



## PHASE 3 TOOLKIT MODULE PART (i): DEVELOPING THE REGULATORY REGIME

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## UNEP-GEF Toolkits for the Development of National Biosafety Frameworks



### Foreword

On 11 September 2003, the Cartagena Protocol on Biosafety entered into force. Between September 2003 and April 2005, 119 countries have answered this call and have ratified or acceded to the Protocol, one of the fastest ever rates of ratification for any international environmental agreement. This high level of participation has brought with it a high demand for capacity building for effective implementation of the CPB from many countries where the introduction, and safe use, of Living Modified Organisms (LMO) biotechnology is new to both national governments and to the general public. UNEP believes that, for the success of the Cartagena Protocol, it is crucial that countries are assisted in building their capacity to implement the Protocol.

This unprecedented demand for capacity building assistance has presented a challenge to CPB Parties, and for this reason, UNEP welcomed the adoption by the Council of the Global Environment Facility in November 2000 of the GEF Initial Strategy on Biosafety, which aimed to assist countries to be prepared for the coming into force of the Cartagena Protocol. One of the components of the Initial Strategy is the UNEP-GEF global project on the Development of National Biosafety Frameworks. This project started in June 2001 and is assisting over 100 countries to develop a draft for a national biosafety framework.

UNEP, in its capacity as an Implementing Agency of the GEF, has been providing administrative and technical assistance to the countries participating in the Development Project through its team of Regional Coordinators, and through the organization of regional and sub-regional workshops. In addition the UNEP Biosafety Unit has coordinated the production of four toolkits that provide guidance on the main steps in the development of a national biosafety framework. Revised versions of the toolkits, incorporating lessons learned from the early participating countries are presented here in this publication as part of the overall efforts that UNEP is making to the successful implementation of the Cartagena Protocol on Biosafety.

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May 2005





## 1. Overview

### 1.1 Purpose of this toolkit module

This is the fourth module of a toolkit that aims to provide a practical “how-to” guide for countries to assist them in developing and implementing a project aimed at preparing their draft National Biosafety Frameworks (NBF), under the UNEP-GEF Project on Development of National Biosafety Frameworks. The toolkit is designed to be flexible and is tailored to meet the diverse needs of different countries, allowing them to select those tools and ideas that are most useful to their situation, needs and priorities. The toolkit is divided into four modules, each addressing one of the phases listed in the national project document:

- Phase 0 Module** the vision (or rationale) of the project design, its guiding principles, and the establishment of institutional and management structures.
- Phase 1 Module** the instigation of surveys and the preparation of inventories in the different sectors pertaining to biosafety and biotechnology within the country, including their entry into national databases.
- Phase 2 Module** the involvement of stakeholders, and the consultation, analysis, and training activities needed to identify the priorities and parameters for the drafting of the National Biosafety Framework (NBF).
- Phase 3 Module** **Parts (i) and (ii)**, this module of the toolkit, on the drafting of the NBF, consists of two parts: formulation of the regulatory regime and design of the administrative systems for handling applications and notifications. This is the first part of the module, and focuses on the regulatory regime, one of the main components of an NBF. The second part of the module on the drafting of the NBF, which will focus on designing and running administrative systems for biosafety, will be available later in 2004.

### 1.2 Using this toolkit module

#### 1.2.1 Purpose and content of the toolkit

The aim of this module of the toolkit is to provide practical advice to countries as they begin to draft their NBF, and particularly the regulatory regime, which forms the central pillar of the NBF. Countries will draft their regulatory regime based on the results of the activities

completed during the first two phases of their NBF Development project.

This document covers the following steps in developing a regulatory regime for biosafety:

1. Identifying and analysing relevant international obligations that a country needs to take into consideration in developing its regulatory regime (*Section 2*);
2. Reviewing and analysing the current status of regulatory instruments related to biosafety within the country (*Section 3*);
3. Choosing and designing a regulatory regime that meets the obligations, needs and priorities of the country (*Section 4*); and
4. Considering the different issues and elements that might form part of a regulatory regime on biosafety (*Section 5*);

**Note: This toolkit module complements the Implementation Guide produced by the UNEP-GEF Implementation Project:**

[http://www.unep.ch/biosafety/implementation/impdocs.htm#A\\_draft\\_guide](http://www.unep.ch/biosafety/implementation/impdocs.htm#A_draft_guide)

The toolkit is designed to be of use to all countries participating in the Project. It is therefore general in nature and recognises that, in the development of their regulatory regime for biosafety, different countries will use a diversity of approaches, legal instruments, and terminology that are best suited to their own situation (see section 1.2.2 below). For this reason, the issues and examples included in this module are intended to illustrate key messages: they do not take into account the individual circumstances of every country that may use the toolkit. Moreover, the toolkit is not exhaustive: depending upon their particular needs, priorities and situation, countries may identify other issues and approaches that are not considered in this toolkit.

This module of the toolkit is not intended to guide countries towards any particular outcome or approach; rather, the main intention is to provide assistance to countries as they begin work on the design and development of their regulatory regimes. This module of the toolkit provides a resource for countries that want to ensure that their NBF reflects their obligations under the Cartagena Protocol on Biosafety as a minimum, but may wish to go beyond the Cartagena Protocol in developing their regulatory regimes. Therefore, this toolkit module has been designed to address primarily those issues that are a priority for the majority of countries participating in the NBF Development project, i.e. the “case by case” notification and assessment system envisaged by the Cartagena Protocol. The toolkit does not deal with the wider policy debates and approaches about biotechnology and biosafety regulation.



### 1.2.2 A note on terminology used in this toolkit

Throughout this toolkit, an attempt has been made to utilise general terminology so as not to prejudge what approach a country may decide to take.

- The term “*Regulatory regime*” is used to cover all those legal instruments (laws, acts, regulations, decrees, orders, guidelines etc) that are relevant to the regulation of GMOs, GM products and activities involving GMOs or GM products, including the institutional arrangements for implementing those regulations. It may thus comprise a single comprehensive system, or a whole “*package*” of measures and institutions (see Section 5).
- The term “*regulatory instrument*” is used to describe in general terms all the various instruments at different “*levels of law*” (see Section 3.2) that might form part of a country’s regulatory regime.
- The term “*genetically modified organism*” or “*GMO*” has been used in most sections of the toolkit. Where there is a specific discussion of the Protocol, the term “*living modified organism*” or “*LMO*” that appears in the Protocol has been used.
- The term “*GM product*” is used to described products which are derived from GMOs but which do not themselves consist of or contain GMOs.
- The term “*applicant*” is used to describe the person or entity who will notify or apply to regulatory authorities in the country when a particular GMO, GM product or an activity involving a GMO or GM product requires notification or prior authorisation under the regulatory regime.

### 1.3 Components of the NBF

**A national biosafety framework (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.

Although national biosafety frameworks vary from country to country, they contain a number of common components (see Figure 1 below):

- A Government policy on biosafety
- A regulatory regime for biosafety; addressed in this module of the toolkit
- A system to handle notifications or requests for authorisations (to be addressed in a forthcoming module of the toolkit)
- Systems for ‘follow up’ such as enforcement and monitoring for environmental effects
- Mechanisms for public awareness, education and participation.

These components of an NBF are linked to one another and are interdependent. A national policy on biosafety provides the rationale for the development of a regulatory regime, which in turn forms the basis for the other components: the administrative systems for handling

applications and decision-making, systems for follow up, and mechanisms for public awareness, education, participation and access to information (Figure 1).

### 1.3.1 National Policies and Strategies<sup>1</sup>

Ideally, the evolution of a national biosafety system begins with the elaboration of a national biosafety policy or strategy consistent with other policy objectives related to food, agriculture, public health, the environment, and sustainable development. This would form the basis for the development of specific legislation and/or regulations, leading finally to the design and implementation of the structural elements necessary for risk analysis, inspection, monitoring, and enforcement. A national assessment of the existing scientific and technical capacity would support and inform the design process. However, in practice, this ideal progression is rarely the case. In reality, portions of these activities are often completed simultaneously, usually in an attempt to meet short-term needs.

#### BOX 1: SOME APPROACHES TO NATIONAL POLICIES ON BIOSAFETY

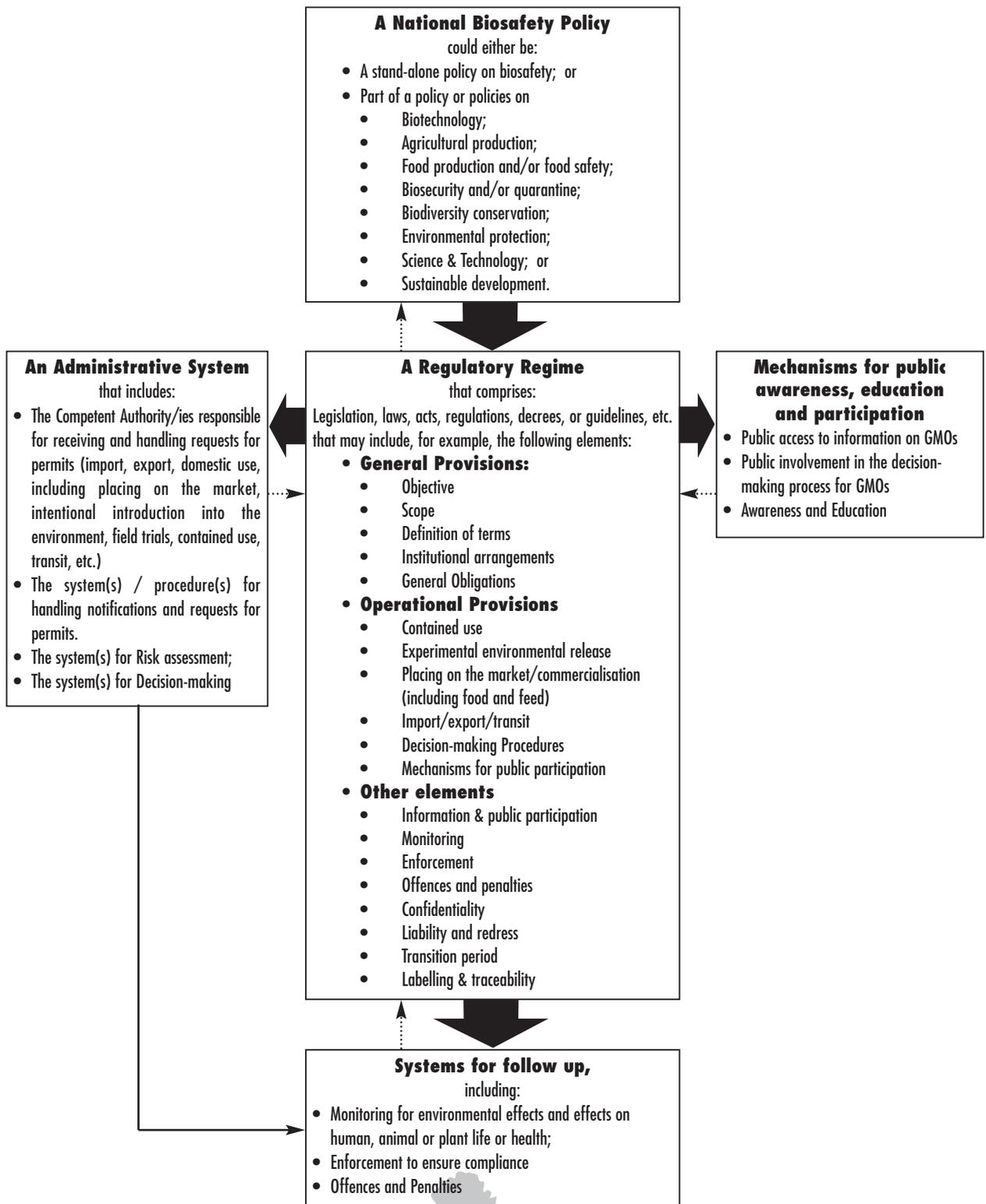
Countries participating in the NBF Development Project have taken a diversity of approaches to developing their NBF within the context of their national policy framework:

- **National sustainable development strategies** - for example the Philippines Agenda 21 addresses biosafety and the safe use of biotechnology as a means to promote sustainable development. In Belarus, a biosafety policy is part of the National Strategy for Sustainable Development.
- **National development plans** – for example, Bangladesh, Bhutan, and Indonesia have included the safe use of biotechnology to achieve their national development goals, whilst ensuring protection of the environment and conservation of biodiversity.
- **Science and technology policies** – for example Lao PDR, Ukraine, Lithuania and Viet Nam have included the safe use of biotechnology within their policy framework for promoting science and technology.
- **Biotechnology and biosafety policy** – some countries, for example the Democratic People’s Republic of Korea, have formulated a policy on the safe use of biotechnology as part of the development of their NBF.
- **National biodiversity strategy and action plans (NBSAP)** – for example Bhutan, Lebanon, Moldova, and Romania include biosafety within the context of their national policies or plans on biodiversity conservation and environmental protection. Macedonia has developed a National Environmental Action Plan (NEAP) aiming at integration of environmental issues into the programmes of economic and social development.
- **Biosecurity** – for example Myanmar, as well as a number of Pacific Island countries, see biosafety within the context of their national policies on biosecurity - plant and animal quarantine, as well as management of invasive species.

<sup>1</sup> Drawn and adapted from McLean et al, A Framework for Biosafety Implementation: Report of a Meeting (ISNAR, 2003).



**Figure 1: The components of a National Biosafety Framework (NBF)**



A national biosafety policy or strategy is important as it provides a set of principles to guide subsequent development and implementation of the regulatory regime for biosafety. A Biosafety policy or strategy articulates a national approach to biosafety regulation and the goals and objectives of the regulatory framework. It serves to integrate political, social, ethical, health, economic, and environmental considerations into decisions regarding the safe and appropriate use of biotechnology methods and products. A national policy or strategy may provide direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations.

Whether formulated prior to the existence of a regulatory regime, or subsequently, a national biosafety policy should serve to articulate a framework whereby seemingly disparate goals, such as economic and regional development, and environmental protection, may be integrated and communicated as a single national vision. In addition, a national strategy could provide for the creation of some form of an advisory committee to serve as a focal point for initiating public dialogue and addressing crosscutting issues related to the ethical, legal, and social implications of biotechnology.

## 2. Identifying and analysing relevant international obligations and instruments

The design and implementation of the regulatory regime for biosafety developed as part of the NBF must reflect, at a minimum, the country's obligations as a Party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. Many countries will also have undertaken other international commitments that will be relevant to the regulatory regime for biosafety. These will be identified in the survey phase of the NBF project<sup>2</sup> and/or in inter-departmental or wider consultations during the development of the regulatory regime.

### This section:

- **Considers specific obligations under the Convention on Biological Diversity and Cartagena Protocol on Biosafety that are binding on all Parties to the Protocol;**
- **Looks briefly at obligations of Members of the World Trade Organisation (on the basis that many, but not all, Parties to the Protocol are also Members of the WTO);**
- **Outlines potentially relevant international standard setting processes in the fields of plant protection, food safety and animal health; and**
- **Identifies other categories of international and regional agreements and instruments that might be relevant to the regulation of GMOs.**

This section is not a comprehensive checklist; it only provides some examples. Each country will need to consider what international

obligations it has undertaken that will affect its regulatory regime for biosafety.

### 2.1 Convention on Biological Diversity

The CBD, in Article 8(g), requires Parties to take domestic measures to regulate, manage or control risks associated with living modified organisms (LMOs):<sup>3</sup>

*Each Contracting Party shall, as far as possible and as appropriate:*

*(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.*

Countries may have addressed this provision when developing their National Biodiversity Strategies and Action Plans under the Convention.

### 2.2 Cartagena Protocol on Biosafety

The Cartagena Protocol contains detailed obligations focusing in particular on the transboundary movement of LMOs. The Protocol requires Parties to ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account human health (Article 2(2)).

Article 2(1) of the Protocol provides that each Party shall take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol.

The COP/MOP<sup>4</sup> has endorsed a checklist (called the "Implementation Toolkit") as a tool for Parties that sets out the various administrative, legal and procedural requirements imposed on Parties under the Protocol. This "Implementation Toolkit" (Annex I to this document) provides a useful checklist of obligations under the Protocol, so that a Party can review how its regulatory regime for biosafety fulfils Protocol obligations. However, the Implementation Toolkit does not go beyond the Protocol to consider some other issues that countries might decide to address in a national regulatory regime for biosafety. These are considered further below in Section 5.

In addition to the procedures and requirements in the Protocol for the transboundary movement of LMOs summarised below, the Protocol covers a number of areas that are relevant to the development of a national regulatory regime for biosafety. These include:

- General Provisions (Article 2);
- Risk assessment and Management (Articles 15 and 16);
- Unintentional transboundary movements and emergency measures (Article 17);
- Requirements for handling, transport, packaging and identification (Article 18);
- Competent national authorities and national focal points (Article 19);

<sup>2</sup> See UNEP-GEF, Phase 1 Toolkit Module: Taking Stock, p.5, pp.8-9.

<sup>3</sup> See section 1.2.2 on the use of the term LMO in this section.

<sup>4</sup> Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol, see Article 29 CPB and IUCN/FIELD/WRI Explanatory Guide at pages 179-184.



- Information sharing and the Biosafety Clearing House (Article 20);
- Confidential Information (Article 21);
- Public awareness and Participation (Article 23);
- Illegal transboundary movement (Article 25);
- Socio-economic considerations (Article 26).

A fuller explanation of the provisions of the Protocol can be found in a number of publications.<sup>5</sup>

### 2.2.1 Procedures for the transboundary movement of LMOs in the Protocol

The Protocol sets out specific procedures or requirements to govern the transboundary movement of LMOs in two specific circumstances:

- First transboundary movement of LMOs into a Party of import for intentional introduction into the environment (advance informed agreement (AIA) procedure);
- Transboundary movements of LMOs for direct use as food or

feed or for processing (Article 11 procedure).

