



# **United Nations Environment Programme**

## **Terminal Evaluation of Selected UNEP-GEF Biosafety Implementation Projects**

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## List of Acronyms and Abbreviations

ABI	Agro Bio Institute (of Bulgaria)
ANUBIS	A New Universal Biosafety Information System
ASEAN	Association of South-East Asian Nations
BCH	Biosafety Clearing House
BSP	UNEP Bali Strategic Plan for Technology Support and Capacity Building
CBD	Convention on Biological Diversity
COP-MOP	Conference of the Parties – meeting of the Parties to the CPB
CPB	Cartagena Protocol on Biosafety
CSO	Civil Society Organisation
DELC	Division of Environmental Law & Conventions (of UNEP)
EAC	Eastern Africa Community
EFSA	European Food Safety Authority
EO	Evaluation Office (of UNEP)
EU	European Union
EURL-GMFF	EU Reference Laboratory for Genetically Modified Food and Feed
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organisms
IA	Implementing Agency (UNEP)
IFAD	International Fund for Agricultural Development
IHCP	Institute for Health and Consumer Protection (of EU)
IO	Immediate Outcomes
IS	Intermediate State (in the ToC)
IT PGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JRC	Joint Research Centre (of the European Commission)
LMO	Living Modified Organism
Log Frame	Logical Framework
MoA	Ministry of Agriculture
MoE	Ministry of Environment
M&E	Monitoring and Evaluation
MTS	Medium Term Strategy (of UNEP)

NABA	Namibian Biotechnology Alliance
NBF	National Biosafety Framework
NBFP	National Biosafety Focal Points
NCA	National Competent Authority
NCC	National Coordinating Committee
NCST	National Council for Science & Technology (of Kenya and Uganda)
NEA	National Executing Agency
NGO	No-Governmental Organisation
NPC	National Project Coordinator
PIR	Project Implementation Review
POW	Programme of Work (of UNEP)
ProDoc	Project Document
RA	Risk Assessment
RM	Risk Management
ROI	Review of Outcomes to Impact
SADC	Southern African Development Community
SC	Supporting Consultant
StC	Steering Committee
TL	Team Leader
ToC	Theory of Change
TOR	Terms of Reference
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation

## Executive Summary

1. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) is an international agreement which aims to ensure “the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology” that may have adverse effects on biological diversity, taking also into account risks to human and animal health. It was adopted on 29 January 2000 and entered into force on 11 September 2003.

2. The Global Environment Facility (GEF) has been designated to serve as the financial mechanism of the Protocol. In this context, since 1997, UNEP, in its capacity as an Implementing Agency of the GEF, has been providing administrative and technical assistance to the countries that gradually came to participate to the CPB, in order to enable them handle all aspects of biosafety, arising from the transboundary movement of food and feed derived from LMOs and the deliberate introduction of LMOs into the environment. For that purpose, the creation and implementation of a coherent combination of policy, legal, administrative and technical instruments, the so-called National Biosafety Framework (NBF), was deemed essential.

3. This terminal evaluation refers to fifteen selected UNEP-GEF projects supporting the implementation of the NBF in fifteen countries, namely:

- Eight (8) 3-year Implementation Projects, also called “Demonstration projects” started in September 2002 in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. The majority of them were completed by 2006.
- Seven (7) 4-year Implementation Projects started in 2006 in Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and Vietnam and completed between 2010 and 2011.

4. The evaluation team consisted of two experts, i.e. a Team Leader, who put emphasis on the methodology development and biosafety risk assessment aspects of the projects, and a Supporting Consultant, who mainly assessed capacity building, policy development and dissemination of lessons learned and best practices. The evaluation approach included a desk review of background and project documentation, made available through the UNEP’s A New Universal Biosafety Information System (ANUBIS), documents available at Biosafety Clearing House (BCH), a questionnaire sent to the fifteen countries and, eventually, field visits to eight of them (Cambodia, Czech Republic, Kenya, Lithuania, Namibia, Poland, Slovakia and Vietnam).

5. The major outcome of all fifteen NBF Implementation Projects was to enable the participating country to convert their draft NBF into a workable, effective, and transparent regulatory regime, in line with national priorities and international obligations. The NBF, though variable from country to country, includes five core components: (1) a national policy on biotechnology and biosafety; (2) a regulatory and administrative regime: law(s), enabling regulations, technical guidelines; (3) building capacity and human skills in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement; (4) information systems on biosafety, including the development of a national Biosafety Clearing-House (BCH); and (5) promoting public information and awareness on issues related to modern biotechnology and biosafety.

6. The mission found that UNEP-GEF funded Projects have successfully supported the selected countries in significantly enhancing their national capacities to implement the National Biosafety Frameworks (NBF). More specifically, the projects have largely contributed to:

- a) the definition of national biosafety policies / strategies, including a national Biosafety Law in virtually all the countries, in line with the Cartagena Protocol and the national needs and priorities;
- b) the setting and implementation of responsive Regulatory and Administrative regimes (Regulations, Guidelines, etc.) capable, at variable levels from country to country, to manage requests, carry out risk assessments and administrative tasks for handling LMOs;
- c) enhance national capacities, through extensive training and capacity building activities of a number of officers and professionals in all the relevant institutions;
- d) the development of a biosafety information system, though at variable levels of implementation;
- e) the promotion of awareness raising and education of the general public in all the countries.

7. The evaluation has equally ascertained that the process of NBF implementation, while appearing mature and solid in few countries, still needs improvement in others. The different baseline situation of the countries has surely played a major role in the delivery of outputs and outcomes. In this context, the solidity and functioning of existing institutional frameworks has played a crucial role in the process of NBF implementation.

8. Furthermore, Biosafety is, by its own nature, a complex and multi-sectorial issue, which requires effective coordination and synergies between different line-ministries, competent for Agriculture, Environment, Health, Science and Technology, Education, Trade and Foreign Affairs, among others. Therefore, the involvement of the institutions and the coordinating role of the National Competent Authority (NCA) is crucial for the consolidation of the process.

9. Some countries are currently smoothly implementing their NBF and show that they have strong institutional and technical capacities to upgrade their systems and to move forward. In other countries, however, the dynamic environment promoted by the project has not always been accompanied by a parallel institutional up-take and consolidation. In these cases, the approval of National Laws on Biosafety and Regulations took longer than was perhaps too optimistically, expected.

10. Overall, the evaluation team has concluded that the project has been successful in achieving its main objective. National Biosafety Frameworks are actually being implemented, though the mechanisms of implementation need, in some cases, to be improved. In some cases, human resources have to be strengthened while, in others, the information system, the institutional networking / coordination, or the public participation needs to be enhanced. Eventually, not all the countries are equally attractive for LMOs developers, due to their different agricultural potential or productive system, capacity and / or to the general development environment in place. In these cases, NBF may be in place, but not significantly stimulated to operate.

11. The Theory of Change of the Project, elaborated by the evaluation team in their Inception Report and validated during the field missions, shows that the main drivers and assumptions that influenced the achievement of the Outcome and will influence the progress towards Impact are:

- a) the ability of the NCA to coordinate the whole process of LMOs management and to motivate national partners in taking part in the decision-making process;
- b) the proactive participation of a large and qualified group of stakeholders representing different sectors and interests, and the increased involvement and participation of the public, based on unbiased information;
- c) the effectiveness and smoothness of the LMOs' management system, which includes: LMOs detection and referral systems, efficient systems of handling applications, capacities of risk assessment and risk monitoring
- d) at different levels (biological, environmental, socio-economic), quality information timely flowing into BCH and national websites.



12. Five, out of the eleven Evaluation Criteria, are rated as Satisfactory (S), while four have been rated Highly Satisfactory (S) and one as Moderately Satisfactory (MS). Sustainability is Moderately Likely (ML). Therefore, as a whole, the projects performance has been considered Satisfactory.

13. Sustainability has been rated as Moderately Likely (ML). In fact, the mission deems that the overall sustainability of the process of NBF implementation is still challenged in some relevant aspects: the socio-political sustainability is likely to be highly conditioned by the political agenda of those who are governing the country, while the institutional frameworks have still to be consolidated in some cases and the financial sustainability may be hampered by the widespread State budget cuts, due to the global economic crisis.

14. As far as Stakeholders Participation and Public Awareness are concerned, and taking into account the fact that, in most of the countries, civil society had not been previously significantly (if any) exposed to Biosafety issues, great improvements have been registered in all the countries. Nevertheless, and notwithstanding some brilliant initiatives, public participation still needs to be generally improved. The National Biosafety Commissions (Councils or Committees), for instance, are basically composed by Ministries and Public Institutions representatives, some academic and research organizations, individual experts and scientists, while Civil Society Organisations and representatives of the Private Sector (biotech developers) are clearly under-represented. Forms of wider, more proactive participation in NBF implementation need therefore to be generally pursued.

15. As far as Country Ownership is concerned, the mission found that NBFs' implementation has been a country-driven process and generally the NCAs have been proactive in mobilising political commitment and available resources for this purpose. However, the Biosafety Agenda is a complex and sensitive issue that can be hardly tackled by any single country, particularly small and / or low-income countries. Therefore, the national interests of those countries and their capacity to actively participate in the implementation of the Biosafety Agenda, would probably find a more appropriate arena in the regional and international fora, such as the COP-MOP.

16. The processes affecting the attainment of project results has been characterized by a "learning by doing" approach that has fostered the progressive inclusion of new countries, based on the experience of those that had been previously involved. Different baseline situations were generally tackled by the national executing agencies and project coordinators with appropriateness and dynamism everywhere, and the implementation approach has been adaptive enough to deal with diverse and complex situations with efficiency. Despite the fact that the UNEP Biosafety Unit has been progressively downsized, its positive role and dynamism in coaching and coordinating the national teams has been remarkable.

17. GEF funding was based on the funding requirement of the incremental cost and depended on the actual needs of the countries during projects design and implementation. The same applied to the co-finance request. Overall, the funding was need-driven and proportionate to the country's capacity to co-finance. All the funds supplied by GEF were entirely used and the overall expenditure ratio (actual / planned) was higher than 100%, due to increased national contribution (co-financing). The main financial / management documents of the projects are uploaded in the online information system put in place by UNEP (ANUBIS), which has been highly effective for the clear and transparent financial management of the projects, all of them having been formally closed without any pending administrative issue.

18. The mission believes that improved decision-making processes and enhanced good governance practices (crucial for enabling the Governments to fulfil the requirements of the CPB) have to be pursued through more focussed and cost-effective measures on a "country by country" basis, and with a regional approach to problem-solving and capacity building. The mission recommends, therefore, that UNEP should strongly encourage and support East Africa countries, Southern Africa countries and South-East countries to jointly assess their NBFs and to establish a

regional / sub-regional plan of NBFs' upgrading, taking into account possible complementarity and cooperation.

19. In the same perspective, the mission further recommends UNEP to coordinate the training and enhancement of regional experts (training of trainers) on crucial areas such as advanced laboratory techniques, technical guidelines definition, risk assessment and management, risk monitoring and evaluation. It is recommended that, based on the regional /sub-regional approach a list of thematic areas of capacity building, a roster of national experts and a regional capacity building plan are prepared.

20. Regarding Civil Society and Private Sector participation in NBF implementation, the mission concluded that more opportunities should be given to those actors for actively participating in the decision-making process on LMOs and recommends that, while the National Biosafety Committees (Commissions or Councils) should enhance the participation of those stakeholders, the NCAs should be more proactive in involving different target groups (e.g. small farmers, commercial farmers, university students, consumers, environmentalist groups) with appropriate, specific contents and means.

21. The evaluation has found that the cooperation on Biosafety between UN agencies and programmes has been weak so far, despite Biosafety encompassing different issues, such as international trade mechanisms, intellectual property rights issues, food security and food sovereignty, among others. Increased coordination and synergy are recommended; more specifically, a strong collaboration with FAO and IFAD should be implemented in those countries where issues like "coexistence" (between LMOs, traditional and organic farming) and "socio-economic considerations" under Article 26 of the Cartagena Protocol, are at stake.

## Main report

### I. Evaluation Background

#### A. Context

22. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs)<sup>1</sup> resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003.

23. Genetic modification is only one of the techniques of modern biotechnology, but it is regarded as particularly controversial because it entails the modification of individual genes, hence the possibility to alter the genetic coding of living organisms. Despite being a contested issue, genetic modification has already numerous scientific and commercial applications, due to its high potential in healthcare, agriculture, industrial production, and environmental protection.

24. The debate on the use and diffusion of LMOs is appropriately defined as “vigorous and often polarized” involving a series of concerns that “range from ethical considerations to potential risks to human health and the environment, and encompass also a number of socio-economic issues”<sup>2</sup>. Some argue that genetic modification can help the world by producing more and better food, green energy (biofuel and biomass), new valuable industrial products (pharmaceuticals, less pollutant chemicals, fibres, etc.) and social services (e.g. better health care).

25. Others claim that there is still insufficient evidence to show increased yields and inadequate knowledge on toxicity and allergenicity of LMOs food products, and that the environmental consequences are likely to be significant and quite unpredictable. Moreover, it is argued, socio-economic consequences could be severe for small scale farming systems in developing countries, while the economic and technologic power of a few companies would make world agriculture dangerously controlled by seeds, feed and food monopolies also putting patents on living organisms, genes and genetic resources, which would be “ethically unacceptable”.

26. Based on the debate summarily sketched above, policy discussions have taken place at national and international levels and regulatory frameworks have been progressively developed and implemented, in pursuit of a balance between the benefits of the technological innovation and the environmental and public health concerns. Considering the increased transboundary movement of LMOs, following the expansion of international trade and globalization, Biosafety has become a challenging issue for the international agenda and that is why the Cartagena Protocol has been negotiated and adopted.

27. The “principle of prevention” is considered one of the foundations of domestic and international environmental law, taking into account the difficulty and the costs of redressing environmental damages. In application of the principle, procedures and methods like risk analysis, or environmental impact assessment, have been increasingly adopted to supply decision-makers with more solid information on the possible consequences (environmental, economic and social) of their

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<sup>1</sup>Under Article 3 of the Protocol, a living modified organism is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The acronym GMO (Genetically Modified Organisms) is more widely used and popularly known.

<sup>2</sup>MacKenzie & Others, “An Explanatory Guide to the Cartagena Protocol on Biosafety”, 2003, IUCN, Gland, Switzerland and Cambridge, UK.

decisions. The “precautionary principle” has therefore become one of the most employed principles in international treaties and national laws<sup>3</sup>. However, there is not a universally agreed definition of what “scientific certainty” is; therefore, there are not universal rules or guidelines to exactly define whether the “precautionary principle” should be adopted or not. International and national instruments that have to deal with the principle (like those implemented by the Projects in question) are therefore constantly challenged by the complexity and the multifaceted nature of the problem.

## B. The Project<sup>4</sup>

28. According to Article 28 of the CPB, the Global Environment Facility (GEF) has been designated to serve as the financial mechanism of the Protocol. In this context, since 1997, UNEP, in its capacity as an Implementing Agency of the GEF, has been providing administrative and technical assistance to countries participating to the CPB. More specifically, the UNEP-GEF Biosafety Unit has been supporting and coordinating four umbrella-projects:

- a) UNEP-GEF Pilot Biosafety Enabling Activity Project, that ran from 1997 until 2000 with a budget of US \$2.7 million. The project aimed to set up National Biosafety Frameworks in 18 countries.
- b) UNEP-GEF Project on Development of National Biosafety Frameworks: started in June 2001 to assist up to 100 countries, taking into account the lessons learned from the UNEP-GEF Pilot Project. Additional countries have joined the project in 2004 for a total of 123 countries participating in this project.
- c) UNEP-GEF Project on Implementation of National Biosafety Frameworks, started in December 2002. Forty (40) countries participated in this project with a total budget of US \$ 36.5 million. There are currently 51 projects.
- d) Biosafety Clearing House (BCH) Capacity Building Project, started in 2004 and implemented in 112 countries with a budget of US\$ 14.9 million. A second phase of the project (BCH II) is currently being implemented in 50 countries.

29. This report refers to the Terminal Evaluation of 15 (fifteen) Projects on Implementation of National Biosafety Frameworks (group c, listed above), divided in two distinct groups, namely:

- Eight (8) 3-year Implementation Projects, also called “Demonstration projects”, started in September 2002 in the following countries: Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. The majority of them were completed by 2006. These countries had previously benefited from the UNEP-GEF Pilot Biosafety Enabling Activity Project (group a, listed above).
- Seven (7) 4-year Implementation Projects in Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and Vietnam, started in 2006 and completed between 2010 and 2011. These countries had previously benefited from the UNEP-GEF Project on Development of National Biosafety Frameworks (group b, listed above).

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<sup>3</sup> Art 1 of the CPB: *“In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.....”*. The Principle 15 of Rio Declaration says : *“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”*

<sup>4</sup>In this report, the terms “the Project” or “the projects” are indistinctly used when referring to the whole of the projects under evaluation.

30. The common objective of all UNEP-GEF Projects on Implementation of National Biosafety Frameworks is to make operational a coherent combination of policy, legal, administrative and technical instruments, the so-called National Biosafety Framework (NBF). National Biosafety Frameworks, though variable from country to country, contain common components, such as:

- A Government policy on biosafety;
- A regulatory (legal and administrative) regime for biosafety;
- A system to handle notifications or requests for authorisations and systems for ‘follow up’ such as enforcement and monitoring for environmental effects;
- A Biosafety Clearing House (BCH) mechanism for circulating and sharing information;
- Mechanisms and initiatives for public awareness, education and participation.

31. Considering that, as stressed in project documents, the NBF implementation is a “country-driven process”, the components outlined above may have different weight, depending on the specific country’s context. Projects on NBF Implementation may, therefore, differ from country to country, as far as the activities and the outputs are concerned. Nevertheless, a common table of synthesis presenting the NBF main components and related project outputs for all the 15 projects can be drawn, as follows.

**Table 1: Main NBF Components and expected projects Outputs**

<b>Main NBF Components</b>	<b>Main expected project Outputs</b>
<ul style="list-style-type: none"> <li>• A National policy on Biosafety</li> </ul>	Support for drafting national policies on Biotechnology and Biosafety and for linking Biosafety to relevant national strategies (e.g. environmental policy, food safety strategy, strategy of sustainable development, etc.)
<ul style="list-style-type: none"> <li>• A regulatory and administrative regime on Biosafety</li> </ul>	Support for drafting national laws and enacting regulations, and technical and methodological support for preparing technical guidelines, risk assessment dossiers, administrative rules and mechanisms, etc.
<ul style="list-style-type: none"> <li>• Capacity Building in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement</li> </ul>	a) Trainings to enhance national capacities and improve human skills in relevant areas, such as: <ul style="list-style-type: none"> <li>- Risk Analysis, Risk Assessment, Risk Management, Risk Monitoring;</li> <li>- LMOs detection and surveillance</li> <li>- Laboratory techniques</li> <li>- Legal and administrative procedures</li> </ul> b) Manuals and other technical material produced
<ul style="list-style-type: none"> <li>• Information system on Biosafety including the BCH</li> </ul>	Support in the Biosafety national database setting and in the establishment of procedures for BCH use.
<ul style="list-style-type: none"> <li>• Public information, awareness and participation</li> </ul>	Support in the production of information, awareness and education material such as newsletter, videos, brochure, website, radio and TV broadcasts, etc.

32. As previously mentioned, the first group of Implementation Projects<sup>5</sup> (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) was conceived to give continuity to 8 UNEP-GEF

<sup>5</sup> Also referred to, in this document, as “The Projects of the first group”

projects carried out in 1999 (12 months projects) for piloting NBF preparation exercises in 19 selected countries. The 3-year implementation projects started in 2002 and have been completed between 2005 (Poland), 2006 ( Bulgaria, Cameroon, Kenya, Uganda), 2007 (Cuba, Namibia), and 2008 (China). (see table 2 here below)

33. The second group of Implementation Projects<sup>6</sup> (Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and Vietnam) was conceived to give continuity to 7 NBF Development Projects (18-months projects) carried out from 2002 onward in a total of 123 countries to put in place the NBF. This second group of projects (designed with a duration of 4 years) started the operations in 2006 and were completed between 2010 and 2011 (except Slovak Republic that concluded the project in 2009).

**Table 2: Calendar of implementation of UNEP-GEP Projects in selected countries** (extension periods are highlighted in red)

Country	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Bulgaria													
Cameroon													
China													
Cuba													
Kenya													
Namibia													
Poland													
Uganda													

Country	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Cambodia													
Czech Rep													
Estonia													
Lithuania													
Moldova													
Slovakia													
Vietnam													

34. The two groups differ, therefore, not only for the different period of implementation, but also in terms of previous experience and preparation, variable from the 12-months Pilot-Projects (1st group) to the 18-24 months Development Projects of the second group, (as displayed in table 2 above).

35. UNEP, as Implementing Agency of the GEF, signed Project Documents with the National Executing Agency (NEA) of the selected countries, which has been, in most of the cases, the Ministry of the Environment (Cambodia, Cameroon, China, Cuba, Czech Republic, Lithuania, Moldova, Slovakia and Vietnam). In some cases, the NEA has been a semi-autonomous governmental institution (Bulgaria, Kenya, Namibia, Poland, Uganda), or a University (Estonia).

36. All the projects have followed some “standard” implementation measures consisting of:

- A National Project Coordinator (NPC) appointed by the NEA, responsible for the overall co-ordination, management and supervision of the project in the country;

<sup>6</sup> Also referred to, in this document, as “The Projects of the second group”

- a National Coordinating Committee (NCC), also established by the NEA to advise and guide the implementation of the National Biosafety Framework;
- a Steering Committee, established to provide guidance and direction to the implementation of the Demonstration projects. Steering Committees were chaired by UNEP, and comprised representatives of the Ministry designated as the National Executing Agency, two other implementing agencies<sup>7</sup>, the GEF Secretariat as well as FAO and UNIDO.

37. Several national governmental institutions have been generally involved in the implementation of the projects at country level, either through the NCC, or through direct responsibility in one or more of the components of the project. The ministries of Environment, Agriculture, Health, Science and Education, were usually integrated in the project.

38. The average GEF contribution per country amounted to US\$ 620,000, from a minimum of US\$ 407,000 (Bulgaria) to a maximum of US\$ 997,000 (China and Vietnam). Co-financing by National Governments was foreseen and actually occurred in the Project, mainly in kind, in a proportion variable from 13% to 42% (with the exception of Czech Republic and Poland, where the Governments co-financing was much higher than GEF funding).

39. Some of the projects of the first group experienced a significant number of extension and revisions, not entailing, in any case, additional costs.

### C. Evaluation objectives, scope and methodology

40. The Terminal Evaluation has been undertaken to assess a significant number (15) of projects supporting the implementation of NBF in countries of different regions of the world. Therefore, besides assessing the project performance (in terms of relevance, effectiveness and efficiency), lessons learned from a variety of socio-economic and institutional situations were of particular interest. In addition, the fact that, in certain cases, some years have elapsed since the end of completion of the operations, made it possible gain more insights into sustainability issues.

41. The evaluation had two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP, governments, the GEF and their partners. The TORs of the Terminal Evaluation are in Annex 1. The evaluation was guided by five (5) key questions:

- (a) How successful were the projects in supporting the 15 countries to put in place a workable and transparent national biosafety framework, in line with national development priorities, Agenda 21, and the Convention on Biological Diversity (CBD)?
- (b) Did the projects assist the countries to establish and consolidate a fully functional and responsive regulatory regime in line with the Cartagena Protocol and national needs and priorities?
- (c) To what extent did the projects assist the countries to establish and consolidate a functional national system for handling requests, carry out risk assessment decision-making and administrative tasks?
- (d) How successful were the projects in assisting the countries to establish and consolidate a functional national system for “follow-up” activities such as monitoring of risk exposure and environmental effects, and strengthening of enforcement mechanisms, institutions and procedures?
- (e) Did the projects assist the countries to establish and consolidate a functional national biosafety system for public awareness, education, participation, and access to information?

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<sup>7</sup> UNDP and the World Bank were also GEF Implementing Agencies in some countries (not in the 15 countries concerned by the evaluation)

42. The evaluation was conducted under the overall responsibility of the UNEP Evaluation Office (EO), in consultation with the UNEP GEF Coordination Office and the UNEP GEF Biosafety Unit (Nairobi). The evaluation was organized in two phases:

- a) phase I, mainly at UNEP Office in Nairobi, focusing on preparation, planning and writing of an extended inception report. The extended inception report contains the evaluation framework (Annex 2) and the review of quality of project design (Annex 10);
- b) phase II, focusing on data collection (including field visits/questionnaires), analysis and report writing.

43. The findings of the evaluation are based on the following:

- (a) A thorough desk review of project documents including, *inter alia*:
  - UNEP and GEF policies, strategies, programmes and guidelines pertaining to biosafety and biosafety projects;
  - Project design documents, work plans and budgets, logical frameworks (where available), periodic projects progress and financial reports, project terminal reports, all of them available on the ANUBIS information system to which the consultants were given access;
  - Relevant documents produced by the projects (e.g. guidelines, manuals, proceedings from workshops, etc.);
  - The national websites of the National Competent Authorities;
  - The analysis of the 15 National Biosafety Clearing Houses (BCH), which contain the most relevant information on NBF implementation: laws, regulations and guidelines, decisions and approvals on LMOs management in the countries (import, production, and release), risk assessments, etc.
- (b) Interviews with:
  - UNEP Task Manager and Fund Management Officer in Nairobi;
  - The Director of the GEF Coordination Office in Nairobi;
  - Relevant staff of UNEP DELC (Division of Environmental Law & Conventions) in Nairobi;
  - Country lead execution partners (National Competent Authority, National Biosafety Focal Points, National BCH Focal Points, National Project Coordinators) and other relevant partners;
  - Government' representatives (the Deputy Minister of the Environment in Namibia).
- (c) Country visits. The evaluation team visited a representative sample of countries from both groups of projects (see Annex 3 with the calendar of the mission). The sample was defined during the preparatory phase in Nairobi, by using the following criteria:
  - To cover at least one (or two if nearby) countries in each geographical region;
  - To contemplate countries of both groups of implementation projects;
  - To include countries with different technical / economic background for a more comprehensive assessment of the NBF under different conditions.

Under these criteria, and taking into account budget availability, the following eight (8) countries were visited, either by one of the two consultants (the Team Leader - TL – or the Supporting Consultant – SC), or jointly, by both of them: Kenya, Poland, Lithuania (TL + SC); Vietnam, Cambodia (TL); Namibia, Czech Rep. and Slovak Republic (SC).

- d) A questionnaire (see Annex 4) was prepared by the evaluation team and sent to the National Biosafety Focal Points (NBFP) and the National Competent Authority (NCA) of the 15 countries. Thirteen (13) out of the fifteen countries answered the questionnaire (except for



Bulgaria and China), which permitted the team to gather relevant, updated information. The questionnaires have been analyzed and the main findings have been of great use in the assessment of the outputs and outcomes of the projects.

44. For the evaluation, two independent consultants were hired, a Team Leader (TL) and a Supporting Consultant (SC), in such a way that the whole of the requirements expected by the team (see TOR in Annex 2) could be fulfilled, i.e. decennial expertise and experience in: (a) Evaluation of GEF projects; (b) Biosafety and biotechnology including risk assessment and management, regulatory frameworks, and biodiversity; (c) Institution and capacity building. The draft evaluation report was reviewed by the UNEP EO and circulated to stakeholders for comments.

## II. Project Performance and Impact

### A. Attainment of objectives and planned results

#### 1. Achievement of Immediate Outcomes, Outputs and Activities

45. As explained in Section I B, each country identified specific activities and outputs depending on their needs and priorities. The evaluation team, in its preparatory phase of the mission, found five main set of common outputs for all the countries, each of them contributing to an immediate outcome. The five Immediate Outcomes were jointly expected to contribute to the achievement of the main Outcome of the Projects. The hierarchical link from Outputs to Immediate Outcomes and then to the Project Outcome is the one diagrammed in the Theory of Change elaborated by the team in its Inception Report (see diagram 2 of Theory of Change, at point 5 of this Chapter).

46. In general, the activities foreseen in the Projects Documents have all been implemented and their results are specified in the following summary table that synthetically describes to what extent the Project has produced the expected Outputs and corresponding Immediate Outcomes.

**Table 3: Project Outputs and Immediate Outcomes**

<b>PROJECT OUTPUTS</b>	<b>IMMEDIATE OUTCOMES</b>
<p><b>1. Expected Output 1:</b></p> <p><i>Advisory support for drafting National Policy on Biotechnology and Biosafety</i></p>	<p><b>Immediate Outcome 1:</b></p> <p><i>A well-defined National Policy on Biosafety</i></p>

### **Output Performance**

The Project has succeeded in mobilizing national capacities towards the definition of a **National Policy / Strategy on Biotechnology and Biosafety**.

In most of the cases, that led to the drafting and approval by the Government of a formal document of Biosafety National Policy that has been an inspiring source for successive legislation and regulatory acts. In some cases, based on the experience gathered and lessons learned, the countries have been updating and improving their National Biosafety Policy (e.g. Lithuania in 2010).

By considering that in many countries, Biotechnology and Biosafety debate were at an early stage, the driving force of the Project, particularly the newly appointed Project National Coordinators and the national teams they were able to mobilise, have been quite decisive.

The Project advisory support for the drafting the **National Laws on Biosafety** has also been relevant and, in some cases, decisive. In 2003 UNEP had, to this purpose, elaborated a sort of guide for implementing regulatory regimes for biosafety. Moreover, national legal advisors hired by the UNEP-GEF Project in some of the countries have extensively supported (or led) the process of law drafting.

### **Immediate Outcome Delivery**

#### **a) National Policies / Strategies:**

While virtually all the countries currently have national acts, regulations and institutional frameworks defining the national strategy on Biosafety, some of them have elaborated and adopted specific National Policies:

- Kenya approved its “National Biotechnology Policy” in 2006;
- Lithuania has prepared its “National strategy on Biosafety GMO policy” (2010), now included in the national Environmental Strategy (2013-2050);
- Moldova has adopted its National Biodiversity Strategy and Action Plan in 2000 and has a Biosafety Action Plan (2009-2015);
- Namibia has produced its National policy “Enabling the safe use of Biotechnology” since 1999;
- Slovakia has published in 2009 its “National Regulatory Framework for the use of GMO”;
- Uganda approved its Biotechnology and Biosafety Policy in 2008;
- The Czech Republic has opted for extensively mainstreaming Biosafety in all the relevant sector policies, such as the Sustainable Development Strategy, the National Biodiversity Strategy, the Food safety and Nutrition Strategy, among others.
- Cambodia, Cuba and Vietnam have prepared an Action Plan on Biosafety.
- Vietnam has prepared an Action Plan on Biosafety which has been integrated into the National Action Plan on Biodiversity.

