communication by Ministry of Ecology and Natural Resources; Deposition of information on the revised, comprehensive biosafety legislation to the nBCH and the SCBD central portal; Amendments and completion of the Biosafety law approved; Biosafety legislation published in the national official gazette; Implementing regulations approved and in operation; Sectorial legislation amended and completed; Guidelines available; Internal manuals available Project quarterly progress reports	Regulatory regime not consistent with CP and country needs, including BCH obligations, GMOs Register, monitoring and transboundary control etc.; Regulatory regime is not responsive to country's changes (technological, social, political, economic etc); An unworkable regulatory regime, resulting in poor implementation and enforcement; Regulatory regime not consistent with national biosafety policy; Regulatory regime cannot be finalized/implemented because of lack of public and institutional support; Regulatory regime cannot be easily adopted because of resistance from interest groups; Regulatory regime cannot be enforced because of lack of staff, implementing regulations, guidelines and manuals	Promote cooperation and exchange of information throughout government structure; Develop tools and training for translation of legislation into practice; Promote broader public awareness and support for Biosafety and the need for regulatory regime; Promote national consensus on Biosafety; Promote awareness on relevant international obligations; Develop regulatory regime in accordance with the biosafety policy; Promote mechanisms for review and adjustment of legislation; Promote consultation with all stakeholders during the initial stages of implementation of the regulatory regime; Promote collection of information on experiences in other countries
Outcome B.1: The National Biosafety Law reviewed, amended and harmonized with the provisions of the Cartagena Protocol, other international requirements related to the inspection, monitoring and	Draft amendments for harmonization of the National Biosafety Law developed and submitted to the Parliament via MENR for approval and enactment by 2007	Official communication by Ministry of Ecology and Natural Resources; Entry of information of the amended National Biosafety Law to the nBCH and SCBD central portal;	Regulatory regime not fully translated into practice; Regulatory regime does not reflect issues of public concerns, monitoring, control, inspection, risk assessment; Institutional arrangements not	Promote training on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country; Promote cooperation and

Summary	Indicators	Means of verification	Risks and constraints	Risk management
control of GMOs, institutional arrangements as well as BCH and GMOs Register requirements.	Division of roles and functions of state authorities regarding: a) the process of examination and decision making; b) involvement of new institutional components e.g. technical biosafety committees of the relevant ministries and departments, and c) development of the legal statutes of these technical biosafety committees; Procedures and methodologies for monitoring, inspection and control of the authorized GMO-related activities; Introduction of a new chapter regarding the Biosafety Clearing House and GMOs Register; Development of procedures and methodologies for testing and risk assessment/ management of biotechnology risks;	Parliamentary materials; Harmonizing amendments to the National Biosafety Law approved by the Parliament and published in the National Gazette of Moldova; Project quarterly progress reports; Specific roles and duties clearly defined and agreed by amendments to the law related to the following: -procedures for examination of applications and decision making clearly stipulated -procedures and methodologies for monitoring, inspection and control defined and available; - Obligatory information deposited in the national BCH and GMOs Register - procedures and methodologies for testing and risk assessment/ management of biotechnology risks available and in use.	appropriate.	exchange of information throughout government structure
Action B.1.1: Set-up an Expert Task force and prepare an Action plan for reviewing, amending and harmonization of the National Biosafety Law to meet the requirements of the Cartagena Protocol and the NBF	The Expert Task force of the MENR (working jointly with other ministries) established, and an Action plan prepared by July 2006	The Expert Task force composition and Action plan approved by the Ministerial (MERN) order Action plan published on project website and nBCH	Insufficient involvment of experts; Poor awareness of experts; Bureaucratic barriers	Awareness actions; Correct expertise in the Expert Task Force; Meetings with selected experts;

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Action B.1.2: Revision and amendment of the Biosafety Law by Expert Task force in order to comply with the national biosafety policy and international obligations	Draft of amendments and completion of the Biosafety Law elaborated, including the following components by 2009: - Segregation of powers and functions of state authorities regarding: a) the process of examination of applications and decision making; b) the technical biosafety committees of the relevant ministries and departments, and development of their legal statutes; - Monitoring, inspection and control of the authorized GMO-related activities; - Biosafety Clearing House and GMOs Register requirements; - Testing and risk assessment/ management of potential risks posed by GMOs to the environment and human health	Biosafety Law reviewed and approved by Parliament Amended Biosafety law published in the National Gazette of Moldova Agreed amendments; Official documents	The Biosafety Law cannot be finalised because of lack of public and institutional support;	Promote consultation with stakeholders during preparation of the amendments and regulations; Prepare tools like operational manuals, and train legal officers on biosafety matters.

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Outcome B.2: Branch legislation revised and amended for the purpose of its harmonization with the Cartagena Protocol, national Biosafety policy and law	Branch laws and regulations revised for the purpose of their harmonization and submitted to the Parliament (for laws) or to the Ministries in charge of relevant sectors (for regulations) for approval and enactment by 2009. Ministry of Agriculture and Food Industry: *Law on Seeds* (no. 659-XIV of 29.10.1999); *Law on Protection of Plant Varieties* (no. 915-XIII of 11.07.1996); *Law on Horticulture* (no. 728-XIII of 06.02.1996); *Phytosanitary Quarantine* (no. 506-XIII of 22.06.1995); *Law on Animal Breeding* (no. 412-XIV of 27.05.1999). Ministry of Health: *Law on Medicines* (no. 1409-XIII of 17.12.1997); *Law on Public Sanitary Epidemiological Security* (no. 1513-XII of 16.06.1993); *Law on Health Care* (no. 411-XIII of 28.03.1995); *Law on Protection of Consumer Rights* (no. 105-XV of 13.03.2003); Standardization and Metrology Department: *Law on Standardization*	Official communication by Ministry of Ecology and Natural Resources; Formal posting of NBP to the BCH Reports; Adequate amended branch laws and regulations approved by the Parliament (laws) or to the Ministries in charge of relevant sectors (for regulations); Regulations consulted with main stakeholders via web-page, submission and publications; Official publication of approved regulation in the National Gazette of Moldova; Quarterly Project progress reports	Regulatory regime cannot be easily adopted because of resistance from interest groups; Regulatory regime cannot be enforced because of lack of implementing regulations, guidelines and manuals; Regulatory regime cannot be enforced because of lack of trained personnel.	Promote cooperation and exchange of information throughout government structure; Develop tools and training for translation of legislation into practice; Promote broader public awareness and support for Biosafety and the importance of having a comprehensive biosafety regulatory regime.

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	(no. 590-XIII of 22.09.1995); *Law on Metrology* (no. 647-XIII of 17.11.1995).			
Action B.2.1: Draft suggestions and amendments to harmonize branch laws related to the national biosafety with the requirements of the Cartagena Protocol Biosafety policy and law and international requirements	Report to the Expert Task Force on harmonization of the branch laws is available and covers: • Imports/exports, customs procedures; • Plant protection; • Consumer rights; • Phytotechnology and seed production; • Licensing; • Animal breeding; • Departmental inspection; • Penal Code, Civil Code and Administrative Violations Code; • Intellectual property rights; • Sanitary-epidemiological issues	• Reports of the Expert Task force (as per B.1.1) regarding its work on revision, amendment and harmonization of the branch laws related to biosafety; • Amendments of branches regulation drafted and submitted for approval • Drafts of amendments for branch legislation published on web-page	Branch laws cannot be harmonized because of lack of support	Promote consultation with stakeholders during preparation of the amendments
Action B.2.2: One-day Workshop for 30 participants to discuss of these amendments to the laws related to the national biosafety regulations	Workshop methodology and program communicated by National Project Manager Suitable workshop speackers and participants identified and approved 30 participants with increased awareness on the amendments and consulted	Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press	Quality of the training tools and workshop activities are unsatisfactory; Developed tools do not cover adequately the issues; Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Outcome B.3: Secondary regulations and guidelines, required by the law, developed and in force ensuring implementation of the Law	Guidelines on monitoring and GMOs inspection for implementation of the Biosafety Law and NBF drafted, submitted to the Government for approval and enactment, and published	Official communication by Ministry of Ecology and Natural Resources; Formal submission of NBP to the BCH Guidelines and regulations are enacted via their publication in the National Gazette of Moldova; Required secondary regulations for implementation of the NBS Law drafted and submitted to the relevant ministries and departments for approval and implementation	Secondary regulatory regime does not comply with CP, Law on Biosafety; Regulatory regime not translated into practice; Institutional arrangements not appropriate	Promote training on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country; Promote cooperation and exchange of information throughout government structure
Action B.3.1a: Drafting secondary regulations and guidelines required for the implementation of the Biosafety Law and NBF	The following regulations for implementation of the NBS Law are drafted guidelines on: - authorization of GMO-related activities; - Contained Use and Disposal of GMOs and Containment of Waste; - GMO Release into the Environment; - Requirements regarding GMO placing to the market; - Risk Assessment and Monitoring; -Operation of technical committees within the relevant ministries and institutions and Technical Committee of the National Biosafety Committee;	Draft secondary regulations and guidelines available; Communication by NPM to the Ministry of Ecology and Natural Resources and Task Force; Communication at the National Biosafety Committee session; Submissions to the Governmental bodies for consultation and agreement; Draft regulations consulted with the main stakeholders and public; Draft regulations placed on the web-page and feedback received; Quarterly project progress reports	Regulations cannot be finalised because of lack of public and institutional support; Internal operational manuals not available	Promote consultation with stakeholders during preparation of the regulations ; Prepare operational manuals, train legal officers

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	-guidelines and checklist for examination of notifications and risks assessment; -procedures and methodologies and requirements for packaging, labeling, storage and transportation; -monitoring of the GMO activities; - GMO inspection system (guidelines for relevant branches inspectorates); -education and training on GMO issues for public servants; -content and maintenance of the National GMOs Register, including providing information to the nBCH and SCBD; -methodology of calculation of costs and charges in the GMO regulation system; -information and management of consequences in case of emergency, accident or unintentional release; -approximation of customs procedures to the international requirements regarding transboundary movement of GMOs; -examination of possibilities to simplify GMO imports/exports customs procedures with the neighboring countries and in the region; -guidelines on protection of confidential information			

Summary	Indicators	Means of verification	Risks and constraints	Risk management
Action B.3.1b: Develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement	Tasks assigned as follows: State Ecological Inspectorate (border-crossing offices) and the Customs Control Department will have the functions of border monitoring, inspection and control over compliance with the requirements for transportation, labeling and packaging of GMOs; - Inside the country the functions of monitoring, inspection and control over transportation, labeling and packaging will be exercised by inspectorates within the Ministry of Health, Department of Standardization and Metrology, and State Ecological Inspectorate.	Draft secondary regulations and guidelines elaborated ; Communication by NPM to the Ministry of Ecology and Natural Resources and Task Force; Communication at the National Biosafety Committee session; Submission to the Governmental bodies for consultation and agreement; Draft regulations consulted with the main stakeholders and public Available in the web-page and feedback received; Regulations specifying requirements for transportation, labeling and packaging approved, published in Official Gazette and available; Reports from the Inspectorates		
Action B.3.2 Organize a Two-day training workshop for 50 Expert Task Force, decision-makers from branches governmental bodies and parliamentarians, legal experts, politicians and NGOs for promoting consensus regarding the biosafety requirements for branch regulation, secondary regulations	Workshop methodology and program communicated by National Project Manager; Suitable workshop speackers and participants identified and approved; 50 experts and public officers from related branches ministries and departments, policymakers, NGOs trained and consensus obtained	Workshop program and training materials; Training certificates; Participants' evaluation of workshop; Summary report placed to the web-page; Press-release; Information disseminated on radio and press.	Quality of the training tools and activities is unsatisfactory; Developed tools do not cover adequately the issues; Resource persons are not appropriate.	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Action B.3.3: A 2-day training workshop on national and branch regulations, the	Workshop methodology and program communicated by	Workshop program and training materials	Quality of the workshop material is not satisfactory; Participants are not accurately	Careful planning of the workshop; Careful identification of the

