A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects

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I. Executive Summary

i. This study looks at the 124 countries in the NBF development project, as well as the 8 demonstration implementation projects, focussing on a comparative analysis of their experiences in order to draw out lessons and best practices applicable to other global initiatives for implementation of MEAs. These projects are implemented by UNEP under the GEF Initial Strategy for assisting countries to prepare for entry into force of the CPB.

ii. The NBF Development Project started in June 2001 and by June 2006 124 countries had joined the project. By 31 October 2006, 77 countries had completed their draft NBF; the remaining countries are expected to complete their NBFs by the end of the project in December 2007. Five of the 8 demonstration projects were completed by the end of mid-2006, and the remaining 3 will be completed by the end of 2006.

The process of developing an NBF:

iii. This paper looks at how each country participating in the NBF project used a process of knowledge mapping, adapted to its own particular social, political, environmental and development situation. Using an iterative learning process, countries collected and analysed information on biotechnology and biosafety within the context of their development priorities, and refined and developed their ideas about the different components of the NBF. This iterative process led to a map of the NBF that is dynamic, and evolves in light of experience as systems are established and become operational. The actual NBF produced by each country is therefore tailored to their own special needs and priorities.

Why did countries develop an NBF:

iv. The 132 countries around the world that joined the UNEP-GEF NBF Projects in order to develop and implement their national biosafety frameworks did so for reasons that included both national development priorities and international obligations. Many countries saw biotechnology and biosafety as being integral to their national development planning priorities, particularly for sustainable development. For some countries, the primary reason for joining the project was to have access to funds from UNEP-GEF for capacity building activities. In most of these countries, the process of developing the NBF resulted in an increased awareness of the importance of biosafety and the potential of biotechnology for development. Thus these countries were able to integrate biosafety into their national development planning processes. Similarly, in those countries where the initial impetus for joining the NBF development project was to enable them to comply with the CPB, the process of collecting and analysing information helped to highlight the importance of biosafety as a sustainable development issue.

NBF: the policy context

v. Participating countries chose to develop national policies that address biosafety in a variety of forms, depending on a country's national priorities. Some chose to develop a stand-alone policy on biosafety, whilst others formulated a combined policy on biotechnology and biosafety. Some policies were part of wider policies on biodiversity conservation and environmental protection, trade related issues, biosecurity and quarantine, or within the overall context of sustainable development or Agenda 21.

NBF: the regulatory regime

vi. A number of countries had some form of regulatory regime (i.e. either primary or secondary instruments) in place before they started their NBF projects. However, most countries that started work on their NBF did so without any pre-existing regulatory regime for biosafety. Many of these countries without a pre-existing biosafety regime decided to select a level 3 primary legal instrument, created under delegated authority. The choice of a level 3 primary legal instrument

enabled countries to build on existing and functional legal systems in order to promulgate a legal basis for regulating GMOs within a short time-frame, allowing them to work with a legal instrument that could be reviewed and revised easily.

vii. Other countries without a pre-existing biosafety regime decided to adopt a level 1 biosafety law as the primary legal instrument for a variety of reasons. These included lack of a suitable existing law that could serve as a 'home' for a level 3 biosafety legal instrument; political support that enabled a level 1 law to be approved relatively quickly; And a lack of existing laws that adequately address or recognise the importance of biotechnology and biosafety.

NBF: the institutional set-up

viii. The proposed institutional setups for the **National Competent Authority (NCA)** in the different NBFs include: a single NCA receiving and processing applications; or more than one NCA, each with Sectoral responsibilities and with either a single window or multiple windows for receipt of applications for GMOs. In the draft NBFs in all regions, the proposals for the **risk assessment** setup usually assign that responsibility to the NCA or overall biosafety body, with advice from either an ad-hoc scientific advisory body, or an established advisory committee.

NBF: Addressing Article 23 of the CPB

ix. Countries have addressed Article 23of the Cartagena Protocol on public awareness, education and participation in different ways, depending on each country's particular social, political and economic situation. The main way in which the public has been involved has been through involvement in the process of developing the NBF, for example through participation in the NCC. On of the main areas of focus for project activities have been on public awareness and education activities.

x. In those countries that have completed their NBFs, the main provisions for promoting participation by stakeholders in Biosafety Decision-making are consistent with Article 23. Public consultation on GMO activities is included in all NBFs. These activities not only include applications for permits for environmental release or importation, but can also involve public participation in biotechnology research. In many countries, the public are invited to make submissions on applications at an early stage of the decision-making process; in many countries, this is enshrined in the biosafety regulatory instrument.

Implementing the NBF

xi. In all the countries participating in the NBF development project, the long term aim is to translate the NBF into practical and workable systems, and as countries complete their NBF, they have started to do this. The process of translation is backed up by government commitment which has been demonstrated in a number of ways: by approval of the NBF, approval of the biosafety policy in the NBF, and by promulgation of the biosafety regulatory instrument by the appropriate body. Most countries that are Parties to the CPB have turned to the GEF for further assistance in order to implement their NBF.

Regional Cooperation

xii. The importance of regional cooperation is recognised by many countries in all regions. However, one of the key lessons emerging from the projects is that **regional cooperation has to be country driven** and not in response to an external agenda. Therefore, for most countries, initial attempts at regional cooperation have taken the form of regional meetings to discuss potential areas for collaboration.

Some lessons from development of NBFs

xiii. The comparative analysis of the experiences of countries developing their NBFs under the UNEP-GEF project highlight some key lessons that will be relevant to future capacity building activities in biosafety as these countries start to implement their NBFs:

- ✓ The most important lesson emerging from the experiences is that Biosafety is a **sustainable development** issue, and that it cannot be considered in isolation from a country's development priorities.
- ✓ Recognition of biosafety as a sustainable development issue means that the development of the NBF, and particularly the resultant product i.e. the national biosafety framework, must be **responsive** to national needs and priorities in order to promote sustainability of the NBF.
- ✓ The importance of a **country-driven process** in preparing the NBF - the strong emphasis on this principle throughout the project has promoted a strong sense of national ownership, illustrated by the support from government in many of the countries to, not only seek outside assistance for capacity building for implementation of their NBF, but also to commit substantial government resources to both setting up the necessary systems and to maintain them on an on-going basis through financial allocations in the national budget for recurrent costs.
- ✓ An **inclusive** approach is needed in order to ensure the involvement of all stakeholders; this is crucial if the NBF is to be accepted by all parties within the country. This will not only help ensure support for the implementation of the NBF, but will also help promote the sustainability of the achievements.

xiv. The experiences of the NBF Development project also highlight the commitment of the countries participating in the project to biosafety and the CPB: 92 out of the 124 countries in the project are already Parties to the Protocol and another most of the other countries are completing their national procedures for ratification. The NBFs not only provide the necessary legal instruments and other systems for implementation of the CPB, but the process of preparation of the NBF has started to build national capacity for *effective* implementation of the Protocol; this will need to be sustained through both externally funded and nationally supported capacity building efforts.

Contents

II. Abbreviations

ASEAN	Association of South East Asian Nations
BCH	Biosafety Clearing House
CAR	Central African Republic
CBD	Convention on Biological Diversity
CEE	Central and Eastern Europe
CPB	Cartagena Protocol on Biosafety
DPR	Democratic People's Republic
DRC	Democratic Republic of Congo
EIA	Environmental Impact Assessment
EU	European Union
FFP	Food and feed products
GEF	Global Environmental Facility
GMOs1	Genetically modified organisms
IBCs	Institutional Biosafety Committees
JMM	Joint Monitoring and Management Commission
LAC	Latin America and Caribbean
LMOs	Living modified organisms
MOA	Ministry of Agriculture
MDGs	Millennium Development Goals
MEA	Multilateral Environmental Agreement
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Coordinating committee
NCBP	National Committee on Biosafety of the Philippines
NEA	National Executing Agency
NGO	Non-governmental organisation
PA21	Philippines Agenda 21
PDR	Peoples' Democratic Republic
PEAP	Poverty Eradication Action Plan
PNG	Papua New Guinea
RAF	Resource Allocation Framework
R&D	Research and development
SAARC	South Asian Association for Regional Cooperation
SEPA	State Environmental Protection Administration
SIDS	Small Island Developing States
SPC	Secretariat of the Pacific Community
UNEP	United Nations Environment Programme

[1] The term "*genetically modified organism"* or "*GMO*" has been used in most sections of the paper. Where there is a specific discussion of the Protocol, the term "*living modified organism*" or "*LMO*" that appears in the Protocol has been used.

III. Introduction

1. The Cartagena Protocol on Biosafety (CPB), adopted in January 2000, establishes rules and procedures for the safe handling, transfer, and use of living modified organisms (LMOs). The CPB focuses on the transboundary movement of LMOs, both those to be introduced into the environment and those to be used directly as food, feed or for processing.

2. The CPB, recognizing the need for capacity building for developing countries to enable them to make informed decisions on LMOs, designated the GEF as the financial mechanism for its implementation. In 2000, the GEF Council adopted an Initial Strategy for assisting countries to prepare for the Protocol's entry into force.

3. Under this strategy, the GEF funded the NBF Development project, implemented by UNEP and with national projects executed by designated government agencies in each country. The main objective of this project is to prepare countries for the entry into force of the Cartagena Protocol on Biosafety. The major components of the project include:

1) Development of National Biosafety Frameworks (NBF) in participating countries; and
2) Promotion of regional and sub-regional collaboration and exchanges of experience on biosafety.

4. The NBF Development Project started in June 2001 and by June 2006 124 countries had joined the project. By 31 October 2006, 77 countries had completed their draft NBF, and a further 30 countries have draft NBFs under review, whilst the remaining countries are at various stages of project implementation, depending upon when they started project activities. It is expected that over 80% of all participating countries will have completed their NBFs by the end of December 2006; the remaining countries are expected to complete their NBF by the end of the project in December 2007.

- The UNEP-GEF Biosafety Unit also manages 8 of the 12 GEF-funded Demonstration Projects on Implementation of National Biosafety Frameworks (NBFs) in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. These 8 countries finished their Pilot Projects, which resulted in draft NBFs, in 1999. The demonstration projects started in September 2002 and were set to last around 3 years, with budgets ranging up to 1 M US$. Five of the 8 projects were completed by the end of mid-2006, and the remaining 3 will be completed by the end of the 2006.

- In addition, the UNEP-GEF Biosafety unit also manages a GEF-funded global project for 139 countries to build capacity for effective participation in the Biosafety Clearing-House (BCH). The lessons emerging from the UNEP-GEF BCH global project have not been included in the study at this time.

5. This study looks at the 124 countries in the NBF development project, as well as the 8 demonstration projects, focussing on a comparative analysis of their experiences in order to draw out lessons and best practices applicable to other global initiatives for implementation of MEAs.

IV. Conceptual Framework

6. This paper begins by looking at the development of an NBF under the project as a process of knowledge mapping; the knowledge mapping process was outlined in the project document prepared by each participating country, and in the toolkit produced by the global project team. The mapping process recommended for all participating countries consists of five steps:

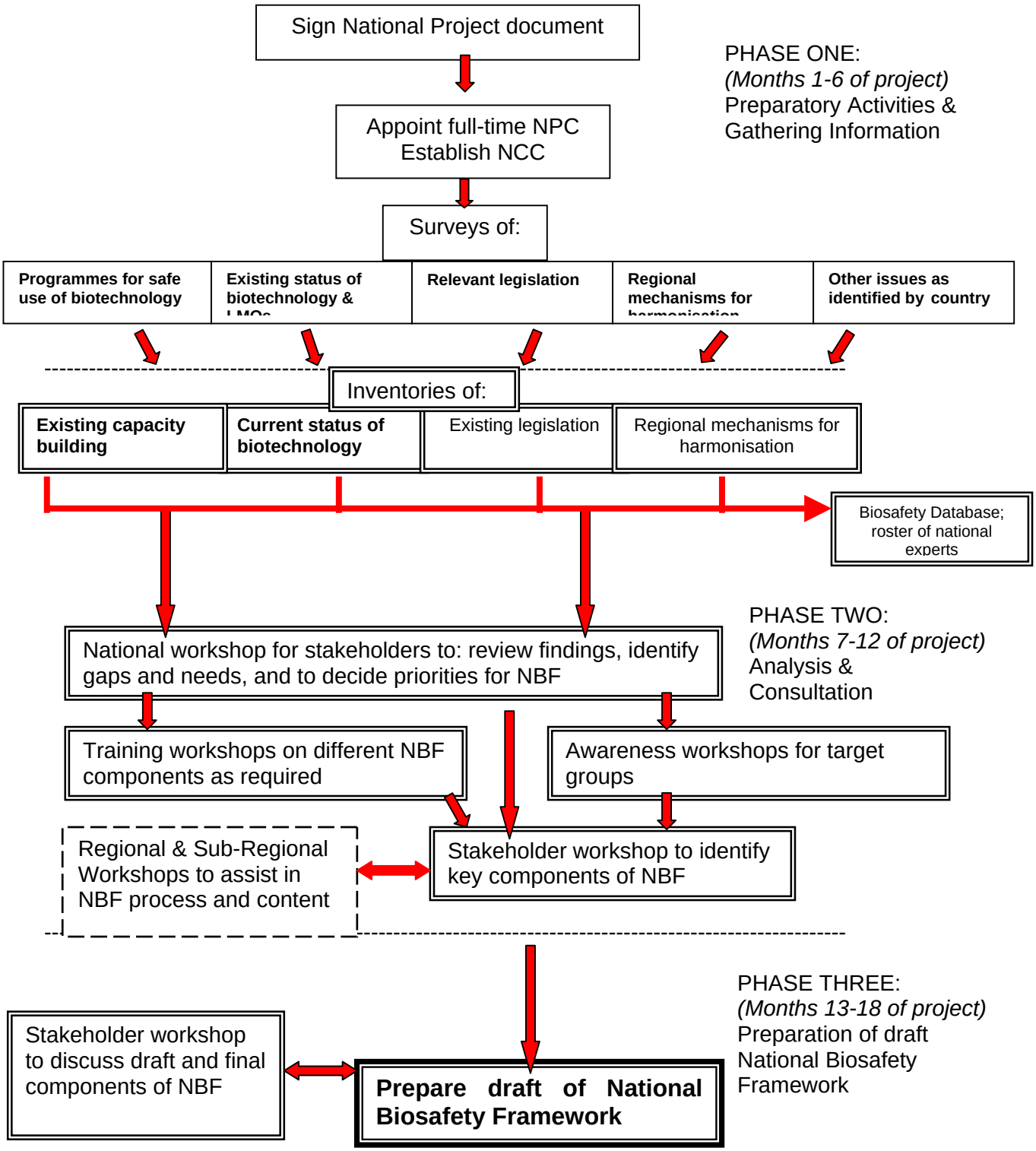
1) A stocktaking exercise to collect information and data on the current status of biosafety and biotechnology within the country, including human and institutional resources;
2) Analysis of the data and information with participation by all stakeholders;
3) Storage of the data so that it is readily available to stakeholders and can be used in the future to implement the NBF;
4) Further analysis and processing of information to determine priorities for the NBF;
5) Preparation of the NBF through a consultative process.

