United Nations Environment Programme

Terminal Evaluation of the Project

"Development of National Biosafety Frameworks"

Camillo Risoli
Julia Niggebrügge

Evaluation Office

May 2016

TABLE OF CONTENTS

Project Identification Table

Project "Development of National Biosafety Frameworks"

GEF project ID:	875 (initial) 2341 (1st add on) 2582 (2nd add on)	**IMIS number:**	GFL/2716-01-4319
GEF OP #:	EA	**Focal Area(s):**	Biodiversity
GEF approval date:	November 2000	**GEF Strategic Priority/Objective:**	Operational Program: Enabling Activity/Capacity Building for Implementation of the Cartagena Protocol on Biosafety
UNEP approval date:	02/01/2001 (ANUBIS)	**UNEP PIMS ID:**	GF/6010-01-01
UNEP Focal Area(s):	Environmental governance	**PoW Output(s):**	Tools to support implementation of an MEA
Expected Start Date:		**Actual start date:**	23/05/2001 (ANUBIS)
Planned completion date:	December 2004	**Actual completion date:**	11/2011 (last completion date of Nat. Projects). Still pending UNEP closure of the Global Project (Expected: September 2016, pending approval of Budget Revision n.13)
Planned project budget at approval:	38.433.546 USD	**GEF Initial Allocation**	26.092.083 USD
1st Add-on GEF (2003)	5.218.420 USD	**2nd Add-on GEF (2005)**	2.609.208 USD
Total GEF Allocation	33.919.711 USD	**GEF grant expenditures reported as of 04/2016**	33.794.709 USD
Expected UNEP & Countries Co-financing	12.341.463 USD	**Secured co-financing reported as of 04/2016**	13.163.286 USD
Total budget	46.261.174 USD	**Total expenditures reported as of 04/2016**	46.957.995 USD
Leveraged extra financing:	202.167 USD (DFID and Sweden)		
Mid-term review/eval. (planned date):	August 2003	**Mid-term review/eval. (actual date):**	August 2003
No. of revisions:	12 (13th pending approval)	**Date of last Revision:**	07/2012 (rev 12) Rev. 13 (04/2016) pending approval
Date of last Steering Committee meeting	June 2007	**Terminal Evaluation (actual date):**	November 2015 – March 2016
Date of financial closure:	Planned 09/2016		

List of Acronyms and Abbreviations

ABS	Access and Benefit Sharing (Nagoya Protocol)
ANUBIS	A New UNEP Biosafety Information System
ASEAN	Association of South East Asian Nations
BCH	Biosafety Clearing House (of the CPB)
BSP	Bali Strategic Plan for Technology Support and Capacity-building
CBD	Convention on Biological Diversity
CEE	Central and Eastern Europe
CGIAR	Consultative Group for International Agricultural Research
CIAT	International Center for Tropical Agriculture
CNA	Competent National Authority
COMESA	Common Market for Eastern and Southern Africa
COP-MOP	Conference of the Parties serving as the Meeting of the Parties
CPB	Cartagena Protocol on Biosafety
DELC	Division of Environmental Law and Conventions (of UNEP)
DEPI	Division of Environmental Policy Implementation (of UNEP)
EA	Expected Accomplishments (of UNEP)
ECOWAS	Economic Community Of West African States
EFSA	European Food Safety Authority
EO	Evaluation Office (of UNEP)
ET	Evaluation Team
EU	European Union
FAO	Food and Agriculture Organization (of UN)
FFP	Food, Feed and Processing (GMOs for)
FMO	Fund Management Officer (of UNEP)
GE	Gender
GEF	Global Environment Facility
GE & HR	Gender and Human Rights
GMO	Genetically Modified Organism
GRULAC	Latin American and Caribbean Group (UN regional group)
HR	Human Rights
ICGEB	International Center for Genetic Engineering and Biotechnology
ICARDA	International Center for Agricultural Research in the Dry Area
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IFAD	International Fund for Agricultural Development
IICA	Inter-American Institute for Cooperation on Agriculture
IS	Intermediate States (Theory of Change)
ITPGRFA	International Treaty on Plant Genetic Res. for Food and Agriculture
IUCN	International Union for Conservation of Nature
LAC	Latin America and the Caribbean
LDC	Least Developed Countries
L&R	Liability and Redress (Nagoya/Kuala L. Suppl. Protocol)
LMO	Living Modified Organism
MEA	Multilateral Environmental Agreements
MoA	Ministry of Agriculture
MoE	Ministry of Environment
M&E	Monitoring and Evaluation
MT	Management Team (of the Project)
MTE	Mid-Term Evaluation
MTS	Medium Term Strategy (of UNEP)
NCA	National Competent Authority
NBC	National Biosafety Committee (Commission)

NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plan
NCC	National Coordinating Committee (Commission)
NEA	National Executing Agency
NEPAD	New Partnership for Africa's Development
NGO	Non-Governmental Organisation
NPC	National Project Coordinator
OECD	Organisation for Economic Co-operation and Development
PIR	Project Implementation Review
PoW	Programme of Work (of UNEP)
ProDoc	Project Document
RA	Risk Assessment
RM	Risk Management
RO	Regional Office (of UNEP)
ROLAC	Regional Office for Latin America and the Caribbean (of UNEP)
ROtI	Review of Outcomes to Impact
SAARC	South Asian Association for Regional Cooperation
SAC	SAARC Agriculture Center
SADC	Southern Africa Development Community
SCBD	Secretariat of the Convention on Biological Diversity
SIDS	Small Islands Developing States
STAR	System for Transparent Allocation of Resources (of GEF)
TE	Terminal Evaluation
TM	Task Manager (Biosafety)
ToC	Theory of Change
ToR	Terms of Reference
UEMOA	West Africa Economic and Monetary Union
UNCCD	United Nations Convention to Combat Desertification
UNCT	United Nations Country Team
UNDAF	United Nations Development Assistance Framework
UNDP	United Nations Development Programme
UNEG	United Nations Evaluation Group
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
USDA	United States Department of Agriculture
UWI	University of West Indies
WB	World Bank
WEOG	Western European and Others Group (UN regional group)
WHO	World Health Organization
WTO	World Trade Organisation

Executive Summary

1 Following the adoption of the Cartagena Protocol on Biosafety (CPB) in 2000, UNEP was asked to conceive and implement a full package of projects covering a global GEF programme, namely "to assist the whole of GEF eligible countries to prepare for the entry into force of the Protocol". In that context, the project "Development of National Biosafety Frameworks" was conceived and gradually implemented in 123 countries through national, regional and global activities guided by the decisions of the parties through COP/MOPs. The main expected project outcome at country level was the preparation of the National Biosafety Framework (NBF), a combination of policy, legal, administrative and technical instruments for managing the safe transfer, handling and use of Living Modified Organisms from modern biotechnology.

2 The project started in June 2001 with an estimated original duration of three and half years (42 months) and the perspective to benefit 100 eligible countries. The initial budget was supplemented by two further GEF allocations as indicated in the table below, in order to integrate additional countries (123 at the end of the project).

	GEF Allocation USD	UNEP & Countries Co-financing USD	Total Budget USD
Initial Allocation (2001)	26,092,083	12,341,463	38,433,546
2nd Allocation (2003)	5,218,420	-	5,218,420
3rd Allocation (2005)	2,609,208	-	2,609,208
TOTAL	33,919,711	12,341,463	46,261,174

3 The project was grounded in the GEF "Initial Strategy for assisting countries to prepare for the entry into force of the CPB" (2000) and was conceived with two main Components plus a third Component of Global Support:

Component 1	Promoting Regional and Sub-regional collaboration and exchanges of experience
Component 2	Preparation of National Biosafety Frameworks (NBF)
Component 3	Global Support Component

4 The project has quite successfully supported the countries to prepare their NBF at the best of their capacities, which were, in fact, very dissimilar. The variable baseline situation has led to uneven results in terms of quality and follow-up of the NBF produced. The analysis of 37 sample NBFs shows that, while many countries produced a pretty workable framework, though at a variable extent, others did not succeed in doing so (see table 1 in chapter 4.3.1). Reasons for that have to be found in the lack of previous experience in biotechnologies and biosafety, the scarce availability of national skilled human resources and the complexity or weakness (fragmentation and dispersion) of the institutional framework. In fact, a GEF Evaluation in 2005 had already pointed out that "the umbrella approach was especially effective in countries that could easily incorporate the support into their own biosafety systems; it was much less effective where the need for support was greater, and/or the initial conditions were less receptive".

5 The initial asymmetry between countries is also at the basis of their uneven progress in NBF implementation (see chapter 4.3.2) and eventually in the pathway towards project impact (see chapter 4.3.3). As a result, admitting certain generalisation, some 25-30% of the countries have moved quite steadily towards NBF implementation and to higher levels of results (improved decision-making and biosafety governance at national level), another 25-30% stayed well behind (no significant steps towards NBF implementation), whereas the majority of the countries (40-50%) has somewhat progressed in setting the

NBF (e.g. a national law, Nat. Competent Authority in place), yet cannot claim to have it fully operational due to evident flaws (e.g. lack of regulations and administrative procedures, insufficient institutional up-take and stakeholders participation, etc.).

6 Similarly, as a consequence of the above, the sustainability of the results achieved so far is also uneven (see chapter 4.4.). Socio-political sustainability is particularly challenged by the controversial nature of Biosafety and by the objective difficulty in taking on board different strategic visions and sociological "discourses", as well as varied and somewhat diverging economic interests around GMOs development.

7 Overall, the setting and consolidation of the National Competent Authorities (NCA) is quite satisfactory but there is room for improving the institutional uptake of national stakeholders by expanding their participation both in the National Coordinating Committees and in other cooperative instruments (e.g. technical committees, working groups, etc.). While alternative forms of participation (e.g. social mobilisation, lobby and advocacy) are absolutely legitimate, the institutional involvement of national stakeholders in formal and inclusive biosafety decision-making bodies is an objective to be firmly pursued if socio-political sustainability has to be improved.

8 The setting of a national legal framework has proved to be a burdensome task in many developing countries for several reasons: the character of Biosafety (involving many key-players), long and heavy institutional mechanisms of decision-making, contrasting views and conflicting interests, governmental changes, lack of knowledge among Parliaments' members and other decision-makers, among others. Solid systems for handling applications and for monitoring and enforcement have still to be achieved in most of the countries (see chapter 4.3.2).

9 The project has hugely increased public awareness and information, yet public participation has to be improved, particularly around the process of decision-making regarding GMOs for Field Trials, for Deliberate Release and for FFP (Food, Feed and Processing). In many cases, the information is irregularly and unevenly uploaded by the countries to the BCH, which is evidently an area of concern, as far as transparency and public information are concerned (see chapter 4.3.2).

10 Capacity building actions have largely contributed to enhance national awareness and information and, to some extent, technical capacities. However, specific priority needs have to be assessed and matched by focussed actions of more practical trainings, particularly in Risk Assessment and Risk Management. Risk Communication is also an area with considerable room for improvement, namely in countries already exposed to GMOs, in order to provide decision-makers at different levels (Politicians, Managers, Farmers, Consumers) with more neutral and scientifically-sound information (see chapter 4.3.2).

11 Moreover, socio-political and institutional sustainability has to prove effective and inclusive under more challenging situations, i.e. when real decision-making processes have to be implemented in response to concrete GMOs applications, which, so far, happened only in 28 countries out of the 147 GEF eligible Parties (last updated data on BCH, 2012, see table in chapter 4.3.3, section d), with a strong concentration (93% of decisions on applications) in just 10 countries: Brazil, Colombia, Costa Rica, Malaysia, Mexico, Philippines, South Africa, Turkey, Uruguay and Vietnam (see graphic in chapter 4.3.3).

12 The integration of Biosafety in National Biodiversity Strategies and in the mainstream of Sustainable Development is timidly visible. Gender and Human Rights issues, substantive parts of both Sustainable Development and GMOs development (due to its bearing on equity and transparency in decision-making process), were absent in virtually all the NBF Development and Implementation projects (see chapter 4.4.1), though, admittedly, the issue falls under article 26, which is still under review and discussions, including conceptual clarity. For instance, new GEF implementation projects under GEF 4 are not approved without linkages to the NBSAPs and in GEF 6 gender issues are highlighted for integration.

13 Biosafety financial sustainability (see chapter 4.4.3) is a growing concern, particularly, but not only, in developing countries, where having a fully operational NBF (creating biosafety legislation and institutions, monitoring and inspection systems, etc.) can bring about relevant opportunity-costs and trade-off with other national priorities.

14 On its side, environmental sustainability will much depend on how crucial issues will be handled, such as Risk Assessment and Risk Management, co-existence with traditional and /or biological agriculture, as well as GMOs development in areas of origin of genetic resources. These, among others, should be priority matters to address by tailored, in-country and practical trainings (case studies, "hands-on" exercises, etc.). The role of International and regional Research Centres and of selected Academic Institutions should be enhanced in the perspective of creating regional and sub-regional "Poles of Excellence" to support countries with scientifically-sound inputs regarding GMOs and Biosafety.

15 The Regional and sub-regional dimension is one of the pillar of GEF "Initial Strategy" on Biosafety (2000) and one of the component of the NBF Development Projects. Actually, Regional and sub-regional workshops have been a relevant tool of the project for increasing and improving countries' capacities in a quite novel subject like biosafety. The NBF Implementation Projects have equally fostered this dimension through sub-regional meetings and workshops, as well as other instruments of exchange and collaboration (e.g. study tours, exchange of training and awareness material). UNEP has also formulated several Regional Projects and submitted to GEF, of which, eventually, only one is on-going in the Caribbean Sub-region. Overall, there is surely room for exploring more incisive and flexible forms of multi-country initiatives at sub-regional level focussing on specific subjects (e.g. the on-going network of GMOs detection laboratories in Southern Africa) and emphasizing South-South Cooperation, so far quite modestly represented in the Biosafety Programme. Regional and sub-regional approach is in fact also challenged by the mechanism of GEF STAR (System for Transparent Allocation of Resources) national allocation, as discussed in chapter 4.3.2, under section g).

16 The growing interest for GMOs development worldwide and particularly in developing countries, calls for more incisive actions to enhance the global capacity to effectively implement the Protocol. GEF-UNEP support has been so far pivotal to create the overall groundwork, which is now in need of more impact-oriented actions emphasising the "programming" dimension, limiting risks of dispersion and fragmentation in a growing number of national projects and improving cost-effectiveness and overall efficiency. The classification of the countries according to their progress in the implementation of the NBF (see chapter 4.3.3. section c) could be helpful in assessing homogeneous needs and priorities and matching them through specific "gap-filling" actions.

17 The sustainability of UNEP Biosafety Strategy (see chapter 4.4.5) presents elements of concern in need to be worked out. Biosafety is generally under-represented in UNEP Mid-term Strategies and Programme of Work (PoW) despite the relevant portfolio of projects implemented. The channels of communication and coordination with the related cross-cutting Sub programmes (e.g. Environmental Governance) are also flawed. The number of Human Resources devoted to Biosafety is actually too low to cope with the growing needs proceeding from the large and diversified portfolio of Projects and initiatives. At decentralised level, there is only one Regional Office (ROLAC / Panama) with a dedicated Biosafety TM.

18 In the framework of the Programming Exercise suggested above, it is necessary to strengthen and "reset" Biosafety Human Resources through a more strategic role of the Biosafety Unit in Nairobi and its increased decentralization at regional level, particularly in Asia-Pacific Region, but probably also at some sub-regional level in Africa and elsewhere, as reflected in Recommendation 4. The shaping of a more strategic programming approach and a more solid institutional anchorage of Biosafety within UNEP strategy, is central in the Recommendations of the Evaluation that are presented below.

19 The role of UNEP and other UN agencies directly involved in GMOs (e.g. FAO) as "neutral broker" and "knowledge organisation" is strongly challenged, as far as biosafety is concerned. Overall, stronger

partnerships have to be pursued to gain credibility and acceptability among national and international stakeholders. More structured forms of cooperation between UNEP and FAO are needed to harmonise their initiatives. The partnership with the international research centres of the CGIAR (Consultative Group for International Agricultural Research) and other partners (e.g. ICGEB, International Center for Genetic Engineering and Biotechnology) has to be consolidated, too. There is also room for a more effective inclusion of GMOs and biosafety agenda in the UN Global Compact on Corporate Social Responsibility.

20 As requested by the TOR of the Evaluation, an overall ratings table for the different evaluation criteria has been prepared. Due to the number of countries, national projects and the variety of situations involved, the "average" rating inevitably leads to a generalisation that is detrimental to the specific of each country. Under this conditionality, the project and the further progress towards NBF Implementation and the consolidation of the whole biosafety programme can overall be rated Moderately Satisfactory (MS).

21 Overall rating for Evaluation criteria:

Criteria	Summary Assessment	Rating
A. Strategic relevance	The Project confirms in retrospect all its relevance in: - Supporting a very high number of countries worldwide to prepare and adopt a National Biosafety Framework; - Creating and/or improving their capacity to fulfil their rights and obligations towards the Cartagena Protocol; - Laying the foundations for more comprehensive and effective actions of Capacity Building at National level; - Largely contributing to fulfil UNEP's mandate and policy, yet without being formally part of a strategic framework at UNEP level; - Meaningfully contributing to fulfil GEF strategy and priorities. (see 4.1.1)	**HS**
B. Achievement of outputs	Considering the scope and complexity of the Project, outputs delivery has to be considered Satisfactory (S).(see 4.2 and Table in Ann.13)	**S**
C. Effectiveness: Attainment of project objectives and results	The Project overall has triggered a global and coordinated process to enable the Parties to fulfil CPB obligations, tough with variable results.	**MS**
1. Achievement of direct outcomes	Despite not all the Outcomes having been fully and satisfactorily achieved and the uneven quality of the NBF produced by the countries, the Project has succeeded in promoting a large, promising and coordinated participation in a complex context of variable baseline situations. (see 4.3.2)	**S**
2. Progress from NBF Development to Implementation	The overall progress towards NBF Implementation has been assessed along eight different criteria. Despite some brilliant cases, the overall rating is Moderately Unsatisfactory (MU). (see 4.3.2).	**MU**
3. Likelihood of impact	Highly variable between three main groups of countries (see 4.3.3, section "d"). Overall, Moderately Unlikely (MU).	**MU**
D. Sustainability and replication	Sustainability is uneven along the five different aspects taken into account. (see below). Overall, its rating is between Moderately Likely (ML) and Moderately Unlikely (MU). There are some relevant examples of very promising sustainability, yet the overall picture is not overall satisfactory.	**MU**
1. Socio-political	Biosafety Socio-political Sustainability is challenged from different points of view and the controversial nature of the issue has to be carefully managed. At the current stage, Socio-political Sustainability is rated Moderately Unlikely (MU). (see 4.4.1)	**MU**
2. Institutional	Considering the baseline situation, the progress of the National Biosafety Frameworks has been quite remarkable. However, biosafety systems are not yet operational in many countries and have to be proved in more challenging situations (concrete opportunities to test collegiality and decision-making in presence of GMOs applications). Overall Institutional sustainability can be rated Moderately Unlikely (MU). (see 4.4.2).	**MU**
3. Financial	Financial sustainability is challenged by the overall economic slowdown (cuts in national budgets) and by many pressing priorities	**MU**

	at national level. Overall, Financial Sustainability is still to be proved and is currently rated Moderately Unlikely (MU) (see 4.4.3).	
4. Environmental	Overall, environmental concerns regarding the deliberate release of GMOs crops is increasing among national stakeholders and Risk Management measures are being discussed with technically sound opinions. On the face of that, Environmental Sustainability can be rated Moderately Likely (ML). (see 4.4.4).	**ML**
5. GEF-UNEP Strategy	Relevant areas of concerns and gaps have been observed. Some of them are due to the fact that all the strategies that are MEA related are mainly shaped by the Convention processes to which the UN contributes. There are, however, also some strategic/institutional issues that UNEP can internally improve within the context of those processes. Sustainability in this context is dynamic and in this context, the evaluation deems that Sustainability of GEF-UNEP Biosafety Strategy is currently still less than suitable, hence rated Moderately Unlikely (MU). (see 4.4.5)	**MU**
6. Catalytic role and replication	The Project has represented the starting point of a growing process of capacity and institution building and has unquestionably played a catalytic role. (see 4.4.6)	**S**
E. Efficiency	Project design (overambitious objectives and modalities of implementation) was not the most conducive to efficiency. The use of financial and time resources has not been optimal despite the huge effort made by the Management Team in ensuring monitoring, transparency and accountability through an innovative Information System (ANUBIS). High Management Costs and excessively protracted timeframe are seriously challenging Cost-Effectiveness and Time-Efficiency. Also considering the "historical" context of the Project, its innovativeness and the challenging implementation conditions, Efficiency cannot objectively be rated satisfactorily. It is Moderately Unsatisfactory (MU).(see 4.5)	**MU**
F. Factors affecting project performance		
1. Preparation and readiness	The MTE of 2003 had already defined the Project Design "too ambitious" and the GEF Evaluation of 2005 concluded that the Project was "not adequately designed and funded to fully take the complexities of local conditions and needs into account". The innovative character of the Project, its complexity and the urgency of its implementation did not probably allow a better preparation. Preparation and Readiness has to be rated Moderately Satisfactory (MS). (see 4.6.1)	**MS**
2. Project implementation and management	In retrospect, UNEP has not shown a clear Biosafety Management Strategy, which is leading to a rather unsustainable management situation, as far as biosafety is concerned (see 4.4.5). The overall capacity of UNEP to respond to project implementation and management challenges has to be rated Moderately Unsatisfactory (MU). (see 4.6.2)	**MU**
3. Stakeholders participation and public awareness	Overall, considering Biosafety baseline situation, considerable progress has to be acknowledged in Stakeholders participation and awareness, which has to be considered Moderately Satisfactory (MS). (see 4.3.2 and 4.6.3).	**MS**
4. Country ownership and driven-ness	The transnational character of Biosafety and the challenging context of Global Environmental Governance may, to a certain extent, limit Countries' Ownership, yet the process of empowerment of national stakeholders is evident and has to be rated, as a whole, Satisfactory (see 4.6.4)	**S**
5. Financial planning and management	The setting and implementation of ANUBIS (see 4.2) has been a breakthrough enabling the MT to manage and oversee financial planning and management in a very complex situation (123 countries). That has been a formidable task, requiring assiduous work of training and coaching, data corrections and revisions and of system upgrading. Financial Management has been up to the strong challenge and is rated Satisfactory. (see 4.6.5)	**S**
6. UNEP supervision and backstopping	Considering the magnitude and dispersion of the Projects, UNEP has been effective in providing supervision and backstopping that should	**HS**

	be considered Highly Satisfactory (HS). (see 4.6.6)	
7. Monitoring and evaluation	Despite some inconsistencies in the Log Frame, the MT has been able to implement an information system (ANUBIS) and other monitoring tools). The MTE took place as planned. Project Monitoring capacity has been rated Satisfactory (S). (see 4.6.7)	**S**
G. Complementarity with UNEP strategies and programmes	Complementarity is challenged by the under-representation of Biosafety and by the absence of GE & HR approach. It is rated Moderately Unsatisfactory (see 4.7)	**MU**
Overall project rating	Despite its complexity and over-ambitiousness, the project has delivered the expected outputs and most of the outcomes in a satisfactory way. However, efficiency has been strongly challenged by high management costs and an excessively protracted timeframe. The progress towards impact has been uneven along the 123 countries and external factors are challenging socio-political and financial sustainability. The UNEP Biosafety Strategy is not clearly defined and there are concerns regarding its sustainability. Overall, the progress towards NBF implementation and the consolidation of the Biosafety Programme can be rated Moderately Satisfactory.	**MS**

Recommendations

22 Taking into account the scope of the Evaluation and based on the main findings, conclusions and lessons learned, the recommendations that follow are principally addressed to UNEP as Implementing Agency of the biosafety programme and to GEF as financial mechanism of the Protocol.

Recommendation 1: General Recommendation to UNEP and GEF

Recommendation 1:

For an increased effectiveness and efficiency, it is strongly recommended to implement a Biosafety Programming Approach with the following main objectives:

a) To strengthen and consolidate the Biosafety Portfolio within the Biodiversity Programme and the global context of Sustainable Development goals;

b) To identify a limited number of Biosafety Programmes encompassing sets of interventions or projects tailored to different countries' needs and priorities;

c) To strengthen stock-taking at sub-regional level (e.g. through Rapid Appraisals[1]) in order to match needs and priorities mentioned above and design "multi-country thematic initiatives" with particular attention to countries and sub-regions already exposed (or prone to be) to GMOs development.

1. More specifically:

Recommendation 2: to UNEP and GEF regarding the implementation of the Programming Approach

Recommendation 2

Based on the Programming Approach recommended above (Rec 1), it is specifically recommended:

a) To undertake specific "needs and priorities" Rapid Appraisals in order to identify "homogeneous

[1] Rapid Appraisal is an approach that permits quick yet systematic data collection, when time and budget are limited.

countries" (see for instance the grouping proposed in chapter 4.3.3), preferably within the same Sub-region, to be matched with multi-country-initiatives addressing specific, yet, common gaps and by exploring forms of South-South Cooperation enhancing the role of "champion-countries" and of a small team of sub-regional consultants to be identified;

b) Design and implement, based on the above, specific multi-country and result-oriented initiatives in thematic areas (e.g. among others: Risk Assessment and Management, Risk Communication, Detection capacities, Co-existence and Socio-economic considerations);

c) To support the countries, particularly those already exposed to GMOs, in producing more neutral and scientifically-sound communication tools for crucial decision-makers at different levels (Politicians, Managers, Farmers, Consumers).

Recommendation 3: to UNEP, regarding UNEP institutional up-take of Biosafety Programme

Recommendation 3:

It is strongly recommended to clarify the strategic position of biosafety at Sub-program level (Environmental Governance / EG) and to define more efficient communication channels allowing adequate strategic planning, institutional monitoring and reporting of the Biosafety Programme. More specifically:

a) to explicitly and meaningfully integrate, as soon as possible, biosafety into the strategic Sub-Programmes, particularly Environmental Governance, as well as within the next possible UNEP PoW (2018);

b) to clearly define and strengthen the institutional anchorage of biosafety either within DEPI (current situation), considering the insertion of Biosafety within the Biodiversity sector, or, perhaps preferably, within DELC, considering the evident linkage with Sub-programme EG;

c) to prepare and discuss a biosafety strategy paper for internal use in order to clarify and detail the points outlined above, as well as a concrete proposal for the implementation of the recommended "programming approach" (Rec. 1 and 2), by October 2016.

Recommendation 4: to UNEP regarding the organizational structure of Biosafety Programme

Recommendation 4

It is recommended to "reset" the Biosafety Programme by an appropriate design of its internal organizational structure, namely:

a) To clearly define and implement the functions of the Global Biosafety Programme Coordinator responsible for the overall oversight of Programme Planning, Monitoring and Evaluation, including ABS, L&R and BCH Projects[2] and also directly responsible for Eastern, Central and Southern Africa (see following point regarding decentralization);

b) To enhance Biosafety Programmes decentralization by adding, in a first phase, at least one Biosafety/Biodiversity TM for Asia / Pacific Region posted in Bangkok RO and, if possible, one Sub-regional Biosafety/Biodiversity TM for the francophone West Africa and Maghreb Sub-regions[3]. Appropriate partnerships could be explored with regional institutions, like IICA (Inter-American Institute for Cooperation on Agriculture) to provide specific support to LAC

[2] Perhaps, more appropriately, the Coordinator should be defined "SCBD Protocols Programme Coordinator".
[3] Probably to be located in Dakar/Senegal or Abidjan/Cote d'Ivoire, which are already sub-regional hubs for different UN Agencies

Biosafety/Biodiversity TM for groups of Latin-America countries (e.g. Central America). Similarly, appropriate partnership could be implemented with IUCN (Int. Union for Conservation of Nature) Regional Offices in Belgrade for the CEE Region and in Fiji for Pacific Islands.

Recommendation 5: to UNEP and GEF regarding Partnership and Cooperation

Recommendation 5

In order to enable the Programming Approach, it is recommended to improve and consolidate the cooperation with partners institutions particularly at Regional and Sub-regional levels (e.g. CGIAR Centres and Institutions, Universities) in order to promote "Biosafety Poles of Excellence" able to support the countries on specific thematic areas. More specifically,

a) UNEP should prepare by the end of 2016 a strategic paper about cooperation with partners at regional and sub-regional level, with, if possible, input from the GEF;

b) Enhanced cooperation could include, for instance, consulting partners institutions at the time of project design, integrating them in a comprehensive stakeholders analysis by assessing their added value and identifying their roles and responsibilities in the projects and by involving them in technical support and backstopping to the programme.

Recommendation 6: to UNEP, GEF regarding coordination within UN system

Recommendation 6

In order to firmly insert Biosafety into the mainstream of Sustainable Development Strategies and to improve the coordination with other UN Agencies, particularly those related to Rural Development, Food Security, Food Safety and Genetic Resources Conservation (e.g. FAO, IFAD, WHO), it is recommended to set-up and/or consolidate coordination mechanisms at global, regional and national level, namely through:

a) Pursuing the initiative of joint webinars (e.g. webinar on "international databases on biosafety" run in 2014 and 2015 by CBD, FAO and OECD) by organizing and launching a joint webinar on "Socio-economic considerations (art. 26 of CPB)" by the end of 2016[4];

b) Establishing an active coordination between Biosafety projects and the UNEP/GEF project for the protection *in-situ* of Crop Wild Relatives (CWR), as well as with FAO / ITPGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture) in all the countries where the CWR Project is on-going or planned;

c) Encouraging the participation of the NCAs in the UNDAF programming exercise and their proactive role in the UNCT (UN Country Team);

d) Encouraging and/or consolidating the coordination of NCAs with the *Codex Alimentarius* national commissions in order to promote coordinated actions between Biosafety and Food Safety;

e) Strengthening and taking an active role in the coordination mechanism under the SCBD, especially in the liaison group on Capacity Building in Biosafety (please see http://bch.cbd.int/protocol/cpb_art22_actionplan.shtml#coord).

[4] Webinars and online forums are being organised under 26 as requested by parties, see http://bch.cbd.int/onlineconferences/portal_art26/se_main.shtml

1 Introduction

1. This is the final report of the Terminal Evaluation of the GEF Project "Development of National Biosafety Frameworks" (GFL/2716-01-4319), a global initiative implemented by UNEP to support the National Governments of 123 countries to develop their National Biosafety Frameworks (NBF). The frameworks are a combination of policy, legal, administrative and technical instruments enabling the countries to manage the safe transfer, handling and use of living modified organisms (LMOs) from modern biotechnology[5].

2. The project started in June 2001 with an estimated original duration of three and half years (42 months) and the perspective to benefit 100 eligible countries. The budget of USD 38.433.546 was financed by GEF[6] (USD 26.092.083, corresponding to 68%) and co-financed by UNEP and the countries (USD 12.341.463 corresponding to 32%). In order to cover additional countries that subsequently applied to the project and following a COP/MOP decision requesting for additional support, a supplementary GEF grant was approved in 2003 for an amount of USD 5.218.420 and, eventually, a third grant of USD 2.609.208 was allocated in 2005 for ten supplementary countries, hence leading to a total budget of 46.261.174 USD for the whole project (see table at 3.6).

2 The Evaluation

2.1 Overall approach and methods of the evaluation

3. In line with the UNEP Evaluation Policy and the UNEP Programme Manual, this Terminal Evaluation (TE) is undertaken after completion of the project, 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.

4. According to its ToR, the evaluation has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote operational improvement, learning and knowledge sharing through results and lessons learned among UNEP and the main project partners in each country. Taking into account the specificity of the project, the ToR of the TE underline the need to identify lessons of operational and strategic relevance for future initiatives on biosafety.

5. The report follows the format for TEs provided by the UNEP Evaluation Office. According to the UNEP evaluation methodology, most criteria have been rated on a six-point scale as follows: Highly Satisfactory (HS); Satisfactory (S); Moderately Satisfactory (MS); Moderately Unsatisfactory (MU); Unsatisfactory (U); Highly Unsatisfactory (HU). Sustainability is rated from Highly Likely (HL) down to Highly Unlikely (HU).

6. The project "Development of National Biosafety Frameworks" contains some peculiarities that have been considered for the design of the TE, namely:

   a) it is a global initiative carried out through 123 National (Sub)Projects worldwide, with a harmonized approach, standard methodology of implementation and common objectives;

   b) it formally started in June 2001 and had a protracted timeframe of execution, due to the gradual integration of the participant countries into the project and the uneven countries' baseline situation (see also Time-efficiency in chapter 4.5).

[5] In this Report, the terms LMO (Living Modified Organism) and GMO (Genetically Modified Organism) are considered synonymous and indifferently used.

[6] According to Art. 28 of the Protocol, the GEF (Global Environment Facility), in its capacity of financial mechanism for the Convention on Biological Diversity (CBD), is also called upon to serve as the financial mechanism of the Protocol.

c) it has been followed, in some 60 countries, by further individual (national) full size and medium size projects so-called "NBF Implementation Projects" (some of them "Implementation Demonstration Projects"), that build upon the achievement of the global project and for which evaluative evidence is, in many cases, already available (see Annex 7).

2.2 Evaluation criteria and key questions

7. The usual five criteria established by UNEG (Relevance, Effectiveness, Efficiency, Impact and Sustainability) have had supplementary criteria integrated into them, namely: Complementarity with the UNEP strategies and programmes, Coordination and partnership, Regional and sub-regional collaboration and exchange and Capacity building. Annex 8 presents a table with the key-questions defined for all the evaluation criteria.

8. Quantitative and qualitative methods and indicators have been used, taking into account that the project was expected to mostly deliver institutional and capacity building outputs and outcomes. As a result, quantitative outputs were also assessed for their quality and effectiveness, particularly their capacity to drive and sustain changes at a higher level of objectives. The findings of the evaluation are based on a range of different sources of information that have been triangulated. Among them, we highlight:

A) Desk Review of a number of documents of different type, as listed in Annex 4 (Bibliography).

B) Interviews (individual or in group, see complete list in Annex 3) with:

- EO (Evaluation Office) Officers at UNEP HQ;
- Current UNEP-GEF Biosafety Task Managers (Nairobi and Panama);
- Current and former UNEP Fund Management Officer;
- Relevant UNEP Officers at HQ (e.g. DEPI - Div. of Env. Policy Implementation, DELC– Div. of Env. Law & Conventions);
- In visited countries (Panama, Honduras, Senegal, Cape Verde, Myanmar): NCA representatives, CPB (Cartagena Protocol on Biosafety) and CBD (Convention on Biological Diversity) Focal Points and other relevant national stakeholders. A short summary of the main findings in the visited countries is presented in Annex 9. In addition, during the visit at UNEP HQ / Nairobi, a meeting was also organised with the Kenya National Biosafety Authority.

C) In depth-analysis of the NBF and its evolution in a sample of 37 countries (30% of the 123 countries that participated to the Project). The sample and the criteria for countries selection are described in Annex 10)

D) Field visits of 2-3 days in a selection of five (5) countries including:

- Four (4) countries which did not apply for follow up funding from the GEF for biosafety-related work after participating in this project and did not receive any evaluation mission on previous GEF-UNEP projects (Honduras, Senegal, Cape Verde and Myanmar);
- One (1) country that has applied for additional funding and for which no evaluative evidence is available so far (Panama).

3 The Project

3.1 Context

9. The Convention on Biological Diversity (CBD), adopted in 1992, recognised, in its art. 19(3), the need for an international protocol on biosafety. On that basis, the Cartagena Protocol on Biosafety (CPB) was prepared, lengthily negotiated and eventually adopted and opened to signature in 2000. Prior to its adoption, however, the Conference of the Parties (COP) of the CBD, GEF and UNEP had already given

substantive, preparatory steps to create an enabling environment to future signatory countries. We can highlight:

- The preparation by UNEP of the International Technical Guidelines for Safety in Biotechnology that were adopted at a global workshop held in Cairo in December 1995;
- The design and implementation of a pilot project called "Pilot Biosafety Enabling Activity" approved in 1997 with a budget of USD 2.7 million. The pilot project was composed of a National Level Component aimed at assisting 18 eligible countries[7] to prepare National Biosafety Frameworks (USD 1.9 million) and a Global Level Component aimed at facilitating the exchange of experience at regional levels (USD 0.8 million).

10. After the adoption of the Protocol and its opening for signature (May 2000), substantive steps were taken and major strategic documents and methodological tools were produced. In November 2000, the GEF Council adopted the "Initial Strategy for assisting countries to prepare for the entry into force of the CPB"[8], which identified three main objectives/components:

> a) assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks, including strengthening capacity for risk assessment and management with a wide degree of stakeholder participation;
> b) promoting information sharing and collaboration at the regional and sub-regional level and among countries that share the same biomes/ecosystems;
> c) promoting identification, collaboration and coordination among other bilateral and multilateral organizations to assist capacity building for the Protocol and explore the optimization of partnerships with such organizations.

11. The first meeting of the Intergovernmental Committee for the Cartagena Protocol (ICCP) on Biosafety, held in Montpelier on 11-15 December 2000, discussed the Initial Strategy and urged UNEP "to expedite the implementation of the project entitled Development of National Biosafety Frameworks in a flexible manner". In that context, the project started its implementation in 2001.

3.2 Objectives and components

12. The overall goal of the project was "to prepare countries for the entry into force of the Protocol". The project was conceived with two main components plus a third component of project support:

Component 1	Promoting Regional and Sub-regional collaboration and exchanges of experience
Component 2	Preparation of National Biosafety Frameworks (NBF)[9]
Component 3	Global Support Component (not explicitly defined as such in the ProDoc)

13. In terms of project design, the project "Development of the National Biosafety Framework" comprised:

a) A Global Project (also called "umbrella project") with a duration of three and half years (42 months) with components 1 and 3 above;

b) National Projects (100 originally planned, eventually 123 at the end of the project), also called "Sub-projects", drafted according to a Model National Project Document, signed with each recipient country under a standard Memorandum of Understanding, with a duration of 18 months within the timeframe of the Global Project, supposed to implement the component 2 in each participating country and financed through the budget of component 2 of the project.

[7] Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Kenya, Hungary, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda, Zambia.
[8] GEF/C.16/4/Rev.1 0, November 2000.
[9] The NBF Model is presented in Annex 11

14. The National Projects contemplated a Standard Phasing as well, with three phases (semesters) each with standard outputs and activities, as illustrated in the Diagram of Annex 12
    - Phase One (months 1 to 6): Preparatory Activities and Gathering Information;
    - Phase Two (months 7 to 12): Analysis and Consultation;
    - Phase Three (months 13 to 18): Preparation of draft National Biosafety Framework.

3.3 Target areas/groups

15. Main target groups were the national institutions involved in the implementation of the NBF, particularly one or more National Competent Authorities (NCA) designated to perform the administrative functions required by the Protocol. The institutional set-up of the designated NCA and the mechanisms of coordination are analysed and discussed in this report under chapter 4.3.2 (section a – Institutional Framework), Institutional Sustainability (4.4.2) and Stakeholders Participation (4.6.3).

3.4 Milestones/key dates in project design and implementation

16. As far as the Global Project is concerned, it was approved by GEF in December 2000 and by UNEP in January 2001, which is also considered its actual start date. However, the integration of the participant countries into the project has been gradual and each National Project has its own commencement and completion date. The last completion and administrative closure of national projects reported in UNEP's biosafety information system, ANUBIS, occurred in 2011 and in 2013, respectively. The Global (Umbrella) Project is planned to be administratively closed in September 2016, pending the approval of a last Budget Revision (n.13).

17. A Mid-Term Evaluation (MTE) of the project took place in August 2003[10] and an overall Evaluation of GEF's Support to the Cartagena Protocol on Biosafety including the present Project took place in October 2005[11]. A thematic evaluation of the toolkits produced by the project also took place in 2005[12].

3.5 Implementation arrangements

18. According to the ProDoc, the Global Project was to be managed by a Management Team (MT) based in Geneva, including a Scientific Coordinator acting as overall Project Manager and also responsible for Central and Eastern European region, three Programme Officers for Africa, Asia and the Pacific, Latin America and the Caribbean, and a Fund Manager. Changes and increase in the MT occurred during the project life, as discussed further in the report (chapter 4.6.2, Project Implementation and management).

19. A Steering Committee was put in place co-chaired by the GEF Secretariat and UNEP and comprising representative of UNDP, the World Bank, the Secretariat of the CBD, FAO, ICGEB (International Center for Genetic Engineering and Biotechnology) and UNIDO to meet on a quarterly basis via teleconferencing. Actually, the Committee has met on a yearly basis from 2001 to 2007 (all Business Plans and Minutes of the Meetings are posted in ANUBIS).

20. At national level, a legal entity responsible for the execution of the National Projects was identified, called National Executing Agency (NEA), as well as a National Project Coordinator (NPC) appointed by the NEA on a full time basis and a National Coordinating Committee (NCC) to guide the preparation of NBFs, all of them with standard ToR defined in the ProDoc.

3.6 Project financing

21. The Initial Budget of the Global Project (Annex 1 to the ProDoc) is subdivided in three components:

[10] Development of National Biosafety Frameworks, Mid-Term Evaluation of a Global Initiative, H. Navajas & J. H. Seyani, 2003.
[11] Final Draft of the Evaluation on GEF's Support to the Cartagena Protocol on Biosafety (GEF Office of Monitoring and Evaluation), 2005.
[12] UNEP-GEF Toolkits Evaluation: Stakeholder Review, ATHENA Institute for Research on Communication and Innovation in Health and Life Sciences, Faculty of Earth & Life Sciences, Amsterdam, 2005.

- Component 1 (Regional and Sub-regional collaboration): sub-total 2.026.000 USD
- Component 2 (National Biosafety Frameworks): sub-total 32.000.000 USD
- Component 3 (Project Management): sub-total 4.077.546 USD
- Total: 38.433.546 USD

22. An additional budget of 5,218,420 USD was financed by GEF in 2003 and a supplementary amount of 2,609,208 USD were allocated by GEF in 2005, always for Component 2, in order to cover the inclusion of new countries into the project. The total budget for the whole project is 46,261,174 USD (123 countries), as summarised in the following table:

	GEF Allocation USD	UNEP & Countries Co-financing USD	Total Budget USD
Initial Allocation (2001)	26,092,083	12,341,463	38,433,546
2nd Allocation (2003)	5,218,420	-	5,218,420
3rd Allocation (2005)	2,609,208	-	2,609,208
TOTAL	33,919,711	12,341,463	46,261,174

3.7 Project partners

23. As expressed in the Project Document (ProDoc), the designated NCAs are "the primary stakeholders" in the project (see 3.3), though it is equally stressed that "wide involvement of many government departments will be required, resulting in high level government acceptance of the outcome of the preparatory activities leading to the drafting of primary or secondary legislation and guidelines".

24. The main mechanism for participation in the development of NBFs and the main way in which the public was involved has been the National Coordinating Committee (NCC), which in some cases were also called National Biosafety Committees, NBC) which was required in every country participating in the project. The assessment of the functioning of the NCCs/NBCs is discussed later in this report under chapter 4.3.2 (section a – Institutional framework), Institutional Sustainability (4.4.3) and Stakeholders Participation (4.6.3).

3.8 Changes in design during implementation

25. The project, despite its wide and diversified geographical dimension and its prolonged timeframe, did not experience any major change in its essential design (the Global/Umbrella Project plus the National Sub-Projects), as briefly summarized here above. Nevertheless, according to information provided both in the MTE of 2003 and in the GEF Evaluation of 2005, the original expected outcome of the project was more ambitious than the actual one.

26. On that regard, the MTE (2003) had highlighted that "The project's primary success indicator - legislation, regulations and/or guidelines will be in place - is proving to be excessively ambitious given the allocated timeframe and budget". Actually, the GEF Evaluation (2005) found that "during the course of the project, the goal was scaled down and aimed only at completing preparation of the draft NBF, not at having the actual mechanisms in place"[13].

27. Moreover, as discussed under chapter 4.6.2 (Project Implementation and Management), there has been a considerable increase of the project staff and a progressive shifting of the budget initially attributed to

[13] This was an adaptive approach based on feedback through the regional workshops, taking into account the national processes to getting legislative instruments passed, as well as the fact that some countries were not yet CPB parties

the National Sub-Projects to the Global/Umbrella Component, through 13 Budget Revisions. This change was due to take into account the actual in-country costs incurred by the Parties, the development of materials globally produced to be used at the national level, additional workshops to be undertaken for Francophone and Lusophone Africa, for the Pacific, the Caribbean and sub regions of Asia. As a result, there has been a significant change in budget allocation within the total budget (see also Efficiency, 4.5).

3.9 Reconstructed Theory of Change of the project

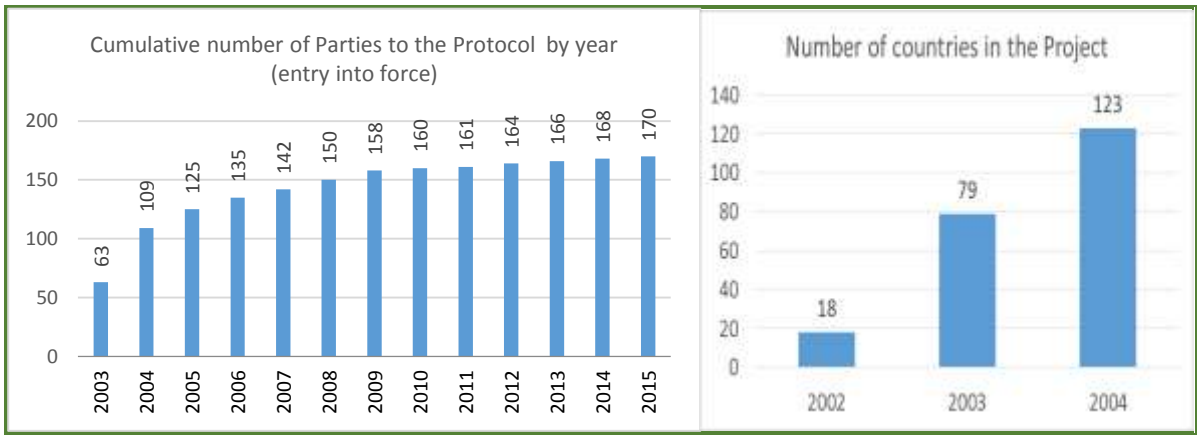
28. In the Inception Report of the mission[14], the Evaluation Team presented a reconstructed Theory of Change (ToC)[15] of the Project, aimed at mapping the possible pathway of change from the projects outputs to the expected outcomes, up to the intended impact. Main drivers and assumptions having a bearing on project achievements were also identified. The reconstructed ToC has been a valuable instrument of analysis all along the evaluation exercise and its design has been tested and revised by the team during the evaluation. It has particularly contributed to the assessment of the effectiveness and the sustainability of the project's results, as well as the likelihood to achieve the intended impact, as discussed in Chapter 4.3 (Effectiveness) of this report and visualised in the Diagrams of that chapter.

4 Evaluation Findings

4.1 Strategic relevance

4.1.1. Environmental issues and needs

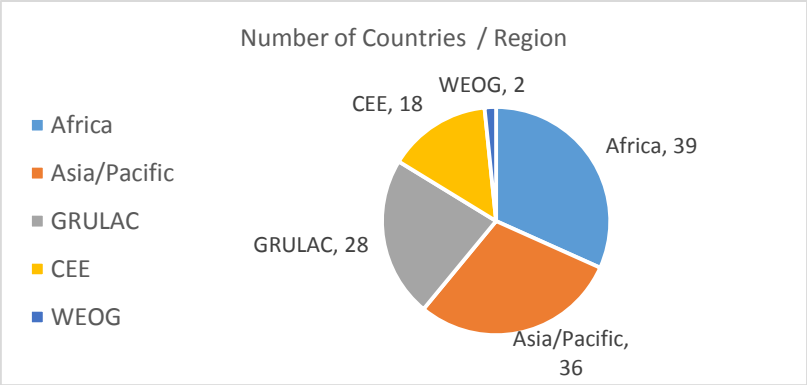
29. The number of the Parties to the Protocol has steadily grown up to 170 (at the time of drafting this report), as well as the number of the countries participating in the NBF Development Project (see diagram below), confirming the interest and motivation of the countries to be part of the process. It has also been observed[16] that there is a strong relationship between countries' participation in the NBF Development Project and the ratification of the Protocol, reasonably due to enhanced awareness of the protocol at administrative and political levels.



Source: Evaluation Team (based on BCH and UNEP data)

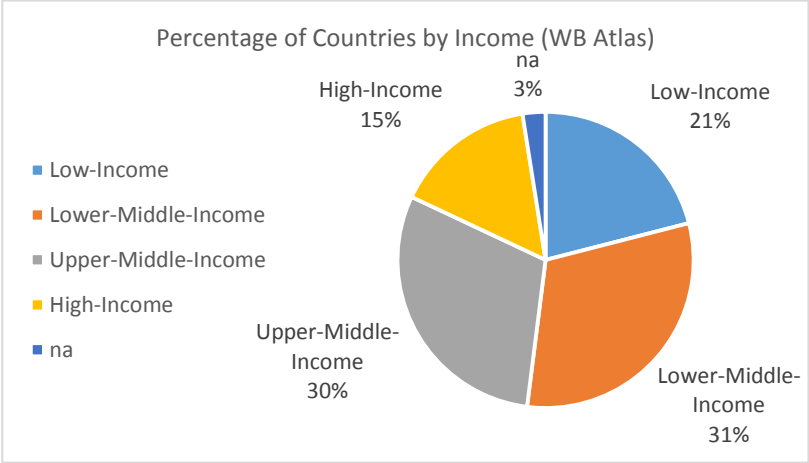
30. The subdivision by region of the 123 beneficiary countries, presented in the diagram below, reflects the number of GEF Eligible Parties in UNEP regions. It has been, therefore, a regionally balanced coverage.

[14] Inception Report of the Terminal Evaluation of the Project "Development of National Biosafety Frameworks", December 2015
[15] See "The ROtI (Review of Outcomes to Impact) Handbook", GEF, 2009.
[16] Evaluation on GEF's Support to the Cartagena Protocol on Biosafety (GEF Office of Monitoring and Evaluation), 2005



GRULAC (Latin America and Caribbean); CEE (Central and Eastern Europe); WEOG (Western Europe and Others). Source: Evaluation Team based on BCH data

31. Eighty (80%) of Low Income countries[17] and 73% of LDC (Least Developed Countries)[18] have benefited from the NBF Development Projects, which can be regarded as a substantive proportion, taking also into account the incidence of causes of *force majeure* that may have hampered their participation (e.g. conflicts, wars). The diagram below shows the subdivision of the countries according to the level of their economies (World Bank Atlas method of classification).



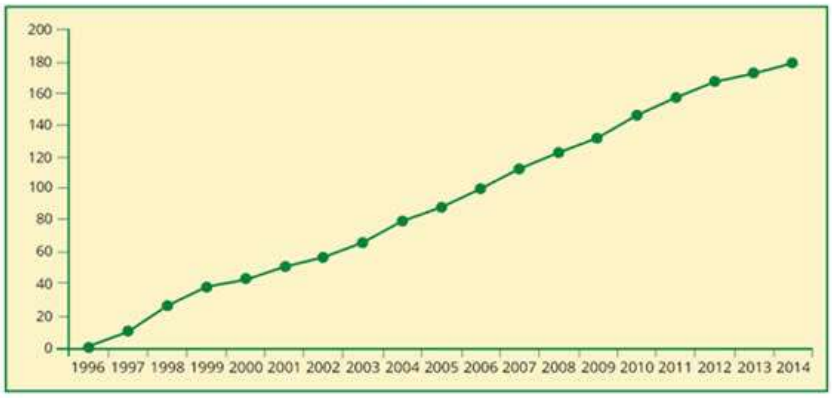
Source: Evaluation Team (based on BCH data and on the WB Atlas)

32. In this regard, it has to be recalled that one relevant rationale of the project was to encompass the largest possible number of countries in order to promote biosafety agenda and encourage CPB ratification. Nevertheless, as concluded by GEF Evaluation of 2005 "the umbrella approach was especially effective in countries that could easily incorporate the support into their own biosafety systems; it was much less effective where the need for support was greater, and/or the initial conditions were less receptive"[19].