Summary	Indicators	Means of verification	Risks and constraints	Risk management
elaboration of secondary level regulation organized for 50 participants comprising Expert Task force members, government officers, legal experts, politicians and NGO representatives.	Suitable workshop speakers and participants identified and approved 50 participants consulted and have increased their awareness on branch regulations; The Action plan of the Task force discussed and conciliated among experts from different government sectoral bodies; Improved awareness of policy-makers, decision-makers and implementing authorities, the public, and NGOs on the need to develop biosafety regulations in order to comply with the CP, NBF and NBAP	Training certificates Participants' evaluation of workshop Workshop report summarized and available via biosafety web-page; Press release;	selected; Resource persons are not appropriate; Duration of the workshop is not adequate	resource persons and participants

Component C: System for handling of requests (it consists of more components than merely administrative system, it is also RA/Rm, decision making etc)

Objective for Component C: Strengthen the administrative system for adequate handling of notifications and authorization issuing complying with the Cartagena Protocol requirements	Advanced use of BCH; Number of decisions made as a result of notifications submitted; National Biosafety Committee in place with clear distinction of responsibilities by 2007; Available set of procedures for handling requests within time frames	Administrative system for adequate handling of notifications and authorization issuing cleared, enforced and in place Procedures for handling requests available and published Information on rules and procedures placed on web-page Personnel trained Manuals and guides published Roster of experts published	Institutional and infra-structure not in place; Lack of expertise Lack of implementing guidelines and manuals Lack of capacity on how to handle the request and how to perform risk assessment	Establish interim measures to handle requests; Conduct training for administrative and institutional support personnel Develop tools and training on handling request Specify roles and responsibilities so as to minimise inefficiencies
Outcome C.1: Functional risk assessment system in place	National roster of risk assessment experts; Appointed entity for risk	Roster of Experts published; Risk assessments rules agreed	Lack of RA experts Lack of consensus in RA decision;	Capacity building in RA; Training workshop for experts and personnel

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	assessment; Rules for appointments of experts and TORs; Agreed procedures for carrying out risk assessment; Trained personnel	and available; Personnel trained Guides and manuals published and available Project quarterly progress reports	Insufficient scientific data/info provided; Credibility of data provided for RA; Bureaucracy hinders decision-making	
Action C.1.1: Updating of Roster of experts for Risk Assessment	Roster of experts and TORs for risk assessment approves and available	Updating of Roster of experts made and published Web-page updated	Roster is not used	Increase awareness and usefulness of the roster
Action C.1.2: Definition of national procedures and guidelines for Risk assessment.	Definite procedures and prepare guidelines for GMO risk assessment on the environment and human health	Guidelines available	Procedures are not clear, roles are not defined and do not cover all the issues	Experts are consulted for a revision of the procedures
Action C.1.3 Establish Technical committees for risk assessment and opinion for decision making within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova	A special Ministerial decision approved; Guidelines regarding operation of technical committees development;	Ministerial decision published and available Guidelines for risk assessment published and available	Procedures are not clear, roles are not defined and do not cover all the issues	Experts are consulted for a revision of the procedures
Action C.1.4: Development check-list for Risk Assessment practitioners **Action C.1.5:** Five-days training workshop on Risk assessment for 30 decision-makers, researchers, experts and personnel (training provided by the invited external experts)	A check-list for Risk Assessment practitioners published on website and bulletin Workshop methodology and program communicated by National Coordinator Suitable workshop speakers and participants identified and approved 20 experts, decision-makers, researchers and technical	Check-List for Risk assessment published and available at the web-page Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	personnel trained on Risk Assessment procedures	Press-release; Information disseminated on radio and press		
Outcome C.2: Strengthened capacities and tools for a functional decision-making system and system for administrative processing	National GMO Register; establish and maintain; Public Relations Office as a component of the Biosafety Clearing House established ; Technical committees within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova established Development of guidelines regarding operation of technical committees; Decision-making with clearly defined roles and responsibilities; Procedure for submission, examination, consultation of notifications and decision making; Procedure for public consultation and public hearings. Responsibility for emergency response, accidental release, illegal movement	National GMOs Register published Communication by NPC to the Task Force, Biosafety Committee and the MERN Public Relation Office as part of the BCH in place and available Technical Committees in place Rules and Guidelines for operation and duties of the comities published and available Decision-making procedures cleared and published Public consultation procedures cleared and available Procedures and responsibilities for emergency and accidental release published and available Placing at the web-page Project quarterly progress reports	Trade, politics and other considerations over-ride decision-making; Negative public opinion on biosafety	Institute a strong decision-making body which enjoys public confidence and credibility; Involve public and other stakeholders in decision-making; Establish an Appeal /Review mechanism for decision-making
Action C 2.1: Development of administrative procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests	Improved administrative procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests	Procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests published and available Posting of the procedures on the web-site	Procedures for handling of requests are not clear, roles are not defined and do not cover all the issues	Experts are consulted for a revision of the procedures for handling of requests
Action C 2.2: Development of the administrative database	Improved administrative procedures for a database	Administrative procedures for databases development and	Procedures for the development of the administrative database	Experts are consulted for a revision of the procedures on the

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	(portal) development and maintaining	maintaining approved and available Placing at the web-page	are not clear and do not cover all the issues	development of the administrative database
Action C 2.3: Development of administrative procedures for system to track dossier and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities	Improved administrative procedures for a system to track dossiers and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities	Aadministrative procedures for a system to track dossiers and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities approved and available Posting on the web-page	Procedures for tracking dossiers are not clear and do not cover all the issues	Experts are consulted for a revision of the Procedures for tracking dossiers
Action C 2.4 : Development of administrative procedures and an operational manual for submission examination, consultation of notifications and decision making	Published a manual for to track dossiers and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities	A manual for to track dossiers and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities published and available Placed at the web-page	The manual is not clear , not well structured and does not cover all the issues	Experts are consulted for a revision of the manual
Action C 2.5: Development of administrative system for the protection of confidential information	Improved administrative procedures for a system for the protection of confidential information	Administrative procedures for a system for the protection of confidential information cleared and published Procedures placed on the web-page	Procedures on confidential information are not clear and do not cover all the issues	Experts are consulted for a revision of the procedures on confidential information
Action C.2.6: Establish electronical National GMOs Register	Identification of roles and responsibilities for handling, storing and exchanging information including the National Register in compliance with the BCH requirements; Development of guidelines for the management of the GMOs Register; Creation of national Biosafety databank/s; Identification, collection, input and update of data;	Roles and responsibilities for handling, storing and exchanging information including the National Register cleared Communication by NPC to the Biosafety Task Force National Databanks on Biosafety published National GMOs Register electronically available	Delay in set up due to bureaucratic procedures; Lack of technical personnel and IT infrastructure needed	Careful analysis of the situation and needs before activity starts

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	Making information available to relevant groups (through websites, etc.)			
Action C.2.7: Two three-day training workshops on notification handling and decision making process in compliance with international obligations organised for decision-makers from involved ministries and departments for 30 participants	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 30 participants trained Improved knowledge on administrative procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests, a database (portal),a system for the protection of confidential information, a system to track dossiers and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities	Workshop program and training materials Training certificates Participants' evaluation of workshop Press-release; Information disseminated on radio and press Training course materials summarized and disseminated among the participants and interested stakeholders; Selected training materials made available for download from Moldova's official biosafety web site; Filled participant assessment questionnaires	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Action C.2.8: Develop guidelines and rules for emergency cases, and remediation develop TORs for responsible persons, define emergency response procedures. Authority and staff nominated	Rules for emergency procedures in place; Authorities, contact persons nominated and made known to public; Connection to the other countries via BCH; Remediation system in place	Written and approved rules for emergency cases and remediation available; Authorities nominated and approved; Staff in these authorities trained and nominated, tasks described in their job description; Functional access to BCH and other means of connection Project quarterly progress reports	Confidentiality is broken as rules are not clear and do not cover all the issues; System exists only on paper, is non-functional or with low capacity; Not enough finances (emergency measures, remediation could be very expensive); Responsible staff does not aware about remediation actions;	Experts are consulted for a improvement of the rules Ensure that people responsible for emergency cases are fully aware of their tasks; Good education/training for responsible persons, duplication of persons; Ensure that means for emergency responses are available; Develop tools (guidelines) for different emergency cases;

Summary	Indicators	Means of verification	Risks and constraints	Risk management
			Emergency cases hidden by government or by companies, blocking info;	Raise awareness so that governments/ companies understand that hiding accidents and delays in eliminating GMOs will lead to bigger disaster than immediate action and that hiding accidents (especially from neighboring countries) is illegal
Action C.2.9: One-day training workshop for emergency operations for all stakeholders, officials, risk management , 20 participants	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 20 participants trained Trained staff able to deal with emergency issues; Improved knowledge of emergency and remediation procedures at the level of nominated staff, inspectors and implementing authorities	Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press Staff of the nominated authorities trained and nominated, tasks described in their job description;	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Component D: The National Systems for Monitoring and Enforcement				
<u>Objective for Component D:</u> Consolidate a fully functional system for monitoring and enforcement	Monitoring, inspection and control systems in place with the relevant functions to: -Perform monitoring, inspection and control of GMOs in situations of contained use, release to the environment and	Responsibilities and duties cleared Procedures and methods for monitoring, inspection and control approved Technical guidelines and manuals on monitoring,	Division of roles and responsibilities either unclear, overlapping of leaving gaps	Awareness raising – how to divide tasks, responsibilities

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	placing on the market; -Control the notifier's compliance with technical requirements and standards specified in the authorization; -Impose penalties according to the applicable laws in case of non-compliance with applicable standards; -Initiate the procedure for authorization withdrawal in exceptional situations; Approved and enacted technical guidelines and manuals on monitoring, inspection and control; Databases are in existence and use	inspection and control published and available; Databases are in place and available		
Outcome D.1: Monitoring, inspection and control procedures and capacities built and in place	Approved and enacted technical guidelines on monitoring, inspection and control; Roles and responsibilities of monitoring, inspection and control agreed.	Roles and duties cleared and agreed Guidelines published and available Project quarterly progress reports List of training activities organized	Division of roles and responsibilities either unclear, overlapping of leaving gaps Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Awareness raising – how to divide tasks, responsibilities; Promote training on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country; Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Action D.1.1: Clarify responsibilities and duties of different agencies to enable them to carry out their responsibilities for monitoring, inspection and	Draft guidelines submitted to the relevant authorities examination and enactment; Uniform Guidelines for	Enacted technical guidelines published and available; Enacted Uniform Guidelines for harmonised data collection and	Lack of clarity and coordination between different agencies to enable them to carry out their responsibilities;	Define clear roles and responsibilities in the institutional system and establish coordination of activities to minimize inefficiencies

Summary	Indicators	Means of verification	Risks and constraints	Risk management
control	harmonised data collection and validation approved and enacted by for MENR, the Ministry of Agriculture, Ministry of Education, and Ministry of Health	validation		
Action D.1.2: A four-day training course on monitoring, inspection and control procedures for 30 trainers: officials of different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services, Standards and Metrology, selected on the basis of their background and current duties	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 30 participants trained Improved knowledge of monitoring, inspection and control procedures at the level of inspectors and implementing authorities	Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press Training course materials summarized and disseminated among the participants and interested stakeholders; Selected training materials made available for download from Moldova's official biosafety web site; Filled participant assessment questionnaires	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
<u>Outcome D.2:</u> Strengthened facilities and capacities for laboratory testing	Provision of the National Testing and Risk Assessment Center (TRAC) with analytical laboratory equipment; Facilitation of TRAC national and international accreditation; Training of TRAC specialists in the field of testing and risk	Laboratory equipped with PSR installation; Researchers trained; Workable databases developed; Methodical instructions and guidelines available; Process of accreditation	Lack of specialist and stuff; Poor laboratory facilities for testing; Poor public information on tasks and services of the laboratory	Promote training on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to GMOs testing and the biosafety in the country Careful identification and