A brief summary of these requirements is provided below for ease of reference. Further explanation of these provisions can be found in materials produced by the Secretariat of the Convention on Biological Diversity, available on the CBD website<sup>6</sup> and in the *Explanatory Guide to the Cartagena Protocol on Biosafety*.

### Procedure for LMOs for intentional introduction into the environment: Advance informed agreement

The AIA procedure established in the Protocol requires that before the first intentional transboundary movement of an LMO into the Party of import for intentional introduction into the environment, the Party of import:

- Is notified of the proposed transboundary movement;
- Receives information about the LMO and its proposed use; and
- Is given an opportunity to decide whether or not to allow the import of the LMO, and upon what conditions (if any).<sup>7</sup>

<sup>5</sup> See pages 8-11 of the UNEP/SCBD brochure "Biosafety and the Environment: An introduction to the Cartagena Protocol on Biosafety", and the IUCN/FIELD/WRI Explanatory Guide.

<sup>6</sup> <http://www.biodiv.org/biosafety>.

<sup>7</sup> IUCN/FIELD/WRI Explanatory Guide, p. 63.



**Table 1: Summary of rights and obligations of Parties under the AIA procedure**

Step	Responsible entity	Key elements
Notification of proposed transboundary movement (Article 8; Annex I)	<ul style="list-style-type: none"> <li>Party of export</li> </ul>	<ul style="list-style-type: none"> <li>Notify competent national authority of Party of import prior to the first transboundary movement of LMOs for intentional introduction into the environment;</li> <li>Provide, at a minimum, information specified in Annex I of the Protocol; Ensure there is a legal requirement for the accuracy of information provided by the exporter.</li> </ul>
Acknowledgment of receipt of notification (Article 9)	<ul style="list-style-type: none"> <li>Party of import (competent national authority)</li> </ul>	<ul style="list-style-type: none"> <li>Acknowledge receipt (within 90 days): State date of receipt; State whether notification contains required information; State decision procedure that will apply (AIA procedure in Article 10, or domestic regulatory framework consistent with the Protocol).</li> <li>Failure to acknowledge receipt shall not imply consent to transboundary movement.</li> </ul>
Decision procedure (Articles 9, 10, 15, 21, 26; Annex III)	<ul style="list-style-type: none"> <li>Party of import</li> </ul>	<ul style="list-style-type: none"> <li>Inform notifier in writing (within 90 days of receipt of notification) whether transboundary movement may proceed only after Party of import has given its consent, or after 90 days without a subsequent written consent (In practice, this should be included in the acknowledgement of receipt);</li> <li>Take decision on basis of risk assessment carried out in a scientifically sound manner in accordance with Annex III of Protocol and taking into account recognised risk assessment techniques (Article 10(1), Article 15(1));</li> <li>Precautionary approach: where there is a lack of scientific certainty due to insufficient relevant scientific information and knowledge about the extent of the potential adverse effects, Party of import may take a decision with regard to import of LMO to avoid or minimize potential adverse effects;</li> <li>May require exporter to carry out risk assessment (Article 15(2));</li> <li>May require notifier to bear costs of risk assessment (Article 15(3));</li> <li>Address confidential information as provided in Article 21 of Protocol;</li> <li>May take into account certain socio-economic considerations arising from the impact of LMOs on biological diversity, consistent with its international obligations (Article 26(1));</li> <li>In accordance with its laws and regulations, consult the public in the decision making process (Article 23(2)).</li> </ul>
Decision (Article 10)	<ul style="list-style-type: none"> <li>Party of import</li> </ul>	<ul style="list-style-type: none"> <li>Within 270 days of acknowledgement of receipt of notification, either:                             <ul style="list-style-type: none"> <li>- approve the import, with or without conditions;</li> <li>- prohibit the import;</li> <li>- request additional information;</li> <li>- inform the applicant that decision taking is extended by a defined period of time.</li> </ul>                             Failure to communicate decision does not imply consent and prevents the import from taking place. In accordance with its laws and regulations, make results of decisions available to the public (Article 23(2));</li> <li>Give reasons for decision, except where approval of import is unconditional;</li> <li>Communicate decision in writing to Biosafety Clearing House.</li> </ul>
Review of decision (Article 12)	<ul style="list-style-type: none"> <li>Party of import (on own initiative, or upon request by Party of export or applicant)</li> </ul>	<ul style="list-style-type: none"> <li>Party of import may review and change a decision in light of new scientific information. It must:                             <ul style="list-style-type: none"> <li>- Inform the notifier and the BCH within 30 days;</li> <li>- Set out the reasons for changing the decision.</li> </ul> </li> <li>Party of export or a notifier may request the Party of import to review a decision on the basis of (i) occurrence of a change in circumstances, or (ii) availability of additional relevant scientific or technical information.</li> </ul>



## Procedure for transboundary movement of LMO-FFPs: Article 11

For the transboundary movement of LMOs intended for direct use as food or feed, or for processing, Article 11 of the Cartagena Protocol establishes a multilateral mechanism (through the Biosafety Clearing House (BCH)) for exchange of information about such LMOs, and national laws and regulations applicable to them. It recognises the right of Parties, if they so wish, to subject first imports of LMO-FFPs to prior risk assessment and approval.

**Table 2: Summary of rights and obligations of Parties under Article 11 procedures for LMO-FFPs**

Step	Responsible entity	Key elements
Notification to BCH of final decision on domestic use (not field trials) of LMO that may be subject to transboundary movement for direct use as food or feed, or for processing.	Party making final domestic decision	<ul style="list-style-type: none"> <li>Notify BCH within 15 days</li> <li>Provide, at a minimum, information specified in Annex II of Protocol</li> <li>Provide copy of information in writing to Parties that do not have access to BCH (Article 11(1))</li> <li>Ensure there is legal requirement for accuracy of information provided by applicant (Article 11(2))</li> <li>Provide additional information to any Party that requests it (Article 11(3))</li> </ul>
Notification of national laws, regulations and guidelines to BCH	All Parties	Make available to BCH copies of any national laws, regulations or guidelines applicable to import of LMO-FFPs (Article 11(5))
	Developing country Party or Party with economy in transition without domestic regulatory framework	May declare through BCH that decisions prior to first import of a LMO-FFP will be taken in accordance with Article 11(6) (below)
Decision procedure for imports of LMO-FFPs	Party of import	Domestic regulatory framework consistent with the objective of the Protocol
	Party of import that is a developing country Party or Party with economy in transition without domestic regulatory framework	<ul style="list-style-type: none"> <li>Risk assessment undertaken in accordance with Annex III of Protocol</li> <li>a decision within predictable timeframe not exceeding 270 days (Article 11(6))</li> <li>Precautionary approach: where there is a lack of scientific certainty due to insufficient relevant scientific information and knowledge about the extent of the potential adverse effects, Party of import may take a decision with regard to import of LMO-FFP to avoid or minimize potential adverse effects (Art. 11(8)).</li> </ul>

### 2.2.2 Procedures for other types/intended uses of LMOs

The Protocol does not set out specific requirements for other types of transboundary movements of LMOs such as:

- Transboundary movements of LMOs destined for contained use in the Party of import (Article 6)
- Transit of LMOs (Article 6)
- Transboundary movements of LMOs that are pharmaceuticals for humans that are addressed by other international agreements or organisations (Article 5)
- Transboundary movements of LMOs that have been identified in a decision of the COP/MOP as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health (Article 7(4)). The COP/MOP has not taken any



decision under this provision to date.

However, every country has the right to regulate such transboundary movements of LMOs within their NBF if they so wish (for example, by subjecting them to risk assessment and approval prior to decisions on import). In any event, Parties will have to ensure that any such transboundary movements are carried out in a manner that fulfils the general requirements in the Protocol and the CBD as to safe handling and use of biotechnology.

Article 2(4) of the Protocol provides that Parties may take more protective action than that called for in the Protocol, provided that such action is consistent with the objective and provisions of the Protocol and is in accordance with that Party's other obligations under international law.

## 2.3 Other relevant international obligations

When designing and implementing the regulatory regime, a Party will also need to consider, any other relevant substantive and procedural international obligations that it has undertaken.

### 2.3.1 World Trade Organisation

Implementation of the Protocol's AIA procedure, and other provisions, as well as other aspects of the domestic regulatory regime for biosafety is likely to involve measures that have an effect on trade. Examples of possible trade measures include, for example: notification and approval requirements; restrictions on imports or conditions attached to imports; or labelling or identification requirements.

A Party to the Protocol that is also a Member of the World Trade Organisation (WTO) will need to consider how the design and implementation of its regulatory regime for biosafety complies with its obligations under relevant WTO agreements.

The WTO is an intergovernmental organisation responsible for administering the WTO agreements, multilateral trade agreements that regulate international trade in goods and services and the protection of intellectual property rights. The WTO's key purpose is to liberalise markets by removing unnecessary, discriminatory and protectionist barriers to free trade. The WTO's institutions provide a forum for negotiation of new trade rules and for reviewing members' trade policies. The WTO also provides a mechanism for the settlement of disputes among Members.

A brief summary of some aspects of relevant agreements is given in Annex 2. However, it is beyond the scope of this toolkit to address WTO obligations in any detail. Some further explanation of the relevance of the WTO to the regulation of GMOs may be found in the Appendix to the Explanatory Guide to the Cartagena Protocol on Biosafety, on which the summary below and in Annex 2 is based. Detailed information on WTO agreements is available on the WTO website at <http://www.wto.org> and from the WTO Secretariat.

The main WTO Agreements likely to be of relevance to biosafety regulation are:

- The General Agreement on Tariffs and Trade (GATT)
- The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
- The Agreement on Technical Barriers to Trade (TBT Agreement).

The WTO does not prohibit countries from taking trade measures, but it disciplines the way that such measures are designed and applied. At the most basic level, the WTO agreements share the common purpose of ensuring that:

- Measures that affect trade in products do not discriminate on the basis of a product's country of origin in manner that harms imports, and
- Those measures are no more trade restrictive than is necessary to achieve the purpose for which they were designed.

Each WTO Agreement has detailed rules, and a growing body of practice that will further develop these rules, including the reports and recommendations of the WTO dispute settlement system. There is no one template for ensuring WTO-consistency in the design or implementation of national laws and regulations on biosafety. Many aspects of the relationship between the Protocol and the WTO remain unclear, and will be worked out in practice in the future. To date, there has been no decision in the WTO as to whether or not any particular provisions contained in existing national biosafety frameworks are consistent with WTO obligations.

In addition to substantive requirements, it should be noted that both the TBT and SPS Agreements also contain procedural transparency requirements which require Members to notify other Members through the WTO Secretariat of existing and proposed trade-related measures. Depending upon their nature and content, regulatory regimes on biosafety are likely to fall within these requirements and should be notified through the relevant WTO Committee (most likely the SPS and/or TBT Committees).

### 2.3.2 International standards

Various international standard-setting bodies are undertaking, or may undertake, work of relevance to the regulation of GMOs and/or products deriving from GMOs. Such bodies are intended to promote international harmonisation of standards. The standards they generate are not legally binding, but, as discussed in Annex II to this document, some international standards are explicitly referenced in the WTO's SPS Agreement and international standards are also referred to in the TBT Agreement.

## 2.4 Other regional and international agreements

In developing a regulatory regime for biosafety, countries should also review and have regard to any other relevant obligations undertaken under regional or international instruments. These could include for example:

- Regional or international biodiversity or environmental protection agreements, including agreements for the protection of the marine environment. – Such agreements might include provisions specifically on GMOs, or more general provisions of potential relevance addressing, for example, alien species or new organisms, environmental impact assessment or protected areas.



**Table 3: Summary of other relevant international bodies**

Organisation /Body	Mandate	GMO-related work
<p>Codex Alimentarius Commission</p> <p><a href="http://www.codexalimentarius.net">http://www.codexalimentarius.net</a></p>	<p>The <i>Codex Alimentarius</i> is a non-binding code developed by the Codex Alimentarius Commission, a body of the FAO and World Health Organization which elaborates standards, general principles, guidelines and recommended codes of practice in relation to food safety and related issues.</p>	<p><b>In 2003, the Codex Alimentarius Commission considered texts on foods derived from biotechnology, which had been elaborated by a Task Force on Foods Derived from Biotechnology:</b></p> <ul style="list-style-type: none"> <li>- Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology</li> <li>- Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants</li> <li>- Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Micro-organisms.</li> </ul> <p>The <i>Codex</i> Committee on Food Labelling is considering recommendations and guidelines on labelling of foods derived from certain techniques of genetic modification.</p> <p>Other <i>Codex</i> Committees, which are undertaking more general work that may be of some relevance to GMOs, include the Committee on General Principles (principles of risk analysis) and the Committee on Food Import and Export Inspection and Certification Systems (traceability/product tracing).</p>
<p>Interim Committee on Phytosanitary Measures (ICPM)</p> <p><a href="http://www.ippc.int">http://www.ippc.int</a></p>	<p>Established under the International Plant Protection Convention</p>	<p>The ICPM has been developing a standard specification on plant pest risks associated with GMOs. A supplement to ISPM No. 11 (Pest risk analysis for quarantine pests) on pest risk analysis for LMOs was endorsed by the ICPM in April 2004. The supplement provides guidance to National Plant Protection Organisations regarding the analysis of pest risk posed by LMOs. Revised ISPM No. 11 is available on the IPPC website.</p>
<p>Office International des Epizooties (OIE or World Organisation for Animal Health)</p> <p><a href="http://www.oie.int">http://www.oie.int</a></p>	<p>The OIE is an international organisation with 166 member countries (in 2004) focusing on animal disease and health. Among other activities, the OIE operates to develop harmonising standards, guidelines and recommendations especially for trade in animals and products of animal origin. Since 2003 it also works on animal production food safety and animal welfare.</p>	



- Regional or international agreements on access to environmental information and/or public participation (for example, for the UN-ECE region, the Aarhus Convention)

Countries may also have undertaken, or may undertake, commitments relating to transboundary movement of GMOs in other bilateral, regional or multilateral agreements or arrangements. These may specifically address GMOs or may be of a more general nature (such as free trade or investment agreements). For Parties to the Protocol, such agreements or arrangements should conform to Article 14 of the Protocol, i.e. they should be consistent with the objective of the Protocol and must not result in a lower level of protection than that provided for in the Protocol.

## 2.5 Practical implications

**A**t the practical level the need to consider the potential relevance of other international agreements to the design and development of the regulatory regime for biosafety means that a wide range of governmental officials, from a range of sectoral ministries, as well as other stakeholders will need to be involved in the NBF process. (see toolkit for Phase 2, and Section 4).

Countries will also need to keep in mind the potential effect on their regulatory regime for biosafety of international and regional agreements and arrangements that they enter into in the future.

## 3. Reviewing and analysing the current status of regulatory instruments related

### 3.1 Introduction

**M**any countries may already have elements of a regulatory regime for biosafety in place. These may have been created to implement other international agreements, to respond to other domestic demands, or as part of earlier efforts to regulate the safety of products of modern biotechnology. As countries move into the final stage of the UNEP-GEF Development Project, they need to know what relevant regulatory instruments they already have in place and how these might fit in (or not) for the regulatory regime they want to create, without creating conflicting or overlapping mandates between the various responsible agencies.<sup>8</sup>

Apart from instruments that explicitly regulate GMOs, there may be many other laws, regulations or regulatory instruments that are relevant. For example, seeds regulations, food safety laws, or Phytosanitary/quarantine requirements. (Some more detailed examples are given below).

**This section explores how a country might go about reviewing and analysing the current status of regulatory instruments related to biosafety at the domestic level.**

A number of guiding questions may assist the review and analysis process. For example:

- What is the country **obliged** to do? (e.g. to fulfil its obligations under the Cartagena Protocol – see Annex 1 to this document; and section 2 above)
- What else, if anything, does the country wish to achieve through its NBF?
- What is already in place (laws; regulations; guidelines etc) that are relevant either directly or indirectly to fulfilling these obligations and objectives?
- What else needs to be done or put in place to fulfil these obligations and objectives?
- If there are relevant instruments already in place, does the regulatory framework need to be made more coherent or coordinated?

### 3.2 Reviewing the current status of regulatory instruments related to biosafety within the country

**M**any countries will have experience of reviewing and analysing existing biodiversity-related laws through their preparation of a National Biodiversity Strategy and Action Plan under Article 6 of the Convention on Biological Diversity. They are also likely to have used a similar approach when determining how to implement other international agreements at the domestic level.

Countries participating in the UNEP-GEF Development Project would also have reviewed their existing biosafety related systems in Phase 1 of the Project. The questions below re-cap some of that review process (see Toolkit Modules for Phase 1 and 2).

In developing their NBF, countries will have to address the following questions:

**What are the objectives to be achieved by the national biosafety framework? And what elements need to be included in a country's regulatory regime to fulfil these objectives?**

These issues will be discussed in section 5.1.

**What are the existing elements of a country's regulatory regime for biosafety?**

Many countries participating in the UNEP-GEF Project will not have in place at this stage a specific regulatory regime on biosafety. However, most, if not all, countries will have some regulatory instruments that are relevant to the regulation of some or all GMOs. Knowing what is already in place enables a country to:

- Know what GMOs, GM products or activities are already being regulated
- Consider whether existing regulatory instruments are sufficient to regulate GMOs, GM products and/or activities involving GMOs that the country decides it wishes to cover in the regulatory regime
- Consider whether there are any regulatory 'gaps' that need to

<sup>8</sup> See the toolkit module for Phase 1 of the NBF project, on "Taking stock".



be filled

- Consider whether there are any overlaps in regulation
- Decide what it needs to do next.

The review of the current status of regulation should cover all relevant 'levels of law' in the country.