7. These steps in the knowledge mapping process for the development of an NBF are illustrated in Figure 1. The process used by countries participating in the NBF development project, helps them to:

- Carry out a stocktaking exercise as the first step in the development of the NBF in order to ensure that the process of developing the NBF builds on existing efforts in the country and that the final product reflects national needs and priorities;
- Ensure that all relevant stakeholders are consulted from the beginning of the process and that they help to determine the final outcome;
- Develop an NBF that is consistent with the development priorities of the country;
- Utilize national expertise in all fields related to biosafety and biotechnology rather than relying solely on external advice and expertise;
- Translate the resulting map into practice through the development of the national biosafety framework or NBF (Box 1). The experiences of the eight demonstration project illustrate how the translation of the map into action works out in practice.

Box 1: A national biosafety framework or NBF is "a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

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



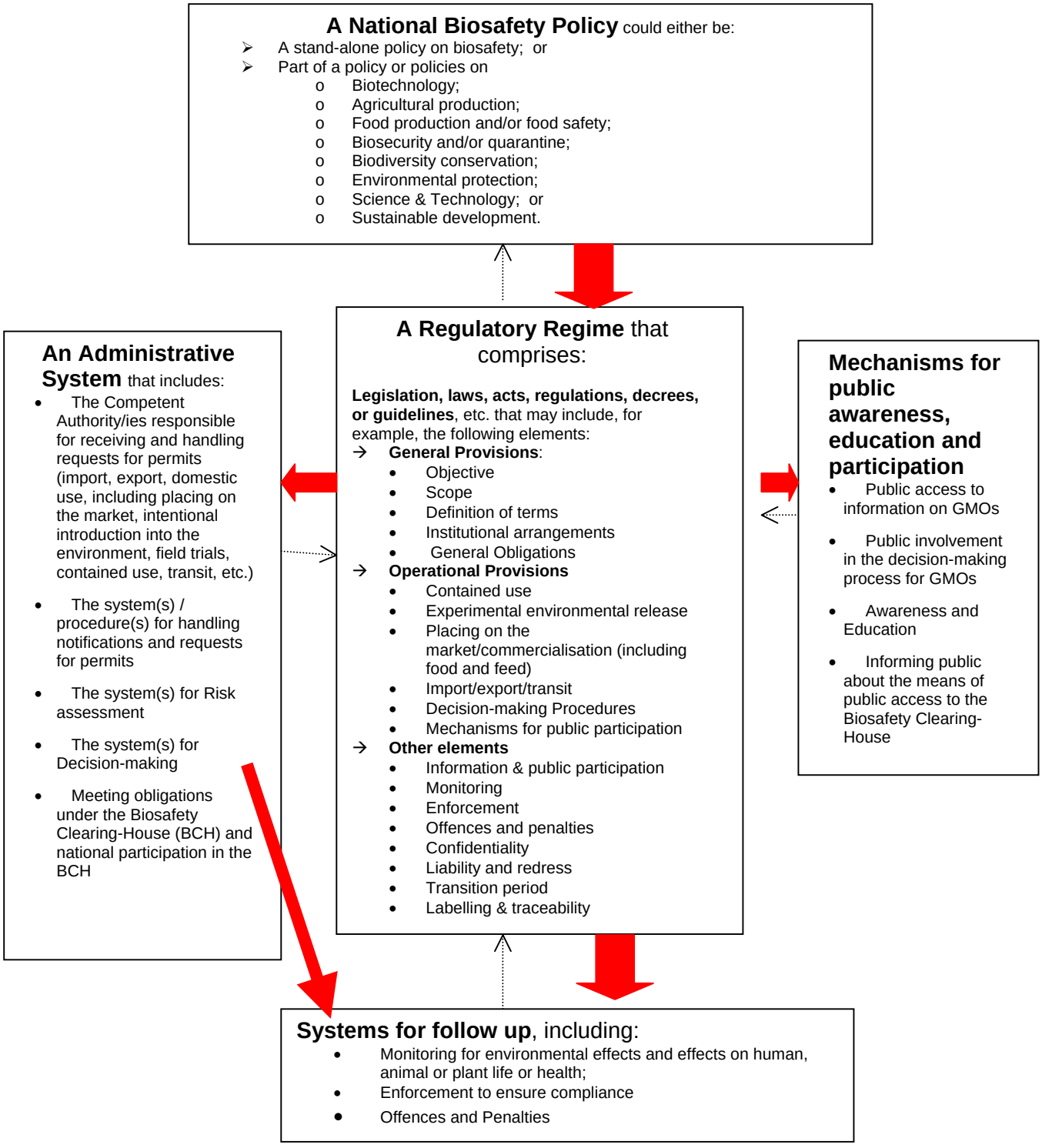
8. Each country participating in the NBF project adapted this process of knowledge mapping to its own particular social, political, environmental and development situation. Thus the resulting NBF produced by each country was tailored to that country's particular situation within a common framework; this common framework can be seen as a knowledge map consisting of five inter-related components (Figure 2).

9. The concept of the NBF as a knowledge map provides a framework of analysis for this paper in discussing the experiences of the countries in developing and implementing their NBFs. The five inter-dependent components of the NBF provide countries working with the NBF development project with a guide to set up the systems necessary not only to comply with the requirements of the CPB, but also to ensure that the systems put in place are tailored to national needs and priorities for sustainable development. The same concept also applies to the eight demonstration implementation projects as they worked on operationalizing the five components of their NBF.

10. The **framework of analysis** used in this paper is based on the following key elements of the NBF:

- The rationale for developing the NBF in the first place;
- The process used by countries to develop their NBF;
- The policy framework within which the NBF will operate;
- The regulatory regime proposed for managing LMOs;
- The institutional set up proposed for managing LMOs;
- How the NBF addresses issues of public participation (Article 23 of the CPB);
- How the NBF addresses socio-economic issues (Article 26 of the CPB);
- How countries have gone about translating the knowledge map of their NBF into action by setting up systems to have the NBF up and running;
- How countries have addressed issues of regional cooperation.

Figure 2: The components of a National Biosafety Framework (NBF)[2]



[2] Based on the UNEP-GEF NBF Development Project toolkit, module 3(i) on regulatory regimes.

V. Current status of countries in the NBF Development and Implementation Projects

Table 1: The current status of NBFs in countries working with the UNEP-GEF projects

Region	**Countries that have completed their NBF**	**Countries implementing their NBF**	**Advanced draft of NBF prepared**	**Still working on NBF**
Africa	Algeria, Benin, Botswana, Burkina Faso, Comoros, Congo, Republic of, Cote d'Ivoire, Gambia, Ghana, Guinea, Lesotho, Liberia, Madagascar, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, Sudan, Swaziland, Tanzania, Togo (25 countries)	The NBF projects were completed in 2006 in: Cameroon, Kenya, Namibia and Uganda Egypt, Mauritius, Tanzania and Tunisia (all will commence implementation projects in late 2006)	Burundi, CAR, Djibouti, DRC, Ethiopia, Gabon, Guinea Bissau, , (7)	Angola, Chad, Cape Verde, Eritrea, Libya, Morocco, , Sao Tome & Principe Zimbabwe (8)
Asia-Pacific	Bhutan, Cambodia, Indonesia, Iran, Jordan, Kazakhstan, Korea DPR, Korea R. of, Kyrgyzstan, Lao PDR, Lebanon, Maldives, Mongolia, Niue, Papua New Guinea, Philippines, Samoa, Sri Lanka, Tajikistan, Tonga, Vanuatu, Viet Nam, Yemen (23 countries)	China – completed its NBF project in Dec 2005. Viet Nam and Cambodia have started their implementation projects in August 2006; Tajikistan will start in early 2007.	Bangladesh, Cook Islands, Kiribati, Myanmar, , Nepal, Palau, Syria, Thailand, (8)	Fiji, Marshall Islands, Micronesia, Nauru, Solomons, Tuvalu,
CEE	Armenia. Belarus, , Croatia, Czech Republic, Estonia, Georgia, Latvia, Lithuania, Macedonia former Republic of Yugoslav, Moldova, , Romania, Slovakia, Slovenia, Turkey (14 countries)	The NBF projects were completed in: Bulgaria (March 2006) and Poland (August 2005) Czech Republic, Estonia, Lithuania, Moldova and Slovakia will start implementation in late 2006.		Albania, Azerbaijan, Malta , Serbia (former Serbia & Montenegro), Ukraine. Bosnia is currently preparing its project proposal for development of its NBF.
LAC	Antigua and Barbuda, Argentina, Bahamas, Chile, Costa Rica, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Peru, Venezuela (12 countries)	Cuba completed its project in September 2006.	Guyana, Jamaica, Haiti, Barbados, Saint Lucia, Suriname	Trinidad and Tobago, St. Vincent and the Grenadines, St. Kitts and Nevis, Belize

VI. Experiences from countries in developing and Implementing their NBF

Why did countries develop an NBF

11. The 120+ countries around the world that joined the UNEP-GEF NBF Projects in order to develop and implement their national biosafety frameworks did so for a variety of reasons that included both national development priorities as well as international obligations. These reasons are so intermingled that it would be impossible to single out any one reason for joining the NBF project. Some countries joined because they were either Parties to the CPB or had signalled their intention to ratify the Protocol by signing it. Many countries joined the NBF projects primarily because they saw the NBF as a way to ensure that they were able to develop biotechnology in a sound and sustainable manner. The range of reasons for developing an NBF is illustrated by the case of the Caribbean countries (Box 2); these experiences o are shared by many of the countries in other regions of the world.

Box 2: Caribbean countries decided to develop NBFs for the following reasons:

- to comply with the Cartagena Protocol on Biosafety
- to set trade in modern biotechnology products in legal and policy frameworks which promote sustainable development, with emphasis on the safe use of biotechnology through systems for minimizing the potential of threats to sustainable livelihoods, human health and the environment, including biodiversity.
- to produce an enabling environment for the development of biotechnology to enhance economic development.
- to integrate biosafety relating to modern biotechnology with areas such as food safety, health, invasive species, environment and consumer rights and protection

12. Many countries saw biotechnology and biosafety as being integral to their national development planning priorities, particularly for sustainable development. As a result, many developing countries started to adopt modern genetic modification technologies in the late 1980s and developed regulations to manage GMOs. Those that later joined the UNEP-GEF NBF projects, included:

- **In Asia** – China joined the NBF demonstration project in order to implement its draft NBF developed under the Pilot project of UNEP/GEF. China recognised the importance of managing the safe application of GM technology across different sectors, and the value of addressing gaps in their existing regulations on GMOs, with a clear division of areas of responsibilities between the two national competent authorities (NCAs) to make the NBF truly workable.
  The Philippines, Iran, Syria, and Indonesia, which had all developed draft regulations or guidelines for biosafety, joined the NBF project in order to review and revise these regulatory instruments in light of the CPB;
- **In Africa** - South Africa is the only country in Africa that had on its own developed regulations for the development of biotechnology. South Africa joined the project with the intention of improving on its public participation and awareness mechanisms.
  Ghana and Nigeria had initiated the development of non-binding guidelines to regulate their scientific institutions.
  Cameroon, Kenya, Namibia and Uganda started to implement their NBFs, which were

produced under the Pilot Biosafety Enabling Activity project funded by GEF and implemented by UNEP. These countries saw themselves as likely recipients of GMOs rather than producers of GMOs. Therefore the initial impetus for these countries was to establish systems and mechanisms (under the implementation project) to manage the international movement of GMOs in, across and out of their countries, and the safe release of GMOs into their environment, without causing adverse effects on the environment, humans and animals. Egypt, participated in the Pilot project to develop draft a NBF in order to regulate both transboundary movement of GMOs and its own biotechnology sector. Egypt will begin to implement its draft NBF in late 2006 under the GEF Interim Strategy for Biosafety.

- **In Latin America** – Cuba joined the implementation project as a progression from the Pilot project, to provide the country with resources to reinforce the national system for inspection, enforcement and monitoring and to develop implementing regulations to make their Decree Law 190/99 on Biological Safety operational as well as in line with the Cartagena Protocol.
- In **CEE** – Bulgaria and Poland moved to the implementation project to make their draft NBFs, which were developed under the UNEP/GEF Pilot project workable and reflective of their changing political situation – entry into the EU. Being a new EU member, the implementation project provided Poland with an opportunity to harmonise its GMO Act 2001 with EU Directives and Regulations. Poland was also able to enhance its capacity to undertake GMO detection and monitoring under the implementation project. Bulgaria similarly focused much of its activities under the implementation project on the development of a regulatory regime, which would be consistent with EU Directives and regulations, in preparation of their entry into the EU in 2007.

13. Where the rationale for developing an NBF focussed initially on GMOs as a development issue, the national debates on biotechnology and biosafety soon brought about an awareness of the need to ratify the CPB as an international instrument to manage transboundary movement of LMOs, e.g. the Philippines (Box 3).

Box 3: Experiences of the Philippines - The Philippines' National Agenda for Sustainable Development for the 21st Century (PA 21) provides the policy framework of the country's strategy for sustainable development. In 2001, the Presidential Policy Statement on Modern Biotechnology reiterated the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development.

The first biotechnology regulatory system in the ASEAN region was established in the Philippines as a result of the recommendations from the scientists asking the national government to formulate a national policy on biosafety, and create a technical body to draft guidelines to ensure that experiments using GMOs do not pose unacceptable risks to human health and the environment. The first guidelines for biosafety were promulgated in October 1990 as Executive Order (EO 430), which established the National Committee on Biosafety of the Philippines. These and other subsequent guidelines issued in 1991, 1998, and 2002, were incorporated into the NBF, which was finalised in 2004 on completion of the NBF project. The NBF, which was issued as Executive order (EO) 514 in April 2006, is seen as supporting the safe use of biotechnology in order to promote sustainable development objectives as stated in the PA 21. The country, as an importer and potential exporter of LMOs, has also recognised the importance of the CPB as an international instrument to manage the transboundary movement of LMOs and has completed national processes for ratification with approval by both the President and the Senate, after extensive public hearings.

14. For some countries, the primary reason for joining the project was to have access to funds from UNEP-GEF for capacity building activities. In most of these countries, the process of developing the NBF resulted in an increased awareness of the importance of biosafety and the potential of biotechnology for development. Thus these countries were able to integrate biosafety into their national development planning processes. However, a small number of countries were not able to mainstream biosafety into their development priorities and the NBF project has failed to make progress in these countries.

15. Similarly, in those countries where the initial impetus for joining the NBF development project was to enable them to comply with the CPB, the process of collecting and analysing information helped to highlight the importance of biosafety as a sustainable development issue. As a result, by the end of their NBF projects, the governments had started to see biosafety within the context of their national development plans, e.g. Samoa (Box 4) and the Caribbean (Box 2).

Box 4: Why did countries decide to develop an NBF?

Samoa recognised that biotechnology can offer potential benefits for both subsistence and commercial agriculture and fisheries - key sectors to its economy. Modern biotechnology however, is a relatively new phenomenon, so while recognising that GMOs as products of modern biotechnology may have development benefits, Samoa also recognised that there are unknown and potential risks of GMOs to its biodiversity, upon which its agriculture and fisheries sectors are based. To realise the benefits of modern biotechnology while safeguarding its biodiversity, and taking into account socio-economic considerations, capacity building in the area of biosafety was seen as a priority.