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	assessment of GMOs Development of GMO sample databanks and access to reference material; Development and approval of methodologies for testing and assessment of risks for the environment and human health; Development of procedures for provision of testing and risk assessment services and for calculation of their costs	facilitated Project quarterly progress reports List of training activities organized	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Action D.2.1: Equipment and related reagents related to the purchased main equipment necessary for testing laboratory procured	Purchase of lacking equipment and reagents necessary for testing laboratory	Testing laboratory equipped with PSR installation and reagents	Equipment does not match needs	Approval of the list of equipment by the Task manager Identification of lab needs before purchase of the equipment
Action D.2.2: Two four-days capacity-building training courses on laboratory testing and risk assessment research methodologies activities for 10 laboratory researchers and technicians	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 10 participants trained Improved knowledge of researchers and laboratory technicians regarding testing and risk assessment methodologies	Workshop program and training materials Training certificates Participants' evaluation of workshop Press-release; Information disseminated on radio and press Filled participant assessment questionnaires Training course materials summarized and disseminated among the participants and interested stakeholders; Selected training materials made available for download from Moldova's official biosafety web	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training

Summary	Indicators	Means of verification	Risks and constraints	Risk management
		site; Filled participant assessment questionnaires		
Outcome D.3: Requirements for packaging, labeling, storage and transportation, transboundary or transit movement control of GMOs established . Strengthened capacity on import/export/transit of LMOs	Developed regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement; National authorities in the field of the environment, standards and metrology, and health care developed methodologies for transportation, labeling and packaging of GMOs.	Regulation and guidelines published and available Personnel trained Project quarterly progress reports	Requirements for packaging, labeling, storage and transportation, transboundary or transit movement control of GMOs are not well defined . Lack of information and understanding Poor public awareness	Simulation exercise if needed to test if the system works Public awareness activities; Training for personnel
Action D.3.1: Establish procedures for custom control over import/export/transit of GMOs	The function to perform customs procedures in respect of GMOs with the customs offices at border-crossing points vested; Inspection, control and monitoring services within the customs office to ensure control over imports/exports/transit of GMOs established; A special section in the customs declaration for the transported goods for the purpose of declaration of presence or absence of GMOs included; Prompt information of the	Customs procedures in respect of GMOs cleared and agreed Inspection, control and monitoring services in place Declaration for the transported goods improved and published Information to the web-page	Procedures are not clear, roles are not defined and do not cover all the issues	Experts are consulted for a revision of the procedures

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	national and international biosafety institutions about transboundary movement of GMOs ensured			
Action D.3.2: Three-days Training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement. Training focused for stakeholders, officials, custom services, inspections, risk management, business, farmers, researchers public, ONGs etc, total for 40 participants.	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 40 participants trained Improved knowledge of transportation, labeling and packaging requirements, as well as monitoring, inspection and control procedures for transboundary or transit movements at the level of inspectors and implementing authorities	Workshop program and training materials Training certificates Participants' evaluation of workshop Summary report placed to the web-page Press-release; Information disseminated on radio and press	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Component E: The National Mechanisms for Public Awareness, Education and Participation				
Objective for Component E: Enhance national capacities for public awareness and participation into decision making process	An efficient public consultations and stakeholder dialogue with the authorities, as required under Article 23 of the Cartagena Protocol; Mechanism for public access to	-Published expert opinions; Web-site in existence providing the possibility for public dialogue MENR reports; Enacted Guidelines on public	Resistance of governmental officials and bodies to make the hadling process transparent and available; Lack of finance to ensure public information and consultation; Lack of clearly strategy for	Awareness and consultation activities; Training workshop for PP and public awareness procedures

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	decision making process in place; Strategy for public awareness via mass media, seminars, books, brochures, etc. developed; Web page created and regular updated with the open information for public; Established permanent contacts and collaboration with the relevant NGOs and other stakeholders with the purpose of involving them into the decision making process and into the process of adequate public information; Developed capacities for implement traceability and transparency; Two opinion pools on the biosafety related issues carried out	consultations Guidelines on public participation published and disseminated; Workshop materials summarized and disseminated among the participants and interested stakeholders; Summary materials made available for download from Moldova's official biosafety web site; Filled participant assessment questionnaires	public awareness	
Outcome E.1: Strategy for public awareness in place and enhance an efficient mechanisms for public consultations developed and implemented to ensure public participation in decision-making as a component part of the Biosafety strategy	Two opinion polls are held; Qualified opinions from NGOs and scientific community requested; Possibility of dialogue with the public via web-site ensured; Telephone hot line on biosafety issues created by MENR	Communication by NPC to the MERN and Task Force Strategy for PP published and in place Published expert opinions; Web-site in existence providing the possibility for public dialogue MENR hot line reports Project quarterly progress reports	Resistance of governmental officials and bodies to make the handling process transparent and available; Lack of finance to ensure public information and consultation; Lack of a clear strategy for public awareness; Plan is worked out in isolation, Plan does not respond to needs	Plan is circulated to all the involved parties for comments and revision till final agreement Involvement of main categories of stakeholders to identify and address needs in public awareness, education and participation in decision making; Plan fed with results of two workshops Awareness and consultation activities; Training workshop for PP and public awareness procedures
Action E.1.1: Development of guidelines and manuals regarding public information and	Draft guidelines and manuals on public consultations developed available and disseminated	Enacted Guidelines on public consultations Guidelines on public		

Summary	Indicators	Means of verification	Risks and constraints	Risk management
participation		participation published and disseminated		
Action E.1.2: Two three-day workshops on the importance of or public information and participation in the framework of Moldova , public consultations and information exchange, inclusive explanation of legislation, systems for public participation etc, for biosafety for 70 government officials, journalists, scientists and NGO representatives, consumers associations, farmers, press, civil society etc.	Workshop methodology and program communicated by National Coordinator Suitable workshop speackers and participants identified and approved 70 participants awared Improved awareness of the importance of and procedures for public consultations and information exchange with government officials, scientists, media and general public	Workshop program and training materials Training certificates Participants' evaluation of workshop Press-release; Information disseminated on radio and press Workshop materials summarized and disseminated among the participants and interested stakeholders; Summary materials made available for download from Moldova's official biosafety web site; Filled participant assessment questionnaires	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Outcome E.2: Increased public awareness, Best practices on Public participation learned and disseminated	The national biosafety web-site is registered with the main search engines in the worldwide web, fully operational and updated on regular basis; Various outreach materials produced and disseminated	Biosafety Web-site published and regularly updated; Plan for workshop and seminars developed; Outreach materials published and disseminated Project quarterly progress reports	Resistance of governmental officials and bodies to make the hadling process transparent and available; Lack of finance to ensure public information and consultation; Lack of clearly strategy for public awareness	Awareness and consultation activities; Training workshop for PP and public awareness procedures; Radio and TV programs develop; Brochures and outreach materials publish
Action E.2.1: Improvement of the National Biosafety web-site to include a public participation platform	Relevant, available and understandable information on GMOs, Biotechnology and Biosafety developed and uploaded	Actualized biosafety information and databases available to the public; follow-up measures Available information for large	Public is not informed about the platform Public is not educated on biosafety Public is not educated on how to	Awareness raising activities Advertisement of this new instrument to promote dialogue and public participation

Summary	Indicators	Means of verification	Risks and constraints	Risk management
	On-line forum to dialogue with the public in place	public to encourage public participation in the decision-making process regarding biosafety issues	use the platform	
Action E.2.2: Production and dissemination of outreach materials, training materials, workshop summaries, technical manuals, publications in mass media, educational videos, brochures, etc.	Various outreach materials produced and disseminated	Samples of outreach products produced under the project	Different categories of audience and related needs are not correctly identified Lessons learnt are not identified	Identification of the audience and messages before preparation of the outreach material Consultative process for the identification of lessons learnt and best practices

Annex C: **BACKGROUND AND CONTEXT**

1. In 1997, responding to the third Conference of the Parties to the Convention which called for GEF to provide the necessary financial resources to developing countries for **Capacity Building In Biosafety**, the GEF Council approved a US$2.7 million Pilot Biosafety Enabling Activity Project.

   The Pilot Project involved 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia and Malawi) and consisted of the following two components:
   A *National Level Component* aimed at assisting the eighteen countries to prepare National Biosafety Frameworks (US$1.9 million), and
   A *Global Level Component* aimed at facilitating the exchange of experience at regional level through the organisation of regional workshops (2 workshops in each of four regions) which involved a very large number of countries (US$0.8 million).

2. The Cartagena Protocol on Biosafety was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity in Montreal, Canada, on 29 January 2000. It was opened for signature in Nairobi, on 24 May 2000 and as of 1 November 2004, 110 countries have already ratified or acceded to the Protocol. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements of LMOs."

3. In November 2000 the GEF Council approved the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety" (GEF/C.16/4). The main objectives of the strategy are to a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and sub-regional level, and c) promote collaboration with other organizations to assist capacity-building for the Protocol.

4. In December 2001, the GEF Council approved 12 demonstration projects to support countries in the implementation of their national biosafety frameworks. Two projects (Malaysia and Mexico) are implemented by UNDP, eight projects are being implemented by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and World Bank is implementing two projects (India and Colombia).

Moldova is a Party to the Cartagena Protocol on Biosafety, which entered into force on September 11, 2003, on the 90th day after the date of deposit of the fiftieth instrument of ratification or accession.

Parties at the seventh Conference of the Parties to the Convention, serving as the first Meeting of the Parties to the Cartagena Protocol (COP7/MOP1), which was held in Kuala Lumpur, (Malaysia) in February 2004 focused on setting up an operational framework for the effective implementation of the Protocol. They approved Decision VII/20 on Further Guidance to the financial mechanism. The decision invites the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.

The COP/MOP decision specifically calls upon the GEF to "provide additional support for the development and/or strengthening of existing national and regional centres for training; regulatory institutions; risk assessment and risk management; infrastructure for LMO detection, testing, identification and long-term monitoring; legal advice; decision-making; handling of socio-economic considerations; awareness-raising and technology transfer for biosafety." This project fulfils these criteria.

Further endorsement of the above is reflected in the decision on *Agenda Item 9, at* the Joint Summary of the Chairs of the GEF Council, held from 19-21 May 2004, which states "*The Council welcomes the guidance of the Conference of the Parties to the CBD inviting the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries*

Annex D

Summary of the National Biosafety Framework for Moldova

The Republic of Moldova ratified the Convention on 16 May 1995 (by Parliamentary Decision no. 457-XIII). To implement the commitments made by Moldova as a signatory party to the Convention on biological diversity, the Government developed and approved *National Strategy and Action Plan in the field of biological diversity conservation and the First National Report on Biological Diversity.*

National Strategy and Action Plan in the field of biological diversity conservation (approved by Parliamentary Decision no. 112-XV of 27 April 2001) provides for development of an integrated plan of urgent actions required to ensure biosafety in Moldova:

- Regulation of imports and expor ts of transgenic organisms;
- Creation of the relevant legisl ative and institutional framework;
- Capacity building via staff training;
- Establishment of a testing laboratory to exercise control over GMOs; and
- Development of special public information pr ograms to raise awareness of the consequences of GMO use.

The Cartagena Protocol on Biosafety was signed by the Republic of Moldova as an integral part of the Convention on Biological Diversity at New York on 14 February 2001 and rati fied by Law no. 1381-XV of 11 October 2002.

The Concept Paper on the National Biosafety Framework was developed in conformity with the Protocol provisions, comprising 5 principal components:

- Political framework;
- Legislative framework;
- Institutional framework;
- Risk assessment and decision-making system;
- Public awareness raising and education.

The Ministry of Ecology and Natural Resources drafted the *Law on Biosafety* (no. 755-XV of 21.12.2001, MO no. 75 of 13.06.2002).