### What are the different types of instruments at various levels of law making?

While domestic legal systems vary significantly, most resemble each other insofar as they contain similar 'levels' of legal instruments.<sup>9</sup> Although the names given to these instruments often differ from country to country, the functions of instruments at the same level are often very similar.

Different countries will use different combinations of these legal instruments. In some countries, some of the 'levels' described below may be of minor significance. Important differences may exist for example, between countries with common law or civil law systems, or mixed, or other systems. Differences may also arise out of the form of government or other factors, such as:

- Divisions of authority between national and sub-national jurisdictions (federal government; provincial or state governments; municipalities/local government);
- The respective roles of the three branches of government: executive, legislature, and judiciary;
- The authority of enforcement and inspection institutions;

The purpose of discussing 'levels of law' here is simply to make clear that:

- (i) When reviewing and analysing the current status of regulatory instruments related to biosafety in the country, the review and analysis should not be limited to 'primary legislation' (Level 1), but should also include all other relevant instruments; and
- (ii) When deciding upon the design and implementation of the regulatory regime for biosafety, countries may decide to use regulatory instruments at different 'levels of law'.

The different types of instruments at the various levels of law-making might 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. Names commonly used for these kinds of instruments include 'primary

legislation', 'law', 'statute', 'act', 'ordinance' and 'code'.

**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. Names commonly used for these kinds of instruments include: 'secondary legislation', 'decree', or 'regulation'.

**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. Names commonly used for these kinds of instruments include: 'secondary legislation', 'guidance', 'regulation', 'sub decree', or 'guidelines'.

**Level 4:** comprises the work of the judicial branch. It can be divided into two parts:

- Binding decisions on the interpretation of instruments in Levels 1-3 by courts or other adjudicators;
- Binding decisions creating law by courts.

These may include, for example, 'case law', 'precedents', 'recommendations', and 'opinions'.

**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. Names commonly used for these kinds of instruments include 'code of practice', 'best practice', 'recommendations', 'opinion', 'guidance' and 'guidelines'.

Countries will also have written or unwritten constitutions that provide the overarching context for the adoption and implementation of regulatory instruments at the different levels of law, and which may also contain specific provisions of relevance to biosafety regulation.

### What sectoral or other regulatory instruments, currently in place in the country, are relevant to regulation of GMOs?

As noted earlier, there are a wide range of sectoral laws and regulations that may have some bearing on GMOs. Countries that have undertaken reviews as part of their NBF process to date have identified a range of instruments that are relevant or potentially relevant to the regulation of certain GMOs, GM products or activities involving GMOs, even if they were not specifically adopted with GMOs in mind.

The most prominent examples are probably plant protection laws and

<sup>9</sup> This discussion on 'levels of law' is based on presentations by David Townend, Sheffield Institute of Biotechnological Law & Ethics at the UNEP-GEF workshops on Regulatory Regimes and Administrative Systems.



regulations that regulate, among other things, the import of plants and plant products. While these may be general in nature, they affect imports of new GM plants and plant products (e.g. seeds/propagation materials) into the country. Other examples could include for example, general food safety laws and regulations (which could impact on GM foods) and perhaps, environmental impact assessment laws.

In addition, some countries will also have regulatory instruments in place that were specifically designed to regulate some aspects of GMOs, GM products, or activities involving GMOs.

Some national examples are given in the box below. The purpose here is merely to emphasise that countries should cast the net widely in reviewing the current status of regulatory instruments related to biosafety.

#### EXAMPLE: EXISTING REGULATORY INSTRUMENTS

The **United Republic of Tanzania** identified a large number of existing regulatory instruments that relate in some way to biosafety. These include the Plant Protection Act 1997, Veterinary Act 2004 and Animal Diseases Act 2004, Fertilizers and Animal Feedstuffs Ordinance, Tanzania Food, Drugs and Cosmetics Act 2003, Merchant Shipping Act 2003, Tanzania Civil Aviation Authority Act 2003, Fisheries Act 2003, Forest Act 2002, Wildlife Act 1974, Public Health Ordinance, Tanzania Commission for Science and Technology Act 1986, Tanzania Bureau of Standards Act 1975, National Environmental Management Act 1983. In addition, relevant instruments were also identified at the sub-national level.<sup>10</sup>

In **Sri Lanka**, a number of pieces of existing legislation were identified that are relevant to biosafety. These include a Science and technology Development Act, various Animal acts, Fisheries and Aquatic resources Act, Plant Protection Act, Food Act, National Environment Act, Quarantine Act, etc.

In **Jordan**, existing legislation included the Environment Law, the Agriculture Law, Public Health Law, Food Control and Hygiene Law, etc.

**Estonia** identified around 20 laws plus many secondary legal acts related to biosafety. Some of them deal with GMOs directly – GMO deliberate release into the environment act, Act on contained use of GMOs, Food Act, Seed and Plant Propagation Material Act etc; while others deal with GMOs only indirectly – Public Information Act, Patent Act, Occupational Health and Safety Act, Strategic Goods Import, Export and Transit Act, Road Transport Act, Customs Code, etc.

#### What institutions currently have authority in relation to various aspects of biosafety regulation?

Another important factor in determining the current status of regulation of GMOs within a country is identifying which institutions, e.g. ministries, departments, agencies or other bodies, currently have authority or competence in respect of various aspects of GMO regulation. Possible examples include:

- health

- environment
- natural resources
- industry
- arts and culture
- science and technology
- agriculture
- indigenous or native affairs
- office of the Vice-President/President or Prime Minister
- trade
- domestic affairs
- religious affairs
- Attorney General's office
- local government bodies
- state governments (for example, where states have competence in respect of agriculture, environment or health etc)
- consumer affairs
- fisheries

#### How can information about the current status of regulatory instruments related to biosafety within the country best be gathered?

Countries have carried out an initial survey of the current status of regulatory instruments related to biosafety in an earlier phase of the NBF Project.<sup>11</sup> As they begin to design and develop the regulatory regime, countries may wish to revisit this survey and consider whether any additional or updated information is required. The review and analysis phase should comprise more than a desk review of existing relevant laws, regulations and guidelines etc. Countries should consider involving various sectoral ministries and departments as well as other relevant stakeholders in order to fully identify what is already in place and how existing regulatory instruments are working in practice. In addition to desk review, workshops or questionnaires might be useful tools here. At this stage of the process, it will be helpful to involve those individuals who will be responsible for actually drafting the regulatory regime.

### 3.3 Analysing the current status of regulatory instruments related to biosafety within the country

Once a country has identified its objectives for biosafety, and the different elements required to reach these objectives, the next step is the analysis of the extent to which the existing system meets those objectives. This analysis may involve addressing the following questions:

- Does the existing legal and regulatory system adequately address the objectives of the national biosafety policy or the objectives established within the NBF? For example, does it adequately cover all GMOs, GM products and/or activities involving GMOs that the country is obliged to or wishes to regulate?
- Are there GMOs, GM products or activities involving GMOs that the country wants to regulate that are not covered by the

<sup>10</sup> Based on a presentation by Dr. Palamgamba John Kabudi at UNEP-GEF workshop on Regulatory Regime and Administrative Systems, Port of Spain, May 2004

<sup>11</sup> See Toolkit module for Phase 1



existing system?

- Does the existing legal and regulatory system give rise to situations where more than one authority regulates the same GMO, GM product or the same activity involving a GMO?
- Do any such situations of overlapping jurisdiction need to be eliminated, or require better coordination?
- What are the strengths of the existing system that can be built upon for biosafety?
- What are the weaknesses of the existing system that need to be addressed?
- How should these strengths, weaknesses, gaps and overlaps be addressed? What are the next steps?

Countries usually carry out the process of reviews that would help identify the gaps and overlaps in the existing systems during Phase 2 of their NBF project.

A number of specific questions need to be addressed in the review and analysis with respect to each specific category of GMOs, GM products, and/or activities involving GMOs that the country is either obliged to regulate, or has decided it wishes to regulate. These questions include:

- Is there an existing regulatory instrument (or instruments) that already addresses the GMO/product or activity in some way (e.g. plant protection; environmental protection; food safety; etc)?
- What institution is responsible for the implementation of the relevant regulatory instrument(s)?
- Do the existing regulatory instruments adequately address all relevant biosafety-related risks? For example:
  - does it apply the safety standard that the country considers appropriate for GMOs?
  - does it incorporate all relevant risk assessment criteria?
  - does it allow for all relevant risk management measures?
- Do the existing regulatory instruments fulfil any applicable requirements of the Cartagena Protocol?

### EXAMPLE: REVIEW AND ANALYSIS OF EXISTING STATUS

The review in the **Philippines** suggested that the existing legal framework could, to a limited extent, be used but would require a very complex undertaking of extrapolating and adapting existing disparate policies, laws and regulations. However, recent developments pointed to a need to specifically address the concern for biosafety arising from the use of modern biotechnology.<sup>12</sup>

**Armenia** and **Georgia** have no legislation dealing with GMOs or biosafety, these issues have been regulated under general nature protection legislation, hence there is a need for drafting completely new legislative acts and also establish new administrative systems (advisory bodies etc).

**Tonga** identified a range of existing relevant mechanisms or instruments relating to GMOs, but not directly addressing GMOs. On this basis, gaps in the national regulatory and administrative systems were identified and statutory amendments proposed. However, the analysis of the gaps in the national regulatory and administrative system concluded that even with amendments to the existing legislation, the obligations under the Cartagena Protocol cannot be fulfilled. Hence the need for developing a new regulatory and administrative system to complement the existing systems.

**Serbia and Montenegro** have in place a specific system for GMOs – a Law on GMOs (2001) and four rulebooks (2002). However, many aspects are not regulated and hence the existing laws will be amended to add aspects dealing with transboundary movements, labelling, public participation, traceability and monitoring.

- One useful tool in reviewing and analysing this information may be to present the information in the form of a matrix.<sup>13</sup> Some examples are given in Annex 3. These help to illustrate whether a particular GMO, GM product or activity involving a GMO is presently being addressed at all, whether it is being adequately addressed, or whether it is being regulated by more than one instrument or ministry/agency.

Once a country has carried out the necessary analysis, and consulted the national stakeholders, the next step is to decide what needs to be done in order to develop a regulatory regime that meets the country's needs and priorities. The following section examines different options for addressing the gaps and overlaps in a country's existing biosafety system as well as factors to take into account when deciding which option to pursue.

<sup>12</sup> Based on presentation by Mary Jean A. Caleda, NPC, Philippines, at UNEP-GEF workshop on Regulatory Regime and Administrative System, Port of Spain, May 2004.

<sup>13</sup> The matrix is a tool to analyze the information collected during the review process, rather than a means of collecting the information.



## 4. Choice of regulatory regime

After completing a review and analysis of their current regulatory regime, most countries will conclude that there are gaps or overlaps in their existing systems with respect to biosafety. Therefore, changes will be required in the existing systems to enable them to meet their obligations, goals and objectives for the regulation of GMOs, GM products and activities involving GMOs. However, some countries may find that their existing regulatory regime is adequate and does not require any major changes.

As part of the NBF process, countries will identify what they wish to achieve in terms of the regulatory regime for biosafety in the long run. However, they may decide that not all aspects of the regulatory regime can be, or need to be, put in place all at once. If this is the case, a country may decide simply to incorporate enabling provisions into the regulatory regime now, with a view to elaborating more detailed requirements on some aspects of the regulatory regime later on.

This section is divided into four parts.

- **Section 4.1** discusses the setting of priorities in making changes to the existing regulatory regime.
- **Section 4.2** considers the range of options that countries can choose from when deciding how to fix a gap or overlap in their system.
- **Section 4.3** examines different factors to consider when deciding upon which option to pursue.

In making their choice for a regulatory regime, countries might address the following questions:

- **What are the most important or pressing gaps to fill?**
- **How should these gaps be filled?**
- **How should the areas of overlap be resolved?**

### 4.1 Setting Priorities

The first step in answering these questions is to prioritise the gaps and overlaps that need to be addressed. Most governments have limited financial and human resources so they need to determine the most important actions that need to be taken in developing a regulatory system. The types of questions that may be asked when setting priorities include (in no particular order):

- What are a country's obligations under international law (i.e. under any relevant international, regional or bilateral agreements)? Do any of these gaps or overlaps mean the country is not complying with the international agreements it has ratified?
- What are a country's obligations in domestic law? Has the country created obligations in its national legal system that are not being met in the regulation of biosafety and that could leave the regulatory regime open to legal challenges?
- Does the domestic law address the same issue in more than one

place, creating competing or conflicting obligations, causing confusion and costing money?

- Which are the most important or pressing gaps and how can these be fixed? For example, are there GM products that may be introduced in the near future that the present system does not cover adequately? Are there GM products that may be introduced at some later date in the future that may not need to be covered by the system immediately?
- Does the country have the human and financial resources to address these gaps?
- Which are the easiest gaps and overlaps to fix?
- Which are the most difficult?
- Which will cost the most and which will be cheapest?
- How do the gaps and overlaps relate to a country's national policy on biosafety/biodiversity/science & technology/agriculture etc?

### 4.2 The Range of Options

Countries have a number of possible options for designing and implementing a regulatory regime for biosafety. These include:

(a) *Interpreting or guiding the existing system*, where there are existing relevant regulatory instruments already in place, to address any gaps or overlaps and, if necessary, to clarify how those instruments should apply to GMOs.

(b) *Amending the existing system*, where there are existing relevant regulatory instruments already in place, to address any gaps or overlaps and, if necessary, to clarify how those instruments should apply to GMOs.

(c) *Designing a new system*, to fill any gaps and/or to address overlaps.

(d) *Designing a comprehensive new system* (which may also include making corresponding amendments to some existing laws or regulations).

The order in which these options are presented is not intended to suggest any hierarchy or preference. It is up to each country to decide, within the context of its NBF, which approach is likely to work best.

There may also be approaches that fall between the options outlined above. As discussed further below, the key consideration is that whatever approach a country chooses to take, it needs to make the regulatory regime clear: i.e. to state how it interacts with other existing (or future) laws; and how regulatory competence is divided etc. It also needs to ensure that all the GMOs, GM products and activities involving GMOs that it is obliged or wishes to regulate are covered by the regulatory regime.

#### What are the implications of the different options?

Each approach raises some specific questions and considerations. However, there are also some common considerations to bear in mind when deciding which approach to take. Some of these are highlighted in section 4.3 below on "Factors to Consider".



## (A) INTERPRETING OR GUIDING THE EXISTING SYSTEM

A country might decide to adopt this approach if, after having reviewed and analysed the current status of regulatory instruments related to biosafety, it decides that only some adjustments are required at this stage to fulfil its obligation and objectives with regard to GMO regulation. For example, a country may decide that existing regulatory instruments (e.g. on plant protection; food safety; environmental protection) cover, or can cover, all types and use of GMOs that are likely to arise in the country in the immediate future.

Interpreting or guiding the existing system does not entail the implementation of new laws or regulations. It may, however, entail existing regulatory bodies issuing a statement of interpretation or a set of guidelines to clarify how the system will operate in respect of GMOs, GM products or activities involving GMOs. Such interpretations or guidelines may also address, for example, the coordination of disparate regulatory instruments relevant to biosafety, clarifying responsibilities with respect to areas of overlap. This approach requires that the regulatory body or bodies concerned have the authority to issue such interpretations or guidance.

The key question with respect to this approach is:

- Will guidelines or an interpretation effectively and adequately address the GMOs, GM products or activities involving GMOs that are to be regulated and will they provide an adequate level of protection?

For example,

- Will they give adequate legal authority to the existing system?
- Will they withstand judicial challenge?
- Will they be used by the courts in their interpretation of the regulatory regime?

**Note** that interpretations or guidelines are not usually legally binding – they do not create law – so they may or may not be used by the courts. They may acquire the force of law, however, if they are applied in such a way that anyone who follows the interpretation or guidelines will, prima facie, be in compliance with the law or not in breach of their responsibilities.

- Will they adequately address problems of coordination?
- Will they be implemented by the civil servants running the system?
- Will they be adhered to by applicants?
- Will they address problems adequately in the medium- to long-term or are they only likely to provide an interim solution – e.g. might other gaps arise in the near future?

## (B) AMENDING THE EXISTING SYSTEM

Amending the existing system requires formal changes in existing pieces of legislation or other legal instruments. Countries may decide to amend existing regulatory instruments, for example, where those instruments provide general coverage or authority that is relevant to GMOs, but do not at present explicitly address GMOs or activities involving GMOs. Amendments could be introduced to provide this explicit coverage. Among the issues to be considered here are:

- What regulatory instruments (at what level(s) of law) will need to be amended?
- How can such amendments be effected (for example, by which branch of government; how quickly?)

### EXAMPLE: AMENDING THE EXISTING SYSTEM

**Palau's** existing laws and regulations did cover Plant and Animal Quarantine but did not address biosafety. It was decided through a process of review and analysis that, in the interim, regulations for biosafety would be addressed through amendments to these existing regulations. In addition, the Republic is currently in the process of developing a legal regime, into which the recently developed LMO regulations will be absorbed, that will address currently known LMO legal issues.

**Slovenia** had in place a set of legislation, but some secondary legislative acts still need to be drafted.

**Estonia** also had in place a general legislative system, but they had to amend some main laws as well as secondary legislation to comply with the Cartagena Protocol. Many sectoral legislative acts were amended accordingly (such as Seeds Act, Fertilizers Act etc).