33. The relevance of the project is also enhanced by the dramatic increase, in recent years, of GMOs development (research and cultivation) and trade, as demonstrated by the steady growth of the global surface cultivated with GMOs, which has passed from around 50 million hectares in 2001 to more than 180 million in 2014, in twenty-eight (28) countries of all the world's regions[20] (see graphic below).

[17] World Bank Atlas classification http://data.worldbank.org/about/country-and-lending-groups#Low_income
[18] UN classification http://www.un.org/en/development/desa/policy/cdp/ldc_info.shtml
[19] See Conclusion n. 7 in "Evaluation on GEF's Support to the Cartagena Protocol on Biosafety", GEF Office of Monitoring and Evaluation, 2005.
[20] http://www.isaaa.org/resources/publications/pocketk/16/

Figure 1. Global Area of Biotech Crops, 1996 to 2014 (Million Hectares)



Source: Clive James, 2014.

Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA)

4.1.2. UNEP mandate and policies

34. As described in chapter 4.6.1 (Preparation and readiness), UNEP, which had been very active on biosafety since the '90s, responded very promptly to the demand for capacity building in biosafety identified by the COP-MOP (Conference of the Parties serving as the Meeting of the Parties) and was chosen as the sole Implementing Agency for the NBF Development Project. As acknowledged by a GEF Evaluation dating from 2005, "UNEP played a very decisive role in initiating the pilot project and formulating both the GEF Strategy and its subsequent proposal to support NBF development in up to 100 countries".

35. It is, therefore, quite incongruous that Biosafety was not formally and explicitly recognized as thematic priority in any of UNEP's instruments of strategic planning that were, in those years, also in a phase of structuring. The project was just mentioned in the UNEP Proposed Biennial Programme and Support Budget for 2002-2003 because of the "regional workshops in which countries share their experience with regard to biosafety". That looks an excessive understatement for a project of more than 42M USD spread over 123 countries. More so, when considering that there is no mention of Biosafety at all, in the Biennial Programmes from 2004 to 2009.

36. In recent years, in parallel with the UNEP's adoption of more structured strategic planning mechanisms (MTS and PoW), Biosafety appears again in the Biennial PoW (Programme of Work), as synthetized in the following table:

PoW 2010-2011: Sub-Programme Environmental Governance, Expected Accomplishment (EA) B: The capacity of States to implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions is enhanced.	
Output	Biosafety reference
Output 2: Legal and policy instruments are developed and applied to achieve synergy between national and international environment and development goals.	• *"Biosafety frameworks are implemented in 50 countries"*
Output 3: Countries' legislative and judicial capacity to implement their international environmental obligations is enhanced through implementation of policy tools.	• *"The capacities of countries in risk assessment and management of modern biotechnology products under the biosafety programme is enhanced"* • *"Capacity-building and support are provided to developing country Parties to enable their participation in the Cartagena Protocol's*

	Biosafety Clearing House"
Output 4: Capacity of government officials and other stakeholders for effective participation in multilateral environmental negotiations is enhanced.	• *"Continued support is provided to developing countries to enable them to meet their planning and reporting obligations under the Convention on Biological diversity, the Cartagena Protocol and the Framework Convention on Climate Change"*
PoW 2012-2013: Sub-Programme Environmental Governance, Expected Accomplishment (EA) A: The United Nations system, respecting the mandate of each entity, progressively achieves synergies and demonstrates increasing coherence in international decision-making processes related to the environment, including those under multilateral environmental agreements.	
Output	Biosafety reference
Output 5: Priority areas of multilateral environmental agreements are increasingly reflected in policies and actions of bodies, funds, programmes and agencies of the United Nations system, including their strategies and activities in countries (Five Priority Areas).	• Biosafety is one of the five Priority Areas (Division: DELC)[21]

37. Despite the above, the MTE of UNEP's Medium-Term Strategy 2010 – 2013 does not mention Biosafety Projects in any of its sections, including Environmental Governance. The current UNEP Medium-Term Strategy (MTS) 2014-17 presents a table comparing the strategic focus and expected accomplishments of the 2014–2017 MTS and the Aichi Biodiversity Targets of the Strategic Plan for Biodiversity 2011–2020. In that table, National Biosafety Frameworks only appear under Target 17 (National Biodiversity Strategy and Action Plans, NBSAPs, as a policy instrument). There is no other explicit mention to Biosafety in any recent UNEP programmatic document the Evaluation had access to.

38. Overall, the impression is that Biosafety, despite its relevance in terms of number of projects and their wide geographical coverage, has not been so far adequately represented in the corporate mechanisms of strategic and operational planning, as discussed further under Sustainability (4.4.5).

4.1.3. GEF Biodiversity focal area, strategic priorities and operational programme(s)

39. As described previously in this report (chap. 2.1), the project was deeply rooted in the GEF Initial Strategy for assisting countries to prepare for the entry into force of the CPB (2000), actually being the main field instrument for implementing the strategy in signatory countries. In December 2006, the Strategy for Financing Biosafety was approved by the GEF Council on an interim basis and became part of the GEF Focal Area Strategies and Strategic Programming for GEF-4 approved by the GEF Council in June 2007 (Focal Area 3: Biodiversity; Strategic Programme 6: Biosafety).

40. Under GEF-5, the strategy for the Biodiversity Focal Area contemplates as its Objective 3: "Build Capacity for the Implementation of the Cartagena Protocol on Biosafety (CPB)". To achieve this objective, a comprehensive project support structure was established, including three types of project: Single-country project, Regional or sub-regional projects, Thematic projects.

41. Biosafety has remained in GEF Programme's priorities under GEF 6 Biodiversity Strategy, Objective 2 (BD2) "Reduce threats to globally significant biodiversity" that contemplates Programme 5 "Implementing the Cartagena Protocol on Biosafety", with a programming target of 30M USD (2014-

[21] It has to be noted, however, that Biosafety Programme is under the responsibility of DEPI.

18)[22]. The progressive decrease of GEF Allocation to Biosafety from around 75 M USD (GEF 4) to around 40 M USD (GEF 5)[23] to the current 30 M (GEF 6) has to be noted.

42. GEF 6 Programming Directions also underline that "Biodiversity Strategy incorporates elements of the new Strategic Plan on Biosafety, with a focus on implementation of National Biosafety Frameworks (NBF) as this remains unfinished business from previous GEF phases". It is specified in the document that, "by the end of GEF-5, as many as 64 countries will have received support for implementation of their National Biosafety Frameworks (NBFs); however, another 71 eligible countries have yet to request support to implement their NBFs. GEF-6 will provide the opportunity for these countries to seek support for these initial phases of basic capacity building".

43. The overall impression, therefore, is that GEF, notwithstanding the decreasing amount of countries' requests for Biosafety projects within STAR allocation mechanism, considers Biosafety as a relevant programme of its Biodiversity Strategy and is prepared to keep up its support in this area.

4.1.4. Overall Strategic Relevance

44. The project confirms, in retrospect, all its relevance in addressing challenging issues and needs by, namely:

- Supporting a very high number of countries worldwide to prepare and adopt a National Biosafety Framework, hence creating and/or improving their capacity to fulfill their rights and obligations towards the Cartagena Protocol;
- Introducing and promoting an innovative methodological tool, the National Biosafety Framework, that has since become one of the backbones of the global Biosafety programme, also used by several other bilateral and regional based programmes;
- Laying the foundations for more comprehensive and effective actions of capacity building at national level to implement regulatory and administrative system for Biosafety management;
- Introducing the concept of regional / sub-regional cooperation in Biosafety programmes;
- Largely contributing to the fulfilment of UNEP's mandate and policy, yet not substantively enabling a more solid institutional uptake of Biosafety by the Implementing Agency (UNEP);
- Meaningfully contributing to the fulfilment of GEF strategy and priorities.

Despite some shortcomings due to its innovative feature and to the strong inherent challenges, the strategic relevance of the project can overall be rated as Highly Satisfactory.

4.2 Achievement of outputs

45. Assessing the delivery of the project's outputs has been quite challenging due to the inconsistent Logical Framework of the Project Document[24].Nonetheless, a table showing outputs delivery has been prepared by the Evaluation Team and is presented in Annex 13. As visualised in the table, the project has delivered virtually all its planned outputs, namely:

- 123 NBFs produced, thus exceeding the planned target of one-hundred (thanks to supplementary GEF allocations);
- Four initial Regional Workshops organized and implemented (four planned) with a total of 289 participants from 129 countries;
- 13 Sub-regional Workshops organized and implemented (out of 15 planned) with a total of 994 participants from 128 countries;

[22] GEF-6 Programming Directions (Extract from GEF Assembly Document GEF/A.5/07/Rev.01, May 22, 2014)
[23] See: "Expert review of the effectiveness of various approaches to biosafety capacity-building: identifying best practices and lessons learned", CBD Secretariat, 2010.
[24] The Logical Framework Matrix (Annex III of the ProDoc) presents some relevant shortcomings, such as the lack of identified and quantified Outputs and a certain confusion between Indicators and Activities.

- UNEP Biosafety Website created (still active);
- Seven electronic newsletters published from 2001 to 2007;
- Relevant training and outreach material of excellent quality produced, among others: NBF Guide, Format and Flow-chart and a comprehensive Toolkit composed by five modules, still a reference document today. The toolkit has been the object of a specific evaluation in 2005;
- A New UNEP Biosafety Information System (ANUBIS) conceived and implemented, still in use also in other projects (e.g. the whole Biosafety Portfolio, as well as ABS/Access and Benefit Sharing and UNCCD/United Nations Convention to Combat Desertification projects).

46. A specific comment regards ANUBIS. The original purpose of the Information System, as envisaged in the ProDoc, was to allow rapid exchange and dissemination of information between participating countries "in order to provide regular updates on significant developments in biosafety and to facilitate the timely provision of specific information, on request, to participating countries". As a matter of fact, the output produced (ANUBIS) has mainly responded to the more pressing need of project monitoring and administration, through a database / file-maker system gathering in one single and accessible web platform all relevant information regarding administrative, financial and technical data of project progress, country by country (milestone dates, budget, financial reports and budget revisions, ProDoc, technical documents produced, Project Implementation Reports, etc.). (See also Chapter 4.6.5, Financial planning and management).

47. The quality and effectiveness of the frameworks produced in the sample of 37 selected is presented in the following chapter 4.3 (Effectiveness). Considering the scope and complexity of the Project, outputs delivery has to be considered Satisfactory (S).

4.3 Effectiveness: Attainment of project objectives and results

4.3.1 Project Outcomes from reconstructed ToC

48. The Evaluation has assessed to what extent the delivery of the outputs has produced short to medium term institutional changes and systemic effects (outcomes), namely:

- Outcome 1: Regional and Sub-regional collaboration and exchange.
- Outcome 2: 100 NBF prepared and containing:
    a) A Government policy on biosafety
    b) A regulatory regime for biosafety
    c) A system to handle notifications or requests for authorisations
    d) Systems for 'follow up' such as enforcement and monitoring for environmental effects
    e) Mechanisms for public awareness, education and participation.
- Outcome 3: Increased access to information and capacity building.

Outcome 1 (Regional and Sub-regional collaboration and exchange)

49. As described in the previous chapter, the outputs have basically consisted of regional and sub-regional workshops, the main objective of which, according to the ProDoc, was "a clear understanding by participating countries of the obligations placed upon them by the Protocol and of the risk analysis and management procedures". Taking into account the complexity of the subjects that were treated in the workshops (e.g. "Risk Assessment", "Biosafety Regulatory Regime"), their short duration (four days on average) and the very high number of participants (from 60 to 100 for each training), it is evident that the workshops had mostly an introductory and awareness-raising character. In fact, the MTE had already concluded that "the reliance on a 'one size fits all' training approach, while understandable in terms of budget and logistics, carries an opportunity-cost in terms of learning – the content is often too superficial for comparatively advanced countries, yet too brief for countries that are new to the NBF process".

50. The Evaluation deems that the causal pathway from Outputs (the workshops) to Outcome is inconsistently formulated in the ProDoc. Though Regional/sub-regional workshops can actually be instrumental to Outcome 1 "Regional and sub-regional collaboration and exchange", regional cooperation is a country-driven process based on "win-win" bilateral or multilateral agreements that cannot be sustained only by capacity building actions promoted by international or regional institutions. Countries, not institutions, are key-drivers of a process of regionalization. Therefore, Outcome 1, as visualised in Diagram 1 of this Chapter, can be achieved only under the **assumption** that countries have converging interests and are willing to establish joint programs to share services and costs, to exchange technical resources, to agree on some instrument of financial cooperation, etc.

51. Notwithstanding the evident shortcomings of the adopted approach, it has to be taken into account the objective difficulty of implementing the regional and sub-regional component in a context where the national knowledge on biosafety was still scarce. Actually, at the time of project formulation, the field experience on biosafety was quite limited (just the Pilot Project) and the "regionalization" of the issue was an envisioned perspective, more than a real need. As the MTE remarked, "it is very unlikely that countries undertake regional or sub-regional activities before having a clear understanding of the biosafety situation in their national context".

52. All the above taken into account, the Evaluation has concluded that the achievement of Outcome 1 has been only Moderately Satisfactory (MS).

Outcome 2 (100 NBF prepared)

53. The achievement of Outcome 2 is not objectively easy to assess, since its enunciation in the ProDoc is vague ("100 NBF prepared") and does not unambiguously mention the elements, the quality and the level of completion requested. The Evaluation Team has considered that a NBF can be considered "prepared" not just when a "hypothetical" document with that title is produced, but when a "real" and workable national framework is described, containing all its five constitutive elements (though imperfectly or partially), ready to be implemented or to be worked out for improvement.

54. Under the specification above, the assessment of the 37 sample NBFs has been carried out through a score-card. The full assessment (scorecards) of the 37 sample countries is in Annex 14 and a Synoptic Table is presented in Annex 15. The score obtained by the sample countries is variable, but on the whole rather positive (see table here below): only seven NBF (19%) scored poorly (U), 11 (30%) scored well (S and HS) and 19 (51%) are in the middle (between MS an MU). With a more "optimistic" view, the majority of the sample NBFs (23 out of 37, i.e. 62%) have scored Moderately Satisfactory and above.

Table 1: Overall NBF score of the sample countries

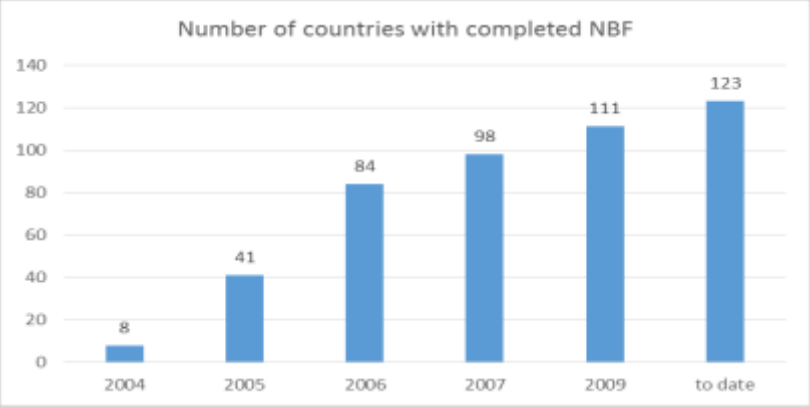
Score	HS	S	MS	MU	U	HU	Total
N. of NBF	4	7	12	7	7	-	37

55. That means that the majority of the sample NBF produced were, in fact, pretty workable documents that in many cases have enabled the countries to move forward their effective implementation. In some remarkable cases (e.g. Bangladesh, Ghana, Indonesia, Philippines and Zimbabwe), that happened in absence of, or before, a follow-up UNEP project on NBF Implementation[25]. Actually, most of the countries made an effort to produce at least a draft Biosafety Bill or draft Regulations that, in some cases, have been subsequently approved and enacted (e.g. Mozambique in 2007, Uruguay in 2008, Senegal in 2009, Iran and Ghana in 2011, Madagascar in 2012).

[25] Some of these countries, however, have benefited from other relevant support (bilateral cooperation).

56. There are, of course, on the other side, countries that did not succeed in presenting a meaningful and workable document, scoring Moderately Unsatisfactory or Unsatisfactory. Reasons for deficient frameworks have to be searched in the baseline situation of the countries, as actually acknowledged and underlined in the NBF documents that point out, as main problems:
    - the lack of previous experience in biotechnologies and biosafety;
    - the scarce availability of national skilled human resources for the sector;
    - the complexity or the weakness (fragmentation and dispersion) of the institutional framework.

57. GEF Evaluation of 2005 had, in fact, concluded that "the umbrella modality for the NBF development project has been effective in countries with prior biosafety experience and a minimum level of existing competence, but not as satisfactory in countries with less prior experience and competence". Ten years on one can only partially agree with that earlier conclusion. At that time, as visualised in the following diagram, only one third of the countries had finalised their NBF, most of them being, as expected, countries with "High baseline" (as the GEF evaluation defined them), meaning "countries actively and significantly involved in the development of GMOs". From 2005 onward, however, the number of countries that completed their NBF increased dramatically and, among them, countries with "medium" and "low" baseline situations, many of them having produced NBF to the best of their capacity and progressed, some of them remarkably, in the definition of their regulatory regime.



Source: Evaluation Team based on UNEP and GEF reports

Overall, the achievement of Outcome 2 can be rated as Satisfactory (S).

Outcome 3 (Increased access to information and capacity building)

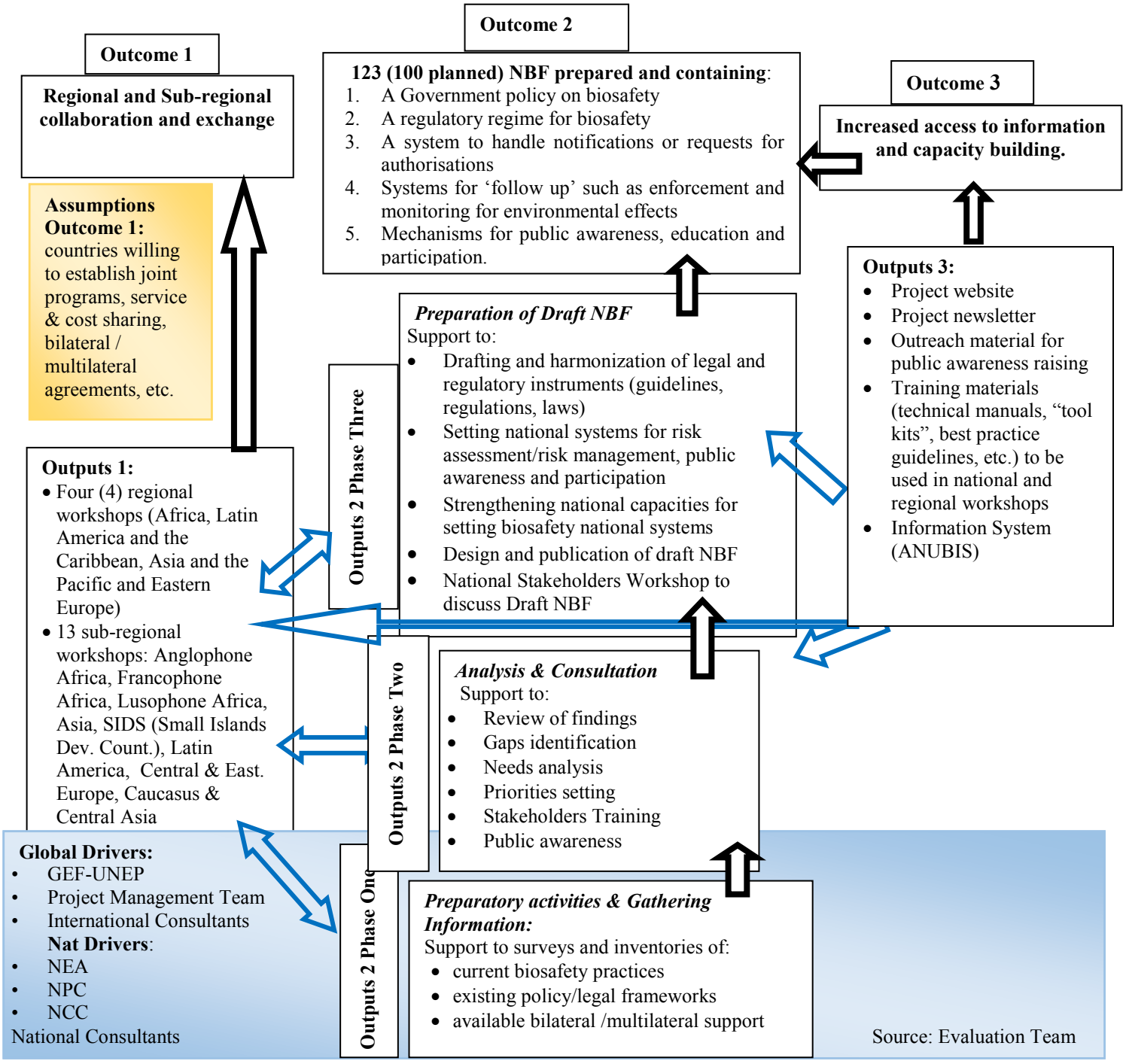
58. Though quite downscaled in the ProDoc, Outcome 3 is actually a strategic outcome. Increased access to information is crucial when running a global programme with uneven baseline situations and different experiences to compare and share. As rightly pointed out in the ProDoc, there is "an important interconnection between information sharing and capacity building".

59. From that perspective, the huge effort made by the project in producing and widely disseminating a remarkable set of training and methodological tools has to be recognised. These tools have been particularly useful for the "low baseline" countries, notably the so-called "toolkit" for NBF preparation and other valuable training and awareness material distributed through the regional and sub-regional workshops. The Biosafety website was also launched in those years and a network tool (newsletter) was regularly circulating until 2005. As a "by-product" of the project, an Information System called ANUBIS was also created (still in use for NBF Implementation Projects) that gathers financial, administrative and technical information regarding each National Project and which has proved to be a valuable instrument of transparent and systematic management of the projects.

60. The Evaluation considers that Outcome 3 was Satisfactorily (S) achieved.

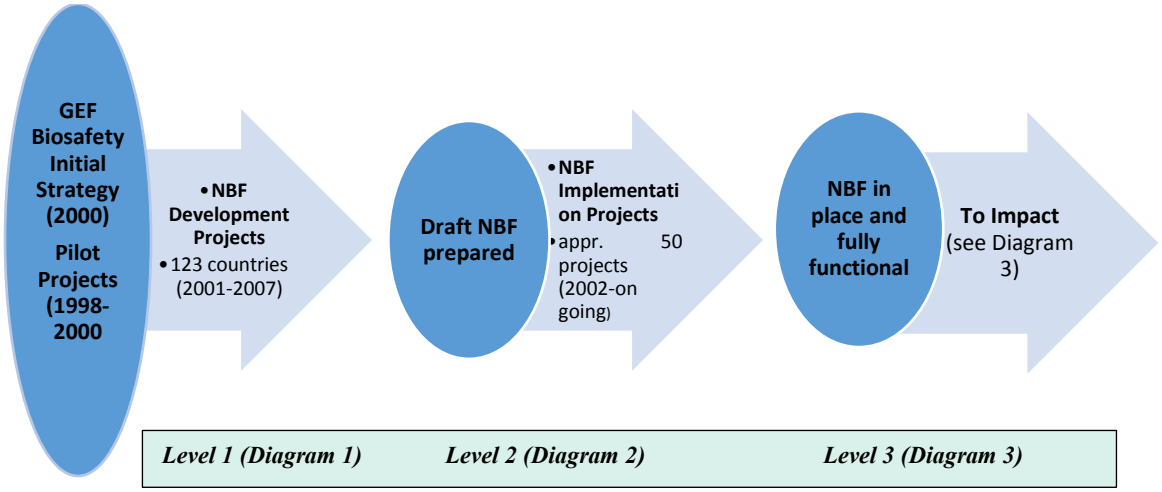
61. All the above considered, the Evaluation rates the outcomes achievement (Effectiveness) as Satisfactory (S). Diagram 1 that follows maps out the reconstructed Theory of Change (from Outputs to Outcomes).

Diagram 1: Theory of Change Project "Development of National Biosafety Frameworks": from Outputs to Outcomes



4.3.2. From NBF Development to NBF Implementation: progress and constraints

62. The NBF Development Project represents the first level of a "linear" process visualised in the following Diagram, from the Initial GEF Strategy on Biosafety to the preparation of the NBF. The second level, which is currently on-going in more than 50 countries, is supposed to lead to the full implementation of the NBF and is visualised in Diagram 2 (Theory of Change from NBF Development to NBF Implementation). The third level is the conclusive step, hopefully leading to the expected Impact, through a series of Intermediate States, as discussed in following chapter 4.3.3 and represented in Diagram 3 (From Outcomes to Impact).



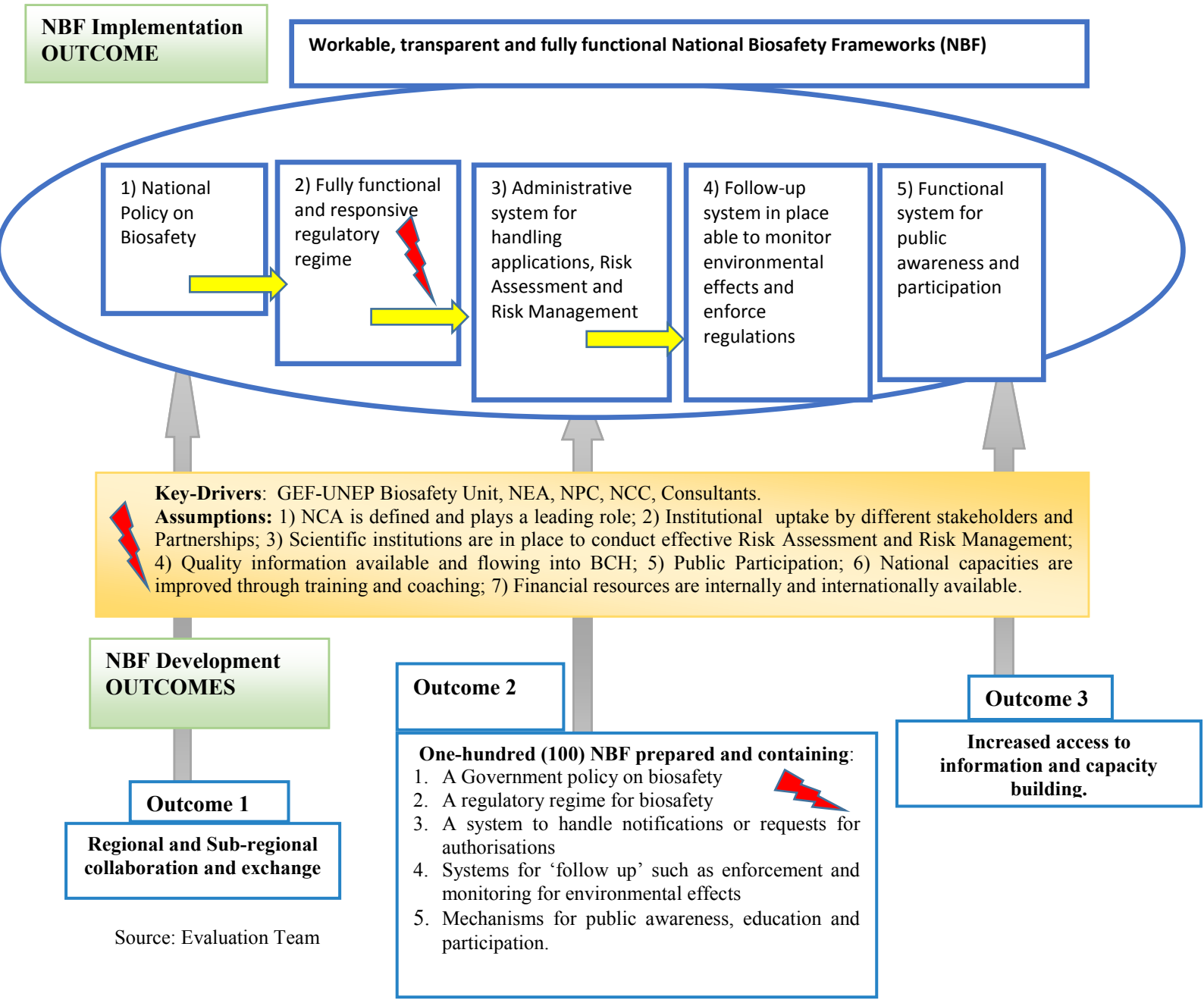
Source: Evaluation Team

63. The transition from a draft NBF to a full regulatory mechanism in place is, indeed, a substantive change that some of the countries have partially achieved through a new round of GEF-UNEP follow-up projects, called "NBF Implementation Projects" or through the support of bi-lateral cooperation agencies.

64. The following Diagram 2 details the pathway from Level 2 to Level 3 and shows how **substantive assumptions** constrain the progress and explain the difficulties experienced by the countries at that stage. As also pointed out in some Terminal Evaluations of NBF Implementation Projects, the main assumptions that, if not present, are still hampering the full implementation of the NBF are:

a) NCA are defined and play a leading role;
b) Institutional uptake by different national stakeholders and their partnership;
c) Scientific institutions are in place to conduct effective Risk Assessment (RA) and Risk Management (RM);
d) Quality information available and flowing into BCH (Biosafety Clearing House);
e) Public participation mechanisms in place;
f) National capacities in place and improved through training and coaching;
g) Financial resources internally and/or internationally available.

Diagram 2: Theory of Change from "NBF Development" to "NBF Implementation"



Source: Evaluation Team

65. The Evaluation has assessed to what extent the Development of NBF (level 2) has been followed by the effective Implementation of the Frameworks (level 3). The assessment has been carried out through three instruments:

a) The analysis of the TE Reports of the NBF Implementation Projects evaluated so far (19 Projects)[26];
b) The analysis of the 3rd National Report on the Implementation of the CPB (when already available) or of the 2nd National Report (when the 3rd is not yet available) of the selected sample of 37 countries[27];
c) By cross-checking the information available through the TE Reports (a) with the answers provided in the National Reports (b) and the "dedicated survey" launched in 2013 by the CBD Secretariat[28].

66. The analysis of the TE of the NBF Implementation Projects shows that the progress towards the full achievement of the components of the NBF is uneven. This is an important finding that underlines the relevance of more tailored and specific support. While some countries have just achieved the approval of primary legislation (a Biosafety Law), others are in need of specific Regulations (Secondary Law) or Technical Guidelines. Some may, instead, be in need of detection and inspection facilities or to upgrade their information systems (BCH) and participatory mechanisms. Therefore, while a NBF can be rated, for instance, as Moderately Satisfactory, one has to assess the weak and strong points that can help to address deficiencies and build upon the results obtained so far.

67. The process of implementation of the NBFs has been assessed through the analysis of eight key-aspects, namely:
    a) Institutional framework
    b) Regulatory regime
    c) Administrative system for handling applications
    d) Monitoring and enforcement system
    e) Public awareness and participation
    f) Capacity building
    g) Regional and Sub-regional dimension
    h) Cooperation and partnership

a) Institutional framework

68. According to art. 19 of the Protocol, one or more National Competent Authorities (NCA) must be designated, *"which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions"*. Recent data[29] show that the model with "one single NCA" is adopted by the majority of the Parties (63%) and the "multiple NCAs model" is present in 30% of them. The "single NCA" model looks particularly attractive for African and Asian countries, while Latin American and Caribbean countries, as well as Central and Eastern European countries are fairly split between the two models, as shown in the table here below.

Table 2: Adopted Model of NCA (Source: BCH)

NCA model	Total	%	Africa	Asia	CEE	GRULAC	WEOG
One single	95	63%	41	23	10	10	11
More than one	46	30%	5	13	10	11	7
No NCA	11	7%	3	3	1	3	1
Total	152	100%	49	39	21	24	19

WEOG (Western Europe and Others); GRULAC (Latin America and Caribbean); CEE (Central and Eastern Europe)

[26] Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and Vietnam (Impl. Dem. Projects in 2012), Costa Rica, Caribbean (regional, MTE), Tanzania, Mauritius, Tunisia, Bhutan, Lao PDR and Mongolia (in 2014), Guatemala, Egypt, Macedonia (FYROM) and Albania in 2015.
[27] See "Analysis of selected questions from the Second and Third National Report on the implementation of the Cartagena Protocol on Biosafety of 37 countries" (Annex 16)
[28] See "Review of the information gathered through a dedicated survey and corresponding to indicators in the strategic plan", CBD Secretariat, 2014. https://bch.cbd.int/database/reports/surveyonindicators.shtml
[29] Source: Second National Report on the Implementation of the Cartagena Protocol on Biosafety, Secretariat of the Convention on Biological Diversity, 2011 (https://bch.cbd.int/database/reports/results/?searchid=638987)

69. Actually, the option of having a single NCA is often regarded as the most practical, in terms of procedural clarity and definition of responsibility. In this case, taking into account that the usual National Focal Point for the CBD and for the CPB is the Ministry of Environment (MoE), it is the MoE that is typically identified and designated as the NCA, in most of the cases. There are, nonetheless, countries where the NCA is the Min. of Agriculture (MoA), as in some Latin American countries, or a National Biosafety / Biotechnology Authority or Council, as in several African countries (e.g. Kenya, Zimbabwe, Ghana, Senegal, among others).

70. It has to be observed that the single NCA model does not imply that all functions and responsibilities are concentrated in just one institution. In practical terms, in fact, what is usually in place is a sort of "devolution" of powers and sectoral responsibilities from the NCA to other stakeholders (e.g. Agriculture or Health Ministries), while the NCA (usually the MoE) retains the overall coordinating function and "represents" the Biosafety agenda in the Government and in the international fora.

71. The main mechanisms for institutional participation and coordination are the so-called National Coordinating Committees (NCC) or National Biosafety Committees (NBC) [30], which, originally required in every country participating to the NBF Development Project, have successively become the overall policy and decision-making body for GMOs, as part of the institutional set-up of the NBF in all the countries.

72. The assessment of the composition and functioning of NCCs (NBCs) is relevant to understand the effective degree of inclusion and participation in the decision-making process, as foreseen in the art. 23 of the Protocol. The analysis of different terminal evaluation reports of UNEP-GEF projects supporting either the initial NBF Development or the subsequent NBF Implementation Projects, shows relevant differences in the composition / membership of the Committees, both in their size (from 6 to 36 members, with an average of 10-12) and in the way they are structured and organized to function and make decisions. These differences reflect the huge variety in countries' priorities and needs, socio-economic situations, as well as political and cultural dimensions.

73. As far as membership is concerned, table 3 here below, based on a comparative analysis of 2006[31], shows the number of countries' NCCs by Region that included representatives of each sector (Government, NGOs, Private, Academic/Research, Media) in their NCCs:

Table 3: number of NCCs (by region) that include representatives of different sectors (listed in the first column)

Sector represented	Asia	Pacific Islands	Africa	Latin Am. & Carib.	Central and East. Europe	Total	%
Government	25 (all)	11 (all)	39 (all)	28 (all)	18 (all)	121	100%
Academic/ Research	16	5	21	15	16	73	60%
NGOs	13	6	23	15	13	70	58%
Private Sector	10	8	15	10	10	53	44%
Media	1	1	4	-	4	10	8%

Source: Evaluation Team

74. While Governmental institutions are obviously present in all the NCCs, other sectors are not always represented. For instance, Academic and Research Institutions (mainly public, too) and NGOs are represented in around 60% of the NCCs and the Private Sector in around 40% of them. Even with the presence of other constituencies, Government representatives tend to be the large majority of the

[30] In the countries where the NCA is a National Biosafety Authority or Council, it is usually the Board of the Authority/Council to carry on the functions of multi-stakeholders decision body.

[31] "A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects", UNEP-GEF Biosafety Unit, December 2006

members in all NCCs, while the other sectors are usually under-represented, particularly NGOs and Private Sector. Women and HR Organisations are virtually absent in all the NCCs. This picture has not changed very much throughout the years, as confirmed by the TE of NBF Implementation Projects in recent years. This is, of course, a major issue that may hamper stakeholders' effective inclusion and meaningful participation, as discussed under Socio-political Sustainability (chapter 4.4.1).

75. Overall, the progress towards a fully operational Institutional Framework is considered Moderately Satisfactory (MS).

b) Regulatory regime

76. A particularly relevant issue is the Regulatory Regime, which remains in many cases an unachieved result that has influenced the achievement of the Administrative System for handling applications and decision-making, of the Monitoring and Enforcement System and, to a certain extent, of Public Participation mechanisms.

Box 1

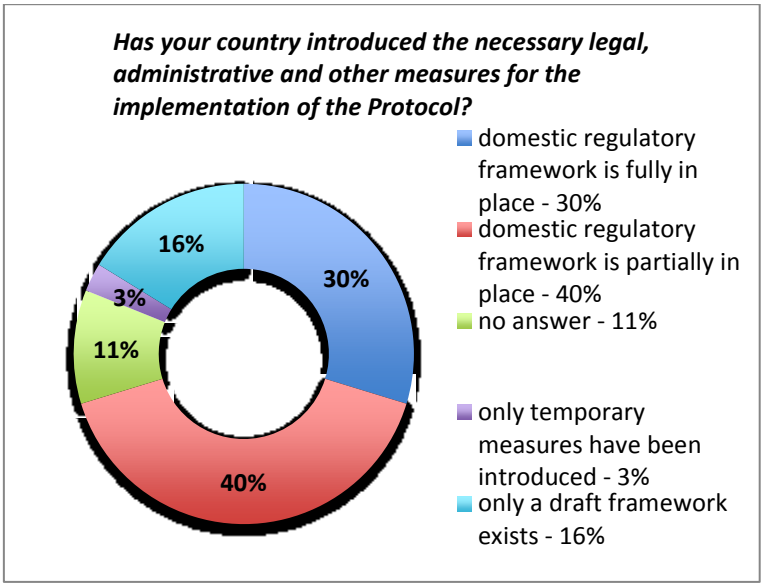
> *Although some outcomes were partially achieved, the lack of implementation of the biosafety framework – due to the partial approval of the regulations - is hampering progress towards impact and causing the loss of acquired skills and capacities.* (TE of Mauritius NBF Implementation Project)
>
> *Objectives partially achieved as the formal approval and operationalization of expanded regulatory framework and integrated administrative and risk management procedures by the new government is uncertain* (TE of Costa Rica NBF Implementation Project)"
>
> *The process of elaboration of the Biosafety Law, started in 2004, went through various and recurrent stages of discussion, revision and decision, eventually receiving a strong impulse from the Project and culminating with the promulgation of the Law, early in 2014.* (TE of Lao PDR NBF Implementation Project)

77. Actually, to prepare, discuss, revise and adopt National Biosafety Laws has been a burdensome task for many developing countries, where the entire process of law adoption has been protracted, in certain cases, for almost ten years (e.g. Lao PDR, Egypt, Kenya). Reasons for that are manifold: the complexity and multifaceted nature of biosafety involving various stakeholders with different and somewhat contrasting views (as discussed under socio-political and institutional sustainability, chapter 4.4), slow and elaborate process of laws discussion, revisions and sequential approvals, changes in Government after elections or overall socio-political instability, among others.

78. It has also to be considered that the revision of a law is a similar intricate process. For instance, Senegal is revising its law (enacted in 2009)[32] and the process is planned to take more than one year (from re-drafting to approval). That is why, for instance, Albania and Tanzania opted for shifting their objective from a "stand alone Biosafety Law" to the inclusion of biosafety in the Law on Environment Protection and to specifically address the deliberate release of GMOs by a Government Decree, which seems a practical and wise solution.

[32] In order to permit the use of biotechnologies in the country (currently not allowed at all), the insertion of provisions regarding the Nagoya-Kuala Lumpur Supplementary Protocol and alignment with UEMOA (Economic and Monetary Union of West Africa Countries) policies.

79. In the National Report[33] formats, countries are asked whether they have introduced "the necessary legal, administrative and other measures for the implementation of the Protocol". As visualised here below, out of 37 sample countries, 11 (30%) reported that a domestic regulatory framework is fully in place and 15 (40%) reported having a NBF partially in place. Seven countries (19%) reported not yet having a regulatory framework in place or just temporary measures and four countries (11%) did not respond (both 2nd and 3rd reports not presented).



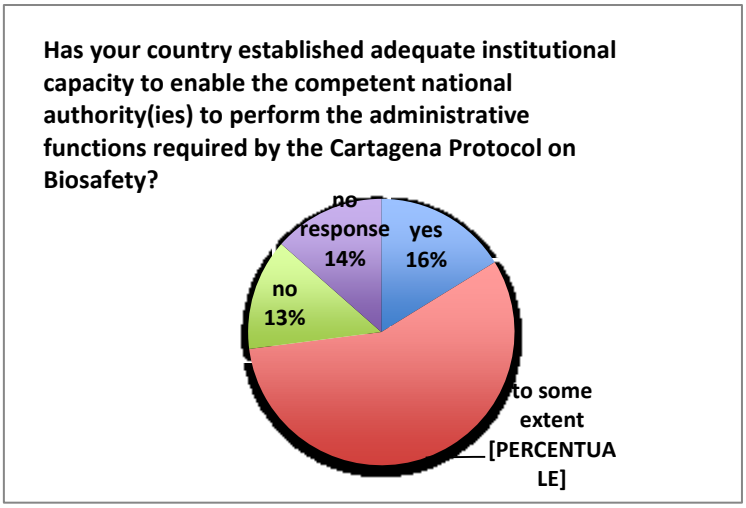
80. Countries' answers reflect their perception of the situation and there is surely a margin of subjective interpretation of words like "fully" and "partially". However, the overall picture may actually give a reasonable approximation of the reality and confirms what has been observed through the TE of the NBF Implementation Projects. As a matter of fact, out of the eleven TE carried out since 2014, three rated Effectiveness (NBF fully operational) as Satisfactory, six rated it as Moderately Satisfactory and two were rated Unsatisfactory, which roughly corresponds to the answers diagrammed above. The discussion of these data with both the Biosafety Task Managers (TM) in Nairobi and Panama has also generally confirmed the situation depicted above (see also chapter 4.3.3, section d).

81. The overall picture conceals large regional differences. Actually, when analysing the whole of the 3rd Nat. Report (112 reports submitted so far), the countries with a "fully operational domestic regulatory framework" are the 81% in Europe, 42% in Asia, 30% in Africa and 25% in Latin America & Caribbean. Overall, the progress towards a fully established Regulatory Framework is rated Moderately Unsatisfactory (MU)

c) Administrative system for handling applications

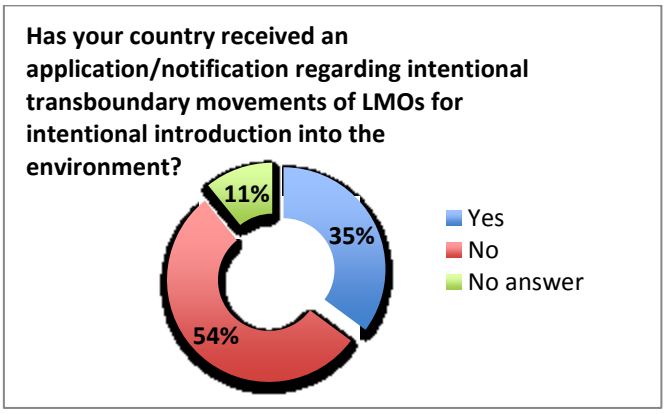
82. Only six countries (out of the 37 sample countries, hence 16%) reported they "have established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the CPB". Since 21 countries (57%) reported having done it "to some extent", it looks like administrative systems are still in need to be fully set and consolidated.

[33] Until February 2016, 22 countries (out of the 37 sample countries) submitted the 3rd National report that was due at the end of November 2015. For 11 countries, the evaluation used the 2nd Nat. Report (2011). Four out of the 37 countries submitted neither of the reports.



83. Of course, the setting of a functional system for handling applications (including the capacity to undertake Risk Assessment and Risk Management) also depends on the concrete opportunities to test and implement it (i.e. applications for GMOs introduction), which has so far occurred in roughly one third of the countries.

84. Actually, out of the 37 sample countries, 13 (35%) have so far received an application for intentional introduction of GMOs into the environment (see diagram below) and 11 (30%) have reported having made a decision, of which six were positive (introduction)[34] and five negative (rejection or request of further information)[35].



85. The percentage of 35% is a considerable fraction of the countries[36]. It was 28% in the 2nd Nat. report of 2011, therefore, having a functional administrative system is an increasingly relevant issue. Actually, according to the TE of the NBF Implementation Projects, this is an area with considerable room for improvement, particularly the capacity to appropriately undertake Risk Assessment and Risk Management.

86. The six countries that have made a decision of authorization (see footnote) claim to have conducted a Risk Assessment (RA). However, only four have published RA reports in the BCH: Philippines (76 RA in the BCH), Honduras (5), Indonesia and Romania (1). Paraguay and Rwanda did not post any decision and any RA in the BCH.

[34] Within the sample: Honduras, Indonesia, Paraguay, Philippines, Romania and Rwanda.
[35] Within the sample: Botswana, Dominican Rep., Fiji, Madagascar and Mozambique.
[36] The Evaluation Team has compared the sample data (37) with the overall data of the 3rd Report (112 countries) to double check the existence of possible sampling "distortions". The percentage is virtually the same (36%).

87. The fact that all the sample countries that introduced GMOs into the environment did so in presence of a RA, it is for sure positive and encouraging. All the RAs posted in the BCH are based on the vast technical dossier produced by the Applicant (e.g. Monsanto) and/or on previous RA and decisions made by other countries (mainly OECD countries, including Non-Parties). In interviews with the NCA in Honduras and Kenya, the mission was told they could not obviously perform a better assessment, which is patently true. Therefore, the real issue is, as clearly pointed out by J. Kinderlerer[37] *"Either the Government performs a risk assessment based on information in the dossier, or the Government audits the risk assessment provided by the applicant. In either event, it must set up a system of scientific oversight of the dossiers received"*. Moreover, once the RA is done, Risk Management (RM) has to be put in place, which implies the capacity to consider *"the nature and magnitude of all identified risks and identifying procedures that eliminate or reduce these risks*" (Kinderlerer, see foot-note).

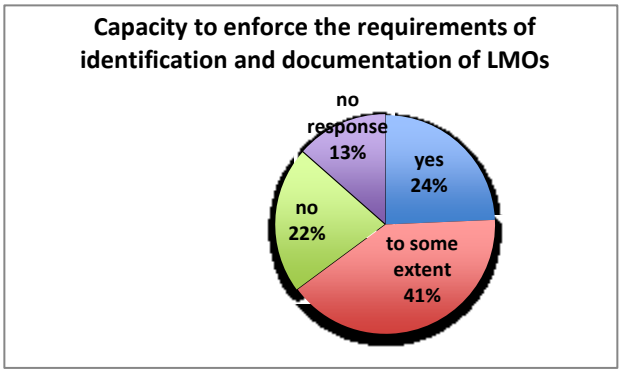
88. The Survey published by the CBD Secretariat in 2014[38] confirms that the percentage of countries *"not having adopted or used any guidance documents for the purpose of evaluating risk assessment reports submitted by notifiers"* is very high in Africa (72% of the countries), in Latin America & Caribbean (76%), in the LDC group (75%) and in the SIDS group (100%). Among the six countries of the sample that declared having made a decision based on RA, only Rwanda affirmed using the "Manual on Risk Assessment of LMOs" (developed by CBD Secretariat) for training in risk assessment.

89. Overall, RA and RM remain areas of deep concern due to their complexity and in need of being addressed in a country-focused manner, after a thorough assessment of in-country capacities. This finding is reflected in the Conclusions and Recommendation of this Report. The progress towards a fully operational Administrative System has been rated Moderately Unsatisfactory (MU).

d) Monitoring and enforcement system

90. Nineteen (19) of the sample countries (51%) reported having the infrastructure (e.g. laboratory facilities) for monitoring or managing GMOs. Only 14 (38%), however, declared to be able to detect GMOs through a certified laboratory. These data are confirmed by the cited CBD Secretariat Survey of 2014 that reported that 50% of the countries did not own a certified laboratory. This average percentage, again, conceals large discrepancies among the Regions (63% in Africa, 50% in Asia & Pacific, 81% in LAC, 20% in CEE and 12% in WEOG countries, which, however, in the case of EU countries, refer to the Joint Research Center (JRC) of the European Commission for GMOs detection.

91. Nine countries (24% of the sample) reported having the capacity to enforce the requirements of identification and documentation of LMOs, while 41% declared "to some extent" and 35% reported not having this capacity or did not answer.



[37] "Regulation of Biotechnology: needs and burdens for developing Countries", J. Kinderlerer, University of Sheffield, http://www.unep.org/biosafety/Documents/BTregulationJK.pdf

[38] "Review of the information gathered through a dedicated survey and corresponding to indicators in the strategic plan", CBD Secretariat, 2014. https://bch.cbd.int/database/reports/surveyonindicators.shtml

92. The analysis of the TE of the NBF Implementation Projects shows that monitoring and enforcement mechanisms are still in an incipient phase, yet represent already a deep concern, for instance in countries like Tanzania, Lao PDR, Mongolia and Bhutan (see Box 2 below).

Box 2

*The shortage of resources to deploy the monitoring and GMO detection system limits the implementation of the BS regulations (*TE of Tanzania NBF Implementation Project)

Considering that Lao PDR is a landlocked country with porous borders, concerns exist that the uncontrolled introduction of Genetically Modified crops (particularly rice) could enhance the risks of contamination from transgenic crops to traditional varieties and of endangering priceless genetic resources (TE of Lao PDR NBF Implementation Project)

Due to the limited quantity of the material needed for the GMOs laboratory, the country has difficulty in purchasing primers and other material for GMOs detection, because companies do not consider the tenders attractive and do not participate. Aggregate purchasing among small neighbouring countries could be a solution. (TE of Bhutan NBF Implementation Project)

93. Overall the progress towards a fully operational Monitoring and Enforcement system has been rated Moderately Unsatisfactory (MU).

e) Public awareness and participation

94. Most of the TE of the NBF Implementation Projects show that the countries have put in place relevant initiatives of information and awareness raising on biosafety with various target groups. (see Box 3 below).

Box 3

- *National Public Surveys implemented (e.g. Estonia, Lithuania, Bhutan) to better understand major public orientations regarding GMOs;*

- *Mongolia has been particularly active in broadcasting several TV programs, TV live-debates, a weekly Radio programme on Biosafety for one year (2012). They also produced an interesting Glossary on Biosafety (Mongolian-English). Lao PDR has produced several CD on Biosafety. Bhutan has produced 3000 calendars with biosafety messages and a cartoon on GMOs in local language aired through the national television channel and uploaded on relevant websites.*

- *A more structured education programme and didactic material has been implemented in Costa Rica, not without polemics for an alleged too "pro" GMO approach. The same initiative is on-going in Guatemala.*

- *The diffusion of the National Biosafety Law in several national languages and its discussion, particularly in rural areas, has been a most remarkable initiative of Namibia.*

95. All the countries have also put in place lobbying and advocacy actions towards the "decision makers" (members of the National Parliaments, central and local Government authorities, farmers and consumers). Admittedly, however, many NCAs think that the effectiveness and incisiveness of their communication is not at a suitable level and feel that their communication and lobbying capacity is lesser than NGOs' and Private Companies' capacity (see also, on this regard, chapter 4.6.3, Stakeholders Participation). That is an area where supplementary efforts have to be deployed. Some focused communication tools have probably to be conceived and produced with the technical support of UNEP.