.(a) creation, multiplication, testing and use in contained conditions, for various purposes, of the microorganisms, plants and animals modified genetically using modern biotechnology methods;

.(b) deliberate release in the environment and market release of the organisms modi fied genetically using modern biotechnology methods, including any living structure capable to reproduce organisms, such as seeds, bulbs, layers, pollen, spores, etc.;

.(c) unintentional release of GMOs in the environment;

.(d) deliberate release in the environment and market release of the processed products containing GMOs and/or living components of the living GMOs – whether processed or unprocessed;

.(e) any and all research of GMOs, including laboratory, clinical or field research as well as production experiments;

.(f) deliberate imports/exports operations with GMOs and products obtained from such organisms;

.(g) deliberate transboundary movement of GMOs;

.(h) storage, burial or disposal of GMOs and/or pro ducts obtained from such organisms, utilization of waste produced from use modern biotechnology methods.

To assess potential danger for human health and environment generated by activities regulated by the above law, the following risk classes were specified for isolated systems for GMOs:

Class I: activities with negligible risks comparable to the risk of using non-pathogenic microorganisms, or without any risk;

Class II: activities with low risks comparable to the risk of using conventional pathogenic microorganisms;

Class III: activities with moderate risks comparable to the risk of using microorganisms potentially capable to spread infections;

Class IV: activities with grave risks comparable to the risk of using microorganisms capable to spread very dangerous infections.

The National Biosafety Committee (NBC) was established by Government Resolution no. 603 of 20.05.2003 and operates as the national inter-ministerial responsible authority.

According to the Regulation, the NBC has the following functions:

a) examination of notification documents;

b) elaboration of reports, synthesis and information for national and international uses;

c) public information;

d) cooperation with the competent research institutions;

e) maintaining and publishing the Register of the GMOs;

f) national and international participation.

The Regulation on authorization of activities connected with production, testing, use and distribution of GMOs (Government Resolution no. 1153 of 25.09.2003) has been drafted in line with the provisions of the Law on Biosafety and harmonized with *the EU Directive 2001/18/EC on deliberate release of GMOs in the environment, Directive 90/219/EEC on contained use of GMOs and Directive 98/81/EEC on contained use of GMOs.*

The Regulations provide for authorization of GMO-related activities via issuance of licenses confirming the holder's right to perform certain activities subject to compliance with the license (authorization) terms and conditions.

The Regulations require authorization of the following activities:

- contained use of GMOs;
- deliberate release of GMOs in the environment;
- deliberate market release of GMOs and products made thereof;
- imports/exports of GMOs and/ or products made thereof.

The National Biosafety Testing Center was established by joint Order of the Minister of Ecology and Natural Resources and Minister of Education no. 19 of 10.02.2004 and based on the decision of the Senate of State University of Moldova. The Center's task is to perform tests and control plants, seeds and foodstuffs to identify GMO presence and content therein. The Center will also perform assessment of potential risks such organisms might present for the environment and human health; and assessment conclusions will be used as the basis for decision-making in this sphere.

The national legislation includes a number of laws, which regulate the spheres indirectly connected with the issues of biosafety and food safety and which can influence decision-making to a certain extent, although they do not have provisions directly relating to the above issues.

These laws include: Laws on animal breeding, horticulture, plant protection, medicines, and other (12 laws on the total). Furthermore, the category of legislation acts indirectly related to the issues of biosafety includes a number of Parliamentary Resolutions and Government Decisions.

In view of the necessity to take urgent measures towards improvement of the situation with foreign trade and integration of Moldova's economy in the global trade system, the Government has approved a list of actions required to fulfill commitments made by the Republic of Moldova to the World Trade Organization (WTO) (Government Resolution no. 1035 of 16.10.2000).

In 1997 Moldova ratified the *Statutes of the Codex Alimentarius Commission* (by Parliamentary Decision no. 1342 –XIII of 8.10.1997). By becoming a member of the above Commission, the Republic of Moldova undertook to ensure protection of consumer health, to promote international trade and to harmonize the national requirements regarding food with the international requirements provided for in *Codex Alimentarius*. Those actions rated among the priority actions to facilitate accession of the Republic of Moldova to WTO.

To prevent spreading and imports of plant pests and unsafe food and to implement the relevant control measures, the Republic of Moldova has joined *the Convention on Plant Protection* (Law no. 926-XIV of 13.04.2000). *The Law on ratification of the Convention on Plant Protection* provides for establishment of state phytosanitary quarantine inspectorate and ensures representation of Moldova's interests in the Convention on Plant Protection of the Global Food and Agriculture Organization (FAO).

The legislation worth mention in that context includes *the Law on Protection of Consumer Rights* (no. 105-XV of 13.03.2003), effective since 27.10.2003 and substituting a similar law preceding it (no. 1453-XII of 25.05.1993).

According to that law, products and services categorized as inoffensive are those products and services, which do not present risks for consumer life, health, heredity or property, or for the environment. The law prohibits production, storage, market release and distribution of products and provision of services, which do not comply with obligatory requirements specified in the relevant regulatory documents, or which might present risks for consumer life, health, heredity or safety in the process of their intended use.

Authorization procedures

To obtain an authorization to perform activities connected with contained use, deliberate release in the environment or market release, the notifier must submit the following documents to the National Committee:

a) application specifying the merchant's name and legal status, registered office (actual location) and a Company State Registration Number or the individual's first name and family name, passport or ID number and issue date and personal State Registration Number as well as the activities for which authorization is requested;

b) special notification for each activity; c) environmental risk assessment report for the environment and human health accompanied with the relevant bibliography and indication of the used methods; and d) short notification information format.

Upon registration of the notification, the National Committee informs the public and starts public consultations, requests opinions from the national authorities for the environment, economy, agriculture and food industry, health care and protection of consumer rights. At the same time it transfers the summary file to a competent research institution for the purposes of risk assessment. Based on the accumulated information, the National Commission decides to issue the authorization or to reject the application, giving the applicant the substantiating argumentation.

Within 90 days upon issuance of the confirmation for being in receipt of the notification the National Committee must make one of the following decisions:

- To issue an authorization for the noti fied activities;
- To prohibit practice of the noti fied activities;
- To request additional information; or
- To extend the period required for decision- making for the time required to assess additional information.

Biosafety Institutional Framework

According to the provisions of the Cartagena Protocol and the Law on Biosafety, the Ministry of Ecology and Natural Resources was appointed the national authority in charge of their implementation.

The relevant institutional framework was established at the national level to ensure implementation of the Law on Biosafety, comprised of:

- National Biosafety Committee;
- National Focal Point for the Cart agena Protocol on Biosafety;
- Relevant scienti fic research institutions;
- Units/directorates and professionals operating within the framework of the Ministry of Ecology and Natural Resources, the Ministry of Agriculture and Food Industry, the Ministry of Health, state departments, agencies and other governmental authorities with functions in the sphere covered by the above law.

The National Biosafety Committee operates as the inter-ministerial authority and consists of 14 members, including:

- 2 members from the national environmenta l authority, which have the functions of respectively the Chairman and the Secretary of the National Committee;
- 4 members from the Academy of Sciences of Moldova;
- 3 members from other scienti fic institutions and universities with biological or medical profile;
- 1 member from each of the following national authorities: for economy, agriculture and food industry, health care, standardization and metrology, and from environmental NGOs.

The National Focal Point for the Cartagena Protocol is the national environmental authority, which has the function to ensure fulfillment at the national level of the responsibilities resulting from provisions of the international legal acts regarding implementation of biosafety measures regarding GMO use.

The National Biosafety Testing Center has been established for the purpose of assessment of risks for public health and the environment, testing of GMOs and products obtained therefrom, and monitoring of the relevant activities.

Monitoring

Monitoring of GMO-related activities is the task of the National Biosafety Committee. The national legislation does not specify the exact control authorities with the function of performing inspection and control of GMO-related activities. Monitoring objectives, general rules and procedures for development of a monitoring plan are specified in Appendix 5 (2) to *Regulations on authorization of activities connected with production, testing, use and distribution of GMOs.*

Although not a single application has been registered as yet regarding authorization of GMO-related activities, the relevant Moldovan authorities take certain actions by way of monitoring. The Ministry of Agriculture and Food Industry developed *Regulations regarding imports and exports of seeds and seedlings* approved by Government Decision no. 360 of 27.03.02. There is an urgent need to complete the existing legislation framework and enforcement system and to specify responsibilities and duties of the governmental inspection bodies with the GMOs monitoring and inspection functions.

Public awareness and involvement in decision making

Regulatory framework has been established in the Republic of Moldova to implement the principles of

public participation in decision-making in the field of biosafety (Article 23 of the Cartagena Protocol). The Ministry of Ecology and Natural Resources drafted the *Law on Biosafety*. (no. 755-XV of 21.12.2001). To ensure transparency of the NBC activities, a special procedure on consultations with the public has been included in the Biosafety law. The National Biosafety Committee should take into consideration the comments received from the public. Public hearings may be organized depending on the comments.

The Commission shall be guided by national legislation and international agreements to ensure public participation – Art. 39. This includes doubtless the *Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*. Based on the information in the submitted notification, the National Committee, acting in conformity with Government Decision no. 1153 of 25.09.2003, Paragraph 29 and 30, must inform the public about the information provided in the notification within 10 days upon its receipt and start consultations; consider the received comments and questions and place the notification documentation within the same time on the official web page of the National Environmental Authority. In decision-making regarding the notified activity, the Committee must consider comments in the nature of advisory received from the public within 30 days after the day of information dissemination. Depending on the received comments, the Committee may organize public hearings regarding any aspect of the issues being considered.

To ensure detailed implementation of the above provisions, the Minister of Ecology and Natural Resources issued Order 19 of 10.02.2004 *on Regulations on Information and Public Consultations on Genetically Modified Organisms* establishing procedures for regulation of public access to information regarding GMOs and mechanisms for influencing the discussion and drafting of decisions.

The Ministry of Ecology and Natural Resources must establish and maintain *the Register of interested parties* where any legal entity or individual may be included upon request. The list of interested parties approved by Order of the Minister for Ecology and Natural Resources should include, in particular:

- Environmental NGOs;
- Consumers and their associations;
- Medics and their associations
- Mass media;
- Scienti fic community;
- Farmers and their associations;
- Seed importers;
- Local public administration authorities;
- Local communities;
- Professional associations.

The National Committee should inform interested parties via Internet or otherwise about the following:

- Proposed activities and noti fication providing the basis for decision making, with the respective summary files;
- The type of decision to be made (issuance of an authorization for GMO imports, deliberate release in the environment or market release, use and location);
- The proposed procedures for examination, disse mination of information to the public, as well as address, procedures and deadlines for submission of comments and questions.

Local communities are considered an interested party where GMO use is proposed on the territory of the community or on the neighboring territory; they must be kept informed via local press, announcements placed on the board in or near the offices of the local administration authorities, public hearings or other methods within the timeframe established for information of interested parties.

Draft opinion of the National Committee with comments received and their assessment by the

Committee must be placed on the official web page of the Ministry of Ecology and Natural Resources, and representatives of the interested parties, which have made proposals in respect of the published information, are entitled to an argumented answer from the National Committee regarding acceptance or rejection of public proposals. The National Committee must make a final decision within 20 days after it places draft opinion on the web page in the Internet.

The National Committee maintains and publishes the *National Register of GMOs and products made with use thereof*, Authorizations regarding their use and the *Register of decisions regarding authorization of the relevant activities* together with non-confidential materials submitted by the applicant and expert opinions issued by the relevant research institutions.

NBF: FUTURE PLANS

Biosafety policy

The most important gaps of current political framework have been identified:

.– Political framework and strategies in the biosafety sphere are not very clearly determined or detailed sufficiently clearly;

.– There is no integration of biosafety to other related strategies or policies.

As mentioned in the above, the principal document, which currently determines the policies and strategy in the field of Biosafety in the Republic of Moldova, is the National Strategy and Action Plan in the field of Biodiversity Conservation. Annual action plans are developed based on this document. In this context it is necessary to include the activities making possible completion of an integral National Biosafety Plan in the action plans for the next 2-3 years.

Legislative framework and enforcement system

In this context, the Law on Biosafety should be amended to bring it in compliance with the National Biosafety Framework described earlier. Currently the Republic of Moldova has a single basic law – the Law on Biosafety and a number of additional regulations covering the issue of regulation of the activities connected with production, use and marketing of GMOs and products containing such organisms.