Samoa's Cabinet approval to ratify the CPB in May 2002 was underpinned by a need to build its capacity through the development of a National Biosafety Framework, to ensure that safety measures are put in place for managing importation of GMOs, and for safe use of biotechnology. The NBF also assist Samoa comply with the Protocol.

The Cartagena Protocol

16. In many countries, the primary reason for joining the NBF Development project, at least at the start of their project, was to comply with their obligations under the CPB to enable them to ratify the Protocol. This is illustrated by the experiences of countries from all the regions as shown in Table 2.

Table 2: Status of Ratification of the CPB in countries participating in the UNEP-GEF NBF projects

	Total	AFR	AP	CEE	LAC
# countries in NBF project	124	39	37	20	28
# countries in NBF project that are Parties to the CPB	91	28	27	17	19
# countries in NBF project that are Parties to the CPB and ratified before they joined project	22	5	6	3	8
# countries in NBF project that signed the CPB before they joined project	63	21	15	10	17
# countries in NBF project that signed the CPB before they joined project and have since ratified the CPB	48	17	11	10	10
# countries that joined the NBF project before signature or ratification of the CPB	102	34	30	17	20
# countries that joined the NBF project before signature or ratification of the CPB and that are now Parties to the CPB (1 November 2006)	69	23	21	14	11
# countries in Demonstration project	8	4	1	2	1
# countries in Demonstration project that are Parties to the CPB	8	4	1	2	1
# countries in Demonstration project that signed the CPB before they joined project	8	4	1	2	1
# countries in Demonstration project that signed the CP before they joined the project and have since ratified the CPB	8	4	1	2	1

17. The following examples illustrate the high level of commitment to the ratification of the CPB in all regions, and the key role of the NBF Development project in fostering this process of ratification:

- Twenty-two countries, became Parties to the Protocol before joining the project, and used the project to develop the systems needed in order to comply with the CPB. Examples include from Asia-Pacific: Bhutan, Fiji, Niue, Samoa, Nauru and Maldives; from Africa: Botswana, Djibouti, Lesotho, Liberia, Mali and Mozambique; CEE – Czech Republic, Belarus, Croatia; Caribbean - the Bahamas, Barbados and Antigua and Barbuda.
- Sixty-three countries that were signatories to the Protocol joined the project in order to develop their NBF so as to be able meet the requirements of the Cartagena Protocol. Just over 75% or 48 countries have ratified the CPB during their project. Examples include:
  - Asia: Bangladesh, Indonesia, Iran, Jordan, and Sri Lanka, ratified the CPB during the course of their project. One, the Philippines, ratified the CPB after completing its NBF. Two countries, Myanmar and Nepal, are close to completing their NBF and are also close to completing their national processes for ratification. One country, Republic of Korea has not yet completed its national formalities for ratification.
  - Pacific: Palau and Kiribati ratified the CPB during the course of their projects. The Cook islands, a signatory, is close to completion of NBF but with changes in governments, it is reviewing process for ratification.
  - Africa: 22 signatories ratified while participating in the project: Algeria, Benin, Burkina Faso, Cape Verde, Congo, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Ghana, Libyan Arab Jamahiriya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sudan, Swaziland, Togo, United Republic of Tanzania, Zimbabwe.
  - CEE region, counties that were signatories and ratified CP during the project or shortly (couple of months) after the end of the project included: Lithuania, Macedonia former Republic of Yugoslav, Moldova, Romania, Slovakia, and Turkey. Two countries started the procedure for ratification during the project, and ratified it after the official end of the project: Estonia and Slovenia. These were the very first countries to complete their project in 2003, soon after the CPB came into force.
  - In the case of the Caribbean, Saint Lucia ratified the CPB during the course of the NBF Development Project.
- One hundred and two countries that joined the NBF project did so prior to ratification or signature. Two-thirds (69) of these countries have ratified the CPB during the course of their project. Examples include:
  - Asia: Cambodia, Iran, Korea DPR, Kyrgyzstan, Laos PDR, Mongolia, Syria, Thailand, Viet Nam and Yemen. Two countries, Kazakhstan and Lebanon, have completed their NBF but are yet to complete the national processes for ratification.
  - Pacific, Marshalls, PNG, and Tonga acceded during the course of their projects. Tonga completed its NBF and ratified during the course of its project, Vanuatu completed its NBF but yet to complete process for accession, Micronesia is in the process of developing its NBF and yet to complete accession process, Tuvalu is in the process of developing its NBF and has completed its national procedures for ratification but has yet to notify the CBD Secretariat.
  - Africa these included: Cape Verde, DR Congo, Eritrea, Ethiopia, and Libya.
  - CEE region, many countries did not sign the CPB, but ratified it during the project: Albania, Armenia, Azerbaijan, Latvia, Ukraine, Serbia and Montenegro. Malta, the

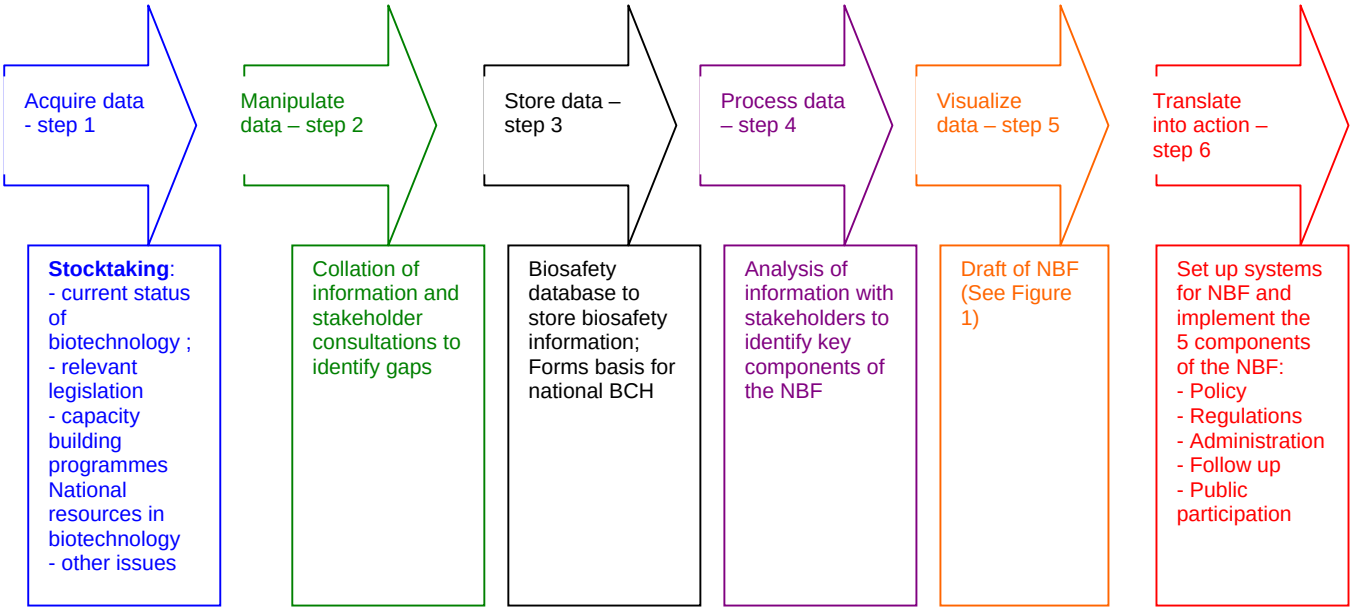
only EU country that has not yet ratified the CPB, expects to do so soon. Georgia is also likely to ratify soon, once remaining obstacles are cleared.

- All of the eight demonstration projects implementing their NBF had been signatories to the CPB prior to joining the implementation projects. All eight countries have ratified the Protocol during their project.

How did countries develop their NBF

18. The guidelines for the process of developing NBF provided by the NBF Development project helped countries to tailor the mapping process for the project to their own particular situation. Figure 3 illustrates the steps in the mapping exercise: the first step helped countries to establish a baseline for their national situation in terms of biotechnology and biosafety. The analysis and storage of the data, and the process of consultation (steps 2-4) helped countries to decide the priorities for their NBF.

Figure 3: The development of an NBF as a Mapping process



19. The countries then drafted their NBFs (step 5); this provided a map to guide them in establishing and operationalizing the five components of their NBF. The translation of the NBF into practice is illustrated by the experiences of the eight demonstration projects as, by the end of the project, they were expected to have in place:

- **A policy on biosafety, either as a comprehensive policy in itself, or as parts of other relevant national policies;**
- **An operational regulatory regime for biosafety, which is in line with the CPB and other relevant international obligations, as well as consistent with existing national sectoral laws;**
- **Workable and transparent systems for handling applications for GMO release (including systems for administrative handling, risk assessment and decision making);**

- **Workable and transparent systems for public information and public participation in decision making;**
- **A functional system for enforcement and post-release monitoring; and**
- **A national website and/or a national Biosafety Clearing House (BCH).**

20. Thus countries with a high level of biotechnology R&D were able to bring together information on the country's experiences with biotechnology research and regulation of GMOs through a process of consultation and analysis. Examples include:

- Asia - Philippines, Indonesia, Thailand Syria, DPR Korea, Republic of Korea;
- Africa – Ghana, Nigeria;
- CEE – current EU member states Estonia, Slovenia, Czech Republic, Lithuania, but also non-EU countries like Belarus, Serbia and Moldova;
- Latin America – Argentina, Chile, Costa Rica.

21. Other countries, such as Myanmar and PNG, with a relatively low level of activity in biotechnology, were able to document these activities, as well as the existing laws and regulations that pertained to the safe use of GMOs in order to be able to make informed decisions on the NBF (Box 5).

Box 5: Mapping the NBF:

Myanmar

The Myanmar NBF project started project activities in mid-2004 with the appointment of 12 national consultants with expertise in the sciences (including biotechnology), management, forestry, and law, to carry out a survey of the *"current situation of biotechnology and biosafety in the country"*. The survey gathered information on:

- Policies related to biosafety, including sustainable development, environment, biodiversity, and science and technology.
- Laws related to biosafety in sectors such as agriculture (pesticides, plant quarantine, fertilisers, seeds) livestock and fisheries, forestry, industry, public health, food, and science and technology.
- How the relevant ministries administered the laws including food and drugs, plant quarantine, and border control.
- The biotechnology resources in the country including research facilities, equipment, scientific personnel, and academic institutions offering educational courses related to biotechnology.
- The status of conventional and modern biotechnology within the country, both within the public and private sectors.

Following the collation of this information, a series of national and regional public consultations were carried out throughout the country to decide on the priorities for the NBF.

Based on the results of this consultation, and analysis by members of the NCC, a draft NBF was prepared. This includes a draft Law on Biosafety, which is currently under consideration by government.

Papua New Guinea

Local consultants carried out surveys in

- Policies of relevance biosafety including, national development, environment, agriculture and livestock, food security, health and population policies.
- Existing legislations of relevance to biosafety and biotechnology categorised into legislations that impact on R&D (such as those in agriculture, environment, science and technology, research, health, etc), and on trade (such as quarantine, customs, food, etc.)
- Existing institutions and programmes in risk assessment and management, including universities and National Agricultural Research Institutions.
- Public perception of GMOs.

A series of four multi-stakeholder workshops decided on, and verified national priorities as articulated in the Biotechnology and Biosafety Policy, and decided on the choices for the regulatory regime, plus other components of the NBF. The draft NBF includes a standalone Biotechnology and Biosafety Bill endorsed by government to be tabled in parliament during implementation phase of the NBF.

22. A number of countries in Africa: Algeria, Benin, Botswana, Burkina Faso, Congo, Gambia, Madagascar, Mali, Mozambique, Niger, Rwanda, Senegal, Sudan, Swaziland, Togo, and United Republic of Tanzania, also went through a similar process of mapping.

23. The development of the NBF in these countries is best seen as an iterative learning process as countries collect and analyse information on biotechnology and biosafety within the context of their development priorities, and refine and develop their ideas about the different components of the NBF. This iterative process leads to a map of the NBF that is dynamic, and one that will evolve in light of experience as systems are established and become operational.

24. The actual NBF produced by each country was also tailored to their own special needs and priorities within the framework provided by the UNEP guidelines. Thus each NBF is different and there is no standard format or content for the NBFs. For example, in Asia, a number of countries used innovative approaches, or example, Viet Nam developed its draft NBF as an Action Plan for biosafety whilst the one for the Philippines was in the form of an Executive Order that was eventually promulgated by the Government after signature by the President.

NBF: the policy context

25. A national policy that addresses biosafety is considered to be an integral part of an NBF. Such policies can take a variety of forms, depending on a country's national priorities. These are not clear-cut divisions between the different policy contexts but indicate main groupings:

- A few countries have chosen to develop a stand-alone policy on biosafety, although usually it is within a broader context of objectives such as biodiversity conservation, sustainable development or environment. Examples of a stand-alone biosafety policy include Slovenia and Bhutan.
- Other countries have developed their NBFs under the umbrella of a policy on biotechnology and biosafety, or a science and technology policy, again within the context of broader development objectives such as sustainable development, food security, biodiversity conservation, agricultural development, etc. Examples of a combined biotechnology and biosafety policy include. Chile, Ghana, Kazakhstan, DPR Korea (see box 6), Iran, Estonia, Sudan, Nigeria, and Papua New Guinea.
- Other countries have developed their biosafety policy as part of policies on biodiversity conservation and environmental protection, that take into account issues such as invasive species, etc. Examples include some of the Caribbean countries such as Bahamas, Antigua, Dominica, Grenada; African countries such as Benin, Madagascar, and Mali; Asian countries such as Lebanon, Laos, and Jordan; Pacific countries such as Niue, Samoa and Kiribati; CEE countries such as Armenia, Latvia and Lithuania; Latin American countries such as Ecuador and Peru.
- Other countries have chosen to develop their policy on biosafety within the context of trade related issues. Examples include Lebanon, Republic of Korea, Argentina, Mozambique, etc.
- Some countries have focussed on issues related to biosecurity and quarantine in developing the context for their biosafety policy. Examples include Fiji, Vanuatu, Palau, and Myanmar.
- A number of countries have chosen the overall context of sustainable development or Agenda 21 as the setting for their biosafety policy, Examples include Indonesia, Philippines, Guinea, Liberia, Lesotho, Sudan, Tonga, Ecuador, and Czech Republic.

Box 6: Biosafety and biotechnology policy for DPR Korea

The main objectives of biotechnology and biosafety policy are;

i) To ensure the safe use of biotechnology in the Democratic People's Republic of Korea, and to eliminate any risks that may be detected in the process of introducing the achievement of research into the various fields of the national economy and to thoroughly protect health of the people and conserve the biodiversity and ecological environment and,

ii) To make up the legal framework of the NBF and establish well-regulated administrative organization, supervisory body and risk assessment and data exchange body, so as to promote the scientific research, development and production of the modern biotechnology on the basis of biosafety guaranteed and at the same time contribute to ensuring maximal safety for movement, handling and use of GMOs including genetically modified crops.