#### **b) National Laws on Biosafety:**

Almost all of the countries have promulgated a Law on Biosafety, namely and chronologically:

Cuba (1999), Estonia (1999, modified in 2004), Czech Republic (2000, modified in 2004), China (2001), Lithuania (2001), Poland (2001), Slovakia (2002), Cameroon (2003), Moldova (2003), Bulgaria (2005), Namibia (2006), Cambodia (2008), Kenya (2009), Vietnam (2010). Uganda has

	currently a draft.
<p><b>2. Expected Output 2:</b></p> <p><i>Technical and Methodological support for preparing enacting law regulations, guidelines and dossiers, administrative mechanisms.</i></p>	<p><b>Immediate Outcome2:</b></p> <p><i>A regulatory and administrative regime for effective implementation of Cartagena Protocol</i></p>
<p><b>Output Performance</b></p> <p>The Project has been very proactive in supporting the countries in preparing Law Regulations, Technical Guidelines and Administrative Mechanisms and Procedures.</p> <p>For different reasons, some countries have experienced delays in the process of law drafting and of setting the National Authority, which have caused subsequent delays in establishing regulations, guidelines and procedures.</p> <p>Nevertheless, the processes triggered by the project have been carried on in all the countries and many of them, even after the completion of the project, have approved, or are in the final stage of approving, enacting regulations and guidelines</p>	<p><b>Immediate Outcome Delivery</b></p> <p>Many countries have adopted national regulations for the application of their National Law. Namely:</p> <ul style="list-style-type: none"> <li>• EU Countries (Bulgaria, Czech Rep., Estonia, Lithuania, Poland and Slovak Republic) have been gradually and fully incorporating EU Directives into their national legislation through Regulations, Decrees and Orders (juridical terminology may vary from country to country). All of them have a robust regulatory and administrative regime (guidelines, procedures, etc.), constantly kept updated.</li> <li>• Cambodia has approved in 2010 the “Sub-Decree on Mechanisms and Procedures for Implementing the Law on Biosafety and the law on biosafety in 2008”.</li> <li>• Cameroon has approved in 2007 The Decree “Regulating Safety in Modern Biotechnology in Cameroon”;</li> <li>• China has approved, from 2002 on, an extensive and detailed number of specific Regulations on different normative aspects of Biosafety. It has a robust regulatory regime and is constantly revising norms and procedures to effectively monitor LMOs management in the country.</li> </ul>

	<ul style="list-style-type: none"> <li>• Cuba has promulgated from 2000 to 2008 several Resolutions to enact the Law of 1999;</li> <li>• Kenya has published Regulations in 2011;</li> <li>• Moldova has promulgated the Regulations of its Law in 2003;</li> <li>• Namibia has draft Regulations not yet approved</li> <li>• Vietnam has published several regulating Decrees and Circulars in 2010;</li> <li>• Uganda, does not yet have an approved National Biosafety Law, but is implementing a set of biosafety guidelines developed under the current/existing regime</li> </ul>
<p><b>3. Expected Output 3:</b></p> <p><i>Trained manpower for risk assessment, risk management and monitoring, laboratory skills, training manuals</i></p>	<p><b>Immediate Outcome3:</b></p> <p><i>Enhanced capacity and improved skills in relevant areas</i></p>
<p><b>Output Performance</b></p> <p>Training and capacity building have been core activities of the Project in all the countries. An impressive number of seminars, workshops, conferences and open meetings have been carried out all over the 15 countries, targeting a large array of public: Ministries Officers, University Professors and Researchers, Professionals of Environmental, Agricultural and Legal sectors, Customs Officers, Laboratory Staff, Members of Parliaments and other policy makers, Media representatives.</p> <p>Considering the baseline situation in the countries, one where biotechnology and biosafety had only sporadically been previously addressed, the efforts of the Project have been remarkable.</p> <p>The total number of the participants in training sessions is extremely high in certain countries (Cambodia, Cuba, Vietnam and Poland) and in any case remarkable almost everywhere (see table in Annex 5).</p> <p>LMO detection laboratories were established in all the countries under the UNEP-GEF funded projects. However, while the facilities established and the available manpower trained to detect any authorized/unauthorized LMO event from a LMO surveillance view point, have good capacities in certain</p>	<p><b>Immediate Outcome Delivery</b></p> <p>Through its numerous training activities, the project has undoubtedly enhanced national capacities for dealing with Biotechnology and Biosafety. While in some countries the project has contributed to create a learning environment around a quite new topic, in others it has fostered an unbiased view on a controversial issue, by providing opportunities to compare and contrast different approaches and to openly debate the matter. That is a remarkable result.</p> <p>The duration of the majority of the training events has been usually short (from 1 to 3 days). In many cases, the public was heterogeneous, belonging to different institutions and sectors. That seems indicating that, in those cases, the workshops have mostly been an opportunity to introduce Biosafety and to raise awareness. The interviews in the field corroborate that idea: the need to clarify concepts and issues, to harmonise the language and to give participants opportunities to hear and understand about Biosafety issues, were the primary objectives of the workshops.</p> <p>There have also been cases of one-day seminars targeting high-level experts on very specific issues. In some cases, specific skills were also matched (e.g. inspections, laboratory skills).</p>

<p>countries (Poland, Lithuania, Czech Republic), in others (eg. in Cambodia) the same is very limited.</p> <p>Especially in countries where LMOs were released for large scale cultivations (China, Poland, Czech Republic), mechanisms were also put in place for post-release monitoring of LMOs in order to assess the environmental impact on the conservation of biological diversity. However, a systematic post-release monitoring on the long term environmental impact needs to be in place to critically assess the long term impacts of released LMOs on the conservation of biodiversity.</p>	<p>In some countries, accredited laboratories with well-trained personnel were established to detect LMOs and monitor their transboundary movements. Other countries are learning how to handle LMOs at the port of entries.</p> <p>Laboratories were also put in place to monitor negative impacts, if any, due to the large scale release of LMOs in the environment. The Second Regular National Reports of the countries submitted to the BCH does confirm such activities.</p>
<p><b>4. Expected Output 4:</b></p> <p><i>Support in the setting of national database and in the establishment of information procedures</i></p>	<p><b>Immediate Outcome4:</b></p> <p><i>A publicly accessible national information system including Biosafety Clearing House (BCH)</i></p>
<p><b>Output Performance</b></p> <p>The Project has supported the setting of national data bases, through the implementation of national surveys or preliminary studies to collect and systematize the existing biotechnology and biosafety information. The contribution to the implementation of a national information system has been considerable and highly appreciated.</p> <p>This activity has been in synergy with the other UNEP-GEF Project specifically supporting the capacity building and setting of the national Biosafety Clearing Houses.</p>	<p><b>Immediate Outcome Delivery</b></p> <p>This Immediate Outcome has been unevenly achieved in the countries, basically depending on the relevance of the Biosafety issue and the existence of meaningful information to be uploaded in the system.</p> <p>Countries like China, Czech republic, and Poland, where Regulations and other normative instruments exist (orders, decisions, circulars, etc.), and where application processes started to be examined, risk assessments be conducted and decision be taken accordingly, have a Biosafety Clearing House updated with relevant information. In addition, most of these countries have national websites linked to the BCH. All European countries have, in their BCH, the record of all EU decisions and risk assessments made at European level.</p> <p>The BCH of countries where the biosafety law and enacting regulations are not yet in place (e.g. Namibia, Uganda), or that have not so far made any approval decisions (e.g. Cambodia, Cameroon), hold little information.</p> <p>Some countries (e.g. Moldova) also uploaded in their BCH the proceedings of National Workshops.</p>

	<p>The section of the BCH dedicated to National Experts is generally very poor or disappointingly empty in all the countries, which hinders the possibility to create a roster / network of experts.</p> <p>The Table in Annex 6 presents the Decisions taken so far and the number of records made available in the central BCH (as on 20/02/2012).</p>
<p><b>5. Expected Output 5:</b></p> <p><i>Awareness materials (posters, booklets, media emissions, websites, etc.)</i></p>	<p><b>Immediate Outcome5:</b></p> <p><i>Public information and awareness mechanisms creating the participation of civil society groups, NGOs, etc., to take part in the decision-making process on the introduction of LMOs.</i></p>
<p><b>Output Performance</b></p> <p>There is a large consensus that the Project has been a driving force to boost initiatives to raise awareness and public participation.</p> <p>All the countries have produced awareness materials and made use of different communication tools: public meetings, school activities, posters, leaflets, newspapers articles, radio and TV emissions, and website pages have been the most popular. Some initiatives have caught the attention of the mission for their peculiarity:</p> <ul style="list-style-type: none"> <li>- Namibia: the translation of the National Policy in six (6) national languages and of the National Act in layman’s language.</li> <li>- Lithuania and Estonia: three annual public opinion surveys / polls on the application of GMOs at national level.</li> <li>- Czech Rep.: yearly meeting of the Czech Commission on the use of GMO and GM products open to the public and with public debate (also broadcasted), and an extensive action of awareness raising in the schools (teachers and students).</li> <li>- Poland: a nationwide information campaign (2009) titled "Genetically modified organisms and the natural environment", including 101 training actions, 6 nationwide conferences and a final international conference.</li> </ul>	<p><b>Immediate Outcome Delivery</b></p> <p>The project has surely contributed to put in place various and interesting actions of public awareness and information.</p> <p>In some cases, new opportunities for public consultation and participation have been implemented, like the meetings organised between commercial farmers and “communal land” farmers in Namibia, or the wide public consultation organized with local authorities and farmers in Poland and Uganda.</p> <p>The national website established in all the countries, and particularly rich in some of them (e.g. Czech Republic), are also powerful instruments for information and participation.</p> <p>In some countries, the collegial bodies in place for advisory or decision purposes on Biosafety (commissions, committees, councils, etc.) contemplate by law the presence of Civil Society organizations.</p> <p>Almost all the national regulations, notably those regarding the approval decisions for GMOs use in the country, foresee mechanisms and procedures for public consultation, both through independent technical bodies and through forms of public hearing. For instance, in Czech Republic, any final decision on authorization contains a detailed record of all the received comments and opinions, as well as the result of the</p>

	public hearing. A detailed map (with the Land Parcel Identification) of the Field Trials is available for Local authorities, Regional Agricultural Agencies and farmers.
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47. Table 3 shows the general positive contribution of the Project to the achievement of the expected Outputs. The table demonstrates as well that the level of attainment of the outputs has been uneven among the five sets of outputs and throughout the countries. The different baseline situation has surely played a major role in the process of Outputs and Immediate Outcomes delivery by the project. European countries usually possess relevant assets, as far as research capacity, scientific knowledge, solid institutions and economic resources are concerned. Moreover, they benefit from a powerful regional instrument like the European integration, which, for many countries, occurred precisely during the project implementation. All these factors enabled them to fully integrate the project contribution into their development strategies and on-going political processes.

48. In other countries, the dynamic environment promoted by the Project has not always been accompanied by a parallel institutional up-take and consolidation. In some cases, the approval of a National Law on Biotechnology and Biosafety took longer than was, perhaps too optimistically, expected. That has been the case, for instance, in Kenya (2009), Vietnam (2010) and Uganda (still pending for approval). In other countries, the law has been timely promulgated, but the approval of the enacting Regulations has proved to be quite a challenging task for different reasons (e.g. governmental changes, inter-ministerial arrangements and coordination). That is, for instance, the case of Namibia.

## 2. Relevance

49. The mission has been able to confirm, in retrospect, the relevance of the Project, for two main reasons:

- The relevance of the issue: the increased development of biotechnologies and transboundary movements make biosafety measures more and more relevant for biodiversity conservation and for addressing health and socio-economic concerns;
- The innovative and leading role of the UNEP-GEF Projects in setting and implementing biosafety agenda in all the countries. All the stakeholders recognise the crucial role of the projects in establishing national capacities (human resources, coordination and networking opportunities, equipment enhancement) on biosafety issue. There is also a generalised consensus on the positive role of the projects in promoting sub-regional and regional networking, hence addressing the regional needs of coordination and interaction on biosafety.

50. The projects were consistent to, and highly relevant for the development of UNEP's overall mandate and policies at the time of design and implementation. The first group of projects developed from 2002 in eight countries (see chapter I.B) was used by UNEP as "demonstration projects" and was extremely relevant for gaining experience and capitalising on lesson learned<sup>8</sup>. Since then, UNEP has been successively supporting the implementation of National Biosafety Frameworks in more than

<sup>8</sup>Cfr. "Guidance towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects", UNEP-GEF Biosafety Unit, 2008

120 countries, hence fulfilling its mandate of assisting the Parties in the implementation of the Cartagena Protocol on Biosafety.

51. The projects are relevant to the Biodiversity / Biosafety GEF Focal Area, to cross-cutting Biodiversity Operational Programmes 1,2,3,4 and 5 and to the Initial Strategy for the Entry into Force of the Cartagena Protocol, approved by the GEF Council in November 2000.

### 3. Effectiveness

52. As described in the table below, the Project has largely contributed to achieve the expected outputs and immediate outcomes in terms of:

- a) Biosafety policy / strategy definition, including a national Biosafety Law in virtually all the countries;
- b) Regulatory and Administrative regimes (Regulations, Guidelines, etc.) implemented in many countries to manage LMOs introduction or production;
- c) Training and capacity building of a number of officers and professionals in all the relevant institutions;
- d) Setting of a biosafety information system, though at variable levels of implementation;
- e) Promotion of awareness raising and education of the general public.

53. As an overall finding, the evaluation team believes that the effectiveness of the Outputs and of the Immediate outcomes in achieving the main expected Outcome of the projects (*"A workable, effective, and transparent NBF - National Biosafety Framework - in line with national priorities and international obligations"*) mainly depended on three key factors:

- The level of attainment of the outputs and their quality;
- The strength and the effectiveness of the institutional framework in place;
- The existing opportunities to make use of the outputs achieved.

54. Two of the five Immediate Outcomes have proved to be a sine qua non for the achievement of the main outcome and for the effectiveness and consolidation of the other three:

- a) the setting of a National Policy, including a National Biosafety Law, and
- b) the consequent setting of a Regulatory and Administrative regime.

55. The level of achievement of the main outcome has basically depended on the position of the Biosafety Agenda in the priorities of the Governments and the subsequent institutional uptake of the process by the national players, particularly the National Competent Authority (NCA). It cannot be said that a National Biosafety Framework is actually implemented, without a National Law and a Regulatory and Administrative Regime under the responsibility and coordination of an affective NCA, as foreseen in the Protocol. Unfortunately, and despite considerable achievements of other outputs, Uganda (lacking a National Law) and Namibia (lacking enabling Regulations) still cannot claim to have a fully operational NBF in place.

Biosafety is, by its very nature, a complex and multi-sectorial issue, which strongly needs coordination and synergies between different line-ministries, competent for Agriculture, Environment, Health, Science and Technology, Education, Trade and Foreign Affairs, among others.

56. Therefore, the involvement of the institutions and the coordinating role of the National Competent Authority is crucial for the consolidation of the process. Although a single Ministry (frequently the Ministry of Environment) is usually the main NCA for the implementation of the Cartagena Protocol, other strong institutional players, like the Ministries of Agriculture and of Health, have a substantive role, as far as Food, Feed, Seeds, Plants and Products Inspection and Analysis are concerned. The deliberate release of LMOs in the environment through field trials and production for



the market are also under the direct supervision and responsibility of the Ministry of Agriculture (MoA) or of Research Institutes linked to the MoA (e.g. Vietnam, Poland). Therefore, even in those countries where the inter-institutional links are clear and well established, the coordination mechanisms always need to be fostered and maintained in good health for a smooth functioning of the system.

57. In some cases, the National Executing Agency of the Project has quite naturally evolved into the National Competent Authority (foreseen in art. 19 of the Protocol) and the institutional uptake has been easier. That has been the case in many European and Asian countries, as well as of Cameroon and Cuba. Some African countries (Kenya, Namibia and Uganda) have opted for a more comprehensive institutional framework, by involving existing multi-sector, semi-autonomous institutions (the National Councils for Science and Technology in Kenya and Uganda) or a new Biosafety Council still to be legally empowered in Namibia. That should give Biosafety a wider institutional dimension, but, on the other hand, that option may entail more time-consuming negotiations and less straightforward responsibilities in the decision-making process. It could not be a coincidence that those countries have experienced more problems in adopting and enabling legal frameworks.

58. Even though an intense programme of capacity building took place in all the countries, its effectiveness depended on the real opportunities to make meaningful use of those capacities. That has not been the case in those countries (such as Namibia, Uganda) where a regulatory and administrative system is not yet fully operational or those countries where a small number of applications, if any, has been presented so far (e.g. Cambodia, Cameroon, Cuba, Estonia, Lithuania, Slovakia, Vietnam). Notwithstanding this drawback, there is strong evidence that all the countries have been able to create widespread knowledge and understanding on biotechnology and biosafety issues and that a considerable number of professionals and officers have benefited from the capacity building program (see Annex 5).

59. It can be argued that the relatively short duration (usually 1-3 days) of the training activities (workshops) and the heterogeneity of the public (from different sectors and agencies) may have hampered the effectiveness of the training. It can be questioned, for instance, how effective a one-day workshop on "Risk Assessment" could be, with participants belonging to a range of institutions, from Customs to Veterinary Laboratories, from Environment to Public Health.

60. However, and notwithstanding the fact that more specific training activities were carried out (and still are strongly needed), the majority of the workshops were very useful in:

- Creating a general and harmonised understanding of Biosafety issues;
- Harmonising languages and enabling communication between different technical sectors;
- Giving the possibility to a larger public to know more about Biosafety and to appreciate different approaches and perspectives on the problem;
- Boosting the interest of university students and professionals for learning more on Biosafety.

61. Moreover, specific and relevant skills have also been enhanced through some focussed training targeting Customs Officers, Phytosanitary, Veterinary and Food Inspectors, as well as Laboratory Technicians that are all key-players in GMOs detection and control and in the smooth and efficient functioning of the referral systems for GMOs management.

62. When analysing the Capacity Building issue, the deep involvement and commitment of the professionals and officers involved at different levels in the process of the establishment of the NBF has to be highlighted. One of the most relevant outputs of the project has been, in fact, gathering people with different professional background (e.g. scientists, researchers, environmentalists, lawyers, politicians, journalists) and to give them the opportunity to work as a team and to be key-players in the definition and implementation of a national policy. In certain cases, notably Namibia, this participatory, team-building process has been so strong that, though many years have elapsed since it

began (the '90s) and each of the actors has professionally evolved in their individual careers, the team is still in place and committed to put forward the biosafety agenda.

63. The capacity building activities need, however, to be considered through a wider lens. They should make part of a larger process of national capacity building on environmental issues that transcend the limits of a single project. Themes like Environmental Impact Assessment, Risk Analysis, Risk Assessment and Monitoring, Liability and Environmental Restoration, Environmental Law and Environmental Management, have to be generally strengthened in the national academic and professional environments, if specific skills and capabilities (for instance on Biodiversity and Biosafety) have to be put in place and improved. All the recent (2011) Second Regular National Reports of the countries to the Cartagena Protocol, in fact, insist on the need of more training and capacity building.

64. As mentioned in the previous table (Immediate Outcome 4), National Information Systems on Biosafety are in place and operational, depending on the amount of the information currently available, which in turn depend on the amount of normative procedures and decisions taken in any single country. As a result, EU countries possess updated BCH that work as a sort of official “gazette” on GMOs situation in the country. They are surely useful for private and public officers and professionals working in the sector. They are less useful for the general public that, if interested, would prefer more appealing national biosafety websites (when existing) or other web sources.

65. BCH implementation and capacity building is specifically addressed by another UNEP-GEF Project, the second phase of which is also starting in some fifty countries (Moldova and Vietnam being included in that group). The functioning and the main problems concerning BCH have already been the object of specific evaluation and surveys<sup>9</sup>. The evaluation mission has registered concerns in all the countries visited, about the duplication and usefulness of the different information instruments in place (the central BCH portal, the national BCH, the national websites, the European biosafety information system for the EU countries). The timely and regular feeding and updating of these instruments (some in English and some in the national language) is excessively time-consuming.

66. Public awareness and participation issues have been tackled in all the countries with similar tools and media (and some outstanding, more original initiative, as shown in table 3). As an overall finding, it can be said that opportunities for people to know more and to understand better about biosafety, to be consulted and to participate in decision-making have risen everywhere. Of course, participation has occurred at different degrees, depending on the level of social participation in each country and in each social group, and on the government agenda regarding citizens' participation.

67. In most of the countries, civil society has been involved in the process of the NBF setting and implementation, though, under the CSO (Civil Society Organisations) category, a vast and heterogeneous mix of organizations (and of interests) can be found. That was the case in all European Countries and in Cameroon, Kenya, Namibia and Uganda, as well. For instance, some proactive environmental groups have been involved in certain cases (notably, the local Green Peace is part of the Biosafety Steering Committee in Lithuania), bringing their clearly critical stand on GMOs, whereas in other cases, NGOs linked to GMOs private companies were also taken on board (e.g. Kenya). Farmers and Consumers Associations have also been actively involved in the GMOs debate both in some European countries (e.g. Poland, Lithuania) and in Africa (Namibia and Uganda).

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<sup>9</sup>See, for instance:

- “The Global UNEP-GEF BCH Capacity Building Project: Learning from Experience” , UNEP-GEF

- “Effective participation in the Biosafety Clearing House: Participation options and impediments to information provision”, A. Gupta, Wageningen University for the UNEP-GEF BCH Project, 2008

- “Terminal Evaluation of project GF/6010-04-02 (4771) GFL/2328-2716-4771 – “Building Capacity for Participation in the Biosafety Clearing-House (BCH)” - Phase I, UNEP, 2009

- COP-MOP Fifth meeting, Nagoya, Japan, 11-15 October 2010, Information-Sharing (Article 20) : “*Study of users and potential users of the Biosafety Clearing-House*”

68. Some European countries are particularly active in the implementation of the UNECE Aarhus Convention<sup>10</sup>. Nevertheless, the participation of CSOs in the National Biosafety Commissions (or Councils), i.e. in the consultative organisms that support the decision-making process coordinated by the NCA, depend more on the decision of the NCA itself, rather than on a legal requirement. Frequently, these Commissions are seen as “expert” or “scientific” groups and, under those circumstances, public participation is not considered very relevant. As a result, environmental organisations or consumers / farmers associations do not significantly contribute to decision-making and this can be considered as a missed opportunity to make Biosafety a more popular theme. Of course, it has to be considered that in most of the countries, civil society had not been previously significantly (if any) exposed to Biosafety issues and, therefore, the efforts of the Governments have to be acknowledged and highly commended everywhere. Nevertheless, and notwithstanding some brilliant initiatives, public participation still needs to be generally improved.

69. Taking into account all these findings and considerations, the evaluation team has concluded that the Project has been successful in achieving its main outcome (effectiveness) and therefore rated as satisfactory. The National Biosafety Frameworks are actually being implemented, though the mechanisms of implementation need, in some cases, to be improved. In certain cases (Cambodia, Cameroon, Kenya, Vietnam) human resources have to be strengthened and there is not sufficient capacity in place to do that, without external technical support. In other countries, either the information system, or the institutional networking / coordination, or the public participation need to be enhanced for a more comprehensive and dynamic process of NBF implementation. Eventually, not all the countries are equally attractive for LMOs developers, due to their different agricultural potential or productive system and / or to the general development environment in place. In these cases, NBF may be in place, but not significantly stimulated to operate. A variety of countries, such as Bulgaria, Cambodia, Cameroon, Cuba, Estonia, Kenya, Moldova, Slovakia and Vietnam, can be included, for one or more of the reasons mentioned above, in this group.

70. It can be equally said that a group of countries have fully achieved the project outcomes and are indeed implementing their NBFs and showing sufficient capacities and potential for coping with the continuous challenges that progress in the development of Biotechnologies poses. Those countries show that they have sufficiently strong institutional and technical capacities to upgrade their systems and to move forward. The only real challenge, in the European countries, can be the budgetary support of the Government for the upgrade of the systems (e.g. more sophisticated lab equipment, training, etc.). Though with great differences among them, China, Czech Republic, Lithuania and Poland can be included in this group.

71. As previously discussed, Namibia and Uganda, despite remarkable results in some fields, still lack a formal legal framework to make their NBF really operational.

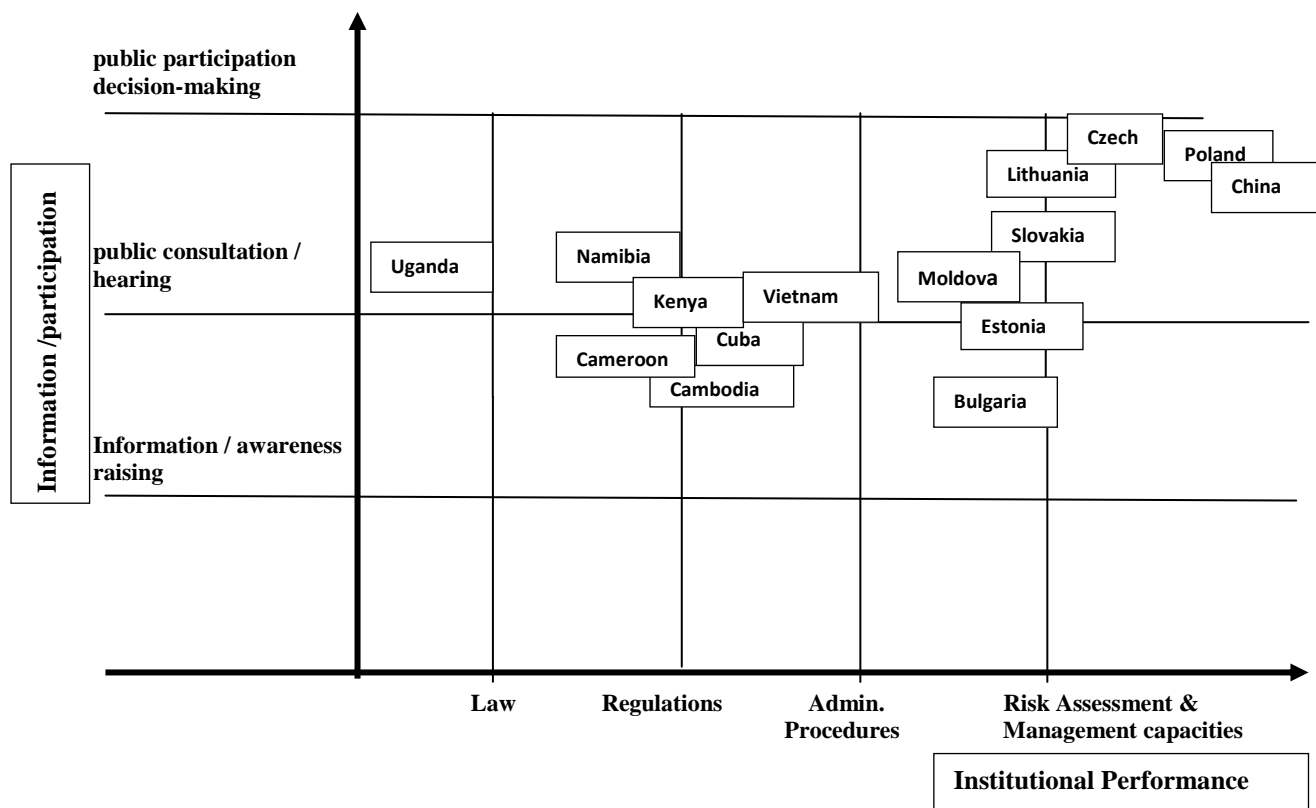
72. The Evaluation team has tried to visualise in the diagram below the level reached so far by each country in the implementation of NBF or, in the other words, one dimension of the level of effectiveness of NBF achieved by the 15 countries, taking into account two main classification criteria. On the one hand (on the horizontal axis) it has been positioned the Institutional Performance

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<sup>10</sup> The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, usually known as the Aarhus Convention, was signed in 1998 in the Danish city of Aarhus and entered into force on 30 October 2001. It has been ratified by 41 countries (primarily European and Central Asian). The Aarhus Convention grants the public rights regarding access to information, public participation and access to justice, in governmental decision-making processes on matters concerning the local, national and transboundary environment. It focuses on interactions between the public and public authorities.

of the country (the level of achievement of the institutional outcomes, such as laws, regulations, administrative procedures, risk assessment & management capacities). On the other and (vertical axis) it has been ranked the Information / Participation Performance of the country, based on its achievements in terms of information initiatives, public consultation / hearing capacities and real citizens' decision-making opportunities. Of course, the diagram has to be considered as an attempt to schematise a variety of situations and, as such, with evident limits of approximation to the reality. Nevertheless, it can have the advantage of giving, at a glance, an idea of the level of the effectiveness of the project in achieving its main Outcome.

**Diagram 1 – Levels of Effectiveness of NBF**



In Annex 7 the main milestones and achievement of the countries are summarised and presented in a compilation of Country Facts Sheets.

#### 4. Efficiency

73. As an overall appreciation, the activities implemented by the projects have been executed efficiently, under the real and diverse conditions of each country. Institutional achievements, like the preparation and promulgation of a National Law or the setting up of a National Competent Authority over a critical and complex issue like Biosafety, take usually the time they need. Low efficiency cannot be accounted for slow political and institutional processes as delays in implementing the NBFs are not uncommon especially when extensive public participation is undertaken.

74. Projects are often regarded as scarcely cost-effective because of their technical, methodological and administrative mechanisms that superimpose existing national structures. In the absence of any single national institution to implement NBFs, National Project Coordinators and technical or administrative staff belonging to various organizations who had the desired background were appointed from various organizations under the UNEP-GEF project itself. This option will be discussed later on in this report for its methodological consequences (see section C.2 – Implementation Approach). It could be that this option may have been the only viable option at the

time of projects implementation, since there was not any national institution able to totally devote some of its staff to establish such a demanding task of development and implementation NBF. Different options, therefore, would have probably caused more delays and could have been less cost-effective.

75. All the countries have, in any case, actively participated in co-financing through in-kind contribution, consisting mainly of infrastructure and equipment, further staff support, events organizations, thus making the projects more cost-effective. Some countries asked for budget (no-cost) revisions and that can be interpreted as a measure to adapt the project to the real needs of the country, hence increasing further its cost-effectiveness.

76. In general terms and with a broad perspective on the whole UNEP-GEF Biosafety programme, some considerations on its cost-effectiveness can be done. On the one hand, the “one size fits all” approach adopted by the programme, might have been differently efficient, depending on the variable capacity of the country to absorb the resources of the projects. It can, therefore, be argued that a more “country-tailored” approach could have been more cost-effective. On the other hand, that option could have implied more preparation costs and an increased, more costly management structure in the Implementing Agency (UNEP). Actually, the fact that a very small UNEP Biosafety Unit is still managing and backstopping a remarkably high number of projects in more than 120 countries has to be regarded as very cost-effective, (although for older projects a larger team was in place to supervise their technical completion).

## 5. Review of Outcomes to Impact (ROtI)

77. In the Inception Report of the mission<sup>11</sup>, the evaluation team presented an initial Theory of Change (ToC) analysis, based on projects design, other UNEP-GEF Biosafety Unit documents and the briefings received at UNEP office. As a result, the mapping of the possible pathways of change between the projects outputs to the expected outcomes, up to the intended impact, was produced. The initial ToC has been a valuable instrument of analysis all along the evaluation exercise and its design has been tested by the team during the evaluation. The diagram<sup>2</sup> maps out the Theory of Change based on the understanding by the evaluation team of the causal logic of the NBF projects and the identification of the impact drivers and assumptions underlying the projects’ logic, validated and improved through the field visits.

### *Projects Impact*

78. The first stage in the ROtI method is to identifying the project’s intended impact, intermediate states, drivers and assumptions based on the Theory of Change of the project. As a matter of fact, the primary aim of any GEF project is to achieve a specific category of impacts called “Global Environmental Benefits” defined as “lasting improvements in the status of an aspect of the global environment that safeguards environmental functioning and integrity, as well as benefiting human society”<sup>12</sup>. The implementation of the National Biosafety Frameworks (NBF) will contribute to the achievement of the main objective of the CPB, as stated in the art. 1 of the Protocol: “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”. The intended impact of the projects is the global environmental benefit to which they contribute: *The enhanced Conservation of Biological Diversity*.

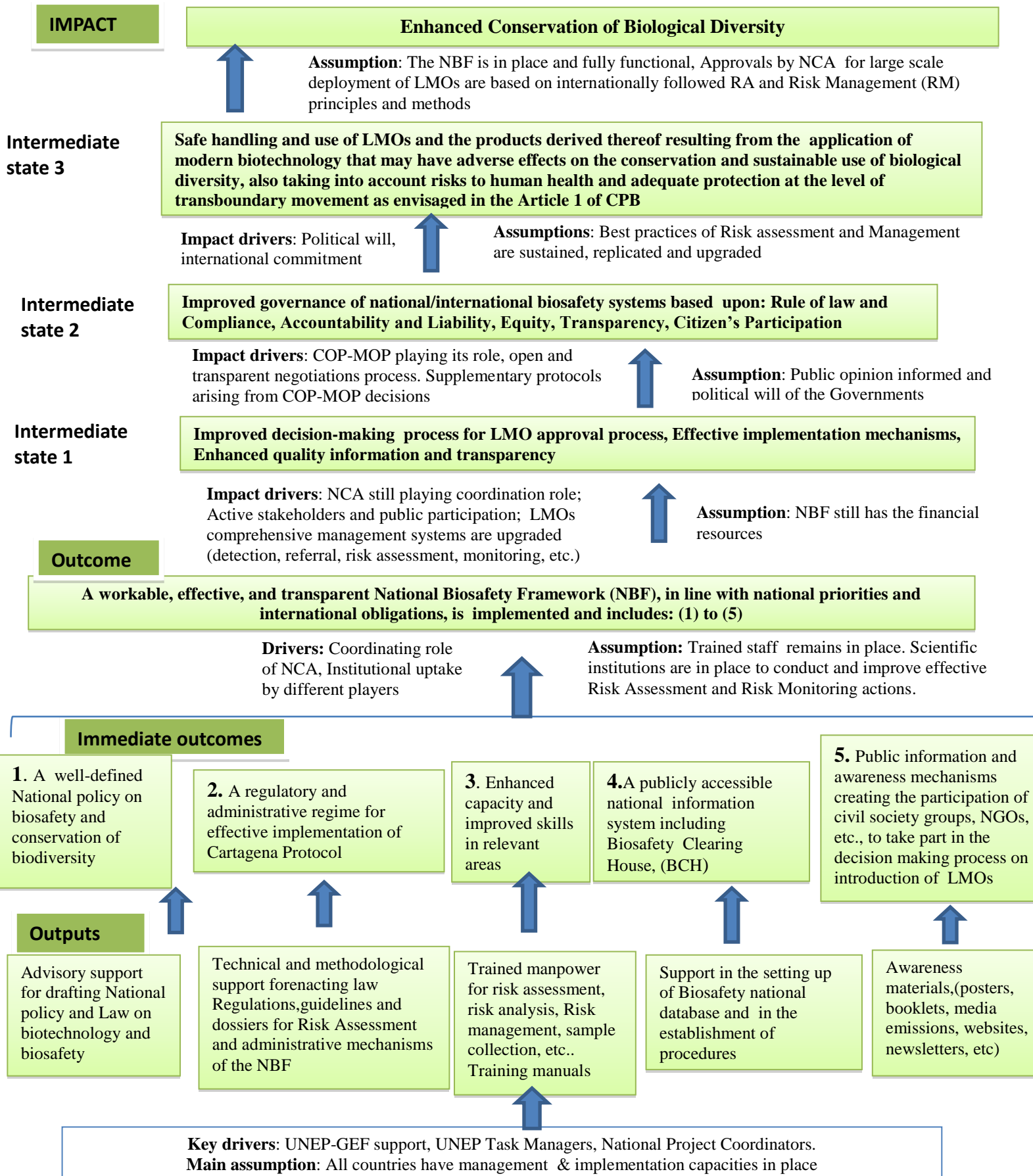
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<sup>11</sup> Inception Report of the Final Evaluation of 15 Selected UNEP-GEF Biosafety Implementation projects, V.S. Reddy, C. Risoli, February 2012

<sup>12</sup> 10 ROtI Practitioner’s Handbook, GEF, 2009

Diagram 2

Theory of Change of UNEP-GEF NBFs Implementation Projects



## *Projects Outcome*

79. The second stage of the ROtI method is the review of the project's Logical Framework (Logframe), to assess to what extent the project design was consistent and appropriate to deliver the intended impact. Only the second group of Projects have a structured Logframe, since, at the time of the implementation of the first group, a logical framework was not requested. From the desk analysis of the 15 Project Documents and of other relevant material produced by the UNEP-GEF Biosafety Unit, it can be deduced that the main Expected Outcome of all the implementation projects is: *A workable, effective, and transparent NBF (National Biosafety Framework), in line with national priorities and international obligations.*

80. For achieving the main expected outcome, the implementation projects have supported the countries in five core areas / components:

1. a national policy on biotechnology and biosafety, in countries where this was deemed relevant;
2. a regulatory and administrative regime: law(-s), enabling regulations, technical guidelines;
3. capacity building in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement;
4. a national information system on biosafety, including the development of a national biosafety clearing-house (BCH);
5. public information and awareness on issues related to modern biotechnology and biosafety.

## *The causal logic from Outputs to Outcome*

81. In their pathway to achieve the main Outcome, the fifteen implementation projects were supposed to deliver specific goods and services (Outputs), according to the priorities and needs of each country. Though different outputs can be found throughout the countries, they can, nonetheless, be grouped in five set / clusters of outputs related to the five common projects components outlined above. Each set of Outputs has delivered a specific Immediate Outcome and the five Immediate Outcomes are leading to the achievement of the main project outcome. The causal logic is outlined here below (see also diagram n.2 above):

- The first set of outputs refers to the advisory support given by the project to the drafting of the National Policy/Law on Biotechnology and Biosafety, which is the expected Immediate Outcome 1 (A national policy on Biosafety).
- The second set of outputs refers to the technical and methodological services provided by the project to set up the regulations, technical guidelines and administrative procedures needed to achieve the expected Immediate Outcome 2 (A regulatory and administrative regime).
- The third group of outputs includes all the training goods and services delivered (seminars, courses, manuals, etc.) in the different areas of intervention (e.g. Risk Assessment and Risk Monitoring, Laboratory skills, etc.) contributing to the achievement of the Immediate Outcome 3 (Enhanced capacity and improved skills).
- The fourth group of outputs refers to the Immediate Outcome 4 (A national information system including the Biosafety Clearing House, BCH) and includes the support provided for the data base setting, the establishment of the procedures, the design of the website, etc.
- Finally, the fifth group of outputs includes all the communication / information products and services provided by the Project leading to the Immediate Outcome 5 (Public information and awareness).

### *Assumptions and Drivers from Outputs to Outcome*

82. There was, at the time of design and starting of the Project, a relevant assumption: that all the countries were prepared to absorb and put in value the different capacity building activities and to assume the implementation and the management of the projects. That assumption led to “standard” instruments of training, monitoring, management, time frame and so on. As a matter of fact, the baseline situation found in the countries was quite variable, as previously discussed in point 3 (Effectiveness), which has eventually contributed, together with other factors, to uneven levels of outputs and of outcomes achievement, as described in Table 3 (Project Outputs and Immediate Outcomes) and showed in diagram 1 (Level of effectiveness).

83. The projects put in place competent staff, key-drivers that played a major role in supporting the countries in the setting and implementation of the NBF, namely: the National Project Coordinator (NPC) and his / her staff, and the Task and Fund Management Officers at UNEP (Geneva and Nairobi Offices).