## (C) DESIGNING A SYSTEM TO FILL THE GAPS OR REMEDY THE OVERLAP

A country may be satisfied that existing regulatory instruments and institutions will be sufficient to address many of the situations in which it would need to or wish to regulate GMOs, GM products and activities involving GMOs. However some important gaps or potential gaps may still remain. In such circumstances, a country may wish to design and adopt regulatory instruments to fill any existing gaps and to act as a "safety net" – i.e. so that where the regulation of a GMO, GM product or activity involving a GMO does not fall under any of the existing instruments or institutions, it could be covered by the new system. Issues to be considered in respect of this approach might include:

- What new instruments would be appropriate to fill any gaps? Possible examples include new administrative functions as well



- as new regulatory instruments at different levels of law.
- How will coordination between the new system and other existing relevant regulatory instruments be achieved?
  - Can a new system be designed and implemented by one responsible government authority? Will it involve coordinating the involvement of different departments?
  - Would any new institutions be required to implement the new system?

### EXAMPLE: SYSTEMS DESIGNED TO FILL GAPS AND REMEDY OVERLAPS

The **Australian Gene Technology Act** regulates all dealings with 'live GMOs'. Numerous GM products were already regulated by other agencies before the Act was adopted (for example, by the Australia New Zealand Food Authority or the Therapeutic Goods Administration). The regulatory body established under the Act is a new Office of the Gene Technology Regulator. It liaises with these other agencies. GM products that were not already covered by a national regulation scheme are regulated under the Gene Technology Act. The provisions of the Act are stated to be in addition to, and not in substitution for, the relevant requirements of any other law. The Act is also designed to establish a nationally consistent regulatory system among different Australian (state) jurisdictions.

The **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 1991 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. Through the NBF development project, an Executive Order has been formulated in order to address gaps in the existing regulatory regime, with a view to adopting a more permanent and comprehensive system in the future (see Section 4.3 below).

In **Indonesia**, the first regulations issued in 1994 were for the risk assessment of biotechnology product, with subsequent initiatives on food labelling, food safety and field releases. The Indonesia NBF project has helped to review and revise, where necessary, existing systems and regulations.

The **Republic of Korea**, had already drafted overall national legislation on biosafety, in conjunction with 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. The NBF project provided an opportunity to review, consolidate and rationalise the various strands of biosafety regulations.

### (D) DESIGNING A COMPREHENSIVE NEW SYSTEM:

A country may decide to regulate GMOs, GM products and activities involving GMOs through a comprehensive system designed specifically for GMOs. Such a system may still allow for different detailed standards and regulatory procedures to apply to different types of GMOs, products or activities (to be adapted within the overall framework of the system), or preserve regulatory competence in respect of certain matters for other regulatory instruments or institutions. It may also contain enabling provisions to allow for certain matters to be left for more detailed regulation at a later date. Among the considerations for this option are likely to be:

- How can such a comprehensive system be designed and put in place? Who will be responsible and who else will be involved?
- How long will it take to implement such a comprehensive regime, and what will it cost ?
- What existing regulatory instruments (at various levels of law) will need to be amended or repealed in the light of the new system?
- Will the new system create any overlaps with other areas of regulation, and, if so, how will these be resolved? For example, it will need to be made clear whether any parallel approvals are required for any category of GMOs or GM products – e.g. if a new GMO is approved for commercial cultivation under the regulatory regime for biosafety, must it additionally fulfil national seed registration requirements, or get a subsequent separate approval for food or feed use?

### EXAMPLE: COMPREHENSIVE NEW SYSTEMS

After a comprehensive review and analysis of existing laws and regulations, **Cambodia** has decided to draft a new comprehensive national law on biosafety. The draft law will consist of 46 articles dealing with the trans-boundary movement of LMOs and risk assessment and management mechanism for the release of LMOs into the environment. A Sub-decree on "Management and Control of Living Modified Organisms" will complement the draft law, and will set out specific regulations to ensure compliance with the Cartagena Protocol. Further discussion will be needed to ensure stakeholder acceptability and active participation in the implementation of the law, when it is enacted in the parliament.

After a review and analysis of existing laws and regulations, **Jordan** decided that these were inadequate in dealing with LMOs, and that a new law was needed. As a result, Jordan has developed a By-Law on biosafety. The objective of this by-law is "to contribute to an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements." A By-Law was chosen as it is a Level 2 instrument that is easier and quicker to promulgate and will allow the country to develop a Level 1 regulatory instrument in the future, based on experiences with the implementation of the By-Law.

**Armenia's** current laws did not regulate the use of GMOs. However, many related acts are in place or being currently drafted, such as the law "On Fauna" and "On Flora", law on "Breeding achievements protection", law on environmental expertise, seeds, etc. Armenia has chosen to draft a new Biosafety Law rather than trying to amend all these existing laws.

**Kenya**<sup>14</sup> used stakeholder meetings to determine that new framework legislation on biosafety was needed. The stakeholder meetings identified that regulation needed to be overarching and not heavily influenced by work in one sector. Existing legislation was closely linked to a specific sector and therefore deemed to be of limited use for regulating the cross-cutting nature of biotechnology and biosafety. Situation analysis showed that many relevant laws and institutions exist but none totally fit the bill. The framework biosafety legislation is expected to amend other relevant laws to bring them into line with the new legislation.

<sup>14</sup> Based on a presentation by Dr. Patricia Kameri-Mbote at UNEP-GEF subregional workshop in Dar Es Salaam, United Republic of Tanzania, March 9-12, 2004.



### 4.3 Factors to Consider

There are many factors that will influence the choice a country makes with regard to its regulatory regime for biosafety. These may include:

- How effectively are existing regulatory instruments related to biosafety implemented and enforced in practice?
- How long will it take to implement new regulatory instrument(s) or other measures and bring them into effect?
- How much will it cost to design and implement any new regulatory instruments or other measures?
- How quickly are changes to the existing system needed? For example, for the sake of speed, a country may decide to use or amend existing regulatory instruments now, or to use regulatory instruments at a level of law that are quicker to adopt, with a view to adopt a more comprehensive approach in due course.
- How flexible does the regime need to be?
- What training or retraining might be needed to ensure that regulators understand how to apply and enforce the regulatory regime?
- What level and what kinds of public consultation will be required in the design and implementation of any new regulatory instruments?
- What approach will most effectively fulfil the country's obligations, objectives and priorities?
- What approach is most likely to secure public trust and confidence in the regulatory regime?

There will also be factors arising specifically out of each country's own legal system and form of government. For example:

- What is the likelihood that the national regulatory regime for biosafety will impinge upon existing provincial or state laws - especially if these pertain to land (including agriculture) and water, or environment which may be under the jurisdiction of the state rather than the federal government?
- How predictable is the legal process in the country? How certain is it that the solution proposed to lawmakers is the one they will accept?
- How easy or difficult would it be to implement the different options in a country? What kinds and what combination of regulatory instruments does the country typically utilise?
- How likely is it that each of the different options will be challenged in the courts?
- Is there a requirement to carry out a regulatory impact assessment of changes or new laws?
- What plans, if any, exist for a future regulatory system? Are there likely to be new developments within a country, in another country, regionally, internationally, or in scientific knowledge or

applications of modern biotechnology that could affect the choice of how to proceed?

#### EXAMPLE: FACTORS THAT COULD BE CONSIDERED

The **Philippines**<sup>15</sup> has used executive/administrative orders to address biosafety-related issues based on existing laws. This approach has been adopted on account of the novelty of and rapid developments in modern biotechnology, and the need for a quick and flexible response – such orders are easier to approve and amend than laws. The use of such measures is seen as an interim step towards a more permanent and comprehensive legislative framework covering all aspects of biosafety, once experience has been gained and lessons learned from implementation of the current framework.

The scope of the Philippines regulatory regime has also developed over time in a phased manner, commencing with contained use, then extending to cover field trials; and more recently covering release into the environment for propagation and commercialisation.

## 5. Possible elements of a regulatory regime

### 5.1 Introduction

This section identifies some of the issues and questions that Parties may need to consider and decide upon as they design a regulatory regime as part of their national biosafety framework.

While there is no 'typical' regulatory regime for biosafety (see Section 3 and 4 above), a regulatory regime for biosafety will need to address issues such as:<sup>16</sup>

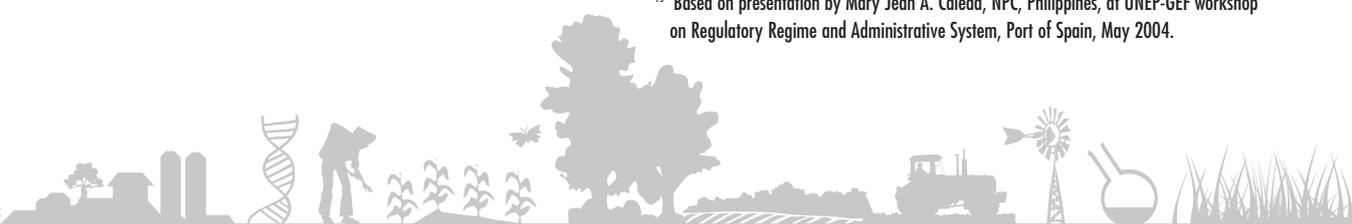
#### What is the objective of the regulatory regime?

- What risks and/or products is the regime designed to regulate?
- What is the regime designed to protect or promote (e.g. biodiversity; health etc)?
- Are there other goals (e.g. capacity-building) to which the regulatory regime can contribute?

#### What is being regulated? (i.e. what is the scope of the regulatory regime?)

- What products and/or activities are covered by the regulatory regime?

<sup>15</sup> Based on presentation by Mary Jean A. Caleda, NPC, Philippines, at UNEP-GEF workshop on Regulatory Regime and Administrative System, Port of Spain, May 2004.



### Who regulates it?

- What body or institution is the competent national authority or authorities?
- How are any relevant institutions/bodies composed?
- How are responsibilities for administrative tasks and decision-making allocated?
- Who has final regulatory approval authority?

### How is it regulated?

- How are decisions taken and upon what criteria?
- Who is involved in the decision-making process?

### How is the regulatory regime enforced?

- How are authorisations monitored and any conditions enforced?
- What sanctions are imposed for violations?

This section of the toolkit highlights some specific questions, issues and options that might be considered in addressing these issues and specific elements of the regulatory regime. Some of these issues are addressed explicitly in the Cartagena Protocol on Biosafety, at least in relation to certain GMOs and certain activities – see section 2 and Annex 1 of this document.

#### WHAT IS A “REGULATORY REGIME” FOR BIOSAFETY?

For the purposes of this toolkit, a regulatory regime for biosafety comprises all those legal instruments (laws, acts, regulations, decrees, orders, guidelines etc) that are relevant to the regulation of GMOs, GM products and activities involving GMOs or GM products, including the institutional arrangements for implementing those regulations.

See Section 3 for further discussion of the kinds of legal instruments that may be relevant.

The various elements of the regulatory regime for biosafety may be set out in a number of different instruments, at different ‘levels of law’ (see section 3.2 above). These elements and instruments may not all be put in place at the same time. Together, however, they will provide the basis for the regulatory process: how GMOs, GM products and activities involving GMOs covered by the regulatory regime will be notified to regulatory authorities and approved (if explicit approval is required).

## 5.2 Key Decisions and Considerations in Designing the Elements of a Regulatory Regime

This section sets out some of the issues that countries may need to consider in deciding the form and content of their regulatory regime for biosafety. These questions are based upon elements that are found in some or all existing domestic regulatory regimes for biosafety. However, they are *not* meant to be used as a template for drafting legislation or other regulatory instruments.

Similarly, examples are used to illustrate a point rather than as models or

recommendations: one country’s experiences may not be relevant or readily transferable to other countries. Existing regulatory regimes for biosafety in many countries are not necessarily the result of a one-off, in-depth, strategic policy process. The usual process is one of evolution over time in the light of early experience with GMOs and implementation of biosafety regulations, new applications for authorisations of GMOs, new applications of modern biotechnology, new scientific knowledge, growing public awareness, and changing concerns over ethical, socio-economic and cultural implications of modern biotechnology.

The questions below are therefore intended to provide an indicative, but not exhaustive, checklist. In the process of considering the appropriate regulatory regime, countries are also likely to need to address additional and different questions according to their own situation.

### 5.2.1 Objective of the regulatory regime

#### What should the objectives of the regulatory regime be? What should it be designed to achieve?

The objective of the regulatory regime provides a context for interpretation and implementation of the other provisions of the regime. The objective of the regulatory regime typically identifies what is to be protected, and may state the level of protection to be sought.

#### POSSIBLE SOURCES FOR THE OBJECTIVE OF THE REGULATORY REGIME MAY INCLUDE:

- The country’s constitution;
- The country’s national biosafety policy or strategy (see section 1 above);
- The country’s national biotechnology policy or strategy;
- The country’s National Biodiversity Strategy and Action Plan;
- The country’s other national priorities, including other national policies and strategies for agriculture, trade, science and technology and sustainable development;
- International agreements, including the Cartagena Protocol, to which the country is a Party (see section 2 above);
- Relevant regional activities; and
- Stakeholder consultations during Phase 2 of the NBF project.

A Party to the Cartagena Protocol on Biosafety will need to ensure that the objective of the regulatory regime for their NBF incorporates, as a minimum, the implementation of the Protocol. The Protocol’s objective refers specifically to the conservation and sustainable use of biological diversity and risks to human health. Existing domestic regulatory regimes on biosafety generally include as objectives the protection of human health and safety and of the environment (not only of biological diversity).

<sup>16</sup> See, McLean et al.



### ARTICLE 1, CPB: OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Some countries also specify additional objectives that go beyond protection of health and environment. A country may wish to consider whether such other considerations should be incorporated into the objective of the regulatory regime. There are a broad range of issues that could be considered here, for example: socio-economic well-being; food safety of GMOs and food products derived from GMOs; sustainable development; promotion of domestic science and technology; food security; consumer choice and information; safeguarding livelihoods of poor farmers and/or traditional or other agricultural practices; ethical considerations; specific protection of centres of origin or of diversity; public education and awareness about biotechnology and biosafety; protection of the rights and interests of indigenous groups or local communities; or cultural, religious or other interests or values. If other such objectives are incorporated, consideration will have to be given as to how they will be reflected in the operational provisions of the regulatory regime – i.e. how will any identified objective be achieved? Where such issues are considered of importance but are not incorporated into the objective of the regulatory regime, a country may decide to address them in some way elsewhere in the regulatory regime to ensure that they play some role in the regulatory process (see examples below, and section 3.2.3 (core principles)).

### EXAMPLE: BROADER OBJECTIVES AND CONSIDERATIONS

The **Norwegian Gene Technology Act 1993**, in its objective, refers to ensuring that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development.

The **Swiss Federal Law relating to Non-human Gene Technology** refers, among others, to ensuring respect for the dignity of living beings, and enabling freedom of choice for consumers and promoting public information, and protection of non-GM production, as well as taking into account the significance of scientific research on gene technology for humans, animals and the environment.

Where such broader issues are not incorporated into the objective of the regime, countries may nonetheless decide to address them in some way elsewhere in the regulatory regime. For example:

The **New Zealand Hazardous Substances and New Organisms (HSNO) Act** requires those responsible for implementing the Act to recognise and provide for certain principles, including ensuring the maintenance and enhancement of the capacity of people and communities to provide for their economic, social and cultural well-being and for the reasonable, foreseeable needs of future generations.

In **Brazil** the Constitution (Art. 225) provides the basis for the regulatory regime on biosafety in a broad way: it states that it is a responsibility of Public Authorities “to preserve the diversity and integrity of the country’s genetic patrimony, and to enforce entities involved in the research and manipulation of genetic material” and “to control the production, commercialization and use of techniques, methods and substances that constitute a risk to life, to the quality of life, and to the environment.”

In **Malaysia**, the Religious Department has decreed that products of genetic engineering which contain genes from non-‘halal’ sources will be considered as non ‘halal’ and will be disallowed for Muslims.

Some countries, as part of their overall biosafety framework, have established committees addressing ethical issues associated with biotechnology (see below institutional arrangements). Examples include **Australia (Gene Technology Act, Articles 111-116), and the European Union (Directive 2001/18/EC, article 29)**.



### 5.2.2 Scope of the regulatory regime

**What should the scope of the regulatory regime be? i.e. to what organisms, products and/or activities should it apply?**

This is a critical question for the design of any regulatory regime and the corresponding provisions must be set out clearly. It tells regulators what they can properly regulate; and it tells those involved in dealing with GMOs (such as researchers, producers, importers, exporters or farmers) what products or activities are subject to regulation.

The answer to this question is likely to depend on a number of factors, for example:

- International obligations:  
The regulatory regime should cover, *at a minimum*, the requirements of the Protocol (see section 2 above, and Annex 1 of this document). It is up to countries to decide whether they wish to go beyond the requirements of the Protocol in their NBF.
- Existing and foreseeable activities involving GMOs in the country: These should have been identified in the survey process. (see toolkit Phase 1 Module).
- Any goals and priorities established in the national biotechnology and biosafety policies, in discussions on the NBF, and in any other relevant policies and strategies
- Any other relevant circumstances in the country

**The scope of the regulatory regime is generally defined in terms of:**

- **the products or organisms that it regulates; and/or**
- **the activities involving those products or organisms that it regulates.**

A useful step in analysing what national laws and regulations already exist that are applicable or relevant to GMOs in the country is to consider the types of products and activities that may need to be regulated, and the risks to be avoided or minimised (see Section 3).

**What products or organisms should the regulatory regime apply to? For example, should the regulatory regime address:**

- GMOs in general
- A broader category of organisms or products, which may include but not be limited to GMOs<sup>17</sup> – for example, new organisms (New Zealand); plants with novel traits (Canada); novel foods; foreign organisms; invasive species; plant protection products/pesticides
- Genetically modified (GM) plants/crops
- GM animals (including fish)
- GM micro-organisms
- GM foods (foods consisting of or containing GMOs; or foods produced from or with GMOs)

- GMOs that are pharmaceuticals for humans
- GMOs for animal treatment
- GM animal feeds?