26. In all countries, the policy context that provides the vision or rationale for the NBF has focussed both on the obligations and responsibilities under the Cartagena Protocol, and the potential of biotechnology in promoting the country's development priorities.

27. The areas of the Protocol addressed in policies include the main areas of focus of the Protocol:

- Transboundary movement of LMOs (Objective and Scope of the CPB);
- Protection of natural and agricultural biodiversity (Objective and Scope of the CPB);
- Protection of human health (Objective and Scope of the CPB);
- Public participation, education and awareness (Article 23);
- Capacity building for biosafety (Article 22).

28. Most national policies on biosafety, across all regions, also include a formulation of the **precautionary approach** (Box 7) applicable to their national situation.

Box 7: Example of how the Precautionary approach or principle is addressed:

Indonesia's Biosafety Policy - "Ensure an adequate level of biosafety in transfer, handling and use of LMOs which may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health, and using the precautionary approach without putting constraints on the research and development of biotechnology in Indonesia."

In the CEE - All non-EU CEE countries mention in their legal acts that their biosafety laws are based on **the** precautionary principle. Some EU member states do not refer to it so clearly (for example, Estonia does not mention precautionary principle in its biosafety law), but as this principle is the basis of EU legislation, and the EU legislation is directly applicable to EU member states, the precautionary principle is implicit for all member states. So, it could be summarized that all CEE countries use precautionary principle in their NBFs as one of the main basis.

Tanzania – *O*ne of the guiding principles for the NBF is the Precautionary Principle*: "This shall be implemented through the decision-making system of the NBF, particularly in accordance with the procedure for risk assessment, risk management and evaluation of socio-economic risks.".*

Caribbean – all the Caribbean countries incorporated the precautionary principle into their respective NBFs.

Policy Development in demonstration project countries

29. Because of historical reasons, not all demonstration countries had a policy in biosafety in place when they embarked on implementing their NBFs. Although it was recognized that a policy could help to frame a regulatory regime for the safe use of biotechnology, experience in other countries has demonstrated that the development of national policy and regulatory frameworks do not need to proceed in tandem.

30. China adopted a policy that promotes research and development of biotechnology, but at the same time, has control over research in genetic engineering, to ensure public and environmental health as well as to maintain ecological balance[1]. China's policy on GM regulation is under the responsibility of the Joint Monitoring and Management Commission (JMM), which was established by the State Council (the highest governmental body in China) . The JMM has a multi-stakeholder membership, which includes the highest representatives from ministries like Agriculture, Health, Commerce, Science and Technology, the National Development and Reform Commission (NDRC), the National Inspection and Quarantine Agency and the State Environmental Protection Administration (SEPA). The primary responsibility of JMM is to coordinate the main functions of biosafety, including the review, approval and development of policies and regulations on GMO production, labelling, and the import/export of GMOs. During the course of the implementation project, China also embarked on the development of a comprehensive national strategy on biotechnology development encompassing a biosafety policy. This is probably a result of cognizance of the rapid growth of biotechnology as well as the vast area planted with GM crops in the country. The mission of this new strategy (policy) would be to ensure that biosafety would be an integral part of biotechnology development and application in the country.

31. Apart from China, Namibia was one of the countries that had a policy for enabling the safe use of biotechnology (1999) when the Implementation project started. Although Cuba has neither a specific policy for biotechnology nor biosafety, it however had an Environmental Policy under Law 81 of the Environment (1997). Under the Environmental Policy the principles and regulations to protect the environment and at the same time achieve sustainable development were established. Kenya and Uganda have each drafted a policy for biotechnology and biosafety under the present project. These were carried out in parallel with the development of the regulatory regime. However, because their Governments decided that a national policy had to be adopted before the approval of a Biosafety Bill, these decisions are still under consideration. The draft Biotechnology and Biosafety Policy of Uganda was developed with a vision to make Uganda a country that will utilise biotechnology safely and as a tool for sustainable national development in the context of the Poverty Eradication Action Plan (PEAP), Vision 2025 and the Millennium Development Goals (MDGs).

32. Although Bulgaria did not have a policy on modern biotechnology, a national policy on co-existence of conventional, organic and GM crops was developed in February 2004. This policy, which was agreed by the Ministry of Agriculture and Forestry, has been presented to the Environmental Commission of the Bulgarian Parliament. The policy is based on economical, political, geographic, biological, social and ethical considerations for several groups of crops of economic importance.

33. Cameroon has yet to develop a national policy on biotechnology and biosafety. However, the Cameroon Academy of Sciences has been recommended to undertake this task through the Ministry of Scientific Research and Innovation and other key ministries. No progress has been made thus far.

NBF: the regulatory regime

34. A number of countries in three different regions had some form of regulatory regime (i.e. either primary or secondary instruments) in place before they started their NBF projects; these consisted of guidelines, rules, regulations, decrees or laws (Box 8):

- Asia –, Bangladesh (guidelines), Indonesia (Ministerial decree), Iran (regulations), Republic of Korea (Biosafety law) Philippines (regulations), Sri Lanka (guidelines), Syria (guidelines), Thailand and Viet Nam (guidelines);
- CEE – Czech Republic (Act and Decrees of the Ministry of the Environment, Croatia (Act and secondary Regulations), Romania (Law and Governmental Ordinances and Orders), Estonia (Act and secondary Regulations), actually, all CEE countries had in place primary act or law and then secondary regulations or ordinances or decrees, there were no country with guidelines;
- Latin America – Argentina (regulations).

35. In these countries, the regulatory instruments for GMOs had originally been developed in response to national priorities on biotechnology and biosafety (in the case of EU countries – a pre requisite for accession to the EU); these were reviewed and revised as part of developing their NBF in order to ensure consistency with the CPB and changing national priorities.

Box 8: Examples of existing regulatory instruments prior to countries joining the NBF Development project

Croatia – their Nature Protection Act had some provisions about use of GMOs, but it was not fully in line with requirements of Cartagena protocol. Hence, new GMO Act was drafted and was adopted, together with secondary regulations.

Romania was the only country there GMOs were allowed to grow commercially. They had a comprehensive system in place, but it was amended to comply with the requirements of the CPB and the EU. .

Argentina – had a detailed system of administrative norms or rules issued by the NCA prior to joining the NBF project.

Philippines - was the first ASEAN country to initiate a biotechnology regulatory system with the issuance of a Presidential Order in 1990 to establish a national biosafety committee. This committee subsequently issued two guidelines for work on GMOs in 991 and 1998. In 2002, the Department of Agriculture issued an administrative order for the importation and release into the environment of plant products derived from modern biotechnology.

Indonesia - the first regulations in the form of a ministerial decree, issued in 1994, were for the risk assessment of biotechnology product, with a subsequent initiatives on food labelling, food safety and field releases.

Republic of Korea - had already drafted overall national legislation on biosafety prior to joining the NBF project; these included sectoral departmental regulations on GMOs in a wide range of areas such as food labelling, field testing, monitoring, health related aspects, food standards, environmental impacts, risk assessment, etc.

36. However, most countries that started work on their NBF had no pre-existing regulatory regime for biosafety prior to embarking on their NBF development project.

37. For the **implementation** projects, the status of NBFs in the 8 countries at the start of the project can be grouped into three categories: those with primary laws in place, those who drafted a new law and those who used an existing law to encompass biosafety. With the exception of Cuba, all other 7 countries have chosen to develop regulatory regimes, which regulate the process rather than the product. Because all genetically modified biological entities or exotics to the country are regulated in Cuba, it appears to have a combination of a process as well as product base for regulation.

Countries with Approved Primary Laws

38. When the Implementation projects started in Sept. 2002, only two countries had an approved Law in place. These were namely Cuba, which had a Decree Law 199/99 on Biological Safety (1999) and Poland, a GMO Act 2001. Cameroon, which was in an advanced stage with its Law to govern Biotechnology (Law 2003/006) at the start of the Implementation project, had the Law approved in June 2003; less than a year after the Implementation project began.

Country using Existing Law

39. Uganda was unique among the 8 because Uganda had initially opted not to develop a new Law, but to expand on its existing Science and Technology Law to include biosafety regulation. However, after more than two years into the Implementation project, it was advised by its Ugandan legal fraternity in a national consultation, that the biosafety regulations being drafted exceeded the legal statute of the Science and Technology Law. A new Biosafety Bill was therefore promulgated.

Countries with New Draft Laws

40. All remaining 4 countries, namely Bulgaria, China, Kenya, Namibia decided to draft a new comprehensive primary legislation. With the exception of Bulgaria, which has called its law the 'GMO Act", others, including Uganda, have chosen to name their legislation as "Biosafety Bill". China is distinct in naming it as "Transgenic Biosafety Law".

41. For the NBF Development project, the various types of legal instruments (Box 9) chosen by countries to regulate GMOs depended both on their previous experiences with regulating GMOs as well as their regulatory set up in relation to areas such as quarantine, biosecurity, science and technology, trade, food safety etc. The level of regulatory instrument (Box 9) chosen was also important and depended both on their pre-existing regulatory regime for biosafety as well as the existence of suitable regulatory instruments that could be used to cover biosafety regulations.

Box 9: Levels of regulatory instruments

The different types of instruments at the various levels of law-making can be categorised as follows:
Level 1: includes legal instruments approved by the legislative branch of government, such as a parliament, congress, legislature, or house of assembly, which are then promulgated with binding effect.
Level 2: includes legal instruments that are created under delegated authority by an individual or group, who then present them back to the legislature for approval; these instruments are then promulgated with binding effect.
Level 3: covers instruments that are created under delegated authority by an individual or group, but which do not need further approval by the legislature before promulgation that is binding.
Level 4: comprises the work of the judicial branch; they include binding decisions on the interpretation of instruments in Levels 1-3 by courts or other adjudicators, and binding decisions creating law by courts.
Level 5: includes non-legally binding instruments that are created by an individual or group with delegated power without the need for further approval before promulgation.

Table 3: Level and type of primary regulatory instrument chosen by countries on completion of their NBF

Region	# of NBFs completed	Level of pre-existing legal instrument	Level of legal instrument selected in NBF
Africa	**23**	No pre-existing specific legal instruments for biosafety 23 countries	Level one: 21 countries Level three 2 countries
Asia	**18**	Level one: 1 country Level three: 8 countries No pre-existing specific legal instruments for biosafety 9 countries	Level one: 1 country Level three none Level one: 2 countries Level three 6 countries Level one: 6 countries Level three 3 countries
Caribbean	**4**	No pre-existing specific legal instruments for biosafety 4 countries	Level one: 4 countries Level three none
Central and Eastern Europe	**14**	Level three: 12 countries No pre-existing specific legal instruments for biosafety 2 countries	Level one: 12 countries Level three none Level one: 2 countries Level three: none
Latin America	**8**	Level three: 1 country No pre-existing specific legal instruments for biosafety	Level one: 1 country Level three none Level one:4 countries Level three 3 countries
Pacific	**4**	No pre-existing specific legal instruments for biosafety 4 countries	Level one: 2 countries Level three 2 countries

42. A number of countries **without** a pre-existing biosafety regime decided to select a level 3 primary legal instrument; in Asia, these countries included Jordan, Lebanon, Maldives, and Bhutan; in Africa two countries, Tanzania and Mozambique chose a level 3 legal instrument for biosafety; in Pacific two countries, Samoa and Vanuatu chose a level 3 law (Box 10); as did four countries in Latin America, Costa Rica, Ecuador, El Salvador, and Venezuela.

Box 10: Examples of countries choosing level 3 primary legal instrument in different regions:

Venezuela - The project elaborated a proposal for a national regulation on development, manipulation, transport and introduction into the environment of GMOs for the implementation of the CPB.

Mozambique - Biosafety regulatory regime consists biosafety regulations and guidelines describing the roles and procedures of the National Biosafety to be enacted by the Council of Ministers.

Vanuatu - The main legislative vehicle for putting the NBF in place is the Animal Importation and Quarantine Act and Plant Protection Act. These Acts are currently being updated and merged into a Biosecurity Bill through activities of the Secretariat of the Pacific Community (SPC). Biosafety is integrated with biosecurity in the Biosecurity Bill. The NBF also calls for amendments of the Plant Protection Act and Environmental Management and Conservation Act to address conflicts, overlaps and gaps.

Bhutan – decided to formulate biosafety regulations for management of GMOs under an existing Act, the Food Act of Bhutan, 2005 as this Act provided for the promulgation of regulations on GMOs by the Minister of Agriculture.

Lebanon, which also started the NBF project without any pre-existing legal instruments on biosafety, on the other hand decided that the country needed some form of biosafety regulation urgently, particularly as a trading nation dependent on export and import of agricultural produce. The NEA, with the backing of the NCC, and on the advice of their national consultant on legal issues, decided to opt for an interim By-law on biosafety, with the intention to develop a full biosafety law at some stage in the future, based on their experiences with the By-law.

Tanzania - The draft Environmental Management Bill provides for the regulation of development, handling and use of GMOs and products thereof. It proposes to empower the Minister responsible for Environment in consultation with sector Ministries to make regulations, issue guidelines and prescribe measures for the regulation of the development, handling, and use as well as the importation and exportation of GMOs and their products.

43. The reasons for choosing a level 3 primary legal instrument included:

- Building on existing legal instruments so as to make best use of a functioning system;
- Expediency - as a by-law or decree requires either ministerial or cabinet approval, and does not require amendment of an existing law and therefore parliamentary approval;
- A By-law or decree can therefore be promulgated fairly quickly and a country would have a legal basis for regulating GMOs within a short time-frame;
- In a rapidly changing scientific field, countries preferred to work with a legal instrument that could be reviewed and revised easily, leaving their options open for formulating a Level 1 legal instrument later if needed, after gaining experience with the level 3 measures.

44. Other countries without a pre-existing biosafety regime decided to adopt a level 1 biosafety law as the primary legal instrument; there are some interesting differences between the different regions in why and how these countries decided to go for a level 1 law (Box 11). Countries that chose to develop a level 1 biosafety law included most of the 25 African countries that have completed their NBF to date (Table 3); six countries in Asia: Cambodia, DPR Korea, Tajikistan, Kyrgyzstan, Laos PDR, Myanmar and Nepal; four countries in the Caribbean (Grenada, Dominica, the Bahamas, and Antigua and Barbuda); four in Latin America (Argentina, Chile, Guatemala and Peru; two in the Pacific, Tonga and PNG; two in the CEE, Armenia and Georgia; and five countries in the Caribbean (Antigua and Barbuda, the Bahamas, Dominica, Grenada and Saint Lucia).

Box 11: Examples of countries choosing level 1 laws in different regions:

Georgia - did not have any legislation in place regulating LMOs prior to joiining the project. During the project, a draft law on ``Genetically Modified Organisms``was prepared, but it is still not adopted and is currently undergaing revision. Secondary legislation or sub-laws (statutory acts) are also being drafted; these include: Decrees of the Government on contained use, deliberate release into the environment and direct use as food or feed, guidelines for risk assessment; joint order of different ministers (Minister of Agriculture - guidelines for GMOs field and laboratory testing, on database of GMO Experts, on work of GMOs Scientific Commission"; etc).