84. The evaluation shows that the transformation of the five Immediate Outcomes (IO) into the single main Outcome of the Projects was, and partially still is, not a straightforward process. The mission found that the main conditions for the successful implementation of the NBFs were (see drivers and assumptions in Diagram 2):

- i) a dynamic National Competent Authority (NCA), able to motivate and coordinate all relevant and necessary partners;
- ii) institutional opportunities for national stakeholders to actively participate in decision-making through National Biosafety Steering Committees (Commissions, Councils, etc.);
- iii) the capacity to integrate into the process the scientific institutions and the technical expertise to conduct and improve effective Risk Assessment and Risk Monitoring actions, and to upgrade them to cope with the increasing challenge of more comprehensive and more sophisticated risks analyses.

85. The NBF implementation is a process that can be maintained and enhanced, but can equally stop or regress, as all processes do. Whether the effective frameworks in place can move upward to improved national decision-making processes and to enhance Biosafety Governance, depends on several drivers and assumptions discussed hereafter.

### *Intermediate States from Outcome to Impact*

86. The path from Outcome to Impact (defined as the environmental benefit of “Enhanced Conservation of Biological Diversity”) has been identified through three main Intermediate States (IS).

Assuming that the outcome is achieved and maintained (under the condition that the NBFs still have the financial resources to effectively monitor all the relevant aspects of the LMOs management), the process will lead to “*Improved decision-making processes for LMOs approval, effective implementation mechanisms and enhanced quality information and transparency*” (IS1). Improved decision-making processes will lead to “*Improved Governance of National/International Biosafety systems based upon: Rule of Law and Compliance, Accountability and Liability, Equity, Transparency and Citizens’ Participation*” (IS2), under the assumption that political will and public participation are sustained. Improved governance at all levels will eventually make possible the attainment of the IS3, that coincides with the objective stated in art.1 of the Protocol (“*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*”), thus enabling the Protocol to enhance the conservation of biological diversity, the expected impact of the projects. .

### *Drivers and Assumptions*

87. The drivers and assumptions that influence the achievement of the outcome also affecting progress towards impact. Actually, improved decision-making (IS 1) on Biosafety essentially relies on the smooth and effective functioning of the NBF. More specifically it relies on:

- a) the ability of the NCA to coordinate the whole process of LMOs management and to motivate national partners in taking part in the decision-making process;
- b) the proactive participation of a large and qualified group of stakeholders representing different sectors and interests, and the increased involvement and participation of the public based on unbiased information;
- c) the effectiveness of the of LMOs’ management system, which includes: LMOs detection and referral systems, efficient systems of handling applications, capacities of risk assessment and risk monitoring at different levels (biological, environmental, socio-economic), quality information timely flowing into BCH and national websites;

88. At the end of project period, some of the countries (the group on the upper-right of diagram 1) reached a desired level in all aspects of project objectives, and, under the conditions outlined above, have the potential to progress towards Impact. Poland, for instance, having already released LMOs in the environment, has started monitoring their impact on the environment (soil, flora and fauna, etc.) and is increasingly approaching socio-economic aspects in LMOs management. A main assumption, further discussed under Financial Sustainability (section B.2 of this report), is that NBFs receive sufficient financial resources to sustain their activities and to upgrade their performance, particularly in the area of Risk Assessment and Monitoring. European countries show serious concerns on that point. Regional networking and cooperation between countries could be a cost-effective measure for the financial sustainability of NBF.

89. Namibia and Uganda (on the left side of Diagram 1) are still in the process of achieving the Immediate Outcome 1 (The National Law, as in Uganda) or the Immediate Outcome 2 (The Regulations, as in Namibia) and this situation is, for the time being, a bottle-neck for further progress towards the main outcome.

90. A group of countries (Cambodia, Cameroon, Cuba, Kenya and Vietnam, in the middle of Diagram 1) have successfully reached the necessary conditions for implementing their NBF, but still have to pull together and enhance the three driving forces outlined above, allowing them to consolidate their outcome and to progress towards impact.

91. A group of European countries (Bulgaria, Estonia, Moldova and Slovakia) has established solid LMO management systems, but did not have so far many opportunities to put it into practice. Therefore, the Intermediate State 1 has been only partially achieved by those countries. Nevertheless, countries like China, Poland and the Czech Republic had an opportunity to put into practice their NBFs by assessing environmental and other risks while approving LMOs for large scale cultivation.

92. The improved decision-making process (IS1) will be converted into improved governance (IS2) under the assumption that the political will of the Governments is not missing and that citizens are kept well informed and participate. The main drivers at that stage will be: the open and transparent negotiation processes at different levels, the COP-MOP (the Conference of the Parties serving as the Meeting of the Parties to the Protocol) playing its role of governing body of the protocol, as well as supplementary protocols arising from COP-MOP decisions. Issues related to socio-political sustainability reflecting on the overall Biosafety Governance at national and international levels are discussed under Socio-political sustainability in section B.1 of this report.

93. The IS3, which in fact corresponds to the objective of the Cartagena Protocol, and the final impact will need further political will and international commitment and negotiations to be achieved, under the assumption that Risk Assessment and Management best practices are continuously sustained, replicated and upgraded.

94. As showed in the ToC in diagram 2, risk assessment and risk Management are recurrent issues all along the pathway from outputs to impact. It could not be otherwise, since they are the main technical instruments at our disposal for effectively and comprehensively apply the Precautionary Principle that underpins the Cartagena Protocol (art. 1) and the Rio Declaration (Principle 15).

## **B. Sustainability and catalytic role**

### **1. Sustainability**

95. All the countries have been able to follow-up and sustain the work implemented with the project support. Different baseline situations and institutional challenges have produced different levels of results, as discussed in the previous section, but overall, the dynamics of the process has been maintained.

#### *Socio-political sustainability*

96. Biotechnology is a very appealing theme for those governments that believe that, through biotechnology, socio-economic development can be quickly boosted, although public funding for scientific research is extensively decreasing due to widespread government budgetary restraints all over the world. At the same time, big corporations able to invest in costly research & development programmes, look at biotechnologies as a very interesting sector, capable to produce high-profit, marketable goods in an oligopolistic situation.

97. In this context, the socio-political sustainability of the NBFs in place depends on the capacity of the governments to set and enforce biosafety regulatory regimes in their countries, which enhances their ability to accommodate private investment opportunities of the biotech sector with citizens' socio-economic and environmental concerns. That is not an easy balance for any single country to achieve, and that is why the international political arena comes to play a crucial role in enabling socio-political sustainability of Biosafety agenda at national level, as showed in the upper part of the ToC diagram (Diagram 2).

98. Biosafety “discourse” is very polarized everywhere. There are no strong reasons to believe that such a radicalisation would progressively ease up as time goes by, since the “pros” do not seem able to convince the large public and the “against” do not seem willing to change their mind. In such a situation, while the “topical” characteristic of Biosafety seems guaranteed, its socio-political sustainability is likely to be highly conditioned by the political agenda of those who are governing the country.

#### *Financial resources*

99. Financial problems have been pointed out as the main issue in all the European (and some Asian) countries, which are experiencing severe budget restrictions and staff reduction in the environmental public sector. As an example, we can mention the recent closure of one important laboratory in the Czech Republic (in its second largest city, Brno). The work of this laboratory was undertaken by another laboratory in the Crop Research Institute, Prague. The financial sustainability of the NBF may not be at risk, but the Biosafety agenda may suffer considerable limitations. Actually, the mission is convinced that the costs for Risk Assessment and Risk Monitoring will increasingly grow if LMOs are expanding, due to the need of up-scaling and upgrading those methods in order to keep them in line with scientific progress and the spatial expansion of LMOs production.

100. The possibility to share some services and costs between neighbouring countries, at sub-regional level, has been mentioned to the evaluation team in Lithuania and in Poland. Asian countries (e.g. Cambodia, Laos, Thailand and Vietnam) have organized several joint capacity building activities and there is already some level of cooperation in terms of sharing the facilities for LMO testing.

101. The cost-effectiveness of a regional approach to Biosafety is more than evident in the case of EU countries, where risk assessments carried out by European institutions like the European Food Safety Authority (EFSA), the European Commission's Joint Research Centre (JRC), the Institute for Health and Consumer Protection (IHCP) and any of the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) can be adopted and used in any of the EU countries, without additional costs.

102. Kenya and Namibia that opted for a semi-autonomous parastatal institution functioning as NCA are confident that that mechanism would allow them to have more financial resources, both from their own Governments and from other potential donors.

103. Fees from the applicants also contribute to the budget of the NCA, though they do not represent a significant source of revenue<sup>13</sup>.

### *Institutional framework*

104. The institutional sustainability of NBFs is not a simple issue because, beside the NCA (usually the Ministry of Environment or inter-institutional bodies, like Biosafety Councils or Commissions), other institutions and line-ministries have a key-role to play. Usually, the Ministries of Agriculture have a more consolidated structure than the Ministries of Environment (particularly in non-European countries). They may include decentralised phytosanitary inspectors, food and veterinary services, well equipped laboratories and experienced research institutions related to plants and livestock genetics and breeding. The Ministries of Health, too, have laboratories and resources dedicated to food safety and microbiological analyses. These are examples showing how multifaceted the institutional framework of NBFs could be and the multiple actors that can influence their institutional sustainability. All these actors have to coordinate their work in order to implement, in a smooth and efficient way, the decision-making system (from the detection, analysis and referral system to risk assessment and decision-making) and the monitoring and enforcement system.

105. As shown in the ToC, institutional achievements and governance should be solid and effective enough to allow projects outcome to progress towards higher levels of results and to the intended impact. In some cases (notably China, Czech Republic and Poland), the institutional framework is currently well established and consists of a National Law and enacting, updated Regulations, clear administrative procedures and referral systems, and enforceable mechanisms of monitoring and control. Notwithstanding national peculiarities, mechanisms for public hearing and consultation are usually also established and transparent enough to allow interested citizens to make a meaningful use of them.

106. In other cases, however, one or more of the institutional achievements are not present or exist in a quite embryonic state. Whether such countries have or do not sufficient capacities in place to complete and consolidate an adequate institutional framework, is a question that can be answered only on a case by case assessment. Namibia, for instance, has applied and has recently started a new GEF funded project of "Institutional Capacity Building towards the implementation of the Biosafety Act 2006", which could imply that the country did not feel yet sufficiently prepared to move forward without external assistance. Kenya, after publishing its Biosafety Regulations in 2011, seems to be quickly moving towards the enhancement of its NCA (new infrastructures have been supplied by the Ministry of Higher Education, Science and Technology and new staff have been appointed).

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<sup>13</sup> e.g. in Kenya applicants fees for a Field Trial authorization are around 2,000 USD.

## *Environmental sustainability*

107. Environmental sustainability is at the core of the Cartagena Protocol on Biosafety and its “parental” Convention on Biological Diversity. Project benefits are constantly challenged by several threats to environmental sustainability imposed by the patterns of global development and only increased cooperation between governments, international agencies, scientific fora and environmental Conventions and Protocols can globally address the challenge.

## **2. Catalytic Role and Replication**

### *Catalytic Role*

108. Policy and institutional changes catalysed by the projects are evident and represent their main outcome: the implementation of a NBF including, among others, new Biosafety Laws and Regulations, guidelines and standard procedures, participation and steering mechanisms. The answers received to the questionnaires circulated by the evaluation team throughout the countries confirm the catalytic role of the projects. All the countries visited by the evaluation team have stressed the key-role played by the UNEP-GEF initiative in introducing the Biosafety agenda. For many countries, the projects represented the first opportunity to deal with Biosafety.

109. An innovative aspect, much appreciated by all the stakeholders in the different countries, has been the multi-sector approach established by the projects in the countries through the instrument of the NBF. The setting of National Coordinating Committees (NCC) of the projects has represented an outstanding opportunity for creating dialogue and coordination mechanisms that are still working, well after the project, under the form of multidisciplinary bodies, like National Biosafety Steering Committees, Commissions or Councils. The presence of Public and Private Sectors and of Civil Society representatives in those bodies is an innovative aspect in some countries.

110. The establishment of National Information Systems on Biosafety has also represented an innovative instrument that has promoted stronger communication and exchange between stakeholders operating in different areas (Environment, Agriculture, Higher Education and Research, Health, Trade). The Biosafety Clearing House (BCH) is considered by the stakeholders as an extremely innovative instrument that has given the impulse, in many countries, for creating their own national website on Biotechnology and Biosafety, open to public participation.

111. The fact that the projects have been simultaneously run in a number of countries, has represented a tremendous opportunity for exchange and horizontal learning, particularly between countries of the same sub-region or region. The promotion of the regional dimension of Biosafety agenda, though not yet fully used in all its potential, has nevertheless created formal and informal networks of people and institutions that are currently being maintained and enhanced after the end of the projects.

112. The national teams of professionals and officers involved in the process have all recognised the key role played by the projects in giving opportunities of “learning by doing” and in championing Biosafety agenda in their institutions. The National Project Coordinators (NPC) have played a pivotal role in this process.

### *Replication*

113. UNEP-GEF Biosafety projects have been implemented in a great number of countries. The capitalisation of the most positive lessons learned is an on-going process that is happening both through UNEP initiative and through horizontal, country-led communication. The mission has observed that some interesting initiatives in education and awareness raising were replicated in

neighbouring countries (e.g. Lithuania and Estonia). Through the internet (national biosafety websites and BCH), workshops proceedings, technical guidelines and manuals, laws and regulations are shared and used by other countries, after adaptation. These circumstances have been registered in Kenya, Uganda and Namibia.

114. Regional meetings and workshops have played a crucial role in fostering networking and replication effects. The existence of regional and sub-regional institutions and mechanisms has dramatically increased the opportunities to replicate experiences. That is clearly evident in EU countries (e.g. in the Czech Republic and Slovakia Joint meetings and workshops - including inception and terminal ones, reciprocal participation of corresponding experts and NPCs in conferences and workshops.), but can also be increasingly observed in EAC (Eastern Africa Community) and in SADC (Southern African Development Community).

## **C. Processes affecting attainment of project results**

### **1. Preparation and Readiness**

115. The need for NBFs to be extensively developed and implemented in all the Signatory parties of the Protocol (more than 160 countries), could not be tackled through a thorough, initial assessment of the specific situation of each country. The gradual approach used, consisting in testing a methodology in some pilot-countries from different regions seems a sensible approach, which, in fact, gave the opportunity to learn lessons and to progressively involve more and more countries. The adoption of a “learning by doing” approach is clearly shown by the gradual publication of outstanding documents that analyse the accumulating experiences of some sample-countries, take stock of the lessons learned and make recommendations for the future<sup>14</sup>.

116. The assessment of the specific conditions of each country, the identification of outputs and activities, and the establishment of a work-program have been some of the first activities of the projects, once the executing agency and the project coordinators were identified and made operational. For doing that, some main orientations were given to the countries, in such a way that all the NBFs to be put in place contemplated the same components (as showed in the Table 1) and the projects had a basic common design.

117. The question of different baseline situations among the countries was actually left to be tackled by the national executing agencies and project coordinators. They were the main players in analysing the situation at the starting point, in negotiating partnerships, in fostering government’s involvement and co-financing, and in identifying activities and outputs. As a result, much time was spent in preparatory actions (in some cases almost two years), while the project timeframe was equal all over the countries. The latter condition (same timeframe), though positive for management purposes and for giving sustained pace to the process, was not actually realistic for many countries. The national capacities to absorb and integrate project methodologies and resources was very uneven, as well as the magnitude and relevance of the problems to be tackled.

118. It is evident that, year after year, the UNEP-GEF Biosafety programme was able to learn from experience: initial mistakes were gradually removed, focussed recommendations were given to the new countries accessing the programme, so that preparation and readiness dramatically improved over the years. Actually, the countries of the second group of projects (2006-2010) have highly appreciated the way in which UNEP prepared and guided them into the process.

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<sup>14</sup> “Development of National Biosafety Frameworks – Mid-Term Evaluation of a Global Initiative”, GEF, 2003; “A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety projects”, UNEP-GEF, 2006; “Guidance towards Implementation of National Biosafety Frameworks: lessons learned from the UNEP Demonstration Projects”, UNEP-GEF, 2008; “The Global UNEP-GEF BCH Capacity Building Project Learning from Experience”, UNEP-GEF, 2008.

## 2 Implementation Approach and Adaptive Management

119. While UNEP acted as the GEF Implementation Agency (IA), designated government agencies acted as National Executing Agencies (NEA). As already mentioned in this report, in most of the cases, the Ministry of the Environment (under somewhat different appellations according to the countries) was the NEA. In some of the countries, other institutions were designated as NEA, namely the National Council for Science & Technology (NCST) in Kenya and Uganda, the Agro Bio Institute (ABI) in Bulgaria, the Tallinn University of Technology in Estonia, the Namibian Biotechnology Alliance (NABA) on behalf of the Ministry of Higher Education, Training and Employment Creation, in Namibia and the Plant Breeding and Acclimatization Institute of the Ministry of Agriculture, in Poland.

120. National Coordinating Committees (NCC) were established to advise and guide the implementation of the NBF with a multidisciplinary and multi-stakeholder approach. Different governmental institutions were largely represented in the NCC and some representatives of NGOs and / or private sectors were also represented.

121. National Project Coordinators (NPC) were appointed after consultation with UNEP and paid through the budget of the project, together with some administrative support staff. The NPC was responsible for the overall management, coordination and supervision of the project. He/she liaised closely with the NCC and the NEA in order to coordinate the work plan delivery, while reporting to UNEP for the management and the administration of the project. The NPCs ended up being key-players in project implementation, being the nodal points of interface for both the Government (the NEA) and UNEP (the IA), fund managers of consistent funds and directly responsible for the organisation and implementation of project activities. They have also largely benefited from training and other capacity building activities (regional workshops, international meetings, study visits, etc.), as well as from the assiduous backstopping from UNEP Biosafety Unit task and finance managers.

122. The implementation arrangement through the NPCs, in liaison with, but not dependent on the NEA, deserves some reflexion. On the one hand, that arrangement has positively defined a clear management responsibility and direct communication lines between the project management and the UNEP task management. On the other hand, however, it might have brought about some communication problems between the project and the NEA and a certain discontinuity of the activities when the project finished. In some cases, the National Competent Authority (NCA), responsible for the Cartagena Protocol implementation, and the National Executing Agency (NEA) of the Project did not coincide (like in Bulgaria) or represented two different Ministries (as it was the case in Poland). In some countries, public officers (e.g. those working in the NEA) are not allowed to suspend their contracts in the public administration for assuming external functions (e.g. in a project) and that situation limited significantly the possibility to find a suitable candidate for the post of NPC (as was the case in Slovakia).

123. Steering Committees (StC) were established to provide guidance and direction to the implementation of the projects. While in the first group of projects (Demonstration Projects) the Implementing Agencies (e.g. UNEP) were represented or chairing the StC, the second group of projects established national StC as part of the execution arrangements by the National Executing Agency. Those StC have then evolved in the current Biosafety National Committees (or Biosafety Steering Committees) that are supporting the NAC in decision-making.

124. Overall and considering the complexity of the management of such a large pool of projects in more than 120 countries, the project execution and implementation arrangements have been very effective and have showed a remarkable capacity to adapt to the circumstances and to address specific challenges. Many of the projects have undertaken budget revisions during their implementation, sometimes quite frequently (up to six in certain cases). All of them implied no-cost revisions.

Extensions have also been granted in most of the cases. That has probably been a consequence of the standard design of the projects (as discussed in the previous point, Preparation and Readiness), that called for adaptations and modifications, that, however, had no consequences on the total amount of the budget.

### 3. Stakeholder Participation and Public Awareness

125. As already discussed in this report, stakeholder participation and public awareness are important impact drivers of the projects all along the pathway from outputs to impact. The mission has observed a remarkable enhancement of stakeholders' involvement and public awareness during the project life, as well as the need of improvement in the institutional uptake and in the proactive participation of the public in the decision-making process, as discussed in the section on effectiveness and sustainability.

126. There are interesting and significant experiences put in place and worth being maintained, upgraded and replicated. The involvement of Local Authorities, registered in some countries, in the discussions and decisions about field trials and deliberate release of LMOs into the environment (e.g. in Poland and in the Czech Republic) is surely a good practice to be extended to all the countries. Similarly, the joint presence (e.g. in Czech republic, Kenya, Lithuania, Poland, Slovakia) in the National Biosafety Steering Committees of LMOs Developers, Environmental NGOs and Consumers Associations, is also a good practice to be maintained and reinforced, no matter its implications in terms of time-consuming debates. The presence of these actors is, however, too small when compared with the number of the public institution representatives and this imbalance should be gradually addressed.

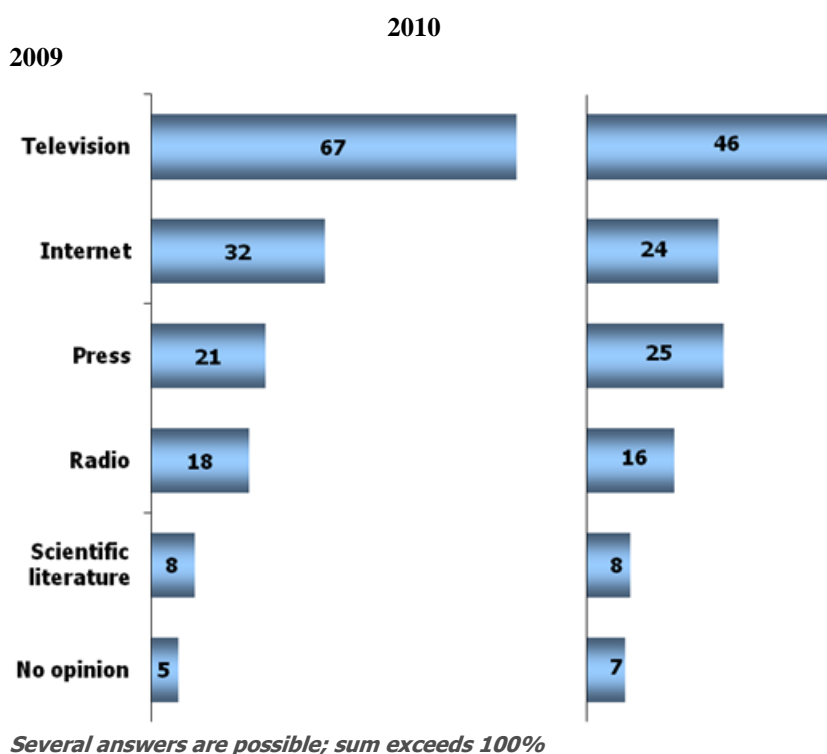
127. The progressive and active participation of Organic Farmers Associations (registered in Poland and Lithuania) in the debate on GMOs release into the environment is surely a relevant example of public participation, with a bearing on the formulation of appropriate rules and measures to manage the so-called "co-existence" between GMOs production, "traditional" agriculture and organic / biological productions.

128. The three national polls on public opinion on LMOs conducted in Lithuania (2007, 2009, 2010) as well as in Estonia, are relevant initiatives that give some interesting insights on the process of public awareness creation. More specifically, the Lithuanian surveys show:

- A remarkable decrease of the population not having opinion on LMOs from 2007 to 2010;
- The dominant role of TV and of the internet in creating opinion on LMOs (see box 1, hereafter).

**BOX 1** Source of information about GMO (%) <sup>15</sup>

*From which media source you acquired the information about GMO mostly?*



Television was mostly mentioned by the respondents older than 35 years old, receiving lower average income or living in small towns and the countryside. People belonging to the 18-35 age group, possessing higher education and receiving higher average income or living in the main towns mostly designated the information from the internet. Radio was generally popular between women, persons living in small towns and the countryside or receiving lower average income.

129. Whether scientific institutions (universities, researchers) and international bodies (UN Conventions and Agencies) succeeded or not in making an effective use of the media for an unbiased communication to the large public on Biosafety, seems to be a relevant point to be analysed and further discussed for the implementation of the Cartagena Protocol.

#### 4. Country Ownership and Driven-ness

130. The implementation of the NBF is a country-driven process and generally the NCAs have been proactive in mobilising political commitment and available resources for this purpose. The drafting and the approval of national laws and regulations on Biosafety represent the most significant evidence of the countries' ownership of the process.

131. All the countries have been able to respect their co-financing commitments and many of them have also succeeded in mobilizing extra-funding from other external sources. That happened not only in the European countries that accessed EU funding for Biosafety agenda, but also in other countries such as Cameroon, Namibia, Uganda and Vietnam. The case of Namibia is a very positive one, with the Government currently financing three fellowships abroad for PhD and MSc on Biotechnology and Biosafety.

<sup>15</sup> "Public opinion survey on GMO in Lithuania", Min. of Environment, 2010 (CD)



132. Nevertheless, as discussed under Socio-political sustainability, the Biosafety agenda is a complex and sensitive issue that can be hardly tackled by any single country, particularly small and / or low-income countries. Therefore, the national interests of those countries and their capacity to actively participate in the implementation of Biosafety Agenda, will probably find a more appropriate arena in the regional and international fora, like the COP-MOP.

## 5. Financial Planning and Management

133. GEF funding was based on the funding requirement of the incremental cost and depended on the actual needs of the countries at the moment of Projects design and implementation. The same applied to the co-finance request. At the time of project implementation, the rules for co-financing were not as strict as today and the countries provided the funds they had planned to contribute into the project. Whereas countries like Uganda pledged 13% of the total budget as national co-financing, some EU countries had the opportunity to obtain co-finance from other sources (some of them had already done it at the time they submitted their proposal and funding request to the GEF). Overall, therefore, the funding was need-driven and proportionate to the country's capacity to co-finance. Tables in Annex 8 show the Projects Costs (Estimated and Actual) and Co-Financing (Planned and Actual) for each country.

134. All the main financial / management documents of the projects are uploaded in the online information system put in place by UNEP (ANUBIS), namely the Initial Budget of the projects, all the Budget Revisions, Annual and Final Audit Reports, the Terminal Financial Statement, the Final Co-Financing Document, the Final Inventory and the Transfer of Equipment declaration. The evaluation team could have access to all this information and confirm that all the countries have succeeded in supplying the system with the necessary information. Thanks to the efforts of the UNEP management team, the functioning of the ANUBIS system has been highly effective for the clear and transparent financial management of the projects, all of them having been formally closed without any pending administrative issue. The tables in Annex 9 (Project Data Compilation) present a summary of the main data regarding the implementation of the projects in each country (General Information, Dates, Budget, Documents produced and available).

135. No-cost budget revisions have been necessary to adapt the budget foreseen at the time of the Project planning to the real needs at the time of implementation. The approval of the revisions and the disbursement of the funds have not caused delays in activities implementation.

136. All the funds supplied by GEF were totally used and the overall expenditure ratio (actual / planned) was higher than 100%, due to the increased national contribution (co-financing). Actually, all the co-financing in-kind pledges have been maintained and in some cases overcome, as shown in the Co-financing Table of Annex 8.

## 6. UNEP Supervision and Backstopping

137. Older projects were supervised and technically completed under the supervision of a larger UNEP Biosafety Team which currently relies on no more than two Officers in Nairobi (a Task Manager and a Finance Manager). UNEP, guided by its obligations, should expedite support in replacements especially when funds are available and committed to support such projects. Despite current staffing situation, all national executing agencies have genuinely highlighted the positive role and dynamism of UNEP in coaching and coordinating the national teams. The European countries have particularly and extensively highlighted the support received from the UNEP Geneva Office<sup>16</sup> at the time of project implementation.<sup>135</sup> The online information system put in place by UNEP (ANUBIS), though difficult to use at the beginning, has resulted to be a very effective and successful instrument for Monitoring & Evaluation. The assiduous and efficient backstopping of the task and

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<sup>16</sup>The UNEP Office in Geneva hosted the Biosafety Unit at that time.

finance managers of the Biosafety Unit of UNEP has been decisive in the implementation of the system.

138. Regional / international meetings have also been a great opportunity for the UNEP task and financial managers to provide specific backstopping to the NPCs and to the NEAs.

## 7. Monitoring and Evaluation

### *M&E Design*

139. The Review of projects design quality (see Annex 10), carried out by the evaluation team in the preparatory phase of the mission, and presented in the Inception Report, rated the monitoring design as Moderately Satisfactory (MS) and the evaluation design as Moderately Unsatisfactory (MU). Actually, as a whole, the M&E Design of the projects did not offer, in the opinion of the evaluation team, sufficient plans and tools for an effective monitoring and evaluation of the projects.

140. The first group of eight projects were not required to present a Log Frame, while the second group of seven projects do have a Log Frame that is more “activity oriented” than “result oriented”. The adequacy of SMART<sup>17</sup> indicators, appropriate means of verification and assumptions was uneven among the projects, as well as the use of project terminology (confusion between levels of results, indicators and outputs, etc.). Actually, some of the national teams met by the mission acknowledged that their familiarity with project planning and M&E tools (e.g. Log Frame) was not very strong at that time. The baseline information was not sufficient for some projects, but quite exhaustive in some others, particularly in the first group. In some cases (mostly in the first group) there was a clear comparison with the baseline situation and the “incremental” value of the project (as required by GEF). Deadlines for technical and financial reporting were clearly defined.

141. As far as the evaluation plans are concerned, though mid-term reviews and final evaluation were mentioned in the project documents, no financial provision was made for their implementation.

### *M&E Implementation*

142. Despite the drawbacks of the M&E design, monitoring mechanisms were implemented and the overall appreciation in the countries is that the projects were well monitored by the UNEP Biosafety team. Again, the establishment and implementation of the ANUBIS System has been crucial for this purpose. Periodic reports may have not always been timely presented by all the countries, and not always in a clear form. Project Implementation Reviews (PIR) are not frequently uploaded in the ANUBIS system, but there has always been good communication between the NEAs and the IA (UNEP), making effective the joint monitoring and steering of the projects through measures of readjustments and revisions (of activities and financial).

143. Unfortunately, not all the NEAs have been able to conduct self-assessments during the project or at its closure, nor were they encouraged by UNEP to do so, in the absence of a formal final evaluation. That could have been most useful, for the national teams, to learn by the experience and to draw relevant conclusions.

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<sup>17</sup> Specific, Measurable, Achievable, Relevant, Time-bound

## D. Complementarity with UNEP Strategies and Programmes

### 1. Linkage to UNEP's Expected Accomplishments and POW 2010-2011

144. Though the projects were designed prior to the production of the UNEP Medium Term Strategy (MTS) / Programme of Work (POW) 2010/11, and therefore not necessarily aligned with the Expected Accomplishments articulated in those documents, complementarities should still exist and be assessed. The UNEP-GEF projects for the implementations of the NBF foreseen in the Cartagena Protocol are surely and tightly linked to the thematic focal area of Environmental Governance, through which UNEP is expected to “support Governments in establishing, implementing and strengthening the necessary processes, institutions, laws, policies and programmes to achieve sustainable development”<sup>18</sup>.

145. As shown in the ToC of the project (diagram 2) “improved decision-making” and “improved governance of national / international biosafety systems” are crucial Intermediate States for reaching the intended project impact. Therefore, the projects are making a tangible contribution to the UNEP Expected Accomplishments b) and d) of the priority area of Environmental Governance:

- “States increasingly implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions” (Exp. Acc. b);
- “National and international stakeholders have access to sound science and policy advice for decision-making” (Exp. Acc. d).

146. The role of UNEP in promoting “cooperation and action based on sound science” while working “with United Nations entities, international institutions, regional and national bodies...” (as expressed in UNEP MTS) should lead to the other two main UNEP Expected Accomplishments, a) and c), of the priority area of Environmental Governance. They are:

- “The United Nations system demonstrates increasing coherence in international decision-making processes.....”
- “National development processes and UN common country programming processes increasingly mainstream environmental sustainability in their implementation”

147. Unfortunately, on these aspects, the role of the UNEP-GEF project has been less incisive and that should deserve a careful analysis within UNEP. As a matter of fact, the evaluation showed that virtually no cooperation has been established in the countries between the NBF of the Cartagena Protocol and other relevant international instruments like the *Codex Alimentarius* Commission and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA), all of them with a Secretariat hosted in another UN Agency (FAO). The latter is particularly relevant for the so-called “coexistence” (between LMOs, traditional and organic farming) and the “socio-economic considerations” under Article 26 of the Cartagena Protocol.

### 2. Alignment with the Bali Strategic Plan (BSP)

148. The project has certainly contributed to address the environmental needs, priorities and obligations of the governments in developing countries and in countries with economies in transition. The needs of the countries in the area of capacity building, policy advising and sound science-based risk assessments have been particularly targeted, in line with the Bali Strategic Plan for Technology Support and Capacity Building(BSP).

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<sup>18</sup>UNEP Medium-termStrategy 2010-13

### 3. Gender

149. Whereas gender aspects are not present so far in the Biosafety issue, the prevailing presence of women heading NCA in all the countries visited by the evaluation team is worth mentioning.

### 4. South-South Cooperation

150. Though the projects did not explicitly address the issue of South-South Cooperation, they have surely promoted exchanges and networking that are already producing some cooperation initiatives, such as the sharing of technical guidelines and manuals, the mutual support in drafting regulatory and administrative procedures, the enhancement of regional biosafety networks (e.g. in the Eastern Africa Community).

## III. Conclusions and Recommendations

### A. Conclusions

151. The UNEP-GEF funded projects have successfully supported the selected countries in significantly enhancing their national capacities to implement the National Biosafety Frameworks (NBF). More specifically, the Projects have largely contributed to:

- a) The definition of national biosafety policies / strategies, including a national Biosafety Law in virtually all the countries, in line with the Cartagena Protocol and the national needs and priorities;
- b) The setting and implementation of responsive Regulatory and Administrative regimes (Regulations, Guidelines, etc.) capable, at a variable level from country to country, to manage requests, carry out risk assessments and administrative tasks for handling LMOs;
- c) Enhance national capacities through extensive training and capacity building activities of a number of officers and professionals in all the relevant institutions;
- d) The setting of a biosafety information system, though at variable levels of implementation;
- e) The promotion of awareness raising and education of the general public in all the countries.

152. Biosafety is, by its very nature, a complex and multi-sectorial issue, which strongly needs coordination and synergies between different line-ministries, competent for Agriculture, Environment, Health, Science and Technology, Education and Trade, among others. **The importance of the Biosafety Agenda in the Governments' priorities and the subsequent institutional uptake of the process by the national players, particularly the coordinating role of the National Competent Authority (NCA), have proved to be key factors for putting in place and effectively implementing the National Biosafety Frameworks.**

153. The projects have surely created institutional capacities and national ownerships on Biosafety issues, but the process of NBF implementation, while it appears mature and solid in few countries, still needs improvement in others. Moreover, not all the countries are equally attractive to LMOs developers, due to their different agricultural potential or to their general development context. Therefore, for the sustainability of the results and for enhanced cost-effectiveness, **more targeted, country-specific actions are needed**, allowing to address and remove the main problems hindering the consolidation of NBFs, on a "country by country" basis. There are countries still needing to set proper regulatory and administrative regimes (e.g. Uganda and Namibia), while others should focus on the capacity building of newly appointed staff (e.g. Kenya) or require more sophisticated laboratory equipment and relative technical skills, especially on current methods of LMOs detection. African and Asian countries with a large base of small farmers relying on biodiversity and traditional

agriculture for their subsistence strongly need to improve their capacity to assess and manage the risks of releasing LMOs into the environment.