**What activities involving GMOs should it cover? For example, should the regulatory regime cover:**

- all activities involving GMOs (e.g. 'handling of' or 'dealing with' GMOs)
- import of GMOs
- export of GMOs
- transit of GMOs
- transshipment of GMOs
- contained use of GMOs (research; industrial processing applications)
- deliberate release/intentional introduction into the environment of GMOs for experimental purposes (field trials)
- deliberate release/intentional introduction into the environment of GMOs for commercial or other purposes (e.g. commercial cultivation; bioremediation involving GM micro organisms)
- commercial marketing of GMOs as seeds or plant propagation materials
- marketing of foods or feeds consisting of or containing, or derived from, GMOs
- transportation of GMOs
- repackaging of GMOs from large to smaller packages for sale or export
- disposal of GMOs and GMO debris after a field trial
- samples, gifts or donations of GMOs?

Countries may decide to regulate some or all of these products and activities. However, the precise regulatory requirements for different products and activities may vary depending upon the nature and extent of the risks posed. For example,

- it is common to subject GMOs in contained use to different regulatory requirements as compared to GMOs for introduction into the environment;
- it is common to subject GM foods (or animal feeds) to different regulatory requirements (e.g. in order more fully to assess food safety aspects).

**Are there GMOs, products or activities that should be exempted from the regulatory regime?**

In designing its regulatory regime a country may decide to exempt certain GMOs from its application, or to provide a mechanism by which certain GMOs may be exempted in the future, subject to certain conditions or criteria being met. There may be a number of factors that could influence such a decision. For example:

- The regulatory regime may provide for certain GMOs or products to be exempted from the regulatory regime, either now or in the future, where they are considered, on the basis of a long history of safe use in the country, to pose no risk. A country may decide to exempt a GMO or GM product from the regulatory regime, where the GMO or product in question has already been

<sup>17</sup> N.B. While countries may choose to adopt this approach, this Toolkit addresses only those aspects relevant to the regulatory regime for GMOs.



approved in the country (under the previously existing regulatory system), and involves the same transformation event, for the same use or release into the same environment. However, in some countries where new regulatory regimes for biosafety have been introduced, existing authorisations have been maintained but subjected to a review under the new regulatory standards within a given time frame.

Any decision to exclude GMOs, products or activities from the regulatory regime must be consistent with the Protocol (see section 2 above).

### Definitions

In addition to a provision setting out clearly the scope of the regulatory regime, the scope of application should also be clarified by carefully defining terms used in the relevant instruments. It is important that the definitions used adequately describe the products and activities that a country wants its regulatory regime to cover.

Where a number of different regulatory instruments form the regulatory regime for biosafety, it is important to check for consistency of definitions across the regime.

Key terms to be defined will include those relating to covered organisms or products (for example, 'genetically modified organism' or 'living modified organism'), and to covered activities (for example, 'handling', 'dealing', 'contained use', 'field trial', 'deliberate release', 'introduction into the environment', 'marketing', 'placing on the market' etc).

It is up to a country to decide whether it wishes to use the term 'GMO' or 'LMO', or some other similar term in its regulatory regime. However, where the implementation of the Protocol is concerned it is important that any definitions used are consistent with those used in the Protocol (see CPB, Article 3).

### 5.2.3 Core principles

#### Are there any basic or general principles that will or should underlie the application of the regulatory regime?

A regulatory regime for biosafety may identify certain basic principles that should underlie and inform its application.

In addition, or alternatively, such principles may be derived from other relevant instruments or sources, such as:

- national policies or laws on the environment, biological diversity, agriculture, indigenous communities, sustainable development, or science and technology;
- other regional or international obligations;
- constitutional provisions;

- judicial decisions etc.

#### EXAMPLE: EXPLICIT OR IMPLICIT REFERENCES IN DOMESTIC REGULATORY FRAMEWORKS

- The precautionary principle (e.g. **European Union, Switzerland**);
- The precautionary approach (**New Zealand**);
- Protection of economic, social and cultural well-being of peoples and communities (**New Zealand**);
- Intrinsic value of ecosystems (**New Zealand**).

Where such principles are applicable, a country will have to consider what weight should be attached to them in the regulatory process - for example, must they be 'adhered to' or 'respected', or only 'taken into account' or paid 'due regard' etc. These distinctions will be important for regulators in decision-making. If a regulator must 'adhere to' or 'respect' certain considerations or principles, those considerations will carry more weight in the decision-making process than if the regulator must only 'pay due regard to' or 'take account of' them. Where such principles or considerations are integrated into the regulatory regime, regulators may be required to explain in their decision how they addressed them in the decision-making process.

### 5.2.4 General/overarching obligations

Closely linked to the objective of the regime, regulatory instruments frequently contain general obligations, such as:

- An obligation to ensure that all activities involving GMOs are carried out with appropriate safety measures and in conformity with the applicable regulatory provisions;
- An obligation to refrain from any activities involving GMOs except under and in accordance with any authorisation required under the regulatory regime.



### EXAMPLE: GENERAL OBLIGATIONS

In **South Africa**, the 1999 Regulations made under the Genetically Modified Organisms Act 1997 provide that no applicant may import to or export from the Republic of South Africa, or develop, produce, use, release or distribute any GMO in the Republic of South Africa except in terms of a permit to undertake such activity. [section 2(1)].

They further provide that an applicant shall, besides complying with the provisions of the regulations, also comply with the provisions of all other laws regulating the importation and exportation of GMOs.

In **New Zealand** the HSNO Act prohibits import, development, field testing, or release of all new organisms without an approval under the Act and imposes penalties for non compliance.

## 5.2.5 Responsible Institutions

**R**esponsibility for implementation of the regulatory regime for biosafety will have to be allocated to one or more institutions or bodies. The types of national institutions that will be responsible for carrying out the functions related to the implementation of the NBF are further elaborated in the second part of the module on administrative systems.<sup>18</sup> The functions to be fulfilled in a regulatory regime for biosafety include:

- Receipt and handling of notifications and applications;
- Risk assessment;
- Decision-making;
- Monitoring and inspection; and
- Enforcement.

Where a country chooses to use existing legislation and institutions to implement the NBF (see Sections 3 and 4), then primary responsibility for implementation of the relevant aspects of the regulatory regime will already have been assigned to existing institutions (most likely sectoral ministries). In such circumstances, new coordination mechanisms or guidelines may need to be considered. Where a new law is developed, institutional competence must be allocated.

The term 'institutions' is used broadly here to cover all government ministries/departments, and other government agencies and administrative bodies etc that play a role in the regulatory regime.

In the design of a regulatory regime for biosafety, a country will need to consider:

- Which institution should have **overall responsibility for implementation and oversight** (generally a Ministry)?
- Which institution will have authority to make **final decisions** granting or denying an approval?
- Which institution or institutions should be **responsible for day-to-day administration** of the decision-making process, and for inspection and enforcement?
- What **other bodies exist or may need to be established to support implementation** of the regulatory regime – for example, advisory bodies, committees?

- Where, as is likely, more than one body or Ministry is involved, **how should coordination and communication** be achieved and appropriate lines of responsibility drawn?

The consideration of the designation and/or establishment of institutions to implement the regulatory regime gives rise to a number of more detailed issues and questions, including:

### Should existing institutions be used and/or are new institutions required?

The issue of whether existing institutions can fulfil all the functions required under the regulatory regime or new institutions are required will be answered in part by the review and analysis of the current status of regulatory instruments related to biosafety (see Section 3). Part of that review and analysis will identify and consider what existing institutions, if any, are currently playing a role in biosafety regulation. As countries consider and decide upon the various elements of their regulatory regime for biosafety they will need to consider at each stage whether existing institutional arrangements are adequate or require only some adjustments, or whether new institutions or bodies are required in place of or in addition to existing institutions.

### How should institutional competences/mandates be defined?

Responsibilities of relevant ministries, agencies, committees or other bodies should be clearly defined, particularly where there are potential overlaps. In addition, it is important to ensure that institutions have the requisite legal authority to fulfil any functions assigned to them under the regulatory regime.

### How should issues of coherence and coordination be addressed?

Some countries have decided to establish inter-agency bodies for coordination. Where such a body is established, its functions could include:

- Establish and strengthen relationships with public and private institutions active in biosafety, including a mechanism for the exchange of information;
- Provide technical support to the Competent National Authority(ies), including participation in the risk assessment process;
- Issue technical documents on biosafety.

### Which body or bodies should be responsible for undertaking risk assessment and/or evaluating risk assessment data?

Information pertinent to risk assessment will generally have to be provided by an applicant as part of the biosafety regulatory process. The evaluation of risk assessment data might be done by a government agency, by a specially constituted and mandated advisory committee, or by some other body.

Where advisory bodies are established additional questions may be raised as to its mandate, composition and operation. For example:

- What areas of expertise or interest should be represented on an advisory committee? What areas of scientific expertise should be represented? What other areas of expertise may be required?
- How should its members be selected and appointed (e.g. through public advertisement and recruitment; through consultation and nomination)?

<sup>18</sup> See Section 2.1 on "Setting up an administration system" of the second part of this toolkit module, (phase 3 (ii)).



- How will recommendations or advice of the advisory body be adopted (by consensus or by a simple majority, or in some other way)?
- How should any actual or perceived conflicts of interest in advisory or other relevant bodies be addressed? For example, are procedures for disclosure and/or withdrawal required where a subject or application is discussed in which a member has a direct or indirect interest, or there is some other actual or perceived conflict of interest?

### EXAMPLES: INSTITUTIONAL ARRANGEMENTS IN THE NBF

**Malaysia** decided to establish a National Biosafety Board (NBB) as the decision-making body under the NBF. The Board is chaired by a representative of the Ministry of the Environment and also comprises Secretary-Generals from other relevant Ministries. Membership also includes other eminent persons and representatives of industry and NGOs.

Other institutional components of **Malaysia's** NBF include:

- The NBB Secretariat: responsible for technical and legal matters; public communications, the Biosafety Clearing House; Training, monitoring and secretarial support to the NBB
- The Genetic Modification Advisory Committee (GMAC): the scientific advisory committee responsible for conducting risk assessment; evaluating risk management strategies; evaluating emergency response plans; and providing scientific advice
- An Appeal Board: Chaired by a Minister and composed of individuals who are not members of the NBB: to evaluate and decide upon appeals.
- Institutional Biosafety Committees (IBCs): to be established in all institutions conducting modern biotechnology activities. At the level of, for example, individual research institutions, the IBC conducts risk assessment, risk management and monitoring and provides reports as required to the NBB.<sup>19</sup>

**Latvia** has two decision making bodies: the Environment Protection Board (under Ministry of Environment, responsible for deliberate release of GMOs into the environment) and Latvian Food Centre (under Ministry of Health, responsible for GMOs in contained use and placing on the market). One advisory body – Council of GMOs and Novel Food - advises both. Members of the Council are from relevant Ministries and scientists.

**Belarus** has three ministries responsible for decision making in the area of biosafety – The Ministry of Natural Resources and Environment Protection (non-pathogenic GMOs: field trials, releases and import), The Ministry of Public Health (pathogenic GMOs), and The Ministry of Agriculture and Foodstuffs (state trials and registration of GM varieties).

### How should transparency and accountability of relevant institutions be safeguarded?

Institutional arrangements will need to take account of any provisions in the regulatory framework for public information and participation (see section 5.2.8 below). For example, what information about applications and products should be made available to the public and how? What provisions will need to be made for forms of public information, consultation and participation. In some countries, provision is made for publication of meeting agendas, minutes of meetings and advice submitted to decision-makers. As regards public consultation and participation, provision might be made for written submissions from the public or for public hearings.

### Should final authorisations for GMOs, products and activities involving GMOs be the responsibility of a government Ministry (or ministries) or of some other body (for example, a national biosafety committee)?

Some countries allocate responsibility for final decisions on GMOs to specific ministries or other sectoral agencies. The competent authority may vary according to the type of GMO or GM product in question. Others have established a national biosafety committee or similar institution to take decisions under the regulatory regime.

### Are other advisory bodies or committees necessary or desirable?

Some countries have established standing committees or advisory bodies on the development and evolution of the regulatory regime, on biotechnology policy, or on ethical issues. These may be established as part of the overall regulatory regime, or separately from it. In other cases, such matters have been mandated to bodies established on an ad hoc basis.

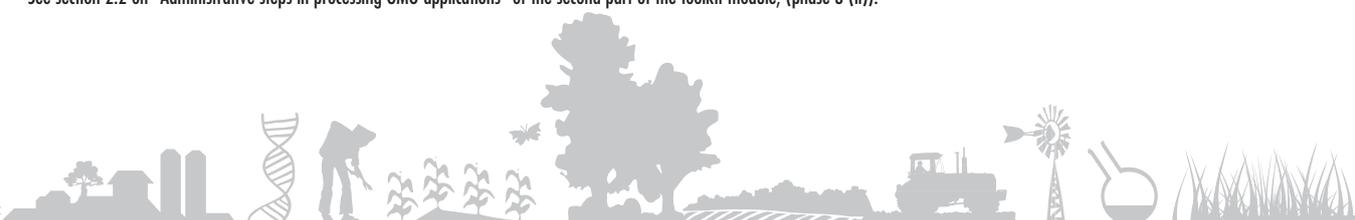
### 5.2.6 The regulatory process

The regulatory regime for biosafety should make clear what the various steps and elements are in the regulatory approval process for specific GMOs, GM products and activities involving GMOs and GM products that are within the scope of the regime. These are described briefly in this subsection. **The specific steps involved in these administrative aspects will be dealt with, in more detail, in the forthcoming toolkit module on administrative systems.**<sup>20</sup>

The regulatory approval process may differ for different kinds of GMOs, GM products or activities involving GMOs or GM products (for example GM micro-organisms for contained use; GM crops; GM foods and feeds; GM pharmaceuticals). Issues to be addressed in relation to the regulatory process are likely to include:

<sup>19</sup> Based on presentation by Dr. Fee-Chon Low, UNEP-GEF Workshop on Regulatory Regime and Administrative Systems, Port of Spain, May 2004.

<sup>20</sup> See section 2.2 on "Administrative steps in processing GMO applications" of the second part of the toolkit module, (phase 3 (ii)).



### **What triggers the authorisation (or notification) process?**

The regulatory regime for biosafety should specify when an authorisation is required – i.e. what GMOs, GM products, or activities require notification or approval under the regulatory regime (see sub-section 5.2.2 above on scope).

### **Who will receive and deal with applications for approval, and how?**

The regulatory regime for biosafety should specify the competent national authority (or authorities), indicating the institution to which applications should be addressed. The regime will also need to indicate whether this institution will deal with all applications, or whether different offices will deal with applications for approvals for different GMOs or GM products (see section 5.2.5 (institutions) above).

### **In what form should applications be submitted, and what supporting information will be required?**

The regulatory regime for biosafety may also specify the format for applications or notifications, identifying the responsible institutions or body. The regime should also specify the requirements, including language, for supporting information to be supplied with an application for approval?<sup>21</sup> Information requirements are likely to vary according to the GMO, GM product or activity in question.

A more detailed description of information requirements will be given in the forthcoming toolkit module on administrative systems. Some typical examples of the types of information required include:

- details of the applicant
- risk assessment data (see section [5.2.7] below)
- information on the regulatory status of the GMO or product in other countries
- proposed risk management measures
- proposed monitoring plan
- emergency response plans

### **What time limits should be established for dealing with an application?**

For the sake of predictability, the regulatory regime will generally establish time limits within which decisions on applications will be reached, and possibly time limits for other steps in the regulatory process (e.g. acknowledgement of application).<sup>22</sup> Countries also need to consider whether and in what circumstances time limits might need to be extended. For example, where further information is requested from the applicant, some countries “stop the clock” on the application. In other cases, time limits may have to be extended where additional information has to be sought from other sources, for example where additional testing or trials are required.

### **How should applications be documented and stored?**

The regulatory regime will also specify how applications are to be documented and stored (paper files, computer records, database, etc), where they will be stored, and who (which institution) will be responsible for their maintenance.

### **What should the decision-making procedure be (see below)?**

The regulatory regime should set out clearly the various steps in the decision-making procedure and the responsibilities of the different institutions involved at each stage of the procedure. These steps will be dealt with in more detail in the toolkit module on administrative systems.

### **What provisions should be made for public information and participation, and in respect of commercial confidential information?**

These questions address who is entitled to information about applications for approval, and on what basis, and who should be entitled to participate in decisions. They are addressed in section 5.2.8 below.

### **Who will be responsible for final authorisation?**

In particular, for the sake of legal certainty for the applicant and others, the regulatory regime should state clearly which institution is responsible for granting or denying final approval for a GMO, GM product or activity involving a GMO covered by the regime. (see section 5.2.5 above).

### **Will it be possible to appeal against decisions to grant or deny an approval made by regulatory bodies?**

Appeal procedures may be available under general provisions of a country’s administrative law. Alternatively, countries may decide to establish specific appeal mechanisms within the regulatory regime for biosafety, or they may decide that regulatory decisions are to be treated as final (subject to procedures for review – see immediately below). Where specific appeal procedures are established as part of the regulatory regime on biosafety, a country will need to decide who may appeal against a decision (for example, only the applicant, or also other interested persons/stakeholders), and on what grounds.

### **What procedures should be available for the review of decisions?**

Countries will need to consider what mechanisms will be available for the review of a decision in the light of new scientific or other information, or changed circumstances.<sup>23</sup> Issues to be addressed here will include, how and by whom a review of a decision can be triggered and how it will be conducted. For example:

- Could reviews be requested by an applicant or a third party on the basis of new scientific information?<sup>24</sup>
- Could a regulatory body review an authorisation on its own initiative on the basis of new scientific information?<sup>25</sup>
- Could a review be initiated based on information and action taken by other countries?