Albania - there was no specific biosafety law, but there are many laws related to biosafety and biotechnology, which can be used and adapted: food safety, nature protection acts, etc. Albania had drafted a general nature protection law, consisting of couple of provisions about GMOs, and this law had been in Parliament for couple of years but has not been adopted because of these provisions. Their current proposal is to exclude GMOs from general law and draft a new special law for biosafety. This draft was done during the project, but it is under revision at the moment.

PNG - There was no existing legislation that dealt with biosafety prior to the UNEP-GEF project. PNG opted for the development of standalone biosafety legislation, namely the "Biotechnology and Biosafety Bill". The Minister is given powers to develop Biosafety and Biotechnology Regulations under the Bill. The driving force behind this option was the importance of biotechnology and biosafety in addressing food security and the lack of existing legislation that adequately covers the protection of biodiversity. The scope covers all activities involving modern biotechnology.

Tonga - There was no biosafety legislation in place prior to the UNEP-GEF project. Tonga opted for a standalone Biosafety Bill with regulations to regulate LMOs. The draft NBF also proposes several statutory amendments to six existing laws: Aquaculture Management Act 2003, Fisheries Act 1989, Consumer Protection Act 2000, Business Licenses Act 2002, Public Health Act 1992, and Therapeutic Goods Act 2001. The scope of the Biosafety Bill includes modern biotechnology techniques beyond the Protocol and covers all activities.

Caribbean - In the absence of an NBF catering for implementation of the Cartagena Protocol on Biosafety, all Caribbean countries submitting draft final NBFs to date reported an absence of laws that could be specifically applied to regulating trade in modern biotechnology, with particular emphasis on transboundary movement of LMOs and their potential threats to biodiversity. These countries considered alternatives to the NBFs catering for implementation of the Cartagena Protocol on Biosafety as amendments of several relevant laws which preceded the advent of the Protocol to make them applicable to its enforcement. The multiplicity of amendments envisaged was deemed legally undesirable and all countries agreed to develop new laws represented by the draft final NBFs which, among other things, will cater for implementation of the Cartagena Protocol on Biosafety.

Rwanda - no laws explicitly address biosafety issues before the project; thus Rwanda committed itself in developing a National Biosafety Law.

Swaziland - Survey of the existing legislations revealed that they do not explicitly address modern biotechnology and Biosafety issues. A draft bill was therefore prepared under the NBF project.

Tajikistan, which started the NBF project without any pre-existing legal instruments on biosafety and with a relatively underdeveloped biotechnology sector and little experience with GMOs, decided to develop a full biosafety law because during the process of analysis and consultation, the NEA realised the importance of biosafety as a sustainable development issue. The NEA also wanted to ensure the full support of the parliament or *Majlis* for implementing their NBF.

China - In the early 1990s, China had already implemented a very pragmatic approach to GM crop regulation. Regulations were basically product based with special attention given to the economic interest of a given application[1]. By 1993, China had already established a biosafety regulation, namely the 'Safety Administration Regulation on Genetic Engineering' under the Ministry of Science and Technology (MOST). This regulation established general principles, safety categories, risk assessment and risk management procedures, application and approval mechanisms and legal responsibilities[2.] This was followed by a regulation on 'Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (1996)' by the Ministry of Agriculture (MOA). In May 2001, the State Council promulgated a new decree on biosafety, entitled the 'Regulation on the Safety Administration of Agricultural GMOs'. This new Regulation replaced the 1993 Regulation issued by MOST. The Ministry of Agriculture (MOA) then issued in 2002, three new implementing regulations under this decree to regulate biosafety management, trade and labeling of genetically modified (GM) agricultural products. Under the MOA, the biosafety management system for agricultural biotechnology applications comprises 3 channels, namely, the Technology System, Monitor and Management and Law and Regulation System, with involvement of multiple agencies and institutions and supported by numerous administrative regulations[3.] Monitor and management are at both the national and provincial levels. The Ministry of Public Health (MPH) also promulgated a new regulation to address GMO food safety in 2002. These regulations resulted in several important changes on regulatory oversight after commercialization. However, despite the comprehensive framework, which was already in place, it was decided that a new primary law on biosafety would be drafted for China, under the leadership of SEPA.

45. Their reasons for choosing a full biosafety law as the primary legal instrument included:

- There were no suitable existing laws that could serve as a 'home' for a level 3 biosafety legal instrument;
- Their legislative systems enabled them to pass the level 1 law relatively quickly, especially with the political support of the government. For example, four of the countries that chose a full biosafety law have had the draft bill passed by their Parliament or Assembly within a year of completion of the NBF. In Cambodia, the parliament is still considering the draft bill although the Cabinet has approved the draft published in the NBF with some changes.
- The drafting and approval of a full biosafety law was considered to be a sign of support not only from a Government Minister, but also from Parliament as a whole, strengthening ownership within the country and making it easier to implement the NBF.
- There were no existing laws that adequately address or recognise the importance of biotechnology and biosafety in addressing national priorities such as food security and protection of biodiversity.

46. Some countries with pre-existing biosafety Level 3 legal instrument, such as Iran and Thailand, have opted for the option of drafting a new national biosafety law (Level 1) since they had considerable experience with implementing regulations for biosafety. In Africa, most of the countries that have published their draft NBFs have chosen a Level one law for the reason that this will enable them put in place a comprehensive law that at the same time will be dynamic, and can evolve with the development of the technology.

47. Others with a pre-existing biosafety regime, such as Philippines, Indonesia, Viet Nam and Sri Lanka, decided to review and revise their existing legal instruments in order to develop a Level 3 legal instrument that is consistent with the CPB, but have all left the option open to develop a Level 1 biosafety Law as the primary legal instrument at some future date.
In all countries that have drafted their regulatory instrument, the scope of the regulatory regime is, as a minimum, in accordance with the Cartagena Protocol, and covers transboundary movement – export, import and transit - referring either to LMOs (examples from Asia include Jordan, Lao PDR, Kyrgyzstan, Cambodia) or to GMOs (examples from Asia include Bhutan, Maldives, Viet Nam). The instruments also address procedures for food and feed products (FFP) in accordance with Article 11 of the CPB.

48. In addition, many of the draft instruments go beyond the CPB in accordance with national priorities to include issues related to the production of GMOs within the country such as: Regulation of biotechnology R&D (for example Iran and DPR Korea, PNG); Contained use of GMOs; Field trials; Commercial release.

49. Box 12 gives an example of types of secondary legislation developed during implementation.

Box 12: Cuba: drafting secondary regulations:

Cuba has supplemented its Decree-Law 190 on Biological Safety with several complementing legislations. Some of these include Resolution 42.1999: Official List of Biological agents, Resolution 8.2000: General Regulation on Biosafety, Resolution 103.2002: Regulation on the confined use of transgenic microorganisms and invertebrates, Resolution 112.2003: Regulation on the confined use of transgenic plants and animals, Resolution 76.2000: Regulation on Granting Biological Safety Authorizations and Resolution 2.2004: Regulation on Accountability and Control.

50. Some examples of the objectives and scope of regulatory instruments from various countries, development and implementation, is given in Box 13; these are from countries with an active R&D programme in biotechnology as well as countries whose primary concern at present is to regulate imports but who are also interested in promoting domestic production of GMOs.

Box 13: Examples of objectives and scope of regulatory instruments from different regions

Philippines –*"The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles."*
Estonia - *The Estonian Act on Release into the Environment of Genetically Modified Organisms* came into force on January 13, 1999 (Official Journal RT, I ,1999, 10, 151).
The objective of the Act is to protect human health and the environment from the consequences of the release into the environment of GMOs, to ensure the safe use of genetic modification techniques and the development of such techniques in an ethically acceptable manner. The Act also aims to implement EC Directive 2001/18/EC.
Tanzania – The NBF applies to the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof that may have adverse environmental, human and animal health and socio-economic as well as ethical and cultural effects on the inhabitants of Tanzania.
PNG - The five objectives of the biosafety bill are:

1. To protect the health and safety of people and the environment, by identifying risks posed as a result of modern biotechnology, and by preventing, reducing and eliminating those risks through regulating genetically modified organisms;
2. To ensure that proper weight is given to both the long-term and short-term social, economic, environmental and equity considerations in deciding all matters relating to genetically modified organisms and to prevent threats posed by genetically modified organisms on the country's unique biodiversity;
3. To protect and sustain the potential of natural and physical resources against threats posed by genetically modified organisms to meet the reasonably foreseeable needs of future generations, and safeguard the life-supporting capacity of air, water, land and eco-systems;
4. To avoid, remedy or mitigate any adverse effects of activities on the environment by regulating in an integrated, cost-effective and systematic manner, activities and dealings relating to genetically modified organisms; and
5. To ensure that dealings with genetically modified organisms are regulated in a way that is consistent with Papua New Guinea's national interests.

Demonstration project countries:
The objective of the regulatory regimes for biosafety in all countries is consistent with the CPB: protection of human and animal health, and the environment. Although the CPB also mentioned 'conservation and sustainable use of biodiversity', not all countries have included this in their biosafety law. Biodiversity is not mentioned in the GMO Act of Bulgaria, Kenya and Poland. Uganda is the only country, which has included 'the need to minimize the impact of international trade' as one of its objectives. All 8 demonstration countries have chosen to regulate genetically modified organisms (GMOs) covering a range of activities beyond the movement of GMOs across national boundaries.

All 8 demonstration countries have expanded the scope of their regulatory regime to include research and development *i.e.* contained use and products of GMOs. Since a majority of GM products are food and feed, it is inferred that GM food and feed are regulated. Although food and feed safety are not mentioned specifically in their biosafety legislation, many countries have, however, chosen to regulate food and feed either by new regulations to be developed under the biosafety legislation or by amendments to existing laws/regulations on food and feed, which often are traditionally under the purview of the Ministry of Health and Ministry of Agriculture, respectively. Additionally, countries like Kenya and Uganda have involved the Bureau of Standards (which controls food/feed quality) to regulate food/feed safety.

China, Namibia and Poland have included 'production or manufacture' to be covered by their law, whereas Cuba has added 'biological agents and exotics' to the scope of its Law 199/99. The official biological agents listed in Resolution 42 are those that affect man, animals and plants.

Uganda is exceptional in that the scope of its proposed Bill only covers confined and commercial releases of GMOs and import of GMOs for these two categories of releases. This means that contained use of GMOs is exempted from regulation, until they are ready for release.

NBF: the institutional set-up

51. In the draft NBFs in the different regions, the proposed institutional setups for the **National Competent Authority (NCA)** as required under Article 19 of the Cartagena Protocol include:

- A single NCA receiving and processing applications; this is usually in consultation with a National Biosafety Committee or Commission (NBC) and line ministries, for example the option chosen by Lebanon (Ministry of Environment), Cambodia (Ministry of Environment), Samoa (Department of Environment and Conservation), Grenada, St Lucia, Antigua and Barbuda (the national biosafety coordinating body), Bahamas (BEST Commission), Argentina (the Secretary of Agriculture, Livestock, Fisheries and Food), Gambia (National Environment Commission), Ghana)National Biosafety Authority), Czech Republic (Ministry of Environment), Georgia (Ministry of Environment and Natural resources, Slovenia (Ministry of Environment, Spatial Planning and Energy).
- The most common model is more than one NCA, each with Sectoral responsibilities. The receipt of applications for GMOs can be either through a:
  - Single window for applications received by a central coordinating body and sent for processing to the relevant NCA- e.g. Iran, DPR Korea, Myanmar;
  - Multiple windows with applications received by the responsible government agencies, with coordination provided by NBC - e.g. Belarus, Estonia, Croatia, Latvia, Philippines (Box 14), Indonesia.

Box 14: Institutional set up proposed in NBF: an example from the Philippines

The national focal point responsible for liaison with the Secretariat shall be the Department of Foreign Affairs.

The following are identified as competent national authorities, responsible for performing the administrative functions required by the Protocol:

- The Department of Agriculture for biosafety decisions concerning plants and plant products derived from modern biotechnology, fisheries and other aquatic resources, domesticated animals and biological products used for animal husbandry or veterinary purposes and biological agents used for biocontrol;
- The Department of Science and Technology, for biosafety decisions concerning research and development;
- The Department of Health, for biosafety decisions concerning pharmaceuticals for humans that are not explicitly excluded under Article 5 of the Protocol, i.e. pharmaceuticals which are not addressed by other relevant international agreements or organizations; and,
- The Department of Environment and Natural Resources, for biosafety decisions that concern regulated organisms intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources, and applications of modern biotechnology with potential impact on the conservation and sustainable use of biodiversity.
- The national focal point and the competent authorities are required to coordinate with the National Committee on Biosafety of the Philippines (NCBP) in accordance with its mandate. For genetically modified organisms not falling under the jurisdiction of the competent authorities enumerated above, the NCBP shall designate the appropriate agency that shall act as such authority.
- *Biosafety Clearing House.* The NCBP Secretariat shall serve as the focal point for the BCH in coordination with the DENR-PAWB serving as the focal point for the Clearing House Mechanism (CHM) of the Convention on Biological Diversity.

Box 15: Institutional set up in demonstration project countries

Six of the eight countries in the demonstration project have chosen the Ministry of Environment as their National Executing Agency (NEA). Kenya and Namibia are different in having the Ministry of Science and Technology and the Ministry of Education as their respective NEAs. The NEA for Uganda is the National Council for Science and Technology, which is under the ambit of the Ministry for Finance, Planning and Economic Development.

Most countries have more than one National Competent Authority (NCA). Cameroon is the only country among the 8 that has one NCA, which is the Ministry of Environment and Nature Protection (MINEP). Although Cameroon has only one NCA, MINEP works closely with other stakeholder Ministries like Ministry of Agriculture and Rural Development, Ministry of Livestock, Fishery and Animal Industry, Ministry of Health, Ministry of Higher Education and designated laboratories. On the other hand, Kenyan has as many as 6 NCAs. These are generally distributed among relevant Ministries and agencies like Ministries of Agriculture and Forestry, Health, Science and Technology, Environment (and Natural Protection, Water and Land) and Commerce, Bureau of Standards, National Environment Management Agency, Plant Health and Inspection Services, etc.

Bulgaria is an example where there is a clear division of responsibilities between two NCAs. The Ministry of Environment and Water is the NCA for contained use and deliberate release whilst the Ministry of Agriculture and Forestry has powers to grant, modify and withdraw authorizations for placing GMOs and their products on the market.

The clear division of roles and responsibilities between different NCAs is not only cost-effective and expedient, but also prudent. Multiple NCA involvement reinforces inter-Ministerial collaboration and greater national ownership of decisions.

52. In the draft NBFs in all regions, the proposals for the **risk assessment** setup usually assign that responsibility to the NCA or overall biosafety body, with advice from either an ad-hoc scientific advisory body, or an established advisory committee. The composition of this advisory body is often determined by the regulatory instrument and in some cases, NGO representation or regional expertise on advisory committees is allowed (e.g. Iran, Samoa, PNG, Niue).