154. In the perspective of more targeted, country-specific actions, **a regional approach to problem-solving and to capacity building could be highly appropriate.** The cost-effectiveness of the regional, integrated system of Risk Assessment established in the EU is evident, while in other regions (e.g. South-East Asia and East Africa) different stakeholders (ministries, research centres, universities, etc.) are more and more interested in cooperating and establishing synergies.

155. As far as public information and participation are concerned, great improvements are registered in all the countries. Considering that, in most of the countries, civil society had not been previously significantly (if any) exposed to Biosafety issues, the efforts of the Governments to support civil society participation have to be acknowledged and highly commended everywhere. Nevertheless, and notwithstanding some brilliant initiatives, public participation still needs to be generally improved. The National Biosafety Commissions (Councils or Committees, terminology may vary), that support the NCA in the decision-making process, are basically composed of representatives of Ministries and public institutions representatives, some academic and research organizations, individual experts and scientists, while Civil Society Organisations and representatives of the private sector (biotech developers) are clearly under-represented. **Forms of wider, more proactive participation in NBF implementation need therefore to be generally pursued.**

156. Improved decision-making and enhanced good governance practices are crucial for enabling the Governments to fulfil the requirements of the CPB and to contribute to the CPB objective (see ToC in diagram 1). In this context, forms of regional integration and coordination (e.g. EU) proved to be highly incisive and cost-effective. **The implementation of the NBF and of the CPB would also gain effectiveness from increased coordination and interaction between UN agencies and programmes,** allowing a comprehensive approach to Biosafety, encompassing relevant related issues, like international trade mechanisms, intellectual property rights issues, food security and food sovereignty, among others.

157. The overall ratings table for the different evaluation criteria described in the TOR of the Evaluation is presented hereafter. Five, out of the eleven Evaluation Criteria, are Satisfactory (S), while four have been rated Highly Satisfactory (HS) and one as Moderately Satisfactory (MS). Sustainability is Moderately Likely (ML). Therefore, as a whole, the project can be rated as “Satisfactory”.

**Table 4 Table of Ratings**

<b>Criterion</b>	<b>Summary Assessment</b>	<b>Rating</b>
<b>A. Attainment of project objectives and results</b> (par. 76-91 / 149-154)	The projects have surely created diffuse institutional capacities and national ownerships on Biosafety issues, but the process of NBF implementation, while it appears mature and solid in few countries, still needs improvement in others.	<b>S</b>
1. Effectiveness (par. 51-75)	The Project has been satisfactorily successful in achieving its main Outcome, since National Biosafety Frameworks are being implemented, though the mechanisms of implementation need generally to be improved.	<b>S</b>
Relevance (par. 48-50)	The increased development of biotechnologies and transboundary movements make biosafety measures more and more relevant. The first group of “demonstration projects” was extremely relevant for gaining experience and capitalising on lesson learned.	<b>HS</b>

<b>Criterion</b>	<b>Summary Assessment</b>	<b>Rating</b>
Efficiency (par. 97-98 / 121 / 128/ 130-136)	The activities implemented have been executed efficiently. The countries have actively participated in co-financing. A very small Biosafety Unit is managing and backstopping a remarkably high number of projects in more than 120 countries.	<b>HS</b>
<b>B. Sustainability of project outcomes</b>		<b>ML</b>
1. Financial (par. 96-100)	Financial problems have been pointed out in all the European countries, which are experiencing severe budget restrictions and staff reduction in the environmental public sector. The financial sustainability of the NBF may not be at risk, but the Biosafety agenda may suffer considerable limitations.	<b>ML</b>
Socio-political (par. 93-95)	Biosafety “discourse” is very polarized everywhere. Socio-political sustainability of the NBF implies the ability of the Governments to accommodate private investment opportunities with citizens’ socio-economic and environmental concerns. That is not an easy balance for any single country to achieve. Socio-political sustainability is likely to be highly conditioned by the political agenda of those who are governing the country.	<b>ML</b>
Institutional framework (par. 101-103)	Biosafety is a complex and multi-sectorial issue, which strongly needs coordination and synergies between different line-ministries. In some cases the institutional framework is currently well established, but in other cases one or more of the institutional achievements are not present or exist in a quite embryonic state.	<b>ML</b>
Environmental (par. 104)	Environmental sustainability is at the core of the Cartagena Protocol on Biosafety and its “parental” Convention on Biological Diversity.	<b>L</b>
<b>C. Catalytic role</b> (par. 105-111)	For many countries, the projects represented the first opportunity to deal with Biosafety. The setting of National Coordinating Committees (NCC) of the projects has represented an outstanding opportunity for creating dialogue and coordination mechanisms that are keeping working, well after the project, under the form of multidisciplinary bodies, like the National Biosafety Steering Committees.	<b>HS</b>
<b>D. Stakeholders involvement</b> (par. 122-126)	There has been a remarkable enhancement of stakeholders’ involvement and public awareness during the project life. There is need of improvement in the institutional uptake and in the proactive participation of the public in the decision-making process.	<b>S</b>

<b>E. Country ownership / driven-ness</b> (par. 127-129)	The drafting and the approval of national laws and regulations on Biosafety represent the most significant evidence of the countries' ownership of the process. All the countries have been able to respect their co-financing commitments.	<b>HS</b>
<b>F. Achievement of outputs and activities</b> (par. 44-47)	The level of attainment of the outputs and their quality (particularly their solidity) has been uneven throughout the countries.	<b>S</b>
<b>G. Preparation and readiness</b> (par. 112-115)	The gradual approach used, consisting in testing a methodology in some pilot-countries gave the opportunity to learn lessons and to progressively involve more and more countries. The question of different baseline situations among the countries was actually left to be tackled by the national executing agencies and project coordinators.	<b>S</b>
<b>H. Implementation approach</b> (par. 116-121)	Considering the complexity of the management of such a large pool of projects in more than 120 countries, the project execution and implementation arrangements have been highly performing and have showed a remarkable capacity to adapt to the circumstances and to address specific challenges.	<b>HS</b>
<b>I. Financial planning and management</b> (par. 130-133)	The funding was need-driven and also proportionate to the country's capacity to co-finance. The functioning of the ANUBIS system has been highly effective for the clear and transparent financial management of the projects, all of them having been formally closed without any pending administrative issue.	<b>HS</b>
<b>J. Monitoring and Evaluation</b>		<b>MS</b>
M&E Design (par. 137-139)	The M&E Design did not offer sufficient plans and tools for an effective monitoring and evaluation of the projects.	<b>MS</b>
M&E Plan Implementation (par. 140-141)	Monitoring mechanisms were implemented. The ANUBIS System has been crucial for the purpose. The good communication between the NEAs and the IA (UNEP), made possible the joint monitoring and steering of the projects. Not all the NEAs have been able to conduct self-assessment activities during the Project or at its closure.	<b>S</b>
Budgeting and funding for M&E activities (paragraph 139)	There was not budgeting for M&E in the ProDoc.	<b>MU</b>
<b>K. UNEP Supervision and backstopping</b>		<b>S</b>
UNEP (par. 134-136)	Despite the UNEP Biosafety Unit having been progressively downsized, the positive role and dynamism of UNEP in coaching and coordinating the national teams has to be acknowledged.	<b>S</b>

## B. Lessons Learned

### *Regional approach and Capacity building*

158. Regional and sub-regional cooperation is highly instrumental for further enhancing capacity building and sharing experiences. There are several small countries that are already engaged in developing long term linkages on a regular basis (e.g. Cambodia, Laos, Thailand and Vietnam). The enhancement of regional and sub-regional cooperation would benefit the region as a whole and, more particularly, small, low-income countries. Actually, a wealth of information, expertise and tools to detect and make risk assessments have been generated in different countries under the UNEP-GEF funded projects, which will be very useful when shared with the countries lagging behind. National experts that acquired an outstanding experience through the Project could be highly effective in disseminating good practices at regional level, in crucial areas such as technical guidelines definition, risk assessment and management, risk monitoring, advanced laboratory techniques, among others. Donors support could also be more cost-effective when addressing nascent regional approaches and increased South-South cooperation.

### *Reference laboratories and Technical skills*

159. LMOs detection laboratories established with the UNEP-GEF support are in place and are functioning in the majority of the countries. However, the capacity to identify any authorized/unauthorized LMO in the food/feed and in the fields is limited to basic methods. As a matter of fact, the current methods of LMO detection rely heavily on the PCR (Polymerase Chain Reaction) based methods that may not provide a clear picture when a gene-knockout or single gene mutations are introduced. Keeping in view its importance, the LMO detection in the risk assessment and the decision making process has to be recognized as a major activity in the future. Therefore, all the stakeholders, future project funding agencies and more so for NCA, should upgrade LMO detection laboratories and enhance the skills of the staff; future funding on biosafety must take into account those needs.

### *Risk Assessment capacities*

160. Risk Assessment is crucial for an effective management of LMOs, particularly in the countries and sub-regions more exposed to large-scale LMOs introduction. Risk Assessment includes a range of different and relevant activities from laboratorial LMOs detection (see above) to wide-scope environmental and socio-economic impact in case of LMOs production for the market. This range of activities needs a variety of different and specialized research institutions. Training on technical skills for LMOs management are more effective where a diffuse know-how and a solid background exist in the countries, in areas such as Environmental Management, Risk Assessment and Management, Social and Environmental Impact Assessment, Environmental Law, among others. The support and consolidation of “regional research and training pole of excellence” can be increasingly relevant to strengthen capacities in those areas.

### *Post-release LMOs monitoring and biological diversity*

161. The need to strengthen environmental post-release monitoring of LMOs and to enhance the conservation of biological diversity is increasing. More emphasis should be laid on post release monitoring of LMOs especially in the areas of “Centres of Origin”<sup>19</sup>, in order to assess any possible negative impacts on environment and biodiversity due to large scale deployment and long term

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<sup>19</sup>The centre of origin is a geographical area where a group of organisms, either domesticated or wild, first developed its distinctive properties. (Source: International Treaty on Plant Genetic Resources for Food and Agriculture -ITPGRFA) Centres of origin are also considered centres of biodiversity.



cultivation of LMOs. In order to achieve such a goal, , there is a need to establish long term studies to develop baseline information on the extent of biological diversity and species composition in those areas where LMOs are deployed on regular basis.

#### *Donors and Implementing agencies*

162. There are multiple donor and implementing agencies working in parallel on biosafety. In those countries where institutional capacities are limited, additional funding has limited scope to achieve any higher levels of outcomes. In the case of biosafety, the different policies and agendas of various donors can give rise to competing approaches to capacity development, which can overwhelm countries with limited institutional capacities. Therefore, there is a need to improve the existing coordination mechanisms and bring in synergy in order to achieve common objectives.

163. There is a strong need to strengthen the technical capacity support of the implementing agencies: GEF implementing agencies and other organizations need to address the issue of their own capabilities to adequately support future biosafety needs. A core team of internal scientific experts within the biosafety implementing agencies may provide a better technical backstopping and quality control for biosafety projects in order to develop more harmonised and internationally uniform risk monitoring and risk assessment procedures.

164. Forms of projects implementation through National Project Coordinators (NPC) linked to, but not dependent from the NEA, deserve a careful analysis before implementation and clear execution arrangements, to avoid the excessive pivotal role of the NPC, problems of communication between the project and the NEA and a certain discontinuity of the activities when the project comes to end.

### **C. Recommendations**

165. Based on the main conclusions and lessons, the evaluation mission's recommendations are the following:

- i. National Biosafety Laws, enacting Regulations and an effective National Competent Authorities (NCA) are the corner-stones of the National Biosafety Frameworks (NBF). Priority should be given to the fulfilment of these conditions in those countries where they are still lacking, such as Namibia and Uganda, or where those achievements are very recent (e.g. Cambodia, Vietnam).
- ii. Taking into account the different levels of consolidation of the NBF achieved and the variable level of exposition to LMOs throughout the countries, future actions should be more focused on the specific, actual countries' needs and framed within a regional / sub-regional approach, allowing more complementary and cost-effective actions of capacity building. UNEP should strongly encourage and support East Africa countries, Southern Africa countries and South-East countries to jointly assess their NBFs and to establish a regional / sub-regional plan of NBFs' upgrading, taking into account possible complementarity and cooperation.
- iii. National capacities already in place should be improved and put in place at regional / sub-regional level. It is strongly recommended that UNEP coordinate the training and enhancement of regional experts (training of trainers) on crucial areas such as advanced laboratory techniques, technical guidelines definition, risk assessment and management, risk monitoring and evaluation. It is further recommended that, based on the regional /sub-regional approach (previous recommendation) a list of thematic areas of capacity building, a roster of national experts and a regional capacity building plan are prepared by the NCA of the Region / Sub Region with UNEP Support.
- iv. Civil Society Organisations and private sector (Biotechnology Developers as well as Farmers) should be given more opportunities to actively participate in the decision-making process on LMOs at country level. While the National Biosafety Committees (Commissions or Councils) should enhance the participation of those stakeholders, the NCAs should also be more

proactive in their role of awareness raising and information, by addressing different target groups (e.g. small farmers, commercial farmers, university students, consumers, environmentalist groups) with appropriate, specific contents and means. UN agencies and programs should jointly support the governments in this endeavour.

- v. The mission also recommends more coordination between UN agencies and programmes as biotechnological approaches are considered as important means to ensure food security in small and poor countries. A specific and tight collaboration with FAO and IFAD should be implemented in those countries where issues such as “coexistence” (between LMOs and small farmers undertaking traditional and organic farming) and “socio-economic considerations” under Article 26 of the Cartagena Protocol, are at stake.

## Annex 1 TERMS OF REFERENCE

### Terminal Evaluation of Selected UNEP-GEF Biosafety Implementation Projects

These terms of reference have been prepared to cover the terminal evaluation of 15 projects from the UNEP-GEF Biosafety projects portfolio and include demonstration projects on “Support for the Implementation of the National Biosafety Framework” in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda and projects on the “Implementation of the National Biosafety Framework” in Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and VietNam.

### PROJECT BACKGROUND AND OVERVIEW

#### Project Rationale

The Cartagena Protocol on Biosafety (CPB) marked a significant milestone in how countries cooperate towards the safe transfer, handling and use of living modified organisms (LMOs) that come from modern biotechnology. However, the ultimate success of this international agreement depends on the capacity of Parties to fully implement the agreement. The Protocol, adopted in 2000, entered into force on September 11 2003.

The Global Environment Facility (GEF), as the financial mechanism to both the Convention on Biological Diversity (CBD) and its CPB, has played an important role in building the necessary capacity in biosafety since the adoption of the Protocol. The GEF, together with UNEP, UNDP and the World Bank, assists countries in developing and implementing national biosafety frameworks (NBFs) and participating in the Biosafety Clearing House (BCH).

UNEP-GEF projects for assisting countries to implement their NBFs have been enabling countries to successfully meet their obligations as Parties to the Protocol. This has been done by building scientific and technical capacity and helping to translate draft NBFs into a workable and effective roadmap to manage a comprehensive biosafety system in the countries.

#### Project objectives and components

The terminal evaluation covers 15 projects from a GEF portfolio of projects assisting countries to implement their NBFs. Eight are UNEP -managed **demonstration projects** – now closed - to support countries in the implementation of NBFs. These projects were approved by the GEF Council in November 2001 for Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. The 3-year projects started in September 2002 and were completed in the period 2005-2007. The demonstration projects were financed under the GEF’s “Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety (CPB)”.

The evaluation will also comprise 7 UNEP-GEF **biosafety implementation projects** in Cambodia, the Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and VietNam, approved by the GEF council in early 2006

Generally, the **goal** of an implementation project is to enable a country to convert its draft NBF into a workable, effective, and transparent regulatory regime, in line with national priorities and international obligations. The projects also assist countries to create administrative mechanisms for handling all aspects of biosafety decision making. By the end of the projects, the participating countries should have: a workable and transparent regulatory regime consisting of enabling legislation, implementing regulations and complementing guidelines that are consistent with the Biosafety Protocol and other relevant international obligations; Implementing systems for: handling of

notifications or requests for approvals (including systems for administrative processing, risk assessment and decision making); enforcement and monitoring public information and public participation.

All projects are very similar in terms of goal because of the primary objective of Implementation the Cartagena Protocol on Biosafety. Common objectives for country projects included - under five components - the following: (1) Formulating a national policy on biotechnology and biosafety, in countries where this was deemed relevant; (2) Developing and implementing a regulatory and administrative regime: law(-s), enabling regulations, technical guidelines; (3) Building capacity and human skills in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement; (4) Setting up national information systems on biosafety, including the development of a national biosafety clearing-house (BCH); (5) Promoting public information and awareness on issues related to modern biotechnology and biosafety.

The biosafety implementation projects differ though at the activities and outputs levels as they comprise a very diverse group of countries.

### **Executing Arrangements**

Biosafety Implementation Projects were implemented through designated government agencies and by National Coordinating Committees (NCCs) established by designed Ministries or agencies as National Executing Agency (NEA), to advise and guide the implementation of the National Biosafety Framework. Committees included representations of all government agencies with mandate relevant to the CPB and representations from the private and public sectors. The committee was multidisciplinary and multi-sectoral in fields relevant to the CPB.

National Project Coordinators were appointed after consultation with UNEP, for the duration of the National Project. The National Project Coordinator was responsible for the overall coordination, management and supervision of all aspects of the National Project. He/she reported to the National Coordinating Committee and UNEP, and liaised 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 was responsible for all substantive, managerial and financial reports from the National Project. He/she provided overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components.

Steering Committees were established and provided guidance and direction to the implementation of the project. They are chaired by UNEP, and comprise representatives of the Ministry designed as the National Executing Agency, two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO.

### **Project Cost and Financing**

The GEF has provided a total of US\$ 9,271,188 of external financing to the projects. Most projects belong to the Medium-Size Project category. The projects were expected to mobilize another US\$ 4,681,105 million in co-financing, mostly from Governments.

### **Project Implementation Issues**

A Mid-term Evaluation of the global initiative on the Development of National Biosafety Frameworks projects was conducted by the UNEP Evaluation and Oversight Unit in 2003.

## TERMS OF REFERENCE FOR THE EVALUATION

### Objective and Scope of the Evaluation

In line with the UNEP Evaluation Policy<sup>20</sup>, the UNEP Evaluation Manual<sup>21</sup> and the Guidelines for GEF Agencies in Conducting Terminal Evaluations<sup>22</sup>, the terminal evaluation of selected GEF projects on “Biosafety Implementation” is undertaken at the end of the projects to assess project performance (in terms of relevance, effectiveness and efficiency), and determine outcomes and impacts (actual and potential) stemming from the project, including their sustainability. The evaluation has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP, governments, the GEF and their partners. Therefore, the evaluation will identify lessons of operational relevance for future project formulation and implementation. It will focus on the following sets of **key questions**, based on the project’s intended outcomes, which may be expanded by the consultants as deemed appropriate:

How successful were the projects in supporting the 15 countries to put in place a workable and transparent national biosafety framework, in line with national development priorities, Agenda 21, and the CBD?

Did the projects assist the countries to establish and consolidate a fully functional and responsive regulatory regime in line with the Cartagena Protocol and national needs and priorities?

To what extent did the projects assist the countries to establish and consolidate a functional national system for handling requests, carry out risk assessment decision-making and administrative tasks?

How successful were the projects in assisting the countries to establish and consolidate a functional national system for “follow -up” activities such as monitoring of risk exposure and environmental effects, and strengthening of enforcement mechanisms, institutions and procedures?

Did the projects assist the countries to establish and consolidate a functional national biosafety system for public awareness, education, participation, and access to information?

### Overall Approach and Methods

The terminal evaluation of the selected “Biosafety Implementation Projects” will be conducted by a team of independent consultants under the overall responsibility and management of the UNEP Evaluation Office (Nairobi), in consultation with the UNEP GEF Coordination Office and the UNEP GEF Biosafety Unit (Nairobi).

It will be an in-depth evaluation using a participatory approach whereby key stakeholders are kept informed and consulted throughout the evaluation process. Both quantitative and qualitative evaluation methods will be used to determine project achievements against the expected outputs, outcomes and impacts.

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<sup>20</sup>

<http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationPolicy/tabid/3050/language/en-US/Default.aspx>

<sup>21</sup>

<http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationManual/tabid/2314/language/en-US/Default.aspx>

<sup>22</sup>

[http://www.thegef.org/gef/sites/thegef.org/files/documents/TE\\_guidelines7-31.pdf](http://www.thegef.org/gef/sites/thegef.org/files/documents/TE_guidelines7-31.pdf)

The evaluation will be organized in two phases: i) phase I focusing on preparation, planning and extended inception report; ii) phase II on data collection and analysis and report writing whose details will be spelled out by the inception report.

The findings of the evaluation will be based on the following:

A **desk review** of project documents<sup>23</sup> including, but not limited to:

Relevant background documentation, inter alia UNEP and GEF policies, strategies and programmes pertaining to biosafety;

Project design documents; Annual Work Plans and Budgets or equivalent, revisions to the logical framework and project financing; also available on the Anubis information system to which the consultants will be given access;

Project reports such as progress and financial reports from countries to the IA and from the EA to UNEP; Steering Committee meeting minutes; annual Project Implementation Reviews and relevant correspondence; also available on the Anubis information system to which the consultants will be given access;

The UNEP Mid-term evaluation report of the global initiative on Development of NBFs; The GEF Mid-term evaluation of GEF's Support for the Cartagena Protocol for Biosafety.

Documentation related to project outputs such as: publications by the UNEP-GEF Biosafety Unit on the biosafety projects on Implementation of NBFs.

**Interviews**<sup>24</sup> with:

Project management and execution support;

UNEP Task Manager and Fund Management Officer (Nairobi);

Country lead execution partners and other relevant partners;

Relevant staff of GEF Secretariat;

Representatives of other multilateral agencies and other relevant organisations as needed  
Governments' representatives.

**Country visits.** The evaluation team will visit a representative sample of countries from both demonstrations and implementation projects. The sample will be proposed by the inception report according to a set of agreed criteria.

### **Key Evaluation principles**

Evaluation findings and judgements should be based on **sound evidence and analysis**, clearly documented in the evaluation report. Information will be triangulated (i.e. verified from different sources) to the extent possible, and when verification was not possible, the single source will be mentioned<sup>25</sup>. Analysis leading to evaluative judgements should always be clearly spelled out.

The evaluation will assess the project with respect to a **minimum set of evaluation criteria** grouped in four categories: (1) Attainment of objectives and planned results, which comprises the assessment of outputs achieved, relevance, effectiveness and efficiency and the review of outcomes towards impacts; (2) Sustainability and catalytic role, which focuses on financial, socio-political, institutional and ecological factors conditioning sustainability of project outcomes, and also assesses efforts and achievements in terms of replication and up-scaling of project lessons and good practices; (3) Processes affecting attainment of project results, which covers project preparation and readiness, implementation approach and management, stakeholder participation and public awareness, country ownership/driven-ness, project finance, UNEP supervision and backstopping, and project monitoring and evaluation systems; and (4) Complementarity with the UNEP strategies and programmes. The lead consultant can propose other evaluation criteria as deemed appropriate.

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<sup>23</sup> Documents to be provided by the UNEP and UNDP are listed in Annex 7.

<sup>24</sup> Face-to-face or through any other appropriate means of communication

<sup>25</sup> Individuals should not be mentioned by name if anonymity needs to be preserved.

**Ratings.** All evaluation criteria will be rated on a six-point scale. However, complementarity of the project with the UNEP strategies and programmes is not rated. Annex 3 provides detailed guidance on how the different criteria should be rated and how ratings should be aggregated for the different evaluation criterion categories.

In attempting to attribute any outcomes and impacts to the project, the evaluators should consider the difference between **what has happened with** and **what would have happened without** the project. This implies that there should be consideration of the baseline conditions and trends in relation to the intended project outcomes and impacts. This also means that there should be plausible evidence to attribute such outcomes and impacts to the actions of the project. Sometimes, adequate information on baseline conditions and trends is lacking. In such cases this should be clearly highlighted by the evaluators, along with any simplifying assumptions that were taken to enable the evaluator to make informed judgements about project performance.

As this is a terminal evaluation, particular attention should be given to learning from the experience. Therefore, the **“why?” question** should be at front of the consultants’ minds all through the evaluation exercise. This means that the consultants needs to go beyond the assessment of “what” the project performance was, and make a serious effort to provide a deeper understanding of “why” the performance was as it was, i.e. of processes affecting attainment of project results (criteria under category 3). This should provide the basis for the lessons that can be drawn from the project. In fact, the usefulness of the evaluation will be determined to a large extent by the capacity of the consultants to explain “why things happened” as they happened and are likely to evolve in this or that direction, which goes well beyond the mere assessment of “where things stand” today.

## **Evaluation criteria**

### **Attainment of Objectives and Planned Results**

The evaluation should assess the relevance of the project’s objectives and the extent to which these were effectively and efficiently achieved or are expected to be achieved.

*Achievement of Outputs and Activities:* Assess, for each component, the project’s success in producing the programmed outputs as presented in Table A1.1 (Annex 1), both in quantity and quality, as well as their usefulness and timeliness. Briefly explain the degree of success of the project in achieving its different outputs, cross-referencing as needed to more detailed explanations provided under Section 3 (which covers the processes affecting attainment of project objectives). The achievements under the regional and national demonstration projects will receive particular attention.

*Relevance:* Assess, in retrospect, whether the project’s objectives and implementation strategies were consistent with: i) Sub-regional environmental issues and needs; ii) the UNEP mandate and policies at the time of design and implementation; and iii) the relevant GEF focal areas, strategic priorities and operational programme(s).

*Effectiveness:* Appreciate to what extent the project has achieved its main objective **to assist governments to fully implement draft NBFs so as to comply with the CPB through Capacity Building**. To measure achievement, use as much as appropriate the indicators for achievement proposed in the Logical Framework Matrix (Logframe) of the project, adding other relevant indicators as appropriate. Briefly explain what factors affected the project’s success in achieving its objectives, cross-referencing as needed to more detailed explanations provided under Section 3.

*Efficiency:* Assess the cost-effectiveness and timeliness of project execution. Describe any cost- or time-saving measures put in place in attempting to bring the project to a successful conclusion within its programmed budget and (extended) time. Analyse how delays, if any, have affected project execution, costs and effectiveness. Wherever possible, compare the cost and time over results ratios of the project with that of other similar projects. Give special attention to efforts by the project teams to

make use of / build upon pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. to increase project efficiency.

*Review of Outcomes to Impacts (ROtI):* Reconstruct the logical pathways from project outputs over achieved objectives towards impacts, taking into account performance and impact drivers, assumptions and the roles and capacities of key actors and stakeholders, using the methodology presented in the GEF Evaluation Office's ROtI Practitioner's Handbook<sup>26</sup> (summarized in Annex 8 of the TORs). Appreciate to what extent the project has to date contributed, and is likely in the future to further contribute to changes in stakeholder behaviour as a result of i) Procedures for handling applications established and updated in accordance with the Cartagena Protocol; ii) Mechanisms and procedures for monitoring of environmental effects and enforcement established; iii) Increased public awareness of biosafety and involvement in decision-making on biosafety and the likelihood of those leading to changes in biosafety implementation: a) countries enabled to convert draft NBF into a workable, effective and transparent regulatory regime on biosafety in line with national priorities and international obligations consisting of enabling legislation, implementing regulations and complementing guidelines.

### **Sustainability and catalytic role**

**Sustainability** is understood as the probability of continued long-term project-derived results and impacts after the external project funding and assistance ends. The evaluation will identify and assess the key conditions or factors that are likely to undermine or contribute to the persistence of benefits. Some of these factors might be direct results of the project while others will include contextual circumstances or developments that are not under control of the project but that may condition sustainability of benefits. The evaluation should ascertain to what extent follow-up work has been initiated and how project results will be sustained and enhanced over time. Application of the ROtI method will assist in the evaluation of sustainability.

Four aspects of sustainability will be addressed:

*Socio-political sustainability.* Are there any social or political factors that may influence positively or negatively the sustenance of project results and progress towards impacts? Is the level of ownership by the main national and regional stakeholders sufficient to allow for the project results to be sustained? Are there sufficient government and stakeholder awareness, interests, commitment and incentives to execute, enforce and pursue the programmes, plans, agreements, monitoring systems etc. prepared and agreed upon under the project?

*Financial resources.* To what extent are the continuation of project results and the eventual impact of the project dependent on continued financial support? What is the likelihood that adequate financial resources<sup>27</sup> will be or will become available to implement the programmes, plans, agreements, monitoring systems etc. prepared and agreed upon under the project? Are there any financial risks that may jeopardize sustenance of project results and onward progress towards impact?

*Institutional framework.* To what extent is the sustenance of the results and onward progress towards impact dependent on issues relating to institutional frameworks and governance? How robust are the institutional achievements such as governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. required to sustaining project results and to lead those to impact on human behaviour and environmental resources?

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<sup>26</sup> [http://www.thegef.org/gef/sites/thegef.org/files/documents/Impact\\_Eval-Review\\_of\\_Outcomes\\_to\\_Impacts-RotI\\_handbook.pdf](http://www.thegef.org/gef/sites/thegef.org/files/documents/Impact_Eval-Review_of_Outcomes_to_Impacts-RotI_handbook.pdf)

<sup>27</sup> Those resources can be from multiple sources, such as the public and private sectors, income generating activities, other development projects etc.



*Environmental sustainability.* Are there any environmental factors, positive or negative, that can influence the future flow of project benefits? Are there any project outputs or higher level results that are likely to affect the environment, which, in turn, might affect sustainability of project benefits?

**Catalytic Role and Replication.** The *catalytic role* of GEF-funded interventions is embodied in their approach of supporting the creation of an enabling environment and of investing in pilot activities which are innovative and showing how new approaches can work. UNEP and the GEF also aim to support activities that upscale new approaches to a national, regional or global level, with a view to achieve sustainable global environmental benefits. The evaluation will assess the catalytic role played by this project, namely to what extent the project has:

*catalyzed behavioural changes* in terms of use and application by the relevant stakeholders of: i) technologies and approaches show-cased by the demonstration projects; ii) strategic programmes and plans developed; and iii) assessment, monitoring and management systems established at a national and sub-regional level;

provided *incentives* (social, economic, market based, competencies etc.) to contribute to catalyzing changes in stakeholder behaviour;

contributed to *institutional changes*. An important aspect of the catalytic role of the project is its contribution to institutional uptake or mainstreaming of project-piloted approaches in the regional and national demonstration projects;

contributed to *policy changes* (on paper and in implementation of policy);

contributed to sustained follow-on financing (*catalytic financing*) from Governments, the GEF or other donors;

created opportunities for particular individuals or institutions (“*champions*”) to catalyze change (without which the project would not have achieved all of its results).

*Replication*, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated (experiences are repeated and lessons applied in different geographic areas) or scaled up (experiences are repeated and lessons applied in the same geographic area but on a much larger scale and funded by other sources). The evaluation will assess the approach adopted by the project to promote replication effects and appreciate to what extent actual replication has already occurred or is likely to occur in the near future. What are the factors that may influence replication and scaling up of project experiences and lessons?

### **Processes affecting attainment of project results**

**Preparation and Readiness.** Were the project’s objectives and components clear, practicable and feasible within its timeframe? Were the capacities of executing agencies properly considered when the project was designed? Was the project document clear and realistic to enable effective and efficient implementation? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities) and enabling legislation assured? Were adequate project management arrangements in place? Were lessons from other relevant projects properly incorporated in the project design? Were lessons learned and recommendations from Steering Committee meetings adequately integrated in the project approach? What factors influenced the quality-at-entry of the project design, choice of partners, allocation of financial resources etc.?

**Implementation Approach and Adaptive Management.** This includes an analysis of approaches used by the project, its management framework, the project’s adaptation to changing conditions (adaptive management), the performance of the implementation arrangements and partnerships,

relevance of changes in project design, and overall performance of project management. The evaluation will:

Ascertain to what extent the project implementation mechanisms outlined in the project document have been followed and were effective in delivering project outputs and outcomes. Were pertinent adaptations made to the approaches originally proposed?

Assess the role and performance of the units and committees established and the project execution arrangements at all levels;

Evaluate the effectiveness and efficiency of project management by the EA and how well the management was able to adapt to changes during the life of the project;

Assess the extent to which project management responded to direction and guidance provided by the Steering Committee and IA supervision recommendations;

Identify administrative, operational and/or technical problems and constraints that influenced the effective implementation of the project, and how the project partners tried to overcome these problems;

Assess the extent to which MTE recommendations were followed in a timely manner.

**Stakeholder<sup>28</sup> Participation and Public Awareness.** The term stakeholder should be considered in the broadest sense, encompassing project partners, government institutions, private interest groups, local communities etc. The assessment will look at three related and often overlapping processes: (1) information dissemination between stakeholders, (2) consultation between stakeholders, and (3) active engagement of stakeholders in project decision making and activities. The evaluation will specifically assess:

the approach(es) used to identify and engage stakeholders in project design and implementation. What were the strengths and weaknesses of these approaches with respect to the project's objectives and the stakeholders' motivations and capacities? What was the achieved degree and effectiveness of collaboration and interactions between the various project partners and stakeholders during the course of implementation of the project?

the degree and effectiveness of any public awareness activities that were undertaken during the course of implementation of the project; or that are built into the assessment methods so that public awareness can be raised at the time the assessments will be conducted;

how the results of the project (strategic programmes and plans, monitoring and management systems, sub-regional agreements etc.) engaged key stakeholders in the operationalization of National Biosafety Frameworks.

The ROTI analysis should assist the consultants in identifying the key stakeholders and their respective roles, capabilities and motivations in each step of the causal pathway from activities to achievement of outputs and objectives to impact.

**Country Ownership and Driven-ness.** The evaluation will assess the performance of the Governments of the countries involved in the project, namely:

in how the Governments have assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various contact institutions in

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<sup>28</sup> Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the project. The term also applies to those potentially adversely affected by the project.

the countries involved in the project and the timeliness of provision of counter-part funding to project activities;

to what extent the political and institutional framework of the participating countries has been conducive to project performance. Look, in particular, at the extent of the political commitment to enforce (sub-) regional agreements promoted under the project;

to what extent the Governments have promoted the participation of communities and their non-governmental organisations in the project; and

how responsive the Governments were to the National Executing Agencies' coordination and guidance, to UNEP supervision and Mid-Term Evaluation recommendations.

**Financial Planning and Management.** Evaluation of financial planning requires assessment of the quality and effectiveness of financial planning and control of financial resources throughout the project's lifetime. The assessment will look at actual project costs by activities compared to budget (variances), financial management (including disbursement issues), and co-financing. The evaluation will:

Verify the application of proper standards (clarity, transparency, audit etc.) and timeliness of financial planning, management and reporting to ensure that sufficient and timely financial resources were available to the project and its partners;

Appreciate other administrative processes such as recruitment of staff, procurement of goods and services (including consultants), preparation and negotiation of cooperation agreements etc. to the extent that these might have influenced project performance;

Present to what extent co-financing has materialized as expected at project approval (see Table 1). Report country co-financing to the project overall, and to support project activities at the national level in particular. The evaluation will provide a breakdown of final actual costs and co-financing for the different project components (see tables in Annex 4).

Describe the resources the project has leveraged since inception and indicate how these resources are contributing to the project's ultimate objective. Leveraged resources are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector.

Analyse the effects on project performance of any irregularities in procurement, use of financial resources and human resource management, and the measures taken by the EA or IA to prevent such irregularities in the future. Appreciate whether the measures taken were adequate.