### **Should the regulatory regime provide for any simplified authorisation procedures?**

Some countries provide for simplified notification or approval procedures, for example in respect of certain GMOs which a country considers can safely be addressed by such procedures due to experience already gained in the country of the GMO in question or of a particular category of GMOs. Provision for such simplified procedures specify under what criteria and/or conditions a particular GMO or category of GMOs may qualify for the simplified procedure.

Parties establishing simplified procedures must ensure that their

<sup>21</sup> See CPB, Article 8 and Annex III.

<sup>22</sup> See CPB, Articles 9 and 10.

<sup>23</sup> See CPB, Article 12.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.



regulatory regime conforms with any relevant Protocol requirements (for example, Article 13).

### What fees may be imposed under the regulatory regime, and by whom?

Regulatory regimes typically make some provision for payment of fees – for example on application for authorisation. It is quite common to delegate authority to set fees so they may easily be revised as appropriate.

Countries may wish to consider whether there should be different fees for different categories of applications. In addition, countries may need to consider how fees generated by the regulatory regime should be used: for example, some seek to apply an element of “cost-recovery” so that fees are applied to meet the costs (or a portion of the costs) of the regulatory regime. In other countries, fees go into the general government budget and costs of the regulatory regime have to be met out of the budget of the ministries or other institutions responsible for administering the regime.

### 5.2.7 The basis for decision-making

The regulatory regime for biosafety will need to establish the basis on which decisions to grant or deny an approval for a GMO, GM product or activity involving a GMO or GM product covered by the regime will be made. For example, what is the safety standard that must be achieved; and what criteria and considerations will be taken into account in the decision-making process. **The specific administrative steps involved in the decision-making are further elaborated in the second part of the toolkit module on administrative systems.**<sup>26</sup>

Subject to an overriding safety standard, the precise criteria and considerations to be taken into account (for example food safety aspects; environmental impacts; impacts on human or animal health; plant pest risks etc) are likely to vary depending upon the type of GMO, GM product or activity involving GMOs in question.

It is important that the regulatory regime sets out clearly and comprehensively the issues that a country wishes to take into account in decision-making on GMOs. For example, if the regulatory regime provides that regulators may only take into account environmental risks in reaching decisions on whether to grant or deny an approval – are regulators then legally entitled under that regime to deny an approval on the basis of risks to human health or economic impacts?

In general terms, a decision regarding the granting or denial or an approval for a GMO, GM product or activity involving a GMO should be

based on risk assessment.<sup>27</sup> However, the risk assessment is not the same as the decision itself. Once a risk assessment has been undertaken, the institution or authority responsible for taking the final decision has to decide, in accordance with the provisions of the regulatory regime, whether to grant or deny the approval, whether to attach conditions to an approval if granted, and what conditions to attach.

### What risk assessment criteria should apply to the evaluation of an application for authorisation?

Approval processes for GMOs, GM products and/or activities involving GMOs generally incorporate risk assessment or safety assessment procedures designed to evaluate the nature and extent of any risks associated with the GMO, and to identify whether and how any risks identified can be managed.<sup>28</sup> The risk or safety assessment forms part of the basis for a decision to grant or deny an approval. For the purposes of this risk assessment process, the regulatory regime needs to identify:

- The kinds of information that should be taken into account - as a starting point, the regulatory regime should ensure that required information is provided by the applicant in the application (see section 5.2.6 above). For example, typically, risk assessment (for the purposes of environmental releases of GMOs) is based, among others, on scientific and technical information about:<sup>29</sup>
- The GMO in question
- The recipient or parental organisms (including centres of origin and genetic diversity)
- The donor organism(s)
- The vector
- The insert(s) and/or characteristics of modification
- Detection and identification methods for the GMO
- The intended use of the GMO (for example, the scale of release and period of release)
- The receiving environment (including location, geographic, climatic and ecological characteristics; biodiversity and any centres of origin).

The precise information requirements and issues for assessment will vary according to the type of GMO/product involved. For example, where a GM food or animal food is concerned, different or additional information will be required, and different issues considered, as part of the assessment process (such as potential allergenicity associated with the GM food).

- The baseline data that should (or might) be available
- The kinds of potential impacts that should be assessed – For example, environmental, health and/or other risks. Some countries specify that potential long-term, cumulative or indirect

<sup>26</sup> See section 2.2 on “Administrative steps in processing GMO applications” and section 3 on “Decision making” of the second part of this toolkit module, (phase 3 (ii)).

<sup>27</sup> See CPB, Article 15.

<sup>28</sup> See CPB, Article 15 and Annex III.

<sup>29</sup> This list is based on Annex III of the CPB.



impacts of GMOs should be assessed (European Union).

- The principles that should guide the risk assessment process
- The sources of scientific information and advice in the decision-making process. Examples of such sources include: the applicant, advisory committees, experts, peer reviewed scientific literature.

### How should decisions be made in the face of scientific uncertainty/lack of full information?

Provisions of the regulatory regime on the decision-making process may provide guidance to regulators as to how they should deal with applications where there is a lack of scientific information about the risks associated with a GMO or scientific uncertainty as to the nature or extent of any possible adverse effects associated with a GMO. For example, in such situations, should regulators take decisions on the basis of the precautionary principle, and what would this mean in practice?

### Should other 'non-scientific' criteria or considerations play a role in decision-making – such as socio-economic considerations?

Science-based risk assessment is a common element of regulatory regimes on biosafety. There is more debate as to what other considerations should be taken into account in reaching a final decision on whether or not to grant or deny an approval for a particular GMO, GM product or activity involving a GMO.

In establishing criteria for decision-making, countries may wish to consider other issues such as:

- Should risk assessment only incorporate scientific and technical considerations, or should other considerations form part of the risk assessment process. (e.g. potential socio-economic impacts)?
- Should other criteria be taken into account in reaching a final decision, and, if so, when, to what extent, and how?

For example, should socio-economic,<sup>30</sup> ethical, cultural or religious considerations be a factor in decision-making. Examples of socio-economic considerations might include the impact of the approval on particular communities (e.g. livelihoods of poor farmers) in the country; the economic impacts on organic farmers of the potential loss of "GM-free" status; the potential loss of export markets for agricultural produce; and concerns about the potential impact of a particular GMO on food security.

If such considerations are to play a role in the decision-making process, countries need to consider related issues such as:

- what kind of information on these issues might be considered, and from what source?
- what tools and mechanisms could be used for the analysis and assessment of such considerations?
- what weight should such criteria be given in the decision-making process?

### EXAMPLE: ECONOMIC, SOCIO-ECONOMIC AND ETHICAL CONSIDERATIONS

The **African Model Law on Safety in Biotechnology** includes within the definition of risk assessment the evaluation of the direct and indirect, short, medium and long-term risk to the environment, biological diversity or human health, including socio-economic conditions or to ethical values" (Article 1). It further provides that no approval shall be given unless that it is considered and determined that there will be no adverse socio-economic impacts and that the GMO or product will accord with the ethical values and concerns of communities and will not undermine community knowledge and technologies (Article 6(9)(c) and (d)).<sup>31</sup>

The draft **Executive Order on Biosafety in the Philippines**, includes the following principle: "Socio-economic, Cultural, and Ethical Considerations. The socio-economic, ethical and cultural benefits and risks, of modern biotechnology to the Philippines and its citizens, and in particular on small farmers, indigenous peoples, women, small and medium enterprises and the domestic scientific community, shall be taken into account in implementing the NBF;"

Under the **EU Directive 2001/18 art 29**, Committee(s) on Ethics could be consulted for their advice on ethical implications.

In **Estonia** the objective of the GMO Act is *inter alia* "to ensure the use of GMOs in an ethically acceptable manner". However, the Act does not specify who should give their opinion about ethics or to what extent ethical considerations could affect the decision; the law regulates only environmental safety and safety for health.

<sup>30</sup> Article 26 of the Protocol allows Parties to take into account in decision-making on imports socio-economic considerations arising from the impact of LMOs on biological diversity, consistent with their international obligations.

<sup>31</sup> (OAU Decision EX/CL/Dec26(III), Decision on the Report of the Interim Chairperson of the Africa-wide Capacity-building in Biosafety (EX/CL/31(III)).



### 5.2.8 Other aspects of the decision-making process

This section highlights two additional important aspects of the regulatory process and decision-making procedure that countries will need to consider in designing and developing their regulatory regimes for biosafety:

- Public information and participation; and
- Confidential business information

**How should public information and participation be addressed in the regulatory regime?**

#### EXAMPLE: PUBLIC PARTICIPATION

In **Australia**, under the Gene Technology Act, members of the public may make submissions to the regulator with regard to applications for authorisation for environmental release of a GMO. There is public notification of applications for authorisations to release a GMO into the environment under the Act, and there is a minimum period of 30 days for the public to comment on the draft Risk Assessment and Risk Management Plan. A publicly available Record of GMOs and GM Product Dealings provides a complete list of all approved GMOs and GM products.

In the **Philippines**, the draft Executive Order (EO) section 7 requires “The concerned government departments and agencies, in developing and adopting biosafety policies, guidelines and measures and in making biosafety decisions, shall promote, facilitate, and conduct public awareness, education, and meaningful participation. They shall incorporate into their respective administrative issuances and processes best practices and mechanisms on public participation in accordance with guidelines” specified in the EO. These guidelines address issues such as when and how the public would be involved, time frames, submissions, and how public concerns should be incorporated in the decision-making.

In **Chile**, Resolution 1. 523/01 SAG, as part of the approval procedure, requires publication of an extract of the application in the Official Journal, initiating a public consultation. The submissions received have to be considered by the Agricultural and Livestock Service (SAG) in evaluating the application.

In **Bolivia**, the National Secretary of Natural Resources, when convening the National Biosafety Committee, publishes a synthesis of the application in two national print media, including a technical one, to allow persons and institutions that wish to provide information about the LMO to the National Biosafety Committee, to do so.

In the EU, according to **EU Directive 2001/18**, all applications are made publicly available, and the public has 30 days to comment. Member countries use different ways to do this: usually, the notification is published in a newspaper, an official gazette or on a special internet site (for example in Estonia)

The toolkit module for Phase 2 deals with the issue of public participation in detail,<sup>32</sup> and the administrative aspects of public participation are discussed in the second part of the toolkit on administrative systems.<sup>33</sup>

Countries also need to consider the extent to which, and how, the regulatory regime for biosafety should provide for public access to information on GMOs, GM products and activities involving GMOs, and for public involvement in the decision-making process. Issues that a country should consider in developing its biosafety regulatory regime include:

- **To what extent, if at all, are issues of public information and participation addressed in other laws and regulations on for example, freedom of information, environmental laws etc?** If such laws and regulations exist, do they address all relevant areas for the NBF?<sup>34</sup>
- **How should the public be made aware of the existence and content of the regulatory regime, and their rights under the regime?**
- **Should the public be informed of specific applications for authorisation, and if so how?** For example, some countries make information about applications available on websites, or through the press, and invite comments within a specified time period.
- **What information mechanisms might be necessary or appropriate in the particular circumstances of the country concerned?**
- **At what stage, and how, should views of the public be received and considered?**
- **What mechanisms for public participation should be established?** For example, should comments from the public be accepted in writing? Are there any circumstances in which public hearings or other forms of consultation should be required? Who should be entitled to submit comments? What timescales should apply to any public consultation provisions?
- **Where public comments are invited, what weight should regulatory authorities attach to them?** Should regulatory authorities explain how comments received from the public have been considered in reaching the final decision on an application?

<sup>32</sup> See also “Public Participation and the Cartagena Protocol on Biosafety”, Part III: The case studies. Published by the Institute of Development Studies, University of Sussex.

<sup>33</sup> See Section 2.2.3 on “Public Participation” in the second part of the toolkit module, (phase 3 (ii)).

<sup>34</sup> Countries were asked to carry out such a survey in Phase 1 of the NBF development project; see Toolkit Module for Phase 1.



- **How should the public be informed of decisions taken pursuant to the regulatory regime?** For example, some countries provide access to a register of GMO decisions, on a website and/or for consultation in hard copy.
- **How should the interest of the public in access to information and participating in decision-making be balanced with requirements relating to confidential commercial information?** (see below)

**What provision should be made for the protection of confidential business information and how does this interact with public information and participation requirements?**

In order to assess the risks associated with a GMO or GM product, a regulatory authority will require detailed information about the GMO and proposed activities involving the GMO (see sections 5.2.6 and 5.2.7 above).<sup>35</sup> Some of this information is likely to be of commercial value. Regulatory authorities have the right to receive full and accurate information about GMOs in order to reach an informed decision, but applicants will wish to ensure that certain information provided to regulatory authorities solely for the purpose of the application is not disclosed to third parties in a manner that may adversely affect their commercial interests.

In order to address these issues, regulatory regimes for biosafety generally provide for certain information to be treated as confidential by the regulatory authority. Provisions on confidential business information affect whether that information may be made available to *third parties*, including the public. They do *not* allow applicants to withhold relevant required information from the regulatory authority itself (and should not affect the provision of all relevant information to those bodies mandated to undertake risk assessment).

Countries developing regulatory regimes need to consider a number of questions regarding the treatment and protection of confidential information, particularly how to balance the rights and interests of applicants in having certain information treated as confidential, and the rights and interests of the public in access to information:

- **When and how can an applicant request that information be treated as confidential, and should justification be required for the request?** For example, some countries require applicants seeking treatment of information as confidential, to provide justification of why such treatment is claimed.
- **What kinds of information should not be considered confidential?** For example, national laws frequently specify certain types of information which cannot be treated as confidential in any circumstances – see examples in Box below.

Article 21(6) of the Protocol also specifies certain information that shall not be considered confidential: the name and address of the notifier, a general description of the LMO and a summary of the risk assessment and any methods and plans for emergency response.

- **Are there other circumstances in which confidentiality claims can be overridden – for example in the public interest, or for reasons of national security?**
- **Who makes the final decision as to whether specific information is to be treated as confidential, and on what basis?**
- **What should happen when the regulatory authority and the applicant disagree about whether information should be treated as confidential?**  
Generally, domestic regulatory regimes provide that it is the regulatory authority that decides whether or not specific information is treated as confidential or not. However this decision may be subject to review. In addition, an applicant may decide to withdraw an application where confidentiality of certain information is not granted.
- **What are the implications of the regulatory authority refusing to treat information as confidential?** For example, must the regulatory authorities respect the confidentiality of information supplied where the applicant withdraw the application (see examples below).
- **What administrative or other mechanisms need to put in place to ensure that confidential business information is properly protected from disclosure?** This issue will be addressed in more detail in the module of the toolkit on administrative systems.<sup>36</sup>

<sup>35</sup> CPB, Article 21 addresses Confidential Information. WTO Members should also have regard to Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

<sup>36</sup> See section 2.2.5 on “Confidential business information” in the second part of this toolkit module, (phase 3 (ii)) (phase 3 (ii)).



### EXAMPLE: CONFIDENTIAL COMMERCIAL INFORMATION

In the **European Union** a notifier may indicate information the disclosure of which might harm its competitive position and which should be treated as confidential. Verifiable justification must be given in such cases. The competent authority, after consultation with the notifier, decides which information will be kept confidential and informs the notifier of its decision. Certain information may not be kept confidential. If the notifier withdraws the notification, the competent authorities must respect the confidentiality of information supplied.

Administrative Order No. 8 in the **Philippines** allows applicants to keep portions of their applications as confidential. A summary of the risk assessment and description of the emergency response plan cannot be kept confidential.

**Argentina** allows applicants to mark portions of their applications as confidential. In this case, only some of the reviewers will see the entire application. Critical information cannot be designated as confidential.

The **New Zealand** regulatory authority will keep commercially sensitive information confidential. Information will only be kept confidential where it does not affect the validity and integrity of any information about possible risks and adverse effects of new organisms.

The Executive Council in **South Africa's** system will consult with the applicant to determine what information will be kept confidential. Descriptions of the organism, the identity of the applicant, the plans for monitoring the organism, the emergency measures to be taken in case of an accident, and the evaluation of the foreseeable impacts are not to be kept confidential although the Executive Council can decide to withhold certain information to protect the intellectual property of the applicant.

In **Australia**, under the Gene Technology Act, the applicant may apply to the regulator for a declaration of confidential commercial information. The applicant must satisfy the regulator that the information falls within a category specified in the Act, such as a trade secret. The regulator may refuse to make a declaration where the public interest in disclosure outweighs the prejudice disclosure would cause to any person. In certain circumstances, the regulator must make publicly available a statement of reasons for making the declaration. If the regulator refuses a declaration it must treat the information as confidential until any review rights of the applicant specified in the Act have been exhausted.

### 5.2.9 Content of the decision

The regulatory regime may specify the elements that a decision to grant or deny an approval must contain. For example, where an authorization is denied, regulators may be required to give reasons for their decision. Where an authorization is granted, specific elements of the decision may include, for example:

- A summary of the risk assessment (the data upon which the decision is based);
- The subject-matter of the authorisation – for example, detailed identification of the GMO or GM product approved, or, where activities involving a GMO are approved, the name of the authorization holder;
- The duration of the authorisation (unlimited; or for fixed duration with possibility of renewal etc);
- If an environmental release of a GMO is involved, the terms of the release (e.g. when, where, how much and for how long);
- Required risk management measures;
- Other conditions attached to the authorization.

### How should any risks identified in the risk assessment process be managed?

The purpose of risk management is to regulate, manage and control risks identified in risk assessment. In addition to considering whether risks identified in a risk assessment can be managed, and by what types of risk management measures, regulators will also need to have regard to the question whether risk management measures are likely to be applied effectively. Risk management measures may be identified in conditions attached to an authorisation.

### What kinds of conditions associated with risk management should be attached to authorisations and under what circumstances?