Box 16: Examples of institutional **responsibilities for risk assessment:**

Tajikistan - Risk assessment will be (the responsibility of) an Expert Board under NBBC. It will consist of experts from research institutions of Academy of Science, Tajik Academy of Agricultural Science and Ministry for Healthcare. All these subdivisions have a relevant capacity, technical equipment and work experience.

Albania – the National Biosafety Committee makes decisions, being advised by Scientific Commission of the National Biosafety Committee. The scientific committee shall consist of seven members. The members of the scientific committee will be experts from the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, agriculture, veterinary science, biotechnology and safety at work.

Tonga - The Director for Department of Environment (the NCA) can specify the means by which scientifically based risk assessments are to be carried out, and appoint appropriate bodies to undertake risk assessments.

Caribbean - The NCA is assisted in its work by a Scientific Advisory Committee, which is responsible for conducting risk assessment. In Grenada and the Bahamas, risk assessment is done by the overall coordinating body mentioned before. In addition to the Scientific Advisory Committee, St. Lucia's National Competent Authority is supported in its work by a legislated entity called the Biosafety Unit. Staffing of the Unit is also legally constituted and is comprised of the following: biosafety coordinator, information technology specialist, biosafety appraisal officer, public education specialist, administrative secretary and inspectors.

Gambia - An inter-sectoral National Biosafety Technical Working Group will be established with primary responsibility for risk assessment; decision making will be through the National Biosafety Technical Committee.

53. Some NBFs allow for non-government representation on the decision making body (e.g. Iran, Jordan, Yemen, Bhutan). In the draft NBFs in the region, the proposals for **decision making** include a variety of different models:

- A multi-stakeholder body (usually madeup of government agencies) for decision-making, sometimes chaired by environment (e.g. Jordan, Kyrgyzstan, Iran, Lebanon Yemen);
- Decision making function vested in a single, after consultation with other agencies or with a multi-stakeholder advisory body (e.g. Bhutan, Cambodia,);
- Decision making function vested in multiple NCAs, after consultation with other agencies and/or with a multi-stakeholder advisory body (e.g. Indonesia, Philippines, Viet Nam).

Box 17: Examples of different decision-making roles and responsibilities

Bhutan – the NCA (BAFRA) is responsible for making the final decision but may consult the NCB for a technical opinion and recommendations. They may also consult with the National Environment Commission (NEC) where it considers that an application may have long term national implications.

Caribbean - The Minister responsible for biosafety is the final decision maker for Grenada, St. Lucia and Dominica whereas in the Bahamas, it is the Director, Department of Environment Protection and Planning or the Undersecretary, Bahamas Environment and Technology Commission following Cabinet approval in each case.

Czech Republic – applications are submitted to Ministry of the Environment. Ministry of Environment sends it to Ministry of Health and Ministry of Agriculture for their opinion, and also to advisory body Czech Commission for the Use of Genetically Modified Organisms and Products. Commission has 15 members, from ministries, academia, institutes, universities, NGOs and organic farming and consumer associations. These two Ministries (through their panels of experts) and the Czech Commission prepare their independent expert opinions. MoE has to consider all comments, objections and standpoints obtained, including that submitted by the public, in its final decision.

PNG - The DEC based on recommendations from a Biosafety and Biotechnology Council (NBBC) consisting of 11 members created under the Bill, to be appointed by the National Executive Council, and to be chaired by the head of DEC. If there is however an appeal, the Minister can either uphold or overturn the decision of the NCA, so the Minister is ultimately the decision maker.

Nigeria - Decision making executed through a National Biosafety Agency with its technical committees that ensure sound scince input into decision making.

Kenya - Under the proposed Bill, Kenya will establish a National Biosafety Authority with a Chief Executive Officer, to be the administrative body. This National Biosafety Authority will be managed by a Board, which has a multi-stakeholder membership of 15, comprising senior representatives from key Ministries and Agencies, academia, consumers and farmers. Board members will have a fixed tenure, receive remuneration and have clearly defined roles and responsibilities Decision-making rests with the Board, whose members will have a fixed tenure, receive remuneration and have clearly defined roles and responsibilities. This National Biosafety Authority will be able to appoint relevant advisory committees on scientific, technical and other matters, when the need arises. Institutions, which are carrying out genetic modification R&D, are required to establish IBCs to oversee biosafety at institutional level. The IBCs are indirectly answerable to National Biosafety Authority via their institutions**.**

Institutional set-ups in demonstration project countries

54. The experiences of the countries that are implementing their NBF in the demonstration projects show that most countries have adopted a 2-tier administrative structure, with separate and distinct administrative and decision-making bodies. Technical and scientific advisory committees often assist the decision-making body by providing advice after evaluating the safety aspects of the applications. Advisory committees can be established at two levels: institutional and national levels. Institutional Biosafety Committees (IBCs) are sometimes required by law to be set up in institutions conducting genetic modification, to ensure safety in contained use. IBCs are usually responsible to the national biosafety advisory committee, either directly or indirectly via their institutions.

55. An administrative body is established under the primary legislation in all countries to give them the power of authority to receive and process biosafety applications and to make decisions. Even in countries, such as Kenya and China, where the Bill is pending approval, interim administrative measures to handle requests are operational and applications are being processed. In Kenya, the interim measures operate within the National Council for Science and Technology under the Science and Technology Act.

56. Under the proposed Bill, Kenya will establish a National Biosafety Authority with a Chief Executive Officer, to be the administrative body. This National Biosafety Authority will be managed by a Board, which has a multi-stakeholder membership of 15, comprising senior representatives from key Ministries and Agencies, academia, consumers and farmers. Board members will have a fixed tenure, receive remuneration and have clearly defined roles and responsibilities. Decision-making rests with the National Biosafety Authority, which will be able to appoint relevant advisory committees on scientific, technical and other matters, when the need arises. Institutions, which are carrying out genetic modification R&D, are required to establish IBCs to oversee biosafety at institutional level. The IBCs are indirectly answerable to National Biosafety Authority via their institutions.

57. In Cameroon , the National Biosafety Committee was set up in accordance with section 5(2) of the Law 2003/006, which states that the 'Competent National Administration' will be the national authority in charge of coordinating activities related to biosafety. The National Competent Administration shall be responsible for carrying out the administrative duties prescribed by the Cartagena Protocol on the prevention of biotechnology risks. It shall take its decision within a National Committee of 19 members from services and bodies concerned. A sub committee within the National Biosafety Committee, called the the Scientific Advisor Committee shall be established and ad hoc membership into this committee is also allowed as the need arises.

58. Namibia will establish a Biosafety Council under the draft Bill, with a Registrar to manage the administrative functions. The appointment of the 7-member Biosafety Council is a transparent process, where nominations from the public would be invited through announcements in the government Gazette and two popular national newspapers. The Council members will to be drawn from diverse backgrounds ranging from environment, animal and public health, molecular biology, law, research and development, trade and economics, etc. The exact composition is not mentioned. By specifying the expertise rather than the organizations/agencies whom the Council members will represent will have flexibility to involve wider public and private participation than having a fixed number of positions allocated to different stakeholders. The prior approval of the Minister is required for appointment of Council members. The Council members receive remunerations; have a fixed term of service with defined roles and responsibilities. *Ad hoc* Expert Committees in technical and scientific matters will be appointed to assist the Council.

59. Poland, on the other hand, has the Minister responsible for the environment to be the Governmental administrative authority. The Minister is the ultimate authority to grant consents and permits. A Commission on GMOs established under the Law, acts as an opinion making and advisory body to the Minister. The 19-member Commission has representatives from relevant Ministries, the President of the Competition and Consumer Protection Agency, the scientific community, the biotechnology business, non-governmental organizations and consumer organizations. Members of Commission have a defined tenure, receive financial support for expenses incurred when on duty outside the locality of their residence and have clear terms of reference.

NBF: Addressing Article 23 of the CPB

60. Countries have addressed Article 23of the Cartagena Protocol on public awareness, education and participation in different ways, depending on each country's particular social, political and economic situation.

61. The main way in which the public has been involved has been through each country's NBF development project. The project required each country to not only carry out awareness and education activities on biosafety, but also required that the process of developing the NBF involved public participation in making key decisions (see Figure 2). The main mechanism for participation in the development of NBFs was through the National Coordinating committee (NCC), which was required in every country participating in the project. The NCC was responsible for overall policy guidance for the development of the NBF, and all countries formed such a body. In these countries, the NCC became the overall policy and decision-making body for GMOs as part of the institutional set-up in the NBF. The NCC included relevant government agencies, as well as representatives from other stakeholders in all countries (Annex 1).

62. **In the countries in Asia, the breakdown of statistics for the NCC is as follows:**

- All countries included government representatives on the NCC;
- 13 countries included NGO representatives in their NCC. These included representatives from Consumer associations (e.g. in Jordan, Yemen), farmers' associations (e.g. Tajikistan), Women's organisations (e.g. DPR Korea), or environmental NGOs (Kazakhstan, Nepal, Sri Lanka);
- 10 countries included private sector representation in their NCC, usually from the Chamber of Commerce (e.g. Nepal, Yemen) or similar commercial associations (e.g. Kyrgyzstan, Philippines) or private firms (e.g. Iran, Indonesia);
- 16 countries included public sector scientists in their NCC, including universities (e.g. Jordan, Myanmar, Syria) and public research institutes (e.g. Syria, Iran, Republic of Korea);
- One (Yemen) included media representation;
- 1 country included NGO representatives in their NCC. These included representatives mainly from Environment NGOs (e.g. Tajikistan).

63. **In the Pacific Island countries, the breakdown of statistics for the NCC is as follows:**
- All countries included government representatives on the NCC;
- 6 countries included NGO representatives in their NCC. These included representatives from Consumer Associations (e.g. Fiji), women's organizations (e.g. Kiribati) and environment NGOs (e.g. Cook Islands, Solomon Islands, Samoa);
- 8 countries included private sector representation in their NCC, usually from the Chamber of Commerce (e.g. Fiji, Kiribati, Vanuatu, Samoa), private firms (Solomon Islands, Samoa);
- 5 countries included public sector scientists in their NCC, in particular universities (e.g. Fiji, Marshall Islands, Samoa, Solomon Islands) or research institutes (e.g. Papua New Guinea);
- 1 country included media representation (e.g. Niue).

64. **In the CEE countries, the breakdown of statistics for the NCC is as follows:**
- All countries included government representatives on the NCC;
- 13 countries included NGO representatives in their NCC. These included representatives from Consumer Associations (e.g. Macedonia, Serbia and Montenegro, Turkey, Albania) and environmental NGOs (e.g. Armenia, Belarus, Georgia, Turkey, Ukraine, Croatia, Slovakia, Moldova);
- 10 countries included private sector representation in their NCC, from the Chamber of Commerce (e.g. Slovenia), similar commercial and trade associations (e.g. Czech Republic, Latvia, Turkey, Albania) or private firms (e.g. Croatia, Lithuania, Slovakia, Belarus);
- 16 countries included public sector scientists in their NCC, including universities and academies (e.g. Albania, Armenia, Belarus, Georgia, Serbia and Montenegro, Turkey, Croatia, Macedonia, Slovakia, Romania) and public research institutes (e.g. Ukraine, Turkey, Serbia and Montenegro, Georgia, Belarus, Armenia, Albania, Estonia, Czech Republic, Latvia, Lithuania, Macedonia, Croatia, Romania, Slovakia);
- 4 countries included media representation (e.g. Belarus, Serbia and Montenegro, Slovakia, Romania).

65. **In the African countries, the breakdown of statistics for the NCC is as follows:**
- All countries included government representatives on the NCC;
- 23 countries included NGO representatives in their NCC. These included representatives from Consumer Associations (e.g. Central African Republic, Chad, Republic of Congo, Djibouti, Ethiopia, Gabon, Togo, Senegal, Côte d'Ivoire, Burkina Faso, Sierra Leone, Mali, Mozambique), farmer's associations (e.g. Nigeria), women's organizations (e.g., Central African Republic, Mali), or environmental NGOs (e.g. Togo, Sudan, Gabon, Guinea-Bissau, Liberia, Democratic Republic of Congo, Republic of Congo, Burundi, Botswana, Algeria, Lesotho, Benin, Guinea, Mali, Mozambique, Sudan);
- 15 countries included private sector representation in their NCC, usually from the Chamber of Commerce (e.g. Chad, Djibouti, Togo, Guinea, Botswana, Guinea, Seychelles), similar commercial associations (e.g. Botswana, Ethiopia, Madagascar, Liberia, Burkina Faso, Nigeria) or private firms (e.g. Gambia, Ethiopia, Liberia, Burkina Faso, Algeria);

- 21 countries included public sector scientists in their NCC, including universities (e.g. Burundi, Central African Republic, Ghana, Madagascar, Liberia, Togo, Republic of Congo, Democratic Republic of Congo, Eritrea, Madagascar, Lesotho, Ghana, Ethiopia, Sierra Leone, Togo, Senegal, Mali, Nigeria, Algeria, Mozambique, Rwanda, Swaziland, Botswana) and public research institutes (e.g. Zimbabwe, Sierra Leone, Ethiopia, Democratic Republic of Congo, Central African Republic, Burundi, Ghana, Tanzania, Lesotho, Senegal, Côte d'Ivoire, Nigeria, Algeria, Mozambique, Rwanda, Swaziland, Gambia, Botswana);
- 4 countries included media representation (e.g. Senegal, Comoros, Guinea-Bissau, Gabon).

66. **In the Latin American and Caribbean countries, the breakdown of statistics for the NCC is as follows:**

- All countries included government representatives on the NCC;
- 15 countries included NGO representatives in their NCC. These included representatives from Consumer Associations (e.g. Ecuador, Costa Rica, Argentina, Saint Lucia), farmer's associations (e.g. Argentina), women's organizations (e.g. Suriname, Trinidad and Tobago), or environmental NGOs (e.g. Ecuador, Peru, Venezuela, Costa Rica, Bahamas, Grenada, Antigua and Barbuda, Belize, Argentina, Guatemala, Honduras, Nicaragua, Saint Lucia, Uruguay);
- 10 countries included private sector representatives in their NCC, usually from forums (e.g. Argentina), Chamber of Commerce (e.g. Ecuador, Nicaragua, Suriname), commercial associations (e.g. Chile, Peru, Costa Rica, Argentina, Saint Lucia, Uruguay) or private firms (e.g. Costa Rica, Grenada);
- 15 countries included public sector scientists in their NCC, including universities (e.g. Barbados, Guatemala, Honduras, Nicaragua, Suriname, Trinidad and Tobago, Dominican Republic, Chile, Peru, El Salvador, Costa Rica, Antigua and Barbuda) and public research institutes (e.g. Barbados, Guatemala, Saint Lucia, Suriname, Trinidad and Tobago, Uruguay, Peru, Venezuela, Bahamas).