96. The analysis of the National Reports of the 37 sample countries (see Annex 15) outlines the following data:

Box 4

- 50% of the countries have an awareness and outreach programme on biosafety;
- 32% of the countries have established a biosafety website;
- 24% of the countries have established a mechanism to ensure public access to information on imported GMOs, another 24% reported having done so to a limited extent and 41% have not established such a mechanism. Four countries (11%) did not respond.
- 32% of the countries have established a mechanism to make available to the public the results of decisions taken on GMOs, 30% have done so to a limited extent and 27% reported that they have not established such a mechanism. Four Parties (11%) did not respond.

97. All the above seems to indicate that, though many interesting initiatives have been put in place, there is room for improvement to achieve larger and more meaningful public information and participation.

98. Regarding the Information Sharing and the Biosafety Clearing-House (Article 20 of the CPB), the respondents were asked to provide an overview of the status of the mandatory information provided by their country to the BCH, by specifying for each category of information whether it is available and whether it has been submitted to the BCH. The answers provided by the 37 sample countries are outlined here below:

Box 5

- *Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure* are reported to be available and in the BCH by **41% of the countries**;
- *National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing* are reported to be available and in the BCH by **35% of the countries;**
- *Final decisions regarding the import or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision)* are reported to be available and in the BCH by **8% of the countries**;
- *Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing* are reported to be available and in the BCH by **11% of the countries.**
- **19% of the countries** reported that they *always use the information available in the BCH in their decision-making processes on LMOs*; **38%** of the respondents reported doing so *in some cases*; **24%** reported that they do not use it and **19%** did not report.

99. It is undeniable that many efforts and projects (e.g. three rounds of GEF-UNEP BCH Projects, the creation of a pool of BCH Regional Advisors, among others) have been deployed to make the BCH more effective. However, as strongly remarked also in the Seventh meeting of the Conference of the Parties (BS COP MOP 7),[39] there is wide room for improvement, if BCH has to become a real instrument of

[39] See BS-VII/2, Operation and Activities of the Biosafety Clearing-House (COP-MOP 7, 2014) that *"urges Parties to register in the Biosafety Clearing-House all their final decisions on the first intentional transboundary movement of living modified organisms for intentional introduction into the environment…..with special emphasis on the first*

public information and transparency. For instance, Paraguay has declared in its 3rd Nat. Report having received in the last three years more than ten applications and having made subsequent decisions. However, none of them has been posted in the BCH. Similarly, Burkina Faso has approved the introduction of GMO cotton (not posted in the BCH)[40] and Kenya has approved GMO maize for deliberate release in January 2016, not yet posted in the BCH.[41]

100. Overall, the progress towards Public Participation and Awareness has been rated Moderately Satisfactory (MS).

f) Capacity building

101. Capacity building is at the core of GEF-UNEP support to CPB implementation. Both Development and Implementation Projects have deployed huge efforts and considerable resources on this aspect (workshops, study tours, learning manuals, information material, etc.). Actually, the survey of the National Reports of the 37 sample countries shows that 28 countries (76% of the respondents) have undertaken, during the last reporting period, activities of capacity building in different areas, such as Risk Assessment (68% of the countries), Public awareness and participation (61%), Identification and detection of GMOs (46%), Information exchange and Data management (43%). The under-represented areas are: Implementation of the documentation requirements under art.18.2 (Handling, Transport, Packaging and Identification) with 14% and Socio-economic considerations (18%). Virtually all the countries are reporting that at least one laboratory personnel has been trained on GMOs detection, but only half of the countries reported having trained customs officers in the identification of LMOs.

102. It has already been discussed in this report the effectiveness of regional and sub-regional workshops (see 4.3.1, Outcome 1) and the critical conclusion of GEF Evaluation of 2005 about the "one size fits all" approach of those workshops. Regional meetings and workshops may have an undisputable role to play in fostering information exchange and in coordinating objectives and strategies, as well as in reducing overall costs through "economy of scale". However, national and "on call", tailored trainings are deemed to be more effective in terms of upgrading national human resources (see box below).

Box 6

Several felt that capacity-building impacts could have been broader and more cost-effective if they had focused more on in-country training. This would have extended training to a "critical mass" of public sector trainees and build institutional commitment.(TE of Costa Rica NBF Implementation Project)

…However, capacity building, particularly technical and procedural capabilities, can only improve through specific and more focused trainings and their concrete application, which has been so far missing, due to the lack of practical opportunities….Risk Assessment and Risk Management remain theoretical notions, so far as applications or "real time" cases have not been handled…(TE of Mongolia NBF Implementation Project)

The decision to focus on in-country training (using international expertise) allowed the project to reach a broad audience, raising the threshold of biosafety awareness and 'buy in' to the proposed system. Institutional knowledge and competence for LMO risk management was improved in most cases, although hands-on training through simulations and mock trials was lacking.(TE of Guatemala NBF Implementation Report).

intentional transboundary movement of living modified organisms intended for field trials, since this category is currently underrepresented in the Biosafety Clearing-House"

[40] According to ISAAA (International Service for the Acquisition of Agri-biotech Applications), Burkina Faso has more than 140.000 farmers cultivating GM Bt Cotton for a total of 454.124 hectares (74% of the area cultivated with cotton).

[41] Interview with the Kenya Nat. Biosafety Authority, March 2016

103. There are some emerging and interesting initiatives regarding the inclusion of biosafety in the academic curricula, either as a specific topic in some faculties (e.g. Biology, in some countries) or as a specific annual or biennial post-graduation courses. In Senegal, for instance, there is an on-going Master Degree on Biosafety at the Faculty of Law and Political Sciences, while in Guatemala a six-month postgraduate diploma course on biotechnology and biosafety has been implemented (Faculty of Agronomy) over two years with more than 40 students and is now available online through the BCH. The UNEP-GEF Project in the Caribbean Sub-region has also promoted the approval and start of a MSc in Biosafety of Biotechnology Products at the UWI (University of West Indies). These are innovative and relevant initiatives for the establishment of solid Biosafety national capacities in the medium-long term.

104. A final remark regards the diffuse perception that training and capacity building would "automatically" lead to institutional building and sustainability, which, in fact, has not to be taken as granted. Actually, all TE of NBF Implementation Projects underscore that the effectiveness of the many training and awareness activities is largely conditioned by the institutional context in which the trained human resources are operating. Weak institutional up-taking and lack of concrete opportunities to put in practice new knowledge and skills play a substantive role in lowering training effectiveness and impact. Overall, the progress in capacity Building has been rated Moderately Satisfactory (MS).

g) Regional and Sub-regional dimension

105. The regional dimension of the NBF Development Project was quite downgraded when compared with the initial expectations and this report has discussed the issue in chapter 4.3.1 (Effectiveness, Outcome 1). However, when analysing the TE Reports of the subsequent, more recent NBF Implementation Projects, it is easy to observe that the regional dimension still remains a thin and rather elusive component (see box below). Actually, according to the 3rd National Report on the Implementation of the CPB, only six out of the 37 sample countries (16% of the respondents to this question) reported having entered into bilateral, regional or multilateral agreements or arrangements (Belarus, Dem. Rep. Congo, Indonesia, Niger, Rwanda and Zimbabwe).

Box 7

A regional approach was missing as the project document did not elaborate a comprehensive strategy to integrate the national NBF in broader contexts, a key issue for their viability in small countries such as Mauritius (TE of Mauritius NBF Implementation Project)[42]

The project strategy lacks a regional dimension and this is a key issue for economizing resources and achieving scale economies in deploying the biosafety procedures (e.g., in authorization, transboundary trade, monitoring) (TE of Tanzania NBF Implementation Project)

"There is a strong need for increased harmonization and coordination among the Parties in the implementation of the Protocol" (interview with the Gen. Secretary of the MoE of Senegal)

106. It is true that UNEP, as Implementing Agency, has been employing energies and resources to organise regional or sub-regional meetings between the NPCs (National Project Coordinators) and to encourage countries' networking, for instance, through information exchange and joint capacity building activities between neighbouring countries (e.g. workshops, study-tours). Proposals for nine regional / sub-regional projects were also prepared by the Biosafety Unit of UNEP under GEF 3 and GEF 4, of

[42] As a matter of fact, an effort was made to put together the Indian Ocean Islands Biosafety Project, but unfortunately only Madagascar did put resources forward (information from UNEP Biosafety TM).

which, eventually, only the Caribbean Sub-regional Project went forward and is currently being implemented.

107. As a matter of fact, the regional approach, though important in principle, is proving difficult to implement. There are various aspects that add complexity to its implementation, among them:

- The identification of regional/sub-regional institutions able to play the role of Project Executing Agency, i.e. with adequate capacity both in the sector of biosafety and in project management;
- The risk of adding one more administrative and bureaucratic step to the project;
- The concerns of the countries regarding their possibility to steer the project within a regional context;
- The existence of different GMOs and Biosafety policies and approach among countries of the same sub-region, limiting the scope of the cooperation and mutual trust;
- The mechanism of STAR national allocation that functions through national allocations (regional and global allocations are only attributed to BCH and National Reporting activities);
- The unclear and weak links of Biosafety Projects with UNEP Regional Offices (RO), except in ROLAC (Regional Office for Latin America and the Caribbean), where there is an out-posted Biosafety TM.

108. The experience of two GEF sub-regional projects (one being implemented by UNEP in the Caribbean and the other concluded in West Africa, implemented by WB and UEMOA[43]), shows the institutional complexity and management difficulties of a (sub)regional project. As emphasised by the MTE of the Caribbean project, "a linear "one size fits all" approach is unfeasible where 12 countries are involved. Differentiated strategies are needed to move clusters of countries forward, based on their momentum and likelihood of achieving results".

109. There is an increasing interest in biotechnology and biosafety coordinated initiatives among Regional Communities and Organizations in the framework of their programmes for regional economic integration and transboundary free trade. Some of them are particularly active, like SAARC (South Asian Association for Regional Cooperation) and ASEAN (Association of South-East Asian Nations) in Asia, UEMOA (Economic and Monetary Union of West Africa), ECOWAS (Economic Community of West African States), COMESA (Common Market for Eastern and Southern Africa) and SADC (Southern Africa Development Community) in Africa.

110. All these organizations have their own political agenda and their approach to GMOs and biosafety may vary, depending on the economic and commercial strategy of the region and on the cooperation and partnership agreements in place with powerful international players (e.g. USA, EU, Financial Institutions, Multi-national Corporations). For this reason, though essential key-players and stakeholders, they may not be the first option as direct point of reference for executing regional projects to support the implementation of the CPB.

111. There are, on the other hand, multi-country initiatives that have to be regarded with much interest for their country-driven and more flexible approach, like those planned between Cambodia, Lao PDR and Vietnam and between Nigeria, Ghana and Liberia in the area of Risk Assessment and Management, as well as the Southern Africa Network of GMOs Detection Laboratories and the Central America Initiative for Biotechnology and Biosafety. Experiences of bi-lateral cooperation on specific areas have also been observed, for instance, between Lao PDR and Malaysia, between Mongolia, South Korea and Japan and between Albania and Slovenia.

[43] Economic and Monetary Union of West Africa

112. Overall, the progress in implementing the Regional and Sub-regional dimension is rated Moderately Satisfactory (MS).

h) Cooperation and Partnership

113. Given the controversial nature of Biosafety, enhanced coordinated initiatives within the UN system could help to widen the spectrum of target groups and gain credibility, synergy and effectiveness. This is particularly evident with FAO, which runs its own GMOs Biosafety Platform and hosts relevant international agreements like the Codex Alimentarius (with WHO) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[44]

114. As a matter of fact, coordination and partnership has been registered here and there in the NBF Implementation Projects and a very interesting initiative of three joint webinars has been implemented during 2014 and 2015 by CBD/UNEP, FAO and OECD on "international databases on biosafety" with the objective of raising the awareness on the different international biosafety resources available online and to explore how synergies between them can be maximized.

115. Overall, however, continuity and effectiveness have not been generally achieved (see box below)

Box 8

It is quite unfortunate that, while national stakeholders do see the linkage between Food Safety and Biosafety, the UN agencies do not adequately help them to build partnerships, for instance linking Codex Alimentarius (supported by FAO/WHO through the Ministry of Agriculture and the Ministry of Health) and Biosafety (supported by UNEP through the Ministry of Environment and Green Development). Dispersion of funds and duplication of efforts do not help institutional sustainability. (TE of Mongolia NBF Implementation Project)

It is discouraging to observe, in a country like Bhutan that has adopted the UN approach "Delivery as One", the fragmentation of initiatives and dispersion of funds within the UN System. As a result, the GEF Biosafety Project implemented by UNEP is little known at UN House and GEF funded Project on Nagoya Protocol implemented by UNDP has no links with UNEP Biosafety Project. (TE of Bhutan NBF Implementation Project)

116. The linkage with research and extension programmes implemented by the Research Centres of CGIAR (Consultative Group on International Agricultural Research), like CIAT (International Center for Tropical Agriculture) and ICARDA (International Centre for Agricultural Research in Dry Areas) is more episodic than systematic, too. Overall, the progress towards Partnership and Cooperation is rated Unsatisfactory (U).

117. The overall progress towards NBF Implementation is resumed in the following synoptic table and scores Moderately Unsatisfactory (MU).

Criteria	Score
a) Institutional framework	MS
b) Regulatory regime	MU
c) Administrative system for handling applications	MU
d) Monitoring and enforcement system	MU
e) Public awareness and participation	MS
f) Capacity building	MS

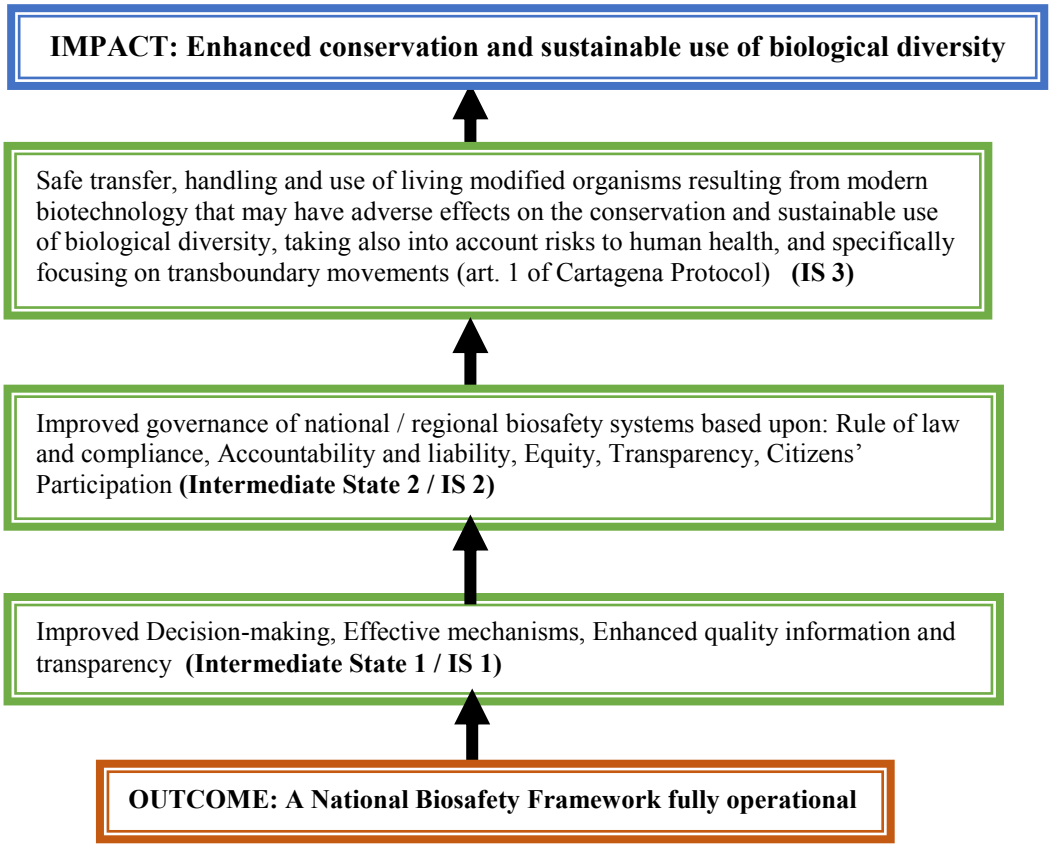
[44] Actually, FAO has been an active partner in the Project Steering Committee of the global NBF Development Project.

g) Regional and Sub-regional dimension	MS
h) Cooperation and Partnership	U
Overall	**MU**

4.3.3. Likelihood of impact using Review of Outcomes to Impact (ROtI) and based on reconstructed Theory of Change (ToC)

118. The intended impact of the project is the Global Environmental Benefit to which it contributes**:** the conservation and sustainable use of Biological Diversity through enhanced Biosafety. The steady and smooth implementation of the NBF represents the main pathway to Impact, a pathway that, however, is not a straightforward process: transitional conditions (called Intermediate States) have to be fulfilled, as shown in Diagram 3 (Theory of Change: from Outcome to Impact). For the sake of simplicity, three main Intermediate States (IS) have been identified. Diagram 3 presents the "ideal" pathway from Outcome (the NBF fully implemented) to Impact.

Diagram 3: Pathway from Outcome to Impact



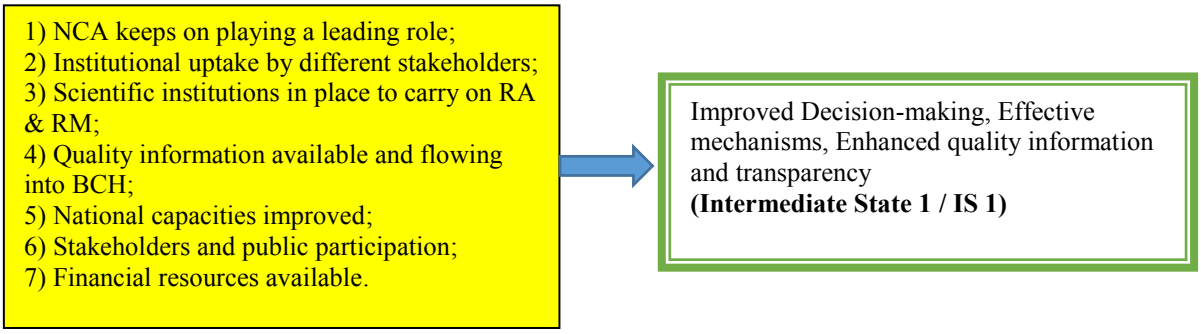
a) Analysis of driving forces, dualities and asymmetries

119. The Evaluation has found that different driving forces, dualities (polarities) and asymmetries are playing a substantive role in the pathway to Impact. Dualities and asymmetries, depending on the dynamics of their (dis)equilibrium, may convert into driving forces or put a conditionality that may hamper the process.

120. The progress towards impact is a "country-driven" process and the main Drivers (Driving Forces) are the national actors, institutions, mechanisms and procedures enabling the progress towards Impact.

The main Assumptions identified in Diagram 2 of chapter 4.3.2 become, once the NBF (Outcome) is operational, the main key-drivers for Impact. They directly contribute to the achievement of Intermediate State 1 (Improved Decision-making, Effective mechanisms, Enhanced quality information and transparency)

KEY-DRIVERS for IS 1



121. As discussed more in depth under Institutional Sustainability (chapter 4.4.2), key-actors at national level are not a homogenous group and different visions and strategies do exist concerning GMOs and biosafety. In the current polarized debate, the duality between "pros and against" is a relevant fact challenging the setting of improved mechanisms and procedures for decision-making.

Duality 1 — National actors "pro GMOs" [redacted] National actors "against GMOs"

122. The relations between two of the main institutional actors, i.e. the MoE and MoA (see 4.4.2, Institutional Sustainability) represents a particular duality that can either create synergies or contribute to polarization, depending on how it is managed.

Duality 2 — Min.of Environment [redacted] Min. of Agriculture

123. Large and medium-scale commercial farming, prone to GMOs cultivation, and traditional smallholders farming or biological farming is an increasingly relevant duality observed in several countries, where the national capacity of implementing and managing co-existence rules and socio-economic considerations plays a major role and has still to prove to be up to the challenge. Other specific dualities have been observed, for instance, in Costa Rica between Central Government and Local Government.

Duality 3 — Large/Medium size Commercial farming [redacted] Traditional / Bio Agriculture

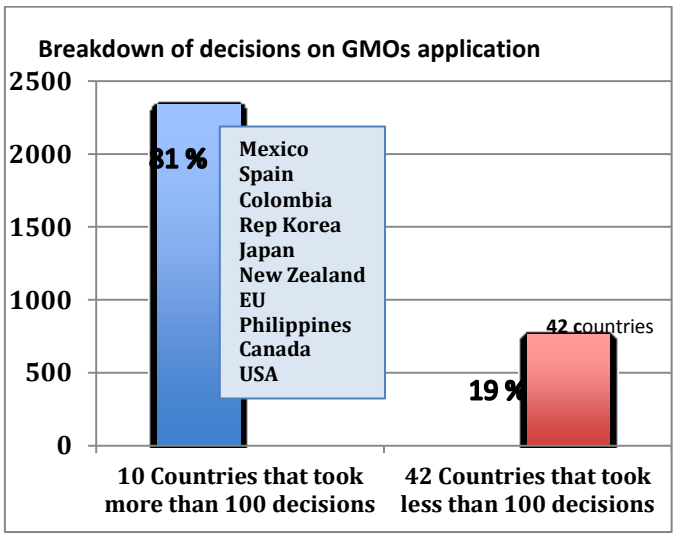
124. There are also driving forces over which Governments have no control, for instance the strategies and the influence of other States, of Multinational Corporations and of Social / Civil Society movements (at national and international level). Given the transnational and controversial nature of Biosafety, these actors can strongly influence the national decision-making process and their attitude is crucial to open or limit dialogue and negotiation.

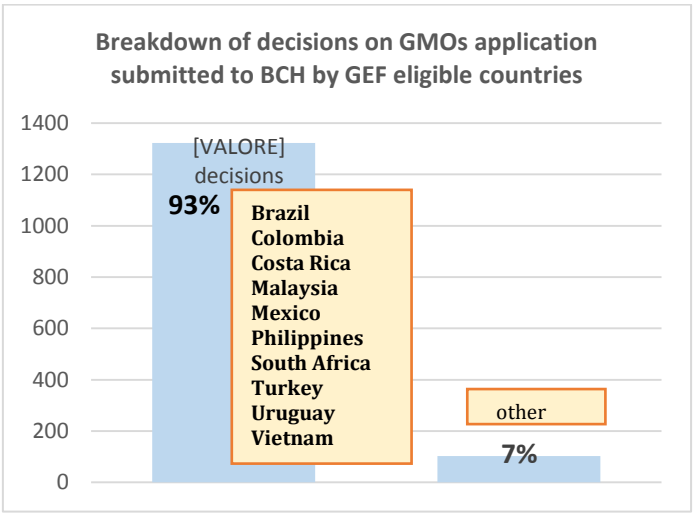
125. There is asymmetry, particularly in Developing Countries, between the capacities of these external actors and those of the Governments and that can unbalance the decision-making process. A case in point, already discussed in this Report, is the capacity of Risk Assessment (see section "c" in chapter 4.3.2) and another one is the capacity of influencing decision-makers (from policy makers to farmers and consumers), as discussed in section "e" of chapter 4.3.2 and under Stakeholders Participation (chapter 4.6.3). When key-drivers are weak in ensuring availability of information and its accessibility through

the BCH (as discussed in chapter 4.3.2 section "e") one of the cornerstones of IS 1 (Enhanced quality information and transparency) may be lacking.

126. There is, however, also a strong asymmetry between countries, as far as decision-making is concerned. When analysing the number of decisions regarding GMOs applications posted in the BCH (3.099 decisions up to February 2016), one can observe (see Diagram below) the strong concentration of decisions (81%) in no more than 10 countries[45], while the other 42 countries made 19% of the decisions and some 120 Party countries did not make any decision at all. Moreover, with few exceptions (Colombia, Philippines and Mexico), the countries with more decisions are Non-Parties or non-eligible countries to GEF funds.

127. The decisions made only by GEF-eligible countries are 1.426 and are distributed among 28 countries. There is a strong concentration (1323 decisions, i.e. 93% of the total) in ten countries (Brazil, Colombia, Costa Rica, Malaysia, Mexico, Philippines, South Africa, Turkey, Uruguay and Vietnam) out of the 147 eligible Parties. This asymmetry has to be taken into account for matching country needs through country-tailored initiatives and projects.

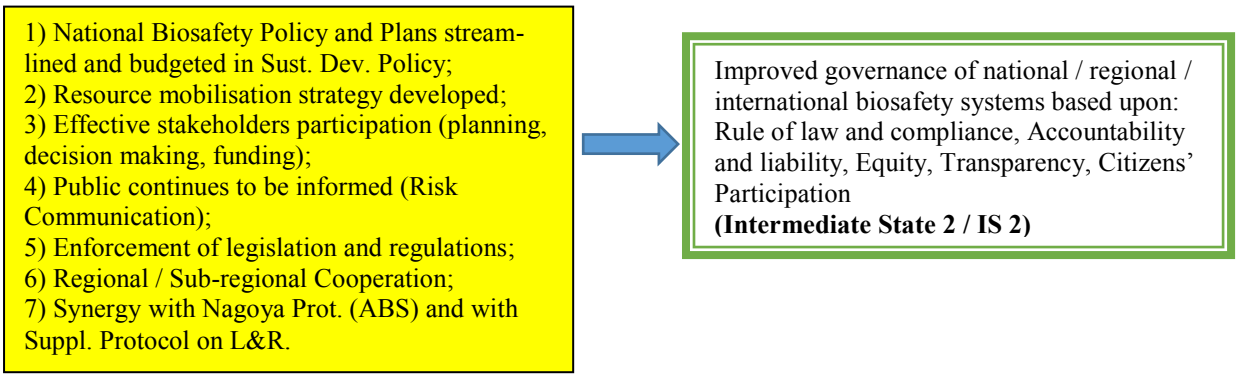




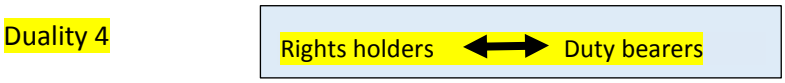
[45] More precisely, 9 countries plus EU. Mexico, Spain and Colombia lead the list with, respectively, 480, 375 and 311 decisions.

128. Improved decision-making can lead to Improved Governance at national and regional level (Intermediate State 2, IS 2), if appropriate policy instruments and mechanisms are put in place (e.g. a Sustainable Development Policy in place, Biosafety planning and budgeting, liability and law enforcement, accountability and transparency, public access to information, public hearing, etc.).

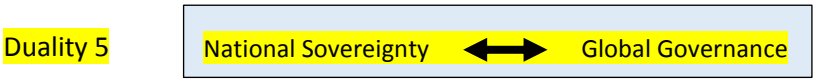
KEY-DRIVERS for IS 2



129. Environmental Governance is often a matter of Global Governance and Biosafety is, by its own nature, a transboundary issue. Therefore, external forces come to play, such as COP-MOP decisions, Regional players (e.g. EU, NEPAD, ASEAN, etc.), International Trade Agreements, Trade Related Aspects of Intellectual Property Rights (TRIPS), among others. Some of these aspects are discussed under Socio-political Sustainability (chapter 4.4.1) and are increasingly regarded as "equity issues", where the duality between "right holders" and "duty bearers" comes to play a role.

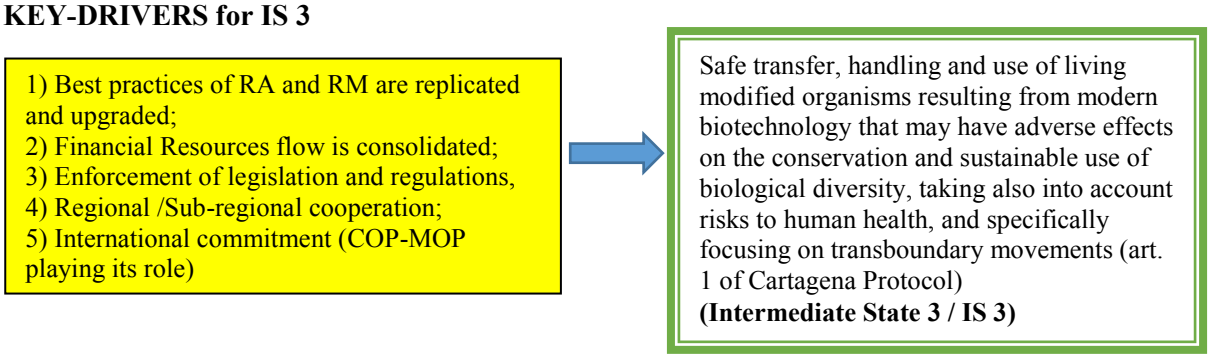


130. The duality between National Sovereignty and Global Governance is considered by many observers and scientists as a source of increasing asymmetries between countries (particularly developing countries) and powerful global players.



131. Improved Governance at national, regional and international level can lead to the fulfilment of the main objective of the Protocol, as stated in its art. 1 ("The safe transfer, handling and use of LMOs…...") if the appropriate mechanisms set in previous step (IS1 and IS2) are maintained and consolidated. Some of them are of particular relevance and are outlined in the following diagram.

KEY-DRIVERS for IS 3



132. The on-going, strong debate regarding the interrelation between Cartagena Protocol and WTO rules, with the alleged superiority of one to the other depending on the viewpoint, is a relevant duality, which comes to play at this level.

Duality 6 | Cartagena Protocol [redacted] WTO rules

133. Eventually, CPB implementation can lead to Impact: "Enhanced conservation and sustainable use of biological diversity", which is the Global Environmental Benefit Biosafety contributes to. National and Global policies and programs, synergies and upgrading / up-scaling of best practices contribute as key-drivers to Impact.

KEY-DRIVERS TO IMPACT

1) Synergy with other Biodiversity Programs;
2) Sustainable Agriculture, Forestry and Fishery;
3) Best practices of Ecosystem Management and Env. Impact Assessment in place for different sectors;
4) Regional /Sub-regional cooperation;
5) International commitments (synergy between MEA, between UN Agencies, etc.)

→ Enhanced conservation and sustainable use of biological diversity **(Impact)**

134. At this stage, the duality between countries and institutions embracing the Precautionary Principle (e.g. EU, UNEP) and those claiming and championing less stringent norms (e.g. USDA) is surely an issue, particularly considering the growing dynamism of the second group and its strong alliances with GMOs corporations also in developing countries.

Duality 7 | Precautionary Principle [redacted] Less stringent norms

b) Overall considerations on the ToC

135. The Diagrams proposed in this chapter, as well as the previous ones in chapters 4.3.1 and 4.3.2, to visualise the complete Biosafety Theory of Change (ToC), are either reconstructed (ex-post) pathways of what happened (or is still happening) in the projects, or envisaged perspectives of what could or should happen in a more or less near future. They represent a "reconstruction" of the reality, which is, indeed, more diversified and complex than the diagrams show.

136. They are a sort of "standard picture" of a situation that is not only different from country to country, but also "moving" and dynamic within the country, with continuous steps forward and backward, incoming new drivers and dualities, unstable equilibrium / asymmetry situations and subsequent "trade-off" to be managed. Therefore, while recognising that the ToC can be a valuable instrument for analysis and discussion, the exercise has to be always regarded as a "starting point" for further pondering and processing.

137. Having said that, three main questions can be highlighted and should be taken into account: :

1) Fragmentation and dynamics
The reality is much more fragmented and dynamic than the ToC can depict. Projects terminal evaluation reports show, for instance, that a project may have been successful in progressing from Outcome to Impact in some specific aspects (e.g. the Regulatory Regime), even without delivering basic outputs in some other aspects (e.g. in Public Participation). Governmental changes or economic crises may have sudden implications

in terms of administrative and follow-up systems (e.g. changes in technical staff or budget cuts). As a result, the real picture is frequently blurry and patchy.

2) Alternative views

The reconstructed ToC presented in this report reflects one point of view, GEF-UNEP point of view: Global Environmental Benefits (GEB) are the ultimate goals. However, countries may look at Biosafety with a different approach, considering biosafety and biotechnologies in a larger context, where economic development and trade rules are also at stake. They would preferably indicate, among others, Economic Development, Poverty Alleviation or Social Inclusion as the ultimate goals of their national policies and programmes. Low-income economies can, for instance, regard biotechnology as a powerful means to boost food security or to increase agricultural export, hence country's revenues. If different visions are to be brought together within the perspective of Sustainable Development, one has to recognise and take on board alternative views.

3) Different priorities

Alternative views orient countries towards different priorities. This may become a crucial issue particularly in low-income economies, where having a fully operational NBF (creating biosafety legislation and institutions, monitoring and inspection systems, etc.) can bring about relevant opportunity-costs. Countries assess and define the "adequate level of protection" (as Art.1 of the CPB goes) against a large spectrum of needs and priorities. When analysing the number of decisions reported on the BCH, one can observe that the vast majority of the Parties to the Protocol (122 countries out of 170, i.e. the 72%) has not been involved in GMOs development, so far. Only 28 GEF eligible countries (16% of the Parties) have made so far at least one decision and posted it in the BCH.

c) Rating on progress towards Impact achievement

138. According to the TOR of the Evaluation, the Evaluation has to assess the likelihood of the project to achieve the expected Impact. A generalised assessment could be too inaccurate, given the high number of countries (123) that integrate the project[46]. Based on the analysis of the progress from NBF Development to NBF Implementation (chapter 4.3.2), countries can be divided in three main groups, as follows:

- **Group 1**: countries with a satisfactory NBF in place and overall operational. Specific weak points may still exist at a variable level and there is the need to fill the existing gaps with technical assistance on thematic issue (e.g. Risk Assessment, detection capacity, etc.). Most of them have been exposed to GMOs and made decisions on applications. They may represent 25-30% of the countries. Likelihood to Impact (see table below) has been overall rated Moderately Likely (ML), though there are some positive cases that could actually deserve a Likely (L) rating;

  Group 2: countries that have somewhat progressed in setting their NBF (e.g. a National Law, NCA in place, capacity building) but cannot claim having it operational because of evident flaws (e.g. lack of regulations and procedures, insufficient institutional up-take and stakeholders participation, etc.). Overall, there is the need of a more resolute political will to progress. Some of them may have received applications for GMOs and also taken some decision. They may represent 40-50% of the countries and an average rating is objectively difficult. Overall, Likelihood to Impact (see table below) has been overall rated Moderately Unlikely (MU) under the current conditions, with the remark that some countries of the group could actually deserve a higher score (Moderately Likely).

[46] The analyses in chapter 4.3.2 (From NBF Development to NBF Implementation: progress and constraints) and in previous sections (a and b) of this chapter provide a more detailed and nuanced assessment.

- **Group 3**: countries that did not give, so far, substantive steps towards the implementation of their NBF after its drafting, for different reasons (e.g. different priorities, lack of resources, little interest, no direct exposure to GMOs, etc.). They may represent 25-30% of the countries. Likelihood to Impact (see table below) has been rated Unlikely (U).

Group 1 (25-30%)
Group 2 (40-50%)
Group 3 (25-30%)

139. The Rating for the three groups is the following:

Group 1	Group 2	Group 3
Overall likelihood of Impact: **Moderately Likely (ML)**	Overall likelihood of Impact: **Moderately Unlikely (MU)**	Overall likelihood of Impact: **Unlikely (U)**

d) Role of GEF-UNEP support in the pathway to Impact

140. The following table resumes the overall GEF-UNEP support to Biosafety (Source: BCH, last updated 2012)[47]. A detailed table with data by country is presented in Annex 17.
A total amount of around 106 M USD[48] has been allocated by GEF to UNEP in the last fifteen years (2001-2015) to finance Biosafety Projects of different kind (see Annex 18 for more detailed data).

Regions / Countries	GEF STAR-BD Eligible	CPB Parties	GEF Capacity Building funded projects						
			Pilot project	NBF-Dev	NBF-Imp Demo	NBF-imp	BCH-I	BCH-II	Regional Projects
Africa: 53	52	49	10	39	4	14	47	23	1 (5 c.)
Asia-Pacific: 56	46	41	2	36	3	13	30	11	-
CEE: 23	15	22	4	18	2	7	16	1	-
GRULAC: 33	33	29	2	28	3	6	27	15	3 (17 c.)
WEOG: 30	1	21	-	2	-	1	2	-	-
Total: 195	**147**	**162**	**18**	**123**	**12**	**41**	**122**	**50**	**4** (22 c.)

Source: BCH (last update 2012)

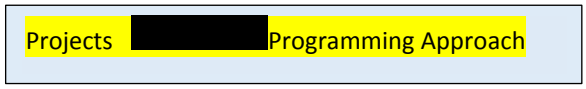
[47] Actually, the table includes also four projects implemented by WB or UNDP (four Demonstration-Implementation projects) and three regional Projects implemented by WB (one in West Africa and two in LAM).
[48] Source: www.thegef.org/gef/project_list?keyword=Biosafety

141. There is no doubt, therefore, that GEF-UNEP projects play a substantive role in implementing the biosafety agenda worldwide. That has been done mainly through global initiatives (e.g. NBF Dev. Projects, BCH projects, support to National Reporting) and an increasing number of National Implementation Projects which, however, have been originally conceived with a quite "standard format" that has given only partial room to countries' specificity (the "fragmentation and dynamics" issue discussed above)[49].

142. Projects are instruments with limited scope (time and budget restriction) and often a short-sighted vision. They are supposed to delivery outputs and to achieve short-medium term outcomes, while impact looks like a distant goal, which "somebody else" will deal with. That could be understandable at the beginning of the Program, whereas nowadays, after almost fifteen years of activities and a considerable budget allocation, there is a compelling argument to have a more impact-oriented approach.

143. There is, in fact, all along the pathway to impact, a pervasive duality between a "Project Approach" and a more strategic "Programming Approach". The latter should be the suitable instrument to frame somewhat dispersed and fragmented interventions (the projects) into a broader context more logically and clearly conducive (causal pathway) to impact.

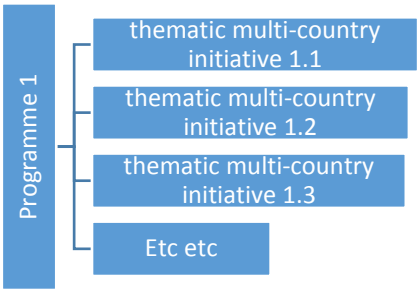
Duality 8



144. The identification of the three groups of countries (Group 1,2 and 3, see previous section) may help to address country needs with different programs, as recommended at the end of this report. For instance, countries with increasing exposure to GMOs could be matched through incisive "hands on" capacity building programs in Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC), whereas those in need of defining their legal framework could be helped in identifying the most viable legal instruments to adopt.

145. Prior to the programming exercise, it is necessary to know and understand the specific "needs and priorities" at country and sub-regional level, i.e. the so-called "stocktaking" activity, which should be one of the main tasks of the Regional TMs (to be increased in number) and a small team of sub-regional consultants.

146. The sub-regional dimension seems more "workable" than the regional one and particularly adequate for exploring a "programming approach" accommodating specific national priorities and common transboundary issues through small-size "thematic multi-country initiatives / activities". South-South cooperation could play a relevant role in this context. Actually, there are already some planned initiatives in that direction, such as those mentioned in section "g" of Chapter 4.3.2, regarding the South African GMOs Laboratory Network and the Sub-regional (Vietnam-Lao-Cambodia) Project for RA an RM.



[49] As a matter of fact, the current strategy is already moving from generic to specific and in some cases thematic approaches as a learning process both for UNEP, the GEF and the countries, which has to be regarded as a positive trend.

4.4 Sustainability and replication

147. The Sustainability of the NBFs in place has been addressed in five main aspects: a) Socio-political sustainability, b) Institutional sustainability, c) Financial sustainability, d) Environmental sustainability, e) Sustainability of GEF-UNEP biosafety strategy.

4.4.1. Socio-political sustainability

148. It is widely recognised that Biosafety is a controversial issue, where contrasting and polarized views ("pros and against") may hamper the development of a balanced national policy taking on board different strategic visions and sociological "discourses", as well as varied and somewhat diverging economic interests. This is often resumed by saying that Biosafety should be regarded as a "Sustainable Development" issue[50]. Virtually all the TE reports of the NBF Implementation Projects underline several hindrances that jeopardise socio-political sustainability. A sample of findings is reported in the following box.

Box 9

The indicators that show more difficulties to be reached are those linked to political decisions. (TE of Guatemala NBF Implementation Project)

..There is also the need to establish stronger links with Civil Society Organizations, particularly those active in environmental and consumers' rights protection, as well as with private sector actors, particularly those interested in making use of Biotechnology. (TE of Mongolia NBF Implementation Project)

The socio-political sustainability of Biosafety in Egypt will be conditioned by the capacity of the stakeholders to lead back divergences to an open and transparent negotiation based on the respect of the Law and on technically sound judgements. (TE of Egypt NBF Implementation Project)

The approval of the Law has been the outcome of a long and tortuous process started not less than ten years ago, which is explicable by the highly centralised structure of the State, the complex and heavy institutional mechanisms of decision-making and a recent governmental reshaping. (TE of Lao PDR NBF Implementation Project)

149. Main factors usually indicated in the TE of the NBF Implementation Projects influencing socio-political sustainability can be summarised as follows:

- The integration of biosafety into national policies. In the most advanced cases, biosafety is inserted into the NBSAP (National Biodiversity Strategy and Action Plan) and that is regarded as a major factor of socio-political sustainability. That is, in fact, only partially true, since it depends on how the NBSAP is interfacing and integrating with other Sustainable Development policies (e.g. economic development plans, Poverty Reduction Strategies, rural development and agriculture policies, Research & Development programs, etc.);

- Biosafety legal framework. As discussed under 4.3.2.b (Regulatory Regime), this is an area with uneven, but sometimes disappointing achievements for many reasons: the character of biosafety (involving many key-players), long and heavy institutional mechanisms of decision-making, contrasting views and conflicting interests, governmental changes, lack of knowledge among Parliaments' members and other decision-makers, among others.

[50] "Recognition of biosafety as a sustainable development issue means that the development of the NBF must be responsive to national needs and priorities in order to promote sustainability of the NBF" (quoted from "A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects", GEF-UNEP, 2006)

- Inclusiveness and public participation. Inclusiveness is a major factor of socio-political sustainability, yet it is not an easy process to orient and implement. Frequently, the NCAs are in a critical position when trying to balance biosafety "pros and against" positions. This difficulty is often reflected in the unbalanced composition of the National Coordinating (Biosafety) Committees, as discussed in chapter 4.3.2.a (Institutional Framework). Though programs of awareness raising and public information have usually been developed through the projects (see chapter 4.3.2.e), established mechanisms and procedures for public hearing and active participation are very rare. (e.g. Check Republic).

150. Human Rights and Gender (HR & GE) dimensions are considered relevant socio-political dimensions to be considered in the framework of Sustainable Development processes. The analysis of the TE of the NBF Implementation Projects shows the virtual absence of any HR & GE dimension in Biosafety programs, which has to be considered as an element of weakness, as far as socio-political sustainability is concerned. Actually, HR & GE approach is not present in any of the ProDocs of the NBF Implementation Projects assessed so far and in any of the Frameworks of the 37 sample countries. Admittedly, the issue falls under article 26, which is still under review and discussions, including conceptual clarity. For instance, new GEF implementation projects under GEF 4 are not approved without linkages to the NBSAPs and in GEF 6 gender issues are highlighted for integration.

151. This drawback is also reflected in the unbalanced composition of most of the NBCs and in the absolute absence of Women and HR Organisations in these bodies. It is true that NCAs do not have any responsibility in the selection of the members representing the respective institutions in the NBC, yet a suggestion or recommendation addressed by the NCA to stakeholders could partially address the issue[51].

152. The HR dimension is timidly approached in the art. 26 of the CPB stating that *"socio-economic considerations"* may be taken into account, particularly *"on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities"*. The reference is implicitly raising an issue of "rights protection" and, in fact, there is an increasing debate on different fora about the linkage between the use and diffusion of GMOs in the world and the protection of some Socio-Economic and Civil Rights, such as the Right to Food, to Health, to Environment and the rights granted by the Aarhus Convention[52] that include also the right to Information (e.g. the "labelling" issue)[53].

153. While Intellectual Property Rights (IPS) are usually protected by law and can actually be claimed to the Court by the GMOs "patent holders"[54] the same does not always apply for the rights of the Indigenous People and of traditional farmers and seeds-producers, which is further increasing the "asymmetry" between "Rights Holders" and "Duty Bearers". The problem of "co-existence" between GMOs crops and traditional and/or biological agriculture is a case in point, further discussed under Environmental sustainability (chapter 4.4.4). Moreover, the large-scale GMOs introduction in agriculture can bring about deep social conflicts related to the right to access to valuable land and water resources by big commercial farming and local communities (e.g. land grabbing and concentration for cultivating GMOs crops in Latin America).

154. Regarding Gender, some argue that the linkage with biosafety is not so evident and straightforward, like for instance, between GE and Health and Education sectors. Though this viewpoint may be partially true, there are some issues that should deserve attention. Actually, households Food Security and Food

[51] Remarkably, the Kenya Biosafety Act (2009) requires that, among the six persons representing the Academic, Civil Society and Private sectors in the Board of the Nat. Biosafety Authority, *"at least two shall be of either gender"*.
[52] The 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.
[53] Not all these "3rd generation Human Rights" are still universally accepted as Human Rights.
[54] There is an increasing number of "case laws" on the issue, particularly, but not only, in USA and Canada (see, for instance, http://foreignpolicyblogs.com/2013/02/19/competing-rights-the-gmo-debate/

Safety are strongly dependant on women, particularly in developing countries, therefore GMOs production and consumption indeed can and should be analysed from a Gender perspective.

155. There are already many interesting studies and assessments to be taken into account regarding the introduction of "cash crops" in traditional farming systems, which shows a progressive economic and social disempowerment of women in rural households related to the introduction of new technologies in agriculture[55]. All the above shows that there is surely room to consider a GE & HR perspective when dealing with GMOs in the agricultural sector and not addressing those dimensions can jeopardise socio-political sustainability of biosafety agenda.

156. It can be argued that all the above regarding GE & HR dimension is more related to Biotechnologies, rather than Biosafety. From a narrow perspective, the argument can be valid, yet, the holistic approach fostered by Sustainable Development calls for a broader view, where socio-economic inclusion, environmental sustainability and technical options are, all of them, regarded as fundamental and interrelated dimensions. Though the Cartagena Protocol, outcome of a complex and laborious process of negotiation occurred almost 20 years ago, may not explicitly recall GE & HR dimensions, there isn't any impediment to national decision-makers taking it into account, for instance when undertaking Risk Assessment, Risk Management and Risk Communication activities. It is just a matter of political will.

157. Overall, the Evaluation deems that biosafety socio-political sustainability is challenged from different points of view and that the controversial nature of the issue has to be carefully managed. At the current stage, Socio-political sustainability is rated Moderately Unlikely (MU).

4.4.2. Institutional sustainability

158. Institutional positive achievements and existing challenges have been discussed in chapter 4.3.2.a (Institutional framework). In terms of sustainability, the institutional set-up and anchorage of the NCA is a relevant issue to consider and not a neutral one. For instance, the designation of the MoE as NCA is not always a consensual issue. Institutional actors in favour of less stringent norms and procedures for the introduction and use of biotechnologies do not look at the MoE as the best option for the role of NCA, arguing that the excessive use of the "precautionary principle", usually championed by the MoE, actually hampers the diffusion of economically valuable biotech solutions, particularly in agriculture. This is, for instance, the opinion expressed in a recent (2014) report published by ADB and IFPRI[56].

159. The nature and quality of the relationship between the Ministries of Environment (MoE) and the Ministries of Agriculture (MoA) have proved to be relevant and somewhat challenging in some countries. The MoE are usually National Focal Points for the Protocol and appointed by the Governments to liaise with the Secretariat and to coordinate all activities pursuing by the Protocol. However, the MoA have been dealing with biotechnologies for years in many countries, sometimes well before the establishment of the MoE. In the socio-political and institutional arena, MoAs are usually more influential and have more abundant resources (human and material) than the MoEs.

160. Actually, somewhat diverging visions and institutional strategies regarding GMOs' introduction and development can be observed particularly in developing countries with a relatively high development of biotechnologies and research centers linked to the MoA since the '80s (for instance, some Latin American countries, Egypt, Philippines) or in countries that authorized the cultivation of GMOs (e.g.

[55] See, for instance and among many others, "Mainstreaming Gender Sensitivity in Cash Crop Market Supply Chains", FAO, 2011 and "Value chain analysis with a Gender Focus", ICRISAT / CGIAR, 2014. See also the seminal Report of the Special Rapporteur on the right to food to Human Rights Council (2015) regarding "Integrating a gender perspective in the right to food".

[56] "GM Agricultural Technologies for Africa: a State of Affairs", African Development Bank (ADB), International Food Policy Research Institute (IFPRI), 2014

Honduras, see on this regard also 4.4.4. Environmental Sustainability). The issue has the potential to become controversial and has to be carefully and wisely handled by the NCAs.

161. It is argued that National Biosafety Authorities (NBA), or National Councils, provide higher institutional sustainability than a NCA established in one Ministry. In fact, NBAs convey a *"super-partes"* and technically-driven image that may help steering stakeholders' divergences and controversies. That can be true, however it is not yet supported by solid evidence. Actually, the fact of the Authorities responding directly to the Prime Minister Cabinet or to the Presidency does not exempt them from political bias and pressure.

162. Even though, as discussed under Stakeholders Participation (chapter 4.6.3), different forms of stakeholders' participation are in place and legitimate (e.g. lobby and advocacy, social mobilisation), NBF institutional sustainability much depends on the effectiveness, transparency and technically-sound decision-making carried out by the National Biosafety / Coordinating Committees (or Boards), which are the recognised institutional instruments contemplated in the National Laws. This is an area in need of further improvement.

163. Other forms of inter-institutional coordination, such as technical committees and *ad hoc* working groups, may be very helpful to improve transparency and collegiality of the decision-making process. They represent a tremendous opportunity of meaningful participation, frank peer-debate, information sharing and practical problem-solving. Bhutan, Costa Rica and some EU countries (e.g. Poland, Lithuania and Czech Rep.) represent valuable examples of the application of these instruments.

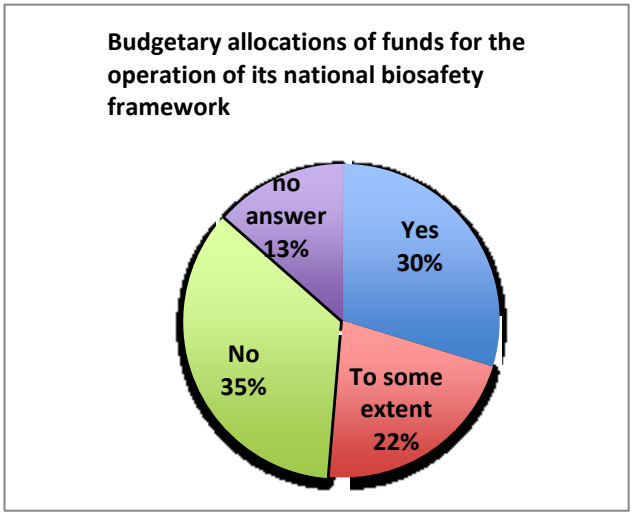
164. The establishment of solid systems for handling applications and for monitoring and enforcement is still in an incipient phase in most of the countries, as discussed in chapter 4.3.2, undermining institutional sustainability.

165. Considering the baseline situation, the progress of the countries towards the institutional sustainability of the Biosafety Frameworks has been quite remarkable. However, national biosafety systems are not fully operational in most of the countries and have to be proved in more challenging situations (concrete opportunities to test collegiality and decision-making in presence of GMOs applications). Overall Institutional Sustainability can be rated Moderately Unlikely (MU).