To these regulatory needs it would be necessary to introduce certain amendments to the Biosafety legislative framework regarding the following:

. • Segregation of powers and functions of state authorities regarding: a) the process of examination and decision making; b) involvement of new institutional components – technical biosafety committees of the relevant ministries and departments, and development of their statutes;

. • procedures and methodologies for monitoring, inspection and control of the authorized GMO-related activities;

. • introduction of a new chapter regarding the Biosafety Clearing House and Biosafety Register;

. • development of procedures and methodologies for testing and risk assessment/ management of biotechnology risks.

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- procedures and methodologies for monitoring, inspection and control of the authorized GMO-related activities;
- introduction of a new chapter regarding the Biosafety Clearing House and Biosafety Register;
- development of procedures and methodologies for testing and risk assessment/ management of biotechnology risks.

It would be necessary to amend and harmonize branch laws with the provisions of the Cartagena Protocol and the National Biosafety Framework.

Furthermore, it would be necessary to amend the following laws and regulations with provisions regarding contained use, deliberate release into the environment, placing on the market, imports/ exports, transport, labeling, packaging and customs procedures:

Within the system of the Ministry of Agriculture and Food Industry:

- Government Decision no. 863 of 21.08.2000 *On approval of the National Concept for ecological farming, production and distribution of environmentally clean food not modified genetically*;
- *Law on Seeds* (no. 659-XIV of 29.10.1999);
- *Law on Protection of Plant Varieties* (no. 915-XIII of 11.07.1996);
- *Law on Horticulture* (no. 728-XIII of 06.02.1996);
- Government Decision no. 697 of 10.10.1995 *on establishment of the State Phytosanitary Quarantine Service*;
- *Law on Phytosanitary Quarantine* (no. 506-XIII of 22.06.1995);
- *Law on Animal Breeding* (no. 412-XIV of 27.05.1999).

Within the system of the Ministry of Health:

- *Law on Medicines* (no. 1409-XIII of 17.12.1997);
- *Law on Public Sanitary Epidemiological Security* (no. 1513-XII of 16.06.1993);
- *Law on Health Care* (no. 411-XIII of 28.03.1995);
- *Law on Protection of Consumer Rights* (no. 105-XV of 13.03.2003);
- Government Decision no. 1297 of 27.11.2001 *On intensification of Consumer Protection Actions;*
- Government Decision no. 477 of 19.05.2000 *On establishment of the national network for laboratory control and monitoring of the bacterial (biological) environment pollution*;
- Government Decision no. 996 of 20.08.2003 *On approval of Requirements to labeling of food and Requirements to labeling of household chemicals;*

Within the system of the Standardization and Metrology Department:

Law on Standardization (no. 590-XIII of 22.09.1995);

Law on Metrology (no. 647-XIII of 17.11.1995).

For efficient application of the Biosafety Law it would be necessary to develop a package of new regulations, which would ensure enforcement and implementation of this law. An Action Plan for emending branch regulations will be elaborated. To this end it would be necessary to develop detailed regulations, guidelines and manuals covering the following:

- procedures and internal documentation for the Testing Laboratory;
- procedures and methodologies for risk assess ment in situations of contained use;
- procedures and methodologies for risk assessment in situations of deliberate release into the

environment;

- procedures and methodologies for risk assessme nt in situations of placing on the market;
- operation of technical committees within th e relevant ministries and institutions and Technical Committee of the National Biosafety Committee;
- guidelines and checklist for examination of noti fications and risks assessment;
- procedures and methodologies and requirements for packaging, labeling, storage and transportation;
- monitoring of the GMO activities;
- establishment of the state GMO inspecti on system (guidelines for relevant branches inspectorates);
- education and training in the field of GMOs for public servants;
- contents and maintenance of the National GM O Register including providing information to the BCH;
- methodology of calculation of costs and charges in the GMO regulation system;
- information and management of consequences in case of emergency, accident or unintentional release;
- adjustments of the Regulation on authorization of activities related to obtaining, testing, use, release into the environment and placing on the market of genetically modified organisms and products containing such organisms to relevant requirements for the comprehensive National Biosafety Framework;
- approximation of customs procedures to the international requirements regarding GMO transboundary movement;
- examination of possibilities to simplify GMO imports/exports customs procedures with the neighboring countries and in the region;
- regulations regarding con fidential information.

System for handling and institutional setting-up

The National Environmental Authority and Branch Authorities

According to the new concept of the Biosafety Framework for the Republic of Moldova, the National Biosafety Committee will be the advisory body in this area, and the National Environmental Authority will be in charge of decision-making.

As Moldova's authority responsible for liaison with the Convention Secretariat, the National Environmental Authority must have the following additional functions in order to:

- develop the national policy in the field of biosafety;
- make decision taking into account the Na tional Committee's recommendations regarding activities connected with GMOs use and issue authorizations;
- administrative procedures to ensure coordina tion at the national level of activities provided for in the Cartagena Protocol;
- establish and maintain the National GMO Register;
- finance and coordinate the activities of the Biosafety Clearing House and Public Relations Office;
- develop the legislative and regulations

The National Biosafety Committee and Ministerial Technical Committees

The National Biosafety Committee will have advisory functions in the process of decision making in the field of biosafety. To achieve these objectives, it will have the tasks to:

- develop opinions in the nature of recomme ndations regarding approval or rejection of GMO-related activities requested by the notifier;
- submit the respective opinion to the National Environmental Authority for approval;
- coordinate its actions with technical comm ittees on biosafety in the relevant authorities and

institutions and with units in charge of monitoring, inspection and control functions;

- coordinate the operation of the Nationa l Testing and Risk Assessment Center;
- develop concepts regarding state strategies and policies in the field of biosafety and GMO;
- coordinate authorization issuance and au thorization withdrawal procedures; and
- monitor the process of information and public consultations.

To ensure efficient examination of notifications and risk assessment, it is proposed to establish technical committees for biosafety within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova.

Such technical committees will have the tasks to:

- assess the noti fier's activities and the degree of risk these activities might present for the environment and human health;
- issue the respective opinion and submit it to the National Committee.

Biosafety Clearing House, Public Relations Office and the GMO Register

To comply with the requirements of the Cartagena Protocol, the National Biosafety Clearing House and Public Relations Office will be established within the National Environmental Authority. This Office will have the functions to:

- gather information and develop databases on GMO-related activities;
- establish and maintain of an interactive sy stem for public consultation to ensure public involvement in the decision making;
- ensure information sharing at th e national and international levels;
- ensure information sharing in emergency situations; and
- develop and maintain the GMO Register;
- establish the national BCH;
- ensure procedures for accurate and timely information flow to the BCH ;
- establish procedures for controlling completnes and accuracy of the information on the BCH.

Testing and Risk Assessment Center

The Center for Testing and Risk Assessment will have the following functions:

- testing of living genetically modi fied organisms to identify if they belong with the GMO category;
- testing of products to identify if they belong with the category of products obtained from genetically modified organisms or containing ingredients obtained from genetically modified organisms;
- assessment of risks presented by production, u se and management of GMOs in contained use and deliberative release;
- assessment of risks presented by placing on the market of products obtained from GMOs.

To comply with the requirements of the Convention and the Protocol, the following activities would be carried out to facilitate testing and risk assessment:

- Provision of the National Testing and Risk Assessment Center (TRAC) with the required analytical laboratory equipment;
- Facilitation of TRAC national and international accreditation;
- Training of TRAC specialists in the field of testing and assessment of risks presented by GMO-related activities;
- Development of GMO sample databanks and access to reference material;
- Development and approval of methodologies for testing and assessment of risks for the environment and human health;
- Development of procedures for provision of testing and risk assessment services and for calculation of their costs.

Monitoring, inspection and control

To ensure monitoring, inspection and control, the institutions with the relevant functions will have the obligation to:

- Perform monitoring, inspection and control of GMOs in situations of contained use, release to the environment and placing on the market;
- Control the notifier's compliance with technical requirements and standards specified in the authorization;
- Impose penalties according to the applicable laws in case of non-compliance with applicable standards;
- Initiate the procedure for authorization withdrawal in exceptional situations.

Transportation, labeling and packaging

For transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement, it is necessary to develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements.

The national authorities in the field of the environment, standards and metrology, and health care would have the task to develop methodologies for transportation, labeling and packaging of GMOs. The following actions will be taken to ensure fulfillment of these tasks:

- State Ecological Inspectorate (border-crossing offices) and the Customs Control Department will have the functions of border monitoring, inspection and control over compliance with the requirements for transportation, labeling and packaging of GMOs;
- Inside the country the functions of monitoring, inspection and control over transportation, labeling and packaging will be exercised by inspectorates within the Ministry of Health, Department of Standardization and Metrology, and State Ecological Inspectorate.

Customs procedures

The following actions are suggested to ensure control over GMO imports/exports/transit:

- To vest the function to perform customs procedures in respect of GMOs with the customs offices at border-crossing points;
- To establish inspection, control and monitoring services within the customs office to ensure control over imports/exports/transit of GMOs;
- To include a special section in the customs declaration for the transported goods for the purpose of declaration of presence or absence of GMOs;
- To ensure prompt information of the national and international biosafety institutions about transboundary movement of GMOs.

FUTURE PLANS FOR THE DECISION-MAKING SYSTEM

According to the concept of the National Biosafety Framework, the decision-making system will be facilitated by a number of the national governmental authorities, depending on the intended use of GMOs.

The following regulations for internal use, guidelines and procedures will be developed to ensure implementation of the National Biosafety Framework:

. • Procedure for submission of notifications to the National Committee;
. • Procedure for preliminary examination of the submitted application for compliance with the requirements of the applicable legislation;
. • Procedure for forwarding of the notification to branch technical committees;
. • Procedure for forwarding of the notification to the National Testing and Risk Assessment Center, if necessary, for assessment of potential risks for the environment and human health;
. • Procedure for placement of information on the web site of the National Biosafety Authority;
. • Procedure for examination by the National Biosafety Committee of opinions issued by technical committees and the National Testing and Risk Assessment Center and consideration of the public opinion;
. • Procedure for issuance of the opinion of the National Biosafety Committee;
. • Procedure for forwarding the application documentation package and the Opinion of the National Biosafety Committee to the National Environmental Authority for approval;
. • Procedure for issuance of authorization by the National Biosafety Committee;
. • Procedure for public consultation and public hearings.

The decision-making methods and procedures are supposed to be similar for situations of contained use, deliberate release into the environment and placing on the market of genetically modified organisms and products derived from GMOs

FUTURE PLANS FOR RISK ASSESSMENT

It is proposed to perform optional assessment of risks presented by activities connected with genetically modified organisms in the Republic of Moldova. The National Biosafety Committee will decide on case-by-case basis regarding the necessity to perform additional tests for the purpose of risk assessment in Moldova's conditions. The notifier would have to submit an application to the National Biosafety Committee to obtain an authorization for activities connected with genetically modified organisms.

Together with the application, the notifier would have to submit a set of documents presenting the findings of prior scientific research or survey of prior practices, which is designed to demonstrate the low or reasonable risks in planned activities connected with genetically modified organisms. If such documents are satisfactory and convincing for the National Committee, the procedure for issuance of the authorization will not involve additional risk assessment tests. If the National Committee finds the argumentation presented in such documents unsatisfactory or insufficient, it initiates the procedure of risk assessment via additional tests to be

performed by the National Testing and Risk Assessment Center.

Taking into account limited experiences of the biosafety risk assessment procedures in Moldova, it is an urgent need to ensure training of decision makers, experts and researchers in risk assessment methodologies.