**UNEP Supervision and Backstopping.** The purpose of supervision is to verify the quality and timeliness of project execution in terms of finances, administration and achievement of outputs and outcomes, in order to identify and recommend ways to deal with problems which arise during project execution. Such problems may be related to project management but may also involve technical/institutional substantive issues in which UNEP has a major contribution to make. The evaluators should assess the effectiveness of supervision and administrative and financial support provided by UNEP including:

The adequacy of project supervision plans, inputs and processes;

The emphasis given to outcome monitoring (results-based project management);

The realism and candour of project reporting and ratings (i.e. are PIR ratings an accurate reflection of the project realities and risks);

The quality of documentation of project supervision activities; and

Financial, administrative and other fiduciary aspects of project implementation supervision.

**Monitoring and Evaluation.** The evaluation will include an assessment of the quality, application and effectiveness of project monitoring and evaluation plans and tools, including an assessment of risk management based on the assumptions and risks identified in the project document. The evaluation will appreciate how information generated by the M&E system during project implementation was used to adapt and improve project execution, achievement of outcomes and ensuring sustainability. M&E is assessed on three levels:

*M&E Design.* Projects should have sound M&E plans to monitor results and track progress towards achieving project objectives. An M&E plan should include a baseline (including data, methodology, etc.), SMART indicators and data analysis systems, and evaluation studies at specific times to assess results. The time frame for various M&E activities and standards for outputs should have been specified. The evaluators should use the following questions to help assess the M&E design aspects:

Quality of the project logframe as a planning and monitoring instrument; analyse/compare logframe in Project Document,) and logframe used in Project Implementation Review reports to report progress towards achieving project objectives;

SMART-ness of indicators: Are there specific indicators in the logframe for each of the project objectives? Are the indicators measurable, attainable (realistic) and relevant to the objectives? Are the indicators time-bound?

Adequacy of baseline information: To what extent has baseline information on performance indicators been collected and presented in a clear manner? Was the methodology for the baseline data collection explicit and reliable?

Arrangements for monitoring: Have the responsibilities for M&E activities been clearly defined? Were the data sources and data collection instruments appropriate? Was the frequency of various monitoring activities specified and adequate? In how far were project users involved in monitoring?

Arrangements for evaluation: Have specific targets been specified for project outputs? Has the desired level of achievement been specified for all indicators of objectives and outcomes? Were there adequate provisions in the legal instruments binding project partners to fully collaborate in evaluations?

Budgeting and funding for M&E activities: Determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

*M&E Plan Implementation.* The evaluation will verify that:

the M&E system was operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period;

annual project reports and Progress Implementation Review (PIR) reports were complete, accurate and with well justified ratings;

the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs;

projects had an M&E system in place with proper training, instruments and resources for parties responsible for M&E.

## Complementarities with UNEP strategies and programmes

UNEP aims to undertake GEF funded projects that are aligned with its own strategies. The evaluation should present a brief narrative on the following issues:

*Linkage to UNEP's Expected Accomplishments and POW 2010-2011.* The UNEP MTS specifies desired results in six thematic focal areas. The desired results are termed Expected Accomplishments. Using the completed ROI analysis, the evaluation should comment on whether the project makes a tangible contribution to any of the Expected Accomplishments specified in the UNEP MTS. The magnitude and extent of any contributions and the causal linkages should be fully described. Whilst it is recognised that UNEP GEF projects designed prior to the production of the UNEP Medium Term Strategy (MTS)<sup>29</sup>/ Programme of Work (POW) 2010/11 would not necessarily be aligned with the Expected Accomplishments articulated in those documents, complementarities may still exist.

*Alignment with the Bali Strategic Plan (BSP)*<sup>30</sup>. The outcomes and achievements of the project should be briefly discussed in relation to the objectives of the UNEP BSP.

*Gender.* Ascertain to what extent project design, implementation and monitoring have taken into consideration: (i) possible gender inequalities in access to and the control over natural resources; (ii) specific vulnerabilities of women and children to environmental degradation or disasters; and (iii) the role of women in mitigating or adapting to environmental changes and engaging in environmental protection and rehabilitation. Appreciate whether the intervention is likely to have any lasting differential impacts on gender equality and the relationship between women and the environment. To what extent do unresolved gender inequalities affect sustainability of project benefits?

*South-South Cooperation.* This is regarded as the exchange of resources, technology, and knowledge between developing countries. Briefly describe any aspects of the project that could be considered as examples of South-South Cooperation.

## The Consultants' Team

For this evaluation, two consultants will be hired to prepare an extended inception report that would define the evaluation framework and approach. After satisfactory completion of inception report the consultant team will conduct the evaluation and if suggested by the inception report a third consultant might be hired. In general, the evaluation team will combine the following decennial expertise and experience in:

Evaluation of GEF projects;

Biosafety and biotechnology including risk assessment and management, regulatory frameworks, and biodiversity;

Institution and capacity building;

The **Team Leader** will be responsible for coordinating the data collection and analysis phase of the evaluation, and preparing the main report. (S)He will ensure that all evaluation criteria are adequately covered by the team. The inception report will provide a matrix which presents the distribution of roles and responsibilities between evaluation team members which will be approved by the Evaluation Office.

The **Supporting Consultant** will prepare a technical working paper that will be appended to the main report, the content of which will be agreed upon with the Team Leader. The Supporting Consultant is

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<sup>29</sup> <http://www.unep.org/PDF/FinalMTSGCSS-X-8.pdf>

<sup>30</sup> <http://www.unep.org/GC/GC23/documents/GC23-6-add-1.pdf>

also expected to contribute to selected sections of the main report as agreed with the Team Leader, and provide constructive comments on the draft report prepared by the Team Leader.

*By undersigning the service contract with UNEP/UNON, the consultants certify that they have not been associated with the design and implementation of the project in any way which may jeopardize their independence and impartiality towards project achievements and project partner performance. In addition, they will not have any future interests (within six months after completion of their contract) with the project's executing or implementing units.*

### **Evaluation Deliverables and Review Procedures**

The recruited consultants will prepare an **inception report** containing a thorough review of the project design quality and the evaluation framework.

The review of design quality will cover the following aspects:

Project relevance (see paragraph 24 (b));

A desk-based Theory of Change of the project (see Annex - ROtI analysis);

Sustainability consideration (see paragraphs 25-26) and measures planned to promote replication and upscaling (see paragraph 28);

Preparation and readiness (see paragraph 29);

Financial planning (see paragraph 34);

M&E design (see paragraph 37(a));

Complementarities with UNEP strategies and programmes (see paragraph 38);

Using the above, complete and assessment of the overall quality of the project design (see Annex 8)

The evaluation framework will present in further detail the evaluation questions under each criterion with their respective indicators and data sources.

The inception report will also propose if additional consultant is needed, scope and length of the field missions, number and types of countries to be visited, responsibilities and roles of team's members and evaluation timeline. The inception report will be submitted for review and approval by the Evaluation Office before the evaluation team conducts any field visits.

**The Team leader will prepare the main evaluation report.** The main evaluation report should be brief (no longer than 35 pages – excluding the executive summary and annexes), to the point and written in plain English. The report will follow the annotated Table of Contents outlined in Annex 2. It must explain the purpose of the evaluation, exactly what was evaluated and the methods used (with their limitations). The report will present evidence-based and balanced findings, consequent conclusions, lessons and recommendations, which will be cross-referenced to each other. The report should be presented in a way that makes the information accessible and comprehensible. Any dissident views in response to evaluation findings will be appended in footnote or annex as appropriate.

**Technical working paper.** The format and contents of the working paper prepared by the Supporting Consultants should be agreed upon with the Team Leader and approved by the UNEP Evaluation Office before any data collection and analysis work is undertaken. It is recommended that the working papers follow the same structure as the main evaluation report, for easy reference by the Team Leader (Annex 2). The Team Leader will carry out a first review of the working papers and provide comments to the Supporting Consultants for improvement. Only a version acceptable to the Team Leader will be submitted to the EO as an appendix to the draft main report.

**Report summary.** The Team Leader will prepare a 15-slide presentation summarizing the key findings, lessons learned and recommendations of the evaluation. This presentation will be presented at the final Steering Committee meetings of the projects if planned during the evaluation timeline. The purpose of this presentation is to engage the main project partners in a discussion on the evaluation results.

**Review of the draft evaluation report.** The Team Leader will submit the zero draft report according to the evaluation timeline proposed in the inception report to the UNEP EO and UNEP/Biosafety Unit and revise the draft following the comments and suggestions made by the EO. The EO will then share the first draft report with the UNEP GEF Coordination Office and the UNEP/Biosafety Unit, both in Nairobi. The UNEP Task Manager will forward the first draft report to the other project stakeholders, for review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. Comments would be expected within two weeks after the draft report has been shared. Any comments or responses to the draft report will be sent to the UNEP EO for collation. The EO will provide the comments to the Team Leader for consideration in preparing the final draft report. The Team Leader will submit the final draft report after reception of stakeholder comments according to the timeline proposed in the inception report. The Team Leader will prepare a **response to comments** that contradict the findings of the evaluation team and could therefore not be accommodated in the final report. This response will be shared by the EO with the interested stakeholders to ensure full transparency.

Consultations will be held between the consultants, EO staff, the UNEP/GEF, UNEP/Biosafety Unit, and key members of the project execution team. These consultations will seek feedback on the proposed recommendations and lessons.

**Submission of the final Terminal Evaluation report.** The final report shall be submitted by Email to:

Segbedzi Norgbey, Head  
UNEP Evaluation Office  
P.O. Box 30552-00100  
Nairobi, Kenya  
Tel.: (+254-20) 762 3387  
Email: [segbedzi.norgbey@unep.org](mailto:segbedzi.norgbey@unep.org)

The Head of Evaluation will share the report with the following persons:

Maryam Niamir-Fuller, Director  
UNEP/GEF Coordination Office  
P.O. Box 30552-00100  
Nairobi, Kenya  
Tel: (+254-20) 762 4686  
Email: [maryam.niamir-fuller@unep.org](mailto:maryam.niamir-fuller@unep.org)

Ibrahim Thiaw, Director  
UNEP/Division of Environmental Policy Implementation  
P.O. Box 30552-00100  
Nairobi, Kenya  
Tel: (+254-20) 762 24782  
Email: [ibrahim.thiaw@unep.org](mailto:ibrahim.thiaw@unep.org)

Alex Owusu-Biney  
Portfolio Manager (Biosafety), GEF Coordination  
Division of Environmental Policy Implementation  
United Nations Environment Programme (UNEP)

P. O. Box 30552 - 00100  
Nairobi, Kenya  
Tel: +254 20 7624066  
Email: Alex.Owusu-Biney@unep.org

The final evaluation report will be published on the UNEP Evaluation Office web-site [www.unep.org/eou](http://www.unep.org/eou) and may be printed in hard copy. Subsequently, the report will be sent to the GEF Office of Evaluation for their review, appraisal and inclusion on the GEF website.

As per usual practice, the UNEP EO will prepare a **quality assessment** of the zero draft and final draft report, which is a tool for providing structured feedback to the evaluation consultants. The quality of the report will be assessed and rated against both GEF and UNEP criteria as presented in Annex 5.

The UNEP Evaluation Office will also prepare a **commentary** on the final evaluation report, which presents the EO ratings of the project based on a careful review of the evidence collated by the evaluation team and the internal consistency of the report. These ratings are the final ratings that the UNEP Evaluation Office will submit to the GEF Office of Evaluation.

### **Resources and Schedule of the Evaluation**

This Terminal Evaluation will be undertaken by a team of independent evaluation consultants contracted by the UNEP Evaluation Office. The consultants will work under the overall responsibility of the UNEP Evaluation Office and they will consult with the EO on any procedural and methodological matters related to the evaluation. It is, however, the consultants' individual responsibility to arrange for their travel, obtain documentary evidence, meetings with stakeholders, field visits, and any other logistical matters related to their assignment. The UNEP Task Manager, and regional and national project staff will provide logistical support (introductions, meetings, transport, lodging etc.) for the country visits where necessary, allowing the consultants to conduct the evaluation as efficiently and independently as possible.

The Consultants in charge of writing the inception report will be hired for 22 days (Team Leader) and 18 days (Supporting Consultant) respectively. They will travel to Nairobi, Kenya to hold talks with the UNEP EO, the UNEP Task Manager and Financial Management Officer and project staff and draft the inception report.

The inception report will propose the number of **consultants** needed to conduct data collection, analysis and report writing, the length of their assignment and the countries to which they will travel.

### **F. Schedule Of Payment**

Lump Sum.

The consultants will be hired under an individual Special Service Agreement (SSA). The fee will be estimated as a lumpsum, inclusive of all expenses such as travel, accommodation and incidental expenses.

The consultants will receive an initial payment covering the travel costs upon signature of the contract.

Fee ONLY.

The consultant will be hired under an individual Special Service Agreement (SSA) and is NOT inclusive of all expenses such as airfares, in-country travel, accommodation, incidental and terminal expenses. Air tickets will be paid separately by UNEP and 75% of the DSA for each authorised travel



mission will be paid up front. Local in-country travel and communication costs will be reimbursed on the production of acceptable receipts. Terminal expenses and residual DSA entitlements (25%) will be paid after mission completion.

The Team Leader will receive 40% of the honorarium portion of his/her fee upon acceptance of a draft report deemed complete and of acceptable quality by the EO. The remainder will be paid upon satisfactory completion of the work.

The Supporting Consultant will be paid the honoraria in one single payment upon satisfactory completion of their work. The Team Leader will advise the EO whether the Supporting Consultant has provided satisfactory inputs in the evaluation.

In case the consultants are not able to provide the deliverables in accordance with these TORs, in line with the expected quality standards by the UNEP Evaluation Office, payment may be withheld at the discretion of the Head of the Evaluation Office until the consultants have improved the deliverables to meet UNEP's quality standards.

If the consultants fail to submit a satisfactory final product to UNEP in a timely manner, i.e. within one month after the end date of their contract, the Evaluation Office reserves the right to employ additional human resources to finalize the report, and to reduce the consultants' fees by an amount equal to the additional costs borne by the Evaluation Office to bring the report up to standard.

## Annex 2 Evaluation Framework

### IV.A Overall approach and methods of the evaluation

According to the TOR received, a participatory approach will be used, where key stakeholders at national level will be contacted by email and met whenever possible during the field visits.

Quantitative and qualitative methods and indicators will be used, taking into account that the projects were expected to mostly deliver institutional and capacity building outputs and outcomes. Being so, quantitative outputs will be assessed against their quality and effectiveness, hence their capacity to drive and sustain changes at higher level of objectives.

That will be possible, by triangulating the information (reports, etc.) with the field visits, questionnaire and personal interviews with stakeholders who have benefited from the training and capacity building activities. Triangulation will also be used in assessing another relevant component of the projects, i.e. public awareness and participation.

The mission intend to meet or contact by email with some “public” actors (e.g. representative of consumers associations, farmers association, environmental groups, as far as possible) to cross-check their involvement in the implementation of the NBF and in the public debate on Biosafety in the countries.

To meet and hear from the “users” of the NBF (the private companies and/or public actors that applied for the use of LMOs in the countries) will also give a better understanding of the actual problems at stake.

Whenever it’s possible, a meeting involving different stakeholders will also be held, trying to capture the highest number of possible opinions and concerns on the issue during the limited timeframe of the country-visits.

The main methods and tools that the mission plans to use are the following:

A **Desk Review** of all project documents listed in the TOR plus other documents and tools the mission has access to (see Table 1 in following Section IV.C).

**Country visits.** The evaluation team will visit a representative sample of countries from both demonstrations and implementation projects as specified in the following Section IV.C.

The **interviews in the country visit** include the NBA (see list in Table 2 of Section IV.C), which will coordinate additional meetings with other stakeholders such as: National Project coordinator, focal point of BCH, National laboratories involved in RA, RM, Civil Society representatives, etc. Once the initial contact is established by the UNEP Biosafety Unit, consultants will approach directly National Biosafety Authority/National Biosafety Focal Point for seeking date and time for personal interviews with them as well as with other personal.

A **Questionnaire** (see section IV.B, here below) has been prepared by the evaluation team and will be circulated to the National Biosafety focal points of the 15 countries through the Task Manager of UNEP Biosafety Unit as soon as possible. The questionnaire will be sent to all the country National Biosafety Authority (NBA) or to the National Biosafety Focal Points (NBFP), depending on the countries, according to the list in Annex 1, provided by the UNEP Biosafety Unit task manager. The countries will have two weeks for answering the questionnaire, but the countries where a visit is scheduled should answer as soon as possible, so that the mission could receive the questionnaire with responses before the visit.

## IV.B Evaluation questionnaire

The evaluation questionnaire consists of five open key-questions, each one with additional, more specific questions, and one financial table regarding the co-financing of the project.

The questionnaire will also be used to gain in-depth information during personal interviews with project partners and stakeholders in the country visits. In these cases, it will be complemented by other, ad hoc, questions.

### Evaluation questions

**What evidence can you provide**, if any, which shows that this project has helped the national government in formulating a national policy on biotechnology and biosafety taking into account the implementation of Cartagena Protocol on Biosafety?

#### Additional questions/indicators

Apart from the Biosafety Law (Act), is Biosafety taken into account in any other national policy, such as national Environmental Policy, Food Security / Food Safety Policy, Development policies ? Please, specify where and how.

**Do you have evidence to show** that this project helped the national government in developing and implementing a biosafety regulatory and administrative regime: law(-s), enabling regulations, technical guidelines ? Please specify

#### Additional questions/indicators

Since when is a National Biosafety legislation in place?

Does the country have administrative rules and procedures in place for handling notifications and requests for: approval of LMOs import as food/feed?

LMOs in-country processing?

LMOs to test Contained Use?

LMOs to test Confined Field Trial?

LMOs release for commercial purpose?

Please specify for any of the items outlined above, the Number of decisions taken so far by the National Competent Authority and the Number of decisions taken in the year 2010-11.

**What evidence can you provide to show** that this project helped the national governments in building capacity and human skills in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement and what materials you have to support the capacity building activities?

#### Additional questions/indicators

Please, specify the Number of people trained, the years they were trained (ex. 2003-2005), the average duration of the training period, the kind of institutions that represented participants. PLEASE note that conferences, panels and public meetings do NOT enter this category.

Area of	Total	Period	Averag	Institutions to which the trainees belong
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Training	Nb of trained people	of training (years)	duration of training (days)	Ministries and other public inst.	University & Research	Parliament members	NGOs	Associations (Consumers, farmers, etc.)	Media
Risk assessment									
Risk Management									
Risk Monitoring									
Laboratory training									
Legal aspects									
Administrative									
Customs procedures									
Liability & Redress									
Other (specify)									

How many of the current Biosafety officers working in the National Biosafety Authority received training listed above?

How many of the current National Biosafety Board or Committee members received the training listed above?

**What evidence can you provide to show** that this project helped the national governments in setting up national information systems on biosafety, including the establishment of a national biosafety information system and linkage to BCH?

Additional questions/indicators

No of administrative decisions taken so far and how many of them uploaded in BCH

No of training materials/ publications/articles, guidance documents on Risk Assessment and Risk Management available on online webpage

How the information dissipated to relevant groups. Provide national biosafety website address

Are the rules and mechanisms for receiving feedback on LMO assessment and release in place (e.g. NGOs, Chamber of Commerce, universities etc.)

How many workshops were organized to train stakeholders on access to biosafety information?

**What evidence can you provide to show** that this project helped the national governments in promoting public information and awareness on issues related to modern biotechnology and biosafety?

Additional questions/indicators

No of events organized to create public awareness (please specify: public conferences, public debates, media broadcasts, exhibitions, etc.)

Which are the mechanisms in place to ensure public participation in NBF and decision-making process? Please discuss.

Web page information: <http://www>. Average number of hits in website/per year

**Please fill in this Co-financing table, which refers to other funding sources of the project (other than GEF funding)**

Co-Financing	Sources						Total (thousand US\$)		Total Disbursed (thousand US\$)
	IA (UNEP) own Financing (thousand US\$) (1)		Government (thousand US\$)		Other (2) (thousand US\$)		Planned	Actual	
Type	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
Grants									
Loans									
Equity investments									
In-kind support									
Other									
Totals									

(1) To be provided by UNEP

(2) This refers to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries. Please specify the source.

#### IV.C Data sources

Table 5:

*Project documents available to evaluators as of 2<sup>nd</sup> February 2012*

S. No	Reference No	Country	Document
	<a href="#">1374</a>	Bulgaria	Support for the Implementation of the National Biosafety Framework for Bulgaria
	<a href="#">2819</a>	Cambodia	Implementation of the National Biosafety Framework of Cambodia
	<a href="#">1367</a>	Cameroon	Support to the Implementation of the National Biosafety Framework for Cameroon
	<a href="#">1369</a>	China	Support to the Implementation of the National Biosafety Framework of China
	<a href="#">1370</a>	Cuba	Support to the Implementation of the National Biosafety Framework of Cuba
	<a href="#">2839</a>	Czech Republic	Support for the Implementation of the National Biosafety Framework
	2837	Estonia	Support to the Implementation of the National Biosafety Framework
	2838	Lithuania	Support to the Implementation of the National Biosafety Framework
	<a href="#">1371</a>	Kenya	Support to the Implementation of the National Biosafety Framework
	<a href="#">3043</a>	Moldova	Support to the Implementation of the National Biosafety Framework
	<a href="#">1372</a>	Namibia	Support to the Implementation of the National Biosafety Framework
	<a href="#">1373</a>	Poland	Support to the Implementation of the National Biosafety Framework
	<a href="#">3023</a>	Slovak Republic	Support to the Implementation of the National Biosafety Framework of Slovakia
	<a href="#">1366</a>	Uganda	Support for the Implementation of the Uganda National Biosafety Framework (NBF) within the context of the Cartagena protocol
	<a href="#">2997</a>	Vietnam	Implementation of the National Biosafety Framework
	ANUBIS	15 focus countries	Available project documents in the Anubis for the 15 focus countries
	GEF <a href="#">875</a>	Global	Development of National Biosafety Frameworks
	GEF <a href="#">2341</a>	Global	Development of National Biosafety Frameworks Project (Add-on)
	UNEP/CBD/BS/COP-MOP/5/INF/9 22 SEPTEMBER	Global	EXPERT REVIEW OF THE EFFECTIVENESS OF VARIOUS APPROACHES TO BIOSAFETY

2010		CAPACITY-BUILDING: IDENTIFYING BEST PRACTICES AND LESSONS LEARNED
UNEP/CBD/BS/COP-MOP/5/4	Global	STATUS OF CAPACITY-BUILDING ACTIVITIES
Projects Prepared by the UNEP-GEF Biosafety Unit As of April 2008	Global	A Comparative Analysis of Experiences and Lessons From the UNEP-GEF, Biosafety Projects December 2006 Guidance towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration
Source: CPB	Global	Cartagena protocol on Biosafety
Source: CPB	Global	Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety
UNEP/GC.23/1, K0473866 291204		Bali Strategic Plan for Technology Support and Capacity- building
UNEP	Global	Medium term strategy of UNEP 2012-13
CPB	Global	Strategic plan of CPB 2011-20
UNEP-GEF biosafety unit	Global	The global UNEP-GEF BCH Capacity building project learning from experience 2008
UNEP-GEF biosafety unit	Global	NEP-GEF Pilot Biosafety Enabling Activity Project
UNEP/Biosafety/documents	Global	Development of National Biosafety Frameworks (100 countries)
UNEP/Biosafety/documents	Global	Add-on Project for “Development of National Biosafety Frameworks Project” (20 additional countries)
UNEP	Global	UNEP-GEF studyVersion170605 NBF experiences
UNEP	Global	UNEP Technical guidelines on biotechnology

#### IV.D Logistics

The table 2 below provides an overview of the **countries** to be visited by the consultants (either as a team, or individually), the **tentative dates** of the visits and the **key persons** in charge of the overall coordination of the mission “in loco”.

As mentioned before, once the initial contact is established by the UNEP Biosafety Unit, the consultants will approach directly those key-persons (usually the NBA/ National Biosafety Authority or the NBFP / National Biosafety Focal Point, in some few cases the NPC / National Project coordinator still in charge) for the fine-tuning of the mission.

The criteria used to select the countries to be visited were the following:

To cover at least one (or two if nearby) countries in each geographical region.

To contemplate countries of both groups of implementation projects (see Section I, Introduction of this Report).

To include countries with different technical / economic background for a more comprehensive assessment of the NBF under different conditions.

In addition, the consultants and the UNEP Evaluation office deemed important that the team would make some joint country visits in order to harmonise the methodology before carrying out individual visits. The joint mission of the Lead Consultant / LC (Dr Vanga Siva Reddy) and the Supporting Consultant / SC (Mr Camillo Risoli) will take place in Kenya, Poland and Lithuania.

The following table provide the countries selected for the visits, the consultants involved, the tentative period and the name of the key-persons / country.

**Table 2: Country visits**

Consultant	Country/City	Tentative Date of beginning	Tentative Date of ending	City(s)	Person(s) to be contacted
Vanga Siva Reddy (LC) and Camillo Risoli (SC)	Kenya	30/01/2011	31/01/2012	Nairobi	Ms. Cecilia Nzua, Director, NBA
	Poland	26/02/2012	29/02/2012	Warsaw	Dr Agnieszka Dalbiak, Head of Department of Nature Conservation, NBA/NBFP
	Lithuania	29/02/2012	03/03/2012	Vilnius	Dr. Odeta Pivorienė Head of GMO division NBA/NBFP
Vanga Siva Reddy (LC)	Cambodia	21/03/2012	25/03/2012	Phnom Penh	Mr. Pisey Oum Deputy Director, Focal Point, ex-Coordinator for DNBF Project NBFP
	Vietnam	25/03/2012	29/03/2012	Hanoi	Ms. Hoang Thi Thanh Nhan National Project Coordinator NBA/NBFP



Camillo Risoli (SC)	Namibia	20/02/2012	23/02/2012	Windhoek	Ms. Dr. Martha Kandawa-Schulz NPC and NBFP
	Check Republic	06/03/2012	10/03/2012	Prague	Ms. Milena Roudna  Adviser, Environmental Risks and Ecological Damage Department, Ministry of the Environment
	Slovakia	10/03/2012	14/03/2012	Bratislava	Ing. Henrieta Čajková Department of environmental risks and biosafety

#### IV.E Distribution of responsibilities and tasks

Notwithstanding the leading responsibility of the Lead Consultant in the final report, overall responsibility on the deliverables of the mission, the two consultants agreed that both will prepare a complete report following the whole format received. The different background and the difference between the countries visited will presumably lead to different documents, that the Team Leader will merge.

As for the specific parts regarding the countries (the country summaries and the data sheets to be prepared by country), the agreed division is as following:

Lead Consultant: Bulgaria, Cambodia, China, Estonia, Moldova, Poland, Vietnam.

Supporting Consultant: Cameroon, Cuba, Czech Rep, Kenya, Lithuania, Namibia, Slovak Rep, Uganda.

L: Lead consultant

S: Support consultant

Evaluation Criteria		LC. SC
Attainment of Objectives and Planned Results	Achievement of Outputs and Activities	
	Relevance	LC. SC
	Effectiveness	
	Achievement of main objective	LC. SC
	Achievement of objectives:	
	Objective I	LC. SC
	Objective II	
	Objective III	
	Objective IV	
	Objective V	LC. SC
	Efficiency	LC. SC
	Review of Outcomes to Impacts (ROtI)	LC. SC
Sustainability and catalytic role	Socio-political sustainability	LC. SC

	Financial resources	LC. SC
	Institutional framework	LC. SC
	Environmental sustainability	LC. SC
	Catalytic Role and Replication	LC. SC
Processes affecting attainment of project results	Preparation and Readiness	LC. SC
	Implementation Approach and Adaptive Management	LC. SC
	Stakeholder Participation and Public Awareness	LC. SC
	Country Ownership and Driven-ness	LC. SC
	Financial Planning and Management	LC. SC
	UNEP and UNDP Supervision and Backstopping	LC. SC
	Monitoring and Evaluation	LC. SC
Complementarities with the UNEP Medium Term Strategy and Programme of Work	Linkage to UNEP's EAs and POW 2010-2011	LC. SC
	Alignment with the Bali Strategic Plan (BSP)	LC. SC
	South-South Cooperation	LC. SC

	Achievement of Outputs and Activities	
Objective 1	Output 1.1: Advisory support for drafting National policy on biotechnology and biosafety	LC. SC
Objective II	Output 2.1: Biosafety enacting Law	LC. SC
	Output 2.2: Development of required regulations for the implementation of law	LC. SC
	Output 2.3: Development of technical guidelines and dossiers for risk assessment	LC. SC
	Output 2.4: Setting up of National Competent Authorities	LC. SC
	Output 2.5: Development of administrative mechanisms for the implementation of NBF	LC. SC
Objective III	Output 3.1: Development of trained manpower for processing applications, risk assessment, risk monitoring and evaluation, risk analysis risk management	LC. SC
	Output 3.2: Development of trained manpower to handle transboundary movement of LMO	LC. SC
Objective IV	Output 4.1: Development and updating of National biosafety database	LC. SC
	Output 4.2: Development and maintain of National biosafety web page	LC. SC
	Output 4.3: Development and maintaining required linkages with BCH	LC. SC

Objective V	Output 5.1: Development of regular programs to improve public awareness	LC. SC
	Output 5.2: Establishment linkages with Stake holders for the preparation of NBF implementation awareness materials,(posters, booklets, media emissions, websites, newsletters, etc.)	LC. SC

#### IV.F Tentative Itinerary

Consultant	Country	From	To
S. Reddy + C. Risoli	Kenya	30/01	31/01
C. Risoli	Namibia	19/02	24/02
S. Reddy + C. Risoli	Poland	26/02	29/02
S. Reddy + C. Risoli	Lithuania	29/02	03/03
C. Risoli	Czech Rep.	06/03	10/03
C. Risoli	Slovak Rep.	10/03	14/03
S. Reddy	Cambodia	21/03	25/03
S. Reddy	Vietnam	25/03	29/03

#### IV.G Tentative Evaluation Schedule

<b>Milestones</b>	<b>Dates</b>
Start contract	18 February 2012
Field visits	19 February –28 March 2012
Zero draft evaluation report to EO	10 April 2012
Comments on zero draft by EO	17 April 2012
First draft evaluation report to EO	20 April 2012
First draft evaluation report circulated	23 April 2012
Comments received, collated and sent to consultants by EO	11 May 2012
Final report to EO	18 May 2012
End contract	30 May 2012

## ANNEX 3: MISSION'S CALENDAR OF ACTIVITIES

**TL:** Team Leader (Mr. Siva Reddy)

**SC:** Supporting Consultant (Mr. Camillo Risoli)

**1<sup>st</sup> Phase:** from 16/01/2012 to 12/02/2012 (TL + SC)

Dates	Activities (TL + SC)	Email addresses
16/01/2012 21/01/2012	Documents Review (Home based)	
21- 22/01/2012	Travel to Nairobi, Kenya	
23/01/2012 02/02/2012	Documents Review Meetings with UNEP Evaluation Office / EO (Ms. Carla De Gregorio, Evaluation Officer; Mr. Michael Carbon, Evaluation Officer; Ms. Mela Shah, Programme Assistant; Mr. Segbedzi Norgbey, Head EO). Meetings with Biosafety Unit (Ms. Lydia Eibi-Kamolleh, Fund Management Manager; Mr. Alex Owusu-Biney, Task manager Officer). Meeting with Ms. Maryam Niamir-Fuller, Director of UNEP-GEF Coord. Office Meeting with Mr. Masa Nagai (Div. of Env. Law and Conventions).  Team work for the preparation of Questionnaires and of Inception Report Drafting and discussion of the Inception Report	
30- 31/01/2012	Evaluation of the Kenya NBF Implementation Project:  Document Desk Review Meeting with Ms. Cecilia Nzau (Acting Chief of National Biosafety Authority) and NBA team Meeting with Mr. Harrison Macharia (former Nat. Project Coordinator)	Ms Cecilia Nzau <a href="mailto:nzaucecilia@yahoo.com">nzaucecilia@yahoo.com</a>
03/02/2012	Travel from Nairobi	
04/02/2012 12/02/2012	Drafting and finalisation of Inception Report (home based)	

**2<sup>nd</sup> Phase: Field Visits** from 19/02/2012 to 25/03/2012 and **Final Report Drafting**

Dates	Activities SC	Email addresses
19/02/2012 24/02/2012	<u>Mission to Namibia</u>	Ms Martha Kandawa-Schulz

	<p>19/02 Travel to Windhoek</p> <p>20/02 Arrival to Windhoek, Meeting with Ms Martha Kandawa-Schulz (NPC, University of Namibia), documents analysis.</p> <p>21/02 Meeting with Mr. Alfred A. van Kent (Director, Min. of Education), Mr, Elmo Thomas (Deputy Director, Min. of Education)</p> <p>21/02 Meeting with Ms Martha Kandawa-Schulz (NPC, University of Namibia), documents analysis.</p> <p>22/02 Visit to the Central Veterinary Laboratory, Meeting with Ms Rosa. S. Mbulu (Head Biotechnology) and Ms Georgina Tjipura-Zaire (Head Serology)</p> <p>22/02 Meeting with Mr. Sem T. Shikongo (Director Tourism, Min. of Environment &amp; Tourism)</p> <p>23/02 Meeting with Hon. Deputy Minister of Education, Mr. David R. Namwandi</p> <p>23/02 meeting with Ms. Jaqueline Scholz (Lawyer, Director of Millennium Ltd.)</p> <p>23/02 Final Meeting with Ms. Martha Kandawa-Schulz (NPC)</p> <p>23/02 Departure from Windhoek</p>	<p><a href="mailto:kschulz@unam.na">kschulz@unam.na</a></p>
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Dates	Activities TL + SC	Email addresses
<p>26/02/2012</p> <p>03/03/2012</p>	<p><u>Mission to Poland and Lithuania</u></p> <p><u>Poland</u></p> <p>26/02 Travel to Warsaw</p> <p>27/02 Meeting at the Ministry of Environment with Ms. Agnieszka Dalbiak (Director of Dept. of Nature Conservation), Ms. Joanna Rybak (GMO Team, BCH Focal Point), Mr. Michal Gizinski (GMO Team, NBFP). Team work with LC</p> <p>28/02 Visit to the Plant Breeding and Acclim. Institute / nat. Research Institute (former NEA) at Radzikow, and meeting with: Mr. Janusz Zimny (Head of Biotechnology and Cytogenetics), M. Slawomir Sowa (GMO laboratory Head), Ms. Barbara Janik-Janiec (GMO Lab. Quality Manager)</p> <p>29/02 Team Meeting with LC / Departure to Vilnius</p> <p><u>Lithuania</u></p> <p>01/03 Meeting at the Ministry of the Environment with Ms Odeta Pivoriené (NBFP), Mr Gintaras Jodinskas (NPC), Mr Justinas Janulevicius (BCH),</p> <p>01/03 Meeting with Min. of Agriculture (Ms. Natalija Guseva, member of the National Biosafety Committee), team meeting with LC</p> <p>02/03 Visit to the National Food and Veterinary Risk Assessment Institute, meeting with Mr Vaclovas Jurgelevicius (Head of Molecular Biology and GMO Section) and his team</p> <p>02/03 Meeting with Ms Lilija Kalediené (Vilnius University, GMO Expert), meeting with Ms Zivile Kazakeviciené (State Consumer Rights Protection Authority)</p>	<p>Poland: Ms Agnieszka Dalbiak <a href="mailto:agnieszka.dalbiak@mos.gov.pl">agnieszka.dalbiak@mos.gov.pl</a></p> <p>Lithuania: Ms Odeta Pivoriene <a href="mailto:o.pivoriene@am.lt">o.pivoriene@am.lt</a></p>