4.4.3. Financial sustainability

166. While financial sustainability does not yet appear a core-issue in the countries with an incipient stage of framework implementation, there is a growing concern among those that are implementing the framework and would like to ensure increased impact and outreach. As a matter of fact, more active countries in NBF implementation in Africa, Asia and Central America already feel that financial resources are not available at the suitable level. The difficulty or impossibility to acquire more sophisticated lab equipment and to upgrade human resources has also been raised in EU countries like Czech Republic, Lithuania and Poland. The closure, a few years ago, of an important laboratory in Czech Republic (in its second larger city, Brno) is an example of the limitations of the overall financial situation.

167. In the National Reports to the COP-MOP, countries are asked if they have established a mechanism for the budgetary allocations of funds for the operation of their national biosafety framework. Out of the 37 sample countries, 11 countries (30%) reported 'yes', eight countries (22%) reported 'yes, to some extent', 13 countries (35%) reported 'no', and five Parties (13%) did not report (see diagram below). It is, however, worrying to observe that eight countries that reported to have a NBF fully or partially in place, actually do not have any budgetary allocations for that purpose, which looks contradictory.



168. There exist a certain expectation that biosafety systems could be at least partially self-sustained by "duties, levies and fees related to authorization and sanctions", as some evaluation reports point out, which, of course, is yet to be proved and not so likely to happen, at least at a sustainable level.

169. Many countries believe that GEF funds within Biodiversity allocation are not sufficient to address Biosafety programs. There is a consensus among biosafety institutional actors who recommend that Biosafety funds should be initially "ear-marked" within the Biodiversity portfolio through clear "windows for Biosafety" because the distribution of GEF funds at national level is not always "equitable and transparent"[57].

170. For the countries that have a more advanced state of NBF implementation, the insertion of biosafety into the NBSAP is regarded as the first, crucial step for accessing public funds and achieving a minimum of financial sustainability. This is the case, for instance, of Bhutan, Mongolia, Albania and EU countries. Nevertheless, even in those cases, national stakeholders do not manifest much optimism, due to the generalised, substantive budgetary cuts for public research and higher education. Overall, Financial Sustainability is still to be proved and is rated Moderately Unlikely (MU).

4.4.4. Environmental sustainability

171. Although Biosafety Projects are inscribed in the mainstream of Sustainable Development, environmental sustainability should not be taken as granted. National legislations, overall, supposedly adhere to the Precautionary Principle, yet much depends on how the procedures and mechanisms of application of the legal instruments reflect the principle in practical terms (regulations, guidelines, etc.). It is, probably, premature to draw some conclusions on that, yet, some cases can already point out areas where environmental sustainability has to be looked at with particular attention.

172. One aspect to be seriously taken into account is the release of GMOs plants in areas within regions characterised as "genetic resources origin" (e.g. South and South-East Asia, Guatemala, see box below),

Box 11

….This is an extremely important point for Guatemala, which is genetic center of origin for maize and domestication of beans, squash and cassava. There are still wild maize relatives and other native crops that are cultivated and need to be protected from LMO seed that crosses the borders. However, at present the project has not had an environmental effect that can be sustained, since the approved regulations are

[57] Opinions of several CPB Focal Points.

lacking and the biosafety system cannot become operational. (TE of Guatemala NBF Implementation Project)

173. The issue of coexistence with traditional agriculture can become an issue, as observed in the country visit of Honduras, where different perspectives between the MoA and the MoE have been observed. The coexistence issue has been regulated in some EU countries (e.g. Czech Republic, Slovenia), but remains a growing controversial issue in many other countries (e.g. Chile, Mexico, Costa Rica, among others). Coexistence with Biological Agriculture has also to be carefully taken into account and, in fact, in some countries (e.g. Poland, Chile, Costa Rica) is already a relevant and somewhat controversial issue.

174. Biosafety projects have largely contributed to underline the relevance of sound procedures for RA and RM for environmental sustainability. Though, as already discussed in previous chapters, there is surely room for more focused and practical training on these subjects, it has been observed that environmental concerns regarding the deliberate release of GMOs crops is increasing among national stakeholders and that technical solutions (in fact, Risk Management measures) are being discussed. Overall, Environmental sustainability can be rated Moderately Likely (ML).

4.4.5. The Sustainability of GEF-UNEP Biosafety Strategy

175. This is an aspect that deserves a specific focus, taking into account the driving role played by GEF as financial mechanism of the Protocol and by UNEP, as hosting organization of the CPB and Implementing Agency of Biosafety Projects.

176. It has already been observed (see chapters 4.1.2 and 4.1.3, under Relevance) that while GEF, in its GEF 6 programmatic documents, has confirmed its commitment in principle on Biosafety, UNEP strategic documents (MTS and PoW) do not convey the idea that Biosafety represents a strong priority. This perception has also been registered among some national stakeholders (NCAs, CPBs Focal Points) and confirmed in some of the interviews entertained with UNEP Officers. This is an issue that deserves attention from UNEP.

177. Some areas of concern have been identified:

- Insufficient definition of a strategic framework for Biosafety actions in future years (someone called it, the "need for a business plan");
- Lack of projects' Exit Strategies, also remarked in some of the NBF Implementation Projects (see box below) and of a clear "road-map" ("what next ?");
- Opening of new "fronts" while the NBF is still in need of consolidation (e.g. ABS projects, Liability and Redress issue);
- Insufficient funds allocated to Biosafety and lack of a "Biosafety Window" ensuring appropriate projects follow-up and consolidation. Some stakeholders have pointed out that the Biosafety agenda is "losing momentum".

Box 12

"The completion of the project activities has to be integrated with the elaboration of the project exit strategy, in order to ensure that the three areas of interest (legal framework, laboratories and accreditation, awareness raising) converge to provide a road map to decision makers on priority actions. (TE of Tunisia NBF Implementation Project)

"The timing of projects and inclusion of "exit strategies" are important to enable the transfer of results and their appropriation by national stakeholders". (TE of Costa Rica NBF Implementation Project)

178. When specifically focusing on UNEP internal organisation and functioning, as far as Biosafety is concerned, the Evaluation has observed that internal communication channels are not at a suitable level.

For instance, both Sub-Programmes Environmental Governance and Ecosystem Management are not regularly and systematically fed with relevant information regarding the Biosafety portfolio and activities. There is in fact a lack of clarity on the strategic position of biosafety at sub-program level leading to a "vacuum" in terms of adequate strategic planning, institutional monitoring and reporting.

179. BCH Projects are placed in DELC (Division of Environmental Law and Conventions), while Biosafety Projects are under DEPI (Division of Environmental Policy Implementation), which, in the absence of a common biosafety institutional strategy, has further hampered exchanges, if not between officers in charge, at a wider institutional level. Annex 21 presents a synoptic table regarding Biosafety integration into UNEP Divisions.

180. A document provided to the Evaluation Team describes the "GEF Biodiversity, Land Degradation and Biosafety Unit" (BDLD) in DEPI as the Unit in charge of "supporting GEF eligible countries parties to access GEF resources to execute Enabling Activities to fulfil their obligations vis a vis the Environment Conventions, but also to implement their national environment agenda through Medium and Full Size projects". Among the list of projects under the responsibility of the Unit, however, NBF Implementation Projects do not appear.

181. While GEF purpose to provide support to further "71 eligible countries to implement their NBFs"[58] is commendable, the impression is that an "ever-growing" Biosafety portfolio of projects is not manageable by UNEP if an exercise of strategic planning, priority definition and programming is not conceived and put in place, so that dispersion and fragmentation of projects could be avoided or at least minimised (see also Recommendations). In fact, every single project, no matter the size, brings about "transaction costs" for UNEP (Project preparation and planning, monitoring and evaluation, technical backstopping, training and coaching, information and knowledge management, administrative and financial mechanisms, among others) that have a negative consequence on the Efficiency and the Effectiveness of Biosafety Programme and of UNEP in general.

182. The number of Human Resources devoted to Biosafety is actually too low (two TM, one in Nairobi and one in Panama) to cope with current needs proceeding from the large, diversified and dispersed portfolio of Projects and initiatives (see also chapter 4.6.2.). In the framework of the Programming Exercise suggested above, it is necessary to strengthen and "reset" Biosafety Human Resources through a more strategic role of the Biosafety Unit in Nairobi and its increased decentralization at regional level, particularly in Asia-Pacific Region, but probably also at some sub-regional level in Africa (see Recommendations).

183. Having said all the above, the Evaluation considers that, in the current situation, Sustainability of GEF-UNEP Biosafety Strategy is less than suitable and overall rated Moderately Unlikely (MU).

Overall Assessment of Sustainability of Biosafety programme

Criteria	Score
4.4.1. Socio-political Sustainability	MU
4.4.2. Institutional Sustainability	MU
4.4.3. Financial Sustainability	MU
4.4.4. Environmental Sustainability	ML
4.4.5. GEF-UNEP Biosafety Strategy Sustainability	MU
Overall	**MU**

Overall Comment: Sustainability is challenged by the controversial existing debate on GMOs and Biosafety. It is also challenged by its Opportunity-Cost, particularly in LDC, which undermines Financial Sustainability. Institutional up-taking is growing and efforts are in place to manage sensitive issues like

[58] GEF-6 Programming Directions (Extract from GEF Assembly Document GEF/A.5/07/Rev.01, May 22, 2014)

coexistence and RA capacities (Environmental Sustainability). UNEP-GEF Strategy is raising serious concerns regarding its Sustainability.

4.4.6. Catalytic role and replication

184. The Project has represented the starting point of a growing process of capacity and institution building that has produced variable results from country to country, as discussed under Likelihood of Impact (chapter 4.3.3, section "d").

185. The catalytic role has been unquestionable and surely Satisfactory, the likelihood of replication being conditioned by several and variable in-country factors that relate to their socio-economic context, priorities and political will and national capacities. The role of more advanced countries in "leading by example" has also not to be underestimated.

4.5 Efficiency

4.5.1 Cost-effectiveness

186. The "one-size fits all" projects are not usually considered efficient projects, since they adopt one single approach and allocate resources (time, technical assistance, financial resources) quite evenly along a great variety of countries and baseline situations. That was partially corrected by the project being evaluated, where the "in-country spent" budget actually varied from, roughly, 100.000 USD to 200.000 USD per country (average: 137.000 USD / country). For instance, the budget allocated to the 37 sample countries varies from 81.000 USD (Chad and Dom. Republic) to close to 200.000 USD (Iran, Indonesia).

187. The Evaluation did not find any document explaining the criterion used in the allocation of the budget among the countries, which hampers the efficiency analysis. Moreover, the Evaluation did not find any direct correlation between the budget injected into the country and the quality of the NBF produced. There are, in fact, high-quality NBF produced with a budget of 100.000 USD (high efficiency) and unsatisfactory frameworks that "costed" 180.000 USD (low efficiency).

188. The budget was actually considerable (GEF total allocation was near to 34M USD, see 3.6), which, theoretically, gives an average "cost" of roughly 275.000 USD for each of the 123 countries. This amount obviously includes the costs of the Regional Component and of Project Management. One could, therefore, speculate about the cost-effectiveness of the project, i.e. if it could have been possible to obtain the same results (or better) at a lower cost. That is objectively difficult to say, yet the different level of efficiency mentioned above may suggest that there was probably room for a more efficient allocation of the resources.

189. Chapter 4.6.5 (Financial planning and management) will describe and discuss how the initial budget was defined and the need for several budget revisions to respond to the real needs of the countries. As a result, the budget of the project was divided in two main blocks (according to the most recent Budget Revision n.13 of 04/2016)[59]:

a) The Global and regional component (Umbrella Project): USD 16.9 M
b) The National Sub-Projects (in-country spent budget): USD 16.9 M

190. While it is clear that the National Sub-Project budget reflects the in-country expenditures for the development of the NBF, the Umbrella Project includes different kinds of expenditures, some of them related to Regional and Global Activities (e.g. workshops, toolkits, website, etc.) and some others corresponding to the Project Management costs (salaries and travels of the Management Team, ANUBIS, etc.). The attribution of some expenditures to one or another of the component (Global

[59] Budget Revision n.13 was waiting for approval and signature at the time of Evaluation

Activities or Project Management) is not straightforward and there is, therefore, an objective difficulty in exactly calculating the cost of the Project Management, which is one of the indicators of Project Efficiency.

191. At any rate, following the budget lines of the UNEP format budget, the costs of the Umbrella Project have been as follows:

Budget Codes	**Sub-total USD**
1100 - Project Personnel	7.419.321
1200 - Consultants	541.354
1300 – Admin Support	970.390
1600 - Travels	1.652.236
2200 – Sub-contracts (includes Workshops organization)	3.616.353
3200 – Training component	26.150
3300 – Meetings / Conferences (includes Workshops and Steer. Committee)	567.772
4100 – 4200 – 4300 (Expendable and non-exp. Equipment, Offices)	516.098
5100 – O&M of Equipment	32.386
5200 – Reporting costs (includes Website, newsletter, outreach mat.)	122.641
5300 – Communications	1.306.920
5500 – Evaluation costs	130.270
Total Umbrella Project	**16.902.591**

192. If attributing budget codes 1600, 2200,3200 and 3300 mostly to Global / Regional Activities, the Project Management costs (highlighted in the table above) can be estimated around 11.039.380 USD, which roughly corresponds to the 33% of GEF allocation (i.e. 33.919.711 USD, see chapter 3.6). This amount is remarkably higher than originally estimated in the ProDoc, where project Management Costs were budgeted around 4M USD).

193. As a matter of fact, the GEF representative in the Project Steering Committee had already expressed in 2003 their concerns about the high number of staff (see Annex 19) and the GEF Evaluation of 2005 had already considered that, at the time, the Management Costs of UNEP were around 17% of the Project Budget and commented "UNEP's resources for implementation and execution of the projects were around 17 percent of the total project cost, which would be quite generous in a normal development project". As also discussed in Chapter 4.6.2 (Project Implementation and Management), the increase of management costs, particularly the Personnel, no matter how justifiable they were, had inevitable implications on Project Efficiency.

4.5.2 Time-efficiency

194. As mentioned in chapter 3.4 the Project had a protracted timeframe, much more than initially foreseen. As a matter of fact, participating countries have integrated the Project gradually and many of them have experienced considerable delays in the inception and implementation phase.

195. The Evaluation has carried out a detailed analysis of the time of execution of the Projects in the 37 sample countries, based on ANUBIS data, which is reported integrally in Annex 20. The main findings are outlined here below:

- The commencement date (date of UNEP signature) spanned from 2002 to 2006;

- The starting of operations occurred after an average of 93 days from the commencement date, which can be considered as reasonable. The delay is usually due to the opening of the bank accounts, the nomination of the NPC and other administrative procedures;
- The gap mentioned above (93 days) actually conceals huge differences among countries, since there were countries able to start the operations after few days and others that suffered considerable delays like Sudan, Romania and Myanmar (from 7 to 10 months), up to the case of Panama that started two years after UNEP signature;
- The average period between the starting of the operations and the completion date (substantive work completed) was 37.5 months (1.125 days), hence more than double that of the planned duration (18 months). The problem of the unrealistic design of the project was early raised by the MTE (2003) and it is discussed in following chapter 4.6.1. The average conceals large differences among countries. Four countries (11% of the sample) were able to complete the activities within two years (Belarus, Ghana, Iran, Romania), 19 (51% of the sample) between 24 and 36 months and the remaining 38% (14 countries) spent from three to eight years to complete the substantive activities foreseen.
- The average of days between completion (substantive work completed) and the UNEP closure (all documents stored) is of 1.075 days (roughly three years) and with ANUBIS closure (Project closed with "red button" in ANUBIS) is of 1.581 days (more than four years). That means that, after the substantive work being completed, it took an average of three years (up to five years) for UNEP to officially close the Project (all documents stored) and at least a supplementary year to financially close the Project. These are remarkable delays.
- As a consequence of the delays described above in every phase of the Project, all countries were granted Project extensions from a minimum of 3 to 6 months (5 countries) up to a maximum of 8 years.
  The table here below shows the average duration of the different steps of the Projects.

Start	Operations	UNEP closure	ANUBIS closure
93 days	1.125 days	1.075days	506 days

Average Total : 2.799 days (7.6 years)

196. The above data were discussed with Biosafety Management Team (TM and FMO). The Evaluation agrees that the Project was overambitious (as already remarked by the Project MTE in 2003) and that the Project Management Team had to fight a "tremendous struggle" to acquire from 123 countries the documents allowing the administrative UNEP closure. Moreover, it has been said, ANUBIS closure is an "internal" step for which "no pressure" was actually applied; in fact, it is argued, ANUBIS was (and is) in force for other Biosafety projects. Nevertheless, while UNEP closure can only occur when all documents are stored, the delayed ANUBIS closure may bring about supplementary transaction costs, since UNEP staff has to follow up until the process is completed, such as final checking, proper filing, etc. (ANUBIS closure).

197. Overall, it can be concluded that the project design, both in its Objectives and in its Implementation modalities, was probably not the most conducive to Project Efficiency. Although the use of financial and time resources could not have been optimal, as described in this chapter, it has nevertheless to be acknowledged the huge effort made by the Management Team in creating and implementing an Information System (ANUBIS) that could warrant sufficient monitoring capacity, transparency and accountability in the context of a global project involving 123 countries. From this viewpoint, the project was up to the challenge and the existence of systematised data and of reliable information regarding the project after fifteen years from its beginning is a proof of that. Overall, despite the satisfactory financial planning and management (see 4.6.5), when taking into account Project Management costs and Time-efficiency, Project Efficiency has been rated Moderately Unsatisfactory (MU).

4.6 Factors affecting performance

4.6.1. Preparation and readiness

198. As described in chapter 3.1, the project was preceded by several initiatives, including a Pilot Project, contributing to shape project's design, contents and methodology. Nonetheless, it was the first time that UNEP was asked to conceive and implement a full package of projects covering a global GEF programme, namely "to assist the whole of GEF eligible countries to prepare for the entry into force of the Cartagena Protocol on Biosafety".

199. As observed by the GEF Evaluation of 2005, "compared to its previous support of enabling activities in climate change, biodiversity, and persistent organic pollutants, the GEF responded expeditiously to the request by the CBD to support biosafety". As a result, UNEP-GEF had a fully fledged support system in place for executing the NBF development phase in the majority of the initial 100 countries by June 2001, i.e. five months after the adoption of the CPB, and more than two years before its ratification, which is highly remarkable. That might be due to the level of international concern surrounding biotechnology at that time.

200. Opinions over the project design, either positive or critical, have accompanied the project since its launch and, in fact, the issue was exhaustively assessed both by the Mid-Term Evaluation (MTE) of the project (2003) and by GEF Evaluation on GEF Support to the Cartagena Protocol on Biosafety (2005). While recognising that the standardisation of formats, objectives, activities and phasing might have posed a significant challenge to a variety of conditions in the field, one cannot fully disagree with GEF Evaluation concluding that "the umbrella approach was, under the circumstances, a necessary tool to deliver assistance expeditiously to the large number of countries requesting assistance, and it entailed economies of scale. The alternative of organizing 100 individual projects without a single coherent system would have been much more demanding both in terms of time and resources".

201. It has to be noted that there has also been a relaxation of the project qualification requirements, allowing non-signatory countries to be eligible for support. On the one hand, that surely brought about a quicker ratification and preliminary national endorsement of the CPB, but, on the other hand, extended the project to a group of countries that were less certain about national priorities and less informed about biosafety matters. As noted in a GEF project brief of 2001, the "objectively verifiable success indicator of the NBF development project is that legislation, regulation and/or guidelines will be in place to allow for the assessment and management of risk associated with the use of modern biotechnology" During the course of the project, the goal was scaled down and aimed only at completing a draft NBF.

202. The short planned duration of the National (Sub)Projects (18 months) has been undoubtedly a major inadequacy in project preparation. At the time of the GEF Evaluation of 2005, the average duration of national projects was found to be 28 months, instead of 18. Eventually, as indicated under time-efficiency (Chapter 4.5.2), the starting and operational phases of the project lasted an average of nearly 40 months. Component 1 (see chapter 3.1 and 3.6) was also abundantly underestimated, while Component 3 confusingly assembled Global Activities and Project Management activities, as discussed under Cost-effectiveness (chapter 4.5.1).

203. Actually, the MTE of 2003 had already defined the project design as "too ambitious" and the GEF Evaluation of 2005 concluded that the Project was "not adequately designed and funded to fully take the complexities of local conditions and needs into account". Of course, the innovative character of the project, its complexity and the urgency of its implementation did not probably allow a better preparation. Preparation and Readiness has to be rated Moderately Satisfactory (MS).

4.6.2. Project implementation and management

204. The Project was managed by a Unit established in 2001 within UNEP's Global Environment Facility (GEF) Coordination in Geneva. The initial Management Team (MT) included a Scientific Coordinator acting as overall Project Manager and also responsible for Central and Eastern European region, three Programme Officers for Africa, Asia and the Pacific, Latin America and the Caribbean, and a Fund Manager.

205. The MT was expanded in 2003 to cope with the rapidly increasing workload required to run the project, as well as the "Project to Build Capacity for Effective Participation in the Biosafety Clearing House (BCH)" that initiated in 2004. Actually, already in 2003, more than ten people (including administrative staff) were working on the Project (see the list in the Explicatory note sent by UNEP responding to GEF concerns, in Annex 19), which is reflected in the high level of expenditures for Project Personnel, as shown by the table in chapter 4.5.1 (Cost-effectiveness). Though absolutely understandable, due to the need of timely delivering the overambitious project outputs, upscaling Project Management costs in such a considerable way can be regarded, in retrospect, as an option that has inevitably downgraded Project Efficiency (see chapter 4.5).

206. The Project Steering Committee (see chapter 3.5) met yearly, essentially via teleconference, and was regularly and timely supplied by the Management Team with exhaustive Business Plans, Work-plans, Technical Papers and Financial information regarding Expenditures and Budget Revisions, until 2007. When revising the impressive documentation posted in ANUBIS, the huge and quality effort made by the Management Team has to be recognised.

207. The MT was operational until 2007-2008 and then, for different reasons, was reduced and reshaped until the current situation where there is only one Biosafety (and ABS) TM in Panama for LAC Region and one Biosafety TM for all other regions (Africa, Asia-Pacific, Central and Eastern Europe)[60]. The latter is accumulating a series of tasks previously covered by other colleagues of the Management Team in such a way that, in practical terms, he carries on functions and responsibilities that correspond to a Portfolio Manager, rather than a TM, as formally defined. For enhanced efficiency and effectiveness, this situation needs to be clarified in the framework of a wider institutional and operational "reprogramming" of Biosafety Strategy, as discussed in chapter 4.4.5 (Sustainability of GEF-UNEP Biosafety Strategy) and reflected in the Recommendations.

208. National Project Coordinators (NPC) were (and are) key-actors in Project implementation and management and usually chosen by the NEA in consultation with UNEP. As already highlighted by the GEF Evaluation of 2005, "NPCs are recipients of a large fraction of the total benefit and capacity development under the NBF development project" and, for that reason, not only the selection, but also the retention of NPCs following project completion are key issues that, however, UNEP cannot influence and control. This situation has also been observed in all the successive NBF Implementation Projects evaluated so far. While there are remarkable and positive exceptions where NPC and project staff are indeed Public Officers organically integrated into the NEA/NCA (e.g. Mongolia), in the vast majority of the cases, the engagement of the NPCs has been discontinued after project completion (see also Lessons Learned, 5.2). This is an issue to be considered and discussed with the NEA/NCA for future actions.

209. Overall, UNEP capacity to identify and put in place suitable arrangements and mechanisms of Project implementation and management has been strongly challenged by the complexity of the task, particularly after the progressive, yet drastic, reduction of the components of the MT and subsequent increasing of workload of the team remained in place (four staff in 2007, three in 2009, two from 2012 onward).

[60] Additionally, there are also a Project Manager in DELC working on BCH Projects and the Administrative Officers in charge of running ANUBIS.

210. Overall, the lack of a clear UNEP management strategy, as far as Biosafety is concerned, is progressively leading to a quite unsustainable management situation, as discussed in chapter 4.4.5 (Sustainability of GEF-UNEP Biosafety Strategy). While recognising the undisputable engagement and professionalism of all MT, the overall capacity of the institution (UNEP) to respond to Project implementation and management challenges has to be rated Moderately Unsatisfactory (MU).

4.6.3. Stakeholder participation and public awareness

211. Wide and meaningful forms of stakeholders participation actually represent a crucial issue in the development and implementation of NBFs. Having said that, questions regarding "who" are the stakeholders to be involved, "how" stakeholders are effectively participating and "when" should they be involved, remain crucial issues to be addressed in practice, opening the field to a large array of interpretation and varying "degrees" of participation. The issue has been discussed from the perspective of socio-political and institutional sustainability (chapters 4.4.1 and 4.4.2).

212. It has been noted that the participation of some groups of stakeholders is lower than expected. Too vocal constituencies "against" GMOs (NGOs, small farmers associations, indigenous organizations) or excessively "pro GMOs" (Private Sector) have not usually been key-actors in Biosafety Projects. In fact, parallel initiatives of lobbying, advocacy and social pressure are taking place and, in a very polarized debate, may actually jeopardise the effectiveness of formal and transparent institutional frameworks like the NBC.

213. While "against" promoters do prefer forms of social and political mobilisation mainly through media, the web and advocacy to political parties, the Private Sector prefers activities of lobbying to Governmental representatives (mainly the MoA) to influence decision-makers. There is also an increasing number of social events (e.g. meetings, workshops) promoted by GMOs Corporations in several African, Asian and Latin American countries, often co-sponsored by Bi-lateral or Regional Agencies (e.g. USDA, USAID, NEPAD, SAC)[61].

214. Overall, when considering Biosafety baseline situation, considerable progress has to be acknowledged in Stakeholders participation and awareness, which has to be considered Moderately Satisfactory (MS).

4.6.4. Country ownership and driven-ness

215. As discussed under Institutional Sustainability (chapter 4.4.2), most of the countries have shown an increased level of ownership. The transnational character of Biosafety and the challenging context of Global Environmental Governance and its asymmetries, as discussed under Likelihood of Impact (chapter 4.3.3), may, to a certain extent, limit countries' ownership, yet the process of empowerment of national stakeholders is evident and has to be rated, as a whole, Satisfactory.

4.6.5. Financial planning and management

216. During Project Implementation, arrangements have been put in place to limit the imbalance of the initial project budget, namely through budget revisions under the guidance of the Project Steering Committee and according to the Business Plans yearly prepared by the Management Team (MT). In practical terms, the MT made use of the total budget as a "bag" from which national allocations were

[61] USDA (United States Department of Agriculture), USAID (United States Agency for International Development), NEPAD (New Partnership for Africa's Development), SAC (SAARC Agriculture Center).

gradually supplied to the countries according to their specific needs and to their capacity of absorption. That can be regarded as a positive form of adaptive management.

217. On the other hand, however, this process has freed a large part of the budget and made it available to the Umbrella Project, which has therefore benefited from a considerably higher allotment than initially planned. A great part of the freed financial resources have gone to cover Project Management costs as they substantially rose, as discussed under Efficiency (chapter 4.5.1).

218. From the Financial Tables posted in ANUBIS (Budget Revisions, etc.) it is not possible to identify which part came from UNEP and from the Governments. The overall table regarding Co-Financing presented in Annex 5 is therefore incomplete.

219. The setting and implementation of ANUBIS has been a breakthrough enabling the MT to manage and oversee financial planning and management over 123 countries. The setting and implementation of the System has been indeed a formidable task, requiring a more than assiduous work of training and coaching, data corrections and revisions and of system upgrading[62]. From a strictly administrative point of view, Financial Management has been up to the strong challenge and is rated Satisfactory.

4.6.6. UNEP supervision and backstopping

220. The inherent complexity of the project and its size have challenged the MT capacity of supervision and backstopping. As mentioned above, the introduction of ANUBIS has been strategically instrumental to warrant the efficient supervision of project implementation, since the System allows the compilation of Progress Reports, Workshops proceedings, Audit Reports, Consultants' reports and different technical and outreach material produced in the framework of the project.

221. Virtually all the TE of the NBF Implementation Projects have rated UNEP Supervision and Backstopping between Satisfactory and Highly Satisfactory, particularly the organization of NPC periodic meetings at sub-regional level, the field missions of the TMs and of the FMO and the effectiveness in timely supporting problem-solving at country level.

222. Overall, considering the magnitude and dispersion of the Projects and the limited staff available, UNEP has been effective in providing supervision and backstopping that should be considered Highly Satisfactory (HS).

4.6.7. Monitoring and evaluation

223. The ProDoc has been analysed in the inception report of the Evaluation and rated only Moderately Satisfactory, due to existing inconsistencies observed in the definition of the outputs and indicators, as commented in chapter 4.2 (Achievement of Outputs). The Information System put in place (ANUBIS) has been able to compensate for this weakness, allowing a systematic and periodic monitoring of activities and outputs delivery.

224. The Project underwent a MTE in 2003 and, due to the protracted time frame, could have fruitfully benefited from a MTR, perhaps in 2007/2008, when around 80-100 NBFs were already completed. However, that coincided with the reduction of the Management Team and the early phases of the new NBF Implementation Projects, which made the materialisation of a supplementary review not possible.

[62] Anubis has further been updated with the Library as a repository for information sharing and is actively used by the Implementation Projects. Further updates have been executed including the ANUBIS 2 training service https://anubis2.unep.org. and the ANUBIS blog, which is work in progress to provide dynamic support to the users.

225. The Evaluation has been able to easily access to substantive and detailed information regarding the progress of the project since the far starting in 2001 up to date, based on the information compiled by country and at global level in ANUBIS, as well as through the Newsletters produced by the MT until 2007 and through the old and new Biosafety Websites. This can be taken as a reliable indicator of Project Monitoring capacity, which can be rated Satisfactory (S).

4.7 Complementarity with UNEP strategies and programmes

226. Biosafety is conceptually and institutionally rooted in Biodiversity and this linkage is well visible in many of the NBF Implementation Projects at country level, where Biosafety Units or Departments are integrated into wider Biodiversity Divisions within the MoE. At UNEP level, Biosafety is currently part of BDLD (Biodiversity, Land Degradation and Biosafety) Unit within DEPI, which should in principle ensure complementarity and synergy and also ensure the Implementation and Executing Roles of the GEF strategy are maintained.

227. Biosafety Projects are contributing to Sub-Programme Environmental Governance (EG) as shown in the following table:

PoW 2010-2011: Sub-Programme Environmental Governance, Expected Accomplishment (EA) B: The capacity of States to implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions is enhanced.	
Output	Project contribution (how)
Output 2: Legal and policy instruments are developed and applied to achieve synergy between national and international environment and development goals.	• Nat. Biosafety Frameworks (NBF) prepared in 123 countries and implemented or under implementation in more than 50 countries • National Biosafety Laws and Regulations enacted • National Biosafety Committees in place
Output 3: Countries' legislative and judicial capacity to implement their international environmental obligations is enhanced through implementation of policy tools.	• National Biosafety Laws and Regulations • Enhanced capacity of Risk Assessment and Risk Management
Output 4: Capacity of government officials and other stakeholders for effective participation in multilateral environmental negotiations is enhanced.	• Capacity building (legislative and administrative instruments for the application of CPB) • Regional and sub-regional workshops • Guidelines and manuals produced
PoW 2012-2013: Sub-Programme Environmental Governance, Expected Accomplishment (EA) A: The United Nations system, respecting the mandate of each entity, progressively achieves synergies and demonstrates increasing coherence in international decision-making processes related to the environment, including those under multilateral environmental agreements.	
Output	Project contribution (how)
Output 5: Priority areas of multilateral environmental agreements are increasingly reflected in policies and actions of bodies, funds, programmes and agencies of the United Nations system, including their strategies and activities in countries (Five Priority Areas).	• Biosafety increasingly integrated in National Biodiversity Strategic Action Plans (NBSAP)

228. This report has already discussed in chapter 4.1.2 the relevance of the Project for UNEP mandate and has pointed out a general under-representation of Biosafety in UNEP strategies, despite the relevant portfolio of projects implemented. Similarly, in chapter 4.4.5, some concerns have been outlined

regarding the sustainability of UNEP Biosafety Strategy. These two factors constrain Biosafety complementarity with UNEP strategies and programs and have to be worked out in that perspective.

229. Biosafety projects have been active in addressing many of the cross-cutting issues listed in the Bali Strategic Plan (BSP), such as the strengthening of national institutions, the development of national law and regulations and the compliance with obligations under multilateral environmental agreements.

230. Gender issues and Human Rights approach are not specifically addressed by Biosafety projects. The issue has been discussed under Socio-political Sustainability (chapter 4.4.1). South-South Cooperation has been addressed through Sub-regional projects and the envisaged support to multi-country initiatives (see 4.3.2 point "g", Regional and sub-regional dimension). Overall, Complementarity has been rated Moderately Unsatisfactory (MU).

5 Conclusions and Recommendations

5.1 Conclusions

5.1.1. About NBF Development Project and progress towards NBF Implementation

231. The Project "Development of National Biosafety Frameworks" has supported a very high number (123) of countries worldwide to prepare and adopt the National Biosafety Framework (NBF), a harmonized instrument to organically approach and coherently implement rights and obligations contained in the Cartagena Protocol. The NBF, a combination of policy, legal, administrative and technical tools, has progressively become the main conceptual and operational point of reference to orient biosafety activities at country and global levels.

232. Despite the complexity and the challenges of its design, the project has been visionary in capturing the need for a common path and a collective effort, which has been able to guide and support the countries in a coordinated and coherent way. By doing so, the project laid the foundations for subsequent actions of capacity building at national level to implement regulatory and administrative system for biosafety management, which has occurred or is happening in some 60 countries through the so-called "NBF Implementation Projects".

233. However, while all 123 countries have been able to draft their NBF, they have unevenly progressed towards NBF implementation, due to the variety of different baseline situations and countries' priorities and also depending on their actual exposure to GMOs.

234. Overall, the setting and consolidation of the National Competent Authorities (NCA) is quite satisfactory but there is room for improving the participation of all national stakeholders by expanding their participation both in the National Coordinating Committees and in other cooperative instruments (e.g. technical committees, working groups, etc.). The establishment of biosafety legal framework (national laws and regulations) has frequently been a lengthy and complex process that has been fully achieved in nearly one third of the countries.

235. Operational systems for handling applications and for monitoring and enforcement have been established and are fully functional only in few countries and have to be proved in more challenging situations (increased number of GMOs applications).

236. Biosafety projects have hugely increased public awareness and information, yet public participation has to be improved, particularly around the process of decision-making regarding GMOs for Field Trials, for Deliberate Release and for FFP (Food, Feed and Processing). In many cases, the information is irregularly and unevenly uploaded by the countries to the BCH, which is evidently an area of concern, as far as transparency and public information are concerned.

237. Capacity building actions have largely contributed to enhance national awareness and information and, to some extent, technical capacities. However, specific priority needs have to be assessed and matched by focussed actions of more practical trainings. Risk Assessment and Management, as well as Risk Communication are areas with considerable room for improvement, namely in a country already exposed to GMOs, in order to provide decision-makers at different levels (Politicians, Managers, Farmers, Consumers) with more neutral and scientifically-sound information.

238. Biosafety is, in fact, a complex, multi-dimensional and transnational issue characterised by several dualities and asymmetries, often leading to polarisation and controversial debates defying the sustainability of the Biosafety Frameworks in place. Aspects like coexistence with traditional agriculture and socio-economic considerations have the potential to be conflicting if not appropriately addressed and managed.

5.1.2. About UNEP's Biosafety strategy and impact

239. The growing interest for GMOs development worldwide, and particularly in developing countries, calls for more incisive actions to enhance the global capacity to effectively implement the Protocol. GEF-UNEP support has been so far pivotal to create the overall structure. There is now a need for more impact-oriented actions emphasising the "programming" dimension and limiting risks of dispersion and fragmentation in a growing number of national projects.

240. The classification of countries according to their progress in the implementation of the NBF (see chapter 4.3.3. section c) could be helpful in assessing homogeneous needs and priorities and matching them through specific "gap-filling" actions. That could be done at multi-country level emphasizing the Sub-regional dimension and the South-South Cooperation, so far quite modestly included in the Biosafety Programme.

241. The sustainability of the Biosafety Strategies (see chapter 4.4.5) presents different elements of concern in need of attention. Biosafety is generally under-represented in UNEP Mid-term Strategies despite the relevant portfolio of projects implemented. The channels of communication and coordination with the related cross-cutting Sub programmes (e.g. Environmental Governance) are also flawed. The number of Human Resources devoted to Biosafety is actually too low to cope with the growing needs proceeding from the large, diversified and dispersed portfolio of Projects and initiatives. At decentralised level, there is, at the time of writing, only one Regional Office (ROLAC / Panama) with a dedicated Biosafety TM.

242. In the framework of the Programming Exercise suggested above, it is necessary to strengthen and "reset" Biosafety Human Resources through a more strategic role of the Biosafety Unit in Nairobi and its increased decentralization at regional level, particularly in Asia-Pacific Region, but probably also at some sub-regional level in Africa.

243. As a matter of fact, one of the pillars of the GEF Initial Strategy on Biosafety, the Sub-regional and Regional dimension, has been so far too weak for a series of reasons related to the institutional and procedural complexity of the issue, the political will of the countries, GEF financing mechanisms based on national allocations and insufficient capacities of UNEP at decentralised level. Multi-country initiatives based on flexible and country-driven initiatives (e.g. the network of detection laboratories in the Southern Africa Sub-region, among others) should be regarded as more appropriate instruments to address specific gaps, to foster cost-effectiveness and to promote South-South Cooperation (see chapter 4.3.2, section g).

244. Overall, the role of UNEP and other UN agencies directly involved in GMOs (particularly FAO, but also UNDP) as "neutral broker" and "knowledge organisation" is strongly challenged, as far as Biosafety is concerned. Overall, stronger partnerships have to be pursued to gain credibility and acceptability among national and international stakeholders. More structured forms of cooperation between UNEP and FAO are needed to harmonise their initiatives (e.g. the BCH and the FAO Biosafety Platform, the linkage Biosafety-Food Safety) and for linking the Protocol with the International Treaty for the Protection of Genetic Resources for Food and Agriculture. The establishment of a structured partnership with the International Research Centres of the CGIAR (Consultative Group for International Agricultural Research) is also necessary to aggregate and consolidate scientifically-sound knowledge around GMOs and Biosafety, particularly at decentralised level. There is also room for a more effective inclusion of GMOs and Biosafety Agenda in the UN Global Compact on Corporate Social Responsibility.

5.1.3. Overall ratings for the Evaluation Criteria

245. As requested by the TOR of the Evaluation, the overall ratings table for the different evaluation criteria is presented hereafter. Rating is a challenging exercise when a number of countries, national projects and a variety of situations are involved. Although groups of countries may have achieved different levels of NBF implementation (see the variable Likelihood of Impact detailed in chapter 4.3.3), an "average" scoring for each of the evaluation criteria is presented. Of course, that brings about a generalisation that is detrimental to the specific situation of each country. Under this conditionality, the Project and the further progress towards NBF Implementation and the consolidation of the whole Biosafety programme can overall be rated Moderately Satisfactory (MS).

Criteria	Summary Assessment	Rating
A. Strategic relevance	The Project confirms in retrospect all its relevance in: - Supporting a very high number of countries worldwide to prepare and adopt a National Biosafety Framework; - Creating and/or improving their capacity to fulfil their rights and obligations towards the Cartagena Protocol; - Laying the foundations for more comprehensive and effective actions of Capacity Building at National level; - Largely contributing to fulfil UNEP's mandate and policy, yet without being formally part of a strategic framework at UNEP level; - Meaningfully contributing to fulfil GEF strategy and priorities. (see 4.1.1)	**HS**
B. Achievement of outputs	Considering the scope and complexity of the Project, outputs delivery has to be considered Satisfactory (S).(see 4.2 and Table in Ann.13)	**S**
C. Effectiveness: Attainment of project objectives and results	The Project overall has triggered a global and coordinated process to enable the Parties to fulfil CPB obligations, tough with variable results.	**MS**
1. Achievement of direct outcomes	Despite not all the Outcomes having been fully and satisfactorily achieved and the uneven quality of the NBF produced by the countries, the Project has succeeded in promoting a large, promising and coordinated participation in a complex context of variable baseline situations. (see 4.3.2)	**S**
2. Progress from NBF Development to Implementation	The overall progress towards NBF Implementation has been assessed along eight different criteria. Despite some brilliant cases, the overall rating is Moderately Unsatisfactory (MU). (see 4.3.2).	**MU**
3. Likelihood of impact	Highly variable between three main groups of countries (see 4.3.3, section "d"). Overall, Moderately Unlikely (MU).	**MU**
D. Sustainability and replication	Sustainability is uneven along the five different aspects taken into account. (see below). Overall, its rating is between Moderately Likely (ML) and Moderately Unlikely (MU). There are some relevant examples of very promising sustainability, yet the overall picture is not overall satisfactory.	**MU**
1. Socio-political	Biosafety Socio-political Sustainability is challenged from different points of view and the controversial nature of the issue has to be	**MU**

	carefully managed. At the current stage, Socio-political Sustainability is rated Moderately Unlikely (MU). (see 4.4.1)	
2. Institutional	Considering the baseline situation, the progress of the National Biosafety Frameworks has been quite remarkable. However, biosafety systems are not yet operational in many countries and has to be proved in more challenging situations (concrete opportunities to test collegiality and decision-making in presence of GMOs applications). Overall Institutional sustainability can be rated Moderately Unlikely (MU). (see 4.4.2).	**MU**
3. Financial	Financial sustainability is challenged by the overall economic slowdown (cuts in national budgets) and by many pressing priorities at national level. Overall, Financial Sustainability is still to be proved and is currently rated Moderately Unlikely (MU) (see 4.4.3).	**MU**
4. Environmental	Overall, environmental concerns regarding the deliberate release of GMOs crops is increasing among national stakeholders and Risk Management measures are being discussed with technically sound opinions. On the face of that, Environmental Sustainability can be rated Moderately Likely (ML). (see 4.4.4).	**ML**
5. GEF-UNEP Strategy	Relevant areas of concerns and gaps have been observed. Some of them are due to the fact that all the strategies that are MEA related are mainly shaped by the Convention processes to which the UN contributes. There are, however, also some strategic/institutional issues that UNEP can internally improve within the context of those processes. Sustainability in this context is dynamic and in this context, the evaluation deems that Sustainability of GEF-UNEP Biosafety Strategy is currently still less than suitable, hence rated Moderately Unlikely (MU). (see 4.4.5)	**MU**
6. Catalytic role and replication	The Project has represented the starting point of a growing process of capacity and institution building and has unquestionably played a catalytic role. (see 4.4.6)	**S**
E. Efficiency	Project design (overambitious objectives and modalities of implementation) was not the most conducive to efficiency. The use of financial and time resources has not been optimal despite the huge effort made by the Management Team in ensuring monitoring, transparency and accountability through an innovative Information System (ANUBIS). High Management Costs and excessively protracted timeframe are seriously challenging Cost-Effectiveness and Time-Efficiency. Also considering the "historical" context of the Project, its innovativeness and the challenging implementation conditions, Efficiency cannot objectively be rated satisfactorily. It is Moderately Unsatisfactory (MU).(see 4.5)	**MU**
F. Factors affecting project performance		
1. Preparation and readiness	The MTE of 2003 had already defined the Project Design "too ambitious" and the GEF Evaluation of 2005 concluded that the Project was "not adequately designed and funded to fully take the complexities of local conditions and needs into account". The innovative character of the Project, its complexity and the urgency of its implementation did not probably allow a better preparation. Preparation and Readiness has to be rated Moderately Satisfactory (MS). (see 4.6.1)	**MS**
2. Project implementation and management	In retrospect, UNEP has not shown a clear Biosafety Management Strategy, which is leading to a rather unsustainable management situation, as far as biosafety is concerned (see 4.4.5). The overall capacity of UNEP to respond to project implementation and management challenges has to be rated Moderately Unsatisfactory (MU). (see 4.6.2)	**MU**
3. Stakeholders participation and public awareness	Overall, considering Biosafety baseline situation, considerable progress has to be acknowledged in Stakeholders participation and awareness, which has to be considered Moderately Satisfactory (MS). (see 4.3.2 and 4.6.3).	**MS**
4. Country ownership and driven-ness	The transnational character of Biosafety and the challenging context of Global Environmental Governance may, to a certain extent, limit Countries' Ownership, yet the process of empowerment of national	**S**

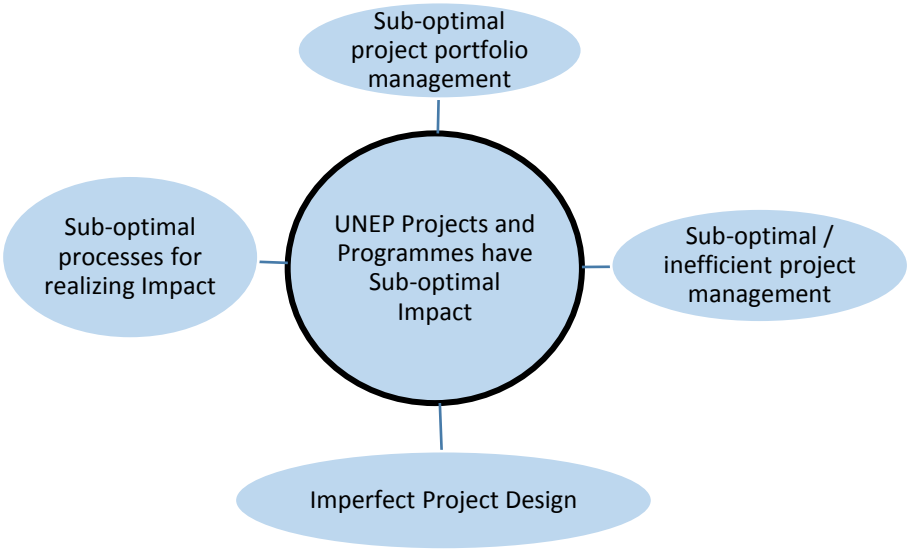
	stakeholders is evident and has to be rated, as a whole, Satisfactory (see 4.6.4)	
5. Financial planning and management	The setting and implementation of ANUBIS (see 4.2) has been a breakthrough enabling the MT to manage and oversee financial planning and management in a very complex situation (123 countries). That has been a formidable task, requiring assiduous work of training and coaching, data corrections and revisions and of system upgrading. Financial Management has been up to the strong challenge and is rated Satisfactory. (see 4.6.5)	**S**
6. UNEP supervision and backstopping	Considering the magnitude and dispersion of the Projects, UNEP has been effective in providing supervision and backstopping that should be considered Highly Satisfactory (HS). (see 4.6.6)	**HS**
7. Monitoring and evaluation	Despite some inconsistencies in the Log Frame, the MT has been able to implement an information system (ANUBIS) and other monitoring tools). The MTE took place as planned. Project Monitoring capacity has been rated Satisfactory (S). (see 4.6.7)	**S**
G. Complementarity with UNEP strategies and programmes	Complementarity is challenged by the under-representation of Biosafety and by the absence of GE & HR approach. It is rated Moderately Unsatisfactory (see 4.7)	**MU**
Overall project rating	Despite its complexity and over-ambitiousness, the project has delivered the expected outputs and most of the outcomes in a satisfactory way. However, efficiency has been strongly challenged by high management costs and an excessively protracted timeframe. The progress towards impact has been uneven along the 123 countries and external factors are challenging socio-political and financial sustainability. The UNEP Biosafety Strategy is not clearly defined and there are concerns regarding its sustainability. Overall, the progress towards NBF implementation and the consolidation of the Biosafety Programme can be rated Moderately Satisfactory.	**MS**

5.2 Lessons Learned

246. Lessons learned refer both to the NBF Development Projects (123 countries) and to the Implementation Projects for which evaluative reports are already available[63]. Lessons have been identified and compiled through the Framework of Lessons Learned[64] that shows the central problem (UNEP Projects and Programmes have Sub-optimal Impact) and the four cornerstones of causal problems, as follows:

[63] Cambodia, Czech Republic, Estonia, Lithuania, Moldova, Slovak Republic and Vietnam (2012), Costa Rica, Caribbean (regional, MTE), Tanzania, Mauritius, Tunisia, Bhutan, Lao PDR and Mongolia (2014), Guatemala, Egypt, Macedonia (FYROM) and Albania (2015).

[64] "Lessons Learned from Evaluation, a platform for Sharing Knowledge", UNEP, 2007



5.2.1. Imperfect Project Design

Causal levels of imperfect project design are manifold:

Global NBF Implementation Project:

- The design of the Global Project was very ambitious in project size (123 countries) and underestimated time and efforts required for its implementation (L1);
- The baseline situation was very uneven among the countries and not appropriately taken into account by the "one size fits all" approach (L2);
- The Regional and sub-regional component of the Global Project was largely undervalued in the project budget and in planned activities (L3);
- Criteria for budget allocation among national sub-projects was not clearly defined and transparent (L4).

NBF Development and Implementation Projects:

- Countries' capacities have been overestimated in some crucial issues, for example the possibility of setting complex Legal Frameworks (Laws, etc.) within the limited timeframe of Projects (L5);

> *Project implementation dynamics are inconsistent with those of governance change processes, generating an underlying tension that is difficult to bridge. Many projects face situations in which the approval of new policies or legislation is held up by national elections, changes of government authorities or simple institutional indifference….* (TE of Guatemala NBF Implementation Project)

- Logical Frameworks lack an homogeneous, harmonized terminology and there is a diffuse misunderstanding of basic concepts, like Outputs, Outcomes, Indicators, Milestones and Targets (L6);
- Stakeholders analysis, particularly key decisions-makers analysis, critically discussing their role in Biosafety, is always flawed, if there is any; different visions and possible conflicts of interest, due to the controversial nature of Biosafety, are usually underestimated; partner institutions at regional and international level are usually not contemplated in the analysis (L7);
- HR & GE approach is not present in any of the ProDocs of the NBF Implementation Projects. The word "gender" does not appear at all in any of them (L8).

5.2.2. *Sub-optimal processes for realizing Impact*

From both NBF Development and Implementation Projects:

- Project are often coming to an end without a clear "exit strategy" identifying appropriate measures to address weak points and to achieve sustainability of results (L9);
- NPCs (Nat. Projects Coordinators) are in most of the cases national consultants hired for the task in order to ensure a full-time dedication to Project implementation. That, however, cannot be the best option for activities follow-up and institutional up-taking once the project comes to end (L10);
- Financial resources are usually not at a suitable level at national level to carry on Biosafety activities without external funding, once the Project is over, particularly in developing countries (L11);
- It is not always possible to channel stakeholders participation into the institutional instruments foreseen (Committees, etc.) due to polarized opinions and to the stakeholders' option for alternative strategies (e.g. lobbying, social mobilisation, campaigns through media, etc.) (L12);
- Civil Society and Private Sector are usually under-represented in the National Biosafety Committees, Women and HR Organisations are always absent (L13);
- The delivery of quality outputs (e.g. guidelines, manuals, procedures, etc.) is often a difficult process due to the lack of national expertise and/or to the insufficient involvement of academic and research institutions (national, regional and international) (L 14);
- National capacities in crucial areas are not always at a suitable level, due to the complexity and technical "sophistication" of the issue (e.g. Risk Assessment and Management, GMOs Laboratory facilities) (L15);
- Capacity of technically-sound Risk Communication to Decision-makers (Government, Parliament members, entrepreneurs, farmers and consumers) is still insufficient. (L16).