67. The main focus of countries in terms of Article 23 during the NBF development, given both the state of awareness of biosafety and biotechnology issues in these countries, was on:

- Increasing public awareness about GMOs through workshops, use of media such as television and radio, regular newspaper articles, and publications on biosafety. This was one of the main activities required for each national project, accounting for some 20% of the total costs of the project. Given the diversity of language in Asia, with over 20 different languages in the 23 countries, the emphasis was on publications and awareness in the main national languages. All countries in the Pacific translate public awareness materials into their local languages.
- Strengthening public education on GMOs, in order to complement this, all 23 countries also carried out extensive activities, mostly using informal means, but in some cases also through more formal channels (e.g. Sri Lanka).
- Enabling public access to information on GMOs for their effective participation in decision-making. This was done both through production of information on GMOs in printed form and by setting up websites on biosafety. For example, 16 of the 23 countries set up websites (usually as part of the NEA's website) on biosafety or specifically on the NBF project. These were in the main national language of the country. One, Yemen, even used its website to conduct a survey on whether Yemen should ratify the CPB.

68. In those countries that have completed their NBFs, the main provisions for promoting participation by stakeholders in Biosafety Decision-making are consistent with Article 23. In many countries, these provisions are enshrined in the Biosafety regulatory instrument (see Box 16 for examples), and include the following examples:

- Public consultation on GMO activities is included in all NBFs. These activities not only include applications for permits for environmental release or importation, but also involved public participation in biotechnology research. For example, some countries that set up institutional biosafety committees to oversee biotechnology research in their public sector research institutions also included provision for representation from civil society on the institutional biosafety committee, for example Iran and Philippines.
- The public are usually invited to make submissions on applications at an early stage of the decision-making process; in many countries, this is enshrined in the biosafety regulatory instrument - for example Myanmar, Lebanon, Philippines, Tajikistan, Samoa, Niue, etc.
- Information on applications made available to the public (Box 18, 19) as required by the regulatory instrument not only through the national BCH, but also in a form that is easily accessible – for example, Philippines, Indonesia, Iran, Yemen. Access to information is usually restricted to non-confidential information as defined in the regulatory instrument, and in conformity with Article 21 of the CPB.
- The public are often given opportunities to provide comments within a specified time (usually 30 days), with the mechanisms for this enshrined in the regulatory instrument, and set out in each NBF in the procedures described for processing of applications – for example, in Asia: Bhutan, Jordan, Sri Lanka, Tajikistan, Maldives; in CEE all EU and also most of other CEE countries.
- The decision-making body is mostly required to take into account public comments in making their decisions on GMOs; this is again usually enshrined in the biosafety regulatory instrument, for example Philippines (Box 13), Jordan, Bhutan, Sri Lanka, Iran.
- Many countries have provided for non-government representation on the biosafety decision-making body. Examples from Asia include:
  - Iran – on institutional and national biosafety committees, private sector and/or public;
  - Jordan – private sector and consumer reps on National Biosafety Committee;
  - Philippines – civil society representation on the National Committee on Biosafety of the Philippines and on institutional biosafety committees;
  - Lebanon – private sector, NGO reps on National Biosafety Council;
  - Yemen – Chamber of Commerce and Consumer Society on National Biosafety Committee.

69. Of the NBFs completed in the Pacific, only PNG has made specific allowance for public input into decision-making, and public participation in the licensing process is a mandatory requirement of the Biotechnology and Biosafety Bill:
"33 (3). The Council shall invite written and oral submissions from individuals, governmental authorities, provincial and local-level governments, holders of traditional knowledge, industry, interest groups and members of the public and stating a period of time (which shall not be less than 30 days and not more than three months) within which submissions may be made to the Council", and
"42 (6). The Council may, after considering submissions from the public and a technical expert panel, renew or cancel the licence."

70. For Samoa, Vanuatu and Tonga, the NBFs place emphasis on public awareness and roles of National Focal Points in facilitating public input but legislations do not specifically provide provisions for how public input are taken into account or considered in the decision-making.

Public Participation in GMO decision-making in demonstration project countries

71. Article 23 of the CPB is one of the biggest challenges in biosafety implementation in all 8 countries, because effective public participation means allowing the public to participate in all steps in the approval process, from the time when an application is received to making a decision on the application. Because this process is novel, full implementation of public participation, especially in decision-making, is yet to be realized in some countries.

72. Most countries have met the requirement of public participation in decision-making by including members of the public like non-governmental organizations, farmers or traders in either the scientific and technical advisory committees and/or the decision-making body. Depending on the rules and procedures of decision-making in these committees, the voice of the public representatives may not always be heard, although this is a start in the right direction.

73. Public access to information and participation in decision-making are enshrined in the GMO Act 2005 of Bulgaria. Information to the public is through three main channels, namely the mass media, the electronic Public Register and public consultation/hearing. The e-Public Register is accessible to the public, and is updated regularly. This Register provides information on all decisions made by the Commission on releases and placing of GMOs in the market. In addition, the Register also records areas where deliberate releases of GMOs have been authorized as well as registered premises where contained use of GMOs is carried out. The public is further informed/consulted through public hearings before any GMOs are to be released into the environment, and before these are placed in the market for sale. Public comments received are considered in decision making by the Commission. Since the Commission has 3 representatives from civil society, public participation in decision-making is further ensured.

74. Namibia has a similar process for public participation and access to information. In the case of Namibia, the applicant is obliged to advertise at its own expense, in the local newspapers for a period specified in the draft law, about its application. The Biosafety Council, which makes decisions on applications, is required to conduct public consultations/hearings and notify the public of the application received in at least two local newspapers. Public participation in decision-making is further guaranteed through the membership of the Council, who are public-nominated. Some countries (Bulgaria, Kenya, Namibia) use the Register to provide information on Council decisions and actions to the public. National websites or Biosafety Clearing Houses is another common avenue for public information.

Box 18: Examples of how information requirements for public participation are handled in the CEE:

Belarus – the National Co-ordination Biosafety Centre within 10 days from the arrival of the application shall place the information (excluding confidential one) at the information web-site of the National Co-ordination Biosafety Centre. Comments and proposals are accepted by the Centre within 60 days from the release of the application materials. The experts, performing the expertise of the application, are obliged to review and, where appropriate, take into account the comments and proposals submitted. In case it is impossible to take into account particular comments and proposals, the experts are obliged to provide written reasonable objections to the Centre. The comments and proposals and results of their review by the Expert Committee should be reflected in the expert opinion.

Czech Republic - notifications are published regularly on the MoE website and at the official desk of the Ministry of the Environment. Public can send comments. Received comments are discussed at public hearing, the results are taken into account in the final decision issued by the CA. Final decisions and the lists of authorised GMOs are published on the website of the Ministry of Environment. Similar system is used in all EU countries and many other countires (Estonia, Latvia, Lithuania, Macedonia Malta, also in Moldova, Romania, Slovakia, Slovenia).

Romania - within 10 days from the date when the CA accepts the notification (the notification contains all needed information), CA informs the public about the application, specifying the means by which information can be obtained and the deadline for receiving comments. CA publishes in its website "The Notification Summary" as well as the "Risk Assessment Study" and other relevant documents (i.e. monitoring reports) and transmits a press release, through the Directorate for Public Relations within the ministry. At the same time, announcements are transmitted to the Territorial Environment Protection Agencies under Ministry. Comments of the public can be submitted within 30 days from the date of public announcement and will be taken into consideration by the CA in the decision-making process for the authorization of the proposed activity. Depending on the received comments, public debates can be organized.

Georgia – NCA provides the announcement about receiving an application. This public announcement shall be made available through the specially designated web-site and publication in the Official Gazette of Georgia and at least in 2 nationwide newspapers. Public announcement shall contain name and address of contact person of the CA who will be responsible for providing of required information to general public. Representatives of the public may send their opinions, observations and standpoints within 90 days of the public announcement. Additionally, the NCA could organize consultations with public representatives. Opinions, observations and standpoints of the public representatives shall be taken into account during decision-making process.

Box 19: Example of requirements for public participation:

Philippines: legal instrument EO 514, states:

7.1 ***Scope of Public Participation****.* Public participation shall apply to all stages of the biosafety decision-making process from the time the application is received. For applications on biotechnology activities related to research and development, limited primarily for contained use, notice of such application through the NCBP shall be sufficient unless public interest and welfare requires otherwise.

7.2 ***Minimum Requirements of Public Participation.*** In conducting public participation processes, the following minimum requirements shall be followed:

7.2.1 *Notice to all concerned stakeholders, in a language understood by them and through media to which they have access.* Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of field trials and commercial releases, in both national and local print and broadcast media. In all cases, such notices must be posted electronically in the internet;

7.2.2 *Adequate and reasonable time frames for public participation procedures.* Such procedures should allow relevant stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public participation processes, including setting a minimum time frame as may be appropriate;

7.2.3 *Public consultations, as a way to secure wide input into the decisions that are to be made.* These could include formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy about the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas shall be utilized;

7.2.4 *Written submissions*. Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages when and the process to be followed for submitting written comments; and,

7.2.5 *Consideration of public concerns in the decision-making phase following consultation and submission of written comments.* Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public must be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision, upon request.

The case of the CEE countries:

Most of CEE countries have ratified Aarhus Convention (see table in Annex 2) and according to this convention, public must have access to information, decision making and also access to justice. All EU countires have trnasposed Directive 2003/4/EC of the European Parliament and of the Council on public access to environmental information. This Directive ensures access to environmental information. The objectives of Directive are:

a) to guarantee the right of access to environmental information held by or for public authorities and to set out the basic terms and conditions of, and practical arrangements for, its exercise; and

b) to ensure that environmental information is progressively made available and disseminated to the public in order to achieve the widest possible systematic availability and dissemination of environmental information to the public. Therefore, in particular, computer telecommunication and/or electronic technology, where available, shall be promoted.

In the EU countries, public has right to give their opinion before decision is made during 30 days after the announcement has been published by NCA.

The case of the Caribbean countries:

The draft final NBFs of Grenada, St. Lucia, Dominica, the Bahamas and Antigua and Barbuda make allowances for public input into the decision making process and for public education. For input into the decision making process, interaction with the public is by way of notifications placed mainly in mass print media by the respective National Competent Authority for each country. In addition to the placement of public notices in the mass print media, each National Competent Authority may establish a more deliberate consultative process with other government agencies, representatives from academia, the business community or other stakeholders to cater for public input into the decision making process. In St. Lucia, the legally constituted Biosafety Unit has responsibility for investigating complaints. Complaints from the public can be taken up after the decision making process in St. Lucia but if criminality is involved, they are sent to the Director of Public Prosecutions for investigation. St. Lucia's draft final NBF also caters for a legally constituted Appeals Tribunal.

NBF: Addressing socio-economic issues

75. The socio-economic impacts of biotechnology are an important consideration for all of the countries in the NBF project; many countries have included the consideration of Socio-economic issues in their decision-making process. These provisions are consistent with Article 26 of the Cartagena Protocol, and usually form part of the national policy on biosafety in the NBF, for example Lebanon, or are part of the regulatory instrument, for example Republic of Korea, Yemen, Philippines and Bhutan (Box 19). Other countries have chosen not to include socio-economic considerations in their NBF; these include Iran and Jordan in Asia; Albania, Belarus, Croatia, Moldova, most of EU countries in the CEE: Czech Republic, Estonia, Latvia, Lithuania, Malta, Slovakia, and Slovenia. The latter is because in the EU, socio-economic issues are evaluated by a special committee on the level of the EU and member states are not supposed to evaluate those issues separately.

Box 20: Example of how Article 26 is addressed in an NBF:

Philippines - the EO 514 states in article 5.4 ***Socio-economic, Ethical, Cultural and Other Considerations.*** Consistent with Article 26 of the Cartagena Protocol, concerned government departments and agencies may take into account socio-economic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Yemen - The draft legal instrument in Yemen states that the decision-making process shall consider an evaluation of Socioeconomic risks in parallel with scientific risk assessment, and that Biosafety decisions shall take into account issues of:

- Poverty alleviation, food security, etc;
- Livelihoods of small farmers, indigenous people, women, small and medium enterprises, etc;
- Cultural integrity of the country and communities.

Caribbean - Consideration of socio-economic impact of trade in LMOs and derived products is catered for by all draft final NBFs as part of the decision making process. Assessment of socio-economic impact is required as part of the risk assessment report prepared by each National Competent Authority. In Dominica, this assessment is specifically delegated to a competent regional authority to make up for the absence of the necessary skills in the country.

Georgia – CA makes decision, based on recommendation of the Advisory Council, standpoints of the Scientific Commission and other ministeies, and they have right to make decision on granting of permit on GMOs use taking into account, inter alia, socio-economic considerations and circumstances.

Romania - The CA takes into consideration the socio-economic aspects, but permits or approval can only be denied on grounds related to the protection of the environment and/or human health.

Swaziland - Socio economic aspects of the people of Swaziland and their ethical considerations shall be taken into consideration when biosafety decisions are made.

Tanzania - In implementing the NBF, the social, economic and ethical considerations shall be taken into account in Biosafety decisions. The NCAs have the mandate to undertake assessment of socio-economic impacts

Samoa - The policy pays attention to socio-economic related issues including; improved quality of life, sustained economic growth, and cultural values. In the decision-making, the NCA will take account of the particular impacts of GMOs on communities; ensure that “Cabinet, and all Ministries and agencies, are fully informed of ….. any other matter associated with GMOs which may affect the well-being of the nation or the health of its people”; and will take into consideration customs and traditions.

Argentina - A key part of the GMO regulatory process consists of verifying that the commercial approval will not have a negative impact on our foreign trade. This specific assessment is carried out by the National Bureau of Agrifood Markets and it includes an analysis of the current status of regulatory systems and public acceptance in the importing countries.

Implementing the NBF: Translating the map into action

76. As described above the process of developing the NBF is a knowledge mapping process that helps the country to identify not only its needs and priorities for the safe use of biotechnology, but also its human, technical and institutional resources needed to translate the NBF into action. Thus the establishment and strengthening of the systems that make up the NBF (Figure 1) are but a first step in this process of translation; the second step is the implementation of the NBF so that these systems are up and running.

77. In all the countries participating in the NBF development project, the long-term aim is to translate the NBF into practical and workable systems, and as countries complete their NBF, they have started to do this. The process of translation is backed up by government commitment, which has been demonstrated in a number of ways: by approval of the NBF, approval of the biosafety policy in the NBF, and by promulgation of the biosafety regulatory instrument by the appropriate body.

78. Most countries that are Parties to the CPB have turned to the GEF for further assistance in order to implement their NBF. In Asia, the current status is as follows:

- Two countries, Viet Nam and Cambodia, that completed their NBFs in 2005 and 2004 respectively, have had their implementation projects approved by the GEF and have already started the process of implementing their NBF; initial activities are focussed on capacity building in order to draft and implement specific biosafety secondary legislation for their primary regulatory instrument. In Viet Nam, the biosafety regulation has been promulgated as a Prime Minister decision (212) whilst in Cambodia, the draft biosafety law has been approved by the Cabinet and is currently under consideration by Parliament.
- Two other countries, DPR Korea and Tajikistan, have had their projects for implementation of their NBF technically cleared by GEF and are awaiting the final approval so that they can start the implementation of their NBF. In both countries, the Biosafety Laws have been approved by their parliament: the People's Assembly in DPR Korea and the Majlis in Tajikistan.
- Six other countries are in an advanced stage of preparation of their project proposals for implementation. All of these have indicated government support for the implementation of the NBF through their endorsement of the proposals as a priority for funding under the new GEF resource allocation framework for each country. The countries with advanced proposals for implementation of their include:
    - Indonesia has a proposal, endorsed by the government, ready for submission to GEF;
    - Iran, Sri Lanka, Laos, Bhutan, and Yemen have started the process of translating their NBFs into practical action plans for implementation by preparing project proposals for funding by GEF through an iterative and participatory process of analysis and planning.
- One country, Republic of Korea, which is not eligible for GEF funding, has started implementation of their NBF entirely with government funding.