	02/03 Final meeting at the Ministry of the Environment with Ms Odeta Pivoriené (NBFP) and Mr Gintaras Jodinskas (NPC). 03/03 Team work with LC and departure from Vilnius	
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Dates	Activities TL	Email addresses
07/03/2012 10/03/2012	<p><u>Mission to Vietnam</u></p> <p>07/03/12 Travel to Hanoi</p> <p>07/03 Meeting at the Biodiversity Conservation Agency, Ministry of Natural Resources and Environment with Ms. Hoang Thi Thanh Nhan – Deputy Director of Biodiversity Conservation Agency and National Coordinator of Vietnam NBF Project, Ms. Ta Thi Kieu Anh – Officer of Biodiversity Conservation Agency and Administrative Officer of Vietnam NBF Project.</p> <p>08/03/ visit to Agriculture Genetics Institute, Hanoi and meeting with Prof. Dr. Le Huy Huyham, Director General, Dr. Xuan <b>Hoi</b> Pham, Scientist, Visited the laboratories involved in the LMO field trials.</p> <p>09/03 Meeting at the Biodiversity Conservation Agency, Ministry of Natural Resources and Environment with Ms. Hoang Thi Thanh Nhan, Ms. Ta Thi Kieu Anh, Dr. Nguyen Thi Thanh Thuy, Deputy Director, Department of Science, Technology and Environment, Ministry of Agriculture and Rural Development, Hanoi, Vietnam</p> <p>10/03 Departure to New Delhi</p>	<p>Vietnam:</p> <p>Ms. TaThiKieu Anh, <a href="mailto:takieuanh@gmail.com">takieuanh@gmail.com</a></p> <p>Ms. Hoang Thi Thanh Nhan, <a href="mailto:hnhan@vea.gov.vn">hnhan@vea.gov.vn</a>, <a href="mailto:(hoangnhan1973@gmail.com)">(hoangnhan1973@gmail.com)</a></p>

Dates	Activities SC	Email addresses
18/03/2012 23/03/2012	<p><u>Mission to Czech Republic and Slovakia</u></p> <p><u>Czech Republic</u></p> <p>18/03: Travel to Prague</p> <p>19/03 : Meeting at the Ministry of Environment with Ms Zuzana Doubková, (Head of Genetically Modified Organisms Unit), Ms Hana Jiráková (CPB NFP, BCH NFP), Ms Milena Roudná (NPC), Ms Zuzana Stratilová (Ministry of Agriculture), Mr Martin Těhník (Czech Environmental Inspectorate), Mr Oldřich Navrátil (Representative of users, Institute of Experimental Botany, Academy of Sciences of the Czech Republic)</p> <p>19/03 Visit to the Reference Laboratory, Crop Research Institute, Prague – Ruzyneň, meeting with Ms Jaroslava Ovesná, Head of Laboratory</p> <p>19/03 Meeting at the Scientific-Technical Society, Prague – Czech Society for Environmental Care, with Mr Jan Mikoláš, independent consultant (former Deputy Minister of the Federal Ministry of the Environment, former Czechoslovakia), Ms Vlasta Mikulová (Czech Agricultural University), Ms Libuše Deylová (Secretary of the Society), Mr Petr Deyl (university student)</p> <p>20/03 Field trip – Eastern Bohemia. Visit to the Regional Museum, Jičín – meeting with Ms Petra Zíková (NGO representative – Czech Union for Nature Conservation), visit to the Centre for Environmental Education and Ethics</p>	<p>Czech Republic:</p> <p>Zuzana Doubkova (Director NCA), <a href="mailto:zuzana.doubkova@mzp.cz">zuzana.doubkova@mzp.cz</a></p> <p>Hana Jirakova (NBFP), <a href="mailto:hana.jirakova@mzp.cz">hana.jirakova@mzp.cz</a></p> <p>Ms Milena Roudna (Assessor), <a href="mailto:milena.roudna@mzp.cz">milena.roudna@mzp.cz</a></p>



	<p>(SEVER), Giant Mountains/Krkonose, community Horní Maršov, meeting with Ms. Milada Dobiášová (training coordinator) 21/03 Return to Prague, departure to Bratislava (train)</p> <p><u>Slovakia</u></p> <p>22/03: Meeting at the Ministry of Environment with Ms. Tatiana Tobiasova (represent the Head of the Department of Environmental risks and Biosafety), Ms. Natalia Mogelska (Focal Point for the Cartagena Protocol on Biosafety and the BCH), Mr. Igor Ferencik (former Director of Biosafety Dept. of the Min. of Env.), Mr. Martin Chovan (Slovak Hydrometeorological Institute, IT expert responsible for national BCH-page), Mr. Peter Siekel (member of the Commission for Biosafety, representative of Association for the Branded Food Products). 22/03: Visit of laboratory at Institute of Molecular Biology of Slovak Academy of Sciences (Mr. Pangallo). 23/03: visit of the National Reference Laboratory for GMOs at the Central Control and Testing Institute of Agriculture, meeting with Mr. Lubomir Horvath (Head of Department of Molecular Biology). 23/03: Final meeting with Ms. Natalia Mogelska. Departure from Bratislava.</p>	<p>Slovakia: Ms Natalia Mogelska <a href="mailto:natalia.mogelska@enviro.gov.sk">natalia.mogelska@enviro.gov.sk</a></p>
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Dates	Activities TL	Email addresses
<p>21/03/2012</p> <p>25/03/2012</p>	<p><u>Mission to Cambodia</u></p> <p>21/3 Meeting at Ministry of Environment with Mr. Pisey Oum, Mr. Pisey Oum and former NPC, Mr. Ke Vongwathana, Deputy Secretary of NSCB (National Steering Committee for Biosafety), Phnom Penh, Mr. Mun Duong Ratanak, BCH, Focal point, MOE. 22/03 Meeting with Mr. Ke Vongwathana, Deputy Secretary of NSCB (National Steering Committee for Biosafety), Phnom Penh, Mr. Mun Duong Ratanak, BCH, Focal point, MOE, Mr. Sith, Local Policy expert on Biosafety and Biotechnology (who assisted Cambodia with the preparation of Biosafety Law), Phnom Penh, Cambodia, Dr. Yi Bunhak, Chief of Agro-Industrial Development Office, Phnom Penh. Ms. Kim Neng, Deputy Director of Planning and Legal Affairs Department, MOE, Phnom Penh, Cambodia 23/03 Visit to LMO detection laboratory, MOE and meeting with Mr. Borath Oum, Dr. Yin Kim Sean, Secretary of state, MOE, Phnom Penh 24/03, Final meeting with Mr. Ke Vongwathana, Deputy Secretary of NSCB. 25/03 Return to New Delhi.</p>	<p>Mr.PiseyOum, <a href="mailto:cambio_coor@online.com.kh">cambio_coor@online.com.kh</a>; <a href="mailto:piseyoum@hotmail.com">piseyoum@hotmail.com</a></p>

Dates	Activities TL + SC	Email addresses
23/03/2012	Preparation and submission of Zero Draft Report	
25/04/2012	Revision of Draft Report after EO comments	
	Preparation and submission of Draft Evaluation Report	

## Additional personnel to send the final report to:

**BULGARIA:** Dr. Galya Tonkova, [gtonkova@moew.government.bg](mailto:gtonkova@moew.government.bg)

**CAMEROON:** Ms Prudence Galega, [galegapru@yahoo.com](mailto:galegapru@yahoo.com)

**CHINA:** Mr. Zhu Guangqing, [zhu.guangqing@sepa.gov.cn](mailto:zhu.guangqing@sepa.gov.cn)

**CUBA:** Mr. Juan Carlos Menendez De San Pedro Lopez, [jc@orasen.co.cu](mailto:jc@orasen.co.cu); [lenia@orasen.co.cu](mailto:lenia@orasen.co.cu)

**ESTONIA:** Ms Tuuli Levandi (NBFP) [tuuli.levandi@envir.ee](mailto:tuuli.levandi@envir.ee); Liina Eek (assessor), [liina.eek@envir.ee](mailto:liina.eek@envir.ee)

**MOLDOVA:** Ms Angela Lozan, [angelalozan@yahoo.com](mailto:angelalozan@yahoo.com)

**UGANDA:** Dr. Peter Ndemere, [uncst@starcom.co.ug](mailto:uncst@starcom.co.ug), [pndemere@uncst.go.ug](mailto:pndemere@uncst.go.ug)

## Annex 4

## QUESTIONNAIRE for the National Competent Authority

**Country Name:**

**Full name and function (title) of the persons that contributed to answer the questions:**

1)

2)

3)

Etc.

**Full name and function (title) of the person collecting, compiling and revising the final questionnaire:  
email address of this person (to be contacted in case of clarifications to be given on the answers):**

**Date of compilation:**

### Introductory Notes

In the framework of the Terminal Evaluation of 15 projects from the UNEP-GEF Biosafety portfolio, please find attached a questionnaire elaborated by the consultants in charge of the evaluation mission.

You are kindly requested to fill the questionnaire and return them directly to both the consultants with copy to Alex.Owusu-Biney@unep.org:

[vsreddy@gmail.com](mailto:vsreddy@gmail.com)

[risolicamillo@hotmail.com](mailto:risolicamillo@hotmail.com)

You may have to consult other colleagues, stakeholders and / or ancient NPCs and collect their contributions in order to fill in all the answers in the questionnaire. All the persons involved in answering should be listed above. In addition, one person with final responsibility for collecting/compiling the answers should also be given.

The questionnaire should be sent back to the consultants as soon as possible, and in any case no later than Friday 18<sup>th</sup> of February 2012.

In addition, The consultants will visit a number of countries (either in a team or separately), most likely between mid-February and mid-March 2012. Those countries should return the questionnaire before the visit takes place (therefore as soon as possible) so that the mission can already discuss the content of the answers with you. The calendar of the field visits will be shared with you as soon as possible.

The countries that have been selected for the field visit are: Cambodia, Czech Rep., Kenya (already done during the briefing in Nairobi), Lithuania, Namibia, Poland, Slovak Rep., Vietnam.

### Evaluation questions

**What evidence can you provide**, if any, which shows that this project has helped the national government in formulating a national policy on biotechnology and biosafety taking into account the implementation of Cartagena Protocol on Biosafety?

#### Additional questions/indicators

Except the Biosafety Law (Act) is Biosafety taken into account in any other national policy, such as national Environmental Policy, Food Security / Food Safety Policy, Development policies ? Please, specify where and how.

**Do you have evidence to show** that this project helped the national government in developing and implementing a biosafety regulatory and administrative regime: law(-s), enabling regulations, technical guidelines ? Please specify

#### Additional questions/indicators

Since when is a National Biosafety legislation in place?

Does the country have administrative rules and procedures in place for handling notifications and requests for: approval of LMOs import as food/feed?

LMOs in-country processing?

LMOs to test Contained Use?

LMOs to test Confined Field Trial?

LMOs release for commercial purpose?

Please specify for any of the items outlined above, the Number of decisions taken so far by the National Competent Authority and the Number of decisions taken in the year 2010-11.

**What evidence can you provide to show** that this project helped the national governments in building capacity and human skills in the areas of risk assessment, risk management, LMOs identification, monitoring and enforcement and what materials you have to support the capacity building activities?

#### Additional questions/indicators

Please, fill in the following table, specify the Number of people trained, the years they were trained (ex. 2003-2005), the average duration of the training period, the kind of institutions that represented participants. PLEASE note that conferences, panels and public meetings do NOT enter this category .

Area of Training	Total Nb of trained people	Period of training (years)	Average duration of training (days)	Institutions to which the trainees belong					
				Ministries and other public inst.	University & Research	Parliament members	NGOs	Associations (Consumers, farmers, etc.)	Media
Risk assessment									
Risk Management									
Risk Monitoring									
Laboratory training									
Legal aspects									
Administrative									
Customs procedures									
Liability & Redressal									
Other (specify)									

How many of the current Biosafety officers working in the National Biosafety Authority received training listed above?

How many of the current National Biosafety Board or Committee members received the training listed above?

**What evidence can you provide to show** that this project helped the national governments in setting up national information systems on biosafety, including the establishment of a national biosafety information system and linkage to BCH?

Additional questions/indicators

No of administrative decisions taken so far and how many of them uploaded in BCH

No of training materials/ publications/articles, guidance documents on Risk Assessment and Risk Management available on online webpage

How the information dissipated to relevant groups. Provide national biosafety website address

Are the rules and mechanisms for receiving feed back on LMO assessment and release in place (e.g. NGOs, Chamber of Commerce, universities etc.)

How many workshops were organized to train stakeholders on access to biosafety information?

**What evidence can you provide to show** that this project helped the national governments in promoting public information and awareness on issues related to modern biotechnology and biosafety?

Additional questions/indicators

No of events organized to create public awareness (please specify: public conferences, public debates, media broadcasts, exhibitions, etc.)

Which are the mechanisms in place to ensure public participation in NBF and decision-making process? Please discuss.

Web page information: <http://www>. Average number of hits in website/per year

Please fill in this **Co-financing table**, which refers to other funding sources of the project (other than GEF funding)

Co-Financing	Sources						Total (thousand US\$)		Total Disbursed (thousand US\$)
	IA (UNEP) own Financing (thousand US\$) (1)		Government (thousand US\$)		Other (2) (thousand US\$)		Planned	Actual	
Type	Planned	Actual	Planned	Actual	Planned	Actual			Planned
Grants									
Loans									
Equity investments									
In-kind support									
Other									
<b>Totals</b>									

(1) To be provided by UNEP

(2) This refers to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries. Please specify the source.

## Annex 5 Number of beneficiaries of capacity building activities undertaken under UNEP-GEF funded project in different countries

Country	Risk Assessment	Risk management	Risk monitoring	Laboratory training	Legal aspects	Administrative	Customs procedures	Liability and redressal	Others	TOTAL
Bulgaria										NA
Cambodia	150	150	150	15	360	360	150	-	100 <sup>31</sup>	1.435
Cameroon	-	-	-	-	1	-	-	-		1
China										NA
Cuba	133	133	133	-	110	110	-	-	193	812
Czech Rep.	20	20	20	15	40	37	-	23	12 <sup>32</sup>	187
Estonia	19	40	-	20	17	84	71	-	193 <sup>33</sup>	444
Kenya	1	1	-	-	-	-	2	1		5
Lithuania	60	60	60	60	10	50	-	-		300
Moldova	35	35	60	15	125	30	30	-	110 <sup>34</sup>	440
Namibia	47	-	50	2	2	30	-	-	68 <sup>35</sup>	199
Poland	72	-	-	32	5959	6018	5976	-		18.057
Slovakia	-	120	-	-	18	18	-	-	23 <sup>36</sup>	179
Uganda	-	-	-	-	-	-	-	-	2 <sup>37</sup>	2
Vietnam	479	211	-	200	70	-	-	100		1.060
<b>TOTAL</b>										<b>23.121</b>

<sup>31</sup> Emergency response

<sup>32</sup> Environmental inspection

<sup>33</sup> Info days (130) and GMO analysis (63)

<sup>34</sup> Public awareness and participation (70) and Labeling, packaging and transportation (40)

<sup>35</sup> Awareness (50+) and BCH (18)

<sup>36</sup> Inspection

<sup>37</sup> Environmental Biosafety

**Annex 6. Decisions taken so far and the number of records made available in the central BCH as on 20/02/2012**

Country	Biosafety Expert	Capacity building needs and priorities	Competent National Authority	Country Decision or any type of Communication	Law, Regulation or Guidance	National Data Base or website	National Focal point	Report on assignment	Risk Assessment	Reports on Implementation of the Protocol	Total number of records posted in BCH
Bulgaria	0	0	4	2	6	0	2	0	0	2	<b>16</b>
Cambodia	0	0	2	0	3	1	4	1	0	2	<b>13</b>
Cameroon	0	0	1	0	2	0	2	0	0	2	<b>7</b>
China	0	0	3	23	43	1	2	0	0	2	<b>74</b>
Cuba	0	0	2	0	11	0	2	0	0	2	<b>17</b>
Czech Republic	2	0	5	0	3	1	1	0	11	2	<b>25</b>
Estonia	0	0	4	0	5	1	1	0	0	2	<b>13</b>
Kenya	1	1	9	1	4	1	2	0	1	2	<b>22</b>
Lithuania	3	0	1	0	13	1	2	0	0	2	<b>22</b>
Moldova	1	1	2	0	6	2	3	0	0	2	<b>20</b>
Namibia	0	0	1	0	1	1	2	0	0	1	<b>6</b>
Poland	1	1	3	0	1	1	3	0	0	2	<b>12</b>
Slovakia	0	0	3	0	7	1	1	0	0	2	<b>14</b>
Uganda	5	0	1	0	0	0	1	0	0	2	<b>9</b>
Vietnam	0	0	5	3	4	0	2	0	1	2	<b>17</b>



## ANNEX 7 COUNTRIES FACT SHEETS ON BIOSAFETY

### FACT SHEET on National Biosafety

### BULGARIA

#### Milestones in GMOs Policy and Legislation

**1996** The Government of Bulgaria undertakes a first step towards the establishing of legislation on LMO by introducing a Regulation for Safe Use of Genetically Modified Higher Plant.

**1998** Under the terms of the above Regulation, an interdepartmental Council for Biosafety of Genetically Modified Higher Plants is established.

**2000** Bulgaria ratifies the Cartagena Biosafety Protocol

**2000** A special Taskforce is set up to prepare the draft of the Living Modified Organisms Act

**2005** the Bulgarian Parliament adopts the Genetically Modified Organisms Act, which enters into force. Two specific Regulations are also approved.

**2007** Bulgaria becomes a member state of the EU and adopts EU directives, regulations, decisions and recommendations on GMOs

#### Milestones in NBF implementation

**1998 / 99** The National Biosafety Framework (NBF) for Bulgaria is prepared through the support of UNEP-GEF Pilot Biosafety Enabling Activity project.

**2002/06** the NBF is implemented with the joint support of UNEP-GEF Implementation Project. A number of training activities for national stakeholders are carried out, technical manuals are prepared and discussed, a national laboratory is strengthened, a BCH is established, a Bulgarian Biotechnology Information Center (BIC), is also established and a national website is launched.

#### National Competent Authority

The Ministry of Environment and Water (MoEW) is the National Competent Authority for Biosafety issues related to the application of the Protocol. The Minister of Agriculture and Forestry (MAF) is the NCA for authorizing placing LMOs or products containing LMOs in the market. The Ministry of Health has administrative functions for the direct use of LMOs as feed, food or for processing.

#### Main National Stakeholders

The Ministry of Environment and Waters (MoEW) formulates GMO state policy together with the MAF and is responsible for control of contained use and deliberate release of GMOs into the environment.

The Ministry of Agriculture and Forestry (MAF) is responsible for the implementation and enforcement of the GMO Act concerning placing on the market of GMOs as or in products that are not intended for direct use as food. The MAF is also responsible for the law enforcement and control on the import and export of GMOs (transboundary movement).

The Ministry of Health is responsible for control on the presence of GMOs in food ingredients according to the Bulgarian Food Stuffs Act.

#### Main country's achievements in NBF implementation

A Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2005) and a number of EC Directives, Regulations and Decisions adopted.

A national system coordinated by the National Competent Authority (Ministry of Environment, MoE) which shares responsibilities with other two Ministries (Agriculture and Health).

A National Reference Laboratory accredited and a National Biosafety Focal Point (NBFP) in the MoEW.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoEW. The BCH currently contains 48 records of EU's decisions / approvals and 29 regulatory / administrative documents.  
Regular Reports on the implementation of CPB submitted: 1st (2007) YES 2nd (2011) YES

**Milestones in GMOs Policy and Legislation**

**2003** Cambodia access the Cartagena Protocol on Biosafety (not ratified)  
**2008** Cambodia approves the Law on Genetically Modified Organisms  
**2010** Cambodia approves the Sub-decree on Mechanism and Procedures for Implementing the Law on Biosafety.  
**2011** The national Action Plan on Biosafety and Modern Biotechnology is conceived

**Milestones in NBF implementation**

**2004** The UNEP-GEF National Biosafety Framework (NBF) Development project is completed. The NBF is set and published  
**2005** The National Biosafety Clearing House (BCH) is implemented  
**2006** The UNEP/GEF project for the implementation of its NBF is implemented and policy and regulatory framework for biosafety management are gradually set  
**2007-2010** several awareness seminars/workshops are conducted in Cambodia, in preparation of the National law and for its implementation. Cambodia also hosts and participated to the regional workshop organized by ASEAN Centre for Biodiversity (ACB) on Risk Assessment and Management in 2008.

**National Competent Authority**

The national Law on Genetically Modified Organisms identifies the Ministry of Environment and Ministry of Agriculture, Forestry at the National Competent Authority (NCA).

**Main National Stakeholders**

Besides the Ministry of Environment, other national authorities are sharing responsibilities on the use of GMOs in Cambodia: the Ministry of Health (MOH), the Ministry of Agriculture, Forestry and Fishery (MOAFF), the Ministry of Commerce (MOC), the Ministry of Industry, Mine and Energy (MOIME), the Ministry of Education, Youth and Sport, The Royal Academy, Universities and relevant laboratories.

**Main country's achievements in NBF implementation**

A National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2008) and a sub-decree on mechanisms and procedures for implementing the Law on Biosafety (2010)

A national biosafety system coordinated by the National Competent Authority (Ministry of Environment, MOE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing.

A dedicated Laboratory for the LMOs detection within the MOE (established under UNEP-GEF project.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MOE currently with no record of decisions.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES                      2nd (2011) YES

**Milestones in GMOs Policy and Legislation**

- 2001 Cameroon ratifies the Cartagena Protocol on Biosafety
- 2003 The “Law laying down safety regulations governing modern biotechnology in Cameroon” is adopted
- 2007 The Decree “Regulating Safety in Modern Biotechnology in Cameroon” is approved by the Government

**Milestones in NBF implementation**

- 1999 Cameroon benefits from funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project.
- 2002 Start-up of the NBF Implementation Project
- 2002 /2006 Several training workshops in different areas, such as Preparation of the National Law, Handling requests for permits, Identification, Inspection, and Monitoring of Living Modified Organisms (LMOs), workshop for Custom officials and other safety Inspectors/controllers. Training manuals and guidelines are produced. Two referral laboratories (the Biotechnology Unit of the University of Buea and the laboratory of the Yaounde Biotechnology Centre) are reinforced with equipment for LMO detection. The administrative body (a Biosafety Office within the Ministry of Environment and Nature Protection) and the National Biosafety Committee (NABIC) are in place.

**National Competent Authority**

The Ministry of Environment and Nature Protection is the NCA for Biosafety.

**Main National Stakeholders**

**Main country’s achievements in NBF implementation**

- A National Law (2003) and Regulations (2007) on Biotechnology promulgated.
- A National Competent Authority established
- A Biosafety Clearing House (BCH) with a National BCH Focal Point in the NCA (0 records so far).
- Regular Reports on the implementation of CPB submitted: 1st (2007) YES                      2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**2001** The State Council issues the Regulations on Safety of Agricultural Genetically Modified Organisms

**2002** The Ministry of Agriculture issues the Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms, the Implementation Regulations on the Safety of Import of Agricultural Genetically Modified Organisms, and the Implementation Regulations on Labelling of Agricultural Genetically Modified Organisms,

**2004** The General Administration of Quality Supervision, Inspection and Quarantine issues the Regulation on Inspection and Quarantine of Import and Export Genetically Modified Commodities

**2005** The Chinese Government approves the Cartagena Protocol (not ratified)

**2006** The Ministry of Agriculture issues the Regulation on Approval of Processing of Agricultural Genetically Modified Organisms

**2007/2011** Orders and Notices on biosafety have been promulgated since 2007:

### Milestones in NBF implementation

**2002/2008** In the framework of the UNEP-GEP Implementation Project, China has developed regulations and management systems, including trans-boundary movement, risk assessment and management, liability and redress, labelling, and public participation.

Methodologies for risk assessment and risk management have also been developed. A certified National Key Laboratory on Biosafety has been established and equipped. A number of technical guidelines have been produced to develop specific indicators for monitoring. A national research program on biosafety has been set up. Various workshops, training courses and dissemination activities have been implemented.

Relevant departments at national level, as well as provincial departments of agriculture and environmental protection in provinces where the GMOs are released, have annual budget for the management, research, supervision, assessment and public education on biosafety.

### National Competent Authority

The National Biosafety Administration Office of Ministry of Environmental Protection (MEP) with four permanent staff, serves as the national focal point for the Protocol and BCH and coordinates domestic environmental management related to biotechnology.

The Biosafety Office of Agricultural GMOs of Min. of Agriculture (MOA), with four permanent staff, is responsible for the safety management on the research, testing, production, processing, marketing and import/export of agricultural GMOs.

### Main National Stakeholders

The Department for Supervision on Animal & Plant Quarantine (AQSIQ), with ten permanent staff, is responsible for national-level management of inspection and quarantine of import and export of GMOs and products thereof, as well as inspection, detection and monitoring of these GMOs. Local branches of AQSIQ in provinces are in charge of inspection, quarantine and supervision on imported/exported GMOs under their respective jurisdictions.

The State Forestry Administration has set up a Forestry Biosafety Office, with four permanent staff, which is responsible for the safety management of genetically modified trees or forests, such as research, testing,

production, processing, marketing and import/export etc. A Safety Committee for Forestry Genetic Engineering has also been set up, which is responsible for the safety assessment of genetically modified trees or forests.

The General Administration of Customs is the national authority for supervision of import and export activities. GAC inspects and verifies the goods containing transgenic components, as well as the Commodity Inspection Certificates issued by AQSIQ and other certificates issued by relevant competent authorities, and handles customs clearance.

### **Main country's achievements in NBF implementation**

A national policy and strategy, a robust Regulatory Regime for the use of GMOs and GMOs products, including national Regulations, Orders and Notices.

A functional national system coordinated by the National Competent Authority (Ministry of Environmental Protection, MEP) in tight coordination with the Ministry of Agriculture, with a set of administrative and monitoring mechanisms and many technical guidelines for handling requests, risk assessment and management, administrative processing, a National Biosafety Focal Point (NBFP) in the MEP.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MEP. The BCH currently contains 43 records of Country's decisions / approvals and 23 records of regulatory documents (mainly for maize and rapeseed processing)

A large number of (more than 100) transgenic plants with insect-resistant, anti-virus and quality-improvement traits are being developed in China. Many of these transgenic crops, such as cotton, bean, potato, tobacco, maize, peanut, spinach, pimiento and wheat, have been put into field trials. Six transgenic crops, such as insect-resistant cotton and anti-virus tomato, have been commercialized.

An extremely rich national website in Chinese and English

Regular Reports on the implementation of CPB submitted: 1st (2007) YES 2nd (2011) YES

### Milestones in GMOs Policy and Legislation

- 1996** the Ministry of Science, Technology, and Environment creates the National Centre for Biological Safety in order to organise, conduct, perform, supervise, and control the National System of Biological Safety. The National Centre for Biological Safety acts as the Regulatory Body in the matter of biological safety.
- 1999** Cuba approves the Decree N.190 on Biological Safety
- 2003** Cuba ratifies the Cartagena Protocol on Biosafety
- 2000-2004** Four resolutions are promulgated to enact the Law of 1999

### Milestones in NBF implementation

- 1998/1999** Cuba executes the UNEP/GEF Pilot Project on Biosafety structuring the National System for Biological Safety and identifying its legislative framework. The Decree and its regulations are drafted. A training program at different levels is prepared. The foundations of the National Biosafety Framework are set.
- 2002/2007** Cuba executes the UNEP / GEF for the Implementation of the NBF. The Technical Committee on Biological Safety Standardization is created. The Action Plan on Biosafety is adopted and inserted in the Action Plan for Biodiversity becoming both a solid document called the National Environmental Strategy. The “Genetically Modified Organisms: Guidelines for risk assessment and management that includes monitoring procedures” are produced. The National Centre for Biological Safety is equipped for training activities. A set of Training / Educational material is produced. A web page is opened.

### National Competent Authority

The National Centre for Biological Safety (of the Ministry of Science, Technology and Environment) is the National Competent Authority.

### Main National Stakeholders

The Ministry of Agriculture, of Health, of Trade, of Transports and the National Customs Office.

### Main country's achievements in NBF implementation

A National Law (1999) and a set of Regulations on the safe transfer, handling and use of GMOs promulgated.

A National Competent Authority established since 1996 (the National Centre for Biological Safety of the Ministry of Science, Technology and Environment) which is also the National Focal Point.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the NCA, with the record of all the national legislation (11 documents). According to the National Report of 2011 to the Protocol Secretariat, Cuba is conducting a Field Trial on GMO Maize (not reported in the BCH).

A set of technical guidelines and manuals, training materials and educational tools prepared and divulgated.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES          2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**1993** the Czech Republic ratifies the CBD

**2001** the Act 153/2000 on the Use of Genetically Modified Organisms and Products enters into force

**2003** the Czech Republic ratifies the Cartagena PB

**2004** a new Act (78/2004) on the use of genetically modified organisms and genetic products, and its implementing Decree, is promulgated incorporating provisions of the corresponding EU Directives 2001/18/EC and 98/81/EC, and provisions of the Cartagena Protocol not implemented by Act 153/2000. A further Amendment reflecting the EC regulations No. 1830/2003 and 1946/2003 is also approved in 2004. This Amendment designates the competent authority (Ministry of the Environment).

**2004** the National Sustainable Development Strategy is adopted and includes, among its pillars, principles of elimination of risk factors to ensure safe management of GMOs.

**2004** the Czech Republic ratifies the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

### Milestones in NBF implementation

**2002/2004** the Czech Republic participates in the UNEP/GEF Project “Development of the National Biosafety Framework”.

**2003** the Czech Republic actively participates in regional co-operation activities within the region of Central and Eastern European countries:

Sub-regional meeting in Prague with representatives of the UNEP Biosafety Unit, European Commission, Slovak Republic, Hungary, Croatia, Slovenia and the Czech Republic;

Sub-regional workshops for Central and Eastern European (CEE) countries on Developing a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBF);

Sub-regional workshop for the countries of Central and Eastern Europe, the Caucasus and Central Asia (CEECCA) on Risk Assessment and Management, and Public Awareness and Participation .

**2004** the National Biosafety Framework is drafted, the Biosafety Clearing-House (BCH-CZ) is established and the Department of Environmental Risks at the Ministry of the Environment of the Czech Republic serves as National Focal Point of BCH.

**2006** two new UNEP/GEF projects start: the “Support for the Implementation of the Draft National Biosafety Framework for the Czech Republic“ (2006-2010) and the “Building Capacity for Effective Participation in the Biosafety Clearing-House“ (2006 – 2008).

**2006** Joint Inception Workshop of the Czech Republic and Slovak Republic for the inception of the two UNEP/GEF projects above.

**2008 /** Intense education, training and awareness activity. Annual workshops for teachers, experts and students and a final Workshop on BCH.

**/2010** Several public information and awareness initiatives concerning environmental treaties, CBD, CPB, Millennium Dev. Goals (MDG). Educational activities in schools for teachers, educators and children. Training workshops for forestry experts. A number of workshop for experts on Precautionary principle, Liability and redress, Risk of genetic erosion and biodiversity conservation. Public workshops on Food Safety. Final workshop of BCH project Final Workshops of UNEP/GEF Project (for experts and public).

### National Competent Authority

The National Competent Authority (NCA) handling the notifications and regulating the use of GMOs in the Czech Republic under EC Directives and Regulations is the Ministry of the Environment , which is also the focal point for the Cartagena Protocol on Biosafety.



## **Main National Stakeholders**

The Ministry of the Environment cooperates closely with the Ministry of Agriculture (Competent Authority under EC Regulation 1829/2003 on genetically modified food and feed and for setting the rules of coexistence) and with the Ministry of Health as regards risks for human health. Three national laboratories are accredited as control laboratories and participate in the European Network of GMO Laboratories (ENGL). A number of training and awareness activities are carried out in cooperation with Czech Universities and Research Centres, as well as Environmental and Educational Associations.

## **Main country's achievements in NBF implementation**

A national policy and strategy, a Regulatory Regime for the use of GMOs and GMOs products, including a new National Law (2004), a number of EC Directives, Regulations and Decisions, National Biosafety Framework and technical guidelines.

A functional national system coordinated by the National Competent Authority (Ministry of Environment, MoE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing, three National Reference Laboratories equipped and EU accredited, a National Biosafety Focal Point (NBFP) in the MoE.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoE. The BCH currently (April 2012) contains 48 records of EU decisions, 25 legal / administrative documents (law, regulations, decrees, etc.) and 11 Country's Risk Assessment for Field Trials (Maize, sugar beet, potato, pea) for a total of 22,9 Ha. Maize MON 810 is cultivated in Czech Republic in 4.680 Ha (2010) by 82 farmers.

A national website exemplarily rich in information, clear and user-friendly (in Czech and English). Many technical reports, workshops proceedings and links to national, European and international sites are available. It also contains graphics and statistics related to GMO use in the country and the map of Confined Field Trials (CFT) in Czech Republic.

An intensive, proactive role in promoting awareness and public information, knowledge, education and public debate on GMO issues.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES

2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**1999** The Estonian Act on Deliberate Release into the Environment of Genetically Modified Organisms comes into force

**2001** Estonia ratifies the UNECE Aarhus Convention (on Access to Information, Public Participation in Decision making and Access to Justice in Environmental Matters) and a national Act on access to information – the Public Information Act - also comes to force.

**2002** The Act on Contained Use of Genetically Modified Microorganisms (01.08.2002) is approved

**2004** Estonia ratifies the Cartagena Protocol on Biosafety

**2004** Estonia adopts a new Act replacing the first Law of 1999 on GMOs.

**2004** Estonia becomes a member state of the EU and since then has adopted all the EU Directives, Regulations and Decisions on GMOs through national regulations.

### Milestones in NBF implementation

**1999** the Advisory Committee for Genetic Modification is established at the Ministry of the Environment as an advisory body for the government in giving licenses for handling LMO matters.

**2003** Estonia participates in the UNEP-GEF Development of NBF Project during 2001 – 2003 and establishes an initial draft framework

### National Competent Authority

As a requirement of CPB, Estonia has nominated the Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs as Competent Authorities, according to the following divisions of tasks: 1) Ministry of the Environment is responsible for issuance of permits for deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs; 2). Ministry of Agriculture is responsible for issuance of permits for handling and marketing of novel food (including genetically modified food), permits of use of seeds and plant propagation material, fertilizers, feed and permits for conducting of tests with animals; 3) Ministry of Social Affairs is responsible for issuance of permits for contained use of genetically modified micro-organisms (GMMs)

The nominated focal point for the Cartagena Protocol is the Ministry of Environment.