FUTURE PLANS FOR PUBLIC INFORMATION, EDUCATION AND PARTICIPATION MECHANISMS

To implement the standards ensuring public participation in the field of biosafety, regarding the issue of risks connected with use of GMOs, the National Biosafety Committee must:

- ensure public access to decision making process;
- ensure public awareness via mass me dia, seminars, books, brochures, etc.;
- create a web page, inform the public about it and ensure its regular updates;
- establish permanent contacts and colla boration with the relevant accredited NGOs and other stakeholders with the purpose of involving them into the decision making process and into the process of adequate public information;
- develop capacities for implement traceability and transparency;
- inform the public regarding the problem s and risks associated with use of GMOs via mass media, workshops, publications, etc.;
- create a specialized web page, inform the public about it and ensure its regular updates;

The awareness of general public of the term ğenetically modi fied"is quite high, but the level of knowledge is low and mostly formed by fright of the unknown due to the following: for the most part adversely presented/ scandalous information on GMOs is disseminated via mass media and enhanced by the lack of understanding regarding basic facts behind modern biotechnology products. However, it was felt that the importance of the issue for the general public is moderate and influenced by other aspects, such as food price.

The following activities could be recommended to raise public awareness and knowledge: 1 dissemination by mass media of information regarding basic facts underlying modern biotechnology – with assistance of popular science writers; it would be recommended to use publications in specialized magazines (health, agriculture) and daily newspapers; 2 raising awareness via qualified intermediaries, such as science teachers at schools; 3 public participation in decision-making processes (facilitated via involvement of local governments).

Information sharing and consultations

Public information and consultations can be ensured via identification of the interested parties and development of their Register with due consideration of the fact that this category may include any party accredited in this field. Provisions of Government Decision no. 1153 of 2003 and Order of the Ministry of Ecology and Natural Resources no. 19 of 2004 must be implemented to this end. The process of information and consultation should be performed with assistance of the relevant nongovernmental sector.

Annex E

Equipment and materials needed for the testing laboratory

Materials and Services					
1.Refrigerate variable speed microcentrifuge (to order rotors separately)					
Catalogue number	Power VAC/Hz	Dimensions		Sh. pg wt libs (KG)	Price $US
H-02550	115/60	23 ½W x 12"x 18 ½D		110 (49,9	8,030.00
Rotors					
Catalog number	Capacity		Shpg W		Price $US
H-02550-60	Eighteen 1.5 ml tubes		4 Jbs (1.8 kg)		694.00
H-02550-61	Twenty-four 500 µl tubes		4 Jbs (1.8 kg)		747.00
H-02550-62	Thirty 250 or 400 µl tubes		4 Jbs (1.8 kg)		747.00
			Sub-total	**$ US**	**10,174.00**
2. Electrophoresis cell					
Cat. Nr.	Description		Gel size		Price $US
H-28553-10	Buffer exchange ports		13x25 cm		384.00
H-28553-30	Buffer exchange ports		20x25 cm		488.00
H-28553-40	Buffer exchange ports		20x40 cm		623.00
Replacement combs. (for horizontal electrophoresis cells)					
Cat. Nr.	Number of veils		Gel thickness		Price $US
For model 28553-10					
H-28553-11	12		1,5 mm		32.00
H-28553-12	16		1,5 mm		32.00
H-26553-13	20		1,5 mm		32.00
For model 28553-30					
H-28553-31	16		1,5 mm		32.00
H-28553-32	24		1,5 mm		32.00
H-28553-33	36		1,5 mm		32.00
For model –40					
H- 28553-41	24		1,5 mm		32.00
			Sub-total	**$ US**	**1,719.00**
3.Variable –flow digital pump systems					Price $US
H-07523-20 Master flex L/S drive, 10 to 600 rpm, 90 to 130 VAC 50/5Hz Shpg wt 15 Jbs (6,8 kg) Pump head and tubing ordering information					1,150.00
Tubing size	Flow rates (ml/min) 10-600 rpm	Pump head cat. nr.	Price $US	Silicon /pk Cat.nr.	Price 25 ft (7,6 m) $US

13	0,6 to 36			H-96410-13	32.00
14	2,1 to 130			H-96410-14	40.00
16	8 to 480	H-07518-10	206.00	H-96410-16	45.00
25	17 to 1000			H-96410-25	62.50
17	28 to 1700			H-96410-17	68.50
18	38 to 230			H-96410-19	73.00
				Sub-total	**$ US 1,677.00**

4. Dual –purpose cross-link/trans illuminator units

Cat. nr.	Filter size	VAC	Price
H-28101-35	200 mm x 350 mm	280	3,270.00
H-09815-59	UV light tube , 254 nm		20.00
		Required 6 x 20=	120.00
H-09814-60	Replacement filter , 200x350mm with UV-protector cover		1,470.00
		Sub-total	**$ US 4,860.00**

5.pH/JON meters

H-59812-50 Model 020A pH/ion meter kit		Price $US 2,400.00
For 110VAC operation		
Accessories		
H-56619-91 Triode 3-in-1 combination pH/ATC electrode sealed; gel filled includes instruction		147.00
Meter starter kit		
H-58819-619 Portable meter starter kit		160.00
	Sub-total	**$ US 2,707.00**

6. Temperature cycler

H-20520-00 Thermal cycler , 36-well x0,5 ml			Price $US 4,110.00
H-20520-50 Tube rack		43.00 x 5	215.00
H-205-60 –free tubes	Pack 1000	272.00/pk	272.00
		Sub-total	**$ US 4,597.00**

7. BOD Refrigerator

H-44187-00	Price $US 4,440.00
Sub-total	**$ US 4,440.00**

8. Access RT –PCR-system

Cat. Nr.	Pack size	Price $US
A 1280	1 kit	1468.00 x 2= 2,936.00

Sub-total	**$ US**	**2,936.00**
TOTAL EQUIPMENT		**33,110.00**

SUPPLIES .
CHEMICALS:
For PCR, RAPD, RFLP
1. N 200435, 10x Taq DNA Polymerase Buffer, 10 ml; **2**.N 600131 Taq DNA Polymerase 100 U; **3**. N 600130 Perfect Match PCR Enhancer 200 U; **4**. N 200415 Deoxynucleotide Mix, 400 µl, 25mM of each dNTP; **5.** Primers; **6.** For Restriction Enzymes and Buffers (N 500220 BamHI, 10000 U; N 500480 EcoRI, 10000 U; N 500600 Hind III 10000 U).
For: electrophoresis, DNA isolation and other techniques:
Agarose, Tris-HCL, SDS, EDTA, NaOH, HCl, NaCl, K-acetat, Boric acid, Acetic acid, Ethidium bromide, Bromphenol blue, Xylene cyanole FF, Glycerol, Isopropanol, Etanol

Sub-total	**$ US**	**5,290.00**
TOTAL SUPPLIES		**5,290.00**
TOTAL EQUIPMENT AND SUPPLIES		**38,400.00**

Annex F : Monitoring and Evaluation Plan

C.6 a Execution performance and delivered outputs

Monitoring of the project execution will assess whether the management and supervision of project activities is efficient and seek to improve efficiencies and overall effectiveness of project implementation. It is a continuous process, which will collect information about the execution of the planned activities, allow for improvements in method and performance, and compare accomplished with planned tasks. This activity will be under direct responsibility of the National Coordination Committee (NCC). The UNEP Task manager will, in collaboration with the NCC, track these indicators (Table 2).

Table 2 Indicators and Means of verification

Indicator	**Means of Verification**
Half-yearly and annual activity and progress reports are prepared in a timely and satisfactory manner	Arrival of reports to UNEP
Half-yearly disbursement plans and half-year and annual financial reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Yearly GEF Project Implementation Review reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Performance targets, outputs, and outcomes are achieved as specified in the annual work plans.	Semi annual and Annual progress reports
Deviations from the annual work plans are corrected promptly and appropriately.	Work plans, minutes of SC meetings
Disbursements are made on a timely basis, and procurement is achieved according to the procurement plan.	IMIS system at UNEP and Bank Account statements of executing agency
Audit reports and other reviews show sound financial practices.	Audit statements
National Coordinating Committee is tracking implementation progress and project impact, and providing guidance.	Minutes of NCC meetings
National Coordinating Committee is providing policy guidance, especially on achievement of project impact.	Minutes of NCC meetings

Monitoring and evaluation of project execution will be conducted through constant interaction, namely exchange via email and technical support or supervision missions. Throughout the project, approaches will be integrated with feedbacks, lessons learnt and best practices gained. The task manager will facilitate exchange of experiences between countries in the process of implementing their NBF. A meeting of the NPCs of the ongoing implementation projects is expected to be held annually.

The monitoring plan also covers the risks associated to project management. In this respect, special attention will be devoted to:

Management structure	so as to monitor whether stability and responsibilities are clearly understood
Work Flow	so as to verify if the project is maintaining its planned work load (key role in this case is played by quarterly reports and constant contacts)
Co-financing	so as to ensure that disbursements are carried out in time and with ease
Implementation	To verify if work plan is progressing according to schedule
Budget	So as to ensure that the work plan is progressing according to budget plans

Fund management[1]	So as to ensure that funds are wisely spent and correctly and transparently accounted for
Reporting	So as to monitor that work progress is reported comprehensively and on time. Reports contains critical analysis
Stakeholder involvement	So as to ensure that a multi-stakeholder process is in place and active
Communication	So as to guarantee that communication between management team members is fluid
Leadership	So as to ensure that project has an active and committed management team
Short term/long term balance	So as to guarantee that project meets short term need without compromising on long term outlook
Political influence	So as to verify project is making politically motivated decisions

C6.b Project impact

Evaluation of the project's success in achieving its outcomes will be monitored continuously through the project progress reports, mid-term and final evaluation reports, all of which will use the **log-frame** presented in Annex B. The full implementation of all components of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main focus for assessing the success of the project.

The Project Management team is responsible for monitoring progress as well as ensuring evaluation of impact. These are described in Tables 3 and 4 (below):

Table 3. Responsibilities of the project management entities regarding monitoring and reporting

UNEP Task Manager	National Executing Agency (NEA)	National Coordinating Committee (NCC)
Monitor the agreed M&E plan in accordance with the terms of agreement with GEFSEC Receive quarterly and annual reports (progress and financial), and copies of all substantive reports from (National Executing Agency). Task manager to attend and participate fully in meetings of the NCC Task Manager to conduct supervision missions to selected project sites and identify implementation problems and suggest remedies to annual meeting of the NCC. Engage and prepare terms of reference for independent M&E consultants to conduct the mid-term and final	Prepare quarterly progress reports (operational and financial) annual summary progress reports for UNEP, and forward quarterly operational and financial reports, with supporting documentation as appropriate, in a timely manner to UNEP. Carry out a programme of regular visits to project sites to supervise activities, and pay special attention to those sites with serious implementation problems	Meet at least on a quarterly basis and receive quarterly progress and financial reports, annual summary progress reports and all substantive reports and outputs and use them to review the progress of work in the project as a whole Advise on implementation problems that emerge, and on desirable modifications to the work-plan Monitor progress of the project, and advise on steps to improve it

[1] The total expenditures incurred during each year ending 31 December, certified by a duly authorised official, will be reported in an opinion by a recognised firm of public accountants according to UNEP regulations

evaluations		

Table 4: The key content required in the quarterly progress reports and financial reports

Report	Format and Content	Timing	Responsibility
Progress Reports			
Document the completion of planned activities, and describe progress in relation to the annual operating/work plan. Review any implementation problems that impact on performance Summary of problems and proposed action Provide adequate substantive data outcomes for inclusion in consolidated project half-yearly and annual progress reports Highlights of achievements	Reports will use standard UNEP Progress Report format. The project log frame (Annex B) will be attached to each report and progress reported against outcome and output indicators.	Quarterly, within 30 days of end of each reporting period,	NEA
The Project Implementation Review (PIR) reports	Per GEFSEC format	Yearly (after project has been under implementation for one year)	UNEP Task Manager
Consolidated Annual Summary Progress Reports			
Presents a consolidated summary review of progress in the project as a whole, in each of its activities and in each output Provides summary review and assessment of progress under each activity set out in the annual work plan-, highlighting significant results and progress toward achievement of the overall work programme	Reports will use a standard format to be developed following the UNEP Progress Report model The project log-frame will be attached to each report and progress reported against outcome and output indicators. A consolidated summary of the half-yearly reports Summary of progress and of all project activities Description of progress under each activity and in	Yearly, within 45 days of end of the reporting period	NEA

Provides a general source of information, used in all general project reporting	each output Review of delays and problems, and of action proposed to address with these Review of plans for the following period, with report on progress under each heading		
Financial reports			
Report on co-financing that has been provided to project as originally estimated in project proposal approved by GEF	Use Annex as found in project document with supporting documentation of realized co-financing	Six-monthly	NEA
Details project expenses and disbursements	Standardized UNEP format as found in project document Disbursements and expenses in categories and format as set out in standard UNEP format, together with supporting documents as necessary	Quarterly	NEA
Summary financial reports	(Standardized UNEP format as found in project document)		
Consolidates information on project expenses and disbursements	Disbursements and expenses by category. Requirement for coming period: request for cash advance.	Half-yearly, within 30 days of end of period	Project financial officer
Financial audits			
Annual audit	Audit of accounts for project management and expenditures	Annual	Recognised firm of public accountants according to UNEP regulations.