79. In the Pacific, Samoa, Tonga, Niue and PNG have started development of implementation project proposals for GEF funding. All Parties in the Pacific have indicated willingness to commit some of their biodiversity Resource Allocation Framework allocations to implementation of NBFs. Given the unique challenges faced by Pacific Small Island Developing States including, limited absorptive capacity, small sizes, no economies of scale, etc., Pacific SIDS will look towards regional mechanisms and pooling of resources in a regional project during implementation to ensure sustainability.

80. In the CEE region, six countries have prepared and submitted their MSPs to GEF, 5 of them have been approved – Czech Republic, Lithuania, Estonia, Moldova, Slovakia. Latvia has been cleared for CEO approval, but the project has not yet been finally approved. In all those countries, former development project staff have been used for preparation of new project and most of them will be involved in implementing the project.

81. A number of CEE countries have started work on proposals for implementation of their NBF:

- Belarus has started work on a proposal;
- Armenia has started to prepare and plan to submit a proposal under RAF;
- Albania has declared biosafety as a priority for them and intend to apply for funding under RAF.

82. Two countries not eligible for GEF funding are implementing their NBF with government funds; these include Slovenia and Malta. Hungary is also implementing its NBF, developed under the pilot project, without GEF assistance.

83. The rest of CEE countries would be interested in implementation, but under RAF they have other priorities and they have to find other resources for biosafety.

84. None of the Caribbean countries have begun implementation of their NBFs. The countries have, however made proposals to the GEF for funds for a regional project to implement their NBFs. Those that have completed their NBFs are in the process of preparing project documents for their implementation.

85. The experience of countries implementing their NBF projects highlights the importance of sustainability. These countries have addressed financial sustainability in their respective legislation by committing Government budget to maintain the administrative and decision making bodies that were set up by the UNEP/GEF Implementation projects. Additional income will be generated through the levy of fees to be charged for requests, applications and other regulatory or monitoring activities carried out by the NCA, to augment the national budget.

86. Under the draft Bill of Namibia, the Commission will defray all expenditure incurred in the administration of the Bill to the National Research, Science and Technology Fund, which was established under the Research, Science and Technology Act, 2004. Even before the conclusion of the project, Government financial support has already been used to maintain a technician to operation a GMO detection laboratory.

87. In Poland, the State Budget covers the expenses incurred by its Commission on GMOs. In addition, Poland has an innovative mechanism to avert large financial loss by the Government by having a mandatory ‘claim security’ in the form of a bank guarantee or insurance policy to be deposited with the Commission. This is needed to protect the Commission from liability, in the event that adverse environmental impact occurs during contained use of a GMO as a result of non-

compliance to the conditions stipulated in the consent granted by the Commission.

88. The commitment of the Chinese Government to sustain biosafety after project closure, is clearly demonstrated by its growing budget to support agricultural research in biosafety over the last few years. From an initial budget of slightly over US$ 80,000 in 1999, China now spends about US$ 3 million annually on agricultural biosafety related activities.[3]

89. Building upon the impetus, momentum and foundation established by the implementation project after the project has completed, is very crucial for long-term implementation of national NBFs. In order to sustain biosafety implementation, financial resources are a prerequisite. Although the incomes accrued from fees and other regulatory levies may be modest at the beginning, these will increase with time, especially if the countries adopt biotechnology. Government commitment may also increase when the value of biosafety implementation is demonstrated.

90. Another key issue is that within a region, countries need to work together, particularly in getting their national decision making systems on GMOs up and running. In other words, regional cooperation is essential for sustainability of the NBF at the national and regional levels. The critical elements for regional cooperation include:

- Sharing of resources between countries within the region; this includes technical facilities, materials, and expertise.
- Sharing of experiences between countries in developing and implementing NBFs; this includes methodologies, materials and know-how.
- Sharing of information on biosafety between countries and through regional networks, including the BCH.
- Building and strengthening regional capacity (Regional Centres of Excellence) for biosafety and biotechnology in order to support national decision-making.

91. The importance of regional cooperation is recognised by many countries in all regions. However, one of the key lessons emerging from the projects is that **regional cooperation has to be country driven** and not in response to an external agenda. Therefore, for most countries, initial attempts at regional cooperation have taken the form of regional meetings to discuss potential areas for collaboration. Examples of such meetings during the development project include:

Asia

- Central Asia – two meetings have been held to discuss sub-regional cooperation in biosafety and biotechnology. These were in Tajikistan in 2004 and in Kyrgyzstan in 2005;
- South Asia – a similar meeting was held in Sri Lanka in April 2005 to discuss future areas for cooperation. This will be followed up by another meeting to be held in Bhutan early in 2007, as chair of the SAARC Environment Working Group to discuss regional cooperation in biosafety and biotechnology;
- South-East Asia – a meeting of ASEAN countries was held in Manila in June 2004 to discuss potential areas for cooperation in biosafety, focussing on capacity building needs within the region for implementing NBFs;
- West Asia – a meeting of West Asian and North African countries is planned for November 2006 in Syria to discuss the formulation of a regional project on capacity building for biotechnology and biosafety within this sub-region.
- As countries start to implement their NBFs, they are starting to build on these initial discussions to work on real areas for cooperation. For example, Cambodia and Viet Nam, as their first activity under their implementation project have planned a joint

subregional training on drafting of biosafety secondary legislation. This training, to be held in October 2006, will bring these two countries together with Thailand (currently finalising its NBF), to discuss secondary legislation for biosafety. One of the aims of this training is to "To work with their neighbouring countries in developing their national regulations with a view to possible harmonisation in the future."

Pacific

- Three regional meetings since 2003 to discuss regional cooperation and share experiences.
- Because of the unique challenges faced by Pacific SIDS, including limited capacity and small sizes, a regional project to pool resources and achieve economies of scale is being considered for implementation of NBFs.
- A Pacific regional node of the BCH is currently being developed to share information and promote regional cooperation.

CEE

92. There is no official regional organization covering the entire CEE, and organized regional cooperation (apart from EU) has been weak. However, the situation has improved a lot during the project. Many countries have used experts or project staff from their neighbouring countries, for example the NPC of Slovenia has been used for reviewing NBFs in Moldova, Macedonia, and Tajikistan.

93. Most cooperation has been on a bilateral basis (Romania – Moldova, Ukraine –Belarus, Czech Republic – Slovakia, Belarus – Russia, etc).

94. The Balkan countries have started to work as a sub-regional grouping again. Croatia has organized many workshops with participants from all over the sub-region, for example the 16-19 December 2004 workshop on Sub-regional collaboration on biosafety between Bosnia and Herzegovina, Croatia, Hungary, Macedonia, Romania, Serbia and Montenegro, and Slovenia. Contacts between Balkan countries are close and they cooperate on a daily basis, sharing experience and trying to work out common future plans. Slovenia as the most developed country in this region is acting as coordinator and assistant to the overall sub-region. Slovenia has also organized at least one sub-regional workshop, 11-12 September 2003, on "Public awareness and Participation"; participants from Slovenia, Croatia, Czech Republic, Macedonia and Moldova were present.

95. The Czech Republic has been very active in organizing sub-regional workshops, for example the 24-25 April 2003 Sub-Regional meeting on Biosafety Frameworks in Prague, which involved participants from Czech Republic, Croatia, Hungary, Slovakia; and the 10-11 November 2004 workshop on Implementation of NBF which involved the Czech Republic, Croatia, Slovakia and Slovenia.

96. The Caucasus countries have shown an interest in setting up a regional reference centre, but there are political constraints in deciding in which country this centre should be established.

97. During 2006, the main regional activities have been among the Balkan countries. Romania and Serbia and Montenegro have developed very close connections and good every-day cooperation. Project coordinators communicate and visit each others' workshops regularly. For example, the NPC of Romania participated in June 2005 in Novi Sad School of Journalism, "Focus: genetically modified organisms". Additionally were there also participants from Moldova, Romania,

Bulgaria, Macedonia, Albania, Bosnia & Herzegovina, Slovenia and Serbia & Montenegro.

98. In June 2005 NPC from Serbia and MN participated in workshop in Romania “Biosafety Public Awareness and Participation, in October 2006 Serbia and MN NPC and Bulgaria NPC (for implementation project) participated in Romania NBF drafting workshop. There were also other members of the Implementation Project from Bulgaria in this meeting.

99. Apart from Balkan, there has been limited regional cooperation in Caucasus countries. In December 2005 Azerbaijan organized a workshop on RARM where they invited expert from Belarus. They plan to use experts from Georgia and Moldova in their next workshops.

Caribbean

100. Caribbean countries are bound by a CARICOM treaty to barrier-free trade among themselves. This arrangement demands high levels of regional cooperation on biosafety. Accordingly the countries have begun, under the auspices of CARICOM, to formulate plans for regional coordination on biosafety and these include a regional project for implementation of NBFs.

VII. Some lessons from development of NBFs

101. The comparative analysis of the experiences of countries developing their NBFs under the UNEP-GEF project highlight some of the key challenges faced by all countries in meeting their obligations as Parties to the CPB. These experiences provide lessons that will be relevant to future capacity building activities in biosafety as these countries start to implement their NBFs.

Biosafety as a sustainable development issue

102. Probably the most important lesson emerging from the experiences is that Biosafety is a sustainable development issue, and that it cannot be considered in isolation from a country's development priorities. Critical elements of this set of lessons are that:

- Biosafety policies need to address both environmental and development concerns, and not just the conservation of biodiversity even though the Cartagena Protocol is part of the CBD;
- Biosafety laws and administrative systems have to complement and strengthen existing national systems, such as quarantine or EIA laws, rather than trying to set up a new parallel system;
- The NBF has to work within the context of national development strategies and plans, and should not be seen as a stand-alone issue.

Responsiveness to national needs and priorities

103. Recognition of biosafety as a sustainable development issue means that the development of the NBF, and particularly the resultant product i.e. the national biosafety framework, must be responsive to national needs and priorities. This will promote sustainability of NBF by helping to:

- Ensure national ownership by grounding biosafety is in a country's national needs and priorities.
- Ensure that the country's obligations under the Cartagena Protocol are used as an external stimulus to kick-start the NBF process, and stimulate public debate on GMOs, rather than being an end in itself. The mapping process advocated by the project in developing the NBF will help the country to decide its priorities for biotechnology and biosafety within the context of the overall national plans for sustainable development.
- Promote political and public support for the NBF; this will depend on how relevant the NBF is to perceived national priorities. This is best achieved through an inclusive and participatory process for preparation of the NBF, as well as making full use of available national expertise and building on existing systems.
- Tailor the NBF to the country's needs and priorities, rather than imposing a set formula on a country. Within the overall framework provided by the NBF project, the development process for the NBF has been flexible so that countries are able to adapt it to their own situation. Moreover, the final form and content of the map of the NBF prepared by countries has been dictated by their national situation, needs and priorities.

A country-driven process

104. A key lesson from the NBF development project is the importance of a country-driven process in preparing the NBF. The strong emphasis on this principle through the project has meant that the NBFs developed have a strong sense of national ownership; this is well illustrated by the support from government in many of the countries to not only seek outside assistance for capacity building for implementation of their NBF, but also to commit substantial government resources to both setting up the necessary systems and to maintain them on an on-going basis through financial allocations in the national budget for recurrent costs.

105. Some of the critical elements helping to ensure a country driven process include:

- A national "champion" to support the process of developing the NBF as well as to ensure that the results of the project, i.e. the components of the NBF have support from a wide range of stakeholders, including government agencies, the private sector and civil society.
- The NBF projects in each country have utilized and strengthened national expertise to help develop the NBF, and then to operationalize the systems, procedures and processes. The role of outside experts has been to support and peer review national contributions rather than to take over the development and running of the NBF.
- Provide access to technical resources from outside to support national resources – this could be in the form of technical resources such as manuals and toolkits, access to training opportunities, study visits, and in-country visits by outside experts. The series of regional and sub-regional training workshops by the global NBF project has been a key factor in helping to strengthen national capacity.
- Each national project has been aimed at building on existing systems in government rather than inventing new ones in order to develop the NBF. The process of mapping the existing institutions, laws and resources has helped the country to identify how best to build on these systems in order to formulate a workable NBF.

An Inclusive approach

106. Another important lesson is that an inclusive approach is needed in order to ensure the involvement of all stakeholders; this is crucial if the NBF is to be accepted by all parties within the country. This will not only help ensure support for the implementation of the NBF, but will also help promote the sustainability of the achievements.

107. The critical elements for an inclusive approach include:

- The active involvement of all relevant government agencies in the development of the NBF, as well as in its implementation: in risk assessment, in decision making on GMOs, and in monitoring. These include not just environment agencies, but also science and technology, agriculture, forestry, fisheries, health, education, etc.
- As the Cartagena Protocol comes under the CBD, the entry point for the NBF project in all countries has been the focal point for the CPB, usually the Ministry of Environment. However, the NBF projects have used the multi-sectoral national coordinating committee (NCC) in each country to ensure the involvement of other stakeholders. The NCC has also helped to ensure that the main messages of biosafety are introduced to all stakeholders so that they become aware of the potential benefits of the safe use of biotechnology.

- Recognition that non-government stakeholders (private sector as well as civil society) have a key role in developing the NBF and in implementing the proposed systems and procedures. The initial emphasis on awareness and education during the NBF project has helped to lay a foundation for the future involvement of stakeholders in decision-making, as awareness and education are pre-requisites for effective participation.
- The NBF developed through the project includes mechanisms for meaningful participation by stakeholders in decision making. This is usually enshrined in the regulatory instrument, with explicit mechanisms for public participation provided in the systems for handling applications.
- The NBFs also seek to provide stakeholders with access to biosafety information in a form that is readily understandable by all stakeholders and using media that any stakeholders can access. The means for access to information in the NBFs of various countries include not only internet based approaches such as the BCH, but also more traditional media such as printed materials, radio, television and public meetings.

VIII. Conclusion

108. The experiences of the NBF Development project demonstrates that building capacity for biosafety and the safe use of biotechnology within a country requires an approach based on harnessing national human and institutional resources rather than relying on outside expertise to develop the NBF and to put its provisions into practice. This means that in each participating country, it is crucial to strengthen national capacity in order to ensure sustainability of the NBF by laying a strong foundation for effective and sustained implementation of the systems in the NBF.

109. The experiences of the NBF Development project also highlight the commitment of the countries participating in the project to biosafety and the CPB: 92 out of the 124 countries in the project are already Parties to the Protocol and another most of the other countries are completing their national procedures for ratification. The NBFs not only provide the necessary legal instruments and other systems for implementation of the CPB, but the process of preparation of the NBF has started to build national capacity for *effective* implementation of the Protocol; this will need to be sustained through both externally funded and nationally supported capacity building efforts.