### Main National Stakeholders

There are two advisory committees in Estonia responsible for making risk assessment for GMOs and products containing of GMOs or consisting of GMOs:

- Advisory Committee for Genetic Modification,
- Novel Food Committee (in addition to GM-food, it also conducts risk assessment for products that are obtained from GMOs, but not containing GMOs)

The Environmental Inspectorate is responsible for surveillance of deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs; the Veterinary and Food Board and Health Protection Inspectorate are responsible for surveillance of novel foods (including genetically modified food); the Plant Production Inspectorate under Ministry of Agriculture is responsible for surveillance of use of seeds and plant propagation material and feed; the Labour Inspectorate is responsible for surveillance of contained use of genetically modified micro-organisms (GMMs); the Consumer Protection Board is responsible for checking the proper labelling of the products at retail level.

### Main country's achievements in NBF implementation

A National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a new National Law (2004), a number of EC Directives, Regulations and Decisions adopted:

A functional national system coordinated by three National Competent Authority (Ministry of Environment, MoE, Ministry of Agriculture and Ministry of Welfare) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing, and a National Biosafety Focal Point (NBFP) in the MoE.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoE. The BCH currently contains 48 records of EU decisions and 28 regulatory / administrative documents.

Regular Reports on the implementation of CPB submitted: 1<sup>st</sup> (2007) YES                      2<sup>nd</sup> (2011)

### Milestones in GMOs Policy and Legislation

**1994:** Kenya ratifies the CBD

**1998:** the National Council for Science and Technology produced the first regulations and guidelines for safety in biotechnology which provided a base for the establishment of the National Biosafety Committee (NBC)

**2003:** Kenya ratifies the Cartagena PB and develops the national Biosafety Bill

**2009:** the Biosafety Act becomes law (No.2 /2009)

**2010:** the government of Kenya establishes the National Biosafety Authority (NBA)

**2011:** Biosafety regulations are published

### Milestones in NBF implementation

**1999:** the National Biosafety Framework is produced under the framework of the UNEP/GEF Biosafety Enabling Activity. A draft Biosafety Law is also prepared.

**2002:** Start-up of the NBF Implementation project, appointment of National Project Coordinator, setting of the National Biosafety Office, appointment of task forces to develop Biosafety bill and Biotechnology policy.

**2003:** start-up stakeholders' workshop for implementing the National Biosafety Framework (114 participants) and for discussing the draft Biosafety bill and Biotechnology policy (120 participants)

**2004:** study tour of the NPC and two other staff in Switzerland, Germany, Netherlands, Belgium and France.. Study tour for Kenya Parliamentarians (41) to visit the Biotechnology facilities within the Country. A Visit of a Kenyan legal expert to Switzerland for approaching Biosafety regulations. Establishment of Biosafety website for Kenya.. One awareness workshop on handling request for LMOs applications (39 participants)

**2005:** Awareness workshop on monitoring and inspection of GMOs (36 part.), workshop of lawyers and scientists to finalise the Biotechnology policy and Biosafety bill (15 part.), seminar for plant, animal and standard inspectors(39 part.), equipping the Kenya Agriculture Research Institute (KARI) and Botany department University of Nairobi with facilities for detection of GMOs.

**2006:** Teaching materials, brochures, stickers and manuals developed for public awareness; setting of the Biosafety database system to serve as Biosafety Clearing mechanism in Kenya; training course on information exchange by using Biosafety clearing house mechanism (32 part.); publishing and dissemination of all the published materials

### National Competent Authority

The national competent authority is the National Biosafety Authority (NBA), under the Ministry of Higher Education Science & Technology. The NBA , established by the Biosafety Act No. 2 of 2009, is also the National Focal Point of the Cartagena Protocol on Biosafety and the agency managing the National Biosafety Clearing House (BCH).

### Main National Stakeholders

According to the Biosafety Act, the NBA has to coordinate with 8 public agencies

The Kenya Plant Health Inspectorate Service (KEPHIS)

The Kenya Bureau of Standards (KEBS)

The Pest Control and Produce Board (PCPB)

The Department of Veterinary Services (DVS)

The Department of Public Health

The National Environmental Management Authority (NEMA)

The Kenya Wildlife service (KWS)

The Kenya Industrial Property Rights (KIPI)

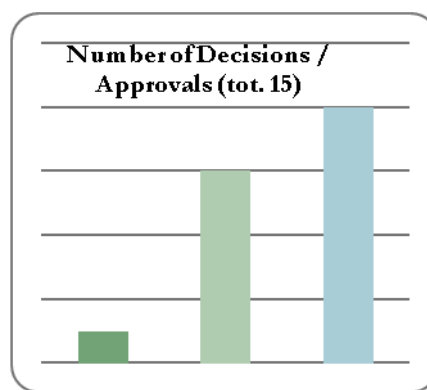
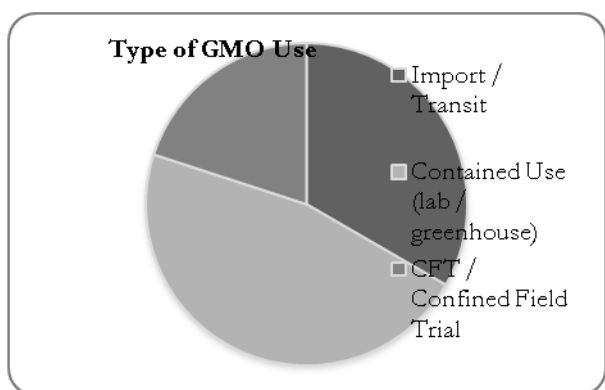
### Main country's achievements in NBF implementation

A National Biotechnology Policy approved by the government (2006) and a National Law (2009) and Regulations (2011) on the safe transfer, handling and use of GMOs promulgated.

A National Competent Authority established in 2010 (the NBA, Nat. Biosafety Authority) and currently setting in the premises of the Commission for Higher Education, with a newly appointed CEO, two Directors and management officers (2011).

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the NBA. The BCH is not yet fully operational (only 1 record of Country's decisions / approvals out of 15 listed in the National Database provided by the NCA to the evaluation mission, see diagrams below). The national website is also in its structuring phase.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES          2nd (2011) YES



N. of decisions	Subject (plant / animal)	Type of use	Applicant
7	Banana, Pigeon Pea, Cassava, Yam, Mice, Cow	Contained Use (lab & greenhouse)	ILRI (Int. Livestock Res. Inst.)
5	Corn-Soya Blend, Maize meal	Import & transit	World Food programme (WFP)
3	Maize, Cassava	CFT (Confined Field Trial)	KARI (Kenya Agr. Res. Inst.)

### **Milestones in GMOs Policy and Legislation**

**1996** Lithuania ratifies the Convention on Biological Diversity

**2002** The Law on Genetically Modified Organisms is promulgated

**2002** Lithuania ratifies the Aarhus Convention and consequently (2003) the “Order on Regulation on Public Information and Participation in Issuing authorizations for Use of GMOs”

**2003** the National Strategy of Sustainable Development is approved by the Government and implemented by the Ministry of Environment (MoE)

**2004** Lithuania ratifies the Cartagena Protocol on Biosafety

**2004** The Republic of Lithuania becomes a Member State of EU and adopts EU directives, regulations, decisions and recommendations on GMOs.

**2004** Ministerial Orders (Regulations) are adopted in application of the National Law and EC regulations.

### **Milestones in NBF implementation**

**2002/2004** Lithuania participates in the UNEP/GEF Project “Development of the National Biosafety Framework”, completed in 2004.

**2003** The National Biosafety Clearing House (BCH) is implemented

**2004** The National Biosafety Framework is drafted

**2006** The UNEP-GEF project “Support for the Implementation of the National Biosafety Framework for Lithuania“ is implemented

#### **2007/2009**

The National “Biosafety Strategy on Perspectives for safe use and application of modern biotechnology in Lithuania” and the National “Manual for implementation of NBF” are prepared, circulated and discussed.

Methodological guidelines on Risk Assessment and Risk Management procedures are also prepared and implemented.

Number of public awareness seminars and scientific are organized, educational materials for target stakeholders & specialists are produced, distributed and available for downloading via the national BCH portal

Three National Public Surveys on GMO carried out



## National Competent Authority

The national Law on Genetically Modified Organisms identifies the Ministry of Environment as the National Competent Authority (NCA).

## Main National Stakeholders

Other national authorities sharing responsibilities on the use of GMOs in Lithuania are the Ministry of Health Care, the Ministry of Agriculture, the State Food and Veterinary Service.

The National Veterinary Laboratory (NVL) under the State Food and Veterinary Service (SFVS) is the national laboratory accredited for GMOs control since 2004.

## Main country's achievements in NBF implementation

National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2002), a number of EC Directives, Regulations and Decisions, National Biosafety Framework (2004) and technical guidelines.

A functional national system coordinated by the National Competent Authority (Ministry of Environment, MoE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing, a National Reference Laboratory accredited and a National Biosafety Focal Point (NBFP) in the MoE.

Two independent bodies, the GMO Steering Committee (23 members representative of relevant institutions) with regulatory / management functions and a Scientific Advisory GMOs Experts Committee (advisory body)

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoE. The BCH currently contains 48 records of EU decisions and 13 legal / administrative documents (laws, regulations).

Regular Reports on the implementation of CPB submitted: 1<sup>st</sup> (2007) YES                      2<sup>nd</sup> (2011)

### Milestones in GMOs Policy and Legislation

**2002** Moldovan Parliament ratifies the Cartagena Protocol on Biosafety and approves the National Law on Biosafety

**2003** The National Law is published and 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), also created by Law n 2003

**2003** The Government approves Regulation on authorisation of the activities regarding testing, production, use or marketing of GMOs

**2008 / 2010** The Law on protection of plant varieties is approved, 16 laws are amended with provisions of biosafety requirements, including amendments drafted to 6 laws in the field of environmental protection, and to the 7 laws in the field of agriculture and food industry, as well as one law on consumer's rights, and on health care.

### Milestones in NBF implementation

**2002/2004** Moldova participates in the UNEP/GEF Project "Development of the National Biosafety Framework" under the Moldovan Ministry of Ecology and Natural Resources. The National Biosafety Framework (NBF) for the Republic of Moldova is prepared.

**2005** Moldova implements 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.

**2009** The Biosafety Action Plan is approved

### National Competent Authority

According to the provisions of the Cartagena Protocol and the Law on Biosafety, the Ministry of Ecology and Natural Resources (MERN) is the national authority (NCA) in charge of their implementation.

### Main National Stakeholders

The Ministry of Agriculture and Food Industry (MAFI) is a relevant partner, with its National Plant Varieties Council (NPVC), the State Committee for Testing of Plant Varieties and the State Seed Inspectorate (SSI), the Phytosanitary Quarantine State Inspectorate (PQSI).

Major Moldovan research institutes, Universities and the Academy of Sciences of Moldova (A.S.M.) are also partners.

### Main country's achievements in NBF implementation

National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2002), Regulations (2003), a number of laws in different sectors amended with provisions of biosafety requirements, a Biosafety Action Plan (2009)

A functional national system coordinated by the National Competent Authority (Ministry of Ecology and Natural Resources), a National Biosafety Committee (14 members) that operates as the interdepartmental authority, a National Focal Point for the Cartagena Protocol on Biosafety and the BCH supported by a National Task Force (8 members from various governmental bodies, research and civil society), and a National Biosafety Testing Center (NBTC) established for the purpose of assessment of risks for public health and the environment.

A Biosafety Clearing House (BCH) that currently contains 6 records of regulatory / administrative documents (laws, regulations) and a National website in three languages (Romanian, Russian and English).

Regular Reports on the implementation of CPB submitted: 1st (2007) YES                      2nd (2011)



### Milestones in GMOs Policy and Legislation

**1997:** the Government of Namibia ratifies the Convention on Biological Diversity (CBD)

**1998:** the Namibian Biotechnology Alliance (NABA), established in 1996 as an inter-disciplinary interest group composed of specialists from government, parastatal organizations and the private sector, is officially launched and it is housed under the ministry responsible for science and technology (Ministry of Higher Education, Training and Employment Creation)

**1999:** A National Policy on Biosafety, "Enabling the safe use of biotechnology in Namibia"; is approved

**2005:** The Government of Namibia ratifies the Cartagena PB.

**2006:** the Namibia Biosafety Act is promulgated (Act No. 7 of 2006)

### Milestones in NBF implementation

**1999:** Namibia benefits from funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project. The national partner (the Namibian Biotechnology Alliance, NABA, see above), prepares a "Country study: Biosafety and Biotechnology in Namibia", identifying a number of needs and recommendations for a National Biosafety Framework in Namibia. The study includes national technical guidelines for the safe use of biotechnology, a draft of the National Policy, which is in the same year was approved by the Cabinet, and a draft act on the safe use of biotechnology, which is submitted to the government legal drafters. The National Biosafety Framework is drafted with the support of UNEP-GEF.

**2003:** Startup Workshop of the NBF implementation Project, NCC Meetings, Risk Assessment Training workshop, Information materials produced and disseminated

**2004:** National Policy translated book in 6 Local Languages; Training Workshop for Inspectors

**2005/2006:** several training workshops and material produced

**2007:** National Training Workshops on the use of the Biosafety clearing House Central Portal, Workshop on inspection and monitoring requirements for GMOs and GMO- products. Closure Workshop

### National Competent Authority

The Act establishes the Biosafety Council as the National Competent Authority. The Council should be composed by 7 members appointed by the National Commission on Research, Science and Technology. The Council is not yet operational. The Directorate of Research, Science and Technology of the Ministry of Education is acting as NCA.

### Main National Stakeholders

According to the Act, the members appointed must be persons bringing skills or experience in the membership of the Council in each of the following areas: (a) environmental issues, including environmental assessment; (b) public health issues, including food hygiene and food safety; (c) animal health and welfare or other related agricultural issues; (d) molecular biology; (e) law; (f) research, science and technology; and (g) trade and economy.

### Main country's achievements in NBF implementation

A National Policy approved by the government (1999) and a National Law (2006) promulgated (Regulations and Guidelines not yet in place) and translated in 6 Local Languages

A National Competent Authority is established through the Namibia Biosafety Act (2006).

Training Manuals produced

A Biosafety Clearing House (BCH) with a National BCH Focal Point is in place but not fully operational. No record of NCA decisions on the BCH website

Regular Reports on the implementation of CPB submitted: 2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**1996** Poland ratifies the Convention on Biological Diversity

**1996** an Interdisciplinary Consultative Group on genetically modified organisms (GMOs) is established by initiative of the Ministry of Agriculture and Food Industry

**2001** the new act "On Genetically Modified Organisms" is signed and enters into force on 26/10/2001

**2002** Many Regulations are published in application of the Act of 2001

**2004** The Republic of Poland becomes a Member State of EU and adopts EU directives, regulations, decisions and recommendations on GMOs.

### Milestones in NBF implementation

**1998** the National Biosafety Framework (NBF) for Poland is prepared through the support of UNEP-GEF Pilot Biosafety Enabling Activity project.

**2002/05** the NBF is implemented with the joint support of UNEP-GEF Implementation Project and the EU

PHARE programme. A number of training activities for national stakeholders are carried out, guidelines are prepared and discussed, national laboratories are equipped and accredited, a Biosafety Database System linked to the BCH central portal is established, public opinion pools are conducted and published, best practices and lessons learned are documented and disseminated.

**2007/09** the Environmental Information Centre (of the MoEnv.) organizes a nationwide information campaign entitled "Genetically modified organisms and the natural environment": 101 training actions, 6 nationwide conferences, a final international conference on 27 February 2009. Project objective was to increase knowledge of public administration and enhance public awareness in this regard. Target groups were: local, regional, provincial government bodies and officers, farmers and entrepreneurs.

### National Competent Authority

The Ministry of Environment is the competent authority responsible for implementation of Cartagena Protocol on Biosafety.

### Main National Stakeholders

The Minister of Agriculture and Rural Development is the governmental administrative authority competent on GM seeds and the placing on the market GM feed.

The Minister of Health through the Chief Sanitary Inspector is the governmental administrative authority making decisions regarding the placing on the market of GMOs intended for food and of food products containing GMOs.

### Main country's achievements in NBF implementation

National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2001), a number of EC Directives, Regulations and Decisions, National Biosafety Framework (1998) and technical guidelines.

A functional national system coordinated by the National Competent Authority (Ministry of Environment, MoE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing, National Reference Laboratories accredited and a National Biosafety Focal Point (NBFP) in the MoE.

A National Commission on GMOs in place and active (19 members)

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoE. The BCH currently contains 48 records of EU decisions and 24 regulatory / administrative documents /law, regulations.

In 2010-11, Poland has taken 202 decisions to test LMOs in Contained Use and 3 decisions on Field Trials.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES 2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**1994** the Slovak Republic ratifies the CBD

**1998** adoption of the National Biodiversity Strategy and Action Plan

**2002** the Act on Genetic Technologies and Genetically Modified Organisms (Act No. 151/2002 Coll.), as well as the Decree to implement it (Decree No. 252/2002 Coll.) come into force

**2003** the Slovak Republic ratifies the Cartagena PB

**2004** the Slovak Republic becomes part of the EU and adopts the Directive 2001/18/EC on the "deliberate release of GMOs into the environment". It also adopts Regulation (EC) No 1829/2003 and Regulation (EC) No 641/2004 on detailed rules regarding "the applications for authorisation of GM food and feed, including the method(s) of detection, sampling and event specific identification of the transformation event". From 2004 onward, as an EU member, Slovak Republic has adopted EC Directives and Regulations, and Council Decisions.

### Milestones in NBF implementation

**2002** the Slovak Republic participates in the UNEP/GEF Project "Development of the National Biosafety Framework".

**2004** the National Biosafety Framework (NBF) is drafted

**2006** first NCC meeting, joint Inception Meeting held in to open close collaboration on Biosafety between Czech and Slovak Rep, first Workshop to present the aims and goals of the project to public

**2007** activities are launched, training for experts and Competent Authorities. The GMO Act (2002) is revised, amended and approved.

**2008** trainings implemented ( Biosafety Officers, Environmental Inspectors), a Workshop on National Strategy on Biological Safety is held and a basic framework is established.

**2009** The National Regulatory Framework is published on the national web-site (NBCH) and on BCH of Cartagena Protocol site. Further trainings are organised: Risk Assessment for all members of Department of Biological Safety MoE and training for Environmental Inspectors. The workshop on the National Regulatory Framework is held, open to public and broadcasted on Internet.

### National Competent Authority

The Ministry of Environment (MoE) of the Slovak Republic is the governmental body, which has an umbrella function in biosafety fields in Slovak Republic. The Department of Environmental Risks and Biosafety of the MoE is the competent authority for approving GMOs under contained use, deliberate releases to the environment and placing on the market. The department is also the focal point for the Cartagena Protocol.

### Main National Stakeholders

The Slovak Environmental Inspection (SEI) of the MoE: providing state supervision and imposition of fines on matters concerning environment protection.

The State Veterinary and Food Agency (SVFA): control of food products on the market, food safety and labelling. Its laboratory is accredited for detection of quality and quantity of GM Food.

The Central Control and Testing Institute of Agriculture (CCTIA): main responsible for GMO monitoring in seed and feed materials. It has its own accredited laboratory.

The Public Health Authority (PHA) is an independent body with functions of assessing and approving any novel food for human consumption including GM foods.

The Institute of Molecular Biology, Slovak Academy of Sciences (IMB SAS Laboratory) has been recently created especially for method development with special focus on the detection of unique GMOs produced for research purposes

### Main country's achievements in NBF implementation

A National Regulatory Framework for the use of GMOs and GMOs products, including a National Law (2002), a number of EC Directives, Regulations and Decisions, National Biosafety Framework (2004) and technical guidelines.

A functional national system coordinated by the National Competent Authority (Ministry of Environment, MoE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing, three National Reference Laboratories equipped and EU accredited and a National Biosafety Focal Point (NBFP) in the MoE.

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MoE. The BCH currently contains 48 records of EU decisions and 30 regulatory / administrative documents (law, regulations, etc.). The national website (also partially in English) is clear, user-friendly and with an active Forum. A national website in Slovak and English.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES                      2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**2003:** Uganda ratifies the Cartagena Protocol

**2008** Uganda prepares its national biotechnology and Biosafety Policy providing overall guidance on national priorities on biosafety and biotechnology.

The Biosafety Law is still in draft form.

### Milestones in NBF implementation

**1997** UNEP/GEF pilot project supports Uganda in drafting and establishing its NBF. The National Biosafety Committee (NBC) is set. in March 2001.

**2001** The Framework is adopted by the Ministry of Environment

**2002/2006** Through UNEP/GEF project support, Uganda implements several trainings on issues of biosafety legislation and procedure for political leaders, legislators and policy makers, senior government officials, university staff and executives of semi-autonomous government bodies. Rural local council chiefs/districts are also trained on biosafety legal and administrative aspects as well as risk assessment and management procedures. Custom officials (45) are also trained. The laboratory of the National Agricultural Research Laboratories Research Institute, Kawanda Biotechnology Centre, is upgraded.

### National Competent Authority

The Uganda National Council for Science and Technology (UNCST) is the National Competent Authority for Biosafety in Uganda. The Council was established in 1990 as a corporate institution under the Ministry of Finance Planning and Economic Development to guide and coordinate research and experimental development throughout Uganda.

### Main National Stakeholders

A national dialogue on the draft national Biotechnology and Biosafety Policy was organised and a NGO group, Advocates Coalition for Development and Environment (ACODE) prepared a special briefing paper on the Policy. The Consumer Education Trust (CONSENT) was contracted to conduct the promotion of public awareness over TV and radio at a frequency of 2-3 times/week for 2 months.

### Main country's achievements in NBF implementation

A National Biotechnology Policy approved (2008) and a National Law in draft form.

A National Competent Authority is identified (the Uganda National Council for Science and Technology) as well as National Focal Point within the National Agricultural Research Organization. The BCH is in place but without significant information.

Regular Reports on the implementation of CPB submitted: 1st (2007) YES

2nd (2011) YES

### Milestones in GMOs Policy and Legislation

**2004** Vietnam access the Cartagena Protocol on Biosafety (not ratified)

**2007:** The National Action Plan on Biodiversity up to 2010 and orientations towards 2020 for implementation of the Convention of Biological Diversity and the Cartagena Protocol on Biosafety is finalised and approved

**2008: Law on Biodiversity with one Chapter on Biosafety has been approved**

**2009:** The Ministry of Agricultural and Rural Development promulgates Circulars on Risk Assessment and a list of permitted GM species

**2010** The Decree N. 69 on Genetically Modified Organisms is promulgated

**2010** the National Assembly also adopts the Law on Food Safety which prescribes requirements for biosafety management of genetically modified food.

### Milestones in NBF implementation

**2002** Vietnam participates in the UNEP/GEF Project “Development of the National Biosafety Framework”, completed in 2004.

**2003** The National Biosafety Clearing House (BCH) is implemented

**2004** The National Biosafety Framework is drafted

**2006** The UNEP-GEF project “Support for the Implementation of the National Biosafety Framework for Vietnam“ is implemented

**2007** With the support of UNEP-GEF project, Vietnam establishes the requisite policy and regulatory framework for biosafety management

**2007-2010** A series of awareness seminars/workshops are conducted, as well as study tours in US, Australia and Philippines, two regional workshops with ASEAN countries are organised.

### National Competent Authority

The national Law on Genetically Modified Organisms identifies the Ministry of Nature Resources and Environment (MONRE) as the National Competent Authority (NCA).

### Main National Stakeholders

Other national authorities sharing responsibilities on the use of GMOs in Vietnam are the Ministry of Agriculture and Rural Development –MARD- (responsible for overseeing the conduct of field trials for GMOs), the Ministry of Health (MOH), the Ministry of Science and Technology (MST), the Ministry of Industry and Trade (MIT), the General Department of Vietnam Customs (GDVC) and Vietnam Environment Police Agency (VEPA).

### Main country's achievements in NBF implementation

A National Policy and a Regulatory Regime for the use of GMOs and GMOs products, including a National Law (2010).

A functional national biosafety system coordinated by the National Competent Authority (Ministry of Nature Resources and Environment, MONRE) with a set of administrative and monitoring mechanisms and procedures for handling requests, risk assessment and management, administrative processing. National Laboratories (Institute of Agriculture Genetics , IAG) for conducting field trials and LMO detection

A Biosafety Clearing House (BCH) with a National BCH Focal Point in the MONRE. The BCH currently contains 3 Decisions on Corn Field Trial..

Regular Reports on the implementation of CPB submitted: 1<sup>st</sup> (2007) YES 2<sup>nd</sup> (2011) YES

## Annex 8. Project costs and co-financing tables

### A) Project Costs

Component/sub-component	Estimated cost at design	Actual Cost	Expenditure ratio (actual/planned)
Bulgaria	504,259	528,214	1.05
Cambodia	1,100,405	1,100,405	1,00
Cameroon	671,400	671,400	1.00
China	1,266,400	1,280,483	1.01
Cuba	930,642	1,080,572	1.16
Czech Republic	1,885,000	1,885,000	1.00
Estonia	953,000	974,588	1.02
Kenya	619,537	652,718	1.05
Lithuania	1,091,400	1,091,400	1.00
Moldova	689,350	689,350	1.00
Namibia	911,000	1,816,000	1.99
Poland	2,616,550	2,616,550	1.00
Slovakia	605,000	577,200	0.95
Uganda	642,000	642,000	1.00
Vietnam	1,634,800	1,634,800	1.00

**B) Co-financing**

**Co-financing: Bulgaria**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			96,380	120,335			96,380	120,335	120,335
- Other (*)									
<b>TOTALS</b>			96,380	120,335			96,380	120,335	120,335

**Co-financing: Cambodia**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			299,025	299,025			299,025	299,025	299,025
- Other (*)					160,100	160,100	160,100	160,100	160,100
<b>TOTALS</b>							459,125	459,125	459,125



**Co-financing: Cameroon**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			111,000	111,100			111,000	111,100	111,100
- Other (*)									
<b>TOTALS</b>			111,000	111,100			111,000	111,100	111,100

**Co-financing: China**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			269,000	283,083			269,000	283,083	283,083
- Other (*)									
<b>TOTALS</b>			269,000	283,083			269,000	283,083	283,083

Co-financing: Cuba

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			284,142	435,572			284,142	435,572	435,572
- Other (*)									
<b>TOTALS</b>			284,142	435,572			284,142	435,572	435,572

Co-financing: Czech Republic

Co financing (Type/Source )	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disburse d (US\$)
	Planne d	Actua l	Planned	Actual	Planne d	Actua l	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			1,432,60 0	1,432,60 0			1,432,60 0	1,432,60 0	1,432,60 0
- Other (*)									
<b>TOTALS</b>			1,432,60 0	1,432,60 0			1,432,60 0	1,432,60 0	1,432,60 0

**Co-financing: Estonia**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			284,000	305,588			284,000	305,588	305,588
- Other (*)									
<b>TOTALS</b>			284,000	305,588			284,000	305,588	305,588

**Co-financing: Kenya**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			108,658	141,839			108,658	141,839	141,839
- Other (*)									
<b>TOTALS</b>			108,658	141,839			108,658	141,839	141,839

**Co-financing: Lithuania**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			404,000	404,000			404,000	404,000	404,000
- Other (*)									
<b>TOTALS</b>			404,000	404,000			404,000	404,000	404,000

**Co-financing: Moldova**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			147,000	147,000			147,000	147,000	147,000
- Other (*)									
<b>TOTALS</b>			147,000	147,000			147,000	147,000	147,000

**Co-financing: Namibia**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			239,000	1,143,904			239,000	1,143,904	1,143,904
- Other (*)									
<b>TOTALS</b>			239,000	1,143,904			239,000	1,143,904	1,143,904

**Co-financing: Poland**

Co financing (Type/Source )	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disburse d (US\$)
	Planne d	Actua l	Planned	Actual	Planne d	Actua l	Planned	Actual	
- Grants			2,068,45 0	2,068,45 0			2,068,45 0	2,068,45 0	2,068,45 0 (*)
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			88,100	88,100			88,100	88,100	88,100
- Other (*)									
<b>TOTALS</b>			2,156,55 0	2,156,55 0			2,156,55 0	2,156,55 0	2,156,55 0

(\*) PHARE Programme

Co-financing: Slovakia

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			139,000	111,200			139,000	111,200	111,200
- Other (*)									
<b>TOTALS</b>			139,000	111,200			139,000	111,200	111,200

Co-financing: Uganda

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			82,000	82,000			82,000	82,000	82,000
- Other (*)									
<b>TOTALS</b>			82,000	82,000			82,000	82,000	82,000

**Co-financing: Vietnam**

Co financing (Type/Source)	IA own Financing (US\$)		Government (US\$)		Other* (US\$)		Total (US\$)		Total Disbursed (US\$)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants									
- Loans									
- Credits									
- Equity investme nts									
- In-kind support			637,000	637,000			637,000	637,000	637,000
- Other (*)									
<b>TOTALS</b>			637,000	637,000			637,000	637,000	637,000

\* This refers to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

## Annex 9 Projects Data compilation

### PROJECT DATA COMPILATION

#### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>BULGARIA</b>	<b>1374</b> Support to the implementation of the Nat. Bios. Framework	AgroBio Institute (ABI) of the National Center for Agrarian Science (NCAS)	<b>407,879</b>	<b>96,380</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>10</b>	<b>31/05/2006</b>	<b>30/06/2006</b>

#### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>504,259</b>	<b>528,214</b>		<b>407,879</b>	<b>120,355</b>
<b>%</b>			<b>105%</b>	<b>77%</b>	<b>23%</b>

Obs: 4+5=2

#### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	√	PIR (Project Internal Review) June / year		Terminal report	√	
				Terminal Fin. Statement	√	
Budget	√	Periodic Progress Report (2/ y)	6	Final Project Output	√	
Log Frame		Periodic Expend. Report (4/y)	8	Terminal Audit	√	
Work Plan	√	Audit Periodic Reports (1/y)	3	Final Inventory	√	
		Project and budget Revisions	5	Transfer of Equipment	√	
		Internal Reviews	1	Terminal Co-financing	√	
		Missions Reports		Final Workshop proceedings		

National Biosafety website: na



## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>CAMBODIA</b>	<b>2819</b> Support to the implementation of the Nat. Bios. Framework	Ministry of Environment	<b>641,280</b>	<b>459,125</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>05/07/2006</b>	<b>48</b>	<b>04/07/2010</b>	<b>6</b>	<b>10/12/2010</b>	<b>04/07/2011</b>

### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution
<b>US\$</b>	<b>1,100,405</b>	<b>1,100,405</b>		<b>641,280</b>	<b>459,125</b>
<b>%</b>			<b>100%</b>	<b>58%</b>	<b>42%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	2	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output	✓	
Log Frame	✓	Periodic Expend. Report (4/y)	2	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	2	Final Inventory	✓	
		Project and budget Revisions	7	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing		
		Missions Reports	1	Final Workshop proceedings		

#### Further information:

National Biosafety website:

## GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>CAMEROON</b>	<b>1367</b> Support to the implementation of the Nat. Bios. Framework	Ministry of Environment and Forestry (MINEF), then Ministry of Environment and Nature Protection (MINEP)	<b>560,300</b>	<b>111,100</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/10/2002</b>	<b>36</b>	<b>30/09/2005</b>		<b>30/06/2006</b>	<b>30/09/2005</b>

## BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>671,400</b>	<b>671,400</b>		<b>560,300</b>	<b>111,100</b>
<b>%</b>			<b>100%</b>	<b>83%</b>	<b>17%</b>

Obs: 4+5=2

## DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year		Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	15	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	8	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	1	Final Inventory	✓	
		Project and budget Revisions		Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports		Final Workshop proceedings	✓	

### Further information:

National Biosafety website: na

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>CHINA</b>	1369 Support to the implementation of the Nat. Bios. Framework	Department of Nature & Ecology Conservation, State Environmental Protection Administration (SEPA)	<b>997,400</b>	<b>269,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>40</b>	<b>31/12/2008</b>	<b>31/12/2008</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>1,266,400</b>	<b>1,280,483</b>		<b>997,400</b>	<b>283,083</b>
<b>%</b>			<b>101%</b>		

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	<b>1</b>	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	<b>2</b>	Terminal Audit		
Work Plan	✓	Audit Periodic Reports (1/y)	<b>4</b>	Final Inventory	✓	
		Project and budget Revisions	<b>6</b>	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports	<b>1</b>	Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://www.biosafety.gov.cn/>

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>CUBA</b>	<b>1370</b> Support to the implementation of the Nat. Bios. Framework	Centro Nacional de Seguridad Biológica (CNSB), Ministerio de Ciencia, Tecnología y Medio Ambiente.	<b>646,500</b>	<b>284,142</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>21</b>	<b>31/05/2007</b>	<b>31/05/2007</b>

### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>930,642</b>	<b>1.081,072</b>		<b>646,500</b>	<b>435,572</b>
<b>%</b>			<b>116%</b>	<b>60%</b>	<b>40%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review)		Terminal report	✓	
		June / year		Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	2	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)		Final Inventory	✓	
		Project and budget Revisions	4	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports	2	Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://www.medioambiente.cu/oregulatoria/cnsb/index.htm>

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>CZECH REP.</b>	<b>2839</b> Support to the implementation of the Nat. Bios. Framework	Ministry of the Environment	<b>452,400</b>	<b>1,432,600</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>22/08/2006</b>	<b>48</b>	<b>21/08/2010</b>	<b>10</b>	<b>30/11/2010</b>	<b>21/06/2011</b>

### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>1,885,000</b>	<b>1,885,000</b>		<b>452,400</b>	<b>1,432,600</b>
<b>%</b>			<b>100%</b>	<b>24%</b>	<b>76%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	√	PIR (Project Internal Review)	2	Terminal report	√	
		June / year		Terminal Fin. Statement	√	
Budget	√	Periodic Progress Report (2/ y)		Final Project Output	√	
Log Frame	√	Periodic Expend. Report (4/y)	2	Terminal Audit	√	
Work Plan	√	Audit Periodic Reports (1/y)	4	Final Inventory	√	
		Project and budget Revisions	5	Transfer of Equipment	√	
		Internal Reviews		Terminal Co-financing		
		Missions Reports		Final Workshop proceedings		

#### Further information:

National Biosafety website: [http://www.mzp.cz/www/webdav\\_biosafety.nsf\\$files/Biosafety/index.html](http://www.mzp.cz/www/webdav_biosafety.nsf$files/Biosafety/index.html)

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>ESTONIA</b>	<b>2837</b> Support to the implementation of the Nat. Bios. Framework	Tallinn University of Technology (Department of Gene Technology)	<b>669,000</b>	<b>284,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>28/08/2006</b>	<b>48</b>	<b>27/07/2010</b>	<b>5</b>	<b>27/12/2010</b>	<b>27/01/2011</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>953,000</b>	<b>974,588</b>		<b>669,000</b>	<b>305,588</b>
<b>%</b>			<b>102%</b>	<b>69%</b>	<b>31%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	3	Terminal report		
				Terminal Fin. Statement		
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output		
Log Frame	✓	Periodic Expend. Report (4/y)	1	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	3	Final Inventory	✓	
		Project and budget Revisions	7	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing		
		Missions Reports		Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://ee.biosafetyclearinghouse.net/>