5.2.3. *Sub-optimal / inefficient project management*

From both NBF Development and Implementation Projects:

- There are frequent and, in certain cases, remarkable delays in project implementation for a series of causes outlined below (L17);
- It is very difficult to accommodate Project timing with complex institutional processes and socio-political situations related to Biosafety (L18);
- The time elapsed between project formulation and implementation is often large, as well as the time-gap between the Development and Implementation Projects. Projects have to stretch their inception phase to revise the baseline situation and update information, to renew contacts with stakeholders (that meantime may also have changed) and to re-discuss with them project's activities, work-plan and budget. Time for actual implementation is reduced and continual extensions are needed (L19);
- Work-plans are often over-ambitious in order to comply with over-ambitious project design. As a consequence, they have to be revised together with expenditures plans. Accordingly, budget revisions are frequent and the whole management system has high "transaction costs" (L20);
- In Global and Regional Projects, the different rate of progress among the countries has brought about delays in the administrative closure of the Project (L21);
- The strong challenges caused by the complexity and level of ambition of the NBF Development Project were tackled by a considerable increase of Project Staff until 2007. As a consequence, effectiveness has been achieved through high management costs, i.e. at the detriment of efficiency (L22).

5.2.4. *Sub-optimal project portfolio management*

From both NBF Development and Implementation Projects:

- NPCs have been key-actors in Projects management, particularly in the NBF Implementation Projects. The Nairobi TM has been successful through technical backstopping and exchange opportunities (sub-regional meetings) in creating a "virtual" team that has been highly instrumental in achieving NBF Implementation results. Though that has resulted in a positive form of "adaptive management", it does not resolve the problems of a medium-long term biosafety strategy, since the involvement of the NPC terminates at the end of the Project (L23);
- The management of a relevant, fragmented and geographically dispersed Biosafety Portfolio is a highly challenging task for an extremely reduced and excessively centralised technical staff (currently two TMs, one in in Nairobi and one in Panama) that has also to cope with extra-tasks (other than Biosafety Projects management) (L23);

5.3 Recommendations

247. Taking into account the scope of the Evaluation and based on the main Findings, Conclusions and Lessons Learned, the Recommendations that follow are principally addressed to UNEP as Implementing Agency of the Biosafety Programme and to GEF as Financial Mechanism of the Protocol.

Recommendation 1: General Recommendation to UNEP and GEF

Recommendation 1:

For an increased effectiveness and efficiency, it is strongly recommended to implement a Biosafety Programming Approach with the following main objectives:

a) To strengthen and consolidate the Biosafety Portfolio within the Biodiversity Programme and the global context of Sustainable Development goals;

b) To identify a limited number of Biosafety Programmes encompassing sets of interventions or projects tailored to different countries' needs and priorities;

c) To strengthen stocktaking at sub-regional level (e.g. through Rapid Appraisals[65]) in order to match needs and priorities mentioned above and design "multi-country thematic initiatives" with particular attention to countries and sub-regions already exposed (or prone to be) to GMOs development.

248. More specifically:

Recommendation 2: to UNEP and GEF regarding the implementation of the Programming Approach

Recommendation 2

Based on the Programming Approach recommended above (Rec 1), it is specifically recommended:

a) To undertake specific "needs and priorities" Rapid Appraisals in order to identify "homogeneous countries" (see for instance the grouping proposed in chapter 4.3.3), preferably within the same Sub-region, to be matched with multi-country-initiatives addressing specific, yet, common gaps and by exploring forms of South-South Cooperation enhancing the role of "champion-countries" and of a small team of sub-regional consultants to be identified;

[65] Rapid Appraisal is an approach that permits quick yet systematic data collection, when time and budget are limited.

b) Design and implement, based on the above, specific multi-country and result-oriented initiatives in thematic areas (e.g. among others: Risk Assessment and Management, Risk Communication, Detection capacities, Co-existence and Socio-economic considerations);

c) To support the countries, particularly those already exposed to GMOs, in producing more neutral and scientifically-sound communication tools for crucial decision-makers at different levels (Politicians, Managers, Farmers, Consumers).

Recommendation 3: to UNEP, regarding UNEP institutional up-take of Biosafety Programme

Recommendation 3:

It is strongly recommended to clarify the strategic position of biosafety at Sub-program level (Environmental Governance / EG) and to define more efficient communication channels allowing adequate strategic planning, institutional monitoring and reporting of the Biosafety Programme. More specifically:

a) to explicitly and meaningfully integrate, as soon as possible, biosafety into the strategic Sub-Programmes, particularly Environmental Governance, as well as within the next possible UNEP PoW (2018);

b) to clearly define and strengthen the institutional anchorage of biosafety either within DEPI (current situation), considering the insertion of Biosafety within the Biodiversity sector, or, perhaps preferably, within DELC, considering the evident linkage with Sub-programme EG;

c) to prepare and discuss a biosafety strategy paper for internal use in order to clarify and detail the points outlined above, as well as a concrete proposal for the implementation of the recommended "programming approach" (Rec. 1 and 2), by October 2016.

Recommendation 4: to UNEP regarding the organizational structure of Biosafety Programme

Recommendation 4

It is recommended to "reset" the Biosafety Programme by an appropriate design of its internal organizational structure, namely:

a) To clearly define and implement the functions of the Global Biosafety Programme Coordinator responsible for the overall oversight of Programme Planning, Monitoring and Evaluation, including ABS, L&R and BCH Projects[66] and also directly responsible for Eastern, Central and Southern Africa (see following point regarding decentralization);

b) To enhance Biosafety Programmes decentralization by adding, in a first phase, at least one Biosafety/Biodiversity TM for Asia / Pacific Region posted in Bangkok RO and, if possible, one Sub-regional Biosafety/Biodiversity TM for the francophone West Africa and Maghreb Sub-regions[67]. Appropriate partnerships could be explored with regional institutions, like IICA (Inter-American Institute for Cooperation on Agriculture) to provide specific support to LAC Biosafety/Biodiversity TM for groups of Latin-America countries (e.g. Central America). Similarly, appropriate partnership could be implemented with IUCN (Int. Union for Conservation of Nature) Regional Offices in Belgrade for the CEE Region and in Fiji for Pacific Islands.

[66] Perhaps, more appropriately, the Coordinator should be defined "SCBD Protocols Programme Coordinator".
[67] Probably to be located in Dakar/Senegal or Abidjan/Cote d'Ivoire, which are already sub-regional hubs for different UN Agencies

Recommendation 5: to UNEP and GEF regarding Partnership and Cooperation

Recommendation 5

In order to enable the Programming Approach, it is recommended to improve and consolidate the cooperation with partners institutions particularly at Regional and Sub-regional levels (e.g. CGIAR Centres and Institutions, Universities) in order to promote "Biosafety Poles of Excellence" able to support the countries on specific thematic areas. More specifically,

a) UNEP should prepare by the end of 2016 a strategic paper about cooperation with partners at regional and sub-regional level, with, if possible, input from the GEF;

b) Enhanced cooperation could include, for instance, consulting partners institutions at the time of project design, integrating them in a comprehensive stakeholders analysis by assessing their added value and identifying their roles and responsibilities in the projects and by involving them in technical support and backstopping to the programme.

Recommendation 6: to UNEP, GEF regarding coordination within UN system

Recommendation 6

In order to firmly insert Biosafety into the mainstream of Sustainable Development Strategies and to improve the coordination with other UN Agencies, particularly those related to Rural Development, Food Security, Food Safety and Genetic Resources Conservation (e.g. FAO, IFAD, WHO), it is recommended to set-up and/or consolidate coordination mechanisms at global, regional and national level, namely through:

a) Pursuing the initiative of joint webinars (e.g. webinar on "international databases on biosafety" run in 2014 and 2015 by CBD, FAO and OECD) by organizing and launching a joint webinar on "Socio-economic considerations (art. 26 of CPB)" by the end of 2016[68];

b) Establishing an active coordination between Biosafety projects and the UNEP/GEF project for the protection *in-situ* of Crop Wild Relatives (CWR), as well as with FAO / ITPGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture) in all the countries where the CWR Project is on-going or planned;

c) Encouraging the participation of the NCAs in the UNDAF programming exercise and their proactive role in the UNCT (UN Country Team);

d) Encouraging and/or consolidating the coordination of NCAs with the *Codex Alimentarius* national commissions in order to promote coordinated actions between Biosafety and Food Safety;

e) Strengthening and taking an active role in the coordination mechanism under the SCBD, especially in the liaison group on Capacity Building in Biosafety (please see http://bch.cbd.int/protocol/cpb_art22_actionplan.shtml#coord).

[68] Webinar and online forums are being organised under 26 as requested by parties, see http://bch.cbd.int/onlineconferences/portal_art26/se_main.shtml

Annexes

1. Response to stakeholder comments received but not (fully) accepted by the evaluators
2. Evaluation TORs (without annexes)
3. List of people met
4. Bibliography
5. Summary co-finance information and a statement of project expenditure by activity
6. Brief CV of the consultant
7. Table of available evaluative evidence
8. Evaluation Criteria and Key-questions
9. Summary / Findings of Country visits (Honduras, Panama, Myanmar, Senegal, Cape Verde)
10. The sample of 37 countries: criteria and selected countries
11. NBF Model (diagram)
12. Flow-chart of the National Projects (NBF preparation)
13. Table of Project Outputs
14. Scorecards (37) of NBF sample countries
15. Synoptic Table of NBF scores
16. Analysis of selected questions from the Second and Third National Report on the implementation of The Cartagena Protocol on Biosafety of 37 countries
17. Synoptic Table of GEF support (Projects) on Biosafety by country
18. Overall GEF-UNEP Portfolio (2001-2015)
19) List of staff of Project Management Team (2003)
20. Project duration by country (37 sample countries).
21. Integration of Biosafety into UNEP Divisions – DELC or DEPI

Annex 1. Response to stakeholder comments received but not (fully) accepted by the evaluators

Annex 2. Evaluation TORs (without annexes)

TERMS OF REFERENCE[69]

Terminal Evaluation of the UNEP/GEF project

Development of National Biosafety Frameworks (NBF development project)

PROJECT BACKGROUND AND OVERVIEW

Project General Information

Table 1. Project summary

UNEP PIMS ID:	GF/6010-01-01	**IMIS number:**	GFL/2716-01-4319
Sub-programme:	Environmental Governance	**Expected Accomplishment(s):**	Development of National Biosafety Framework (article 2.1 of the Cartagena Protocol on Biosafety
UNEP approval date:	June 2001	**PoW Output(s):**	Tools to support implementation of an MEA
GEF project ID:	875 (2341 and 2582, add on projects)	**Project Type:**	Enabling Activity
GEF OP #:	EA	**Focal Area(s):**	Biodiversity
GEF approval date:	November 2000	**GEF Strategic Priority/Objective:**	Operational Program: Enabling Activity/Capacity Building for Implementation of the Cartagena Protocol on Biosafety
Expected Start Date:	June 2001	**Actual start date:**	June 2001
Planned completion date:	December 2005	**Actual completion date:**	June 2007[70]
Planned project budget at approval:	26,092,000 + 5,218,420 + 2,609,208 = 33,919,6288 USD	**Total expenditures reported as of [date]:**	
GEF Allocation:	26,092,000 + 5,218,420 + 2,609,208 = 33,919,6288	**GEF grant expenditures reported as of [date]:**	

[69] TOR template version of April 2015

Legend: yellow=GEF only; green=UNEP only; purple=MTE only; Blue=TE only; Red=Info to be added

[70] An Add-on project was submitted to the GEF in December 2003 to extend support to 20 additional countries and prolong the duration by 24 months. This was in line with the statement in the Project Document for the main project which specified that "If the number of eligible countries seeking GEF assistance exceeds 100, additional financial resources will be required".

	USD		
PDF GEF cost:		**PDF co-financing:**	
Expected EA co-financing:	12,341.00 + 750,000 = 13,091,000 USD	**Secured EA co-financing:**	
First Disbursement:		**Date of financial closure:**	
No. of revisions:	1	**Date of last revision:**	December 2003
Date of last Steering Committee meeting:			
Mid-term review/ evaluation (planned date):	August 2003	**Mid-term review/ evaluation (actual date):**	August 2003
Terminal Evaluation (actual date):	October 2015 – January 2016		

Projects rationale

The objective of the Cartagena Protocol on Biosafety, opened for signature in Nairobi, on 24 May 2000 is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movement."

This project built on the Pilot Biosafety Enabling Activity project approved in 1997. The National Level Component of the project aimed at assisting eighteen eligible countries to prepare National Biosafety Frameworks (US$ 1.9 million), with the Global Level Component aiming at facilitating the exchange of experience at regional levels through the convening of 2 workshops in each of four regions (US$ 0.8 million).

In order to meet the requirements of the Protocol, Parties need to develop comprehensive frameworks for biosafety, and to put in place appropriate legal and regulatory systems to assess any possible impact on their environment. The First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpellier on 11-15 December 2000 stressed the need for capacity building and strengthening of human and institutional resources of developing countries, especially in least developed and Small Island Developing States, and countries with economies in transition. The meeting also stressed the importance of a regional approach.

As the financial mechanism of the Convention on Biological Diversity, the GEF was also called upon to serve as the financial mechanism of the Protocol. The GEF Council at its November 2000 meeting adopted the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety" (GEF/C.16/4). The main objectives of this initial strategy were to: a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and subregional level, and to promote collaboration with other organizations to assist capacity-building for the Protocol.

Project objectives and components

5. The project's fundamental objective is to prepare countries for the entry into force of the Protocol. Specific objectives of the project were to assist up to 100 eligible countries (123 by the time of the end of the project) to prepare their national biosafety frameworks and to promote regional and sub-regional collaboration and exchange of experience on issues of relevance to the national biosafety frameworks. The project was structured around two components. The first focused on promoting regional and sub-regional collaboration and exchanges of experience, the second revolved around the actual preparation of National Biosafety Frameworks. The two components were complemented by supporting global activities. The table below presents the relevant components and expected outputs.

Table 2 – Projects components and outputs

Project component	Outputs
Promotion of regional and sub-regional collaboration and exchanges of experience on	• Four regional workshops (Africa, Latin America and the Caribbean, Asia and the Pacific and Eastern Europe)

issues of relevance to national biosafety frameworks	• Fifteen sub-regional workshops (North Africa, West Africa, Central Africa, Eastern Africa, Southern Africa, Caribbean region, South America, Central America, West Asia, South East Asia, South Asia, Central Asia, Pacific Islands, Eastern Europe, and the Baltic countries).
Preparation of National Biosafety Frameworks in 100[71] countries	• surveys and inventories of current biosafety practices, existing policy/legal frameworks and available expertise • harmonization of legal and regulatory instruments • strengthening of risk assessment/management capabilities, public awareness and mechanisms for public participation • design and publication of the NBF
Global activities	• setting up of national databases • creation of a web page and newsletter • design and dissemination of "tool kits" to assist countries in developing their national biosafety frameworks

Executing Arrangements

6. The ***Implementing Agency*** for the project was the United Nations Environment Programme (UNEP). In this capacity, UNEP had overall responsibility for the implementation of the projects, project oversight, technical support and co-ordination with other GEF projects.

7. The project was managed by a Geneva-based Global Biosafety Team that was headed by a Scientific Coordinator/Task Manager and Regional Coordinators for Africa, Asia-Pacific (with an Assistant Coordinator for the Pacific Countries), Central and Eastern Europe and GRULAC (with an Assistant Coordinator for the Caribbean Countries). The team was intended to include three programme officers and one fund manager, but was eventually composed of twelve staff by the end of the project. Implementation activities were supervised and monitored by Regional Coordinators, while the project's Financial Manager handles administrative matters and prepares cash advance requests.

A **Steering Committee** was created which held meetings and teleconferences on a quarterly basis to monitor progress, discuss issues related to implementation process and recommend adjustments. The Steering Committee is co-chaired by the GEF Secretariat and UNEP, and includes representatives from UNDP, the World Bank, the CBD Secretariat, FAO, ICGEB, STAP and UNIDO; the project Task Manager is Secretary to the Steering Committee.

A National Project Document was prepared for each participating country, detailing the specific workplan for the country. Participating countries had to designate a competent national authority. Criteria for participation included: eligibility for GEF funding, Party to the Convention on Biological Diversity, signatory or intention to accede to the Cartagena Protocol, no previous assistance received during the initial pilot project or recipient of support from the GEF to develop/implement an NBF and submission of a formal expression of interest.

Project Cost and Financing

The GEF contribution to the main project was 26,092,000 USD, which was expected to be matched by 12,341,000 USD in co-financing from UNEP and participating countries. The add-on projects approved in 2003 included a GEF grant of 5,218,420 million USD to cover an additional 20 countries and a further grant to cover 10 additional parties with a GEF Grant of $2,609,208[72], based on the full range of costs to implement all the activities as outlined in the main project under both components for the additional countries. No additional co-financing was required for the-add on project.

[71] Plus an additional 30 countries through the "two add on projects" for a total of 123 countries as not all elegible countries decided to join the project.

[7272] The total number of eligible parties was extended to 130 Parties, but the actually number of parties which submitted the commitment letter and requested for support funding were 123 Parties

Implementation Issues

According to the project document, it was not possible for the GEF and UNEP to predict exactly how many countries would be eligible for support and submit a request to obtain it. It was therefore estimated that approximately 100 countries would want to join the project and a provision was inserted on the release of additional funding in case additional requests were received by the 30th of June 2003. As 20 additional requests were received, an add-on project was prepared, effectively extending the initial project by two years and increasing its budget by approximately 5 million USD.

The mid- term review highlighted the fact the project was well-designed and was performing at satisfactory and highly satisfactory levels. However, it also pointed at some challenges, including the fact the key outcome of having "National Biosafety Frameworks in place" was overambitious and the timing was too short. It also noted that the regional component, although useful, was perceived to be too superficial and the workshops were deemed too brief to allow for more in-depth discussion on cooperation needs and complex technical issues. It was also noted that more flexibility in budget allocation at country level was needed. Additionally, the need to increase public awareness efforts, especially by targeting decision-makers specifically. The mid-term included country visits to eight countries.

In addition to this project and its add-on, twelve countries received funds to implement their biosafety framework as part of a series of demonstration projects of which eight projects were managed by UNEP (2001-2007). In 2006, seven countries received funds managed by UNEP for implementation projects to convert their NBFs into a workable, effective and transparent regulatory regime. These projects have all been evaluated. Several countries received individual follow up funding after the NBF development project ended and in several cases, evaluation of these projects are already available or are being prepared. The table below presents the current situation as of July 2015.

Table 3 – Available evaluative evidence

Countries visited at MTR stage	Demonstration (D) and implementation (I) projects (2012)	Evaluation of follow up individual project completed	Evaluation of follow up individual project ongoing (at the time of this Terminal Evaluation)	Evaluation of follow up individual project planned
• Antigua and Barbuda • Chile • Jordan • Moldova • Republic of Korea • Slovenia • Togo • United Republic of Tanzania	• Bulgaria (D) • Cameroon (D) • China (D) • Cuba (D) • Kenya (D) • Namibia (D) • Poland (D) • Uganda (D) • Cambodia (I) • Czech Republic (I) • Estonia (I) • Lithuania (I) • Moldova (I) • Slovak Republic (I) • Vietnam (I)	• Costa Rica (2014) • Caribbean (regional, MTE) (2014) • Tanzania (2014) • Mauritius (2014) • Tunisia (2014) • Bhutan (2014) • Lao PDR (2014) • Mongolia (2014) • Guatemala (2015)	• Egypt (2015-16) • Macedonia (Former Yugoslavic Republic of) (2015-16) • Albania (2015-16)	Ecuador (2016) El Salvador (2016) Namibia (2016) Nigeria (2016) Liberia (2016)

TERMS OF REFERENCE FOR THE EVALUATION

Objective and Scope of the Evaluation

In line with the UNEP Evaluation Policy[73] and the UNEP Programme Manual[74], the Terminal Evaluations are undertaken at completion of the project 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 operational improvement, learning and knowledge sharing through results and lessons learned among UNEP and the main project partners in each country. Therefore, the evaluation will identify lessons of operational relevance for future project formulation and implementation, especially for the additional phases of the biosafety projects, if applicable.

It will focus on the following sets of **key questions**, based on the projects' intended outcomes, which may be expanded by the consultants as deemed appropriate:

1. To what extent was the project able to promote regional and sub-regional collaboration and exchanges of experience on issues of relevance to national biosafety frameworks?
2. To what extent was the project able to support the preparation of National Biosafety Frameworks in 124 countries? To what extent were the objectives realistic and how far in the preparation process could the project take the 124 participating countries?
3. To what extent did the global activities effectively support the delivery of the two main components of the project (regional collaboration and preparation of national biosafety frameworks)?

Overall Approach and Methods

The Terminal Evaluation of the Project will be conducted by independent consultants under the overall responsibility and management of the UNEP Evaluation Office in consultation with the UNEP Task Manager.

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. It is highly recommended that the consultant(s) maintains close communication with the project team and promotes information exchange throughout the evaluation implementation phase in order to increase their (and other stakeholder) ownership of the evaluation findings.

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

(a) A **desk review** of:

Relevant background documentation, inter alia inter alia UNEP and GEF-3 and GEF-4 policies, strategies and programmes pertaining to biosafety at the time of the project's approval

Project design documents (including minutes of the project design review meeting at approval); Annual Work Plans and Budgets or equivalent, revisions to the project (Project Document Supplement), the logical framework and its budget;

Final project reports, as published for each participating country, and progress reports from collaborating partners, meeting minutes, relevant correspondence, if necessary to assess particular aspects of implementation;

Project outputs

MTR

Review of available evaluative evidence as showed in table 3.

Interviews (individual or in group) with:

UNEP-GEF Task Manager and Biosafety team at the time, to the extent possible

Project management team

UNEP Fund Management Officer;

[73] http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationPolicy/tabid/3050/language/en-US/Default.aspx

[74] http://www.unep.org/QAS/Documents/UNEP_Programme_Manual_May_2013.pdf

Project partners, including national executing agencies, project coordinators, members of the NCCs;
Relevant resource persons;u

Field visits of 2-3 days in a selection of countries, including:

- 2 countries which did not apply for follow up funding from the GEF for biosafety-related work after participating in this project
- 2 countries which have applied for additional funding and for which no evaluative evidence is available (see table 3).
- The selection of countries is to de decided in cooperation with the UNEP Task Manager, with a view to select of sample of countries at different stages of implementation of their Biosafety Framework and taking into account the availability of local stakeholders to facilitate the field visits.

Presentation of the lessons learned on the implementation of UNEP-led and GEF-funded biosafety projects to relevant UNEP and GEF staff as well as governments during an official meeting of the COP or other subsidiary body, if possible (the MOP-08 – 8th Meeting of Parties is scheduled for December 2016 in Cancun, Mexico, the possibility of using other meetings as platforms will be considered).

Survey: the option of conducting a survey of countries which will not be recipient of a field visit and for which a recent evaluation report is not available will be considered by the team. A separate survey of countries which chose not to request GEF funding while being entitled to them, based on the GEF criteria for disbursement, should also be considered, if contact details of focal points can be obtained by UNEP or the Secretariat of the Protocol.

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. 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 six categories: (1) Strategic Relevance; (2) Attainment of objectives and planned result, which comprises the assessment of outputs achieved, effectiveness and likelihood of impact; (3) Sustainability and replication; (4) Efficiency; (5) Factors and processes affecting project performance, including preparation and readiness, implementation and management, stakeholder participation and public awareness, country ownership and driven-ness, financial planning and management, UNEP supervision and backstopping, and project monitoring and evaluation; and (6) Complementarity with the UNEP strategies and programmes. The evaluation consultants can propose other evaluation criteria as deemed appropriate.

Ratings. All evaluation criteria will be rated on a six-point scale. Annex 3 provides guidance on how the different criteria should be rated and how ratings should be aggregated for the different evaluation criterion categories.

Baselines and counterfactuals. In attempting to attribute any outcomes and impacts to the project intervention, 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, trends and counterfactuals in relation to the intended project outcomes and impacts. It 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, trends or counterfactuals 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.

The "Why?" Question. As this is a terminal evaluation and a follow-up project is likely or similar interventions are envisaged for the future, particular attention should be given to learning from the experience. Therefore, the "*Why?*" question should be at the front of the consultants' minds all through the evaluation exercise. This means that the consultants need 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 F – see below). 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 review of "*where things stand*" at the time of evaluation.

A key aim of the evaluation is to encourage reflection and learning by UNEP staff and key project stakeholders. The consultant should consider how reflection and learning can be promoted, both through the evaluation process and in the communication of evaluation findings and key lessons. In particular, as this evaluation reviews a large enabling activity project which was followed by several individual full size and medium size projects for which evaluative evidence is available, a particular focus of the evaluation should be the preparation of a **compendium of lessons learned** which will act as reference for the formulation of future UNEP-led and GEF-funded projects in the area of biosafety.

Communicating evaluation results. Once the consultant(s) has obtained evaluation findings, lessons and results, the Evaluation Office will share the findings and lessons with the key stakeholders. Evaluation results should be communicated to the key stakeholders in a brief and concise manner that encapsulates the evaluation exercise in its entirety. There may, however, be several intended audiences, each with different interests and preferences regarding the report. The Evaluation Manager will plan with the consultant(s) which audiences to target and the easiest and clearest way to communicate the key evaluation findings and lessons to them. This may include some or all of the following; in person presentation to relevant meetings, a webinar, conference calls with relevant stakeholders, the preparation of an evaluation brief or interactive presentation.

Evaluation criteria

Strategic relevance

The evaluation will assess, in retrospect, whether the project's objectives and implementation strategies were consistent with global, regional and national environmental issues and needs.

The evaluation will assess whether the project was in-line with the GEF Biodiversity focal area's strategic priorities and operational programme(s).

The evaluation will also assess the project's relevance in relation to UNEP's mandate and its alignment with UNEP's policies and strategies at the time of project approval (Biennial Programme and Support Budget 2000-2001, 2002-2003, 2004-2005 and 2006-2007). Additionally, the evaluation should assess the extent to which biosafety is currently adequately integrated into the current UNEP Programme of Work, including by making reference to current Medium Term Strategy (2014-2017), and make recommendation on institutional arrangements for future work in this area.

The evaluation should assess the project's alignment / compliance with UNEP's policies and strategies. The evaluation should provide a brief narrative of the following:

4. *Alignment with the Bali Strategic Plan (BSP)*[75]. The outcomes and achievements of the project should be briefly discussed in relation to the objectives of the UNEP BSP.
5. *Gender balance*. 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. Are the project intended results contributing to the realization of international GE (Gender Equality) norms and agreements as reflected in the UNEP Gender Policy and Strategy, as well as to regional, national and local strategies to advance HR & GE?
6. *Human rights based approach (HRBA) and inclusion of indigenous peoples issues, needs and concerns*. Ascertain to what extent the project has applied the UN Common Understanding on HRBA. Ascertain if the

[75] http://www.unep.org/GC/GC23/documents/GC23-6-add-1.pdf

project is in line with the UN Declaration on the Rights of Indigenous People, and pursued the concept of free, prior and informed consent.

7. *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.

Based on an analysis of project stakeholders, the evaluation should assess the relevance of the project intervention to key stakeholder groups.

Achievement of Outputs

The evaluation will assess, for each component, the project's success in producing the programmed outputs and milestones, both in quantity and quality, as well as their usefulness and timeliness.

Briefly explain the reasons behind the success (or failure) of the project in producing its different outputs and meeting expected quality standards, cross-referencing as needed to more detailed explanations provided under Section F (which covers the processes affecting attainment of project results). Were key stakeholders appropriately involved in producing the programmed outputs?

Effectiveness: Attainment of Objectives and Planned Results

The evaluation will assess the extent to which the project's objectives were effectively achieved.

The **Theory of Change** (ToC) of a project depicts the causal pathways from project outputs (goods and services delivered by the project) through outcomes (changes resulting from the use made by key stakeholders of project outputs) towards impact (long term changes in environmental benefits and living conditions). The ToC will also depict any intermediate changes required between project outcomes and impact, called 'intermediate states'. The ToC further defines the external factors that influence change along the major pathways; i.e. factors that affect whether one result can lead to the next. These external factors are either drivers (when the project has a certain level of control) or assumptions (when the project has no control). The ToC also clearly identifies the main stakeholders involved in the change processes.

The evaluation will reconstruct the ToC of the projects based on a review of project documentation and stakeholder interviews. The evaluator will be expected to discuss the reconstructed TOC with the stakeholders during evaluation missions and/or interviews in order to ascertain the causal pathways identified and the validity of impact drivers and assumptions described in the TOC. This exercise will also enable the consultant to address some of the key evaluation questions and make adjustments to the TOC as appropriate.

The assessment of effectiveness will be structured in three sub-sections:

(a) Evaluation of the **achievement of outcomes as defined in the reconstructed ToC**. These are the first-level outcomes expected to be achieved as an immediate result of project outputs. For these projects, the main question will be to what extent the projects have contributed to the immediate outcomes (see tables 2,3,4). Additional questions would be to what extent the projects were able to successfully use available drivers to ensure progress towards the adoption of the relevant regulatory systems, even in the wake of political changes.

(b) Assessment of the **likelihood of impact** using a Review of Outcomes to Impacts (ROtI) approach[76]. The evaluation will assess to what extent the projects have to date contributed, and are likely in the future to further contribute, to intermediate states, and the likelihood that those changes in turn to lead to positive changes in the natural resource base, benefits derived from the environment and human well-being. The evaluation will also consider the likelihood that the intervention may lead to unintended negative effects.

Evaluation of the **achievement of the formal project overall objective, overall purpose, goals and component outcomes** using the project's own results statements as presented in the Project Document[77]. This sub-

[76] Guidance material on Theory of Change and the ROtI approach is available from the Evaluation Office.

[77] Or any subsequent **formally approved** revision of the project document or logical framework.

section will refer back where applicable to the preceding sub-sections (a) and (b) to avoid repetition in the report. To measure achievement, the evaluation will use as much as appropriate the indicators for achievement proposed in the Logical Framework (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 F. Most commonly, the overall objective is a higher level result to which the project is intended to contribute. The section will describe the actual or likely **contribution** of the project to the objective. As the objective was considered ambitious and to some extent unrealistic at MTR stage, the evaluation should consider, in particular, the extent to which the projects were successful in paving the way for future interventions and the extent to which follow up individual projects took key lessons into account in order to design project which would achieve the implementation of transparent and workable biosafety frameworks. Where possible, based on available evaluative evidence of individual follow op projects projects, an assessment of the status of achievement of the overarching objective should be provided and lessons for future interventions should be distilled.

The evaluation should, where possible, disaggregate outcomes and impacts for the key project stakeholders. It should also assess the extent to which HR and GE were integrated in the Theory of Change and results framework of the intervention and to what degree participating institutions/organizations changed their policies or practices thereby leading to the fulfilment of HR and GE principles (e.g. new services, greater responsiveness, resource re-allocation, etc.)

Sustainability and replication

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, based on the results of this project and the available evaluative evidence of follow up projects. 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 the sustainability of benefits. The evaluation will ascertain that the project has put in place an appropriate exit strategy and measures to mitigate risks to sustainability as well as any persisting challenges to long term sustainability in the implementation of workable and transparent biosafety frameworks in the countries receiving GEF support. The reconstructed ToC will assist in the evaluation of sustainability, as the drivers and assumptions required to achieve higher-level results are often similar to the factors affecting sustainability of these changes.

Four aspects of sustainability will be addressed:

(a) *Socio-political sustainability.* Are there any social or political factors that have influenced positively or negatively the sustenance of projects' results and progress towards impacts? Is the level of ownership by the main stakeholders sufficient to allow for the projects' results to be sustained? Are there sufficient government and other key stakeholder awareness, interests, commitment and incentives to implement biosafety frameworks in each country? Did the projects conduct 'succession planning' and implement this during the life of the project? Was capacity building conducted for key stakeholders? Did the interventions' activities aim to promote (and did they promote) positive sustainable changes in attitudes, behaviours and power relations between the different stakeholders (see MTR findings and consider the extent to which these were integrated into follow up projects as well as this project)? To what extent has the integration of HR and GE led to an increase in the likelihood of sustainability of projects' results?

Financial resources. To what extent were the continuation of projects' results and the eventual impact of the project dependent on financial resources? What is the likelihood that adequate financial resources[78] will be or will become available to use capacities built by the projects? Are there any financial risks that may jeopardize sustenance of projects' results and onward progress towards impact?

Institutional framework. To what extent was the sustenance of the results and onward progress towards impact dependent on issues relating to institutional frameworks and governance? How robust were the

[78] Those resources can be from multiple sources, such as the national budget, public and private sectors, development assistance etc.

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, goods or services?

Environmental sustainability. Were there any environmental factors, positive or negative, that influenced the future flow of projects' benefits? Were there any projects' outputs or higher level results that are likely to affect the environment, which, in turn, might affect sustainability of project benefits? Were there any foreseeable negative environmental impacts that may occur as the project results are being up-scaled?

Catalytic role and replication. The *catalytic role* of UNEP 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 also aims 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:

(a) *catalyzed behavioural changes* in terms of use and application, by the relevant stakeholders, of capacities developed;

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

contributed to *institutional changes*, for instance institutional uptake of project-demonstrated technologies, practices or management approaches;

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

contributed to sustained follow-on financing (*catalytic financing*) from Governments, private sector, donors etc.;

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

Replication 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 determine 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?

Efficiency

The evaluation will assess the cost-effectiveness and timeliness of project execution. It will describe any cost- or time-saving measures put in place in attempting to bring the project as far as possible in achieving its results within its (severely constrained) secured budget and (extended) time. It will also analyse how delays, if any, have affected project execution, costs and effectiveness. Wherever possible, costs and time over results ratios of the project will be compared with that of other similar interventions. The evaluation will also assess the extent to which HR and GE were allocated specific and adequate budget in relation to the results achieved.

The evaluation will 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. For instance, the previous phases of biosafety support received by the countries.

Factors and processes affecting project performance

Preparation and readiness. This criterion focusses on the quality of project design and preparation. Were project stakeholders[79] adequately identified and were they sufficiently involved in project development and ground truthing e.g. of proposed timeframe and budget? Were the projects' objectives and components clear, practicable and feasible within its timeframe? Are potentially negative environmental, economic and social impacts of the projects identified? 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

[79] 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.

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? What factors influenced the quality-at-entry of the project design, choice of partners, allocation of financial resources etc.? Were any design weaknesses mentioned in the Project Review Committee minutes at the time of project approval adequately addressed?

Project implementation and management. This includes an analysis of implementation approaches used by the project, its management framework, the project's adaptation to changing conditions and responses to changing risks including safeguard issues (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:

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

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

Assess the role and performance of the teams and working groups established and the project execution arrangements at all levels.

Assess the extent to which project management responded to direction and guidance provided by the UNEP Task Manager and project steering bodies including the NCCs.

Identify operational and political / institutional problems and constraints that influenced the effective implementation of the project, and how the project tried to overcome these problems.

Stakeholder participation, cooperation and partnerships. The Evaluation will assess the effectiveness of mechanisms for information sharing and cooperation with other UNEP projects and programmes, external stakeholders and partners. The term stakeholder should be considered in the broadest sense, encompassing both project partners and target users of project products. The TOC and stakeholder analysis should assist the evaluators in identifying the key stakeholders and their respective roles, capabilities and motivations in each step of the causal pathways from activities to achievement of outputs, outcomes and intermediate states towards impact. The assessment will look at three related and often overlapping processes: (1) information dissemination to and between stakeholders, (2) consultation with and between stakeholders, and (3) active engagement of stakeholders in project decision making and activities. The evaluation will specifically assess:

(a) the approach(es) and mechanisms used to identify and engage stakeholders (within and outside UNEP) in project design and at critical stages of project implementation. What were the strengths and weaknesses of these approaches with respect to the projects' objectives and the stakeholders' motivations and capacities?

(b) How was the overall collaboration between different functional units of UNEP involved in the project? What coordination mechanisms were in place? Were the incentives for internal collaboration in UNEP adequate?

(c) Was the level of involvement of the Regional, Liaison and Out-posted Offices in project design, planning, decision-making and implementation of activities appropriate?

(d) Has the project made full use of opportunities for collaboration with other projects and programmes including opportunities not mentioned in the Project Document? Have complementarities been sought, synergies been optimized and duplications avoided?

(e) What was the achieved degree and effectiveness of collaboration and interactions between the various project partners and stakeholders during design and implementation of the project? This should be disaggregated for the main stakeholder groups identified in the inception report.

(f) To what extent has the project been able to take up opportunities for joint activities, pooling of resources and mutual learning with other organizations and networks? In particular, how useful are partnership mechanisms and initiatives to build stronger coherence and collaboration between participating organisations at regional level (first component)?

(g) How did the relationship between the projects and the collaborating partners (institutions and individual experts) develop? Which benefits stemmed from their involvement for project performance, for UNEP and for the stakeholders and partners themselves? Do the results of the projects (strategic programmes and plans, monitoring and management systems, sub-regional agreements etc.) promote participation of stakeholders, including users, in environmental decision making?

Communication and public awareness. The evaluation will assess the effectiveness of any public awareness activities that were undertaken during the course of implementation of the project to communicate the project's objective, progress, outcomes and lessons. Specifically, it will assess the extent to which MTR recommendations on this point were addressed and the extent to which follow up projects strengthened this component at design phase. This should be disaggregated for the main stakeholder groups identified in the inception report. Did the project identify and make us of existing communication channels and networks used by key stakeholders? Did the project provide feedback channels?

Country ownership and driven-ness. The evaluation will assess the degree and effectiveness of involvement of government / public sector agencies in the project, in particular those involved in project execution for each participating country:

(a) To what extent have Governments assumed responsibility for the projects and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project?

How and how well did the project stimulate country ownership of project outputs and outcomes?

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:

(a) 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;

(b) Assess 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 the extent to which co-financing has materialized as expected at project approval. 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 UNEP to prevent such irregularities in the future. Determine whether the measures taken were adequate.

Supervision, guidance and technical 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 evaluator should assess the effectiveness of supervision, guidance and technical support provided by the different supervising/supporting bodies including:

(a) The adequacy of project supervision plans, inputs and processes;

The realism and candour of project reporting and the emphasis given to outcome monitoring (results-based project management);

How well did the different guidance and backstopping bodies play their role and how well did the guidance and backstopping mechanisms work? What were the strengths in guidance and backstopping and what were the limiting factors?

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 assess 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:

(a) *M&E Design*. The evaluators should use the following questions to help assess the M&E design aspects:

Arrangements for monitoring: Did the project have a sound M&E plan to monitor results and track progress towards achieving project objectives? Have the responsibilities for M&E activities been clearly defined? Were the data sources and data collection instruments appropriate? Was the time frame for various M&E activities specified? Was the frequency of various monitoring activities specified and adequate?

How well was the project logical framework (original and possible updates) designed as a planning and monitoring instrument?

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? For instance, was there adequate baseline information on pre-existing accessible information on global and regional environmental status and trends, and on the costs and benefits of different policy options for the different target audiences? Was there sufficient information about the assessment capacity of collaborating institutions and experts etc. to determine their training and technical support needs?

To what extent did the project engage key stakeholders in the design and implementation of monitoring? Which stakeholders (from groups identified in the inception report) were involved? If any stakeholders were excluded, what was the reason for this? Was sufficient information collected on specific indicators to measure progress on HR and GE (including sex-disaggregated data)?

Did the project appropriately plan to monitor risks associated with Environmental Economic and Social Safeguards?

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;

PIR reports were prepared (the realism of the Task Manager's assessments will be reviewed)

Half-yearly Progress & Financial Reports were complete and accurate;

Risk monitoring (including safeguard issues) was regularly documented

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

The Consultants' Team

For this evaluation, the evaluation team will consist of two consultants. The consultants should have experience in project evaluation. A Master's degree or higher in the area of environmental sciences or a related field and at least 15 years' experience in environmental management, with a preference for specific expertise in the area of biosafety and

biodiversity is required for the team leader. Experience in evaluation and at least 8 years' experience in environmental management is required for the supporting consultant.

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 the contract) with the project's executing or implementing units.

Evaluation Deliverables and Review Procedures

The evaluation team will prepare an **inception report** (see Annex 2(a) of TORs for Inception Report outline) containing a thorough review of the project context, project design quality, a draft reconstructed Theory of Change of the project, the evaluation framework and a tentative evaluation schedule.

It is expected that a large portion of the desk review will be conducted during the inception phase. It will be important to acquire a good understanding of the project context, design and process at this stage. The review of design quality will cover the following aspects (see Annex 7 for the detailed project design assessment matrix):

Strategic relevance of the project
Preparation and readiness;
Financial planning;
M&E design;
Complementarity with UNEP strategies and programmes;
Sustainability considerations and measures planned to promote replication and up-scaling.

The inception report will present a draft, desk-based reconstructed Theory of Change of the project. It is vital to reconstruct the ToC *before* most of the data collection (review of progress reports, in-depth interviews, surveys etc.) is done, because the ToC will define which direct outcomes, drivers and assumptions of the project need to be assessed and measured – based on which indicators – to allow adequate data collection for the evaluation of project effectiveness, likelihood of impact and sustainability.

The inception report will also include a stakeholder analysis identifying key stakeholders, networks and channels of communication. This information should be gathered from the Project document and discussion with the project team. See annex 2 for template.

The evaluation framework will present in further detail the overall evaluation approach. It will specify for each evaluation question under the various criteria what the respective indicators and data sources will be. The evaluation framework should summarize the information available from project documentation against each of the main evaluation parameters. Any gaps in information should be identified and methods for additional data collection, verification and analysis should be specified. Evaluations/reviews of other large assessments can provide ideas about the most appropriate evaluation methods to be used.

Effective communication strategies help stakeholders understand the results and use the information for organisational learning and improvement. While the evaluation is expected to result in a comprehensive document, content is not always best shared in a long and detailed report; this is best presented in a synthesised form using any of a variety of creative and innovative methods. The evaluator is encouraged to make use of multimedia formats in the gathering of information eg. video, photos, sound recordings. Together with the full report, the evaluator will be expected to produce a 2-page summary of key findings and lessons.

The inception report will also present a tentative schedule for the overall evaluation process, including a draft programme for the country visit and tentative list of people/institutions to be interviewed.

The inception report will be submitted for review and approval by the Evaluation Office before the any further data collection and analysis is undertaken.

The main evaluation report should be brief (no longer than 40 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. To avoid repetitions in the report, the authors will use numbered paragraphs and make cross-references where possible. The report should contain a **compendium of lessons learned** about the biosafety portfolio of projects implemented by UNEP and **recommendations** on the way forward.

Review of the draft evaluation report. The evaluation team will submit a zero draft report to the UNEP EO and revise the draft following the comments and suggestions made by the EO. Once a draft of adequate quality has been accepted, the EO will share this first draft report with the Task Manager, who will alert the EO in case the report would contain any blatant factual errors. The Evaluation Office will then forward the first draft report to the other project stakeholders for their review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. It is also very important that stakeholders provide feedback on the proposed recommendations and lessons. 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 evaluation team for consideration in preparing the final draft report, along with its own views.

The evaluation team will submit the final draft report no later than 2 weeks after reception of stakeholder comments. The team will prepare a **response to comments**, listing those comments not or only partially accepted by them that could therefore not or only partially be accommodated in the final report. They will explain why those comments have not or only partially been accepted, providing evidence as required. This response to comments will be shared by the EO with the interested stakeholders to ensure full transparency.

Submission of the final evaluation report. The final report shall be submitted by Email to the Head of the Evaluation Office. The Evaluation Office will finalize the report and share it with the interested Divisions and Sub-programme Coordinators in UNEP. The final evaluation report will be published on the UNEP Evaluation Office web-site www.unep.org/eou.

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 the criteria specified in Annex 3.

The UNEP Evaluation Office will assess the ratings in the final evaluation report based on a careful review of the evidence collated by the evaluation consultants and the internal consistency of the report. Where there are differences of opinion between the evaluator and UNEP Evaluation Office on project ratings, both viewpoints will be clearly presented in the final report. The UNEP Evaluation Office ratings will be considered the final ratings for the project.

At the end of the evaluation process, the Evaluation Office will prepare a Recommendations Implementation Plan in the format of a table to be completed and updated at regular intervals by the Task Manager. After reception of the Recommendations Implementation Plan, the Task Manager is expected to complete it and return it to the EO within one month. (S)he is expected to update the plan every six month until the end of the tracking period. As this is a Terminal Evaluation, the tracking period for implementation of recommendations will be 18 months, unless it is agreed to make this period shorter or longer as required for realistic implementation of all evaluation recommendations. Tracking points will be every six months after completion of the implementation plan.

Logistical arrangements

This Terminal Evaluation will be undertaken by two independent evaluation consultants contracted by the UNEP Evaluation Office. The consultants will work under the overall responsibility of the UNEP Evaluation Office and 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, visa, obtain documentary evidence, plan meetings with stakeholders, organize online surveys, and any other logistical matters related to the assignment. The UNEP Task Manager and project team will, where possible, provide logistical support (introductions, meetings etc.) allowing the consultants to conduct the evaluation as efficiently and independently as possible.

Schedule of the evaluation

Table 7 below presents the tentative schedule for the evaluation.

Table 7. Tentative schedule for the evaluation

Milestone	Deadline

Inception Report	15 November
Evaluation Missions	15 December
Telephone interviews, surveys etc.	15 December
Zero draft report	10 January
Draft Report shared with UNEP Task Manager	17 January
Draft Report shared with stakeholders	30 January
Final Report	28 February

Annex 3. List of people met

UNEP Nairobi Office:

- Ms Elisa Calcaterra – Evaluation Officer – EO
- Mr Michael Spilsbury – Director EO
- Mr Johan Robinson – Chief Biodiversity Unit (DEPI)
- Mr Alex Owusu-Biney – Biosafety TM Biodiversity Unit
- Ms Lydia Eibl-Kamolleh – former Biosafety FMO
- Mr Paul Vrontamitis – FMO
- Ms Cristina Zucca – Sub-Programme Coordinator – Env. Governance
- Mr. Niklas Hagelberg - Sub-Programme Coordinator – Ecosystems Management
- Ms Ileana C. Lopez – Project Manager – DELC
- Mr Naysan Sahba – DEPI
- Mr Chris Briggs – Former Project Manager (Geneva / Skype meeting)

UNEP Panama Office

- Ms Marianela Araya – Biosafety / ABS TM

Kenya

- Mr Willy K. Tonui, Chief Ex. Officer of the National Biosafety Authority; wtonui@biosafetykenya.go.ke
- Mr Dorington Ogoyi, Director, National Biosafety Authority; dogoyi@biosafetykenya.go.ke

Panama

- Mr Dario Luque, Env. Agency of the Min.of Environment, CPB Focal Point; dluque@miambiente.gob.pa
- Mr Israel Tejada, Env. Agency of the Min.of Environment, current focal point for the NBF Impl. Project itejada@miambiente.gob.pa
- Ms. V. Villavicencio, Technical Officer of AUPSA (Panama Authority for Food Safety); lbenavides@aupsa.gob.pa

Honduras

- Mr. Carlos Almendares, Chief of Seeds Certification Department, National Service of Animal and Plant Health (SENASA), Min. of Agriculture (MIDA), also CPB Focal Point; (calmendares81@yahoo.com)
- Mr. José Lenin O'Connor, Technical Officer of the External Cooperation of the Min. of Environment, responsible for Biosafety issues. cooperacionexterna@miambiente.gob.hn
- Ms. Carolina Alduin, National University of Honduras, member of the National Biosafety Commission (NBC); carolinalduvin46@gmail.com
- Mr. Rafael Amaro, Director of the Biodiversity Department (DiBio) of the Min. of Environment; rafaelamarog@gmail.com
- Ms. Carolina Ponce, Technical Officer of the DiBio. cponce@miambiente.gob.hn

Myanmar

- Dr. Ye Tint Htun BCH Focal Point Director General, Department of Agricultural Research, Ministry of Agriculture and Irrigation; yesst842003@gmail.com, dgdar.moai@gmail.com
- Mr. Hla Maung Thein, GEF Focal Point, Deputy Director General, Environmental Conservation Department, Ministry of Environment, Conservation and Forestry, hlamaungthein.env@gmail.com
- Ms. Kyi Kyi Thet, Deputy Director, Department of Agricultural Research, Ministry of Agriculture and Irrigation, kktstar@gmail.com
- Dr. Ohm Mar Saw, Research Officer, Department of Agricultural Research, Ministry of Agriculture and Irrigation, ohmmar96@gmail.com
- Dr. Min San Thein, Research Officer, Myanmar Seed Bank, Department of Agricultural Research, Ministry of Agriculture and Irrigation, minsanthein@gmail.com
- Dr. NweNwe Yin, Director, Biotechnology Division, Department of Agricultural Research, Ministry of Agriculture and Irrigation, nnyin86@gmail.com
- U Tin Aung Shein, Deputy Director, Department of Planning, Ministry of Agriculture and Irrigation
- Ms. Khin Mar Oo, Deputy Director, Department of Planning, Ministry of Agriculture and Irrigation;, khinmaroo@gmail.com
- Ms. Naw Jenny Loo, Deputy Director, Project Planning, Management and Evaluation Division, Ministry of Agriculture and Irrigation; nawjennyloo@gmail.co
- Aung Myat San, Staff Officer, Environmental Conservation Department, Ministry of Environment, Conservation and Forestry; aungmyatsan@gmail.com

Senegal

- Mr Osseynou Kasse, Exec. Director of the National Biosafety Authority (Min. of Environment and Sust. Dev., MEDD); ouzin12@gmail.com;
- Mr Lamine Kane, CPB Focal Point, Direction of National Parks, MEDD; kanelamine@hotmail.com; kanelamine1969@gmail.com
- Mr Souleyman Diallo, Director of the Minister cabinet, MEDD; souldiallo@yahoo.fr
- Ms. Ramatoulaye D. Ndiaye, General Secretary of the MEDD; ramatoulaye.ndiaye@environnement.gouv.sn
- Mr Abdul A. Mbaye, Member of the NBC, Association of "Traditional Communicators"
- Mr Momah Cisse, member of the NBC, repr. ASCOSEN (Consumers Associations of Senegal)
- Mr Mory Traoré, Professor at the University of Dakar, Faculty of Law Sciences; moryuu@yahooo.fr
- Ms Mame O. Sy, Professor at the University of Dakar, Faculty of Sciences, Lab. of Molecular Biology; oureye.sy@ucad.edu.sn

Cape Verde

- Mr Iderlindo Santos, CPB Foc. Point, Director of Env. Quality, Min. of Environment, Housing and Land Management; iderlindo.santos@mahot.gov.cv
- Mr Jorge Brito, Researcher at INIDA (Nat. Institute of Research for Agr. Development); jbrito@inida.gov.cv

Annex 4. Bibliography

1) Evaluation principles and guidelines

- ROtI - Review of Outcomes to Impact: Practitioners Handbook, 2009, GEF
- UNEP Programme Manual, May 2013
- Lessons Learned from Evaluation, a platform for sharing knowledge, UNEP, 2007
- Integrating Human Rights and Gender Equality in Evaluations, UNEG, 2014

2) GEF-UNEP overall strategies and programmes

- UNEP and GEF-3 and GEF-4 policies, strategies and programmes pertaining to biosafety at the time of the project's approval, including Biennial Programme and Support Budget 2000-2001, 2002-2003, 2004-2005 and 2006-2007;
- GEF Revised Strategy for Financing Biosafety, 2006
- Biodiversity Strategy for GEF 5;
- GEF-6 Programming Directions (Extract from GEF Assembly Document GEF/A.5/07/Rev.01, May 22, 2014);
- UNEP Programme of Work (PoW) 2008-09, 2010-11, 2012-13, 2014-15;
- UNEP MTS 2010-2013 and 2014-2017;
- Formative Evaluation of UNEP's Programme of Work 2010-2011, UNEP EO 2011;
- Mid-Term Evaluation of UNEP's Medium-term Strategy 2010 – 2013, UNEP EO, 2013;
- The GEF Biodiversity, Land Degradation and Biosafety (BDLD) Unit, draft DEPI;
- Bali Strategic Plan for Technology Support and Capacity-building (Note by the Executive Director), 2004.