Conditions to be attached to an authorisation are generally decided on a case-by-case basis, there may also be some common conditions. They will tend to vary according to the type of GMO or product involved and the activity being undertaken. The regulatory regime may impose a general requirement that appropriate risk management measures should be taken, and conditions attached to authorisations as appropriate. Some regulatory regimes may require that some specific measures are addressed in the authorisation. Examples of risk management measures include:

- required containment measures;
- handling and packaging requirements;
- conditions for the protection of particular ecosystems or environments and/or geographical areas;
- measures to limit the dissemination or persistence of the GMO or genetic material in the environment, such as isolation distances to contain gene flow through pollen;
- removal of all flowering parts or reproductive structures;
- use of male sterile genes;
- buffer zones' to delay insect-resistance build-up;
- washing and cleaning of farm equipment and vehicles after use;
- removal of volunteer plants in next planting season;
- allowing GM-crop fields to fallow;
- post-release treatment or control;



- geographic or other restrictions on use;
- labelling or marking requirements;
- product tracing or traceability requirements.

### What other types of conditions should be attached to authorisations?

Other types of conditions attached to authorisations may relate, for example, to: labelling obligations; documentation and record-keeping obligations; data collection and monitoring; supervision by institutional biosafety committee; reporting of new or unexpected information or results to the relevant regulatory authority; the frequency and period of post-release monitoring; and insurance requirements.

### Should authorisations be indefinite or time limited and subject to regular review/renewal?

For example, in the European Union, consents for placing on the market of GMOs are given for a maximum period of ten years (renewable).

#### 5.2.10 Labelling

### Should any specific labelling requirements be imposed for GMOs and/or GM products?

Some regulatory regimes impose requirements as to marking or labelling of GMOs and/or products derived from GMOs. While the issue has mainly arisen in the context of GM foods, it may also arise more generally.

Labelling requirements may be imposed as a condition for an authorisation of a GMO or GM product, or may be addressed more generally as part of the regulatory regime. It is beyond the scope of this Toolkit to go in detail into the scope, nature and implications of possible labelling requirements. The types of issues to be considered may include:

- What kinds of GMOs or products, if any, should be subject to domestic labelling requirements?
- Should any labelling of GMOs or GM products be mandatory or voluntary?
- What should the purpose of any labelling requirement be? For example, should they be imposed only to protect the environment and/or human health or should they be imposed to provide information and choice to potential consumers of GMOs or GM products?
- If labelling requirements are imposed, what form of label should be required in relation to different GMOs or GM products – for example as to the wording, format, placement or size of any label?
- Should thresholds be established for the unintentional presence of GMOs in products, below which labelling would not be required?
- How would any labelling requirements for GMOs or GM products relate to other relevant product-labelling requirements?

#### EXAMPLE: LABELLING

In **Switzerland**, the Federal Law on Non-human Gene Technology, requires that any person marketing GMOs must label them as such for the benefit of the recipient in order to ensure freedom of choice for the consumer. The labelling must contain the words “genetically modified”. The Law provides for threshold values to be established below which labelling is unnecessary for mixtures, articles and products that unintentionally contain traces of GMOs (provide the person responsible for providing the labelling can prove that the product flows have been carefully monitored and recorded to avoid such traces). It also provides for the regulation of the labelling of products, in particular foodstuffs and additives obtained from GMOs. (Article 17).

In **Brazil** Decree N°1.871 of June 18 2001, states that foods for human consumption that contain or are produced with GMOs in an amount that constitutes 4% or more of the product, must identify this fact on their labels. The label must contain one of the following statements: “genetically modified (type of product)” or “contains genetically modified (type of ingredient)”. The label must be written in the Portuguese language, and must be easily visible. If the product contains more than one genetically modified substance, the content levels must be listed for each one.

The **Australia New Zealand Food Standards Code** was amended in 1999 to include a requirement for the labelling of food produced using gene technology in both these countries. The mandatory standard requires labelling of packages of genetically modified food. The package must include the statement ‘genetically modified’ in conjunction with the name of the food, ingredient, or processing aid. Genetically modified foods are defined to include foods produced using gene technology that contain novel DNA and/or a novel protein, or have altered characteristics. Exemptions to the labelling requirement include highly refined foods where the effect of the refining is to remove the novel DNA or protein, food prepared at the point of sale, and food that unintentionally contains up to 1% genetically modified ingredients.

In April 2004, the **Canadian General Standards Board** published a new national standard on the “Voluntary Labelling and Advertising of Foods that Are and Are Not Products of Genetic Engineering”. The standard sets the criteria for those who want to label foods as containing or not containing genetically engineered products but it does not require the labelling of genetically engineered foods. It uses the terms ‘genetic engineering’, ‘genetically engineered material’, and ‘product of genetic engineering’ rather than GMO or LMO. The standard allows for up to 5% adventitious inclusion of food from genetically engineered sources in foods labelled as not genetically engineered. This adventitious presence must be accidental and foods to which a genetically engineered variety has been intentionally added, even if it is less than 5%, cannot be labelled as not genetically engineered.

#### 5.2.11 Monitoring

*Note: The administrative aspects of monitoring are elaborated further in the second part of the toolkit module on administrative systems<sup>37</sup>*

### How should the regulatory regime provide for monitoring of the effects of an authorised GMO or GM product?

<sup>37</sup> See section 4.2 on “Monitoring” in the second part of the toolkit module, which will be available later in 2004



The regulatory regime will need to address how the effects of any authorised GMO or GM product will be monitored – i.e. for example, with regard to an environmental release, how will the regulatory authorities confirm whether or not the effects of GMO in the environment reflect the assumptions in the pre-authorisation risk assessment, and identify any unanticipated effects of the GMO. Monitoring may be particularly important with regard to early identification of any unintended or unforeseen effects of the GMO once it is released into the environment or placed on the market. There are at least three aspects that might be considered:

- Should post-marketing/release monitoring requirements in relation to authorised GMOs be implemented, and, if so, how?
- Who is responsible for any post-authorisation monitoring? For example, the authorisation holder; users; a government inspection agency; or some other body?
- Should there be an obligation on the applicant to provide to the regulatory authority any new information that becomes available after authorisation is received as to risks associated with the GMO?

#### EXAMPLE: MONITORING

The **European Union** requires that any authorisation for placing on the market of a GMO shall specify monitoring requirements. It places an obligation on the notifier to ensure that monitoring and reporting are carried out according to any conditions specified in the consent, and submitted to the relevant competent authorities. The notifier is also under an obligation to inform the competent authority of any new information that becomes available from the users or other sources about risks of the GMO to human health or the environment.

The **Philippines'** Administrative Order No. 8 includes a duty on the permit holder for a genetically modified plant to submit monitoring reports to the Bureau of Plant Industry. The permit holder must also notify the Bureau if new information about the risks of the plant or its characteristics become available.

In **Argentina**, both government inspectors and the permit holder carry out monitoring. The permit holder has an obligation to notify the proper authority if there is an escape of a GMO, at the end of a field trial, of unexpected characteristics or unforeseen effects during an experimental release, of dates of sowing and harvesting GM seeds and of the subsequent use of a trial plot. Government authorities can carry out inspections during field trials and the post-harvest period if deemed necessary.

The **New Zealand** the Environmental Risk Management Authority is responsible for monitoring compliance with the Hazardous Substances and New Organisms Act.

#### Should product tracing/traceability requirements be imposed?

To facilitate monitoring, some countries have introduced product tracing or 'traceability' requirements as a risk management mechanism in relation to GMOs and certain GM products. These comprise essentially obligations to retain and transmit certain information regarding GMOs and GM products, thus generating information and documentation trails that are designed to enable the tracing and recall of GMOs or GM products where necessary. In case of harm from GMOs or GM products, traceability measures allow regulators to track the organism or product through the chain of production to the source thus facilitating its removal from the market.

Countries wishing to consider such mechanisms for their regulatory regime will need to consider issues such as:

- The kind of record keeping requirements that might be imposed.
- The types of information that should be transmitted to those to whom GMOs or GM products are supplied, and how (in what form) such information might be transmitted
- Who would be responsible for keeping and passing on information.
- For how long records should be retained, and in what form.
- How any record keeping and information requirements might be enforced?

#### EXAMPLE: LABELLING AND TRACEABILITY REQUIREMENTS

The **EU** has established a framework for the traceability of products consisting of or containing GMOs, and food or feed produced from GMOs. The stated objectives of the framework are to facilitate accurate labelling, monitoring the effects of the environment, and, where appropriate, on health, and the implementation of appropriate risk management measures, including, if necessary, withdrawal of products.

In 2003, the **Canadian Grain Commission** (the federal government department responsible for Canada's grain quality standards) established a voluntary Canadian Identity Preserved Recognition System (CIPRS).<sup>38</sup> The System is intended to maintain the unique traits or qualities of a crop from seed through transportation and handling to processing. CIPRS includes all crop types and is not limited to GMOs. The System uses third party auditors to assess the identity preservation quality management systems of companies who, if they meet the standards under CIPRS, are then certified and can use the CIPRS mark. An important part of the Standard is proper documentation and sampling that accompanies the movement of grains and shifts of accountability through the handling and transportation system. The first shipment certified under CIPRS was of non-GM soybeans destined for the UK.

<sup>38</sup> Information derived from Canadian Grain Commission website, <http://grainscanada.gc.ca/Prodser/ciprs/ciprs1-e.asp>.



### 5.2.12 Inspection, enforcement and emergency provisions

*Note: The administrative aspects of monitoring are elaborated further in the second part of the toolkit module on administrative systems<sup>39</sup>*

#### What inspection and enforcement functions may need to be undertaken and what institution should undertake them?

Inspection and enforcement functions will be critical to the overall effectiveness of the regulatory regime for biosafety and need to be carefully considered in the design and development of the regime. Issues are likely to include questions of adequate authority to undertake inspections, as well as more practical questions of capacity and resources, coordination issues among different agencies, and raising public awareness so as to support enforcement efforts. An important question to consider will be what training or retraining of government or other officials will be necessary for them to carry out inspection or enforcement functions under the regulatory regime for biosafety.

Among specific challenges for enforcement posed by GMOs may be dealing with informal transboundary movements or dealings with GMOs (e.g. GM seeds)

#### EXAMPLE: INSPECTION PROVISIONS

The **South African** Genetically Modified Organisms Act 1997 provides for inspections under warrant (section 15) and routine inspections without warrant (section 16). Under warrant, an inspector may conduct an investigation to determine whether the provisions of the Act have been complied with, and may enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of the Act is taking place. Under routine inspections, inspectors may, during office hours, without warrant, enter any place or facility registered under the Act to, among others, examine materials and take samples; inspect any activity or process carried out in or on the place or facility in connection with GMOs; and require the owner or occupier of the place or facility to produce for inspection (or for providing copies or extracts) of documentation in respect of administration of the Act.

#### What offences and penalties should be established for contraventions of the regulatory regime?

As with other regulatory regime, countries will need to determine appropriate and proportionate penalties for non-compliance with the regulatory regime for biosafety. These offences and penalties could fall under one or more of the following categories:

- Administrative
- Civil and/or
- Criminal.

#### EXAMPLE: OFFENCES AND PENALTIES

Administrative Order No. 8 in the **Philippines** does not create either civil or criminal liability. However, the draft Executive Order, prepared as part of the NBF project addresses this issue in Section 9, which allows for remedies in cases of violations of laws, rules, and regulations related to biosafety. These cover administrative remedies, as well as civil and criminal liability.

The draft Biosafety law in **Cambodia** also provides for civil and/or criminal penalties in cases of violations of the law (Chapter X).

**Argentina's** system is based on guidelines so it likewise does not have provisions on civil or criminal liability.

**New Zealand's** HSNO Act creates both civil and criminal offences and includes strict liability for most offences.

The GMO Act in **South Africa** also includes civil and criminal penalties.

#### What should happen in emergency situations?

Applicants may be required to submit emergency response plans with their applications for authorisation. These emergency response plans would deal with different types of emergencies that may arise as a result of accidents or unintentional release. However, an additional question is what steps inspection or other agencies should be permitted or required to take in the event if an emergency situation arises.

#### EXAMPLE: EMERGENCY RESPONSE PROCEDURES

Under **New Zealand's** Hazardous Substances and New Organisms (HSNO) Act, an emergency is defined to mean "Actual or imminent danger to human health or safety; or [a] danger to the environment or chattels so significant that immediate action is required to remove the danger arising from a hazardous substance or new organism" (s. 135). When an enforcement officer has reasonable grounds to believe that there is an emergency, he or she can declare an emergency and has wide powers to manage it. During a declared emergency, an enforcement officer may, among other things, enter any premises without a warrant, direct any person to stop any activity that may contribute to the emergency, and destroy any property in order to prevent or limit the emergency (s. 137). Any person with an interest in property destroyed or requisitioned as part of the emergency is to be compensated except where the person caused or contributed substantially to the emergency.

Under the HSNO Act, the response to an emergency would depend upon the nature of the emergency. If it relates to accidental/unintentional release from containment then the contingency plan to deal with the situation will be activated. Contingency plans are a part of the containment manual that has to be developed for managing new organisms in containment on a case-by-case basis and includes measures to be implemented and authorities to be informed. In respect of using a new organism in an emergency for remedial purpose, the HSNO Act has specific provisions for use of a new organism in an emergency.

<sup>39</sup> See section 4.3 on "Inspections" and section 4.4 on "Enforcement" in the second part of this toolkit module on administrative systems, (phase 3 (ii)).



### 5.2.13 Liability and redress

The issue of liability and redress for any damage caused by the transboundary movement of GMOs has been hotly discussed at the international level under the Protocol. The matter has not yet been resolved, but will be the subject of further discussion over the next few years. The first meeting of the COP/MOP, in Decision BS-1/8, established an Open-Ended Ad Hoc Working Group of legal and technical experts on liability and redress in the context of the Protocol. This Working Group will consider and elaborate rules and procedures for liability and redress, and the elements to be included; the Working Group is scheduled to complete its work in 2007.<sup>40</sup>

Some countries have considered how this matter might be addressed at the national level.

It is beyond the scope of this toolkit to go into the range of different approaches to liability and redress that countries might consider. Some countries have included specific provisions on liability in their national regulatory regimes on biosafety, while others have not. Others are still in the process of considering this issue. Some examples of countries that have included specific provisions on liability are given below.<sup>41</sup>

#### EXAMPLE: LIABILITY AND REDRESS

Norway's Gene Technology Act provides that the person responsible for an activity under the Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release of emission of GMOs into the environment.

In Switzerland, the Federal Gene Technology Law addresses liability principles in Article 30, and damage to the environment in Article 31.

According to Danish Act on Growing of GM crops (2004) Minister of Food, Agriculture and Fisheries shall pay compensation to any farmer who suffers a loss due to the occurrence of GM material in his crops in certain conditions (see art 9 of this act). All persons violating rules set in this act and rules laid according to this act, shall be subject to a fine.

### 5.2.14 Evaluating the operation of the regulatory regime

**How should the effect of the regulatory regime as a whole be monitored?**

Countries may wish to consider in the design of the regulatory regime, how the effectiveness of the regime as a whole, may be monitored over time. The issues to be considered include:

- **How should the cumulative effect of releases of different GMOs in the environment be monitored?**<sup>42</sup>

While risks associated with a GMO and specific activities involving a GMO are assessed on a case-by-case basis, the analysis of the potential cumulative effects of releases of different GMOs may also be a factor to be considered in risk assessment. Countries may wish to consider how this issue might be addressed in monitoring the effect of the regulatory regime as a whole.

- **How should a country monitor the effectiveness of the regulatory system as a whole?**

For example, should there be some automatic periodic review of the regulatory regime after a defined period of operation?<sup>43</sup>

**How should knowledge and information gathered in the implementation of the regime be marshalled and managed?**

Once it is in operation, the regulatory regime will gather and give rise to significant amounts of information – for example in the form of GMO authorisation applications; authorisations; risk assessment data; information on field trials; information gathered in post-authorisation monitoring. Countries need to consider how best to manage this information in order to be able to use it effectively for example:

- for monitoring overall effectiveness of the regulatory regime;
- for fulfilling obligations to provide information through the Biosafety Clearing House;
- for meeting reporting requirements under the Protocol; or
- for making information about GMOs available to the public.

<sup>40</sup> UNEP/CBD/BS/COP-MOP/1/15.

<sup>41</sup> See UNEP/CBD/ICCP/3/3 for a synthesis of information on national measures in the field of liability and redress for damages resulting from transboundary movement of LMOs.

<sup>42</sup> See also the toolkit module on administrative systems. (phase 3 (ii))

<sup>43</sup> See also the Conclusion, Section 6.



### 5.2.15 Transitional provisions and entry into effect

#### What transitional arrangements may need to be put in place?

Where a new regulatory regime, or new elements of the regulatory regime, is being put into place, countries may need to consider a number of “transitional” issues, such as:

- **How should existing activities/GMOs notified or authorised under existing/ interim provisions be dealt with?**  
For example, should existing authorisations remain valid, or should they be renewed in accordance with the new regulatory regime within a given timeframe?
- **What interim provisions, if any, should apply pending establishment of the regulatory and administrative regime?**  
For example, what will the country do if it receives an application under the Protocol’s AIA procedure, before the entry into force or establishment of its NBF?
- **Will the country have the capacity to implement the regime once it is in place?**  
What assistance is available to enhance regulatory capacity?

#### When will the regulatory regime enter into effect?

The date of entry into force must be clearly identified – this tells potential applicants when they need to conform to the requirements of the regulatory regime. What needs to be in place before the regulatory regime takes effect? For example, do certain administrative measures need to be in place before elements of the regulatory regime become fully operational?

## 6. Conclusion

### 6.1 When is a regulatory regime for biosafety final?

The countries that are preparing their NBFs need to be aware that the development of a regulatory regime for biosafety is, in many ways, a work in continuous progress. Biotechnology is a rapidly evolving field in which new issues and activities are constantly emerging, and governments have to be able to deal with changes in their national priorities and in public concerns. Therefore, a regulatory regime is a living document constantly reviewed and revised in the light of these changes.