**PROJECTS DATA COMPILATION**

**GENERAL INFO**

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>KENYA</b>	<b>1371</b> Support to the implementation of the Nat. Bios. Framework	The Kenya National Council for Science and Technology (NCST)	<b>510,879</b>	<b>108,658</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>14</b>	<b>31/10/2006</b>	<b>31/10/2006</b>

**BUDGET (US\$)**

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>619,537</b>	<b>652,718</b>		<b>510,879</b>	<b>141,839</b>
<b>%</b>			<b>105%</b>	<b>78%</b>	<b>22%</b>

**Obs:** 4+5=2

**DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)**

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year		Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	<b>3</b>	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)		Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	<b>2</b>	Final Inventory	✓	
		Project and budget Revisions	<b>6</b>	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports				

**Further information:**

National Biosafety website: [www.biosafetykenya.go.ke](http://www.biosafetykenya.go.ke)

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co- Financing
<b>LITHUANIA</b>	<b>2838</b> Support to the implementation of the Nat. Bios. Framework	<b>Ministry of Environment, GMO Division</b>	<b>687,400</b>	<b>404,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>31/07/2006</b>	<b>48</b>	<b>31/07/2010</b>	<b>2</b>	<b>30/07/2010</b>	<b>29/09/2010</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>1,091,400</b>	<b>1,091,400</b>		<b>687,400</b>	<b>404,000</b>
<b>%</b>			<b>100%</b>	<b>63%</b>	<b>37%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	2	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output	✓	
Log Frame	✓	Periodic Expend. Report (4/y)		Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)		Final Inventory	✓	
		Project and budget Revisions	6	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co- financing		
		Missions Reports		Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://gmo.am.lt/>



## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>MOLDOVA</b>	<b>3043</b> Support to the implementation of the Nat. Bios. Framework	Ministry of Ecology and Natural Resources	<b>542,350</b>	<b>147,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>20/07/2006</b>	<b>48</b>	<b>19/07/2010</b>	<b>6</b>	<b>24/12/2010</b>	<b>19/01/2011</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>689,350</b>	<b>689,350</b>		<b>542,350</b>	<b>147,000</b>
<b>%</b>			<b>100%</b>	<b>79%</b>	<b>21%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	3	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)		Final Project Output	✓	
Log Frame	✓	Periodic Expend. Report (4/y)		Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	2	Final Inventory	✓	
		Project and budget Revisions	5	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing		
		Missions Reports		Final Workshop proceedings		

#### Further information:

National Biosafety website: [www.biosafety.md](http://www.biosafety.md)

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>NAMIBIA</b>	<b>1372</b> Support to the implementation of the Nat. Bios. Framework	The Namibian Biotechnology Alliance (NABA) on behalf of the Ministry of Higher Education, Training and Employment Creation	<b>672,000</b>	<b>239,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>61</b>	<b>23/08/2007</b>	<b>30/09/2010</b>

### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>911,000</b>	<b>1,816,000</b>		<b>672,000</b>	<b>1.144.000</b>
<b>%</b>			<b>199%</b>	<b>37%</b>	<b>63%</b>

Obs: 4+5=2

(\*) 655,000 (salaries); 436,000 (fellowship for MSc and PhD abroad)

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review)	2	Terminal report	✓	
		June / year		Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	20	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	8	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)		Final Inventory	✓	
		Project and budget Revisions	5	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports	2	Final Workshop proceedings	✓	

### Further information:

National Biosafety website: n.a

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co- Financing
<b>POLAND</b>	<b>1373</b> Support to the implementation of the Nat. Bios. Framework	Plant Breeding And Acclimatization Institute (PBAI)	<b>460,000</b>	<b>2,156,550</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>0</b>	<b>31/08/2005</b>	<b>31/08/2005</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>2,616,550</b>	<b>2,616,550</b>		<b>460,000</b>	<b>2,156,550</b>
<b>%</b>			<b>100%</b>	<b>18%</b>	<b>82%</b>

Obs: 4+5=2

(\*) EU ( PHARE programme): USD 2,068,450

Gov.nt Poland Co-financing (in-kind): USD 88,100

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	1	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	1	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	1	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	4	Final Inventory	✓	
		Project and budget Revisions	4	Transfer of Equipment	✓	
		Internal Reviews	1	Terminal Co- financing		
		Missions Reports		Final Workshop proceedings		

### Further information:

National Biosafety website: <http://gmo.ekoportal.pl/>

## PROJECTS DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET	Total Co- Financing
<b>SLOVAK REP.</b>	<b>3023</b> Support to the implementation of the Nat. Bios. Framework	Biosafety Department of Slovak Hydrometeorological Institute, Ministry of Environment	<b>466,000</b>	<b>139,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/08/2006</b>	<b>48</b>	<b>31/07/2010</b>	<b>0</b>	<b>31/12/2009</b>	<b>31/07/2010</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>605,000</b>	<b>577,200</b>		<b>466,000</b>	<b>111.200</b>
<b>%</b>			<b>95%</b>	<b>81%</b>	<b>19%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review) June / year	1	Terminal report	✓	
				Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	1	Final Project Output	✓	
Log Frame	✓	Periodic Expend. Report (4/y)	1	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)		Final Inventory	✓	
		Project and budget Revisions	6	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co- financing		
		Missions Reports				

### Further information:

National Biosafety website: <http://www.gmo.sk>

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>UGANDA</b>	<b>1366</b> Support to the implementation of the Nat. Bios. Framework	Uganda National Council for Science and Technology (UNCST),	<b>560,000</b>	<b>82,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>01/09/2002</b>	<b>36</b>	<b>31/08/2005</b>	<b>16</b>	<b>01/09/2006</b>	<b>31/12/2006</b>

### BUDGET (US\$)

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>642,000</b>	<b>642,000</b>		<b>560,000</b>	<b>82,000</b>
<b>%</b>			<b>100%</b>	<b>87%</b>	<b>13%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review)	2	Terminal report	✓	
		June / year		Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	1	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	2	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)		Final Inventory	✓	
		Project and budget Revisions	6	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing	✓	
		Missions Reports	4	Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://www.uncst.go.ug/>

## PROJECT DATA COMPILATION

### GENERAL INFO

COUNTRY	Project GEF SEC CODE and Title	National Executing Agency (NEA)	Approved GEF BUDGET (USD)	Total Co-Financing
<b>VIETNAM</b>	<b>2997</b> Support to the implementation of the Nat. Bios. Framework	Vietnam Environment Protection Agency (VEPA) of the Ministry of Natural Resources and Environment (MONRE)	<b>997,800</b>	<b>637,000</b>

Commencement Date (date of signature)	Planned Duration (months)	Estimated End (date)	Total Extensions (months)	Completion Date (activities completed)	Official End (Date)
<b>20/07/2006</b>	<b>48</b>	<b>19/07/2010</b>	<b>5</b>	<b>30/11/2010</b>	<b>19/12/2010</b>

### BUDGET (US\$)

	1	2	3	4	5
	Total Planned budget	Total Expenditures	Expenditure ratio % (2/1)	Actual GEF Contribution	Actual Gov. Contribution (*)
<b>US\$</b>	<b>1,634,800</b>	<b>1,634,800</b>		<b>997,800</b>	<b>637,000</b>
<b>%</b>			<b>100%</b>	<b>61%</b>	<b>39%</b>

Obs: 4+5=2

### DOCUMENTS AVAILABLE (Tick or enumerate as appropriate)

INITIAL DOCUMENTS		OTHER DOCUMENTS		TERMINAL DOCUMENTS		OBS & NOTES
Project Doc	✓	PIR (Project Internal Review)	3	Terminal report	✓	
		June / year		Terminal Fin. Statement	✓	
Budget	✓	Periodic Progress Report (2/ y)	14	Final Project Output	✓	
Log Frame		Periodic Expend. Report (4/y)	3	Terminal Audit	✓	
Work Plan	✓	Audit Periodic Reports (1/y)	3	Final Inventory	✓	
		Project and budget Revisions	6	Transfer of Equipment	✓	
		Internal Reviews		Terminal Co-financing		
		Missions Reports		Final Workshop proceedings		

#### Further information:

National Biosafety website: <http://en.antoansinhhoc.vn/>

## Annex 10. Review of project design

### Assessment of the quality of project design of UNEP-GEF Biosafety Implementation Projects (from Inception Report)

***Introductory Note:** The current assessment refers to a portfolio of 15 projects (8 Demonstration projects and 7 Implementation Projects) implemented in 15 countries, with similar expected outcomes and objectives. As the conditions under which each project was developed vary from country to country, many relevant aspects of the project design (e.g. outputs, activities) may differ accordingly. The evaluation team tried to capture the quality of the projects design of the whole group, though, by doing so, some specificities might have been undervalued. Nevertheless, in most cases strong and weak points of projects design are recurrent elements in all of the countries, making the assessment quite applicable to the entire group. The assessment is based on the analysis of the 15 Project Documents; nevertheless, Prodoc references (third column) are impossible to be given, since they vary from project to project.*

Relevance	Evaluation Comments	Prodoc reference
Are the intended results likely to contribute to UNEP's expected accomplishments and programmatic objectives?	YES. The projects aim to assist countries to develop and implement their National Biosafety Framework (NBF) in order to meet the requirements of the Cartagena Protocol on Biosafety (CPB). This is in line with UNEP mandate and role for supporting environmental governance at all levels, and with Bali Strategic Plan.	Prodoc TOR (1.A and 1B)  UNEP mandate
Does the project form a coherent part of a UNEP-approved programme framework?	YES. The 15 implementation projects make part of a larger UNEP-GEF programme that, through under successive phases, has been giving supporting to more than 100 countries in implementing their NBF.	Prodoc TOR1.A UNEP GEF websites
Is there complementarity with other UNEP projects, planned and ongoing?	YES. There is complementarity with all the other NBF implementation projects throughout the world, as well as with other UNEP-GEF projects, notably the "BCH Capacity Building Project".	Prodoc TOR 1A Biosafety Unit Documents

Are the project's objectives and implementation strategies consistent with:	i) Sub-regional environmental issues and needs?	YES. Biosafety is a global challenge, also with transboundary / regional implications.	Prodoc Biosafety Unit Documents
	ii) the UNEP mandate and policies at the time of design and implementation?	YES, The projects respond to the UNEP mandate of facilitating the implementation of international environmental agreements, notably the CPB, the CBD, the Rio Declaration..	UNEP mandate
	iv) Stakeholder priorities and needs?	YES. Biosafety is an increasing priority for all the countries, due to the expansion of biotechnologies. Many countries show interest in adopting or producing LMOs and the need for a BNF is imperative.	Biosafety Unit Documents
<b>Overall rating for Relevance</b>		<b>Highly Satisfactory (HS)</b>	
<b>Intended Results and Causality</b>			
Are the objectives realistic?		YES, the Outcome (which is common for all the projects) and the Outputs (different from country to country) are generally realistic.	Prodoc TOR 1.B
Are the causal pathways from project outputs [goods and services] through outcomes [changes in stakeholder behaviour] towards impacts clearly and convincingly described? Is there a clearly presented Theory of Change or intervention logic for the project?		As an overall assessment, the answer is NO. Though there may be a certain coherence between activities, outputs and outcome, a clear presentation of the causal pathway is lacking, assumptions and drivers are not well identified, a TOC showing the link and the path from Outcome to Impact is lacking. Different projects use different terminology to define the same element of a Log Frame (confusion between activities, outputs, outcomes, targets, indicators, etc.). In the first group of 8 Dem. Projects, the LogFrame was not required and is not	Prodoc,



	there.	
Is the timeframe realistic? What is the likelihood that the anticipated project outcomes can be achieved within the stated duration of the project?	Generally speaking the timeframe is NOT realistic. The development and implementation of a NBF is a complex and time-consuming process, involving different stakeholders and several components (legal, technical, administrative)..	Prodoc
Are the activities designed within the project likely to produce their intended results?	YES. Activities are coherent with the expected outputs..	Prodoc
Are activities appropriate to produce outputs?	YES, they are appropriate.	Prodoc
Are activities appropriate to drive change along the intended causal pathway(s)	YES, though much depend on the quality of the outputs achieved through the activities	Prodoc
Are impact drivers, assumptions and the roles and capacities of key actors and stakeholders clearly described for each key causal pathway?	NO. They are not well identified and described.	Prodoc
<b>Overall rating for Intended Results and causality</b>	<b>Moderately Satisfactory (MS)</b>	
<b>Efficiency</b>		
Are any cost- or time-saving measures proposed to bring the project to a successful conclusion within its programmed budget and timeframe?	NOT clearly specified in the ProDocs	Prodoc
Does the project intend to make use of / build upon pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. to increase project efficiency?	YES, whenever possible.	Prodoc
<b>Overall rating for Efficiency</b>	<b>Satisfactory (S)</b>	
<b>Sustainability / Replication and Catalytic effects</b>		
Does the project design present a strategy / approach to sustaining outcomes / benefits?	YES. The projects design generally shows the concern for sustaining the results (capacity building, national institution involvement, co-financing, etc.)	Prodoc

Does the design identify the social or political factors that may influence positively or negatively the sustenance of project results and progress towards impacts? Does the design foresee sufficient activities to promote government and stakeholder awareness, interests, commitment and incentives to execute, enforce and pursue the programmes, plans, agreements, monitoring systems etc. prepared and agreed upon under the project?		The Projects generally foresee sufficient activities to promote stakeholders involvement and to improve their capacity to plan and monitor Biosafety issues. On the contrary, social and political factors affecting the sustainability of the results and progress towards impact have been clearly underestimated	Prodoc
If funding is required to sustain project outcomes and benefits, does the design propose adequate measures / mechanisms to secure this funding?		YES, the commitment of the Governments	Prodoc
Are there any financial risks that may jeopardize sustenance of project results and onward progress towards impact?		In some countries there may be problems in accommodating Biosafety issues in the National Budgets at the suitable level.	
Does the project design adequately describe the institutional frameworks, governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. required to sustain project results?		NO. This a major drawback of the projects design.	Prodoc
Does the project design identify environmental factors, positive or negative, that can influence the future flow of project benefits? Are there any project outputs or higher level results that are likely to affect the environment, which, in turn, might affect sustainability of project benefits?		YES. Actually, the projects are supposed to support the countries in assessing and managing any environmental risk from LMOs, based on the Precautionary Principle (as stated in the CPB). Any failure in attaining higher level results may jeopardise the sustainability of the projects benefits and undermine the Precautionary Principle.	Prodoc
Does the project design foresee adequate measures to catalyze behavioural changes in terms of use and application by the relevant stakeholders of (e.g.):	i) technologies and approaches show-cased by the demonstration projects;	YES, many capacity building activities are foreseen	Prodoc
	ii) strategic programmes and plans developed	YES, national laws, regulations and guidelines are foreseen. .	Prodoc
	iii) assessment, monitoring and management systems established at a national and sub-regional level	YES, at national level. Not yet at Regional level	Prodoc

Does the project design foresee adequate measures to contribute to institutional changes? [An important aspect of the catalytic role of the project is its contribution to institutional uptake or mainstreaming of project-piloted approaches in any regional or national demonstration projects]	YES. The Projects foresee relevant measures for that purpose, namely the BCH (Biosafety Clearing House), the NCC (National Coordinating Mechanisms), the support to the NBA (Nat. Biosafety Authority)	Prodoc TOR 1.C
Does the project design foresee adequate measures to contribute to policy changes (on paper and in implementation of policy)?	YES, for instance through Biosafety National Laws and through institutional mechanisms such as the BCH.	ProDoc
Does the project design foresee adequate measures to contribute to sustain follow-on financing (catalytic financing) from Governments or other donors?	YES, through Co-Financing	ProDoc
Does the project design foresee adequate measures to create opportunities for particular individuals or institutions ("champions") to catalyze change (without which the project would not achieve all of its results)?	YES. Again, the BCH is a good example of a mechanism that can catalyze changes also in other institutions, leading by example. NPC (Nat. Project Coordinator) can surely upgrade their management capacities through the project	Prodoc
Are the planned activities likely to generate the level of ownership by the main national and regional stakeholders necessary to allow for the project results to be sustained?	YES, national priorities and ownership are at the core of the projects approach.	Prodoc
<b>Overall rating for Sustainability / Replication and Catalytic effects</b>	<b>Satisfactory (S)</b>	
<b>Risk identification and Social Safeguards</b>		
Are critical risks appropriately addressed?	There has been a general underestimation of the critical risks of implementing projects in an area (biosafety) with strong political significance, economic and social conflicting interests and scientifically controversial issues.	ProDoc

Are assumptions properly specified as factors affecting achievement of project results that are beyond the control of the project?	NO. There has not been a thorough assessment of assumptions and risks	Prodoc
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Are potentially negative environmental, economic and social impacts of projects identified?	Potential negative environmental, social and economic impacts of LMOs have not been identified and analysed in the ProDocs.	Prodoc
<b>Overall rating for Risk identification and Social Safeguards</b>	<b>Moderately Unsatisfactory (MU)</b>	
<b>Governance and Supervision Arrangements</b>		
Is the project governance model comprehensive, clear and appropriate?	Partially. The model is clear (Support to NBA, and to NCC) but perhaps too much “public sector –oriented”. It is not clear, in fact, how Civil Society comes into the picture as far as governance issues are at stake (e.g. farmers associations, consumers associations, environmental NGOs, private sector). Appropriateness of the model is therefore questionable.	Prodoc
Are roles and responsibilities clearly defined?	Yes, they are clearly defined.	Prodoc
Are supervision / oversight arrangements clear and appropriate?	Again, they are clear but not sure about appropriateness.	Prodoc
<b>Overall rating for Governance and Supervision Arrangements</b>	<b>Moderately Satisfactory (MS)</b>	
<b>Management, Execution and Partnership Arrangements</b>		
Have the capacities of partners been adequately assessed?	This is, perhaps, the weakest point of the project design. In fact, a certain “fit for all” approach has been adopted under the implicit general assumption that partners management capacities would be evenly found in the countries,	Prodoc

Are the execution arrangements clear?	Yes, they are clear. In-country partners have the main responsibility for implementing the project, under the coordination and supervision of UNEP.	Prodoc
Are the roles and responsibilities of internal and external partners properly specified?	Yes, as far as internal partners are concerned. Role and responsibilities of external partners are not clear..	Prodoc
<b>Overall rating for Management, Execution and Partnership Arrangements</b>	<b>Moderately Satisfactory (MS)</b>	
<b>Financial Planning / budgeting</b>		
Are there any obvious deficiencies in the budgets / financial planning	No obvious deficiencies as far as activities / operation budgeting is concerned	Prodoc budget
Cost effectiveness of proposed resource utilization as described in project budgets and viability in respect of resource mobilization potential	YES. The projects generally take into account the potential of available financial resources and plan their cost-effective utilisation.	Prodoc budgets
Financial and administrative arrangements including flows of funds are clearly described	YES. Financial and administrative arrangements are clear.	Prodoc
<b>Overall rating for Financial Planning / budgeting</b>	<b>Highly Satisfactory (HS)</b>	
<b>Monitoring</b>		
Does the logical framework: <ul style="list-style-type: none"> <li>capture the key elements in the Theory of Change for the project?</li> <li>have 'SMART' indicators for outcomes and objectives?</li> </ul>	The first group of Demonstration Projects (8) were not required to present a Log Frame. The second group of Implementation Projects (7) do have a Log Frame, but are	Prodoc

<ul style="list-style-type: none"> <li>• have appropriate 'means of verification'</li> <li>• adequately identify assumptions</li> </ul>	<p>generally inappropriate to capture the key elements of the TOC (either because too poor or excessively long). The level of adequacy of SMART indicators, appropriate means of verification and assumptions is uneven among the projects, as well as the use of project terminology (confusion between levels of results, indicators and outputs, etc.)</p>	
<p>Are the milestones and performance indicators appropriate and sufficient to foster management towards outcomes and higher level objectives?</p>	<p>Appropriate milestones and indicators are unevenly present in the projects. Whether they are sufficient to foster management towards outcome and higher level objectives is questionable, since they are (when present) mostly quantitative. When dealing with Capacity Building issues, quality is essential.</p>	Prodoc
<p>Is there baseline information in relation to key performance indicators?</p>	<p>The baseline information is not sufficient for some projects, but quite exhaustive in some other, particularly the first group.</p>	Prodoc
<p>Has the method for the baseline data collection been explained?</p>	<p>The methodology for establishing the NBF foresees some steps to be done, among them a baseline data collection, mainly through national surveys.</p>	Prodoc
<p>Has the desired level of achievement (targets) been specified for indicators of outcomes and are targets based on a reasoned estimate of baseline?</p>	<p>In many cases the level of achievement is specified. In some cases (mostly in the first group) there is a clear comparison with the baseline situation and the "incremental" value of the project (as required by GEF)</p>	Prodoc;
<p>Has the time frame for monitoring activities been specified?</p>	<p>There are clear and defined deadlines for technical and financial reporting.</p>	Prodoc;

Are the organisational arrangements for project level progress monitoring clearly specified?	Yes, through output delivery (see above), as well as project backstopping and coordination by UNEP.	Prodoc;
Has a budget been allocated for monitoring project progress in implementation against outputs and outcomes?	Yes, there is the "lump sum" / project given by GEF to UNEP for its overhead cost	
Overall, is the approach to monitoring progress and performance within the project adequate?	Yes, the approach to monitoring is adequate.	Prodoc;
<b>Overall rating for Monitoring</b>	<b>Moderately Satisfactory (MS)</b>	
<b>Evaluation</b>		
Is there an adequate plan for evaluation?	NO. Terminal reports cannot be considered as evaluation report. No internal final reviews (e.g. at NCC level) are foreseen.	Prodoc
Has the time frame for Evaluation activities been specified?	Not clearly defined	Prodoc,
Is there an explicit budget provision for mid term review and terminal evaluation?	NO, There were no explicit budget for MTR or TE because at the time these projects were prepared evaluation had to be funded by the Fee.	Prodoc,
Is the budget sufficient?	NO	
<b>Overall rating for Evaluation</b>	<b>Moderately Unsatisfactory (MU)</b>	



## Annex 11. BIBLIOGRAPHY

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## Annex 12. BRIEF CVs of the CONSULTANTS

### Team Leader, VANGA SIVA REDDY, Ph.D.

PRESENT POSITION AND ADDRESS: Dr. Vanga Siva Reddy Ph.D., Group Leader, Plant Transformation Group, International Center for Genetic Engineering and Biotechnology (ICGEB), Aruna Asaf Ali Marg, New Delhi, India. Tel: +91-11- 26741358/61, ext 351, email: vsreddy@icgeb.res.in

#### Qualifications:

Nagarjuna University, Andhra Pradesh	B.Sc.	1977	Botany
Institute of Advanced Studies Meerut University	M.Sc.	1980	Botany
Bose Institute, Calcutta University	Ph.D.	1988	Science

#### Professional Experience:

1981-1982 Junior Research Fellow, Andhra University, India; 1983-1984 Senior Research Fellow (ICAR), Bose Institute, India; 1984-1986 Research Associate, (ICAR), Bose Institute; 1986-1987 Research Officer, Bose Institute; 1987-1988 Senior Research Fellow, Bose Institute; 1988-1996 Research Scientist, ICGEB; 1996-1997 Visiting Scientist, Waksman Institute, NJ, USA, 1997- Senior Research Scientist and Group Leader, ICGEB.

#### Research experience, biosafety related activities and organizational skills, in brief:

Dr. V Siva Reddy, Ph.D. is the Group Leader at ICGEB New Delhi Component, India. Dr. Reddy received Ph.D from the University of Calcutta in 1988, joined ICGEB in the same year 1988 (the same year it was established) and continued to work as the Group Leader. He also worked at the University of Purdue, USA and the Waksman Institute, Rutgers, USA as a visiting scientist. He is a member of Research Advisory Committee of Vasantdada Sugar Institute (VSI) and Central Institute for Cotton Research (CICR). He served as member of several DBT task Force committees, Review Committee on Genetic Manipulation (RCGM) the second highest Biosafety regulatory body in India, involved in various aspects of the Risk assessment of GMO's in India and made significant contributions in the revised biosafety guidelines that are being followed currently. Organized a number of Biosafety training courses for researchers and regulators from India and various countries. Participated in the Ministry of Environment and Forests (MoEF) activities supported by World bank on Biosafety, contributed significantly as a PI of one sub-project and organized training workshops. Prepared a document for MOEF under the World bank project "Environmental Risk Assessment, Socio-Economic Considerations and Decision-Making Support for LMOs in India. He also organized important CBD meetings on behalf of MoEF: The fourth Coordination Meeting and 5th Liaison group meeting for Governments and Organizations Implementing and Funding Biosafety Capacity-Building of the Convention on Biological Diversity (CBD) in 2008 at ICGEB. Dr Reddy is serving as a Board member of the International Society for Biosafety Research (ISBR) for the last three years that publish Environmental Biosafety Research (EBR Journal) and also organize ISBGMO meetings biannually. Dr. Reddy is a co-author in a recent publication related to biosafety risk assessment and regulatory frameworks covering worldwide situation [W. Craig, V. S. Reddy, J. C. Medaglia (2011) Transgenic Crops, Risk Assessment and Regulatory Framework (Worldwide) Encyclopedia of Sustainability Science and Technology: Article 00837].

Major areas of interest is Plant Molecular Biology and Biotechnology. Focus of the research is plant based molecular farming for large scale production recombinant proteins of interest in human health and their downstream process. Development of technologies for transgene containment. Also a major interest is in the area of biofuels/bioenergy. Other areas of interest include genomics of cotton fiber development with a major emphasis on the identification of genes associated with the quality of the fiber using proteomic and transcriptomic approaches.

Published more than 45 papers in peer reviewed journals, filed/obtained patents, trained a large number students in various aspects of biotechnological applications, guided Ph.D students from India and abroad.

Organized a FAO and BARC supported Practical course “Hands-on Training on Application of Genetic Engineering in Crop Improvement: Dhaka, Bangladesh. Generated extramural funding and created infrastructure for dosing advanced genomics research at ICGEB.

### **Supporting Consultant, CAMILLO RISOLI**

Camillo Risoli (Italy, 24/11/1953) is a seasoned international expert in rural development and environmental management. He has a long experience (more than 30 years) in the implementation, coordination and management of projects and programs in Africa and Latin America, with different donors and agencies. Capacity and Institution Building for Rural Development is his main area of expertise.

Camillo has worked as an expert, a chief technical adviser and an independent consultant for UN agencies (FAO, UNEP), Bi-lateral Cooperations (SDC – Swiss Cooperation, Italian cooperation, EC Delegations) and for International NGOs. He has been Team Leader in Long-Term Missions in Nicaragua (1980-82), Cape Verde (1986-96), Mozambique (1996-99) and Zimbabwe (2003-2005).

Food Security and Poverty Reduction have been at the core of his professional commitment, through Community-based projects and participatory actions, Organization & training of rural associations, Sustainable land use and agriculture, Partnership strengthening and networking (Public, Private, Civil Society) for decentralised and participatory local development.

Mainstreaming Environmental issues in Pro-Poor Strategies has been a main component of his action, through Soil & water conservation projects, Reforestation and agro-forestry initiatives, Watershed management and land use planning, Sustainable management of natural resources (soil, water, forests and bio-diversity).

Camillo has acquired a robust experience in advising on national policies and strategic planning for rural development and a solid background in PCM (Programme Cycle Management) and in Project Monitoring & Evaluation (M&E) skills.

Since 2005, Camillo works as an Independent Consultant and has carried out and led relevant Evaluation missions, such as the Mozambique National Action Plan for Food Security (FAO), the LADA Project - Land Degradation Assessment in Drylands - (FAO/UNEP-GEF) in Argentina and China, the Post-Conflict Rural Development in Ivory Coast (FAO/ADB), the setting of the M&E System for FAO/CLCPRO Program (Commission for Locust Control in Western Africa and Maghreb Region).

Camillo has a graduate degree in Agricultural Sciences, a Post-Graduate Diploma in Environmental Management at London University and a PhD in Adult Education. He has published with FAO training manuals and methodological guides for trainers and extensionists.

## Annex 13. Stakeholders' Comments on First Draft Evaluation Report and Evaluators' response

COMMENTS by Countries	EVALUATORS' REPLY
<p>SLOVAKIA: In Annex 2, part IV.D , table 2: country visits (on page 92) is Ing. HenrietaČajková mentioned as NPC (National Project Coordinator), which is not true.</p> <p>Mrs.Čajková is the head of the Department of environmental risks and biosafety, which is the NBA (National Biosafety Authority), „NPC“ shall be deleted.</p>	<p>NPC deleted</p>
<p>MOLDOVA: Minor redaction in the text might improve the report</p>	<p>We will consider their suggestion after we are reach the final stages after incorporating suggestions from all the stakeholders</p>
<p>LITHUANIA: No major comment to be taken into account</p>	<p>We sincerely appreciate their comments</p>
<p>KENYA: the achievements made so far are to a great extent linked to the support and facilitation received through the UNEP-GEF implementation Project.</p> <p>Please note that the NBA website is now functional and linked to the National BCH. The weblink to the Kenyan National Biosafety Authority is <a href="http://www.biosafetykenya.go.ke">www.biosafetykenya.go.ke</a></p> <p>One outcome that is still a challenge to us is public awareness, information and participation in decision making. We have various programmes within our institutions and the National Council for Science and Technology that are aimed at improving the present situation.</p>	<p>Indeed what is being pointed out is reflected in the report (see co-financing tables). Besides the UNEP-GEF support, the Kenyan Government support increased, though slightly, from what it has committed initially. This reflects the positive aspect of the Government towards NBFs.</p> <p>National BCH weblink is already mentioned in Annex 9: Projects data compilation</p> <p>NBFs is a dynamic process and several aspects needs to be addressed from time to time. Public awareness is one such aspect and should be part of all future activities of the NBFs.</p>
<p>CZECH REPUBLIC: List of Acronyms: To add: IFAD (missing) Correction: UNEP - United Nations Environment Programme</p>	<p>IFAD: International Fund for Agricultural Development (included Error corrected</p>

Report

P. 34, ad 99

Closure of the laboratory in Brno, Czech Republic was not good but with no serious consequences as the task of this laboratory was overtaken by the Laboratory of the Crop Research Institute, Prague

On the other hand some other envisaged restrictions due to funds limitation can be more important for the function of National Biosafety system.

P. 35 ad 100, p. 37 ad 113, 114

Cooperation between Czech and Slovak Republics can be also underlined - during preparation, implementation and closure of the Project (joint meetings and workshops - including inception and terminal ones, reciprocal participation of corresponding experts and NPCs in conferences and workshops, mutual consultations).

P. 37 ad 117

preceding projects were useful in this respect.

P. 39 ad 128

Polls on public opinion give interesting results, nevertheless they are relatively costly. Therefore it is questionable if to use funds available (either from national or international sources) for this or for other purposes supporting proper functioning of the National Biosafety System.

P. 40 ad 131, 136

Extra funding was used also in the Czech Republic but strictly to the Project we tried to be in line with planned budget as requested (at least at the beginning of the Project).

Ad 156

Participation in activities of the National Commission on the Use of GMOs depends on its main task - if this is meant as scientific advisory body, in such a case participation of civil society or NGO representatives is a little complicated. Usually such organizations could not find corresponding experts.

On the other hand in other national fora for GMOs use participation of mentioned group is requireable.

Ad 165

Communication between NPC and NEA represented no problem in the Czech Republic, very close contact existed thanks to

Closure of any laboratory (in this particular case) or any other component or change of roles of a component is anticipated considering the way Governments function. As long as such closure is not affecting the normal function of NBF, it will not be viewed as a setback. In this specific case the function of the laboratory at Brno is taken over by the other laboratory at the Crop Research Institute at Prague, the NBF is expected to function normally.

Suggestion incorporated in Para 111

This view is reflected at several places in the report

An important feature of UNEP-GEF funded projects is the flexibility in focusing on a particular aspect as the country feels it necessary. Each country was given enough scope to take up issues as per their national policies keeping in view the implementation of the Cartagena protocol. This is viewed by the funding agency as an important aspect in the development of a NBF project to address various articles of Cartagena protocol and Czech Republic has taken up public opinion as an important aspect.

From the comment it is not clear if they have spent any additional amount than what was shown in the co-financing table..

There are certain countries (Eg. Lithuania) who have taken civil society and NGO

<p>facilities offered by NEA.</p> <p>P. 49 Recommendations  i Legislation framework is crucial. Nevertheless it could not be functioning as such, its implementation has no minor importance (see e.g. experience from the Aarhus Convention).  iv See ad 156 - expertise availability</p> <p>P. 92  Table - Czech Republic: Correction required - Milena Roudna, adviser, Environmental Risks and Ecological Damage Department, Ministry of the Environment</p> <p>P. 106, 108 - Table  Numbers indicated  Great differences among countries, these numbers exceeding 1 000 are a little suspicious, at least on the basis of experience with organization of numerous workshops and trainings in our country.  Maybe that the reason consists in different criteria or understanding taken into account while responding questionnaire.</p> <p>P. 117 - Table Czech Republic  Final Workshop on BCH in 2008 (closure of corresponding sub-Project)</p> <p>GMO instead of OGM - 2x  Czech Republic (R - capital letter)</p> <p>Note.  At the end of the Report pages numbering missing.</p>	<p>representatives at the highest decision making bodies. Although, they may not be fully aware of all scientific aspects of GMOs but their views are considered equally important in the overall decision making process as they too are the major stakeholders.</p> <p>Page 165 contained only bibliography where some information from the following two articles (5 and 6) were referred. Camillo-any comment.</p> <p>Seems important point but not clear on what is expected in the report.</p> <p>Milena Roudna,: Affiliation corrected</p> <p>Final workshop BCH in 2008 included</p> <p>OGM corrected in three places (one in fact sheet of national Biosafety of Lithuania also)</p>
<p>VIETNAM: see addition in the text in track changes</p>	<p>All three suggestions incorporated</p> <p>Both suggestions incorporated</p>

<p>CAMBODIA: see addition in the text in track changes</p>	<p>Web site incorporated</p> <p>Sentence changed to "... different agricultural potential or productive system, capacity and / or to the general development...."</p> <p>Changed from Biosafety National Laws to "National Laws on Biosafety"</p> <p><b>Sentence modified</b> "and the law on biosafety in 2008"</p>
<p>UGANDA: page 21 See comment from Alex on this. Quoted in email sent to you on 28 May</p>	<p>"handling" is changed to "handle"</p> <p>Deleted "the"</p> <p>Sentence changed to "Uganda approved its Biotechnology and Biosafety Policy in 2008;"</p> <p>"streamline" changed to "streamlining"</p> <p>Sentence changed to "Uganda, does not yet have an approved National Biosafety Law, but is implementing a set of biosafety guidelines developed under the current/existing regime"</p> <p>Sentence changed to "Countries where the biosafety law and enacting regulations are not yet in place (e.g. Namibia, Uganda), or that have not so far made any approval decisions (e.g. Cambodia, Cameroon), consequently have a BCH with little information.</p> <p>Sentence changed to "still cannot claim to have a fully operational NBF in place"</p> <p>Whereas a biosafety law is necessary, having it in place may not necessarily imply an NBF is effective.</p> <p>The suggestion from Uganda is not very convincing to take off "Uganda" from</p>



	<p>that list.</p> <p>The Project Document includes laws and regulations as conditions for a workable and effective NBF. In any way this is the opinion also of the evaluation team. Uganda may have different opinions and if they want, their statement can be kept in record.</p>
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