3) CBD Secretariat and COP-MOP documents

- Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020, CBD Secretariat (BS-V/16, Annex I) http://bch.cbd.int/protocol/issues/cpb_stplan.shtml;
- Summary of the Sixth Meeting of the Parties to the Cartagena Protocol on Biosafety (COP- MOP 6), 2012, http://www.iisd.ca/vol09/enb09585e.html;
- Documents from the Seventh Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7), 2014, https://www.cbd.int/mop7/doc/.
- Second National Report on the Implementation of the Cartagena Protocol on Biosafety, CBD Secretariat, 2011, https://bch.cbd.int/database/reports/results/?searchid=640313
- Third National Report on the Implementation of the Cartagena Protocol on Biosafety, CBD Secretariat (of the 37 sample countries, when available), 2016; https://bch.cbd.int/database/reports/results
- Review of the information gathered through a dedicated survey and corresponding to indicators in the strategic plan, CBD executive secretary, 2014, https://bch.cbd.int/database/reports/surveyonindicators.shtml;
- "Expert review of the effectiveness of various approaches to biosafety capacity-building: identifying best practices and lessons learned", CBD Secretariat, 2010;
- BS-VII/2, Operation and Activities of the Biosafety Clearing-House (COP-MOP 7, 2014)

3) GEF-UNEP Biosafety Programme

- Initial strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety (GEF/C.16/4/Rev.1 0, November 2000);

- Indicative framework for capacity-building under the Cartagena Protocol on Biosafety (Note by the Executive Secretary, UNEP/CBD/ICCP/, October 2000);
- Building Capacity for the Implementation of Cartagena Protocol on Biosafety (brochure), UNEP/GEF, 2002
- Building Biosafety Capacity in Developing Countries – Experiences of the UNEP-GEF Project on Development of National Biosafety Frameworks, UNEP, 2005;
- A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects, UNEP-GEF Biosafety Unit, December 2006;
- Building Biosafety Capacity: The Role of UNEP and the Biosafety Unit, 2006;
- Guidance towards implementation of National Biosafety Frameworks: Lessons learned from the UNEP demonstration projects, GEF-UNEP 2008;
- Learning from Experience: the Global UNEP-GEF BCH Capacity Building Project, GEF-UNEP 2008.

4) NBF Development and Implementation Projects

- ProDoc "Development of National Biosafety Frameworks" (Global Project and Model of the National Sub-Project Document) ;
- Logical Framework, Annual Work Plans and Budgets of the Global project;
- Budget Revisions (13) posted in ANUBIS;
- Main information posted in ANUBIS on the National Sub-Projects (37 sample countries) and on the Global (Umbrella) Project, including Project Steering Committee minutes and Business Plans;
- Drafts National Biosafety Frameworks (NBF) produced by the 37 sample countries;
- Methodological Toolkits (4) produced by UNEP Biosafety Unit;
- Proceedings and reports of the Regional and Sub-regional Workshops;
- UNEP/GEF Biosafety Newsletters (7) produced in the framework of the Project;
- Project Newsletters and relevant information posted in http://www.unep.org/biosafety/Default.aspx and in the "old" Biosafety website http://www.unep.ch/biosafety/old_site/index.htm;

5) Relevant evaluative evidence

- Mid-Term Evaluation report (Development of National Biosafety Frameworks, Mid-Term Evaluation of a Global Initiative, 2003);
- Evaluation on GEF's Support to the Cartagena Protocol on Biosafety (GEF Office of Monitoring and Evaluation), 2005;
- Terminal Evaluation of the Pilot Biosafety Enabling Activity in 18 countries (2000);
- Terminal Evaluation of the NBF Implementation-Demonstration Projects (2012, 15 countries);
- Terminal Evaluation of the NBF Implementation Projects evaluated so far (Albania, Bhutan, Costa Rica, Egypt, Guatemala, Lao PDR, Macedonia, Mauritius, Mongolia, Tanzania, Tunisia and MTE of the Caribbean Sub-regional Project);
- Terminal Evaluation of project "Building Capacity for Participation in the Biosafety Clearing-House (BCH)" - Phase I. 2009
- UNEP-GEF Toolkits Evaluation: Stakeholder Review. ATHENA Institute for Research on Communication and Innovation in Health and Life Sciences, Faculty of Earth & Life Sciences, Amsterdam, 2005;

6) Support and Resource Documents

- World Bank Atlas classification http://data.worldbank.org/about/country-and-lending-groups#Low_income
- UN classification http://www.un.org/en/development/desa/policy/cdp/ldc_info.shtml

- Regulation of Biotechnology: needs and burdens for developing Countries, J. Kinderlerer, University of Sheffield, http://www.unep.org/biosafety/Documents/BTregulationJK.pdf
- Mainstreaming Gender Sensitivity in Cash Crop Market Supply Chains, FAO, 2011;
- Value chain analysis with a Gender Focus, ICRISAT / CGIAR, 2014;
- GM Agricultural Technologies for Africa: a State of Affairs, African Development Bank (ADB), International Food Policy Research Institute (IFPRI), 2014;
- http://foreignpolicyblogs.com/2013/02/19/competing-rights-the-gmo-debate/
- http://www.isaaa.org/resources/publications/pocketk/16/
- Iniciativa Centroamericana De Biotecnología y Bioseguridad (ICABB), IICA, 2013;
- An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN, 2003;
- Genetically Modified Organisms and Biosafety: A background paper for decision-makers and others to assist in consideration of GMO issues, IUCN – The World Conservation Union, 2004;
- Public Participation and the Cartagena Protocol on Biosafety, a review for DfID and UNEP-GEF;
- Biosafety Regulations of Asia-Pacific Countries, Asia-Pacific Association of Agricultural Research Institutions, Asia-Pacific Consortium on Agricultural Biotechnology, FAO;
- Biosafety of Genetically Modified Organisms: Basic concepts, methods and issues, FAO, 2008
- The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture, FAO, 2010;
- Biosafety Resource Book, module E, Legal Aspects, FAO, 2011;
- Narrative report of the Technical Consultation on low levels of GM crops in international food and feed trade, FAO, 2014;
- Comparative Analysis of the National Biosafety Regulatory Systems in East Africa, IFPRI, 2006
- Africa Agriculture Status Report – Focus on Staple Crops, AGRA, 2013;
- Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?, AgBio Forum;
- Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?, UNU-IAS, 2008
- The Regulation of Genetically Modified Organisms in Latin America: Policy Implications for Trade, Biosafety, and Development, Katovich, 2012
- Biosafety of Genetically Modified Organisms in the Latin American and the Caribbean Region: Main Needs and Opportunities for Strategic Capacity Building, AgBioForum (Araya, Graig, Ripandelli), 2012;
- The GM Cold War: how Developing Countries can go from being dominos to being players, Meijer and Stewart, 2004.

Annex 5. Project costs and co-financing tables

Project Costs (GEF allocation) USD

Component	Estimated cost at design	Actual Cost	Expenditure ratio (actual/planned)
Global and regional component (Umbrella Project))	**4.792.083**	**16.902.591**	**350%**
123 National Projects	**21.300.000 (1st GEF all.)** **5.218.420 (2nd GEF all.)** **2.609.208 (3rd GEF all.)** **Sub Tot. GEF 29.127.628**	**16.892.118**	**58%**
Total	**33.919.711**	**33.794.709**	**99.7%**

Co-financing

Co financing (Type/Source)	UNEP own Financing and Government contribution (US$1,000)		Other* (US$1,000)		Total (US$1,000)		Total Disbursed (US$1,000)
	Planned	Actual	Planned	Actual	Planned	Actual	
– In-kind support	**12.341**	**12.961**					
– Loans							
– Credits							
– Equity investments							
– Other grants(*)				**202** (DFID / Sweden)			
Totals	**12.341**	**12.961**		**202**	**12.341**	**13.163**	**13.163**

* This refers to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

Annex 6. Brief CV of the consultants

CV profile of the Supporting Consultant (Julia Niggebrugge)

Education

- Master's Degree in Peace and Security Studies, University of Hamburg (2005).
- Master's Degree in Philology (major), Applied Cultural Studies, and Political Science (minors), Wilhelms University Muenster, Germany, and Arizona State University, Tempe, USA (2003).
- Post Graduate Certificate in Strategic Sustainable Development, Blekinge Institute of Technology, Karlskrona, Sweden (2010)
- Certified Prince2 Practitioner

Area of expertise

Includes Programme Management, Project Planning, Development and Evaluation, Organizational and Institutional Capacity Assessments, Enterprise Risk Management, Sustainable Development, Quality Assurance/ Internal Controls, and Partnership Management.

Professional experience

Julia (USA, 1977) has worked as an Evaluator, Programme Specialist, and as independent Consultant for different UN agencies (IFAD, UNICEF, UNOPS, UNDP, UNEP), Embassies, Local and International NGOs in Myanmar, Kenya, Egypt, Somalia, Denmark, Chile, New York/ USA, Nicaragua, Russia, New Zealand and her home country Germany. With more than 10 years of professional experience in results-based programme and operations management in international organizations across the world, Julia has a solid practical background in project planning, development, implementation, M&E and quality assurance in emergency and development settings.

Employment

2013-Present:	Independent Consultant in Myanmar (Evaluations/ Project Development/ Capacity Assessments in the areas of Conservation, Disaster Risk Reduction, Education, and Rural Development)
2010-2013:	UNICEF (Nairobi, Kenya), Quality Assurance Specialist
2008-2010:	UNEP (Nairobi, Kenya), Evaluation Officer
2007-2008:	UNDP (Cairo, Egypt), Operations Manager
2005-2008:	UNOPS (New York, USA and Copenhagen, Denmark), Associate Portfolio Manager

CV profile Camillo Risoli (Team Leader)

Camillo Risoli (Italy, 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, a solid background in PCM (Programme Cycle Management) and strong skills in Project Monitoring & Evaluation (M&E).

Since 2005, he 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), the Biosafety National Frameworks .Evaluation (UNEP-GEF) in Kenya, Namibia, Poland, Lithuania, Czech Republic, Slovakia, Mongolia, Bhutan, Lao PDR, Albania, Macedonia and Egypt, the terminal evaluation of the FAO Programme of Food Security through Commercialization in West Africa (Gambia, Guinea, Liberia, Senegal, Sierra Leone), the Evaluation of FAO's Decentralization in Latin America & the Caribbean.

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 7. Typology of Biosafety Projects and table of available evaluative evidence

1) UNEP-GEF Biosafety Frameworks Projects

The **Pilot Biosafety Enabling Activity Project:** approved by the GEF Council in November 1997. The project aimed to set up National Biosafety Frameworks **in 18 pilot countries** and develop systems for cross boundary movement of living modified organisms.

The Project **"Development of National Biosafety Framework (NBF)"** (main object of this TE): started in 2001 and included 123 countries that were supported to produce their national biosafety framework (draft). The Project included a Global Project (Umbrella Project) with a regional and a global support component, and 123 national sub-projects.

The **"Demonstration Projects on the Implementation of the National Biosafety Framework**": 12 Projects (eight of which implemented by UNEP) to support selected "demonstration" countries to implement the NBF, hence having it operational by the end of the 3-year project period (all concluded and evaluated).

The Projects **"Implementation of the National Biosafety Framework"** (NBF Implementation Projects)**:** they represent the follow-up of the 123 "Projects of Development of the NBF" and support a large number of countries to implement their NBF (so far some 50 countries). Some of them have been concluded and evaluated (see table below)

2) Available evaluative evidence

Countries visited at MTR stage	Demonstration (D) and implementation (I) projects (2012)	Evaluation of follow up (implementation) project completed	Evaluation of follow up individual project planned
• Antigua and Barbuda • Chile • Jordan • Moldova • Republic of Korea • Slovenia • Togo • United Republic of Tanzania	• Bulgaria (D) • Cameroon (D) • China (D) • Cuba (D) • Kenya (D) • Namibia (D) • Poland (D) • Uganda (D) • Cambodia (I) • Czech Republic (I) • Estonia (I) • Lithuania (I) • Moldova (I) • Slovak Republic (I) • Vietnam (I)	• Costa Rica (2014) • Caribbean (regional, MTE) (2014) • Tanzania (2014) • Mauritius (2014) • Tunisia (2014) • Bhutan (2014) • Lao PDR (2014) • Mongolia (2014) • Guatemala (2015) • Egypt (2015-16) • Macedonia (FYROM) (2015-16) Albania (2015-16)	Ecuador (2016) El Salvador (2016) Namibia (2016) Nigeria (2016) Liberia (2016)

Source: UNEP EO

Annex 8. Evaluation Criteria and Key-questions

Criteria	Key-questions
A) Relevance	1) To what extent has the Project been able to address National, Regional/Sub-regional and Global needs and priorities on Biosafety ?
	2) How relevant has been the Project to Sustainable Development priorities and programmes, particularly towards Developing Countries ?
	3) To what extent has the Project responded to different stakeholders' priorities and needs ?
B) Attainment of planned results, effectiveness and likelihood of impact	1) To what extent was the project able to assist countries in achieving Outcome 1 (Regional and Sub-regional collaboration and exchange promoted)?
	2) To what extent was the project able to assist countries in achieving Outcome 2 (One-hundred (100) National Biosafety Frameworks prepared)?
	3) To what extent was the project able to assist countries in achieving Outcome 3 (Increased access to information and capacity building)
	4) Did participating countries progress towards the effective implementation of the drafted NBF and the fulfilment of rights and obligations established in the Protocol?
C) Sustainability	1) To what extent does Biosafety agenda in the countries show socio-political sustainability and national ownership ? (Socio-political Sustainability)
	2) Is Biosafety institutional framework satisfactorily consolidated? (Institutional Sustainability
	3) To what extent do NCAs and relevant national stakeholders have regularly budgeted financial resources to implement their functions? (Financial Sustainability);
	4) Which are the major challenges as far as Environmental Sustainability is concerned?
D) Efficiency	1) To what extent has the Project been able to make an efficient use of the resources allocated (time, budget, human resources)?
	2) Have national stakeholders and relevant key-actors (including regional, sub-regional players and supporting agencies) been able to identify and implement mechanisms (agreements, synergies and complementarities) in order to share and/or reduce Biosafety investments and management costs?
E) Complementarity with the UNEP strategies and programmes	1) Has been the Project consistent with the UNEP mandate, policies and strategy at the time of its approval and execution?
	2) Is Biosafety currently adequately integrated into the current UNEP Programme of Work, including on-going Medium Term Strategy (2014-2017) and UNEP organogram?
F) Coordination and Partnership	1) To what extent has UNEP been able, through the Project, to establish partnerships with other cooperation programmes (UN and bilateral)?
	2) Is there any anecdotal evidence of UNEP playing a "neutral broker" role promoting "win-win" solutions in controversial cases on Biosafety issues?
G) Regional and Sub-regional collaboration and exchange	1) To what extent has UNEP been able to support and/or consolidate regional/sub-regional initiatives in the area of Biosafety? (see also first question on criterion B)
H) Capacity Building	1) To what extent has UNEP been able, through the Project, to match needs and priorities identified in main GEF-UNEP strategies and documents regarding Capacity Building?
	2) To what extent has UNEP been able to match national needs and priorities through specific, country (sub-region, region) tailored capacity building programmes?
	3) To what extent has UNEP established effective partnerships with International, Regional and National institutions to conceive and implement capacity Building programmes in Biosafety sector?

Annex 9. Summary / Findings of Country visits

PANAMA (country visit 15-16 and 19 February 2016)

The consultant has met:

- Mr Dario Luque, Env. Agency of the Min.of Environment, CPB Focal Point;
- Mr. Israel Tejada, Env. Agency of the Min.of Environment, current focal point for the NBF Implementation Project (approved by CEO, not yet started);
- Ms. V. Villavicencio, Technical Officer of AUPSA (Panama Authority for Food Safety)

Main issues discussed with the partners:

- **Current situation of the Legal and Institutional Framework**

The Law n.48 of 2002 (posted in the BCH) is still in force and no amendment or regulations have been so far implemented. The National Biosafety Commission (NBC) foreseen by the Law in place and includes all main national stakeholders under the coordination of the MoE. Customs Authorities, however, are not yet included.

Three Technical Committees are also in place, one for Agriculture, one for Health and one for Environment. They provide advises to the NBC.

- **Decisions and Authorizations**

So far, there is one on-going confined trial approved in 200o (Transgenic salmon), which is on-going in the northern highlands carried out by a foreign private company under the supervision of the MoA. A second authorization for GMO maize for feed has also been approved, but not yet implemented. Both decisions are posted in the BCH.

- **AUPSA (Panama Authority for Food Safety**) does not have any specific provision for FFP, yet they are currently discussing the setting of an internal working group on Biosafety.

- **The new Project** (BS Consolidation of National Capacities) approved by GEF (USD 954.927) years ago has suffered excessive delays in its commencement, due to several institutional problems, such as the indecision about its institutional anchorage, the change of Government (2014), protracted discussion with GEF and UNEP about the content of the PCA (the Government wanted to change some clauses), the setting of administrative and financial arrangements (responsibility of funds management, opening of the bank account, etc.). Currently, all main issues seem resolved and the Project should hopefully becoming operational in 2016.

- **Sub-regional issues**

A Sub-regional Project (Central America and Dominican Republic) was drafted some years ago, but has never moved forward. There has been reticence both on the side of the GEF and of some countries, which would have preferred national projects.

There has been, nevertheless, a sub-regional initiative, called ICABB (Centro American Initiative for Biotechnology and Biosafety), proposed in 2012 to the CAC (Centro America Agricultural Council) for the implementation of a sub-regional mechanisms to manage GMOs issues in a coordinate way, through the technical support of IICA (Inter-American Institute for Agricultural Cooperation).

HONDURAS (country visit the 18-19 February 2016)

The consultant has met :

- Mr. Carlos Almendares, Chief of Seeds Certification Department, National Service of Animal and Plant Health (SENASA), Min. of Agriculture (MIDA), also CPB Focal Point;
- Mr. José Lenin O'Connor, Technical Officer of the External Cooperation of the Min. of Environment, responsible for Biosafety issues.
- Ms. Carolina Alduin, National University of Honduras, member of the National Biosafety Commission (NBC);
- Mr. Rafael Amaro , Director of the Biodiversity Department (DiBio) of the Min. of Environment;
- Ms. Carolina Ponce, Technical Officer of the DiBio.

Main issues discussed with the partners:

- **Current Legal and Institutional Framework**
  Biosafety is still regulated through a Regulation of 1998 (posted in the BCH), which stems from the Phytosanitary Law and only regards Plants.
  There is a National Biodiversity Commission coordinated by the Min. of Environment (SERNA) which is supported by four Committees (Bioethics, Nat. Resources, Sust. Use of Biodiversity, Biosafety). The Biosafety Committee is composed by several institutions, among them the MoE, the MoA, the Min.of Health (less active so far), the National University of Honduras, the Zamorano Agricultural University (Escuela Agricola Panamericana) , the Council for Science & Technology, the National Council of Entrepreneurs (Private sector). At a certain point, Standard Fruit Co. was involved due to their expertise on Biotechnology.

- **Applications and Authorisations**
  The country has so far received five applications for environmental release, four of which have been approved (Maize) and one rejected (Soya). The entry-point for the application is the MoA through the SENASA and the application is evaluated by the Biosafety Committee. The Committee gives advise and recommendations.
  SENASA thoroughly evaluates the application, makes its own risk assessment (also posted in then BCH) and provides recommendations to the applicant. A follow up in the field is also granted by SENASA and other services of the MoA (MIDA).
  By the interviews, the process of decision-making is participatory, though the Min. of Environment believes that the Committee should be more inclusive and foster the supplementary participation of Small Farmers Committees, NGOs, Indigenous People Associations, Private Sector and more Academic institutions.

- **BCH**
  The BCH is well maintained and updated, ensuring satisfactory transparency. SENASA (MIDA) believes that the BCH should be maintained by the National University of Honduras (not by MIDA) to decentralise responsibilities and to ensure more continuity in case of change of Government.

- **Future challenges**
  There is a certain reluctance towards sub-regional and regional projects for fear of increased delays in project's preparation, approval and implementation and because of possible differences in vision and

approach among the countries. However, the country is open to sub-regional cooperation and participates in the ICABB (Centro American Initiative for Biotechnology and Biosafety).

Possible areas of cooperation, according the interviews, are Capacity Building, the production of technical manuals (possibly with the support of the IICA (Inter-American Institute for Agricultural Cooperation) and of information tools for different audiences (e.g. students, consumers, farmers, etc.).

Honduras did not apply for an NBF Implementation Project, since, according to the Min. of Env., GEF funds allocation is not sufficient to cover Biosafety without depriving other priority areas (e.g. Protected Areas) of sufficient funds.

Different visions and approaches have been observed between SENASA (MIDA) and the DiBio (Min. of Env.), which have been so far smoothly addressed. The Ministry of Environment is preparing a draft Law on Biodiversity and would like Biosafety being treated in a more comprehensive and structured way than it currently is (inserted in the PhytoSanitary Law of 1998). That would probably imply that the National Focal Point should be the Min. of Environment (already FP for the CBD), while the current CPB FP is SENASA (MIDA).

The release into the environment of the transgenic maize is not an uncontroversial issue. The Min. of Environment is currently working with more than 30 Rural Communities creating their own Seeds Bank of the local, traditional maize ("criollo") and would like to register the local varieties to be certified by SENASA and protected. Those communities are strongly against GMOs maize. This is an issue that may create possible conflicts in the future, to be appropriately addressed by the NBC.

MYANMAR (country visit 24-25.2.2016)

People met:

- Dr. Ye Tint Htun **BCH Focal Point** Director General, Department of Agricultural Research, Ministry of Agriculture and Irrigation; yesst842003@gmail.com, dgdar.moai@gmail.com, Phone: +95 67 416597, +9595302454

- Mr. Hla Maung Thein, **GEF Focal Point**, Deputy Director General, Environmental Conservation Department, Ministry of Environment, Conservation and Forestry, hlamaungthein.env@gmail.com, +9567431326

- Ms. Kyi Kyi Thet, Deputy Director, Department of Agricultural Research, Ministry of Agriculture and Irrigation, kktstar@gmail.com, +959448540485, +959787952488

- Dr. Ohm Mar Saw, Research Officer, Department of Agricultural Research, Ministry of Agriculture and Irrigation, ohmmar96@gmail.com, +959250805163

- Dr. Min San Thein, Research Officer, Myanmar Seed Bank, Department of Agricultural Research, Ministry of Agriculture and Irrigation, minsanthein@gmail.com, +95949208124

- Dr. NweNwe Yin, Director, Biotechnology Division, Department of Agricultural Research, Ministry of Agriculture and Irrigation, nnyin86@gmail.com, +9598303546

- U Tin Aung Shein, Deputy Director, Department of Planning, Ministry of Agriculture and Irrigation, +95973259188

- Ms. Khin Mar Oo, Deputy Director, Department of Planning, Ministry of Agriculture and Irrigation; +95933013392, khinmaroo@gmail.com

- Ms. Naw Jenny Loo, Deputy Director, Project Planning, Management and Evaluation Division, Ministry of Agriculture and Irrigation; nawjennyloo@gmail.co, +959420706988

- Aung Myat San, Staff Officer, Environmental Conservation Department, Ministry of Environment, Conservation and Forestry; aungmyatsan@gmail.com, +95 67 40 50 15

- There is no ownership for the NBF project or for biosafety in general. Ministries are and have been frequently renamed, closed, merged, split and restructured in Myanmar, which is why Biosafety as a field of work has been falling under different departments within different ministries in the past. De facto no one is working on biosafety.

- In 2015, Biosafety was moved from the Department of Conservation of the Ministry of Environment, Conservation and Forestry (MOECAF) to the Department for Agricultural Research of the Ministry of Agriculture and Irrigation. The DG of the latter would like to hand it back as he does not see sufficient capacity within his department, while the DG of the former thinks Biosafety is of little relevance to Environmental Conservation.

- All interviewees agreed that the NBF should be revised and that Biosafety should be made a priority, as there is a general concern about GMOs entering the country from China and India. The work on Biosafety, however, should start after March 2016 as the new government might yet again make changes to the ministries and their responsibilities.

- There was consensus about the major challenges for the NBF implementation, which are:

  - A lack of coordination - There is no NCA, and very little communication between Departments in general.

  - Low human resource capacity - Biosafety is not taught in University and not even the Biotechnology Division has staff that has had training or work experience with GMOs. So even with a good Biosafety framework was in place, enforcement and implementation would not be possible. All people interviewed expressed their interest for technical assistance and capacity building from UNEP and stated to know how to apply for follow-up projects; but again, no one was clear about whom within the government should take the lead on this.

  - The lack of a biosafety law or regulations - The NBF has been revised in 2009. This 3rd draft has never been submitted to UNEP of BCH. According to the interviewees it is a product of the military government that is not workable. There is also a draft Biosafety Law in English and Burmese that has never been submitted to Cabinet for approval. Expert support in the formulation of a biosafety law and the rewriting of the NBF is needed.

- There is no inspection board that could detect transboundary movement. Currently, there is a Seed Law that forbids the introduction of GM food or feed but allows GM non-food to be grown (GM cotton from India is grown in Myanmar).

- Myanmar is exporting to countries that are increasingly asking for GM labeling of Myanmar export products, which is why a laboratory under the MOAI has been established in Yangon to test for GMOs, using a GM test kit. Staff of the Department for Research admitted that this kit is not adequate/ fit for purpose and the lab not prepared for the volume of work.

- The little outreach material that existed has disappeared. However, in 2011 a Biodiversity Strategy has been published with the support from UNEP and GEF that has marginal mentioning of GMOs. The pertaining Action Plan for 2015-2020 has one GMO related activity, but implementation has not started and currently no Department has been given the responsibility for it.

- The GEF Focal Point, the Deputy Director General of the Environmental Conservation Department has been in charge of the 2nd National Report and showed interest in producing the 3rd National Report. He had sent a letter of commitment to UNEP HQ but the following signing of the Agreement had fallen between the cracks.

- No interviewee had ever heard about the Biosafety Clearing House (BCH), not even the current BCH Focal Point (the Director General of the Department of Agricultural Research).

- There is no exchange or cooperation with other countries in the region on Biosafety.

- The UNEP Regional Office has not been involved in the NBF project. The RO is in contact with the MOECAF concerning other activities and has been visiting recently. Apparently working relations are good.

- No one that has been involved in the project is still working in the respective ministries. It was not possible to get answers on the project efficiency and expenditure.

SENEGAL (country visit 24-25-26 / 02/ 2016)

The consultant has met:

- Mr Osseynou Kasse, Exec. Director of the National Biosafety Authority (Min. of Environment and Sust. Dev., MEDD),
- Mr Lamine Kane, CPB Focal Point, MEDD
- Mr Souleyman Diallo, Director of the Minister cabinet, MEDD
- Ms. Ramatoulaye D. Ndiaye, General Secretary of the MEDD
- Mr Abdul A. Mbaye, Member of the NBC, Association of "Traditional Communicators"
- Mr Momah Cisse, member of the NBC, repr. ASCOSEN (Consumers Associations of Senegal)
- Mr M. Traoré, Professor at the University of Dakar, Faculty of Law Sciences
- Ms Mame O. Sy, Professor at the University of Dakar, Faculty of Sciences, Lab. of Molecular Biology

Main issues discussed:

- **Legal and Institutional Framework**

After the formulation of the NBF (Biosafety Development Project) in 2005, the country has prepared and approved the National Biosafety Law in 2009. The National Biosafety Authority, also created in 2009, has effectively started working in 2014, with the nomination of a new Executive Director. It currently has administrative autonomy from the Min. of Environment and Sustainable Development (MEDD) and depends directly from the Cabinet of the Presidency of the Republic.

Various activities related to Biosafety have been resumed and increased in the last few years and the national Biosafety Committee (a consultative body that gives technical advice to the Authority) has also been revitalised. It has a large membership (around 30 people), with a majority of Public Institutions related to different Ministries, five representatives of the Academic and Research Institutions and five NGOs (Consumers Ass., Farmers Ass., environmental NGOs, Traditional Communicators). The Committee held four meetings from 2014 up to date, to discuss the revision of the Law and other issues related to the reorientation of Biosafety agenda in the country.

The Authority has started working on a Law revision for three main reasons: a) to include Nagoya-Kuala Lumpur issues in the Law; b) To allow for the use of Biotechnologies in the country (the current law does not permit it); c) to take into account the sub-regional dimension of Biosafety within the UEMOA (Economic and Monetary Union of West Africa Countries, which use the same currency).

Eight Decrees and Decisions (Secondary Legislation) have also been prepared to complement and implement the Law under revision. That has been done through the financial support of NEPAD (the New Partnership for Africa Development, promoted by the African Union)

- **Outreach Activities**

Senegal is attributing great importance to the work with Civil Society and a team of “Traditional communicators” is used to inform and discuss with local communities issues related with the sustainable use of Biodiversity, including Biosafety, and Nature and Ecosystems Conservation. The Biosafety Law is being translated into national languages.

Two workshops have been organised for the members of the Parliament, with the support of USDA (US Department of Agriculture) in order to supply Biosafety and Biotechnology information both in French and in National languages.

Two workshops have been also organised for Journalists and the Media with the same purpose as above.

- **Regional and African initiatives**

The countries and the regional institutions of West Africa Region have been pretty active on Biosafety, since the joint Bamako Declaration of 2006 that underscored the relevance of Biotechnology for Food Security, the need for strengthening national capacities and, more specifically, the need for training and outreach activities for a technically sound public information.

The CILSS (Inter-Governmental Commission for Fighting Drought in the Sahel), the ECOWAS (Economic Organization of West Africa States, CEDEAO in French) and, more recently and effectively, the UEMOA (the Economic and Monetary Union of West African Countries, actually eight French speaking countries using

the same currency) have been proactive in producing position papers, several documents and supporting joint initiatives.

UEMOA has been the regional Executing Agency of a regional GEF/World Bank Project that has given momentum to the Biosafety agenda in the Region and was finalised in 2012. Burkina Faso and Senegal (Ivory Coast to a lesser extent) are particularly active in this context. As already mentioned, the African Union initiative NEPAD (the New Partnership for Africa Development) has also supported Senegal in improving its Biosafety legal framework.

- **Challenges**

Budget restrictions are a worrying issue for the National Authority, limiting the scope of the activities, particularly specialists' training and outreach activities with the rural communities and the public in general. This is currently a strong challenge for the implementation of Biosafety agenda in the country.

There are strong concerns about the transparent and equitable repartition of the GEF funds in the Country and the need for a clear "window" for financing of Biosafety (earmarked funds) has been raised by several actors, including the CPB Focal Point and the General Secretary of the MEDD (see following bullet).

Same concerns have been raised by the Responsible of the Molecular Biology Laboratory at the faculty of Sciences of the Dakar University (UNAD) that has been established through the UEMOA/GEF/WB Project but does not have funds to recruit Lab Technicians and to assure the maintenance and functioning of the equipment.

To convey objective and technically sound messages to the public is another strong challenge, taking into account the existence of a part of Civil Society strongly adverse to the introduction of GMOs in the country. However, according to the opinions of the Biosafety Authority, "the taboo has been removed".

The Faculty of Law Sciences (UNAD) have put in place two relevant Master Degree courses, which are raising a large interest among the students, one in Environmental Law and one specifically on Biosafety. The reinforcement of these courses looks crucial for the sound development of Biotechnologies and Biosafety in the country, but the funds for outreach activities, needed to ensure a suitable mix between theoretic and practical activities, are highly insufficient.

- **Meeting with the General Secretary of the MEDD**

Ms. Ndiaye, General Secretary of the Min. of Environment and Sustainable Development (MEDD) has focussed on five main points:

a) The fact that Senegal has created a specific National Biosafety Authority that is exclusively addressing Biotechnology and Biosafety issues;
b) The need of a harmonised approach and improved coordination between CPB Parties (Senegal is an active player at Sub-regional on Biosafety);
c) Gender: there is a strong recommendation to implement a gender approach in GEF/UNEP projects, particularly in Biosafety sector. In the case of Senegal, women are the majority of heads of family, particularly in the rural areas. They are the main key-player as far as Food Security and Food Safety are

concerned and that has to be taken into account when addressing messages regarding Biosafety and involving Civil Society in the decision-making on the Biosafety agenda;
d) There is a strong concern regarding the financial support to Biosafety initiatives in the country. Though the Government ensures the functioning of the Biosafety Authority, there is an impellent need for external financial sources to implement the Biosafety agenda in the country at a suitable level. The General Secretary considers that the funds of GEF 4-5-6 have been too limited for running Biodiversity programmes in Senegal and particularly Biosafety. There is a strong recommendation to clearly "open a window" exclusively for Biosafety within GEF Funds (the country would support this orientation at the next COP-MOP);
e) The country is willing to actively work on Biotechnologies and consequently needs solid national capacities in Biosafety sector. External support is particularly needed to improve the Academic Sector and the National Research Centers.

CAPE VERDE (country visit 2-4/03/2016)

The consultant has met:

- Mr Iderlindo Santos, CPB Foc.Point, Director of Env. Quality, Min. of Environment, Housing and Land Management; iderlindo.santos@mahot.gov.cv
- Mr Jorge Brito, Researcher at INIDA (Nat. Institute of Research for Agr. Development); jbrito@inida.gov.cv
- Mr A. Fortes – Professor at UNI.CV (University of Cape Verde, Agric. and Env. Sciences)

Main findings

- Biosafety gained momentum in Cape Verde during the NBF Development Project that was finalised in 2007 and the participation to the first BCH Project. Several activities of public information were carried out, including three national workshops in the islands of Santiago, S. Vicente and Fogo with a very high number of participants from Min, of Agr. and Environment, Min. of Health, Min.of Education, National Institutes and Agencies related to Agricultural Research and to the Regulation of Food and Drugs.
- A thorough analysis of the national legislation with possible implications with GMOs was carried out and a first Draft of a National Law was also prepared.
- There has been afterward an institutional change that has brought about the creation of the Min. of Environment, Housing and Land Management (separated from Agriculture). The Min. of Environment has subsequently become the new National Competent Authority.
- The country participates to the COP-MOP (also through fund-raising activities in order to enable a more consistent participation) and keeps on its interest on Biosafety, taking into account that Cape Verde is importing a great part of food and feed and has the potential to develop high-tech horticulture through the on-going Hydroponic Agriculture Programme sponsored by WB.
- The country has presented in 2011 its 2nd National Report that put in evidence the main needs: a national legal framework, capacity building, institutional articulation. Nevertheless, the follow-up of the activities triggered years ago has been sporadic, mainly due to the lack of financial and human resources dedicated to Biosafety.
- GEF is currently supporting the country with actions in the area of Climatic Change Adaptation and of Protected Areas (integration with Eco-tourism). Cape Verde is participating in a Regional UNEP Project regarding the efficient use of drainage water.

○

Annex 10. The sample of 37 countries: criteria and selected countries

The sample of countries was selected according to the **following criteria**:

- The sample covers 30% of the 123 countries participating in the NBF Development project Project;
- Countries for which there is already evaluative evidence have been excluded from the sample, such as the 26 countries that had a Terminal Evaluation of NBF Implementation Projects from 2012 to 2015, the 12 countries of Caribbean Sub-region that had a Mid-term Evaluation in 2014, and the 5 countries that will have a Terminal Evaluation in 2016. For these countries, the Evaluation reports are separately analysed and used as a source of information for the current Report;
- Countries where UNEP is GEF Implementing Agency (excluding countries where WB is the Implementing Agency);
- Countries with GMOs development on-going, neighbouring to GMOs countries or within sub-regions where GMOs are likely to expand, then more in need of a transparent and effective regulatory/administrative/management Biosafety systems;
- Countries more likely to be exposed to GMOs development due to their good agricultural potential and to their market potential;
- Countries within areas of genetic resources origin.

The sample reflects approximately the repartition of the 123 countries by Region, as follows:

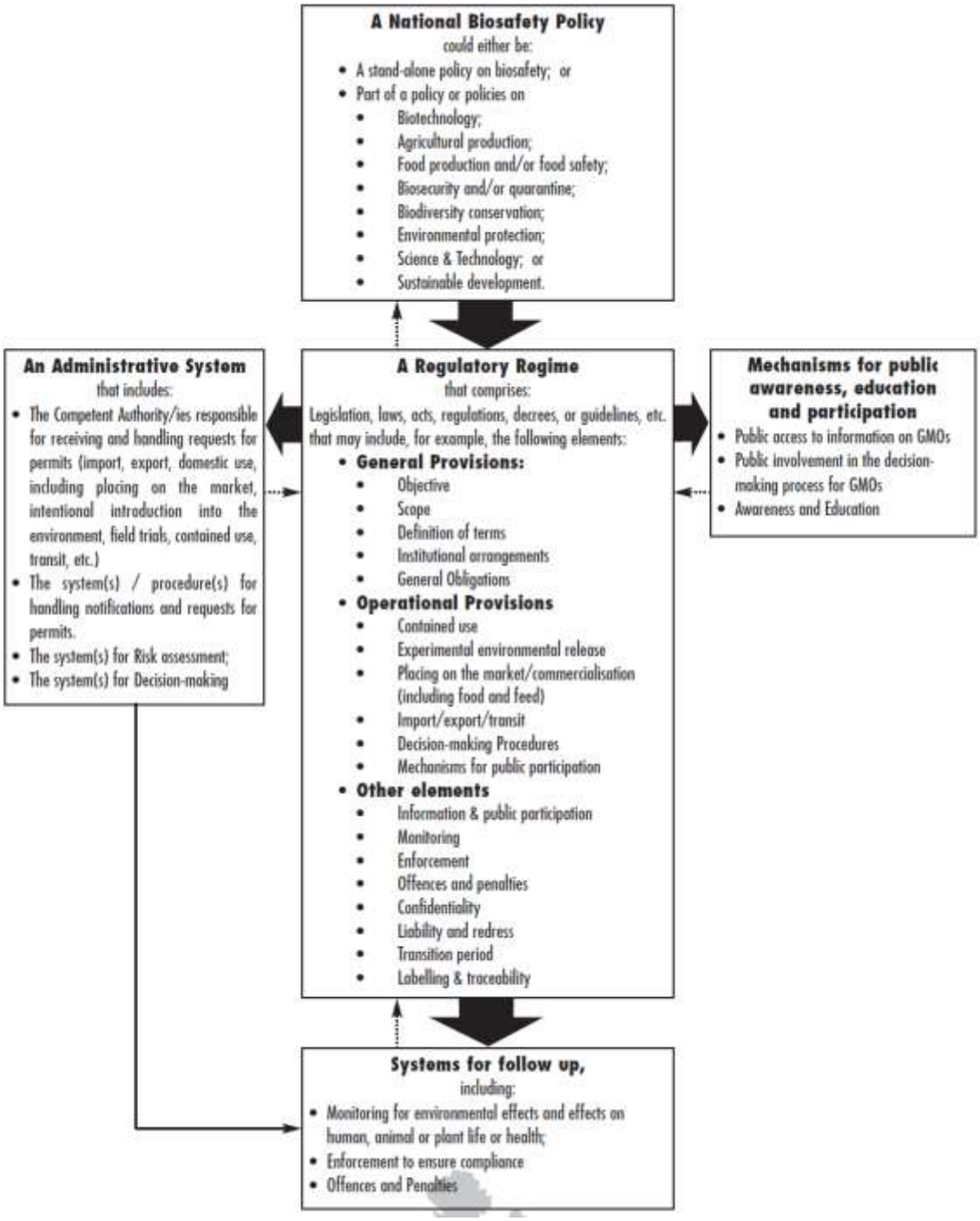
- Africa: 12 countries (31% of African countries participating in the Project)
- Asia / Pacific: 12 countries (33% of Asian countries participating in the Project)
- GRULAC (Latin America and Caribbean): 8 countries (29% of GRULAC countries participating in the Project)
- CEE (Central & Eastern Europe): 5 countries (28% of CEE countries participating in the Project).

Countries eventually selected are the following:

1) Region Africa (12): Botswana, Chad, Dem. Rep. Congo, Ethiopia, Ghana, Madagascar, Morocco, Mozambique, Niger, Rwanda, Sudan and Zimbabwe.
2) Asia / Pacific (12): Bangladesh, Dem. P. Rep. Korea, Fiji, Indonesia, Iran, Kyrgyzstan, Myanmar, Nepal, Papua-New Guinea, Philippines, Thailand and Vanuatu.
3) Latin America & The Caribbean (8): Dominican Republic, Honduras, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela.
4) Central and Eastern Europe (5): Armenia, Belarus, Georgia, Romania and Ukraine.

Annex 11. NBF Model (diagram)

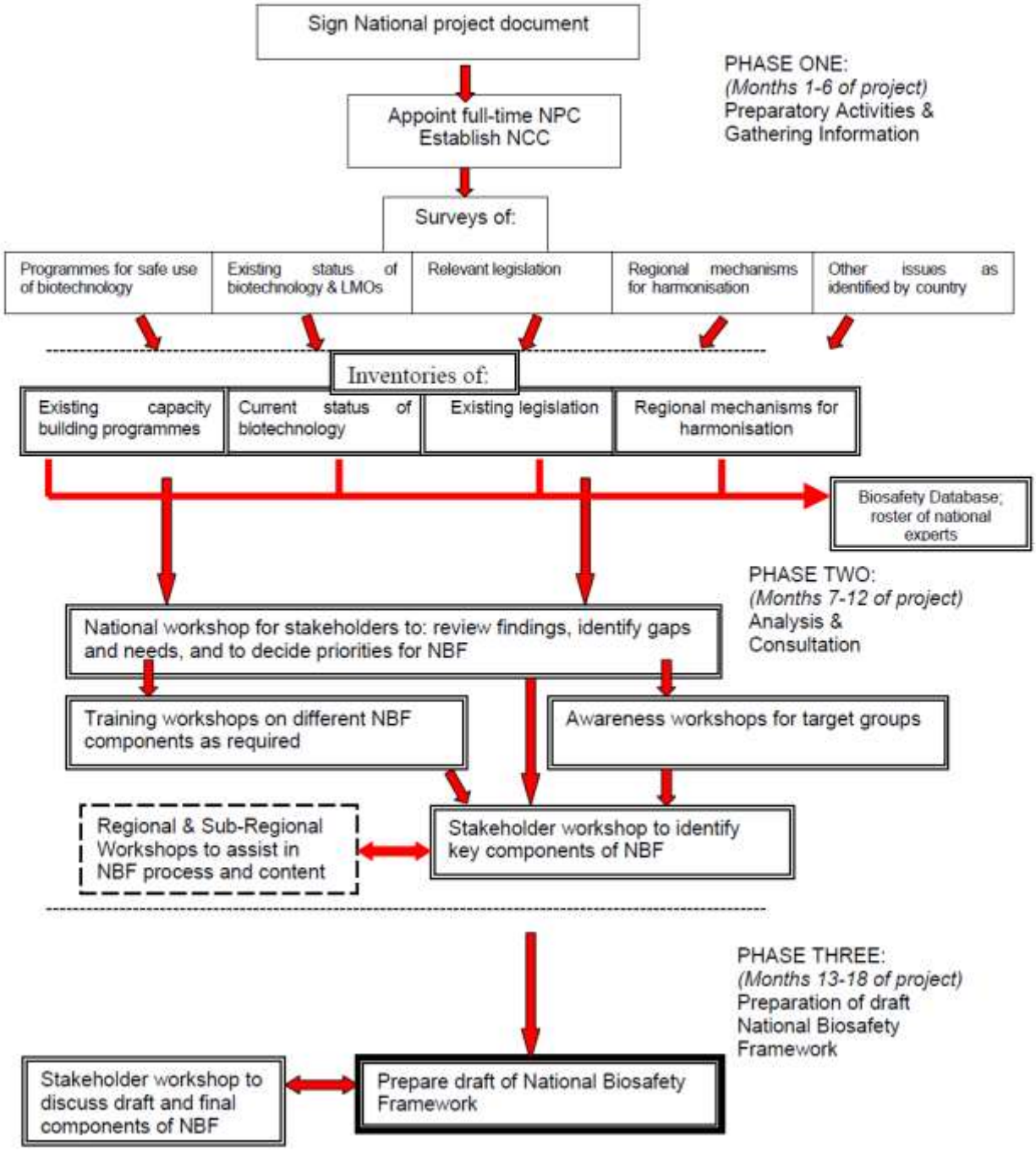
The components of the National Biosafety Framework (Source: UNEP-GEF Toolkit)



Annex 12. Flow-chart of the National Projects (NBF preparation)

(source: National ProDoc Model)

Figure 1: Suggested Flow Chart for National Project to develop National Biosafety Framework



Annex 13. Table of Project Outputs

Table: Assessment of Outputs Delivery Project "Development of National Biosafety Frameworks"

Expected Outcomes / Outputs	Outputs delivered by the Project	Comments
Outcome 1: *Regional and Sub-regional collaboration and exchange promoted*		
Output 1.1 *Four (4) regional workshops (Africa, Latin America and the Caribbean, Asia and the Pacific and Eastern Europe)*	In 2002 four initial Regional Workshops have been organized and implemented with a duration variable from 3 to 5 days. Overall, 298 participants from 129 countries have assisted to the 4 Workshops.	Table 2 below presents a synthesis of all regional and sub-regional workshops by Region and Sub-region (Number of participating countries, number of participants, duration and subject of the workshop). Main subject of the Regional Workshops: General introduction of the CPB, the NBF development project and the main elements of work in the preparation of NBF. The reports of the Workshops are available in the old site of the Biosafety Unit (not in the current one) http://www.unep.ch/biosafety/old_site/resources.htm
Output 1.2 *Fifteen (15) sub-regional workshops (North Africa, West Africa, Central Africa, Eastern Africa, Southern Africa, Caribbean region, South America, Central America, West Asia, South East Asia, South Asia, Central Asia, Pacific Islands, Eastern*	From 2002 to 2004, 13 Sub-regional Workshops have been organized and implemented with a duration of 4 days each: - 2 in Francophone Africa (Senegal, B. Faso) - 2 in Anglophone Africa (Namibia, Tanzania) - 2 in Asia (Malaysia, Iran)	Table 2 below presents a synthesis of all regional and sub-regional workshops by Region and Sub-region (Number of participating countries, number of participants, duration and subject of the workshop). Main subjects of the Sub-regional Workshops: · 1st Workshops: Risk Assessment and Management and Public Awareness and Participation (4 days)

Europe, and the Baltic countries).	- 2 for SIDS (Small Islands Dev. Count.) (Fiji, Trinidad & T.) - 2 in Latin America (Mexico, Chile) - 2 for Central & Eastern Europe, Caucasus & Central Asia (Lithuania, Turkey) - 1 in Lusophone Africa (Maputo, Mozambique) Overall, 994 participants from 128 countries have assisted to the 12 workshops.	· 2nd Workshop: Development of a Regulatory Regime and Administrative Systems (4 days). The reports of the Workshops are available in the old site of the Biosafety Unit (not in the current one) http://www.unep.ch/biosafety/old_site/resources.htm
Outcome 2: *One-hundred (100) National Biosafety Frameworks*		NBF should contain: a) A Government policy on biosafety b) A regulatory regime for biosafety c) A system to handle notifications or requests for authorisations d) Systems for 'follow up' such as enforcement and monitoring for environmental effects e) Mechanisms for public awareness, education and participation.
Output 2.1 (Phase 1): *Surveys and inventories of:* • *current biosafety practices* • *existing policy/legal frameworks* • *available bilateral /multilateral support* • *available expertise (roster of national experts)*	123 countries have implemented Phase 1 of NBF development, producing a survey of current biosafety situation, existing policy and legal frameworks and potential national stakeholders.	Like the whole NBF documents, the initial surveys, too, are of variable quality and completeness. Some of them present clear and exhaustive socio-political and institutional analyses. Others, though too generic, represent, at any rate, a valuable and preliminary effort of collection and editing of dispersed information. Rosters of available national expertise are generally missing.
Output 2.2 (Phase 2): • *Review of findings* • *Gaps identification* • *Needs analysis* • *Priorities setting* • *Stakeholders Training* • *Public awareness*	123 countries have implemented Phase 2 of NBF preparation, identifying main needs and setting priorities. Public awareness has been generally carried out through a variety of methods and tools (workshops, campaigns, meetings, etc.), while real training did not generally occur.	As above, the quality of the Output is uneven. Countries previously exposed to biotechnologies and biosafety issues have been able to deliver quality gap analyses and to focus on real institution and capacity building needs, conducing to concrete proposal of improvement. Public awareness has been overall a positive aspect that has permitted spreading information and opening ground for more focused activities.
Output 2.3 (Phase 3):	123 countries have produced their NBF, discussed it with national	Though all the countries have concluded the process of NBF

• *Drafting and harmonization of legal and regulatory instruments (guidelines, regulations, laws)* • *Setting national systems for risk assessment/risk management, public awareness and participation* • *Strengthening national capacities for setting biosafety national systems* • *Design and publication of draft NBF* • *National Stakeholders Workshop to discuss Draft NBF*	stakeholders and made it public also through BCH.	elaboration, only a part of them can claim having prepared and harmonized their regulatory instruments and set up national systems for risk assessment/risk management, public awareness and participation. The issue is discussed in the following chapter (Effectiveness). Notwithstanding the objective difficulties that some countries may have experienced in producing a consistent NBF, all of them have significantly enhanced their national capacities concerning GMOs and Biosafety issues.
Outcome 3: *Increased access to information and capacity building*		
Output 3.1: • *Project website linked to BCH*	The UNEP Biosafety Website has been created and is still active	Original website: http://www.unep.ch/biosafety/old_site/index.htm Current website: http://www.unep.org/biosafety/Default.aspx
Output 3.2: · *Project newsletter*	The Project has launched and produced an electronic Newsletter. Seven issues have been produced from 2001 to 2005.	The Newsletter provides a synthetic update of the implementation of the Project and of other Biosafety initiatives and GEF/UNEP projects (e.g. BCH Project).
Output 3.3: *Outreach material for public awareness raising*	Diffusion of outreach material for public awareness raising has occurred but not systematically	
Output 3.4: *Training materials (technical manuals, "tool kits", best practice guidelines, etc.) to be used in national and regional workshops*	The Project has produced and diffused to participating countries relevant methodological instruments to guide and assist them in the formulation of the NBF, among others: - An initial Information Paper	Very useful material, though not always timely produced (e.g. toolkit) The toolkit has been assessed in 2005 by an independent team (University of Amsterdam) through a survey (in total 500 Questionnaires were sent out to contacts in 30 countries, and 40 to

	- Guide for the implementation of National Biosafety Frameworks - Proposed format for preparation of a draft National Biosafety Framework - Proposed Flow-chart for the development of the NBF - A comprehensive Toolkit composed by: 1) Phase 0 - Module: Starting The Project 2) Phase 1 - Module: Taking Stock 3) Phase 2 - Module: Consultation and Analysis for the NBF 4) Phase 3 - Module: Developing the Regulatory Regime (part 1) 5) Phase 3 - Module: Developing the Regulatory Regime (part 2) - Various technical and methodological supports for the regional and sub-regional workshops.	informants representing global industries, NGOs, and Academia). The overall appreciation was positive regarding the three main criteria: Consistency, Country needs and Professional Quality.
Output 3.5 *A project list server for rapid exchange and dissemination of information between participating countries*	A New UNEP Information System (ANUBIS) has been created and implemented in all the countries	ANUBIS is a database / file-maker system that gathers in one single web platform all relevant information regarding administrative, financial and technical data of the Project, country by country (milestone dates, budget, financial reports and budget revisions, ProDoc, technical documents and reports, Project Implementation Reports, etc.).
Output 3.6: *Database of national, regional and global level resources*	Though many efforts have been deployed to promote public awareness and education, a real database at national, regional and global was not created. A national roster of experts has been created in some countries, yet it has not achieved widespread acceptance and use.	The purpose was "to establish a database of global, regional and national level resources for biotechnology and biosafety public awareness and education, and for monitoring and contributing to press coverage of biosafety issues in collaboration with participating countries".