ANNEX G : EXAMPLE OF AN INCREMENTAL COST ANALYSIS

Project Components	Baseline	Alternative	Increment
Biosafety strategy	Biosafety is part of the Biodiversity Action Plan	Biosafety is integrated into an agreed strategy on biotechnology	The implementation of the Cartagena Protocol is supported by a biosafety strategy
Biosafety regulatory regime	The biosafety regulatory regime is in the last stage of preparation	A regulatory regime reflecting existing policies and defining all the elements of the NBF and related implementing procedures in line with CP and international obligations are in force.	The implementation of the Cartagena Protocol is supported by a legal regime, which includes 2 laws, three decrees and three orders. Decision-makers and personnel involved in the application of the regulatory regime are trained.
System for handling requests for permits	Country needs to set up procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively.	A system for handling requests for LMOs, including administrative processing, risk assessment and decision-making is set up. National capacities are strengthened in terms of training and equipment. Laboratories are equipped with upgraded facilities for LMO detection studies	The implementation of the Cartagena Protocol is supported by an operational system for handling requests, which includes administrative processing, risk assessment and decision-making
System for follow-up, namely monitoring for environmental effects and enforcement	Country needs to set procedures for follow-up activities, namely monitoring of environmental effects and enforcement. Technical means and training are needed so as to enable inspectors and technicians to carry out their tasks	Systems for monitoring of environmental effects and enforcement are in place. National capacities are strengthened in terms of training, and laboratory equipment needed for LMOs detection and enforcement are provided	The implementation of the Cartagena Protocol is supported by an operational system for monitoring for environmental effects and enforcement
Public information, participation, awareness and education	Awareness and education need to be further strengthened, involvement of the public need to be part of the system so as to reflect Article 23 of the Cartagena Protocol	A plan for public education, awareness, participation and access to information is formulated and implemented. Public debates and discussions in media are carried out, the national website for biosafety is operational and updated regularly.	The implementation of the Cartagena Protocol is supported by a strengthened system for public information, education, awareness and involvement.

Incremental cost assessment

Broad development goals

This project is part of GEF's wider effort in assisting countries to implement a biosafety regulatory regime in accordance with Agenda 21 and the CBD. More specifically, GEF resources will be used to assist Moldova to meet the objective of the Cartagena Protocol (*i.e.* to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements) through the full implementation of its NBF.

The project is consistent with, and based on, stated national priorities, plans and programmes in both the development and conservation sectors, including the National Agenda 21 and the National Strategy of Biological Diversity

Baseline

Within the context of the project, the baseline includes the activities carried out at domestic level with respect to each specific project component; the increment includes the activities proposed under this project proposal for the purpose of meeting the requirements of the Cartagena Protocol, to be financed through GEF contribution and national co-financing.

The cost of baseline activities at the national level is detailed in Table 5 . The various components of the NBF are important; but these amounts can support only very minimal activities.

The project builds on experience gained up to date through the demonstration projects, which can add to the baseline and is complemented by the BCH project approved in autumn 2005.

The commitment of the Moldovan Government is demonstrated by the national co-financing to the project, in-kind (US $147 000). Details of the budget are enclosed in Annex I.

Finally, though baseline refers only to activities other than the GEF sponsored ones, the Moldova benefited from previous funding through the UNEP/GEF Project to develop a National Biosafety Framework The project is therefore a logical follow-up to the support already provided to Moldova to meet the obligations of the Protocol.

GEF alternative

Although Moldova has absorbed the costs of global benefits with respect to biosafety as a priority goal at national level, limited human capacity and financial resources would not allow Moldova to meet its obligations as Party to the Cartagena Protocol, when this comes into force in the Moldova.

In summary, the incremental cost of the project components is estimated as follows (see table 5):

The total baseline expenditure amounts to US $ 122 200. The alternative has been estimated at

US $811,550. The country will cover more than 20 % of the cost of the project as in-kind contribution. A sum of US $ 542 350, corresponding to the remaining 80 % of the total cost of implementing the project, is required for GEF support.

Annex H. PROJECT IMPLEMENTATION PLAN

Duration of project (in months)	48 months							
ACTIVITIES	PROJECT-MONTHS							
	6	12	18	24	30	36	42	48
Component A The National Biosafety Policy for Moldova								
Activity A.1: Strengthened national Biosafety policy to guide the implementation of the Cartagena Protocol, National Biosafety Framework, National Biodiversity Strategy, and other national and international requirements								
Action A.1.1: Develop the Draft National Biosafety Action Plan, as a policy paper in conformity with national and international requirements	X	X						
Action A.1.2: Provide a Macroeconomic assessment survey, quantifying economic benefits and incremental risks/costs associated with the implementation of the National Biosafety Action Plan to the national economy and social development in Moldova	X	X						
Action A.1.3: 2 days Workshop with key decision-makers and public to discuss the Draft NBP and the economical assessment conclusions. The workshop will involve 50 participants form the parliament, government, sectorial bodies, stakeholders, public, NGOs, farmers etc.		X						
Action A.1.4: Consultation of the NBAP with the main decision-makers of the government in the pre-approval process			X					
Action A.1.5: Submit Draft NBAP to the Government for approving			X					
Activity A.2: Strengthened public and political support for Biosafety policy implementation								
Action A.2.1: Training on Biosafety policy for decision makers, NCC members, parliamentarians, public, etc. 20 participants, 2 days long training for feedback and proposals for the strategy			X					
Action A.2.2: Meetings with specific groups of stakeholders in different districts and communities. 5 one-day workshops				X				

(Northern, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of farmers, local politicians and authorities, consumers etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy. Total number of participants attracted – about 125 persons								
Component B The National Regulatory Regime (Legislation)								
Activity B.1: The National Biosafety Law reviewed, amended and harmonized with the provisions of the Cartagena Protocol, other international requirements related the inspection, monitoring and control of GMOs, institutional setting-up, as well as BCH and GMOs Register considerations								
Action B.1.1: Set-up an Expert Task force and prepare an Action plan for reviewing, amending and harmonizing the National Biosafety Law to meet the requirements of the Cartagena Protocol and the NBF	X							
Action B.1.2: Revise and amend of the Biosafety law by expert Task force in order to comply with the national biosafety policy and international obligations	X	X						
Activity B.2: Revise and amend the Branch legislation for the purpose of its harmonization with the Cartagena Protocol, national Biosafety policy and law								
Action B.2.1: Drafting suggestions and amendments to harmonize branch laws related to the national biosafety with the requirements of the Cartagena Protocol Biosafety policy and law and international requirements		X	X	X	X	X	X	
Action B.2.2: One-day Workshop for 30 participants to discuss of these amendments and completation to the laws related to the national biosafety regulations					X			
Activity B.3: Develop Secondary regulations and guidelines, required by the law, d and in force ensuring implementation of the Law								

Action B.3.1a: Drafting secondary regulations and guidelines required for the implementation of the Biosafety Law and NBF			X	X	X	X	X	
Action B.3.1b: Develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement			X	X				
Action B.3.2 Organize a Two-day training workshop for 50 Expert Task force, decision makers from branches governmental bodies and parliamentarian, legal experts, politicians and NGO representatives for promoting consensus regarding the biosafety requirements for branch regulation, secondary regulations	X							
Action B.3.3: Discuss and conciliate the Action plan of the Task force on national and branch regulations, secondary level regulation elaboration during a two-days training workshop on biosafety regulatory framework organized for Exert Task force, government officers, legal experts, politicians and NGO representatives for 50 participants	X							
Component C Administrative System for handling of requests								
Activity C.1: Functional risk assessment system in place								
Action C.1.1: Updating of Roster of experts for Risk Assessment			X	X				
Action C.1.2: Definition of national procedures and guidelines for Risk assessment.			X	X				
Action C.1.3 Establish Technical committees for risk assessment and opinion for decision making within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova				X				
Action C.1.4: Development check-list for Risk Assessment practitioners			X	X				

Action C.1.5: Five-days training workshop on Risk assessment for 30 decision-makers, researchers, experts and personnel (training provided by the invited external experts)				X				
<u>Activity C.2:</u> Strengthened capacities and tools for a functional decision-making system and system for administrative processing								
Action C 2.1: Development of administrative procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests			X	X				
Action C 2.2: Development of the administrative database	X	X	X	X	X	X	X	X
Action C 2.3: Development of administrative procedures for system to track dossier and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities			X	X	X	X		
Action C 2.4 : Development of administrative procedures and an operational manual for submission examination, consultation of notifications and decision making			X	X	X	X		
Action C 2.5: Development of administrative system for the protection of confidential information			X	X				
Action C.2.6: Establish electronic National GMOs Register	X	X	X	X	X	X	X	X
Action C.2.7: Two three-day training workshops on notification handling and decision making process in compliance with international obligations organize for decision-makers from involved ministries and departments for 30 participants				X				X
<u>Activity C.3:</u> Emergency response procedures established and operational								
Action C.3.1: Develop guidelines and rules for emergencies, and remediation plans, development of TORs for responsible persons, define emergency response procedures. Authority and staff nominated					X	X		
Action C.3.2: One-day training workshop for emergency operations for all stakeholders, officials, risk management , 20 participants						X		

Component D The National Systems for Monitoring and Enforcement								
Activity D.1: Monitoring, inspection and control procedures and capacities built and in place **Action D.1.1:** Clarify responsibilities and duties of different agencies to enable them to carry out their responsibilities for monitoring, inspection and control **Action D.1.2:** A four-day training course on monitoring, inspection and control procedures for 30 trainers: officials of different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services, Standards and Metrology, selected on the basis of their background and current duties				X	X X	X		
Activity D.2: Strengthened facilities and capacities for laboratory testing **Action D.2.1: :** Procurement Equipment and relevant reagents neede to operate the purchased main GMO detection equipment necessary for testing laboratory **Action D.2.2**: Two four-day capacity-building training courses on laboratory testing and risk assessment research methodologies activities for 10 laboratory researchers and technicians		X	X			X		
Activity D.3: Requirements for packaging, labeling, storage and transportation, transboundary or transit movement control of GMOs established. Strengthened capacity on import/export/transit of LMOs **Action D.3.1:** Establish procedures for custom control over import/export/transit of GMOs **Action D.3.2:** Three-day Training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement. Training focused for stakeholders, officials, custom services, inspections, risk management, business,				X	X X			

farmers, researchers public, ONGs etc, total for 40 participants								
Component E The National Mechanisms for Public Awareness, Education and Participation								
Activity E.1: Strategy for public awareness in place and enhance an efficient mechanisms for public consultations developed and implemented to ensure public participation in decision-making as a component part of the Biosafety strategy								
Action E.1.1: Development of guidelines and manuals regarding public consultations and participation					X	X		
Action E.1.2: Two three-day workshops on the importance of public consultations and information exchange, incl explanation of legislation, systems for public participation etc, for biosafety for 70 government officials, journalists, scientists and NGO representatives, consumers associations, farmers, press, civil society etc.			X				X	
Activity E.2: Increased public awareness, Best practices on Public participation learned and disseminated								
Action E.2.1: Regular updates of the national web-site on biosafety by the Biosafety Committee via Project	X	X	X	X	X	X	X	X
Action E.2.2: Production and dissemination of outreach materials, training materials, workshop summaries, technical manuals, publications in mass media, educational videos, brochures, etc.	X	X	X	X	X	X	X	X