The development of a regulatory regime is, therefore, an ongoing, iterative exercise, and that the feedback from the actual implementation of the NBF gives a country an opportunity to ensure that the NBF is able to respond to changing needs, priorities and circumstances. In developing and implementing their NBF, countries need to make sure that they have some means for gathering information on how the NBF systems work in

practice, what problems are arising, and how the NBF responds to changing circumstances. This could be done, for example, through the administrative system of the regulatory regime for biosafety, through a national committee on biosafety or biotechnology, or an auditor general’s office that is responsible for reviewing the operations of government. Feedback from the regulators and applicants, as well as the general public, will indicate how well the regulatory regime is working in practice.

As noted earlier in this module, in many countries existing regulatory regimes for biosafety have not been the result of a one-off process, but have evolved over time as new issues, activities, priorities and concerns have emerged. There are several examples of countries conducting reviews or consultations on their legal frameworks for biosafety, in light of experiences from implementing their regulatory regime. A number of countries that have had regulatory regimes in place for biosafety have carried out extensive reviews of these regimes, for example New Zealand, South Africa, the UK and Canada.

#### EXAMPLES: REVIEWING THE REGULATORY REGIME FOR BIOSAFETY

In **New Zealand** a Royal Commission<sup>44</sup> was appointed in 2000 to report on issues of genetic modification in New Zealand. Pending the Commission’s work and consideration of its recommendations, first a voluntary moratorium on field trials was agreed between government and industry and researchers. This was followed by a statutory moratorium on authorisation of commercial releases of GMOs under the existing regulatory regime. The moratorium was put in place to give New Zealand the time to investigate potential benefits from GM technology and explore ways to more effectively minimize any risks, and, more importantly, to put in place legislative requirements to implement the recommendations of the Royal Commission. The moratorium was lifted in October 2003 when legislative changes were put in place.

**South Africa** promulgated the Genetically Modified Organisms Act in 1997; this Act has been implemented since 1999. South Africa is currently reviewing and amending this Act in light of its experiences over the last five years, as part of the process of reviewing and revising its NBF under the UNEP-GEF NBF Development project.

In the **UK**, before any decision was taken on approvals for commercial cultivation of GM crops, the government established farm scale field trials to assess certain specific risks associated with a category of GM crops. It also sponsored a three-pronged dialogue on GM crops comprising a public debate, a study of economic costs and benefits of commercialisation of GM crops, and a review of the science.

**Canada** created its first National Biotechnology Strategy (which covers the regulation of biosafety) in 1983. In 1998, the government undertook a complete review of the strategy and created the Canadian Biotechnology Strategy. The new strategy included the creation of an advisory committee that advises the government on the ethical issues of biotechnology, amongst other things, a subject that was not of such concern to Canadians when the first strategy was created.

<sup>44</sup> <http://www.gmcommission.govt.nz/RCGM/index.html>



## 6.2 Useful characteristics of a regulatory regime for biosafety

Once a country has developed its regulatory regime for its NBF, how can it ensure that the systems work well in practice, and are responsive to changing needs, priorities and circumstances? The following questions are useful for determining the most useful characteristics of a regulatory regime:

- **Clarity** - Is it clear what regulatory processes apply to GMOs, GM products and activities involving GMOs? Will users of the system – be they government, the public, or applicants – understand how the regulatory regime works? Is a clear message or consistent instructions being communicated through a country's policy, laws, websites, employees, messages to the media, etc.?
- **Transparency** - Is the system transparent? Can applicants and others stakeholders find out and understand how the regulatory system works? Is it possible to follow the decision-making process from the initial filing of an application through to the final decision?
- **Consistency** - Are terms and definitions used in the regulatory system in a consistent manner? Are they used in a manner that is consistent with the Cartagena Protocol?
- **Practicality** - Is the solution as designed a workable one for the problem in question? Can this idea work in practice as well as on paper? Are the resources available to implement this solution? Do the stakeholders understand the solution? Are they willing to comply with it or will it create enforcement problems?
- **Authority** - What sorts of authority are required to implement the regulatory regime solution? For example, the authority to search private property or the authority to request test data from an applicant. Does the government department or institution that is being charged with implementing this solution actually have the authority to implement it?
- **Participation** - Is the system participatory? Are there mechanisms for all interested stakeholders to participate in the decision process? Is public participation allowed at various stages in the regulatory process?
- **Effectiveness** - Does the regulatory regime achieve its objective?
- **Predictability** - How predictable is the regulatory system? Has it been designed in such a way that applicants and other stakeholders can expect the regulatory process to work in a predictable manner? Is it clear to applicants and other stakeholders who is responsible for taking decisions and on what basis? Are the time frames, for example, clear and definite?
- **Enforceability** - Do the resources exist to carry out this enforcement? Is enforcement likely to be a problem or will there be willing compliance? Can there be non-governmental enforcement through the help of industry and/or the public? What sort of training will be needed if existing enforcement mechanisms are to be used?
- **Adaptability** - How adaptable does the system need to be? How adaptable is it? Will changes be difficult, costly, or confusing? Are the elements that will most likely need changing relatively easy to change?



## USEFUL SOURCES OF BACKGROUND INFORMATION

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McLean *et al.*, *A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation*, ISNAR Briefing Paper No. 47, 2002, available at <http://www.isnar.cgiar.org/ibs.publicat.htm>

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*UNEP/GEF draft chapter on regulatory regimes for guides to implementation of National Biosafety Frameworks available at* [http://www.unep.ch/biosafety/impdocs.html#a\\_draft\\_guide](http://www.unep.ch/biosafety/impdocs.html#a_draft_guide)

Mackenzie, Burhenne-Guilmin, La Vina and Werksman, in cooperation with Ascencio, Kinderlerer, Kummer and Tapper, IUCN/FIELD/WRI, *Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN Environmental Policy and Law Paper No. 46, 2003, available at <http://www.iucn.org/themes/law/info04.html>

SCBD/UNEP, *Biosafety and the Environment: An Introduction to the Cartagena Protocol on Biosafety*, 2003, available at <http://www.biodiv.org/biosafety>



## Annex 1: implementation toolkit

### Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety

#### Decision BS I/5, Annex III

This implementation tool kit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- Administrative tasks (initial and future)
- Legal requirements and/or undertakings
- Procedural requirements (AIA and Article 11)

#### I. ADMINISTRATIVE TASKS

	Tasks	Article	✓
	<b>Initial actions</b>		
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing-House: - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMOs-FFP; and - any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	
	<b>Follow-up actions</b>		
9.	Provide to the Biosafety Clearing-House: - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; - Final decisions concerning the import or release of LMOs; and - Article 33 reports.	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		



## II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	<b>Tasks</b>	<b>Article</b>	✓
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMOs-FFP.	8(2) 11(2)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
8.	Endeavour to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	
11.	Take measures to require that documentation accompanying LMOs-FFP - clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and - provides a contact point for further information.	18(2)(a)	
12.	Take measures to require that documentation accompanying LMOs destined for contained use: - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: - Clearly identifies them as LMOs; - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, as appropriate, the name and address of the importer and exporter; and - Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	
14.	Provide for the designation of confidential information by applicants, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with applicants and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavour to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavour to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	



### III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

Tasks	Article	✓
1. Notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1	8(1)	
2. Provide written acknowledgement of receipt of notification to notifier within 90 days, including: - Date of receipt of notification; - Whether notification meets requirements of Annex I; - That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; <b>OR</b> - Whether the import may proceed after 90 days without further written consent.	9(2)(a) 9(2)(b) 10(2)(a), 9(2)(c) 10(2)(b)	
3. Communicate in writing to the notifier, within 270 days of receipt of notification: - Approval of the import, with or without conditions; - Prohibition of the import; - A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or - Extension of the 270 day period by a defined period of time; AND Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(3)(a)-(d)          10(4)	
4. Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)	
5. Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2), (3)	

### IV. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

Tasks	Article	✓
1. Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2. Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)	
3. Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4. In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMOs-FFP: - either as approved under the domestic regulatory framework consistent with the Protocol; OR - in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4), (6)	



## Annex 2: WTO agreements

### General Agreement on Tariffs and Trade (GATT)

GATT rules govern trade in all products traded between WTO members, including GMOs and GM products. Among other things, GATT prohibits quantitative restrictions on imports, such as import bans or quotas, and measures that discriminate between 'like products' on the basis of their country of origin. Measures that violate GATT rules against such measures may qualify for an exception under Article XX GATT. The general exceptions provided in Article XX include measures that are necessary for the protection of human, animal or plant life or health or which are, under certain conditions, related to the conservation of natural resources. A Member seeking to invoke one of the general exceptions to justify a domestic trade measure must also demonstrate that the measure is not applied in an arbitrary or unjustified manner and is not a disguised restriction on trade.

There is significant case law in the GATT/WTO dispute settlement system on the interpretation of obligations under GATT, and on the general exceptions in Article XX.

### SPS Agreement

The SPS Agreement governs all measures which may directly or indirectly affect international trade in any products where those measures are applied with the policy objective of protecting human, animal or plant life or health within the territory of a Member from risks arising from pests, diseases or contaminants.

WTO members have the right to take SPS measures that are necessary for the protection of human, animal, or plant life or health, and to establish their own 'acceptable level of protection', provided that such measures are not inconsistent with the provisions of the SPS Agreement. In addition, a member must avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members are to ensure that any measure taken is:

- applied only to the extent necessary to protect human, animal, or plant life or health;
- based on scientific principles; and
- not maintained without sufficient scientific evidence, except as provided for under Article 5.7 of the SPS Agreement.

SPS measures must not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, and must not be applied in a manner that would constitute a disguised restriction on international trade. In order to satisfy this requirement, the SPS Agreement requires members to base their SPS measures on international standards, guidelines, or recommendations where they exist. Where such standards, guidelines, or recommendation do exist, measures that conform to those standards shall be deemed to be necessary to protect human, animal, or plant life or health, and rebuttably presumed to be consistent with the relevant provisions of the agreement and of the GATT.

The standards, guidelines, and recommendations of the Codex Alimentarius (food safety), the IPPC (plant health), and the International Office of Epizootics (animal health and zoonoses) are explicitly identified in this regard.

However, the existence of international standards, guidelines, or recommendations does not prevent a member from introducing or maintaining measures resulting in a higher level of protection if there is scientific justification. In order to establish the scientific basis for any SPS measure, a member is required to carry out a risk assessment that takes into account "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."

The SPS Agreement recognizes that governments will sometimes have to apply precautionary measures in situations where full scientific certainty is not available. In this regard, Article 5.7 provides that:

"[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and Phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary and Phytosanitary measure accordingly within a reasonable period of time."

### TBT Agreement

The TBT Agreement covers all products traded between WTO members, including GMOs and GM products. However, it applies only to particular kinds of trade-related measures. TBT-covered measures include technical regulations, voluntary standards, and conformity assessment procedures, which are based upon product characteristics. TBT measures include "marking or labelling requirements as they apply to a product, process or production method" compliance with which is mandatory. They can, however, also include import prohibitions or exceptions to these prohibitions when these measures are based on product characteristics.

WTO members must ensure that technical regulations are not more trade restrictive than necessary to fulfil a *legitimate objective*, including (but not limited to) protection of human health or safety, animal or plant life or health, or the environment. WTO members should use relevant international standards, where they exist, as a basis for their technical regulations unless these standards are inappropriate to fulfil the legitimate objectives pursued, for example, because of fundamental climatic or geographical factors or fundamental technological problems. Conformity with international standards creates a rebuttable presumption that the technical regulation does not create an unnecessary obstacle to international trade.



## Annex 3: examples of matrices used by countries

### 1. Matrix for comparison of existing legislation with the Cartagena Protocol – an example from Estonia<sup>45</sup>

Article	Obligation or definition in the CP	Relevant national (international) legislation	Are the definition or obligation in line with current legislation	If not, then who is responsible for harmonizing and how it will be done with a law (primary act), or secondary legislation (which one)
2.2	The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	Release into the Environment of Genetically Modified Organisms Act, Contained Use of Genetically Modified Micro-organisms Act plus its secondary acts, Rules for carriage of dangerous goods by road, European Agreement concerning the International Carriage of Dangerous Goods by Road, Environmental Supervision Act, Feed Act, Food Act, etc. etc.	no	Responsible Ministry of Environment, Ministry of Agriculture, Ministry of Economy – several Acts and secondary legislation should be amended. No new legislation needed.
....				
3b	"Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;	Contained Use of Genetically Modified Micro-organisms Act (art 2.4)	yes	No action needed
3c	"Export" means intentional transboundary movement from one Party to another Party;	Customs Act (art. 2.6), Strategic Goods Import, Export and Transit Act (art ...)	yes	No action needed
....				
9.1	The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.	No legislation in place	no	Responsible – Ministry of Environment. New secondary legislation to Release into the Environment of Genetically Modified Organisms Act.

<sup>45</sup> Based on Matrix format used by EU accession countries for harmonizing their legislation with EU legislation, slightly modified by lawyers of Estonian Ministry of the Environment.



## 2. Matrix for analysis of existing legislation –example from Bahamas

<b>Title</b>	<b>Status</b>	<b>Area</b>	<b>Responsible institution (s)</b>
Ch. 242 Agriculture and Fisheries	1963; Amended in 1965	Agricultural industry	Ministry of Agriculture, Fisheries & Local Government Department of Agriculture Department of Fisheries
Ch. 358 Bahamas Agricultural and Industrial Corporation	1981; Amended in 1992	Promotion of agriculture	Bahamas Agricultural and Industrial Corporation Ministry of Trade and Industry
Ch. 232 Environmental Health Services	1987	Environmental and public health	Ministry of Health and Environment Department of Environmental Health Services
Ch. 299 Export Control Regulations	Subsidiary legislation	Control of exports; permitting	Bahamas Customs Department Department of Agriculture
Ch. 236 Food	1985	Food safety	Department of Agriculture Department of Environmental Health Services
Ch. 298 Import Control Regulations	Subsidiary legislation	Control of imports; permitting	Bahamas Customs Department Department of Agriculture
Ch. 227 Pharmacy	1962; Amended in 1966	Use of pharmaceuticals	Ministry of Health and Environment
Ch. 250 Plants Protection	1951	Protection of native plant species	Ministry of Agriculture, Fisheries & Local Government Department of Agriculture
Ch. 237 Quarantine	1909; Amended in 1928	Protection of plants and animals as well as public health	Department of Agriculture Ministry of Health and Environment
Ch. 323 Copyright	1998	Intellectual property rights	Ministry of Trade and Industry Attorney-General's Office Bahamas Customs Department
Ch. 324 Industrial Property	1965; Amended in 1994	Property rights for industry	Ministry of Trade and Industry Attorney-General's Office Bahamas Customs Department



### 3 Matrix for analysis of existing legislation –example from Samoa

Legislation	Relevant Scope of Act	Responsible Agencies
Agriculture, Forests and Fisheries Ordinance 1959 and Regulations	<ul style="list-style-type: none"> <li>To strengthen the capabilities of agricultural inspection and quarantine services</li> </ul>	MAFFM
Animal Ordinances 1960 and Regulations	<ul style="list-style-type: none"> <li>To develop control measures to protect and conserve biodiversity</li> <li>To control and/or prevent the introduction of inappropriate foreign plants and animals</li> </ul>	MAFFM
Noxious Weeds Ordinance 1961	<ul style="list-style-type: none"> <li>To control the propagation of harmful plants</li> </ul>	MAFFM
Forest Act 1967	<ul style="list-style-type: none"> <li>To develop control measures to protect and conserve biodiversity</li> </ul>	MAFFM - Forestry
Development Bank Act 1974	<ul style="list-style-type: none"> <li>To encourage new cash crops</li> <li>To encourage local entrepreneurial activities</li> </ul>	Development Bank
National Parks & Reserves Act 1974	<ul style="list-style-type: none"> <li>To preserve native species</li> </ul>	MAFFM
Customs Act 1977	<ul style="list-style-type: none"> <li>To control and/or prevent the introduction of inappropriate foreign plants and animals</li> </ul>	MR - Customs
Plants Act 1984 and Regulations	<ul style="list-style-type: none"> <li>To prevent the introduction of inappropriate foreign plants</li> </ul>	MAFFM MR-Customs
Lands, Survey and Environment Act 1989	<ul style="list-style-type: none"> <li>To ensure and promote the conservation and protection of the natural resources and environment of Samoa</li> </ul>	MNRE
Trade, Commerce & Industry Act 1990	<ul style="list-style-type: none"> <li>To encourage new cash crops</li> <li>To develop resource-based industries</li> <li>To encourage local entrepreneurial activities</li> <li>To attract foreign investment</li> <li>To negotiate trade agreements</li> </ul>	TCI
Enterprise Incentives & Export Promotion Act 1992	<ul style="list-style-type: none"> <li>To encourage new cash crops</li> <li>To encourage local entrepreneurial activities</li> </ul>	TCI
Protection and Conservation of Wild Animals Amendment Regulations 1993	<ul style="list-style-type: none"> <li>To develop planning controls to protect and conserve biodiversity</li> </ul>	MNRE
	<b>PROPOSED</b>	
Environment Impact Assessment Regulation 1998	<ul style="list-style-type: none"> <li>To regulate and guide impact assessments in Samoa for both private and public development proposals</li> </ul>	MNRE - PUMA
Environment Bio-Propecting Regulation 1999	<ul style="list-style-type: none"> <li>To regulate access to Samoa's genetic resources and the equitable sharing of benefits derived from users</li> </ul>	MNRE - DEC
Biosecurity Bill 2003	<ul style="list-style-type: none"> <li>To regulate importation of articles associated with biosecurity risk</li> </ul>	MAFFM - Quarantine