Table 2: Regional and Sub-regional Workshops

	Regional Workshops				**Tot**	**Sub-regional Workshops**						**Tot**
	Africa	Asia & Pacific	LAC*	CEE		Angl. Africa	Franc. Africa	Asia	SIDS*	Latin Ameri	CEE CCA*	
N.	1	1	1	1	4	2	2	2	2	2	2	12

workshops												
N. countries	35	40	30	24	129	18	20	21	28	16	25	128
N. particip. / workshop	60	97	58	83	298	73	90	82	103	59	90	497 (2 times)
Duration	4 days 2002	5 days 2002	3 days 2002	3 days 2002		4 +4 d 2002 2004	4+4 d 2003 2004	4+4d 2003 2003	4+4 d 2003 2004	4+4 d 2002 2003	4+4 d 2003 2003	
Subject	General introduction of the CPB, the NBF development project, and the main elements of work in the preparation of NBF					1st) Risk Assessment and Management and Public Awareness and Participation (4 days) 2nd) Development of a Regulatory Regime and Administrative Systems (4 days)						

* LAC: Latin America & the Caribbean; CEE: Central & Eastern Europe; SIDS: Small Islands Developing Countries; CEECCA: Central & Eastern Europe, Caucasus & Central Asia
Source: Evaluation Team based on Project Reports

Annex 14. Scorecards (37) of NBF sample countries

Copia di NBF scorecards combine

Annex 15. Synoptic Table of NBF score cards

	Country	Year	Policy	Regulatory Regime	Admin System	Monitoring Enforcement	Public awar. participation	Total NBF
1	Armenia	2004	MS	S	S	MU	MS	**MS**
2	Bangladesh	2006	HS	HS	HS	MS	S	**S**
3	Belarus	2004	S	HS	S	MS	S	**S**
4	Botswana	2006	MS	MU	U	U	U	**U**
5	Chad	2008	MS	MU	MS	MU	MS	**MU**
6	Dem Rep Congo	2007	HS	S	S	MU	MS	**MS**
7	Dem Rep Korea	2004	U	U	U	MU	U	**U**
8	Dominican Rep	2007	MS	MS	U	U	U	**MU**
9	Ethiopia	2007	S	MS	MS	MS	MU	**MS**
10	Fiji	2005	MU	U	U	U	U	**U**
11	Georgia	2005	MS	MS	MS	MU	MU	**MS**
12	Ghana	2004	S	HS	HS	HS	HS	**HS**
13	Honduras	2007	S	MU	U	U	U	**MU**
14	Indonesia	2004	MS	S	S	S	HS	**S**
15	Iran	2004	S	S	S	S	MS	**S**
16	Kyrgyzstan	2005	MU	MS	S	MU	MU	**MS**
17	Madagascar	2004	MS	S	S	U	MU	**MS**
18	Morocco	2009	MU	U	U	U	MU	**U**
19	Mozambique	2005	S	HS	HS	HS	S	**HS**
20	Myanmar	2006	U	U	U	U	U	**U**
21	Nepal	2006	MU	U	U	MU	MS	**MU**
22	Nicaragua	2008	U	U	U	U	U	**U**
23	Niger	2005	S	MU	U	U	S	**MU**
24	Panama	2007	MU	S	HS	U	U	**MS**
25	Papua NG	2005	MS	MS	MS	MS	MU	**MS**
26	Paraguay	2007	MU	MU	U	U	U	**U**
27	Peru	2005	HS	HS	S	S	S	**HS**
28	Philippines	2004	S	S	S	S	HS	**S**
29	Romania	2006	S	S	MS	MS	MS	**MS**
30	Rwanda	2005	MU	MU	MU	MU	MS	**MU**
31	Sudan	2007	MS	MS	MU	MU	S	**MS**
32	Thailand	2007	MS	MS	S	S	MS	**MS**
33	Ukraine	2008	S	MS	S	S	MS	**S**
34	Uruguay	2007	S	S	HS	S	MS	**S**
35	Vanuatu	2005	MU	MU	MU	U	MS	**MU**
36	Venezuela	2005	U	MS	MS	MU	S	**MS**
37	Zimbabwe	NA	HS	HS	HS	HS	S	**HS**
	TOTAL		**MS**	**MS**	**MS**	**MU**	**MU**	**MS**

Annex 16. Analysis of selected questions from the Second and Third National Report on the implementation of The Cartagena Protocol on Biosafety of 37 countries (sample)

Julia Niggebrügge, Supporting Consultant

A) SELECTED COUNTRIES

Country	3rd National Report (2015)	2nd National Report (2011)
Armenia	no	yes
Bangladesh	yes	yes
Belarus	yes	yes
Botswana	no	yes
Chad	yes	yes
Democratic Republic of Congo	yes	yes
Dominican Republic	yes	yes
DPRK	no	yes
Ethiopia	no	yes
Fiji	no	yes
Georgia	yes	yes
Ghana	yes	yes
Honduras	yes	yes
Indonesia	yes	yes
Iran	yes	yes
Kyrgyzstan	yes	yes
Madagascar	yes	yes
Morocco	yes	yes
Mozambique	no	yes
Myanmar	no	yes
Nepal	no	no
Nicaragua	no	no
Niger	yes	yes
Panama	yes	yes
Papua New Guinea	no	yes
Paraguay	no	yes
Peru	yes	yes
Philippines	no	yes
Romania	yes	yes
Rwanda	yes	yes

Sudan	yes	yes
Thailand	yes	no
Uruguay	no	no
Vanuatu	no	no
Ukraine	no	yes
Venezuela	yes	yes
Zimbabwe	yes	yes

B) QUESTIONNAIRE

The following 66 (sixty-six) questions are a selection from the format prepared for the collection of data for the second and third National Reports as required under Article 33 of the Cartagena Protocol on Biosafety. Questions are based on the requirements of the Protocol and are related to the indicators of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020. A total amount of 2.442 answers (66 questions x 37 countries) have been processed.

As sample countries have submitted different National Report, the following numbering has been included:
(1) This question originates from the 2nd National Report where it was mandatory;
(2) This question originates from the 2nd National Report where it was optional;
(3) This question originates from the survey to gather information corresponding to indicators in the Strategic Plan;
(4) This question was introduced in the third National Report.

Article 2 – General provisions	
1. Has your country introduced the necessary legal, administrative and other measures for the implementation of the Protocol? (1) *This question is relevant to indicators 1.1.1, 2.1.1, 2.1.2 and 3.1.2 of the Strategic Plan*	☐ A domestic regulatory framework is fully in place ☐ A domestic regulatory framework is partially in place ☐ Only temporary measures have been introduced ☐ Only a draft framework exists ☐ No measures have yet been taken ☐ *No changes since the previous report*

2. If you indicated that a national biosafety framework exists in the above question, when did it become operational? [3] *If you indicated that a national biosafety framework does not, please select "Not applicable"* *This question is relevant to indicator 1.1.1 of the Strategic Plan*	☐ 2001 or earlier ☐ 2002 ☐ 2003 ☐ 2004 ☐ 2005 ☐ 2006 ☐ 2007 ☐ 2008 ☐ 2009 ☐ 2010 ☐ 2011 ☐ 2012 ☐ 2013 ☐ 2014 ☐ Not applicable
3. Which specific instruments are in place for the implementation of your national biosafety framework? [2]	☐ One or more national biosafety laws ☐ One or more national biosafety regulations ☐ One or more sets of biosafety guidelines ☐ Other laws, regulations or guidelines that indirectly apply to biosafety ☐ No instruments are in place ☐ *No changes since the previous report*
4. Has your country established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework? [2]	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ *No changes since the previous report*
5. Does your country have permanent staff to administer functions directly related to the national biosafety framework? [2]	☐ Yes ☐ No ☐ *No changes since the previous report*
6. If you answered *Yes* to question 18, how many permanent staff members are in place whose functions are directly related to the national biosafety framework? [2] *If you answered No to question 18, please select "Not applicable"*	☐ One ☐ Less than 5 ☐ Less than 10 ☐ More than 10 ☐ Not applicable ☐ *No changes since the previous report*
Article 5 – Pharmaceuticals	

7. Does your country regulate the transboundary movement, handling and use of living modified organisms (LMOs), which are pharmaceuticals? [(1)]	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ No changes since the previous report
Article 6 – Transit and Contained use	
8. Does your country regulate the transit of LMOs? [(1)] *This question is relevant to indicators 1.8.1 of the Strategic Plan*	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ No changes since the previous report
9. Does your country regulate the contained use of LMOs? [(1)] *This question is relevant to indicators 1.1.2 and 1.8.2 of the Strategic Plan*	☐ Yes ☐ No ☐ No changes since the previous report
Articles 7 to 10: Advance Informed Agreement (AIA) and intentional introduction of LMOs into the environment	
10. Has your country adopted law(s) / regulations / administrative measures for the operation of the AIA procedure of the Protocol OR a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment? [(4)] *This question is relevant to indicators 1.1.2 and 3.1.4 of the Strategic Plan*	☐ Yes ☐ No

11. Has your country ever received an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment? [2] *This question is relevant to indicators 1.1.4 of the Strategic Plan*	☐ Yes ☐ No
12. Has your country ever taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment? [1] *This question is relevant to indicators 1.1.5 of the Strategic Plan*	☐ Yes ☐ No ☐ *No changes since the previous report*
13. If you answered *Yes* to question 35, how many LMOs has your country approved to date for import for intentional introduction into the environment? [1] *If you answered No, please select "Not applicable"*	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10 ☐ Not applicable ☐ *No changes since the previous report*
14. If you answered *Yes*, how many LMOs, not imported, has your country approved to date for intentional introduction into the environment? [1] *If you answered No, please select "Not applicable"*	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10 ☐ Not applicable ☐ *No changes since the previous report*
15. In the current reporting period, how many applications/notifications has your country received regarding intentional transboundary movements of LMOs for intentional introduction into the environment? [2]	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10

16. In the current reporting period, how many decisions has your country taken regarding intentional transboundary movements of LMOs for intentional introduction into the environment? (1)	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10
17. Has your country acknowledged receipt of the notifications to the notifier within ninety days of receipt? (1)	☐ Yes, always ☐ In some cases only ☐ No ☐ Not applicable ☐ *No changes since the previous report*
18. What percentage of your country's decisions fall into the following categories? (2)	[%] Approving the import without conditions [%] Approving the import with conditions [%] Prohibiting the import [%] Requesting additional information [%] Extending the period for the communication of the decision ☐ Not applicable ☐ *No changes since the previous report*
Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)	

19. Has your country adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP? [(2)] *This question is relevant to indicator 1.1.2 of the Strategic Plan*	☐ Yes ☐ No
20. Has your country ever taken a decision on LMOs-FFP (either on import or domestic use)? [(1)]	☐ Yes ☐ No ☐ *No changes since the previous report*
21. How many LMOs-FFP has your country approved to date? [(1)]	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10 ☐ *No changes since the previous report*
Article 13 – Simplified procedure	
22. Has your country ever applied the simplified procedure? [(1)]	☐ Yes ☐ No ☐ *No changes since the previous report*
Article 14 – Bilateral, regional and multilateral agreements and arrangements	
23. Has your country entered into any bilateral, regional or multilateral agreements or arrangements? [(1)]	☐ Yes ☐ No ☐ *No changes since the previous report*
24. Please provide a brief description of the scope and objective of the agreements or arrangements entered into: [Type your text here] ☐ *No changes since the previous report*	
Articles 15 & 16 – Risk Assessment and Risk Management	

25. How many people in your country have been trained in risk assessment, monitoring, management and control of LMOs? [3]

This question is relevant to indicator 2.2.3 of the Strategic Plan

i. Risk assessment:	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more
ii. Management / Control:	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more
iii. Monitoring:	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more

26. Is your country using the "Manual on Risk Assessment of LMOs" (developed by CBD Secretariat) for training in risk assessment? [4]

This question is relevant to indicator 2.2.5 of the Strategic Plan

☐ Yes
☐ No

27. Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health? [3]

This question is relevant to indicators 1.4.2 and 1.6.3 of the Strategic Plan

i. Detect:	☐ Yes ☐ No
ii. Identify:	☐ Yes ☐ No
iii. Assess:	☐ Yes ☐ No

iv. Monitor:	☐ Yes ☐ No
28. Has your country ever conducted a risk assessment of an LMO including any type of risk assessment of LMOs, e.g. for contained use, field trials, commercial purposes, direct use as food, feed, or for processing? (3) *This question is relevant to indicator 1.3.3 of the Strategic Plan*	☐ Yes ☐ No
29. If you answered *Yes*, please indicate the scope of the risk assessments (select all that apply): (4)	☐ Contained use (in accordance with article 3) ☐ Intentional introduction into the environment for experimental testing or field trials ☐ Intentional introduction into the environment for commercial purposes ☐ Direct use as food ☐ Direct use as feed ☐ Processing ☐ Not applicable
30. If you answered *Yes*, how many risk assessments were conducted in the current reporting period? (1)	☐ None ☐ 5 or less ☐ 10 or less ☐ More than 10 ☐ Not applicable
31. Does your country have the infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs? (3) *This question is relevant to indicator 2.2.4 of the Strategic Plan*	☐ Yes ☐ No
Article 17 – Unintentional transboundary movements and emergency measures	

32. Does your country have the capacity to take appropriate measures in the event that an LMO is unintentionally released? [3] *This question is relevant to indicator 1.8.3 of the Strategic Plan*	☐ Yes ☐ No
Article 18 – Handling, transport, packaging and identification	
33. Has your country taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases *where the identity of the LMOs is not known* through means such as identity preservation systems, they *may contain* living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information? [1] *This question is relevant to indicator 1.6.1 of the Strategic Plan*	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ *No changes since the previous report*
34. Has your country taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases *where the identity of the LMOs is known* through means such as identity preservation systems, they *contain* living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information? [1] *This question is relevant to indicator 1.6.1 of the Strategic Plan*	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ *No changes since the previous report*
35. Does your country have the capacity to enforce the requirements of identification and documentation of LMOs? [2]	☐ Yes ☐ Yes, to some extent [Here you may provide further details] ☐ No ☐ *No changes since the previous report*

36. How many customs officers in your country have received training in the identification of LMOs? (3) *This question is relevant to indicator 2.3.1 of the Strategic Plan*	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more
37. How many laboratory personnel in your country have received training in detection of LMOs? (3) *This question is relevant to indicator 2.3.1 of the Strategic Plan*	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more
38. How many of the certified laboratories in the previous question are currently operating in the detection of LMOs? (3) *If you answered None, please select "Not applicable"* *This question is relevant to indicator 2.3.4 of the Strategic Plan*	☐ None ☐ One or more ☐ 5 or more ☐ 10 or more ☐ 50 or more ☐ Not Applicable
Article 19 – Competent National Authorities and National Focal Points	
39. In case your country has designated more than one *competent national authority*, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs? (2)	☐ Yes ☐ No ☐ Not applicable ☐ *No changes since the previous report*
40. Has your country established adequate institutional capacity to enable the *competent national authority(ies)* to perform the administrative functions required by the Cartagena Protocol on Biosafety? (2)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
Article 20 – Information Sharing and the Biosafety Clearing-House (BCH)	
41. Please provide an overview of the status of the mandatory information provided by your country to the BCH by specifying for each category of information whether it is available and whether it has been submitted to the BCH. (1) *This question is relevant to indicator 3.1.5 of the Strategic Plan*	

a.	Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20, paragraph 3 (a))	☐ Information available and in the BCH ☐ Information available but not in the BCH ☐ Information available but only partially available in the BCH ☐ Not applicable ☐ *No changes since the previous report*
b.	National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 5)	☐ Information available and in the BCH ☐ Information available but not in the BCH ☐ Information available but only partially available in the BCH ☐ Not applicable ☐ *No changes since the previous report*
c.	Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10, paragraph 3 and 20, paragraph 3(d))	☐ Information available and in the BCH ☐ Information available but not in the BCH ☐ Information available but only partially available in the BCH ☐ Not applicable ☐ *No changes since the previous report*
d.	Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, paragraph 1)	☐ Information available and in the BCH ☐ Information available but not in the BCH ☐ Information available but only partially available in the BCH ☐ Not applicable ☐ *No changes since the previous report*

e. Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with annex III (Article 11, paragraph 6) (requirement of Article 20, paragraph 3(d))	☐ Information available and in the BCH ☐ Information available but not in the BCH ☐ Information available but only partially available in the BCH ☐ Not applicable ☐ *No changes since the previous report*
42. Does your country use the information available in the BCH in its decision-making processes on LMOs? (2)	☐ Yes, always ☐ Yes, in some cases ☐ No ☐ Not applicable ☐ *No changes since the previous report*
43. Please indicate the number of regional, national and international events organized in relation to biosafety (e.g. seminars, workshops, press conferences, educational events, etc.,) in the last 2 years: (3) *This question is relevant to indicator 4.3.1 of the Strategic Plan*	☐ None ☐ One or more ☐ 5 or more ☐ 10 or more ☐ 25 or more
44. Please indicate the number of biosafety related publications that has been made available in your country in the last year: (3) *This question is relevant to indicator 4.3.2 of the Strategic Plan*	☐ None ☐ One or more ☐ 10 or more ☐ 50 or more ☐ 100 or more
Article 22 – Capacity-building	

45. Has your country received external support or benefited from collaborative activities with other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety? (1)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
46. If you answered *Yes*, how were these resources made available? (1) *If you answered No, please select "Not applicable"*	☐ Bilateral channels ☐ Regional channels ☐ Multilateral channels ☐ Not applicable ☐ *No changes since the previous report*
47. Has your country provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety? (1)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
48. During the current reporting period, has your country undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety? (1)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No

49. If you answered *Yes*, in which of the following areas were these activities undertaken? (1)	☐ Institutional capacity ☐ Human resources capacity development and training ☐ Risk assessment and other scientific and technical expertise ☐ Risk management ☐ Public awareness, participation and education in biosafety ☐ Information exchange and data management including participation in the Biosafety Clearing-House ☐ Scientific, technical and institutional collaboration at subregional, regional and international levels ☐ Technology transfer ☐ Identification of LMOs, including their detection ☐ Socio-economic considerations ☐ Implementation of the documentation requirements under Article 18.2 of the Protocol ☐ Handling of confidential information ☐ Measures to address unintentional and/or illegal transboundary movements of LMOs ☐ Scientific biosafety research relating to LMOs ☐ Taking into account risks to human health ☐ Other (please specify): [Enter text here] ☐ Not applicable
50. Does your country still have capacity-building needs? (1) *This question is relevant to indicator 1.2.7 of the Strategic Plan*	☐ Yes ☐ Yes, a few ☐ No ☐ *No changes since the previous report*

51. If you answered *Yes*, indicate which of the following areas still need capacity-building. (1) *If you answered No, please select "Not applicable"*	☐ Institutional capacity ☐ Human resources capacity development and training ☐ Risk assessment and other scientific and technical expertise ☐ Risk management ☐ Public awareness, participation and education in biosafety ☐ Information exchange and data management including participation in the Biosafety Clearing-House ☐ Scientific, technical and institutional collaboration at subregional, regional and international levels ☐ Technology transfer ☐ Identification of LMOs, including their detection ☐ Socio-economic considerations ☐ Implementation of the documentation requirements under Article 18.2 of the Protocol ☐ Handling of confidential information ☐ Measures to address unintentional and/or illegal transboundary movements of LMOs ☐ Scientific biosafety research relating to LMOs ☐ Taking into account risks to human health ☐ Other (please specify): [Enter text here] ☐ Not applicable ☐ *No changes since the previous report*

52. Has your country developed a capacity-building strategy or action plan? (1) *This question is relevant to indicator 1.2.2 of the Strategic Plan*	☐ Yes ☐ No ☐ *No changes since the previous report*
53. How many biosafety short-term training programmes and/or academic courses are offered annually in your country? (3) *This question is relevant to indicator 1.2.3 of the Strategic Plan*	☐ None ☐ Less than 1 per year ☐ 1 per year or more ☐ 5 per year or more ☐ 10 per year or more
54. Has your country submitted the details of national biosafety experts to the Roster of Experts in the BCH? (1)	☐ Yes ☐ No ☐ *No changes since the previous report*
Article 23 – Public awareness and participation	
55. Does your country have any awareness and outreach programmes on biosafety? (3) *This question is relevant to indicator 5.3.1 of the Strategic Plan*	☐ Yes ☐ No
56. Has your country established a biosafety website searchable archives, national resource centres or sections in existing national libraries dedicated to biosafety educational materials? (2) *This question is relevant to indicators 2.5.3 and 5.3.3 of the Strategic Plan*	☐ Yes ☐ No ☐ *No changes since the previous report*
57. Has your country established a mechanism to ensure public access to information on living modified organisms that may be imported? (1)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*

58. Has your country established a mechanism to make available to the public the results of decisions taken on LMOs? (1) *This question is relevant to indicator 2.5.1 of the Strategic Plan*	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
59. If you answered *Yes* please indicate the modalities used to inform the public: (3) *If you answered No, please select "Not applicable"* *This question is relevant to indicator 2.5.2 of the Strategic Plan*	☐ National websites ☐ Newspapers ☐ Forums ☐ Mailing lists ☐ Public hearings ☐ Other (please specify): [Enter text here] ☐ Not applicable
60. If you indicated more than one modality for public participation, which one was most used? (3) *If you did not indicated more than one modality, please select "Not applicable"* *This question is relevant to indicator 2.5.2 of the Strategic Plan*	☐ National websites ☐ Newspapers ☐ Forums ☐ Mailing lists ☐ Public hearings ☐ Not applicable
61. How many academic institutions in your country are offering biosafety education and training courses and programmes? (3) *This question is relevant to indicator 2.7.1 of the Strategic Plan*	☐ None ☐ One or more ☐ 3 or more ☐ 5 or more ☐ 10 or more

62. Please indicate the number of educational materials and/or online modules on biosafety that are available and accessible to the public in your country: (3) *This question is relevant to indicators 2.7.2 and 5.3.4 of the Strategic Plan*	☐ None ☐ One or more ☐ 5 or more ☐ 10 or more ☐ 25 or more ☐ 100 or more
Article 25 – Illegal transboundary movements	
63. Has your country established a strategy for detecting illegal transboundary movements of LMOs? (2)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
Article 26 – Socio-economic considerations	
64. What is your country's experience, if any, in taking socio-economic considerations into account in LMO decision making? Please give details: (3) *This question is relevant to indicator 1.7.3 of the Strategic Plan* [Type your text here]	
65. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs? (1)	☐ Yes ☐ Yes, to some extent [Here you may provide further details...] ☐ No ☐ *No changes since the previous report*
Article 28 – Financial Mechanism and Resources	

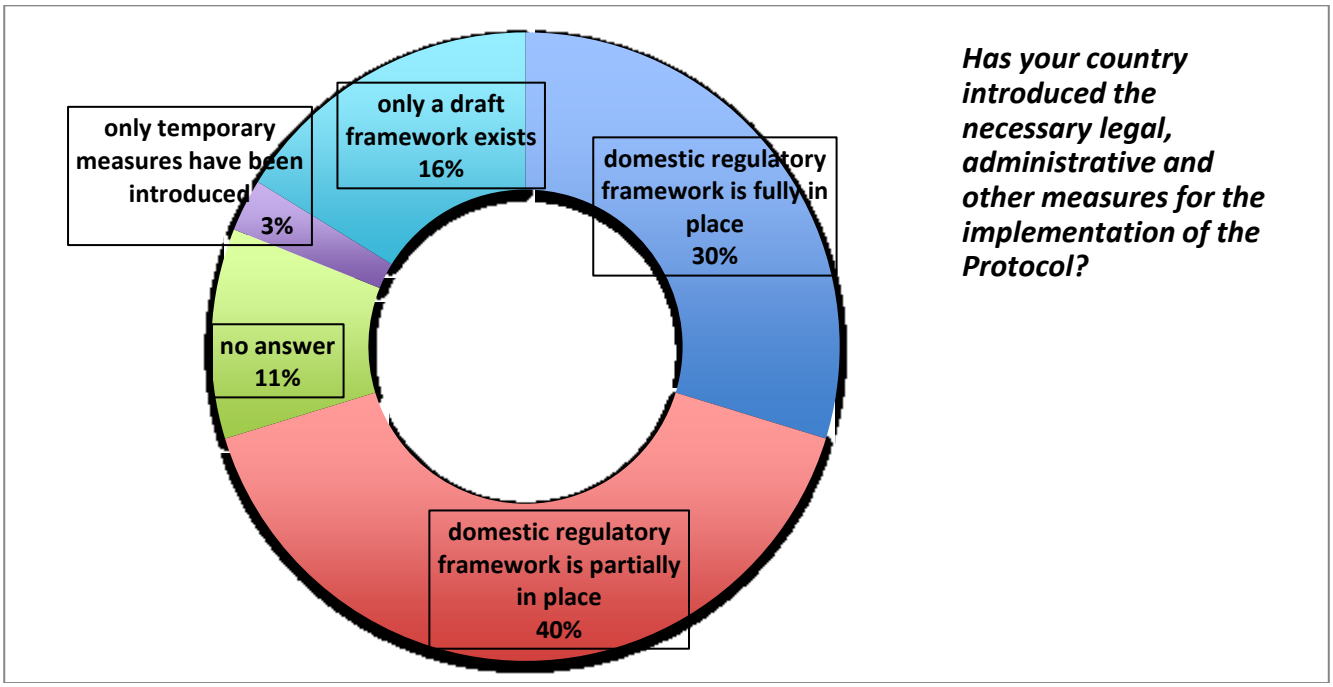
66. How much additional funding (in the equivalent of US dollars) has your country mobilized in the last four years to support implementation of the Biosafety Protocol, beyond the regular national budgetary allocation? *This question is relevant to indicator 1.2.5 of the Strategic Plan*	☐ Less than 5,000 USD ☐ 5,000 USD or more ☐ 50,000 USD or more ☐ 100,000 USD or more ☐ 500,000 USD or more ☐ 1,000,000 USD or more ☐ 5,000,000 USD or more ☐ Not applicable

C) ANALYSIS

Article 2 (General Provisions)

To assess the state of implementation of the Biosafety Framework 37 countries that had participated in the project were sampled based on the answers they gave in the 2nd and 3rd National Report to the BCH. Four out of 37 countries submitted neither of the reports. 11 countries submitted the 2nd National Report by December 2011, and 22 countries submitted the 3rd National report that was due at the end of November 2015.

In both National Report formats countries were asked whether they had *introduced the necessary legal, administrative and other measures for the implementation of the Protocol*. Out of 37 Parties, 11 reported that a *domestic regulatory framework* is *fully in place* and 15 reported that it is *partially in place.* Seven Parties reported not yet having a regulatory framework in place. Of these, one Party stated that *only temporary measures have been introduced*; 6 Parties stated that *only a draft framework exists.* Four countries did not respond. From those seven Parties who do not yet have a regulatory framework in place, four are from Asia and the Pacific and three are from Africa. No country stated that *no measures have yet been taken*.



Countries were asked to provide details regarding *which specific instruments are in place for the implementation of their national biosafety framework*. Respondents could provide multiple answers. In this regard, of the responses twenty-four Countries (65%) referred to *biosafety laws, and/ or regulations and/ or guidelines*, six Countries (16%) stated that only *other laws, regulations or guidelines that indirectly apply to biosafety* and three (8%) of the responses indicated that *no instruments are in place.* Four countries (11%) did not respond.

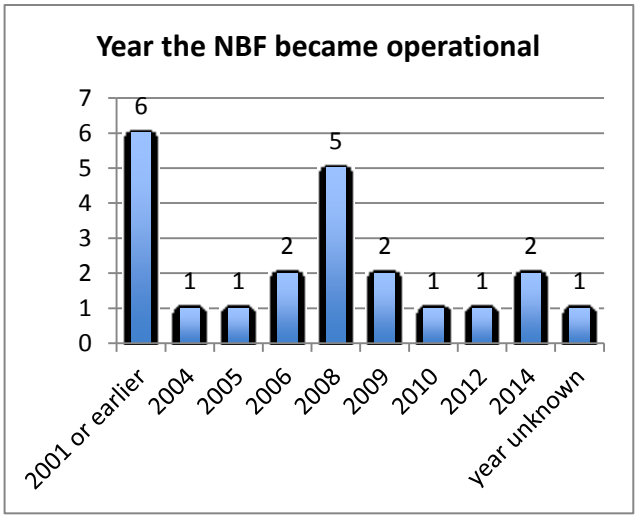
Hence, some countries, e.g. the Dominican Republic and the Democratic Republic of Congo who indicate that their NBFs are *partially in place* have also stated that *no instruments are in place* for the their implementation.

The NBF rating for six out of 26 Parties who responded that they have a *domestic regulatory framework fully or partially in place* was *Moderately Unsatisfactory* or *Unsatisfactory*, hence these positive statements

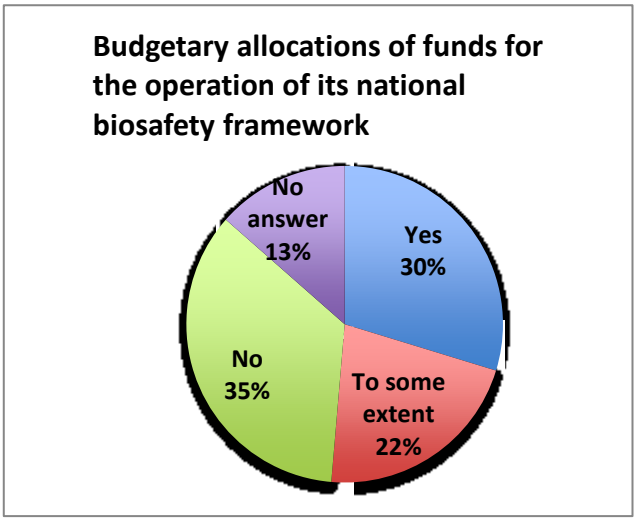
on the existence of a framework may not be a reliable statement on the quality and the instruments of the same.

On the other hand, in some cases more than a decade passed between the development of the NBF and the submittal of the 3rd National Reports, during which the quality of framework could have improved.

Only the 3rd National Report asked for the year the NBF became operational. Looking at the information provided by 21 countries one can see that six NBFs became operational before 2001. The rest is rather evenly spread over the years from 2004 to 2014, with a peak of five NBFs in 2008.

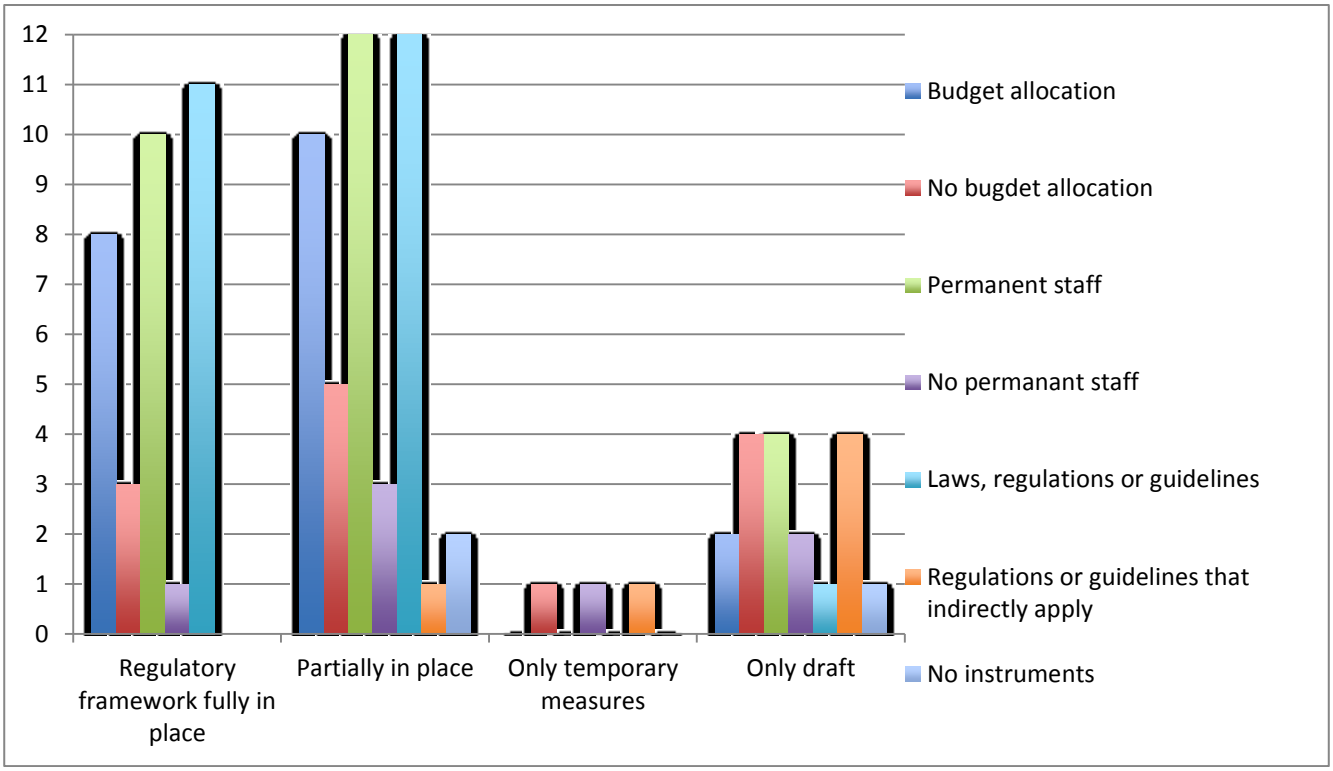


Countries were asked if they have *established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework*. Eleven Parties (30%) reported 'yes', eight Parties (22%) reported 'yes, to some extent', 13 Parties (35%) reported 'no', and five Parties did not report.



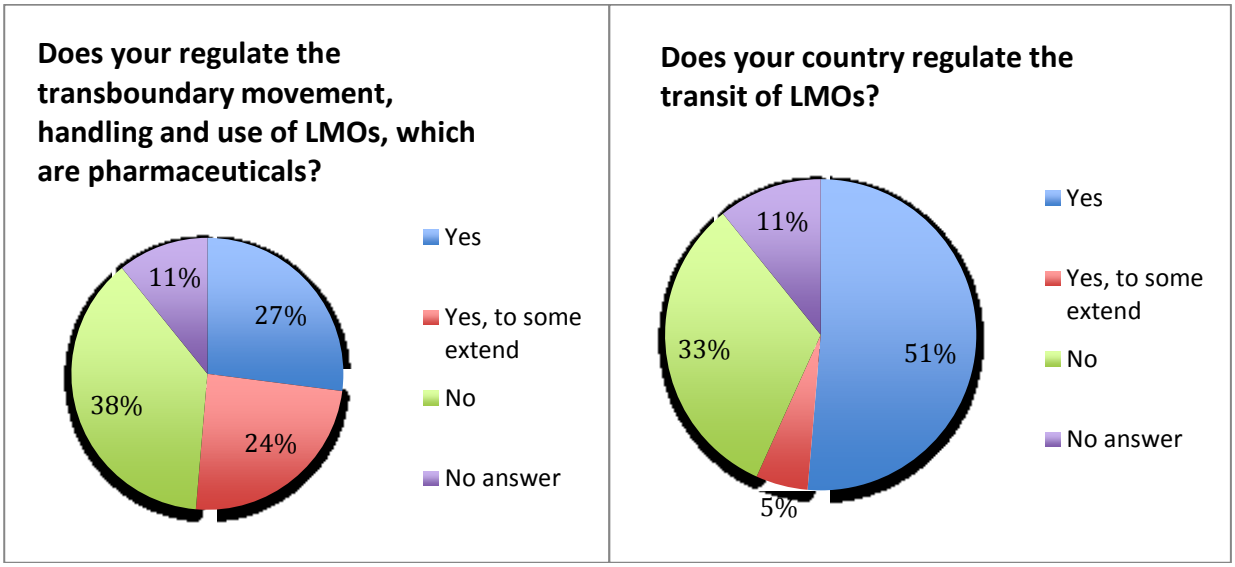
Furthermore, 23 (62%) out of 37 Parties stated that they have *permanent staff to administer functions directly related to the NBF*. Of these, three of the respondents (8%) reported that they have in place *more than 10 staff members*, nine (24%) have *less than 10 staff*, twelve (32%) have *less than 5 staff* and two Parties (5%) have *one* staff member.

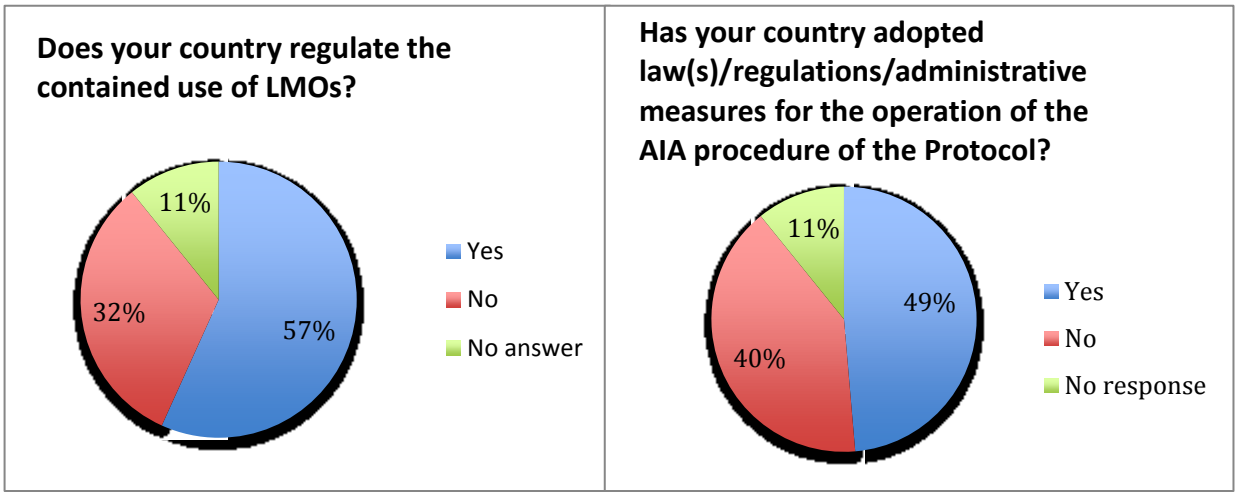
Eight Countries (22%) that reported to have a NBF *fully* or *partially in place* have no budgetary allocations for them. While the absence of a budget normally sheds a negative light on the effectiveness of a NBF (or any legal tool for that matter), it needs to be mentioned that in seven cases Parties without budgetary allocations still had permanent staff to manage their NBFs. Presumably salaries are, in these cases, charged to alternative budget lines.



Articles 5 (Pharmaceuticals), 6 (Transit and contained use), and 7 (AIA)

In response to the question on whether countries do *regulate the transboundary movement, handling and use of LMOs, which are pharmaceuticals*, ten Parties (27%) answered *yes*, while nine Parties (24%) reported that they do so *to some extent*. 14 Parties (38%) reported that they have no regulations in place for LMOs, which are pharmaceuticals. Four Parties (11%) did not respond.





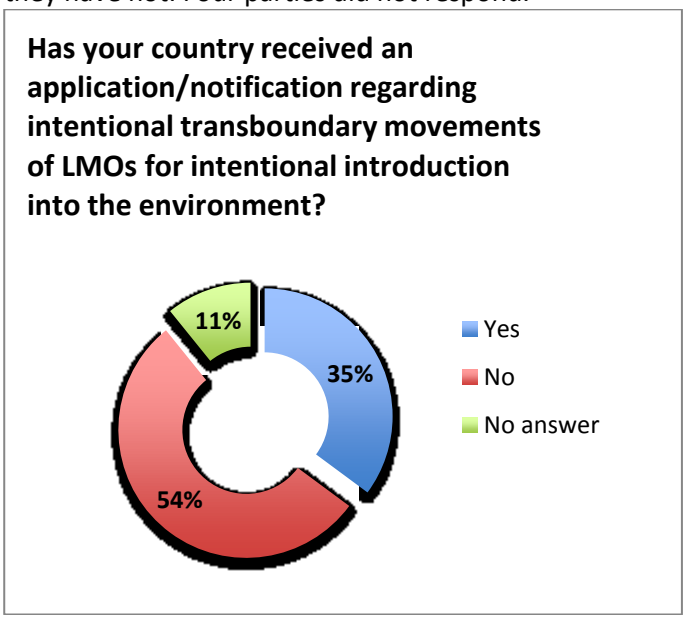
19 Parties (51%) reported that they *regulate the transit* of LMOs, two Parties (5%) said they do so *to some extent*, and twelve Parties (32%) reported that they do not. Four Parties (11%) did not respond.

21 Parties (57%) reported that they regulate the *contained use of LMOs* and twelve Parties (32%) reported that they do not. Four Parties (11%) did not respond.

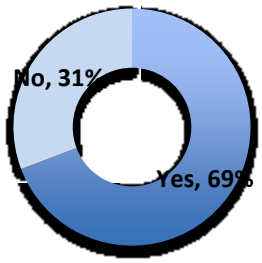
Countries were asked if they have *adopted law(s)/regulations/administrative measures for the operation of the AIA procedure of the Protocol*. 18 Parties (49%) answered "yes" and 15 Parties (41%) answered "no". Four Parties (11%) did not respond.

Articles 7 to 10: intentional introduction of LMOs into the environment

13 out of 37 Parties reported that they have *received an application/notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment*, and 20 reported that they have not. Four parties did not respond.



If yes, have you taken a decision on an application/ notification regarding intentional trans-boundary movements of LMOs for intentional introduction into the environment ?



Out of these 13 Parties reporting that they have received an application/ notification, nine Parties reported that they have *taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment* and four Parties reported that they have not done so. Paradoxically, the Dominican Republic and Paraguay reported that they have not received such application but that they have nevertheless taken decisions.

This means that even though 71% of countries reported to have a regulatory framework fully or partially in place, only 24% reported that they have actually taken a decision on LMOs.

Out of the nine Parties, which reported having taken a decision:

(a) One Party (Indonesia) reported that, to date, it has approved importation of *more than 10 LMOs* for intentional introduction into the environment; two Parties (Philippines and Romania) have approved *less than 10 LMOs*; two Parties (Honduras and Rwanda) have approved *less than 5 LMOs*, and four Parties (Botswana, Fiji, Madagascar and Mozambique), have approved *none*.

(b) One Party (Indonesia) reported that, to date, it has approved *more than 10* non-imported LMOs for intentional introduction into the environment; one Party (Philippines) has approved *less than 5* LMOs and seven Parties have approved *none*.

One Party (3%, Paraguay) reported that during the current reporting period it has received *more than 10 applications/notifications regarding intentional transboundary movements of LMOs for intentional introduction into the environment;* one Party (3%, Indonesia) received *less than 10 applications*; nine Parties (24%) received *less than 5 applications* and 22 Parties (60%) reported that they received *none*. Four Parties (11%) did not respond to the question.

From the eleven countries that reported to have received applications/ notifications during the current reporting period, almost all have taken the same number of decisions as applications.

From the 13 countries that have received applications/ notifications, two (15%) reported that they have *acknowledged receipt of the notifications to the notifier from ninety days of receipt 'in some cases'* and four countries (31%) reported '*yes, always'.*

Countries were asked to indicate the *percentage of their decisions* according to different categories. The percentages indicated by the nine Parties, which answered to this question, are as follows:

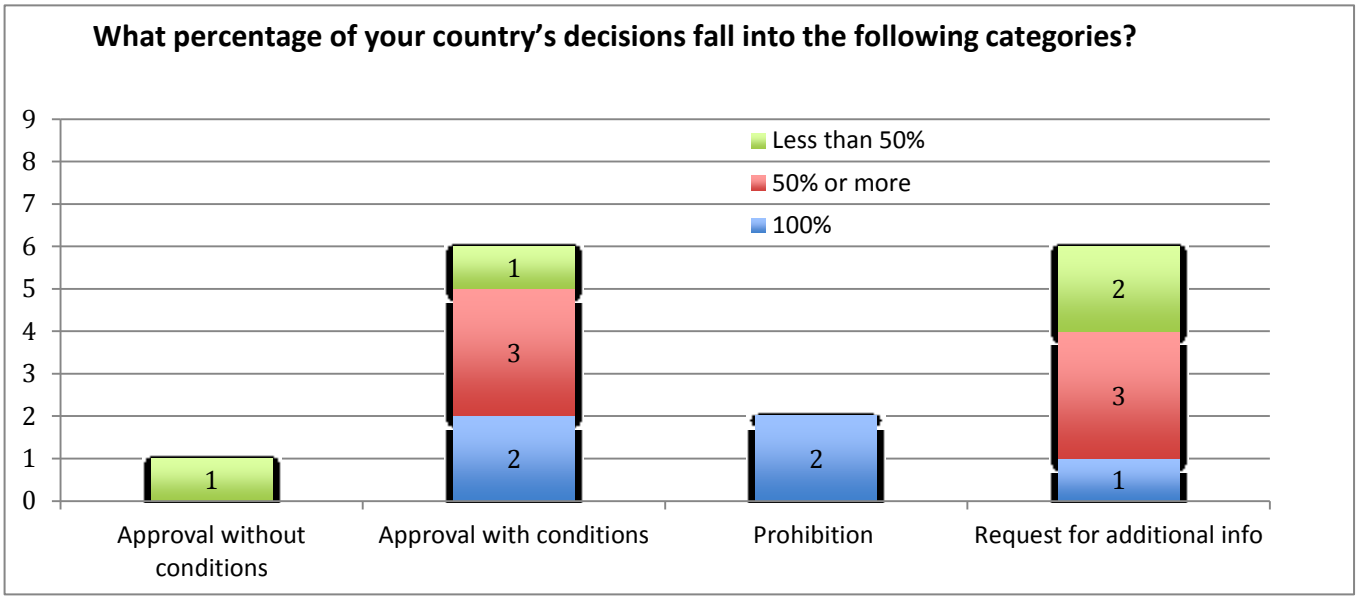
Approval of the import of LMO(s) without conditions*:* eight Parties indicated that no decisions fall into this category, One Party indicated less than 50% of its decisions fall into this category;

Approval of the import of LMO(s) with conditions*:* Four Parties indicated that no decisions fall into this category, one Party indicated less than 50% of their decisions, three Parties indicated 50% and one Party indicated that all of its decisions fall into this category;

Prohibition of the import/use of LMOs*:* seven Parties indicated that no decisions fall into this category, and the other two Parties indicated that all of its decisions fall into this category;

Request for additional information*:* Three Parties indicated that no decisions fall into this category, two Parties indicated less than 50% of their decisions, three Parties indicated 50% and one Party indicated that all of its decisions fall into this category;

Extension of the period for the communication of the decision*:* Nine Parties (100% of the respondents to this question) indicated that no decisions fall into this category.



The two countries that have reported that 100% of their decisions resulted in a prohibition of the import or use of LMOs are Botswana and Fiji. Both countries only have draft domestic regulatory frameworks for the implementation of the Cartagena Protocol in place and no laws or regulations that directly apply to biosafety. Hence, the decision to prohibit LMOs might stem from precaution.

Articles 11 (Procedure for LMOs-FFP) and 13 (Simplified procedure)

15 Parties (41%) stated that they have *adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP*, 18 Parties answered '*no*', and four Parties did not respond.

14 out of 37 Parties (38% of the respondents to this question) reported that they have *taken a decision on LMOs-FFP (either on import or domestic use)*: Out of those 14 Parties that reported that they have *taken a decision on LMOs-FFP*: One Party (Philippines) reported that it has *approved to date more than 10 LMOs-FFP*; One Party (Georgia) *less than 10*; seven Parties *less than 5*; and five Parties *none*.

Only two Parties (Zimbabwe and Indonesia) reported that they have *applied the simplified procedure*, four Parties did not respond and 31 parties responded *'no'.*

Article 14 ***(Bilateral, regional and multilateral agreements and arrangements)***

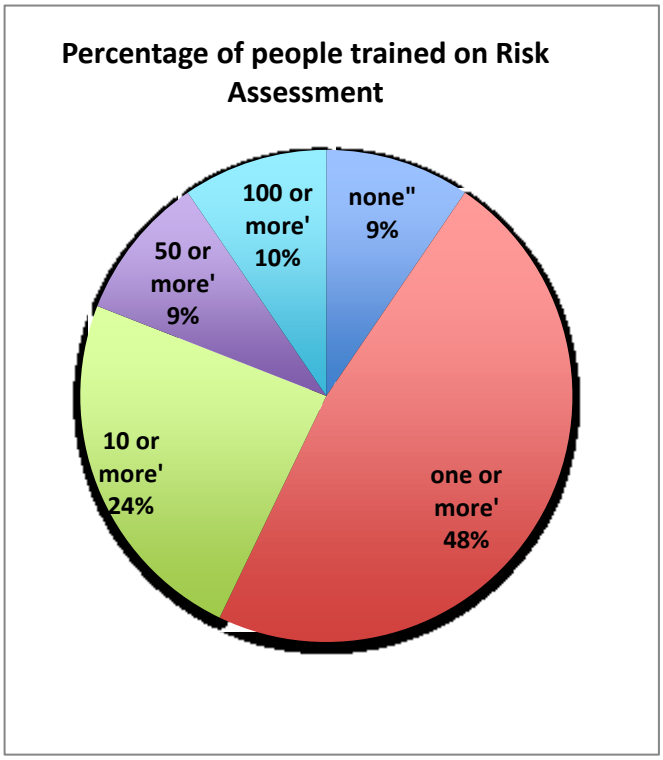
6 Parties (16% of the respondents to this question) reported that they have *entered into bilateral, regional or multilateral agreements or arrangements.* These Parties were invited to provide a brief description of the scope and objective of agreements or arrangements entered into:

Country	**Description of arrangement**
Belarus	Technical Regulations of the Customs Union of the EurAsEC CU TR 021/2011 and CU TR 022/2011 are in effect within a framework of the Technical Regulations of the EAEU Customs Union.
DRC	Dans le cadre du Marché Commun pour l'Afrique de l'Est et Australe (COMESA) auquel la RD Congo est Partie, les politiques et les directives pour manipuler les cultures commerciales génétiquement modifiées, le commerce des OVM et l'aide alimentaire d'urgence contenant les OVM ont été développées et adoptées. Les politiques et les directives COMESA reconnaissent dûment la souveraineté et l'existence de lois et des politiques nationales de biosécurité. Un comité d'experts (PoE) a été établi en tant que comité permanent de guidage des politiques au sein du COMESA pour les domaines liés aux biotechnologies et à la biosécurité.
Indonesia	There has been a guidelines on risk assessment of GMO in ASEAN Region and GM Food testing Network ASEAN; Research on rice on green house gas emission, tomatoes resistant to virus disease.
Niger	REGIONAL AGREEMENTS WITH WEST AFRICAN ECONOMIC COMMUNITY (ECOWAS) AND WEST AFRICAN MONETERY UNION (UEMOA) INCLUDING DIRECTIVES AND REGULATIONS
Rwanda	Rwanda belongs to different organizations: CEPGL, EAC, COMESA. Members States of the EAC have an Environment Protocol, which covers all aspects related to the environment in general and Biosafety. The COMESA treaty calls for member states to among others: establish a customs union; and simplify and harmonize their trade documents and procedures. Key priorities for COMESA in consolidating its strategic objectives include implementing major programs in infrastructure, trade and agriculture. The importance of regional cooperation in harnessing the technology safely and responsibly and handling of other GMO related issues is evident from the experience of other global regional blocs. In cognizance of this reality, COMESA endorsed in 2003 the implementation of the RABESA initiative (Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa), which has the objective of supporting harmonization of biosafety policies among its member states.