ANNEX I : ACTIVITY BASED BUDGET

Activity code	Project activities	1st year GEF	GOV	2nd year GEF	GOV	3rd year GEF	GOV	4th year GEF	GOV	**Total GEF**	**Total GOV**
1 Biosafety policy											
Action A.1.1	Develop the Draft National Biosafety Action Plan, as a policy paper in conformity with national and international requirements	20 000	10 000							**20 000**	**10 000**
Action A.1.2	A Macroeconomic assessment survey provided, quantifying economic benefits and incremental risks/costs associated with the implementation of the National Biosafety Action Plan to the national economy and social development in Moldova	5 000	2 500							**5 000**	**2 500**
Action A.1.3	2 days Workshop with key decision-makers and public to discuss the Draft NBP and the economical assessment conclusions. The workshop will involve 50 participants form the parliament, government, sectorial bodies, stakeholders, public, NGOs, farmers etc.	4 240	1 500							**4 240**	**1 500**
Action A.1.4	Consultation of the NBAP with the main decision-makers of the government in the pre-approval process			2 000	2 000					**2 000**	**2 000**
Action A.1.5	Submit Draft NBAP to the Government for approval			3 000	3 000					**3 000**	**3 000**
Action A.2.1	Training on Biosafety policy for decision makers, NCC members, parliamentarians, public, etc 20 participants, 2 days long training for feedback and proposals for the strategy			2 260	1 000					**2 260**	**1 000**
Action A.2.2	Meetings with specific groups of stakeholders in different districts and communities. 5 one-day workshops (Northen, Central and Southern parts of the country, and in 2 large villages) will be held to clarify opinions of farmers, local politicians and authorities, consumers etc. regarding the biosafety strategy and taking into consideration their opinion for the final drafting of the Strategy. Total number of participants attracted – about 125 persons.			5 210	1 000					**5 210**	**1 000**

Total: Biosafety policy:		***29 240***	***14 000***	***12 470***	***7 000***					***41 710***	***21 000***
2 Regulatory regime											
Action B.1.1	Set-up an Expert Task force and prepare an Action plan for reviewing, amending and harmonizing the National Biosafety Law to meet the requirements of the Cartagena Protocol and the NBF	3 000	1 000							**3 000**	**1 000**
Action B.1.2	Revision and amendment of the Biosafety law by expert Task force in order to comply with the national biosafety policy and international obligations	3 000	1 000							**3 000**	**1 000**
Action B.2.1	Draft suggestions and amendments to harmonize branch laws related to the national biosafety with the requirements of the Cartagena Protocol Biosafety policy and law and international requirements	7 000	3 000	7 000	3 000	3 000	1 000	1 000	500	**18 000**	**7 500**
Action B.2.2:	One-day Workshop for 30 participants to discuss of these amendments to the laws related to the national biosafety regulations					1 490	500			**1 490**	**500**
Action B.3.1a	Drafting secondary regulations and guidelines required for the implementation of the Biosafety Law and NBF			5 000	2 500	5 000	2 500	5 000	2 500	**15 000**	**4 500**
Action B.3.1b	Develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement			2 000	500					**2 000**	**500**
Action B.3.2	Organize a Two-day training workshop for 50 Exert Task force, decision makers from branches governmental bodies and parliamentarian, legal experts, politicians and NGO representatives for promoting consensus regarding the biosafety requirements for branch regulation, secondary regulations	3 550	1 000							**3 550**	**1 000**
Action B.3.3	Action plan on national and branch regulations, secondary level regulation	3 980	1 000							**3 980**	**1 000**

	elaboration of the Task force discussed and conciliated during a two-days training workshop on biosafety regulatory framework organized for Exert Task force, government officers, legal experts, politicians and NGO representatives for 50 participants										
	Total: Regulatory regime	***20 530***	***7 000***	***14 000***	***6 000***	***9 490***	***4 000***	***6 000***	***3 000***	***50 020***	***20 000***
3 Handling requests											
Action C.1.1:	Updating of Roster of experts for Risk Assessment			5 000	2 500					**5 000**	**2 500**
Action C.1.2	Definition of national procedures and guidelines for Risk assessment			3 000	3 000					**3000**	**3 000**
Action C.1.3	Establish Technical committees for risk assessment and opinion for decision making within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova			3 000	1 500					**3 000**	**1 500**
Action C.1.4	Development check-list for Risk Assessment practitioners			3 000	1500					**3 000**	**1 500**
Action C.1.5	Five-days training workshop on Risk assessment for 30 decision-makers, researchers, experts and personnel (training provided by the invited external experts)			9 240	3 000					**9 240**	**3 000**
Action C 2.1	Development of administrative procedures for handling of notifications and requests for permits, including a manual for the administrative handling of requests			5000	2 000					**5000**	**2 000**
Action C 2.2	Development of the administrative databases	1 000	500	2 000	1 000	1 000	500	1 000	500	**5 000**	**2 500**
Action C 2.3	Development of administrative procedures for **s**ystem to track dossier and guard procedural steps at the level of policy-makers, decision-makers and implementing authorities			3 000	1500	2 000	1 000			**5 000**	**2 500**
Action C 2.4	Development of administrative pprocedures and an operational manual for submission examination, consultation of notifications and decision making			3 000	1 500	3 000	1 500			**6 000**	**3000**
Action C	Development of administrative system for the			3 000	1 500					**3 000**	**1 500**

2.5	protection of confidential information										
Action C.2.6	Establish electronical National GMOs Register	2 000	1 000	1 000	500	1 000	500	1 000	500	**5 000**	**2 500**
Action C.2.7	Two three-day training workshops on notification handling and decision making process in compliance with international obligations organized for decision-makers from involved ministries and departments for 30 participants			4 425	2 000			4 425	2 000	**8 850**	**4 000**
Action C.2.8	Develop guidelines and rules for emergency cases, and remediation develop TORs for responsible persons, define emergency response procedures. Authority and staff nominated					3 000	1 000			**3 000**	**1 000**
Action C.2.9	One-day training workshop for emergency operations for all stakeholders, officials, risk management , 20 participants					1 040	500			**1 040**	**500**
	Total: Handling requests	***3 000***	***1 500***	***44 665***	***21 500***	***11 040***	***5 000***	***6 425***	***3 000***	***65 130***	***31 000***
4 Follow-up, monitoring and surveillance											
Action D.1.1	Clarify responsibilities and duties of different agencies to enable them to carry out their responsibilities for monitoring, inspection and control			3 000	1 000	3 000	1 000			**6 000**	**2 000**
Action D.1.2	A four-day training course on monitoring, inspection and control procedures for 30 trainers: officials of different Inspectorates of MENR, Ministry of Agriculture, Ministry of Health, Custom services, Standards and Metrology, selected on the basis of their background and current duties					4 820	1 640			**4 820**	**1 640**
Action D.2.1	Equipment and related reagents related to the purchased main equipment necessary for testing laboratory procured	38 400	10 000							**38 400**	**10 000**
Action D.2.2	Two four-days capacity-building training courses on laboratory testing and risk assessment research methodologies activities for 10 laboratory researchers and technicians			3 360	1 680	3 360	1 680			**6 720**	**3360**

Action D.3.1	Establish procedures for custom control over import/export/transit of GMOs			3 000	1 000	3 000	1 000			**6 000**	**2 000**
Action D.3.2	Three-days Training workshop on transportation, labeling and packaging requirements and harmonizing them at the regional level and to the EU requirements for transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement. Training focused for stakeholders, officials, custom services, inspections, risk management, business, farmers, researchers public, ONGs etc, total for 40 participants					4 850	2 000			**4 850**	**2 000**
	Total: follow-up:	***38 400***	***10 000***	***9 360***	***3 680***	***19030***	***7 320***			***66 790***	***21 000***
5 Public awareness and participation											
Action E.1.1	Development of guidelines and manuals regarding public information and participation							10 000		**10 000**	
Action E.1.2	Two three-day workshops on the importance of or public information and participation in the framework of Moldova , public consultations and information exchange, inclusive explanation of legislation, systems for public participation etc, for biosafety for 70 government officials, journalists, scientists and NGO representatives, consumers associations, farmers, press, civil society etc.			8 250	3 000			8 250	3 000	**16 500**	**6 000**
Action E.2.1	Regular updates of the national web-site on biosafety by the Biosafety Committee via Project	4 000	2 000	2 000	1 000	2 000	1 000	2 000	1 000	**10 000**	**5 000**
Action E.2.2	Preparation and dissemination of outreach materials, training materials, workshop summaries, technical manuals, publications in mass media, educational videos, brochures, etc	11 000	3 000	13 000	3 000	22 000	5 000	10 000	3 000	**56 000**	14 000
	Total: public awareness and participation	***15 000***	***5 000***	***23 250***	***7 000***	***24 000***	***6 000***	***30 250***	***7 000***	***92 500***	***25 000***
	SubTotal A-E	***106 170***	***37 500***	***103 745***	***45 180***	***63 560***	***22 320***	***42 675***	***13 000***	***316 150***	***118 000***
6 Project coordination											
6.1	National Project Manager	9 600		9 600		9 600		9 600		**38400**	

6.2	Two Project Assistants	9 600		9 600		9 600		9 600		**38 400**	
6.3	One staff (half time) in charge of monitoring and evaluation issues and financial reporting	3 600		3 600		3 600		3 600		**14 400**	
6.4	National Coordination Committee Meetings, NCC travels	5 000	3 000	5 000	3 000	5 000	3 000	5 000	3 000	**20 000**	**12 000**
6.5	Equipment and premises component (expendable and non-expendable equipment)	5 000	10 000							**5 000**	**10 000**
6.6	Miscellaneous and others	3 000	1 250	3 000	1 250	3 000	1 250	3 000	1 250	**12 000**	**5 000**
6.7	Audit	1 000		1 000		1 000		1 000		**4 000**	
	Total: project coordination	***36 800***	***14 250***	***31 800***	***4 250***	***31 800***	***4 250***	***31 800***	***4 250***	***132 200***	***27 000***
7 Other project support											
7.1	Printing of reports and published work	2 500	500	2 500	500	2 500	500	2 500	500	**10 000**	**2 000**
7.2	Translation	1 000		1 000		1 000		1 000		**4 000**	
7.3	Postage cost for dissemination of documents	2 500		2 500		2 500		2 500		**10 000**	
7.4	Technical support	17500		17500		17500		17500		**70 000**	
	Total: project support	***23 500***	***500***	***23 500***	***500***	***23 500***	***500***	***23 500***	***500***	***94 000***	***2 000***
	Grand total	**166 470**	**52 250**	**159 045**	**49 930**	**118 860**	**27 070**	**97 975**	**17 750**	**542 350**	**147 000**

ANNEX J

Draft Terms of Reference for:

- **National Executing Agency (NEA)**
- **National Project Manager (NPM)**
- **National Coordinating Committee (NCC)**

a) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:

- Establish a National Co-ordinating Committee (NCC);
- Appoint a full time National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final version of the National Biosafety Framework no later than eighteen months from signature of this Memorandum of Understanding.

b) The **National Coordinating Committee (NCC)** will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

- Develop a common understanding of what is needed to expedite the implementation of the National Biosafety Framework;
- Oversee the implementation of the National Biosafety Framework
- Approve the detailed workplan and budget produced by the NPC;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project;
- Ensure that information on the implementation of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
- Assist in mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;
- Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;

c) The **National Project Manager (NPM), who will operate, as the National Project Coordinator (NPC)** will carry out the following tasks

- The National Project Coordinator (NPC) will act as the chair of the NCC

- Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Prepare detailed workplan and budget under the guidance of the NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP National Project Team;
- Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NCC, regular progress and financial reports

The **Project Assistants (PA)** will carry out the following tasks

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation detailed work plan and budget under the guidance of the NCC;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outp uts of the NBF;
- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports
- Assist with the preparation of a project monitoring and evaluation plan

- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact
- Assist with capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines
- Assisting in identifying problems in the implementation of the project and to alert the NPC and NCC.