Zimbabwe	Zimbabwe is a member of COMESA and has signed the COMESA Policy on Biotechnology and Biosafety. The policy seeks to provide a mechanism for harmonizing matters to do with emergency food aid, commercial planting and trade of GMOs. Zimbabwe is a member of SADC. An Advisory Committee for Biotechnology and Biosafety exists within SADC. The Committee's recommendations guiding the region on handling of food aid, policy regulations, capacity building and public awareness and participation were approved by SADC in 2003. SADC has recommended the region to develop a harmonized policy and regulatory system based on the African Biosafety Model law, the Cartagena Protocol on Biosafety and other relevant international processes.

Article 16 ***(Risk management)***

The Third National Report asks for the *number of people who have been trained on Risk Assessment*. Out of 22 Parties, two responded '*none'*, ten responded '*one or more'*, five responded '*10 or more'*, two Parties responded '*50 or more'* (Sudan and Ghana), and two Parties (Indonesia and Zimbabwe) responded '*100 or more'*.



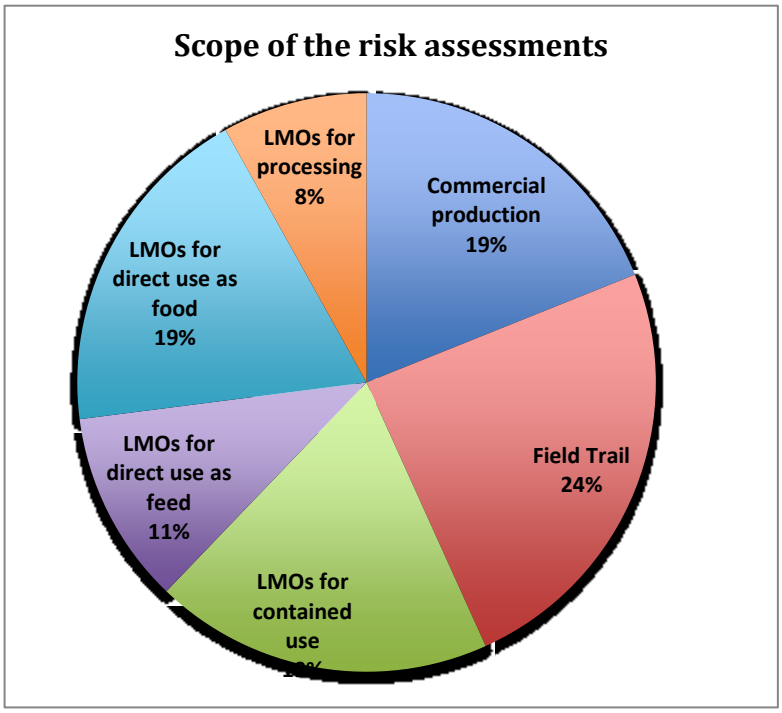
Seven out of 22 Parties (19% of the respondents to this question) answered "yes" to the questions *Is your country using the "Manual on Risk Assessment of LMOs" (developed by CBD Secretariat) for training in risk assessment*?

Asked the question *Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health?* seven Parties answered '*yes*' to all three categories. The Dominican Republic and Bangladesh answered "*no*" to every category.

Ghana responded it can only "*assess*", Kyrgyzstan, Morocco and Panama can only "*detect*", and Madagascar can only "*identify*" LMOs; Honduras can "*detect and assess*" and DRC can "*detect and identify*" LMOs.

13 Parties (35% of the respondents to this question) reported, that they have *conducted a risk assessment of an LMO,* 20 Parties (54% of the respondents to this question) responded that they have not conducted a risk assessment before, and four Parties did not respond to the question.

Countries who had answered that they had conducted risk assessments before were asked to indicate *the scope of the risk assessments* (multiple answers were possible)



Commercial production:	7 Countries
Field trail:	9 Countries
LMOs for contained use:	7 Countries
LMOs for direct use as feed:	4 Countries
LMOs for direct use as food:	7 Countries
LMOs for processing:	3 Countries

Countries who had answered that they had conducted risk assessments before were asked to indicate *how many risk assessments were conducted in the current reporting period*.

None:	1 Country (3%; Iran)
Less than 5:	7 Countries (19%)
Less than 10:	3 Countries (8%)
More than 10:	2 Countries (5%; Paraguay and Philippines)

The Third National Report asks parties to state whether they *have the infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs*. 19 Parties (86%) responded '*yes*' and 3 Parties (14%) responded '*no*' (Honduras, Madagascar and Panama). Nine of the 19 Parties (47%) that have adequate infrastructure have, however, never conducted a risk assessment.

Article 18 *(Handling, transport, packaging and identification)*

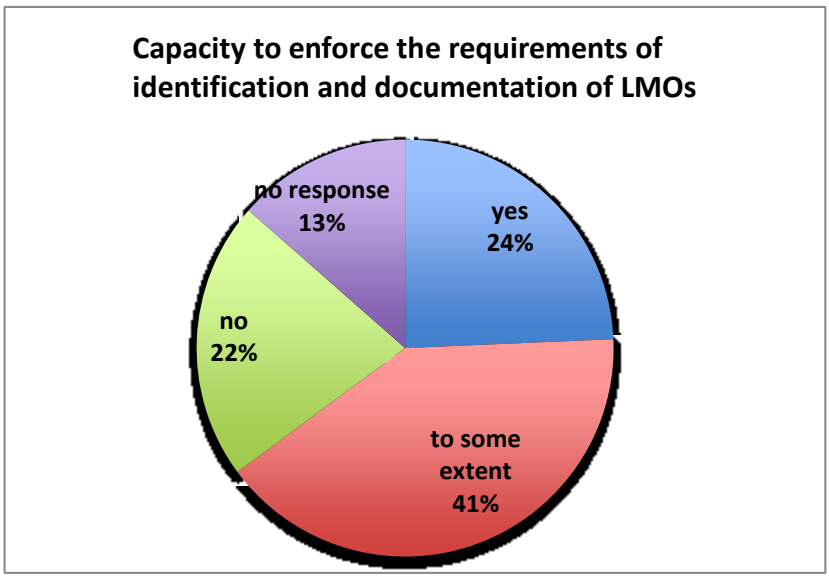
The Third National Report asks parties to state whether they have *appropriate (emergency) measures in in place should LMO be unintentionally released.* 10 out of 22 Parties (45%) responded "*yes*" and 12 Parties (55%) responded "*no*".

Eight Parties (21% of the respondents to this question) reported that they have *taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs is not known through means such as identity preservation systems, they may contain living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information*; five Parties (14% of the respondents to this question) *to some extent*; and 20 Parties (54% of the respondents to this question) reported not having done it. Four Parties (11% of the respondents to this question) did not respond.

Seven Parties (19% of the respondents to this question) reported that they have *taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs is known through means such as identity preservation systems, they contain living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information*; six Parties (16% of the respondents to this question) *to some extent*; and 20 Parties (54% of the respondents to this question) reported not having done it. Four Parties (11% of the respondents to this question) did not respond.

Nine Parties (24% of the respondents to this question) reported that they have *the capacity to enforce the*

requirements of identification and documentation of LMOs; 15 Parties (41% of the respondents to this question) *to some extent*; and eight Parties (21% of the respondents to this question) reported not having this capacity. Five Parties (14% of the respondents to this question) did not respond.



The Third National Report asks three more questions under this Article:

Ten Parties (45% of the respondents to this question) reported *no customs officers in their country have received training in the identification of LMOs*; eight Parties (36% of the respondents to this question) reported that *one or more* customs officers were trained; four Parties (18% of the respondents to this question) reported that *10 or more* were trained.

14 Parties (64% of the respondents to this question) reported that *one or more laboratory personnel in their country have received training in detection of LMOs* and eight Parties (36% of the respondents to this question) reported that *10 or more* were trained.

14 Parties reported that they have *certified laboratories that are currently operating in the detection of LMOs.* Ten Parties (71% of the respondents to this question) reported that in their countries *one or more certified laboratories are currently operating in the detection of LMOs;* three Parties (22% of the respondents to this question) reported that *5 or more* were operating in the detection of LMOs; one Party (7%, Belarus) reported that *10 or more* were operating.

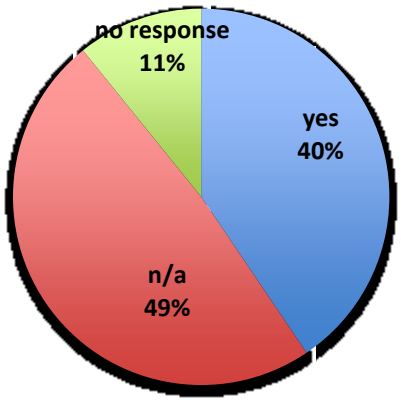
Hence, from the 19 Parties who reported to *have the infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs* only 14 (74%) are able to *detect* LMOs.

Article 19 (*Competent National Authorities*)

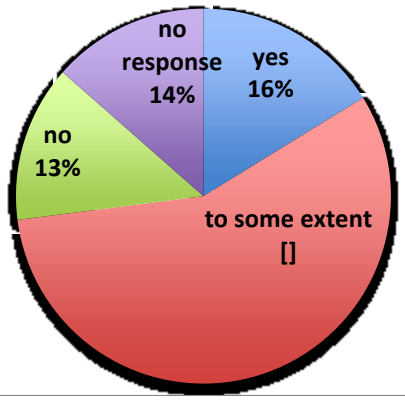
15 Parties (40% of the respondents to this question) reported that they have *established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs*.

Six Parties reported that they have *established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety*; 21 Parties reported having established adequate institutional capacity *to some extent*; and five Parties reported not having done so. Five Parties did not report on this question.

In case your country has designated more than one competent national authority, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs?



Has your country established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety?



Article 20 ***(Information Sharing and the Biosafety Clearing-House)***

Parties were asked to provide an overview of the status of the mandatory information provided by their country to the BCH by specifying for each category of information whether it is available and whether it has been submitted to the BCH.

1.

(a) *Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure* are reported to be available and in the BCH by 15 Parties (41% of the respondents to this question); available, but not or only partially available in the BCH by eleven Parties (30%); and not available by seven Parties (19%). Four Parties (11%) did not respond.

2.

(b) *National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing* are reported to be available and in the BCH by 13 Parties (35% of

the respondents to this question); not available by ten Parties (27%); and available, but not or only partially available in the BCH, by ten Parties (27%). Four Parties (11%) did not respond.

(i) *Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision)* are reported to be available and in the BCH by three Parties (8% of the respondents to this question); not available by 19 Parties (51%); and available, but not or only partially available in the BCH, by 11 Parties (30%). Four Parties (11%) did not respond.

(k) *Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing* are reported to be available and in the BCH by four Parties (11% of the respondents to this question); not available by 25 Parties (68%); and available, but not or only partially available in the BCH, by four Parties (11%). Four Parties (11%) did not respond.

(l) *Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks or in accordance with Annex III* are reported to be available and in the BCH by one Party (3% of the respondents to this question); not available by 26 Parties (70%); and available, but not or only partially available in the BCH, by 6 Parties (16%). Four Parties (11%) did not respond.

Seven Parties (19% of the respondents to this question) reported that they use *the information available in the BCH in their decision-making processes on LMOs*; 14 Parties (38% of the respondents to this question) reported doing so *in some cases*; and nine Parties (24% of the respondents to this question) reported that they do not use it. Seven Parties (19%) did not report.

The Third National Report asks Parties about the *number of regional, national and international events organized in relation to biosafety (e.g. seminars, workshops, press conferences, educational events, etc.,) in the last 2 years*. Out of 22 Parties, eight Parties (36%) reported "*one or more*", eight Parties (36%) reported "*5 or more*", four Parties (18%) reported "*10 or more*", and two Parties (9%) reported "*25 or more*".

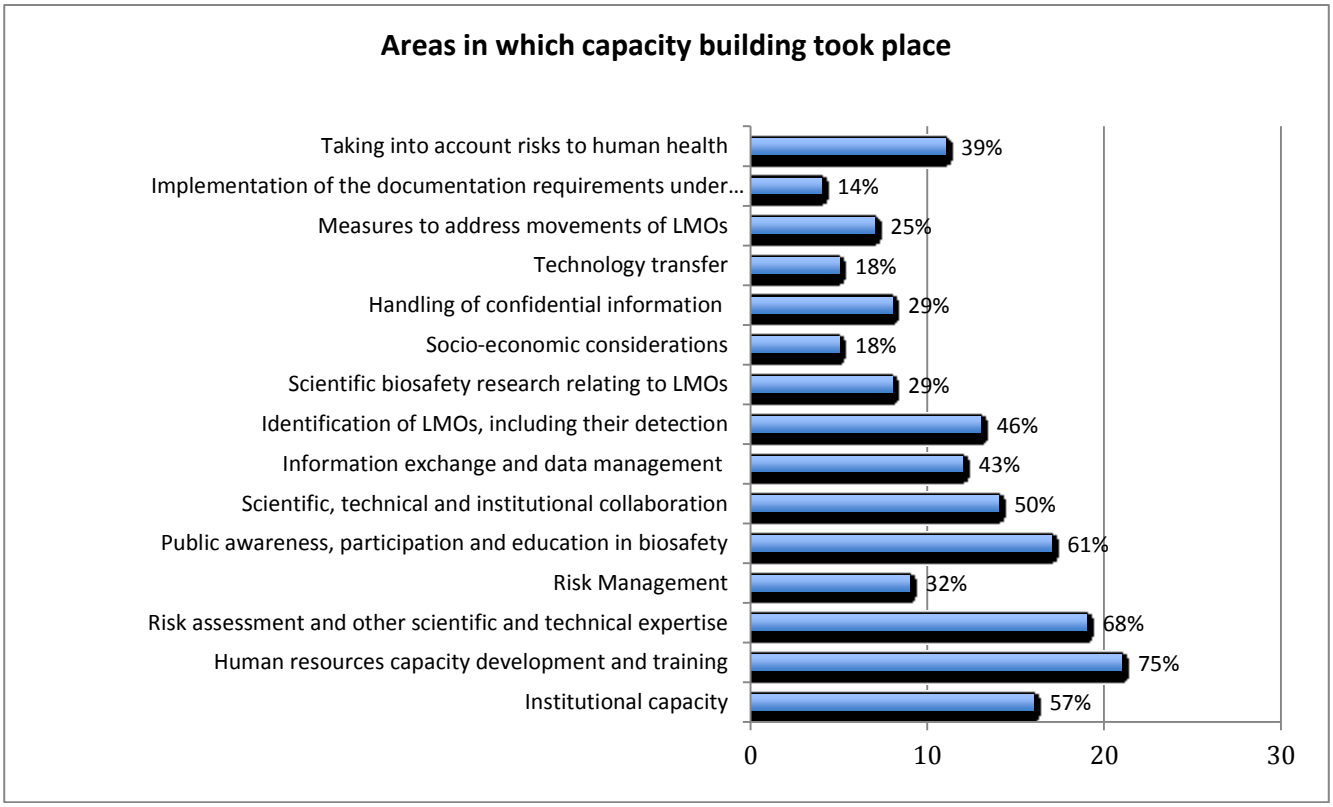
It also asks parties about the *number of publications on Biosafety made available in the last year.* Six Parties (27%) reported "*none*", ten Parties (45%) reported "*one or more*", and six Parties (27%) reported "*10 or more*" publications.

Article 22 *(Capacity-building)*

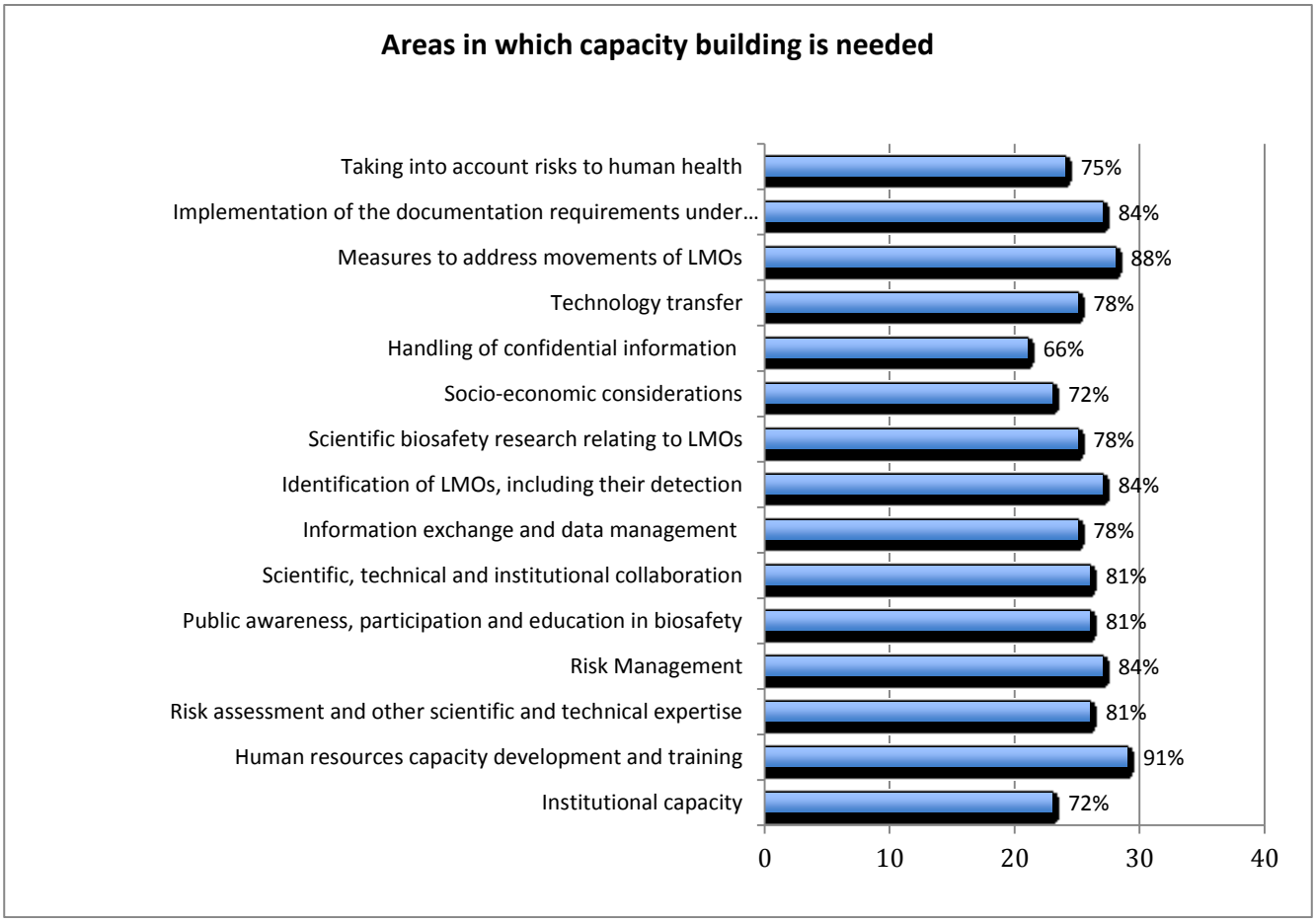
25 out of 37 Parties, which reported having *received external support or benefited from collaborative activities with other Parties*, were asked to indicate how the support has been made available. Five Parties (14% of the 37 Parties) refer to *bilateral channels*; ten Parties (27%) refer to *regional channels*; and ten Parties (27%) to *multilateral channels*.

Ten Parties, which reported having *provided support to other Parties*, were asked to indicate how the support has been made available. Four Parties (11% of the 37 Parties) of the responses refer to support through *bilateral channels*; two (5%) to *regional channels*; and four (11%) to *multilateral channels*.

28 Parties (76% of the respondents to this question) reported that, *during the current reporting period,* they have *undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety.* These 28 parties were asked to indicate *in which areas those activities were undertaken. The questionnaire* allows each respondent to provide multiple answers. The following are the percentages of the responses relating to the different areas:



The 32 Parties which reported still having capacity-building needs were asked to indicate *in which areas they still need capacity-building*. The following are the percentages of responses received*:*



Six Parties (16% of the respondents to this question) reported that they have *developed a capacity-building strategy or action plan.*

Twelve Parties (32% of the respondents to this question) reported that they have *submitted the details of their national biosafety experts to the Roster of Experts in the BCH.*

The Third National Report asks *how many biosafety short-term training programmes and/or academic courses are offered annually* in the countries. Seven Countries (32%) reported "none", five (23%) Countries reported "less than one per year", nine Countries (41%) reported "one per year or more", and one Country (5%) reported "5 per year or more".

Article 23 ***(Public awareness and participation)***

Eleven out of 22 Parties (50%) that submitted the Third National Report responded that they have an *awareness and outreach programmes on biosafety* in their country.

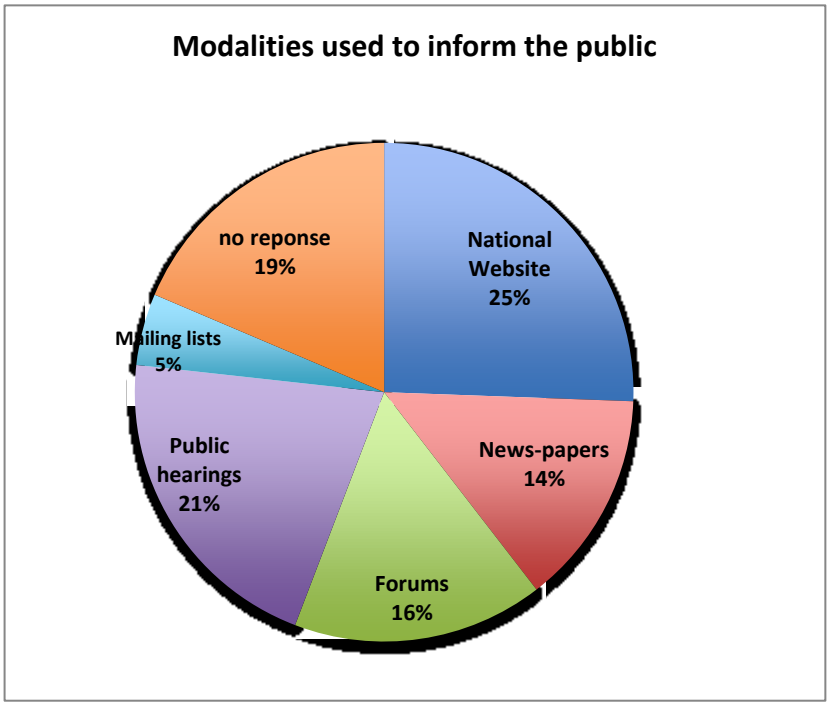
Twelve Parties out of 37 (32% of the respondents to this question) reported that they have *established a biosafety website.*

Nine Parties (24% of the respondents to this question) reported that they have *established a mechanism to ensure public access to information on living modified organisms that may be imported*; nine Parties (24% of the respondents to this question) reported having done so *to a limited extent*; and 15 Parties (41% of the

respondents to this question) reported that they have not established such a mechanism. Four Parties (11%) did not respond.

Twelve Parties (32% of the respondents to this question) reported that they have *established a mechanism to make available to the public the results of decisions taken on LMOs*; eleven Parties (30% of the respondents to this question) reported that have done so *to a limited extent*; and ten Parties (27% of the respondents to this question) reported that they have not established such a mechanism. Four Parties (11%) did not respond.

The Third National Report asked three more question under this Article. The first one asked Parties to indicate *the modalities used to inform the public.*



The chart shows the modalities used by percentage. Twelve Parties indicated to use more then one mode of informing the public, two Parties indicated only one mode and eight Parties did not respond.

The second question asks Parties *How many academic institutions in your country are offering biosafety education and training courses and programmes.* Five Parties (23%) reported "none", nine Parties (41%) reported "one or more", five Parties (23%) reported "three or more", two Parties (Iran and Rwanda, 9%)reported "five or more", and one Party (Indonesia, 5%) reported "ten or more".

Thirdly, Parties were asked to *indicate the number of educational materials and/or online modules on biosafety that are available and accessible to the public in your country*. Seven Parties (32%) reported "none", nine Parties (41%) reported "one or more", two Parties (9%) reported "five or more", two Parties (Ghana and Indonesia, 9%) reported "ten or more", and two Parties (Belarus and Romania, 9%) reported "25 or more".

Articles 25 *(Illegal transboundary movements),* 26 (Socio-economic considerations), and 28 (Financial Mechanism and Resources)

Eight Parties (22% of the respondents) reported having *established a strategy for detecting illegal transboundary movements of LMOs,* three Parties (8%) reported "to some extent", and 22 Parties (60%) reported "no". Four Parties (11%) did not report.

Five Parties (14% of the respondents to this question) reported that*, when taking a decision on import,* they have *taken into account socio-economic considerations arising from the impact of the LMO on the conservation and sustainable use of biological diversity*; or in LMO decision making in general. Four of them provided the following details:

Honduras	Se ha tomado en cuenta las evaluaciones relacionadas con los híbridos de maíz y su impacto en la economía de los productores.
Indonesia	National Biosafety Committee has established a special team for socio-economic and law culture. This team provides the consideration related to law, socio-economic and culture for GMO's, which are assessed to be released.
Niger	EXISTING OF 3N STRATEGY FOR RURAL DEVELOPMENT TAKING INTO ACCOUNT SOCIOECONOMIC CONSIDERATIONS.
Zimbabwe	The National Biotechnology Authority Act has provisions for taking into account socioeconomic considerations. Zimbabwe's scope for the socioeconomic considerations is much wider than that of the Protocol. Specific approaches or requirements that facilitate how socio-economic considerations should be taken into account in LMO decision-making are not available since the matter is highly contentious at national and regional level. Hence this complicates decision.

Two Parties (5% of the respondents to this question) reported that they have *cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs*; three Parties (8% of the respondents to this question) reported doing so *to a limited extent*; and 28 Parties (76% of the respondents to this question) reported that they have not *cooperated with other Parties* in this regard. Four parties (11%) did not report.

The Third National Report asks *how much additional funding (in the equivalent of US dollars) has your country mobilized in the last four years to support implementation of the Biosafety Protocol, beyond the regular national budgetary allocation*. Two Parties (9%) reported “less than 5,000 USD”, five Parties (23%) reported “5,000 USD or more”, three parties reported “50,000 or more”, five parties reported “500,000 USD or more”, one Party (Ghana, 5%) reported 1,000,000 USD or more). Seven parties reported “not applicable”.

Annex 17. Synoptic Table of GEF support (Projects) on Biosafety by country

Capacity building activities funded by the GEF in biosafety

Data extracted from the GEF project database (last update January 2012).

Regions: Africa | Asia-Pacific | CEE | GRULAC | WEOG

Total count

Regions / Countries	GEF STAR-BD Eligible	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Africa: 53	52	49	10	39	4	14	47	23	5
Asia-Pacific: 56	46	41	2	36	3	13	30	11	-
CEE: 23	15	22	4	18	2	7	16	1	-
GRULAC: 33	33	29	2	28	3	6	27	15	17
WEOG: 30	1	21	-	2	-	1	2	-	-
Total: 195	**147**	**162**	**18**	**123**	**12**	**41**	**122**	**50**	**22**

CBD Region: Africa (AFR)

Regions / Countries	GEF Eligible (BD)	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Algeria	x	x		x			x	x	
Angola	x	x		x			x		
Benin	x	x		x			x	x	Imp-

									WAfr
Botswana	x	x		x			x		
Burkina Faso	x	x		x			x	x	Imp-WAfr
Burundi	x	x		x			x		
Cameroon	x	x	x		x				
Cape Verde	x	x		x			x		
Central African Republic	x	x		x			x	x	
Chad	x	x		x			x	x	
Comoros	x	x		x			x	x	
Congo	x	x		x			x		
Congo, Democratic Republic of the	x	x		x			x	x	
Côte d'Ivoire	x			x			x		
Djibouti	x	x		x			x		
Egypt	x	x	x			x	x		
Equatorial Guinea	x						x		
Eritrea	x	x		x			x		
Ethiopia	x	x		x		x	x	x	
Gabon	x	x		x			x		
Gambia	x	x		x			x		
Ghana	x	x		x		x	x	x	
Guinea	x	x		x			x	x	
Guinea-Bissau	x	x		x			x		

Kenya	x	x	x		x				
Lesotho	x	x		x		x	x	x	
Liberia	x	x		x		x	x	x	
Libyan Arab Jamahiriya	x	x		x			x	x	
Madagascar	x	x		x		x	x	x	
Malawi	x	x	x				x		
Mali	x	x		x			x		Imp-WAfr
Mauritania	x	x	x				x	x	
Mauritius	x	x	x			x	x	x	
Morocco	x	x		x			x		
Mozambique	x	x		x		x	x		
Namibia	x	x	x		x	x			
Niger	x	x		x			x	x	
Nigeria	x	x		x		x	x	x	
Rwanda	x	x		x		x	x		
Sao Tome and Principe	x						x		
Senegal	x	x		x			x	x	Imp-WAfr
Seychelles	x	x		x			x		
Sierra Leone	x			x			x		
Somalia		x							
South Africa	x	x					x		
Sudan	x	x		x			x	x	

Swaziland	x	x		x		x	x	x	
Tanzania, United Republic of	x	x		x		x	x		
Togo	x	x		x			x	x	Imp-WAfr
Tunisia	x	x	x			x	x	x	
Uganda	x	x	x		x				
Zambia	x	x	x				x		
Zimbabwe	x	x		x					

CBD Region: Asia Pacific (AP)

Regions / Countries	GEF Eligible (BD)	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Afghanistan	x								
Bahrain									
Bangladesh	x	x		x		x	x		
Bhutan	x	x		x		x	x	x	
Brunei Darussalam									
Cambodia	x	x		x		x	x	x	
China	x	x	x		x				
Cook Islands	x			x					
Cyprus		x							
Fiji	x	x		x			x		
India	x	x			x	x		x	

Indonesia	x	x		x		x	x		
Iran, Islamic Republic of	x	x		x		x	x		
Iraq	x								
Japan		x							
Jordan	x	x		x		x	x	x	
Kazakhstan	x	x		x			x		
Kiribati	x	x		x			x		
Korea, Democratic People's Republic of	x	x		x			x		
Korea, Republic of	x	x		x					
Kuwait									
Kyrgyzstan	x	x		x			x		
Lao People's Democratic Republic	x	x		x		x	x	x	
Lebanon	x			x			x		
Malaysia	x	x			x			x	
Maldives	x	x		x			x		
Marshall Islands	x	x		x			x		
Micronesia, Federated States of	x			x					
Mongolia	x	x		x		x	x		
Myanmar	x	x		x			x		
Nauru	x	x		x					
Nepal	x			x			x		
Niue	x	x		x					

Oman		x							
Pakistan	x	x	x				x		
Palau	x	x		x			x		
Papua New Guinea	x	x		x			x		
Philippines	x	x		x			x	x	
Qatar		x							
Samoa	x	x		x			x		
Saudi Arabia		x							
Singapore									
Solomon Islands	x	x		x					
Sri Lanka	x	x		x			x		
Syrian Arab Republic	x	x		x		x	x	x	
Tajikistan	x	x		x		x	x		
Thailand	x	x		x			x		
Timor-Leste	x								
Tonga	x	x		x			x	x	
Turkmenistan	x	x				x			
Tuvalu	x								
United Arab Emirates									
Uzbekistan	x								
Vanuatu	x			x					
Viet Nam	x	x		x		x	x	x	
Yemen	x	x		x			x	x	

CBD Region: Central and Eastern Europe (CEE)

Regions / Countries	GEF Eligible (BD)	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Albania	x	x		x		x	x		
Armenia	x	x		x			x		
Azerbaijan	x	x		x			x		
Belarus	x	x		x			x		
Bosnia and Herzegovina	x	x							
Bulgaria	x	x	x		x				
Croatia	x	x		x			x		
Czech Republic		x		x		x	x		
Estonia		x		x		x	x		
Georgia	x	x		x					
Hungary		x	x						
Latvia		x		x			x		
Lithuania		x		x		x	x		
Macedonia, The Former Yugoslav Republic of	x	x		x		x	x		
Moldova, Republic of	x	x		x		x	x	x	
Montenegro	x	x		x			x		
Poland		x	x		x				
Romania	x	x		x			x		

Russian Federation	x		x						
Serbia	x	x		x					
Slovakia		x		x		x	x		
Slovenia		x		x			x		
Ukraine	x	x		x			x		

CBD Region: Latin America and Caribbean (GRULAC)

Regions / Countries	GEF Eligible (BD)	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Antigua and Barbuda	x	x		x			x	x	Imp-Car
Argentina	x			x					
Bahamas	x	x		x			x		Imp-Car
Barbados	x	x		x			x		Imp-Car
Belize	x	x		x			x	x	Imp-Car
Bolivia	x	x	x						
Brazil	x	x					x		LAM-PubAw LAM-Compl
Chile	x			x					
Colombia	x	x			x				LAM-PubAw LAM-Compl
Costa Rica	x	x		x		x	x	x	LAM-PubAw

									LAM-Compl
Cuba	x	x	x		x	x		x	
Dominica	x	x		x			x		Imp-Car
Dominican Republic	x	x		x			x	x	
Ecuador	x	x		x		x	x	x	
El Salvador	x	x		x			x		
Grenada	x	x		x			x		Imp-Car
Guatemala	x	x		x		x	x	x	
Guyana	x	x		x			x	x	Imp-Car
Haiti	x			x			x		
Honduras	x	x		x			x	x	
Jamaica	x			x			x		
Mexico	x	x			x				LAM-Compl
Nicaragua	x	x		x			x		
Panama	x	x		x		x	x	x	
Paraguay	x	x		x			x		
Peru	x	x		x		x	x	x	LAM-PubAw LAM-Compl
Saint Kitts and Nevis	x	x		x			x	x	Imp-Car
Saint Lucia	x	x		x			x	x	Imp-Car
Saint Vincent and the Grenadines	x	x		x			x	x	Imp-Car

Suriname	x	x		x			x		Imp-Car
Trinidad and Tobago	x	x		x			x		Imp-Car
Uruguay	x	x		x			x		
Venezuela	x	x		x			x	x	

CBD Region: Western Europe and Other Groups (WEOG)

Regions / Countries	GEF Eligible (BD)	CPB Parties	GEF Capacity Building funded projects						
			Pilot project (1)	NBF-Dev (2)	NBF-Imp Demo) (3)	NBF-imp (4)	BCH-I (5)	BCH-II (6)	Regional Projects (7)
Andorra									
Australia									
Austria		x							
Belgium		x							
Canada									
Denmark		x							
European Union		x							
Finland		x							
France		x							
Germany		x							
Greece		x							
Iceland									
Ireland		x							
Israel									

Italy		x							
Liechtenstein									
Luxembourg		x							
Malta		x		x			x		
Monaco									
Netherlands		x							
New Zealand		x							
Norway		x							
Portugal		x							
San Marino									
Spain		x							
Sweden		x							
Switzerland		x							
Turkey	x	x		x		x	x		
United Kingdom of Great Britain and Northern Ireland		x							
United States of America									

Note: The exact name of the GEF funded projects are the following:

(1) Pilot Biosafety Enabling Activity (Pilot project, 1998-2000);
(2) Development of National Biosafety Frameworks (NBF-Dev, 2001-2007);
(3) Support to the Implementation of the National Biosafety Frameworks (NBF-Imp-Demo, 2002-2006);
(4) Support to the Implementation of the National Biosafety Frameworks (NBF-Imp, 2002-ongoing);
(5) Building Capacity for Effective Participation in the Biosafety Clearing House BCH (BCH-I, 2004-2008);
(6) UNEP-GEF Project for Continued Enhancement of Building Capacity for Effective Participation in the BCH (BCH-II, 2010-2012);
(7) Regional projects: West African Regional Biosafety Program (Imp-WAfr, 2007-2012); Latin-America: Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety (LAM-PubAw, 2008-2011); Latin America: Multi-country Capacity-building for Compliance with the Cartagena Protocol on Biosafety (LAM-Compl, 2008-2011).

Annex 18. Overall GEF-UNEP Portfolio (2001-2015)

The total amount allocated by GEF to UNEP for Biosafety until 2005 is visualised in the Table below:

Project	Number of countries	Allocation (USD millions)
Pilot Phase	18	2,7
NBF Development	100	26,1
NBF Development add –on 1	20	5,2
NBF Development add –on 2	3 (10)	2,6
Implementation Projects	8	4,2
BCH Mechanism	50	4,6
BCH mechanism add-on 1	89	8,9
Total		**54,3**

The amount allocated by GEF to UNEP has roughly duplicated from 2005 to 2015 (plus 52,4M USD) up to the current 106,7M USD , as the following Table shows:

Project	Number of countries	Allocation (USD millions)
Implementation Projects (closed, under implementation or approved)	44	35,3
Reg. Project Impl. Caribbean	12 (14)	5.9
2nd Nat. Report	na	2,9
BCH	na	4,7
3rd Nat Report	na	3,6
Total		**52,4**

Annex 19. List of staff of Project Management Team (2003)

(extract from the Explanatory Note from UNEP to GEF) (Source: ANUBIS)

The current technical staffing of the project with all these additions is now as below:

1) Global Manager and as Regional Coordinator responsible overall for 19 CEE Countries
2) Assistant Regional Coordinator for CEE Region is responsible for 19 CEE countries.
3) Administrative and Financial Manager, Geneva is responsible for all finances and administrative matters for 120+ countries.
4) Financial Manager, Nairobi is responsible for internalization of all finances in UNON and handling of cash requests and advances for 120+countries.
5) Regional Coordinator for Africa Region is responsible for 20 Anglophone Countries and overall for 39 African countries
6) Assistant Regional Coordinator for Francophone Africa is responsible for 19 Francophone Countries
7) Regional Coordinator for Asia-Pacific Region is responsible for 22 Asian countries and overall for 36 Asia-Pacific countries
8) Assistant Regional Coordinator is responsible for 14 Pacific Island countries
9) Regional Coordinator, GRULAC is responsible for 29 Latin American and Caribbean countries
10) Workshop Manger is responsible for handling all organization of the 12 subregional workshops reporting to Financial Manager.
11) Information Officer is responsible for all informational needs of project.

Annex 20. Project duration by country (37 sample countries)

○

ANNEX 20 DATES AND DURATION OF PROJECT PHASES / country (see chapter on Efficiency in the main Report)

Country	Commencement date (B)	Operational starting date (C)	Time between Commence date and Operational start in days (C-B)	Granted extensions (months)	Completion date (F)	Time from Operational Start to Completion (months) (F-C)	UNEP Project closure (H)	Time between Completion and UNEP closure in days (H-F)	ANUBIS closure (I)	Time between Completion and Anubis closure in days (I-F)
Armenia	22/07/2002	01/01/2003	163	22	03/11/2005	35	20/02/2012	2300	16/04/2012	2356
Bangladesh	31/07/2003	22/10/2003	83	32	12/12/2006	38	22/08/2008	619	15/12/2010	1464
Belarus	21/11/2002	01/01/2003	41	3	06/12/2004	24	26/01/2006	416	15/10/2009	1774
Botswana	07/08/2002	12/12/2002	127	64	10/08/2006	45	16/12/2010	1589	15/09/2011	1862
Chad	24/11/2005	08/03/2006	104	28	15/05/2008	27	09/05/2011	1089	02/11/2011	1266
Demo R Congo	02/12/2004	23/11/2004	-9	36	06/12/2007	37	05/07/2010	942	10/05/2011	1251
Dominican Republic	30/06/2003	20/08/2003	51	42	26/02/2008	55	14/04/2010	778	06/09/2010	923
DPRK	28/02/2002	24/04/2002	55	11	20/09/2004	29	27/09/2005	372	15/10/2009	1851
Ethiopia	31/10/2002	13/11/2002	13	62	05/09/2007	59	12/04/2011	1315	10/05/2011	1343
Fiji	10/04/2003	02/05/2003	22	39	03/11/2011	104	08/06/2012	218	23/01/2013	447
Georgia	28/08/2002	04/10/2002	37	15	04/07/2005	33	30/11/2009	1610	10/05/2011	2136
Ghana	02/09/2002	04/11/2002	63	7	26/09/2004	23	06/02/2008	1228	10/07/2009	1748
Honduras	31/10/2002	15/01/2003	76	48	28/11/2007	59	08/01/2010	772	21/04/2011	1240
Indonesia	02/08/2002	23/08/2002	21	5	22/10/2004	26	21/01/2006	456	15/10/2009	1819
Iran	29/11/2002	10/03/2003	101	4	31/10/2004	20	08/03/2006	493	14/09/2011	2509

Kyrgyztan	07/04/2003	10/07/2003	94	22	23/11/2005	29	14/10/2008	1056	13/04/2010	1602
Madagascar	15/08/2002	30/08/2002	15	11	16/10/2004	26	03/02/2009	1571	25/03/2011	2351
Morocco	05/02/2004	09/02/2004	4	51	15/07/2009	66	16/03/2011	609	12/07/2011	727
Mozambique	23/09/2002	30/08/2002	-24	69	21/07/2005	35	23/02/2010	1678	10/05/2011	2119
Myanmar	28/07/2003	27/05/2004	304	29	06/12/2006	31	20/07/2009	957	10/05/2011	1616
Nepal	30/06/2004	25/06/2004	-5	42	01/03/2007	33	14/12/2009	1019	10/05/2011	1531
Nicaragua	31/10/2002	11/12/2002	41	56	31/03/2008	65	22/08/2012	1605	14/01/2014	2115
Niger	07/02/2002	22/02/2002	15	28	19/01/2005	35	06/07/2010	1994	10/05/2011	2302
Panama	23/06/2003	13/05/2005	690	99	27/03/2008	35	not closed	0	not closed	0
Papua New Guinea	31/03/2003	23/07/2003	114	38	10/11/2005	28	04/11/2010	1820	10/05/2011	2007
Paraguay	01/07/2003	18/09/2003	79	45	11/10/2007	49	18/03/2011	1254	14/09/2011	1434
Peru	23/01/2003	07/03/2003	43	20	28/02/2006	36	14/12/2009	1385	14/09/2010	1659
Philippines	02/10/2002	15/10/2002	13	5	14/02/2005	28	21/09/2005	219	15/10/2009	1704
Romania	23/06/2003	30/03/2004	281	4	20/02/2006	23	14/04/2010	1514	08/07/2010	1599
Rwanda	23/01/2003	25/04/2003	92	50	30/08/2005	29	05/07/2010	1770	10/05/2011	2079
Sudan	14/11/2002	06/07/2003	234	49	20/12/2005	30	08/09/2009	1358	19/09/2010	1734
Thailand	27/01/2006	27/01/2006	0	17	11/03/2009	38	07/01/2010	302	10/05/2011	790
Urugay	02/02/2004	13/05/2004	101	30	27/11/2007	43	08/09/2009	651	14/09/2011	1387
Vanuatu	20/01/2003	19/05/2003	119	84	12/12/2005	31	12/03/2012	2282	16/04/2012	2317
Ukraine	29/11/2002	13/04/2003	135	58	09/07/2009	76	02/02/2012	938	16/04/2012	1012
Venezuela	11/08/2003	11/12/2003	122	13	23/02/2006	27	20/07/2009	1243	07/09/2011	2022
Zimbabwe	08/10/2002	30/10/2002	22	89	13/10/2010	97	11/10/2011	363	02/11/2011	385
				Average duration (months between Start and Completion of Operations): **37,5**						

Average # of days between signature and start of ops	**93**

Average # of days between completion and a) UNEP closure, b) Anubis closure	**1075**		**1581**

Annex 21 Integration of Biosafety into UNEP Divisions – DELC or DEPI

(unofficial paper provided by UNEP Biosafety Unit)

The UNEP Biosafety Portofolio is guided by the current BS Strategy 2011 – 2020, which is mainly focused on the strengthening capacity of parties to implement the protocol and have direct bearing on the PoW in the area of Environmental Governance and Ecosystems Management.

The keys issues to consider

Division	Pros	Cons
DELC	• Implementation of the Biosafety Protocol is a conventions related issue. • Implementation of the National Biosafety Framework have direct bearing on normative convention related issues including implementation of BS decisions at the COP/MOPs and feedback of field data and experiences to the work of the SCBD and the Bureau. • Potential for leveraging additional resources for a UNEP Biosafety Programme based on complementarity with the PoW on Environmental Governance on global interventions to ensure safe transboundary movements of Living Modified Organisms • Joint inertia to provide support for the early entry into force of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety	Potential Firewalling issue – IA versus EA issues [DELC is already executing the BCH II (and follow up BCH projects). And could also be executing a potential Liability and Redress project to provide support to enable countries The Biosafety team would need administration support which was shared with the BD/LD group (in DGEF) but the group will be sitting in DEPI
DEPI	Potential to implement convention related issues including BD activities which are currently on going Current biosafety projects are focusing on technical and institutional capacity building beyond implementation of regulatory regimes (environmental law) – these tailor specific issues could benefit from	Potential synergies with Environmental Law and Conventions could be lost due to limited capacity on normative convention related issues

	related ecosystem interventions handled by DEPI Potential to develop a UNEP Biosafety program aimed at providing leadership beyond convention related issues to mainstreaming biosafety related policies and tools into the national/global policy agenda on safe use of modern biotechnology Provide IA roles separate from EA roles handled by countries and other Divisions as required in maintaining the firewall including rapid Assessments, environmental governance issues etc. as envisaged in the PoW Strengthened GEF inertia for the synergies and combined effort including backstopping on project management with the GEF BD/LD group	

Annex 22: UNEP Evaluation Quality Assessment

Evaluation of the Project: Global Biosafety project

All UNEP evaluations are subject to a quality assessment by the Evaluation Office. The quality assessment is used as a tool for providing structured feedback to the evaluation consultants.

The quality of both the draft and final evaluation report is assessed and rated against the following criteria:

	UNEP Evaluation Office Comments	Draft Report Rating	Final Report Rating
Substantive report quality criteria			
A. ***Quality of the Executive Summary**: Does the executive summary present the main findings of the report for each evaluation criterion and a good summary of recommendations and lessons learned? (Executive Summary not required for zero draft)*	Final report:		5
B. ***Project context and project description**: Does the report present an up-to-date description of the socio-economic, political, institutional and environmental context of the project, including the issues that the project is trying to address, their root causes and consequences on the environment and human well-being? Are any changes since the time of project design highlighted? Is all essential information about the project clearly presented in the report (objectives, target groups, institutional arrangements, budget, changes in design since approval etc.)?*	Draft report: Good overview, changes described and precise presentation of key points. Final report: Same as above	6	6
C. ***Strategic relevance**: Does the report present a well-reasoned, complete and evidence-based assessment of strategic relevance of the intervention in terms of relevance of the project to global, regional and national environmental issues and needs, and UNEP strategies and programmes?*	Draft report: Very good analysis building on previous evaluations as well as project in itself Final report: Same as above	6	6
D. ***Achievement of outputs**: Does the report present a well-reasoned, complete and evidence-based assessment of outputs delivered by the intervention (including their quality)?*	Draft report: Detailed assessment Final report: Same as above, based on sample due to size of the project	5	5

E. ***Presentation of Theory of Change**: Is the Theory of Change of the intervention clearly presented? Are causal pathways logical and complete (including drivers, assumptions and key actors)?*	Draft report: ToC was of good quality and subject of extensive analysis taking into account effectiveness of portfolio so far Final report: Same as above	6	6
F. ***Effectiveness - Attainment of project objectives and results**: Does the report present a well-reasoned, complete and evidence-based assessment of the achievement of the relevant outcomes and project objectives?*	Draft report: Yes, very detailed assessment Final report: Same as above	6	6
G. ***Sustainability and replication**: Does the report present a well-reasoned and evidence-based assessment of sustainability of outcomes and replication / catalytic effects?*	Draft report: Yes all dimensions considered Final report: Same as above	5	5
H. ***Efficiency**: Does the report present a well-reasoned, complete and evidence-based assessment of efficiency? Does the report present any comparison with similar interventions?*	Draft report: Yes, including comparison and detailed analysis Final report: Same as above	6	6
I. ***Factors affecting project performance**: Does the report present a well-reasoned, complete and evidence-based assessment of all factors affecting project performance? In particular, does the report include the actual project costs (total and per activity) and actual co-financing used; and an assessment of the quality of the project M&E system and its use for project management?*	Draft report: Good analysis Final report: Good analysis, considering constraints due to time elapsed since end of the activities.	5	5
***J. Quality of the conclusions:** Do the conclusions highlight the main strengths and weaknesses of the project, and connect those in a compelling story line?*	Draft report: Conclusions highlight key points Final report: Same as above	5	5
K. ***Quality and utility of the recommendations**: Are recommendations based on explicit evaluation findings? Do recommendations specify the actions necessary to correct existing*	Draft report: R are targeted Final report: R are targeted and cover scope for improvements in terms of UNEP internal	6	6

conditions or improve operations ('who?' 'what?' 'where?' 'when?)'. Can they be implemented?	organisational structure		
L. ***Quality and utility of the lessons**: Are lessons based on explicit evaluation findings? Do they suggest prescriptive action? Do they specify in which contexts they are applicable?*	Draft report: Lessons are very detailed and summarise experience of UNEP in biosafety so far (15 years) Final report: Same as above	6	6
Report structure quality criteria			
M. ***Structure and clarity of the report**: Does the report structure follow EO guidelines? Are all requested Annexes included?*	Draft report: Very good structure Final report: Same as above	6	6
N. ***Evaluation methods and information sources**: Are evaluation methods and information sources clearly described? Are data collection methods, the triangulation / verification approach, details of stakeholder consultations provided? Are the limitations of evaluation methods and information sources described?*	Draft report: Yes good description Final report: Same as above	5	5
O. ***Quality of writing**: Was the report well written? (clear English language and grammar)*	Draft report: Good writing style, minor editing required Final report: Same as above	5	6
P. ***Report formatting**: Does the report follow EO guidelines using headings, numbered paragraphs etc.*	Draft report: Yes well layouted and formatted report Final report: Same as above	6	6
	OVERALL REPORT QUALITY RATING	5.6	5.7

The quality of the evaluation process is assessed at the end of the evaluation and rated against the following criteria:

	UNEP Evaluation Office Comments		Rating
Evaluation process quality criteria			
Q. ***Preparation:** Was the evaluation budget agreed and approved by the EO? Was inception report delivered*	Yes and budget was sufficient for a comprehensive analysis, inception report delivered on time		5

	and approved prior to commencing any travel?			
R.	***Timeliness:*** *Was a TE initiated within the period of six months before or after project completion? Was an MTE initiated within a six month period prior to the project's mid-point? Were all deadlines set in the ToR respected?*	Yes, it took longer than expected to conduct the data analysis for a sample of the 123 countries and to plan for the visits. It should be noted that the TE was indeed initiated before the closure of the project, but most activities had actually ended in 2007-8, making the timing of this exercise rather late. TE initiated following a request by GEF EOU		4
S.	***Project's support:*** *Did the project make available all required documents? Was adequate support provided to the evaluator(s) in planning and conducting evaluation missions?*	Yes		5
T.	***Recommendations:*** *Was an implementation plan for the evaluation recommendations prepared? Was the implementation plan adequately communicated to the project?*	Yes, webinar as well as standard discussion		5
U.	***Quality assurance:*** *Was the evaluation peer-reviewed? Was the quality of the draft report checked by the evaluation manager and peer reviewer prior to dissemination to stakeholders for comments? Did EO complete an assessment of the quality of the final report?*	Yes		5
V.	***Transparency:*** *Were the draft ToR and evaluation report circulated to all key stakeholders for comments? Was the draft evaluation report sent directly to EO? Were all comments to the draft evaluation report sent directly to the EO and did EO share all comments with the commentators? Did the evaluator(s) prepare a response to all comments?*	Yes		5
W.	***Participatory approach:*** *Was close communication to the EO and project maintained throughout the evaluation? Were evaluation findings, lessons and recommendations adequately communicated?*	Yes		5
X.	***Independence:*** *Was the final selection of the evaluator(s) made by EO? Were possible conflicts of*	Yes		5

interest of the selected evaluator(s) appraised?			
	OVERALL PROCESS RATING		4.9

Rating system for quality of evaluation reports

A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1

The overall quality of the evaluation report is calculated by taking the mean score of all rated quality criteria.